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Kintara Therapeutics, Inc. (KTRA - NASDAQ)

A Farewell to GBM

Based on our DCF model and a 15% discount rate, Kintara Therapeutics is valued at approximately $5.00 per share. Our model applies a 60% probability for VAL-083 in unmethylated GBM, a 50% probability in methylated GBM and a 50% probability of approval and commercialization in REM-001 for CMBC. The model includes contributions from the United States and Europe. Other regions will be included upon further clarity.

Current Price (2/11/2022)	$0.45
Valuation	**$5.00**

OUTLOOK

Kintara Therapeutics is an oncology-focused R&D company pursuing an indication in GBM with VAL-083 & CMBC with REM-001. The two products were recently joined in a merger by sponsors DelMar Pharmaceuticals and Adgero Biopharmaceuticals.

VAL-083's profile is well-known as it has been assessed in 40+ Ph1 & Ph2 trials sponsored by the NCI. VAL-083 is approved in China for CML and lung cancer and is being investigated in two Ph2 GBM trials in the US and China sponsored by Kintara.

The GCAR is underway and should yield Ph3 topline results at end of 2023. Working within the GCAR AGILE study framework is anticipated to accelerate results in recurrent and newly diagnosed methylated and unmethylated patients while limiting total cost.

REM-001 is expected to start a confirmatory trial in 2Q:22 which will subsequently move into a 100-patient Ph3 trial. Trial completion expected by the end of 2024 followed by an NDA filing.

Our valuation assumes a 2025 regulatory approval and subsequent large pharma partner deal for commercialization of VAL-083 and a 2024 approval and deal followed by a launch of REM-001.

SUMMARY DATA

52-Week High	**$2.85**
52-Week Low	**$0.33**
One-Year Return (%)	**-82.6**
Beta	**1.62**
Average Daily Volume (sh)	**675,956**
Shares Outstanding (mil)	**48.5**
Market Capitalization ($mil)	**21.8**
Short Interest Ratio (days)	**1.19**
Institutional Ownership (%)	**12.4**
Insider Ownership (%)	**1.16**
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 2020 Estimate	**N/A**
P/E using 2021 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 USD)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2021	-$1.33 A	-$0.22 A	-$0.23 A	-$0.21 A	-$1.60 A
2022	-$0.17 A	-$0.12 A	-$0.15 E	-$0.15 E	-$0.59 E
2023					-$0.55 E
2024					-$0.54 E

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WHAT'S NEW

Second Quarter Fiscal Year 2022 Operational and Financial Results

Kintara Therapeutics, Inc. (NASDAQ: KTRA) announced second quarter fiscal year 2022 financial and operational results in a February 12th press release and concurrently filed its 10-Q with the SEC.

Highlights for the second quarter ended December 31, 2021 and to-date include:

- Appointment of Robert E. Hoffman as President and CEO, adding to Chairman role - November 2021
- Saiid Zarrabian transitions to Head of Strategic Partnerships - November 2021
- Phase II trials updates at 2021 SNO[1] Annual Meeting - November 2021
- First international site activation in GCAR - November 2021
- Grant from Luxembourg National Research fund - January 2022
- New US patent for VAL-083 and MGMT resistance - February 2022

Upcoming clinical milestones:[2]

- GCAR AGILE first EU site - 1Q:22
- REM-001 first patient enrollment - 2Q:22
- REM-001 topline results - 3Q:23
- GCAR AGILE topline results - 2023

Kintara received no revenues in fiscal year 2Q:22 and incurred operating expense totaling ($5.9) million, yielding net loss attributable to common stockholders of ($5.9) million, or ($0.12) per share.

For the second quarter ending December 31, 2021 versus the same ending December 31, 2020:

- Research & development expense was $3.9 million, up 51% from $2.6 million, largely attributable to higher clinical development costs, including data compilation and assessment, partially offset by lower non-cash, share-based compensation expenses;
- General & administrative expenses totaled $2.0 million, down 29% from $2.8 million due to lower non-cash, share-based compensation expenses partially offset by higher personnel costs due to the recognition of employee severance costs;
- Net loss attributable to common shareholders totaled ($5.9) million vs. ($5.4) million, or ($0.12) and ($.22) per share, respectively.

As of December 31, 2021, cash and equivalents totaled $14.1 million compared to $10.5 million at the end of the fiscal year. Kintara continues without debt. Cash burn for the quarter totaled $5.0 million. The NASDAQ extended Kintara's minimum closing bid requirements to June 1, 2022. Kintara has until June 1st to regain compliance, having a $1.00 minimum per share bid price for a minimum of ten consecutive business days. If unable to meet this requirement, Kintara's shares may be delisted from the NASDAQ.

CEO Zarrabian Transitions to Head of Strategic Partnerships, Chairman Hoffman Succeeds

On November 9, 2021, Kintara announced that President and CEO Saiid Zarrabian would transition to head Kintara's strategic partnerships initiative, while Chairman of Kintara's board, Robert E. Hoffman, would succeed him, effective November 8, 2021. Hoffman will continue as Board Chairman and Zarrabian will also remain a member of Kintara's Board. Zarrabian held the position of CEO since 2018.

Robert Hoffman has served as a director of Kintara since April 2018 and Chairman since June 2018. He currently serves as a Board member of Aslan Pharmaceuticals, Inc., Antibe Therapeutics, Inc., and Saniona AB. Hoffman's previous experience includes serving as Senior Vice President and Chief Financial Officer of Heron Therapeutics

[1] Society for Neuro-Oncology
[2] Calendar quarters

from April 2017 to October 2020. He was part of the founding management team of Arena Pharmaceuticals, Inc. in 1997, serving in various roles until 2015, including Senior Vice President, Finance and Chief Financial Officer. Mr. Hoffman served as a member of the Financial Accounting Standards Board's Small Business Advisory Committee. Mr. Hoffman holds a B.B.A. from St. Bonaventure University.

Phase II Trial Updates at 2021 SNO Annual Meeting

On November 18, 2021, Kintara announced data from two posters presented at the 26th Annual Scientific Meeting. The data were from Kintara's two Phase II clinical studies, at Sun Yat-sen University and MD Anderson Cancer Centers, of VAL-083 in GBM[3]. The first poster was entitled "Phase 2 clinical trial of dianhydrogalactitol (VAL-083) in patients with newly diagnosed MGMT-unmethylated GBM" and featured results from the 25 efficacy-evaluable patients who participated in the Sun Yat-sen University Cancer Center study. Subjects were treated with a starting dose of 30 mg/m^2/day x 3 days every 21 days. Progression-free survival (PFS) was 8.7 months and median overall survival (mOS) was 19.1 months. This compares to the historical temozolomide (TMZ) control ranging from 5.0-6.9 months PFS and 12.7-16.0 months mOS. One patient remained progression free for over 37 months after diagnosis.

The second poster, entitled "Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT unmethylated, bevacizumab naïve glioblastoma in the adjuvant or recurrent setting", reported results from the open-label, Phase II study in recurrent and adjuvant unmethylated GBM conducted at MD Anderson Cancer Center. For the 48 efficacy-evaluable patients at the 30 mg/m^2/day starting dose enrolled in the recurrent group, mOS was 8.0 months (CI 6.6-10.3). Kintara previously provided topline data from the recurrent arm in a July 1 press release where it reported mOS for the 48 efficacy-evaluable patients at the 30 mg/m^2/day dose level was 8.0 months with a 95% confidence interval of 5.9 to 9.9 months. While the mOS remained consistent, the confidence interval did shift upwards. This again compared to historical lomustine control mOS of 7.2 months.[4]

For the 36 efficacy-evaluable patients in the adjuvant group, PFS was 9.5 months (CI 8.2-10.8) and mOS was 16.5 months (CI 13.6-19.3). This compares with the previously released results with the same 36 subjects but a cutoff date of September 13, 2021 stating PFS of 10.0 months (CI 8.2-10.8) and mOS of 16.5 months (CI 13.3-19.3). Overall PFS decreased by half a month, with confidence interval unchanged, while mOS remained consistent, with a slight change in confidence interval.

GCAR AGILE Trial

In January 2021, Kintara announced the start of patient recruitment in the Global Coalition for Adaptive Research (GCAR) registrational Phase II/III clinical trial for glioblastoma multiforme (GBM). Kintara's candidate, VAL-083, will be considered in three subpopulations: newly-diagnosed methylated O^6-methylguanine-DNA methyltransferase (MGMT) GBM, newly-diagnosed unmethylated MGMT GBM and recurrent GBM.

In the January press release, Kintara announced that GCAR would be adding an additional active arm to VAL-083's study in newly-diagnosed methylated GBM patients, complementing the existing arms investigating newly-diagnosed unmethylated and recurrent GBM. Methylated GBM patients see some benefit from the current standard-of-care temozolomide (TMZ) and may be better served by VAL-083.

As of May 18th, 2021 GCAR had screened over 600 patients for the AGILE trial. Based on conversations held between Kintara management and GCAR, it is estimated that the first stage of the adaptive trial will graduate into the second stage in 2H:22.

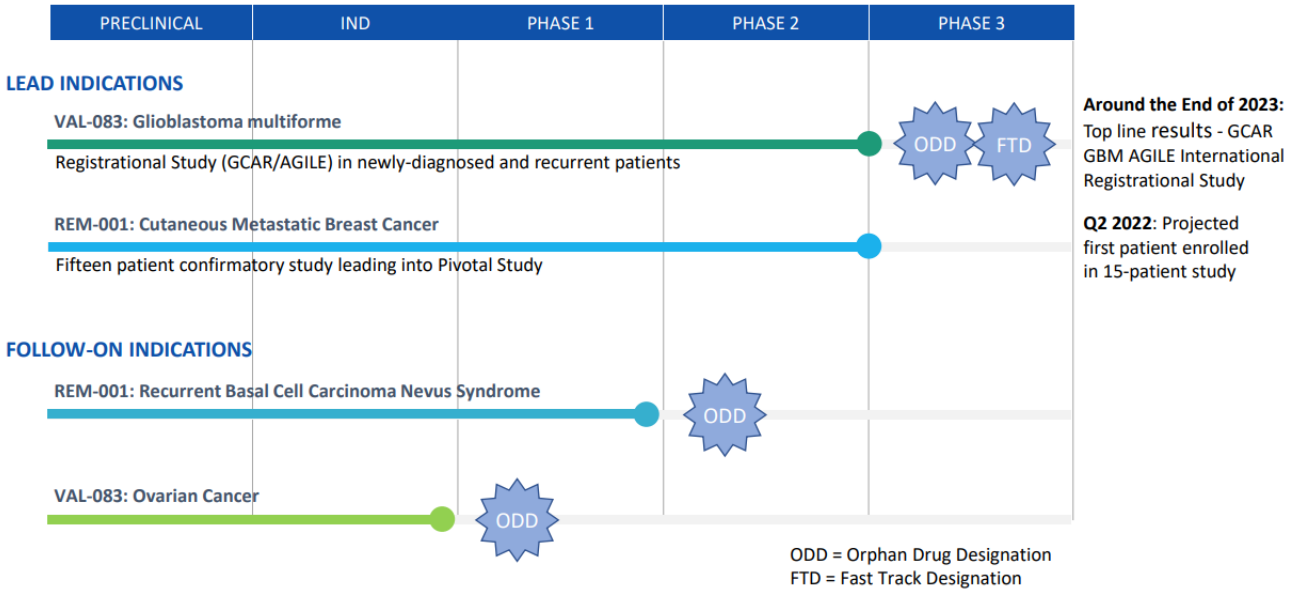
On August 17, Kintara provided an update that 26 US sites had been activated in the GCAR trial as of August 16, 2021. It is expected that 39 sites will be active by year end. Since January, GCAR has accelerated the pace of clinical site activation. GCAR is targeting 150-200 patient enrollment in the Kintara arm of the study at over 40 sites in the US and Canada, with potential of 65 clinical trial centers worldwide.

On November 30, 2021, Kintara informed that the first Canadian site had been activated: Sunnybrook Health Sciences Centre, Toronto. The release also updated the currently actively recruiting sites in the US to 30, as of November 24, 2021.

On January 10, 2022, Kintara updated the number of US and Canada sites to 31.

[3] Glioblastoma multiforme
[4] Wick et al N.Eng.J.Med (2017)

Exhibit I – Kintara Pipeline[5]



Luxembourg National Research Fund Grant

On January 12, 2022, Kintara announced that Drs. Simone Niclou and Anna Golebiewska at the Luxembourg Institute of Health had been awarded a multi-year project grant from the Luxembourg National Research Fund and Cancer Foundation. Drs. Golebiewska and Niclou co-lead the NORLUX Neuro-Oncology laboratory at the Luxembourg Institute of Health. The grant is intended to support Dr. Golebiewska's research on the mechanism of action for VAL-083's utility to treat glioblastoma (GBM), who has researched GBM, namely tumor heterogeneity, plasticity, and tumor microenvironment. The research project is titled "Deconvolution of heterogeneity in the Glioblastoma cellular ecosystem for understanding treatment resistance and improving patient stratification (DIOMEDES)," and will combine expertise in GBM biology and computational methods for the deconvolving the complex biological systems underlying the disease. By combining the latest preclinical models, transcriptomic analyses at the single and multicellular level, and deconvolution methods, the project aims to elucidate the mechanisms that influence treatment resistance in GBM. Temporal transcriptomic changes will be analyzed upon treatment with TMZ and VAL-083 in GBM xenografts. Insights resulting from this research may allow stratification of patients for personalized therapies.

New Patent for VAL-083 and MGMT Resistance

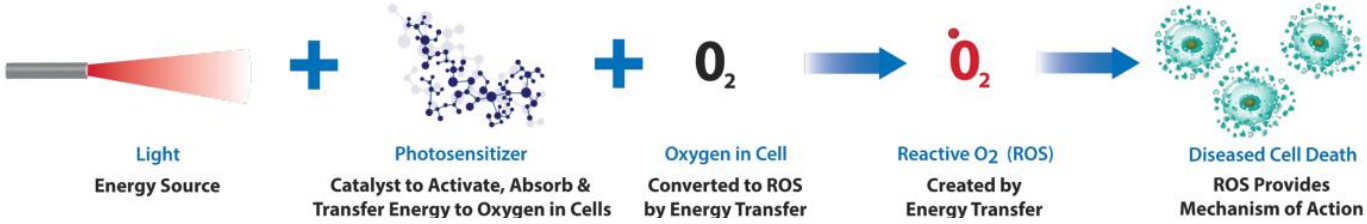
On February 3, 2022, Kintara announced a new US patent No. 11,234,955, totaling 15 US patents covering VAL-083. The patent covers methods of treating brain tumors including GBM, medulloblastoma and cancer brain tumor stem cells with MGMT-driven drug resistance. In particular, treatment-resistant brain cancer stem cells are of interest as they are potentially the ultimate cause of brain tumor therapy resistance and suspected to be the source of most brain tumor recurrences.

REM-001

Kintara expects to launch its 15 patient REM-001 confirmatory study in cutaneous metastatic breast cancer (CMBC) in the second quarter of 2022 with topline results expected in 3Q:23. This is expected to be followed by a Phase III that will enroll 100 to 150 CMBC patients that have received prior radiation therapy and chemotherapy.

[5] Source: Kintara Corporate Presentation January 2022

Exhibit II – Photodynamic Therapy[6]



Summary

Kintara announced second quarter fiscal year 2022 financial and operational results. Highlights for the second quarter and to date included the transition of Saiid Zarrabian to Head of Strategic Partnerships, and the appointment of Chairman Robert Hoffman as President and CEO. Kintara presented Phase II trial updates at 2021 SNO Annual Meeting, and announced the first international site activation in GCAR. Kintara received a grant from the Luxembourg National Research Fund and was granted a new US patent for VAL-083 and MGMT resistance.

In the financial sphere, Kintara produced no revenues in the second quarter of fiscal year 2022 and incurred operating expense totaling ($5.9) million, yielding net loss attributable to common stockholders of ($5.9) million, or ($0.12) per share. As of December 31, 2021, cash and equivalents totaled $14.1 million compared to $10.5 million at the end of the fiscal year. Kintara continues without debt. Cash burn for the quarter totaled $5.0 million.

Assuming continued favorable results, Kintara's VAL-083 candidate is poised to make a material impact in treatment-resistant GBM patients, a population that represents more than half of the total GBM population. REM-001 is expected to begin enrolling in 2Q:22 and topline results in 3Q:23. Kintara offers exposure to two large oncology markets and is developing two assets primed to enter pivotal studies. With a wealth of data available for VAL-083 and an unmet need in CMBC, we see Kintara as diversified and undervalued. We maintain our target price of $5.00 per share.

[6] Source: Kintara Corporate Presentation August 2021

PROJECTED FINANCIALS

Kintara Therapeutics, Inc. - Income Statement[7]

Kintara Therapeutics, Inc.	2021 A	Q1 A	Q2 A	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$11,815	$3,793	$3,902	$5,150	$5,200	$18,045	$23,200	$23,330
General & Administrative	$9,757	$2,178	$1,993	$2,210	$2,190	$8,571	$8,959	$9,228
Income from operations	($21,572)	($5,971)	($5,895)	($7,360)	($7,390)	($26,616)	($32,159)	($32,558)
Change in Fair Value of Derivative	$0	$0	$0	$0	$0	$0	$0	$0
Foreign Exchange Loss	$12	($4)	$0	$0	$0	($4)	$0	$0
Interest Income	$26	($1)	($2)	($1)	($1)	($5)	($5)	($5)
Other Items	$16,688	$0	$2	$0	$0	$2	$0	$0
Preferred Stock Dividend	$3,206	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($41,504)	($5,966)	($5,895)	($7,359)	($7,389)	($26,609)	($32,154)	($32,553)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	**($41,504)**	**($5,966)**	**($5,895)**	**($7,359)**	**($7,389)**	**($26,609)**	**($32,154)**	**($32,553)**
Reported EPS	**($1.60)**	**($0.17)**	**($0.12)**	**($0.15)**	**($0.15)**	**($0.59)**	**($0.55)**	**($0.54)**
YOY Growth	*83%*	*-86.9%*	*-44.2%*	*-33.4%*	*-27.0%*	*-63%*	*-6%*	*-0.02540569*
Basic Shares Outstanding	25,886	34,281	48,529	48,721	48,950	45,120	58,000	60,250

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

[7] Financial statement information presents data as originally reported.

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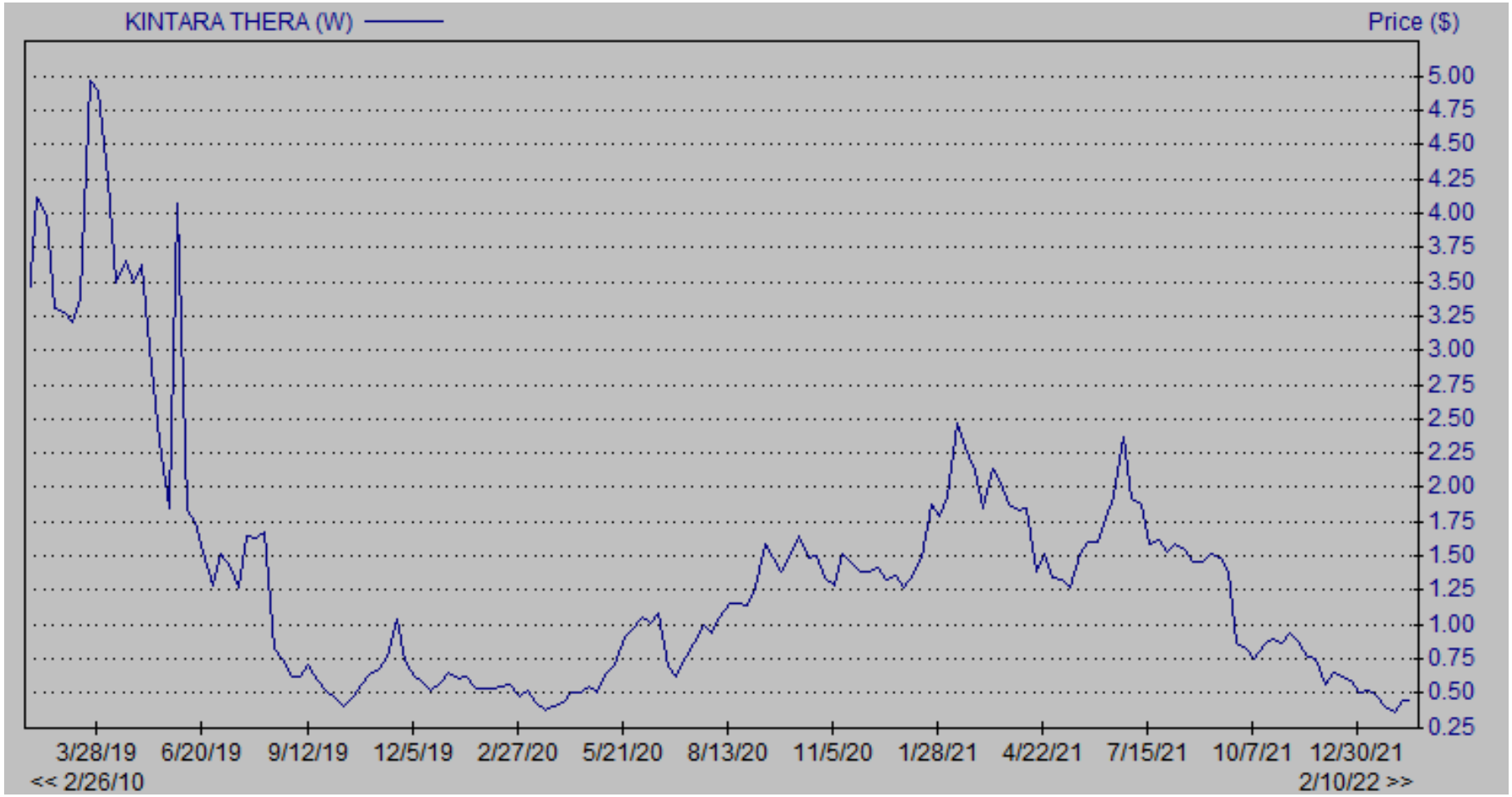
HISTORICAL STOCK PRICE

Kintara Therapeutics, Inc. – Share Price Chart[8]



[8] Source: Zacks Research System

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