Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive

August 21, 2025
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

TuHURA Biosciences, Inc. (HURA: NASDAQ)

HURA: IFx-2.0 Phase III Begins

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 (8/20/2025)	$2.98
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 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	**$8.40**
52-Week Low	**$1.80**
One-Year Return (%)	**-62.8**
Beta	**0.8**
Average Daily Volume (sh)	**471,306**
Shares Outstanding (mil)	**50.0**
Market Capitalization ($mil)	**149.0**
Short Interest Ratio (days)	**8.0**
Institutional Ownership (%)	**12.9**
Insider Ownership (%)	**31.0**
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 A	$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	-$0.21 A	-$0.16 E	-$0.16 E	-$0.68 E
2026					-$0.65 E
2027					-$0.74 E

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Operational and Financial Results

On August 15th, 2025, TuHURA Biosciences, Inc. (NASDAQ: HURA) reported second quarter 2025 financial and operational results and filed its Form 10-Q with the SEC. The company has begun its IFx-2.0 Phase III trial in Merkel cell carcinoma (MCC) and has completed the acquisition of Kineta along with its newly named lead asset TBS-2025. TuHURA recently launched a Phase Ib/II study for IFx-2.0 in MCC patients not eligible for the Phase III trial which is expected to read out in 1Q:26. Other important milestones included presentation of clinical data at the American Association of Cancer Research (AACR) annual meeting in Chicago and the raise of additional capital. Below, we summarize TuHURA's quarterly financial results.

TuHURA generated no revenues in 2Q:25 and expended $9.9 million on operational activities related to advancing IFx-2.0 and other programs producing a net loss of ($9.5) million or ($0.21) per share. For the quarter ending June 30th, 2025 and versus the same prior year period:

- Research & development expense totaled $4.9 million increasing due to greater expenses for the IFx-2.0 program, 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 $4.9 million, due to increases in non-cash stock compensation, merger transaction costs and expenses related to being a public company;
- Other items included $322,000 in grant income related to Kintara's REM-001 asset and reimbursements from Health and Human Services;
- Interest income was $29,000 related to income paid on cash balances held;
- Net loss was ($9.5) million or ($0.21) per share.

As of June 30th, 2025, TuHURA held $8.5 million in cash on its balance sheet. 1H:25 cash burn was ($11.0) million while cash generated from financing was $8.2 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. Following the end of the quarter and in August 2025 we expect TuHURA to receive an additional $4.7 million in funding.

Private Placement

In early June, TuHURA entered into a $12.6 million equity financing transaction in a private offering with Paulson Investment Company. The arrangement was structured in tranches attached to development milestones related to the advancement of the IFx-2.0 program and the close of the Kineta merger. Four equity investments were made in June totaling approximately $9 million in shares. Funds were disbursed in equal amounts at: the initial closing, the lifting of the partial clinical hold on IFx-2.0, the start of the Phase III IFx-2.0 trial and satisfaction of all material conditions for closing the Kineta merger. A total of 4,759,390 shares were offered at $2.65 per share. Warrants were attached with an exercise price of $3.3125 and a five-year life. There is an additional $3.7 million related to the offering funded by December 31st, 2025. This share purchase also includes warrants with a $3.3125 exercise price and a five-year life. Management expects this amount to close in August 2025.

Close of Kineta Merger

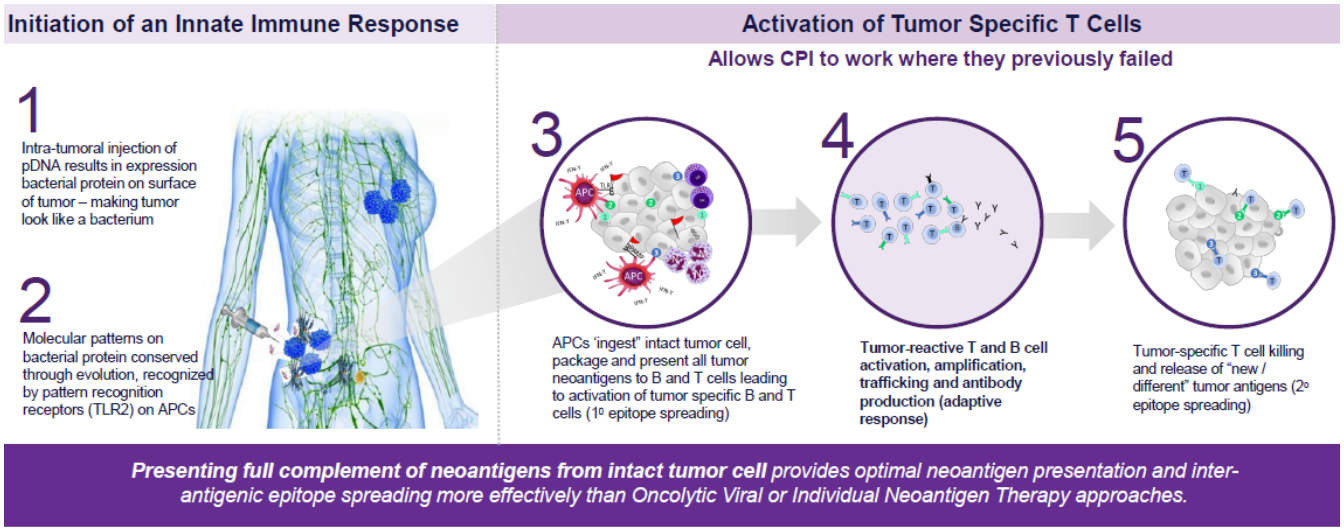
TuHURA closed its merger with Kineta on June 30th, 2025 and renamed its anti-VISTA asset TBS-2025. In addition to TBS-2025, the deal brought worldwide patents, patent rights, patent applications, product and development program assets, technical and business information and other rights. TuHURA anticipates that it will realize many synergies from owning both its IFx-2.0 and anti-VISTA platforms. The company executed several consulting agreements with former Kineta executives to help guide the transition to TBS-2025 and start of the related Phase III trial.

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 following the removal of the partial clinical hold related to chemistry, manufacturing and controls (CMC) requirements. Achieving this milestone freed up the associated $2.23 million of funding from early June's private placement. In the second quarter report, TuHURA set forth two related milestones for the study. Management will provide an update on enrollment progress by year end and distribute topline results by 2H:26.

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 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

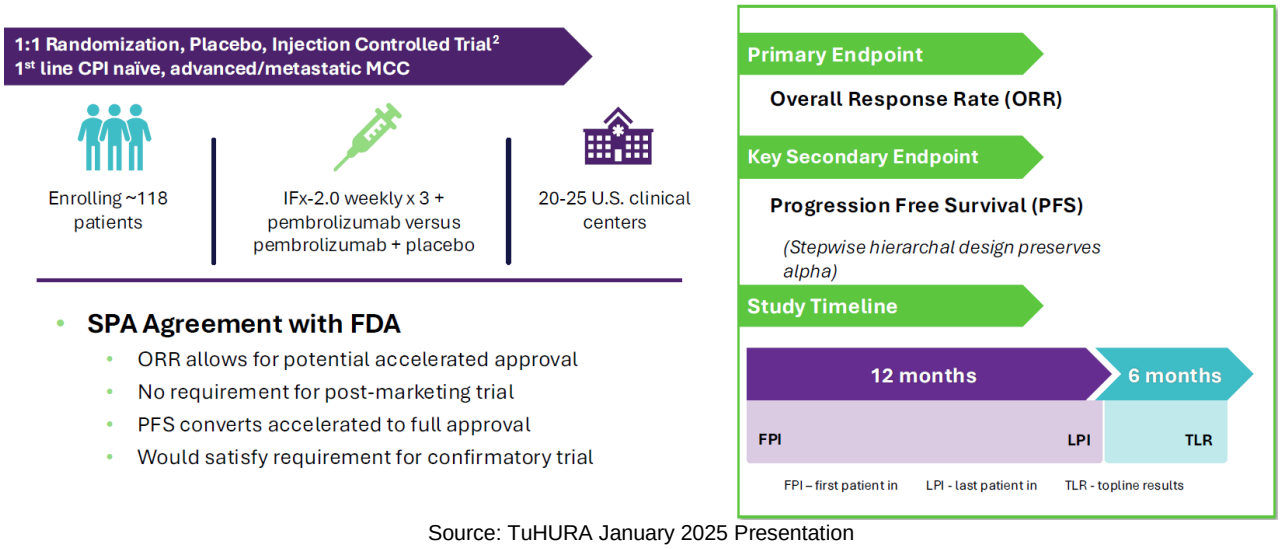


Source: TuHURA August 2025 Corporate Presentation

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 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 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

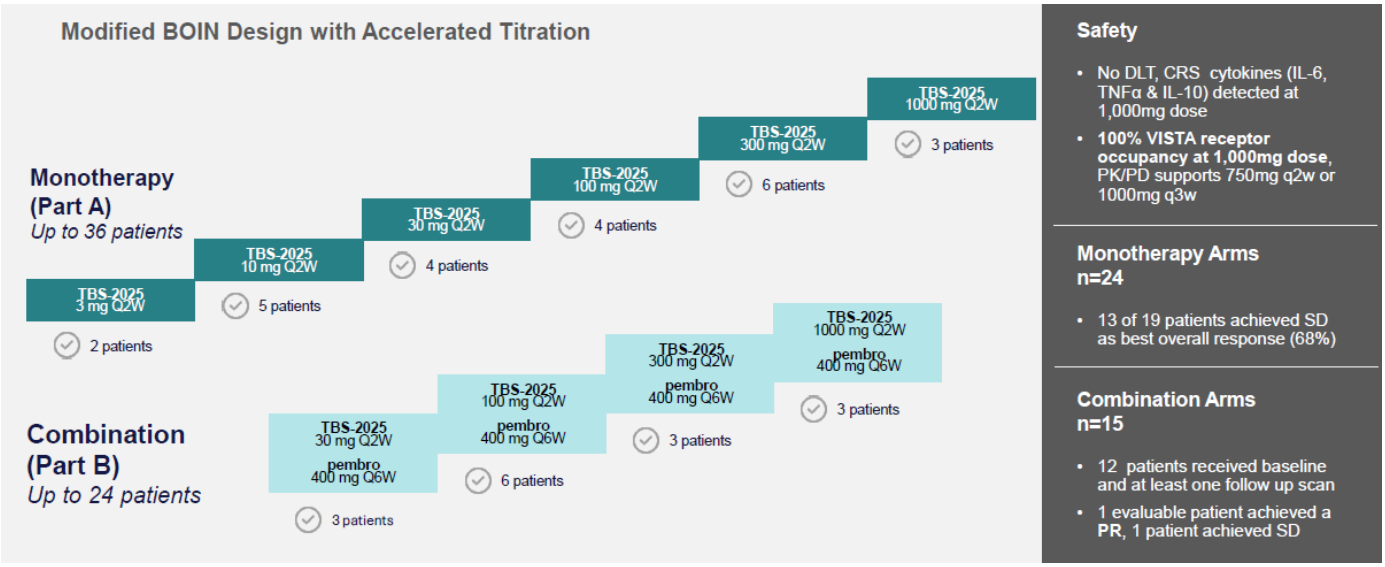


Source: TuHURA January 2025 Presentation

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 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 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

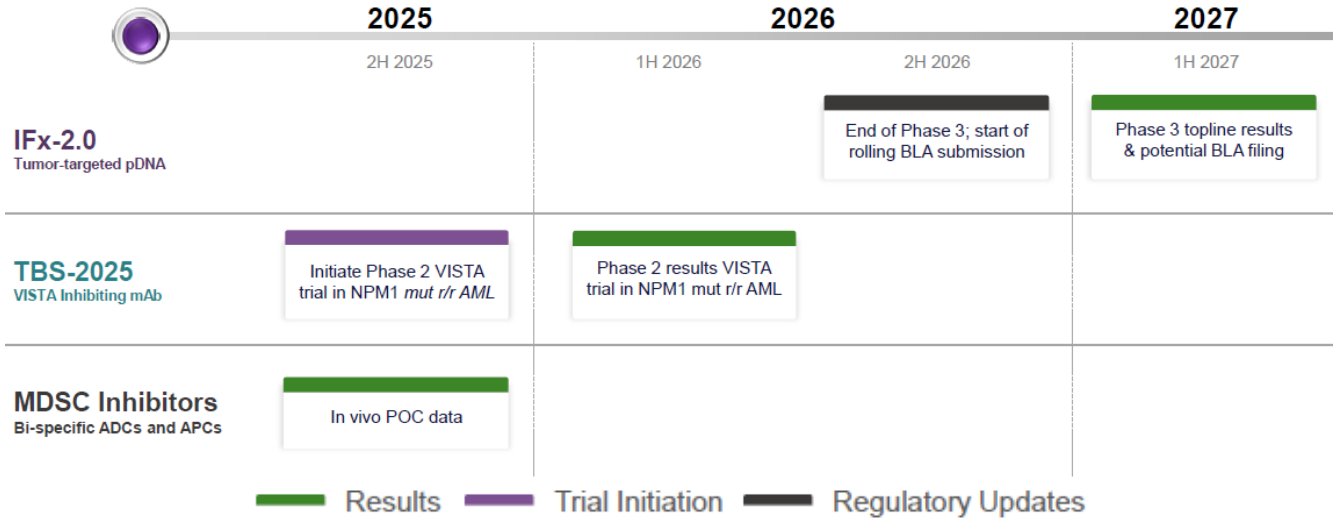


Source: TuHURA August 2025 Corporate Presentation

TuHURA is now in the process of closing out the Phase I study report for TBS-2025 and is targeting the Phase II trial start towards the end of 2025. Before it can begin, it must deliver the clinical trial protocol to the FDA, 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

Exhibit IV – TuHURA Milestones



Source: TuHURA August 2025 Corporate Presentation

Milestones

- American Association for Cancer Research (AACR) abstracts accepted – April 2025
- IFx-2.0 presentation at ASCO – June 1st, 2025
- Executed multi-tranche, milestone-linked equity financing series with Paulson – June 2025
- IFx-2.0 partial hold lifted followed by trial launch – June 2025
- IFx-2.0 IR basket trial – May 2025
- Close of Kineta acquisition – June 2025
- Special meeting of the stockholders – June 2025
- TuHURA added to Russell 2000 & 3000 indices – June 2025
- 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
- Participation in HC Wainwright Investment Conference – September 2025
- Launch VISTA inhibitor (TBS-2025) Phase II trial in NPM1 mutated AML – 4Q:25
- Presentation of VISTA inhibitor (TBS-2025) non-clinical data at medical meetings – 2H:25
- Enrollment progress update for IFx-2.0 - Year end 2025
- IFx-2.0 Phase Ib/II topline results – 1Q:26
- IFx-2.0 Phase III topline results – 2H:26

Company Pipeline

Exhibit V – TuHURA Pipeline

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

Source: TuHURA August 2025 Corporate Presentation

Summary

TuHURA reported 2Q:25 financial results on the heels of launching its IFx-2.0 Phase III study in MCC, closing the acquisition with Kineta and raising additional capital that will support the pipeline. 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 continuation of high-pace 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 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	$4,927	$4,580	$4,770	$18,859	$24,000	$30,000
General & Administrative	$4,314	$2,435	$4,949	$3,200	$3,150	$13,734	$12,000	$13,500
Other Operational Items								
Income from Operations	($17,649)	($7,017)	($9,876)	($7,780)	($7,920)	($32,593)	($36,000)	($43,500)
Restructuring & Impairments								
Other Items	($256)	$253	$323	$0	$0	$575	$0	$0
Net Interest Expense	($3,777)	$100	$29	$0	$0	$130	$0	$0
Pre-Tax Income	($21,682)	($6,664)	($9,524)	($7,780)	($7,920)	($31,888)	($36,000)	($43,500)
Provision for Income Tax	$0	$0		$0	$0	$0	$0	$0
Tax Rate								
Net Income	**($21,682)**	**($6,664)**	**($9,524)**	**($7,780)**	**($7,920)**	**($31,888)**	**($36,000)**	**($43,500)**
Net Margin								
Reported EPS	**($1.16)**	**($0.16)**	**($0.21)**	**($0.16)**	**($0.16)**	**($0.68)**	**($0.65)**	**($0.74)**
YOY Growth								
Basic Shares Outstanding	18,663	42,250	44,555	50,000	51,000	46,951	55,000	59,000

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

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE

TuHURA Biosciences, Inc. – Share Price Chart[1]



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

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

© Copyright 2025, Zacks Investment Research. All Rights Reserved.