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Kintara Therapeutics, Inc. (KTRA - NASDAQ)

2Q:21 Update & Target Price Increase

Based on our DCF model and a 15% discount rate, Kintara Therapeutics is valued at approximately $5.25 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 (2/24/21)	$2.20
Valuation	**$5.25**

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 study should launch before year-end 2020 and yield Ph3 topline results in 2023. Working with the GCAR AGILE study should accelerate results in recurrent and newly diagnosed methylated and unmethylated patients while limiting total cost.

REM-001 to start a confirmatory trial in 2021 which will subsequently move into a 100-patient Ph3 trial. Trial completion expected by the end of 2023 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	**$3.35**
52-Week Low	**$0.38**
One-Year Return (%)	**291**
Beta	**1.54**
Average Daily Volume (sh)	**1,102,452**
Shares Outstanding (mil)	**50.0**
Market Capitalization ($mil)	**$110.0**
Short Interest Ratio (days)	**0.4**
Institutional Ownership (%)	**1.2**
Insider Ownership (%)	**34.4**
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 2021 Estimate	**N/A**
P/E using 2022 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 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Sep)	Year (Jun)
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2022					$0.0 E
2023					$0.0 E

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Sep)	Year (Jun)
2020	-$0.21 A	-$0.15 A	-$0.17 A	-$0.33 A	-$0.87 A
2021	-$1.33 A	-$0.22 A	-$0.21 E	-$0.15 E	-$1.52 E
2022					-$0.64 E
2023					-$0.48 E

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WHAT'S NEW

Second Quarter Fiscal Year 2021 Operational and Financial Results

Kintara Therapeutics, Inc. (NASDAQ: KTRA) announced second quarter financial and operational results in a February 12th press release and filed its 10-Q with the SEC for its fiscal second quarter ending December 31, 2020. The reporting period included the execution of the agreement between Kintara and the Global Coalition for Adaptive Research (GCAR) for participation in GCAR's Glioblastoma Adaptive Global Innovative Learning Environment (GBM AGILE) study. Interim data from the MD Anderson newly-diagnosed, MGMT-unmethylated study demonstrated improved survival. Data was released in November and final patient enrollment was announced on February 17th. In January, VAL-083 was started in the GCAR trial with the initiation of patient recruitment.

Financial Summary for 2Q:21

Kintara reported no revenues in 2Q:21, identical to the prior year result. Operating costs were $5.4 million which includes a full quarter of expenses after the combination with the former Adgero Biopharmaceuticals in August 2020. Research and development expenses rose substantially over prior year levels by almost 200% to $2.6 million. Increases were attributable to higher clinical development costs related to the GCAR GBM AGILE study and additional expenditures related to the REM-001 program. Non-cash share based compensation was also greater year over year. General and administrative expenses increased 160% due to higher non-cash compensation and additional personnel related to the Adgero merger.

Other loss was $35,000 comprised predominantly of amortized deferred loan costs. There was a small component of net interest expense and a $3,000 foreign exchange loss.

Cash on the balance sheet as of December 31, 2020 was $17.2 million, compared to $2.4 million as of fiscal year end 2020. The change in the balance was the sum of cash from financing of $23 million offset by ($9.5) million in cash burn. Shares outstanding as of February 10, 2021 were 30.6 million in active equity shares with another 19.5 million shares represented by the unconverted Series B and Series C preferred stock (see share balance on page 1).[1] The increase in shares on page 1 of our report is represented by exercised warrants and options up to February 10, 2021.

Operational Update for 2Q:21 and to Date

In January, 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. We had hypothesized this eventuality in our initiation, highlighting the benefits of the adaptive nature of the GCAR structure, which allows for multiple subtypes of GBM to be evaluated. Methylated GBM patients see some benefit from the current standard-of-care temozolomide (TMZ) and may be better served by VAL-083.

VAL-083

Kintara is completing multiple Phase II trials for VAL-083 to treat brain cancer, one of the most difficult malignancies to address. Interim data that we reviewed in our recent update shows activity against GBM tumors compared to first line standard-of-care TMZ in a difficult to treat patient subpopulation. VAL-083 has several features that make it particularly suitable for GBM, including its ability to cross the blood brain barrier and its mechanism of action which introduces irreversible DNA crosslinks which are not easily overcome by MGMT repair enzymes.

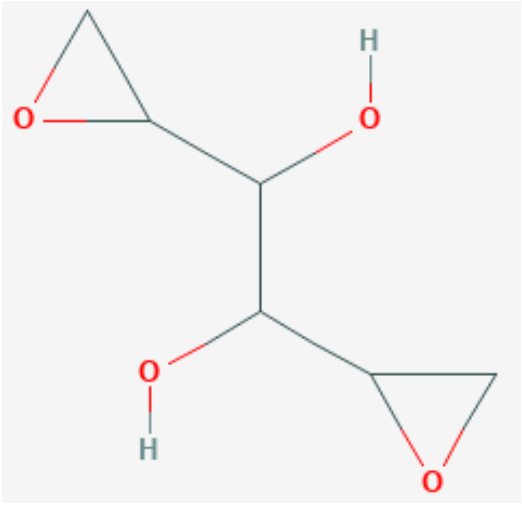
While VAL-083 offers a mechanism of action that is agnostic of MGMT expression and is efficacious in the treatment-resistant GBM population (MGMT-unmethylated), we also consider VAL-083's potential in the MGMT-

[1] Note that shares outstanding used to calculate our target price includes share balance as of February 10, 2021 as reported on page 1 of the second quarter FY2021 10-Q, assumed conversion of the Series B Preferred Stock and assumed conversion of the Series C Preferred Stock.

methylated population. MGMT is a repair enzyme that can counteract the intentional genetic damage induced by chemotherapy agents, and is expressed when the DNA promoter is unmethylated. When the DNA is methylated, the repair enzyme is not expressed, allowing common chemotherapies such as TMZ to effectively damage the tumor cells, leading to apoptosis. This makes the tumor easier to treat and blocks a DNA repair pathway in GBM cells. While this GBM patient subpopulation is served, albeit imperfectly, by TMZ, VAL-083 has not been clinically evaluated in the MGMT-methylated population where it may provide an alternative to TMZ.

The addition of the MGMT-methylated population to the GCAR trial opens up an additional opportunity for Kintara. Of the estimated 11 to 12 thousand GBM cases per year in each of the US and Western Europe markets, the methylated population comprises about 40% of the total, compared with the other 60% which is the unmethylated population. We think that Kintara could gain market share in this segment if trial results are favorable, although it will be at a lower level than the unmethylated market, where TMZ is ineffective. The probability of success for the methylated market is smaller as VAL-083 will have to demonstrate that it is better than TMZ; however, the addition of the methylated arm to GCAR is a positive that we will revisit when there is more data supporting its superiority to standard of care in this group.

Exhibit I – Chemical Structure of Chemotherapy Dianhydrogalactitol (VAL-083)[2]

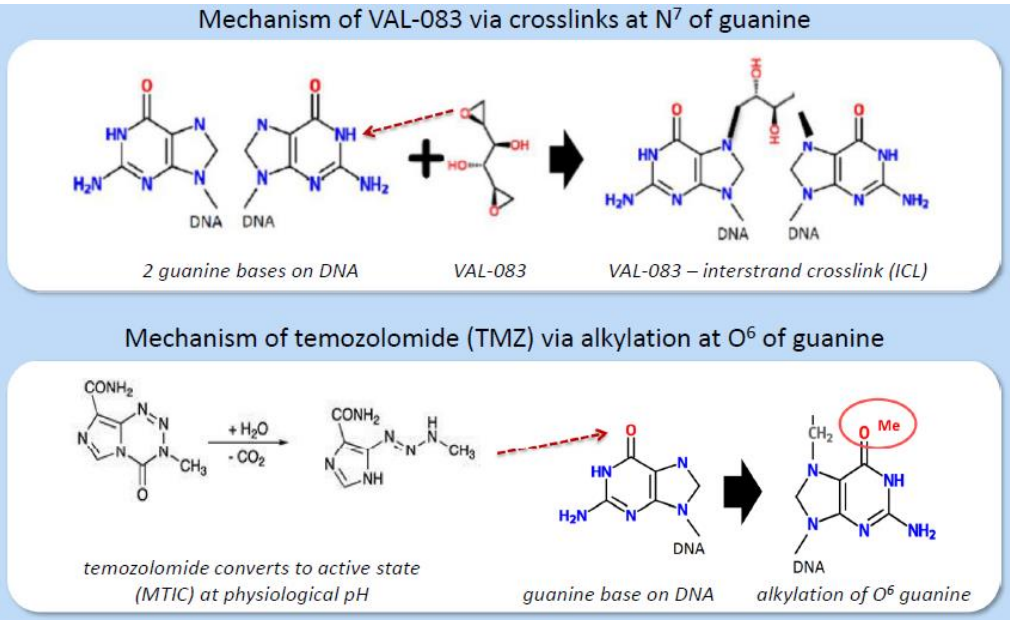


VAL-083 History and Mechanism of Action

VAL-083, also known as dianhydrogalactitol, is a DNA damaging, alkylating chemo-therapeutic agent that was first developed by the NCI in the 1970s.[3] The drug is approved in China for treatment of chronic myeloid leukemia and lung cancer. The compound is a bifunctional DNA-targeting agent causing N^7-guanine alkylation[4] and interstrand DNA crosslinks. The crosslinks induce DNA double strand breaks which inhibits cancer cell proliferation. VAL-083 induces cytotoxicity when cells advance to the S-phase with unrepaired N^7-guanine DNA crosslinks. The crosslink damage causes replication-dependent DNA double-strand breaks that prevent repair, resulting in apoptosis.[5] The agent is able to overcome MGMT-mediated drug resistance and has shown the ability to kill MGMT-unmethylated GBM cell lines and cancer stem cells *in vivo*. It maintains cytotoxic activity in mismatch repair deficient cancer cells providing an alternative for treatment-resistant cancers reliant on TMZ and nitrosoureas. The drug also works well with other approaches including poly ADP ribose polymerase (PARP) and topoisomerase inhibitors as well as acting as a radiosensitizer in GBM. We provide a detailed discussion of VAL-083, the importance of methylation status, GBM and the GCAR AGILE study in our February 8th article.

[2] Source: PubChem, NIH National Library of Medicine, National Center for Biotechnology Information. Accessed February 8, 2021.
[3] Perry, M.C., *et al.* Phase II Studies of Dianhydrogalactitol and VP-16-213 in Colorectal Cancer. Cancer Treat Rep 60:1247-1250, 1976.
[4] Alkylation of DNA is used in chemotherapy to damage the DNA of cancer cells.
[5] Zhai, B., *et al.* Dianhydrogalactitol induces replication-dependent DNA damage in tumor cells preferentially resolved by homologous recombination. Cell Death & Disease volume 9, Article number: 1016 (2018)

Exhibit II – VAL-083 Mechanism of Action[6]



Series C Preferred Stock

After completing the merger between DelMar and Adgero, Kintara issued 25,028 units of Series C Preferred Stock. This instrument can be converted to regular shares of common stock at any time in a ratio of 862 shares of common stock for each Series C Preferred unit. On each anniversary of the issue date, for continuing holders of the Series C Preferred, a Series C Preferred Stock dividend will be paid over the four year life of the instrument. A dividend of 10%, 15%, 20% and 25% will be paid on each anniversary based on the original number of shares issued. This structure encourages the long term holding of Kintara Series C Preferred shares as dividends are only paid for continuing holders. Once the shares are converted to common equity, they no longer produce a preferred stock dividend. As of year-end 2020, 1,358 units of Series C Preferred stock were converted to common shares, leaving a balance of 23,670 Series C units.

Our Thesis

Kintara is developing multiple oncology assets. The first, VAL-083, is expected to yield topline results in 2023, followed by a new drug application (NDA) and a 2025 launch of the product in selected geographies. The second is REM-001, a photodynamic therapy (PDT) that consists of a drug, a laser light source and a light delivery device, which is expected to start a confirmatory trial in 2021 and later convert into a Phase III study, generating data by late 2023, followed shortly after by NDA submission and commercialization in 2024.

VAL-083 presents a differentiated mechanism of action and a favorable safety profile, especially in contrast to other agents. It is a bifunctional compound that is able to alkylate N^7-guanine to form interstrand crosslinks and force double strand breaks. Unlike standard of care TMZ, the response to VAL-083 is not dependent on MGMT promoter methylation status. At the target dose, only a minority of patients presented dose limiting toxicities and the drug is well tolerated.

REM-001, will begin a dose identifying confirmatory study in 2Q:21 enrolling up to 15 patients as a direct lead-in to Phase III. Extensive studies have been conducted that have characterized the safety and efficacy of REM-001 to address CMBC. The cancer has no effective treatments despite minor benefits from surgery, chemotherapy, radiotherapy and other approaches.

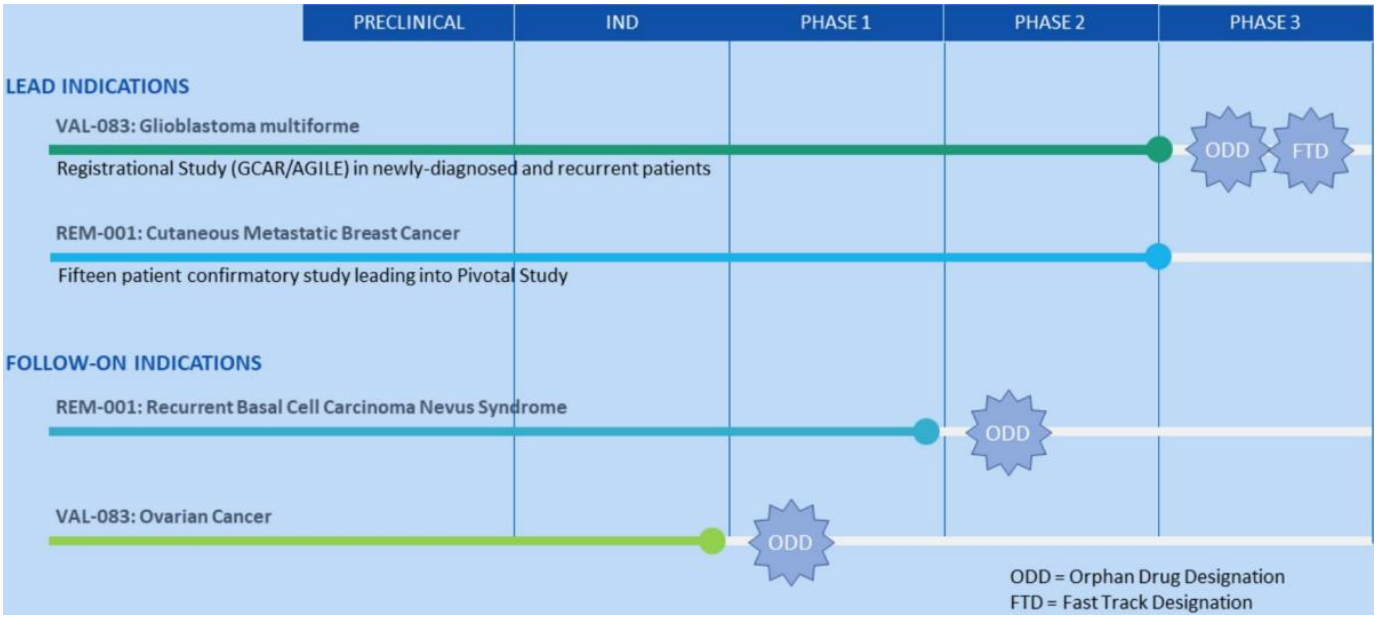
Current approaches to both GBM and CMBC are insufficient. If Kintara's VAL-083 and REM-001 are successful in clinical trials, we see these treatments fulfilling an unmet need in two areas that command strong pricing and significant populations. Each of Kintara's candidates have other indications that may also be addressed, providing additional opportunities for this small cap company.

[6] Source: Kintara Corporate Presentation, February 2021

Kintara History

Kintara Therapeutics was formed from the combination of DelMar Pharmaceuticals and Adgero Biopharmaceuticals, with the former sponsoring VAL-083 and the latter developing REM-001. Adding REM-001 provides a second Phase III-ready asset and additional pipeline expansion opportunities including future possible indications. This includes cancers such as recurrent basal cell carcinoma nevus syndrome (BCCNS), locally advanced basal cell carcinoma (laBCC) and cutaneous metastatic cancers other than breast, such as lung, ovarian and colon.

Exhibit III – Kintara Pipeline[7]



Corporate Milestones

Kintara is conducting multiple clinical trials for GBM in VAL-083 and will soon launch a pivotal study for REM-001. The focus for the company is to complete the various Phase II trials underway. Kintara began the GCAR registrational effort and is on the cusp of enrolling patients. It aims to start Phase II for REM-001 by 2Q:21. Below we list recent milestones and anticipated future events.

- Launch GCAR AGILE registration study, stage 1 – 4Q:20
- Top-line preliminary results for Newly Diagnosed Phase II GBM study at SNO – 4Q:20
- Top-line preliminary results for Recurrent Phase 2 GBM study – 1Q:21
- Begin enrollment, GCAR GBM AGILE Study – January 2021
- Initiate CMBC confirmatory trial – 2Q:21
- Top-line preliminary results for Adjuvant Phase 2 GBM study – 2Q:21
- AACR Data Updates for Phase II GBM – 2Q:21
- CMBC confirmatory trial results & Phase III start – 4Q:21
- GCAR AGILE registration study, stage 2 – 1Q:22
- CMBC trial complete – 2023
- CMBC NDA filing - 2024
- GCAR AGILE top-line results – 2023

[7] Source: Kintara 2Q:21 10-Q Filing

Valuation

We update our valuation based on the addition of **1)** a methylated arm to the GBM AGILE trial, **2)** updated share count and **3)** estimate of future capital needs in light of materially improved share price. We have identified approximately 11,500 US and 11,400 top 5 European market cases of GBM per year. We assume that if VAL-083 is successful in the methylated population, VAL-083 can penetrate 10% of this 40% of the GBM market. Due to the higher hurdle that must be overcome against a population in which temozolomide has demonstrated some effectiveness, we apply a 50% probability of success compared to the 60% we use for VAL-083 in the unmethylated population. Similar to our estimates for VAL-083 in the unmethylated population of GBM, we forecast a 2025 launch of the product in both US and EU markets. Initial penetration into the addressable market is expected to be 5% rising to 10% over the next three years.[8] Other components of our model such as pricing and exclusivity periods match the details we use to estimate value for the unmethylated market.

We had originally estimated the need to issue an additional 42 million shares to advance VAL-083 and REM-001 to approval. However, with the strong and steady improvement in share price over the last six months, we reduce the number of shares needed to fund the effort to 15 million.

The addition of the new possibility for VAL-083 in the methylated population and fewer shares required to fund Kintara's lead programs to fruition support an increase in our target price to $5.25 per share.

Summary

Kintara's VAL-083 candidate is poised to make a great impact in GBM patients that are treatment resistant, a population that comprises greater than half of the total GBM population. VAL-083 may also acquire market share in the MGMT-methylated population as well, although its efficacy in that population is only now being evaluated in the GCAR AGILE trial. We will update our assessment of success in the methylated population based on additional data for VAL-083 provided in this population.

Kintara is developing a pair of well-researched therapies in oncology with several characteristics that make the candidates particularly amenable to addressing GBM and CMBC. For VAL-083, the ability to cross the blood brain barrier and overcome DNA-repair enzyme resistance combined with the agent's affinity to be absorbed by cancer cells provides a mechanism of action that may provide superior safety and efficacy compared with the current standard of care. In the case of REM-001, the targeted nature of the approach avoids systemic exposure and addresses many of the shortcomings of surgery, chemotherapy and radiotherapy. 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. Based on our updated model we increase our target price to $5.25 per share.

[8] This contrasts to 50% initial penetration into the unmethylated market. See our initiation for details on our estimates for the unmethylated market.

PROJECTED FINANCIALS

Kintara Therapeutics, Inc. - Income Statement[9]

Kintara Therapeutics, Inc.	2020 E	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$3,630	$1,357	$2,584	$3,950	$4,000	$11,891	$24,450	$23,200
General & Administrative	$4,515	$1,534	$2,794	$1,395	$1,355	$7,078	$4,400	$4,500
Income from operations	($8,145)	($2,891)	($5,378)	($5,345)	($5,355)	($18,969)	($28,850)	($27,700)
Change in Fair Value of Derivative	$0	$0	$0	$0	$0	$0	$0	$0
Foreign Exchange Loss	$3	$0	$3	$0	$0	$3	$0	$0
Interest Income	($75)	$7	$7	($7)	($4)	$3	($20)	($20)
Other Items	$1,054	$16,620	$25	$0	$0	$16,645	$0	$0
Preferred Stock Dividend	$9	$3,188	$0	$0	$0	$3,188	$0	$0
Pre-Tax Income	($9,135)	($22,706)	($5,413)	($5,338)	($5,351)	($38,808)	($28,830)	($27,680)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	**($9,135)**	**($22,706)**	**($5,413)**	**($5,338)**	**($5,351)**	**($38,808)**	**($28,830)**	**($27,680)**
Reported EPS	**($0.87)**	**($1.33)**	**($0.22)**	**($0.21)**	**($0.15)**	**($1.52)**	**($0.64)**	**($0.48)**
YOY Growth	*-72%*	*522.3%*	*42.6%*	*23.5%*	*-54.3%*	*74%*	*-58%*	*-26%*
Basic Shares Outstanding	10,444	17,106	24,845	25,200	35,000	25,538	45,000	58,000

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

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

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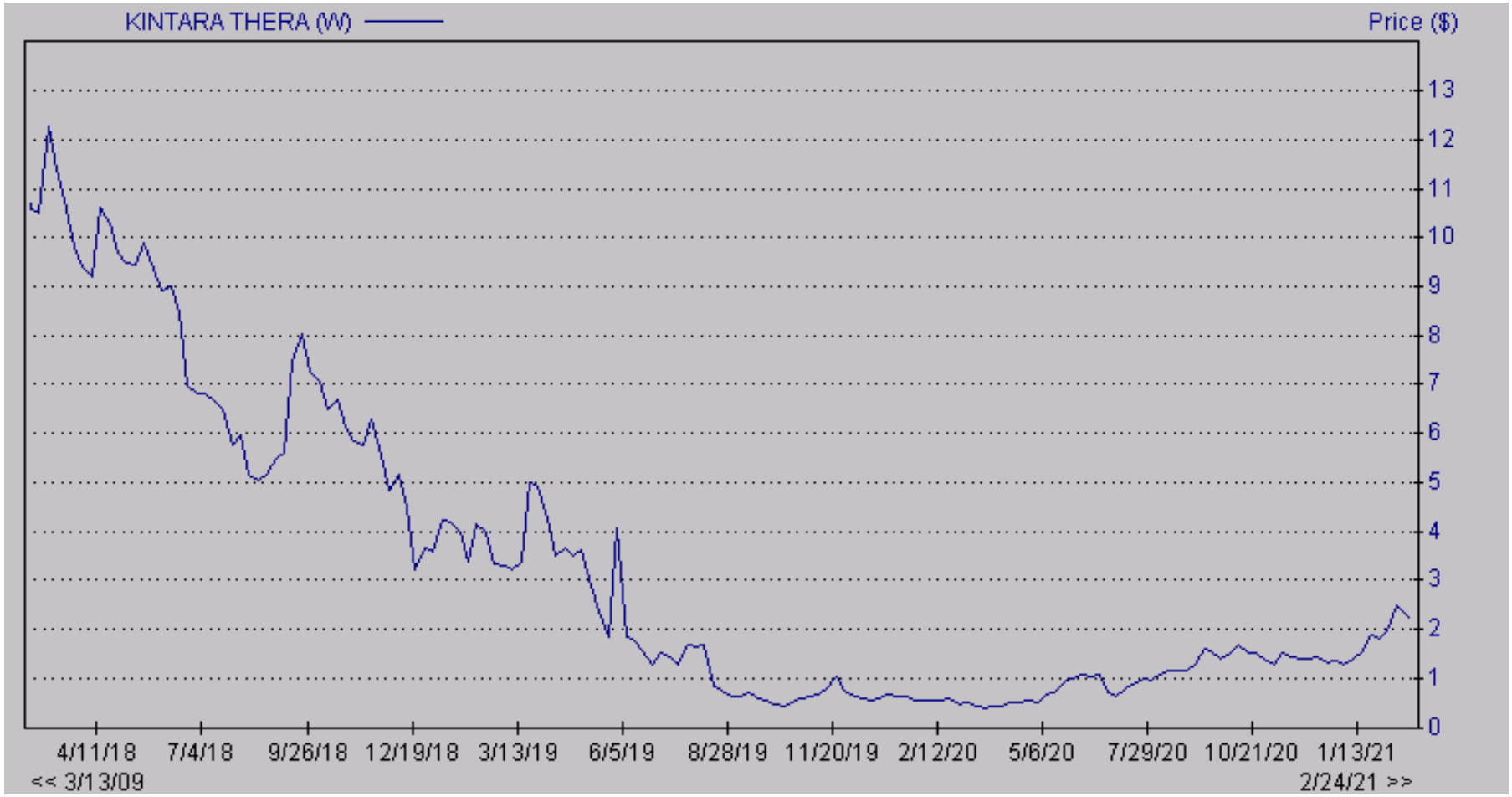
HISTORICAL STOCK PRICE

Kintara Therapeutics, Inc. – Share Price Chart[10]



[10] Source: Zacks Research System

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