
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2022

KINTARA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

001-37823
(Commission
File Number)

99-0360497
(IRS Employer
Identification No.)

12707 High Bluff Dr., Suite 200
San Diego, CA 92130
(Address of principal executive offices)

Registrant's telephone number, including area code: (858) 350-4364
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Trading Symbol(s)

Name of each exchange
on which registered

Common Stock

KTRA

The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events

Kintara Therapeutics, Inc. (the “Company”) has prepared presentation materials (the “Investor Presentation”) that management intends to use with its presentation at the H.C. Wainwright Bioconnect 2022 Virtual Conference to be held on January 10 - 13, 2022. A copy of the Investor Presentation has been posted to the Company’s website and is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KINTARA THERAPEUTICS, INC.

Date: January 10, 2022

By: /s/ Scott Prail
Name: Scott Prail
Title: Chief Financial Officer

KINTARA Therapeutics

Developing Advanced Oncology Therapies for Rare Unmet Medical Needs

Corporate Presentation January 2022

CONFIDENTIAL

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Forward Looking Statements

This presentation contains forward-looking statements based upon Kintara's current expectations. This communication contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by terminology such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar words. These statements are only predictions. Kintara has based these forward-looking statements largely on its then-current expectations and projections about future events, as well as the beliefs and assumptions of management. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Kintara's control, and actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to: (i) risks associated with the impact of the COVID-19 pandemic; (ii) risks and uncertainties relating to Kintara's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of Kintara's products and technology; the availability of substantial additional funding for Kintara to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, Kintara's business, research, product development, regulatory approval, marketing and distribution plans and strategies, and (iii) those risks detailed in Kintara's most recent Annual Report on Form 10-K and subsequent reports filed with the SEC, as well as other documents that may be filed by Kintara from time to time with the SEC. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Kintara cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements made in this communication relate only to events as of the date on which the statements are made. Except as required by applicable law or regulation, Kintara undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. Investors should not assume that any lack of update to a previously issued "forward-looking statement" constitutes a reaffirmation of that statement.

Late-stage Oncology Company with Two De-Risked Product Candidates

VAL-083: A first-in-class small molecule with unique MOA (MW = 147)

- Pivotal, pre-eminent GBM AGILE International registrational study for three GBM patient subtypes initiated January 2021
- ~\$1B¹ market opportunity in lead program: Glioblastoma Multiforme (GBM)
 - Multiple shots on goal via parallel enrollment of three GBM patient subtypes
 - Over 1,200 patient safety database via ~40 prior studies

REM-001: 2nd generation photodynamic therapy platform

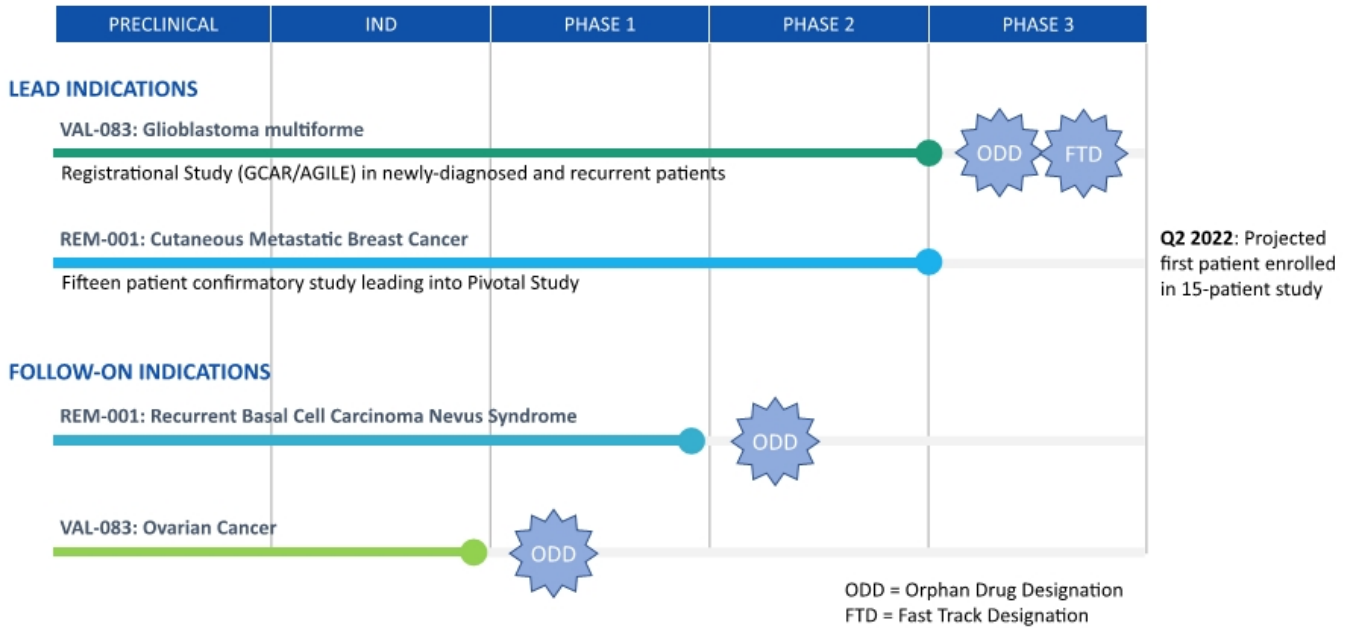
- 15-patient confirmatory study planned for Q2 2022, prior to Phase 3 trial
- ~\$500M² market in lead program: Cutaneous Metastatic Breast Cancer
 - Extensive Phase 2/Phase 3 efficacy data (80% complete responses across four trials)
 - Over 1,100 patient safety database

Multiple follow-on indications with existing orphan designations and/or approved INDs

¹GlobalData November 2018

²Charles River Associates April 2018

Kintara Product Pipeline – Multiple Shots on Goal



VAL-083: GBM Opportunity

“Survival rates for patients with GBM have shown no notable improvement in population statistics in the last three decades.”

Tamimi AF, Juweid M. Epidemiology and Outcome of Glioblastoma. In: De Vleeschouwer S, editor. Glioblastoma [Internet]. Brisbane (AU): Codon Publications; 2017 Sep 27. Chapter 8. PMID: 29251870.

“No new systemic therapy has been approved for use against glioblastoma in almost two decades.”

Lyne SB, Yamini B. An Alternative Pipeline for Glioblastoma Therapeutics: A Systematic Review of Drug Repurposing in Glioblastoma. Cancers (Basel). 2021;13(8):1953. Published 2021 Apr 18. doi:10.3390/cancers13081953

>\$800M market growing to \$1.4B in 2027¹

- ~30,000 newly-diagnosed patients in US/EU
- ~14,000 recurrent patients in US/EU

GBM AGILE Phase 2/Phase 3 international registration study:

- FDA approved & strongly endorsed adaptive design
- Involvement from numerous KOLs
- Partnership with Global Coalition for Adaptive Research (GCAR)

Kintara is the only company currently approved, and enrolling in all three GBM AGILE patient subtypes:

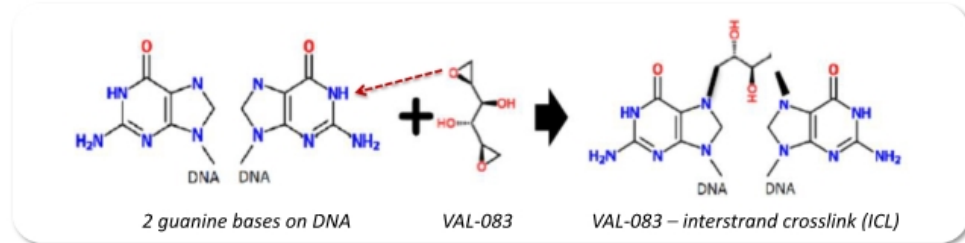
- Newly-Diagnosed Unmethylated (>60% of GBM patients)
- Newly-Diagnosed Methylated (<40% of GBM patients)
- Recurrent

¹GlobalData November 2018

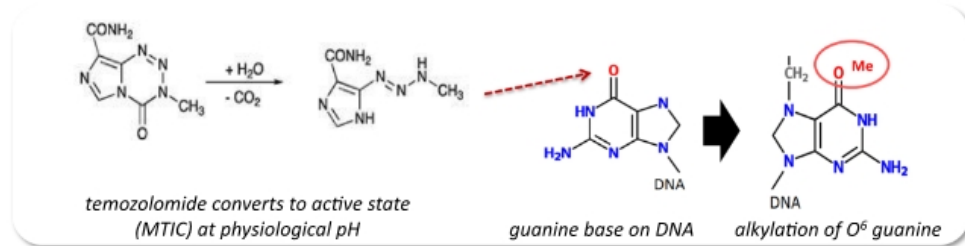
VAL-083 Mechanism of Action

VAL-083's unique DNA targeting mechanism circumvents MGMT-mediated chemoresistance and differentiates it from other therapies used in the treatment of GBM, including TMZ.

VAL-083's unique mechanism of action creates inter-strand DNA cross-links at the N⁷ position of guanine, resulting in double-strand DNA breaks and cancer cell death via apoptosis



Mechanism of VAL-083 via crosslinks at N⁷ of guanine



Mechanism of temozolomide (TMZ) via alkylation at O⁶ of guanine

VAL-083 vs Standard-of-Care TMZ

VAL-083	TMZ
Bifunctional DNA alkylating agent	Monofunctional
Induces DNA interstrand crosslinks	Does not induce DNA interstrand crosslinks
Induces double strand DNA breaks (DSB): non-repairable and lethal to tumor cells	Induces single strand DNA breaks (SSB): tumor cells can repair
Administered IV with very reproducible pharmacokinetics	An oral prodrug with varying bioavailability
Achieves peak brain concentrations that are ~20% higher than corresponding plasma levels	Achieves peak brain concentrations ~80% lower than peak plasma levels
Activity similar in both methylated and unmethylated MGMT GBM cells	Unmethylated MGMT GBM cells very resistant to TMZ
Twice as potent as TMZ for methylated MGMT GBM cells	Half as potent as VAL-083 for methylated MGMT GBM cells

VAL-083: Clinical Data- Phase 2 Studies Top Line Results

Newly-Diagnosed Patients (MGMT-unmethylated)	Evaluable 30 mg Patients	Median Progression Free Survival	Median Overall Survival
<i>TMZ Historical Comparator</i>		5.0-6.9 months ^{1,2,3}	12.7-16.0 months ^{1,2,3}
SYSUCC Newly-Diagnosed [First Line]	n=25	8.7 months	19.1 months
MDACC Newly-Diagnosed [Adjuvant]	n=36	9.5 months	16.5 months

Recurrent Patients (MGMT-unmethylated)	Evaluable 30 mg Patients	Median Overall Survival
<i>Lomustine Historical Comparator</i>		7.2 months ⁴
MDACC Recurrent	n=48	8.0 months

¹Hegi et al N Eng J Med (2005)

²Tanguturi et al. NeuroOncol (2017)

³Alnahhas et al. Neurooncol Adv (2020)

⁴Wick et al N.Eng.J.Med (2017)

Open label Phase 2 studies in unmethylated patients; treatment dose for GCAR GBM AGILE Study;

VAL-083: FDA Approved Expedited Development and Registration Pathway

Collaboration with the Global Coalition for Adaptive Research (GCAR)

- Founded in 2017 by world's foremost clinical, translational, basic science investigators, and health authorities
- Sponsor of innovative and complex platform trials utilizing adaptive design
- Prior success via I-SPY with similar design for breast cancer

GBM Adaptive Global Innovative Learning Environment (AGILE) Study

- International effort in newly-diagnosed and recurrent glioblastoma
- Master Protocol with three or more experimental arms versus a common control
- Primary endpoint: overall survival
- "Seamless" transition to Stage 2, with Stage 1 patients included in final analysis
- Final analysis 12 months after last patient randomized

150 to 200 Patients Maximum Stratified by Three Subtypes

- Newly-diagnosed methylated
- Newly-diagnosed unmethylated¹
- Recurrent²

¹Comparable to MDACC Phase 2 trial – adjuvant cohort

²Comparable to MDACC Phase 2 Trial – recurrent cohort



GCAR/GBM AGILE Advantages

Utilized non-profit funding to design and initiate GBM trial (1st patient enrolled: June 2019)

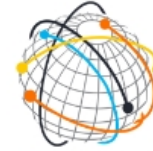
Principals successful in platform and adaptive design paradigm per highly successful breast cancer trial

- (I-Spy): 10-year trial, 16 compounds tested, three received FDA accelerated approval

Regulatory buy-in at highest level with strong FDA support

Rapid study startup and patient enrollment

- Turn-key solution
- 31 sites currently enrolling Kintara arm:
 - Includes one site in Canada
- Expanding into additional sites in the EU in the near future
- Shared control group:
 - Contains costs and accelerates speed of study
 - Has been enrolling for over two years
- Provides significant time and cost savings vs. multiple trials
- Avoids company scale up of fixed expenses for trial execution



**GLOBAL COALITION
FOR ADAPTIVE RESEARCH™**

*"Platform trials can accelerate the time from discovery in the laboratory to implementation in the clinic. **GBM AGILE will raise the bar for all clinical trials.**"*

Janet Woodcock, M.D.
Director of the Center for Drug Evaluation and Research
U.S. Food and Drug Administration

<https://www.businesswire.com/news/home/20190619005230/en/Global-Coalition-Adaptive-Researchs-Innovative-Clinical-Trial>

GCAR: GBM AGILE Major Clinical Sites/Investigators

Principal Investigators of Kintara's arm of the GBM AGILE study:



Dr. John de Groot
Division Chief Neuro Oncology Division
Department of Neurological Surgery
University of California San Francisco



Dr. James Perry
Professor of Neurology
University of Toronto
Sunnybrook Research Institute

With 40 sites enrolling, GBM AGILE includes Key Opinion Leaders and leading clinical sites:



Henry Ford Health System - Detroit



Dana Farber Cancer Institute - Boston



Memorial Sloan Kettering Center - New York



Mount Sinai - New York



MD Anderson Cancer Center - Houston



Cleveland Clinic - Cleveland



Mayo Clinic Cancer Center - Jacksonville



Duke University Medical Center - Durham

“GBM AGILE is an innovative clinical trial approach that enables us to simultaneously and dynamically study the effects of multiple new drug candidates. With the inclusion of paxalisib and VAL-083 for newly-diagnosed unmethylated and recurrent GBM patients, as well as VAL-083 for the additional methylated GBM patient group, we are excited to offer all GBM patients access to these latest therapies.”

- Dr. James Perry

VAL-083: FDA Approved Expedited Development and Registration Pathway

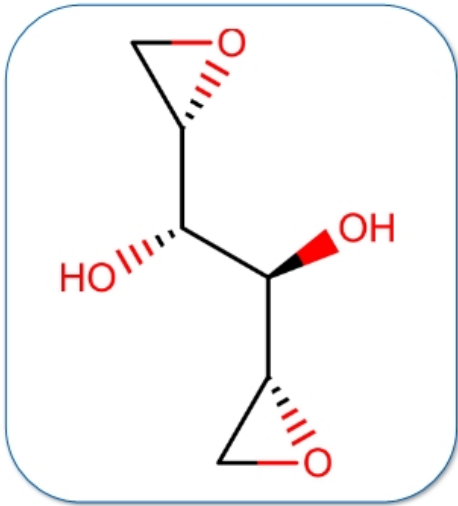
Current Clinical Status

January 2021:

- Kintara jumps on “a fast-moving train” with GBM AGILE
- Current patient enrollment better than initially anticipated
- GBM AGILE/Kintara initiate patient randomization joining Bayer’s regorafenib, and Kazia’s paxalisib as the three compounds in this trial

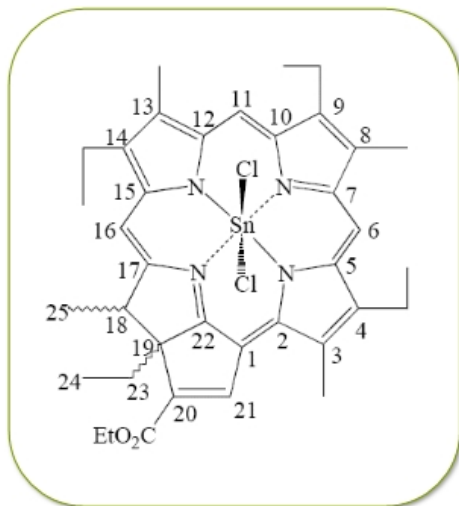
Kintara’s VAL-083 is the only drug currently participating in all three patient subtypes:

- Newly-diagnosed MGMT-unmethylated (>60% of GBM patients)
- Newly-diagnosed methylated (<40% of GBM patients) — Kintara / VAL-083 only
- Recurrent



REM-001: 2nd Generation Light Activated Cancer Therapy

CMBC Overview



Cutaneous Metastatic Breast Cancer is a major unmet medical need

Up to 40,000 patients in the U.S.¹, representing \$500M market opportunity²

Clinical aspects: Highly morbid form of breast cancer

- Bleeding, infectious and malodorous lesions on chest wall, neck and back
- Narcotics for pain control

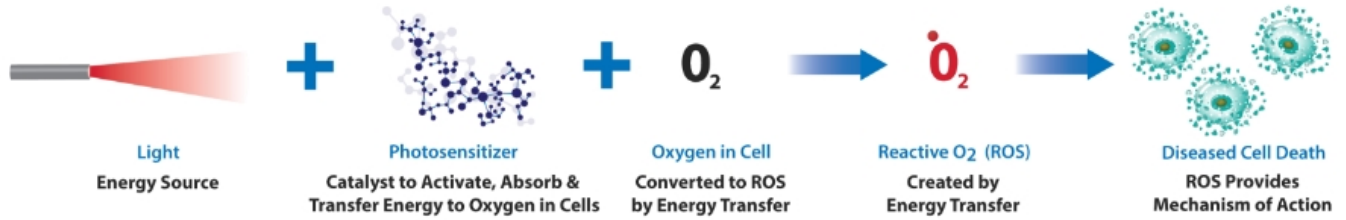
Limited current therapies

- Chemotherapy: generally non-responsive
- Radiation: dose limiting toxicities, lesions are often refractory to radiation

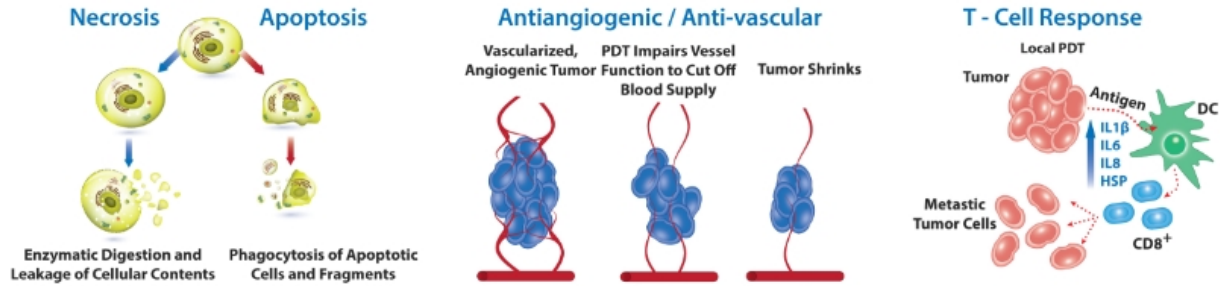
¹Source (a): Saika et al, 2009; Kamaraju et al, 2016; Vano-Galvan et al, 2009; GlobalData Report on Metastatic Breast Cancer; Schoenlaub et al, 2001

²Charles River Report April 2018

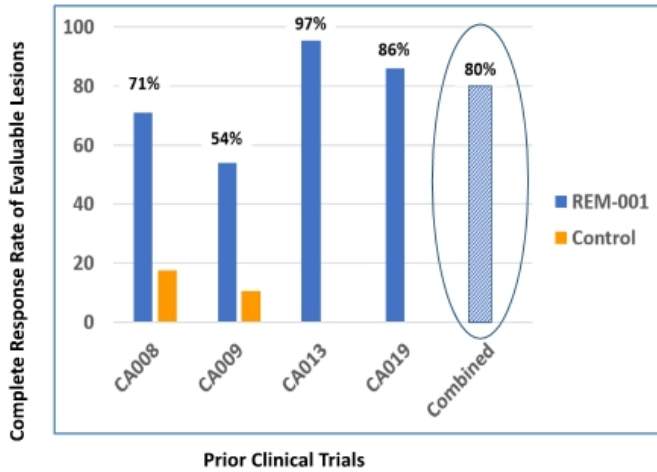
Photodynamic Therapy Mechanisms of Action



PDT induces elimination of diseased cells by immune response, apoptosis, antiangiogenesis and necrosis



REM-001: High Response Rates in CMBC



Second Generation Photodynamic Therapy

- Light activated cancer therapy

Extensive data from prior Phase 2/Phase 3 clinical trials

- 149 patients treated in 4 trials
 - 80% complete response rate in 674 evaluable lesions

Localized Outpatient Treatment

- IV drug infusion accumulates in tumors
- Activated by simple red light

Safety database ~1,100 patients

Previous trial experience used to optimize current trial design

REM-001: CMBC Development Plan

Development plan optimized for success while minimizing cost

- Phase 3 ready
- Initial open-label, 15-patient study to confirm lower dose and optimize trial design
- Leverages prior data indicating lower dose can improve outcome
 - Faster healing
 - Less photosensitivity
- De-risks full Phase 3 study

Anticipated study start in Q2 2022



Indication Expansion Opportunities

VAL-083

- Platinum resistant Ovarian Cancer¹
- Non-Small Cell Lung Cancer¹
- Other Solid Tumors, including pediatric indications

REM-001

- Other Cutaneous Metastatic Cancers
- Recurrent Basal Cell Carcinoma Nevus Syndrome²
- Locally Advanced Basal Cell Carcinoma (laBCC)
- Peripheral Lung Cancer
- Hemodialysis Arteriovenous (AV) Access

¹Prior Phase 1 and Phase 2 studies completed by NCI

²Demonstrated positive results in prior sponsor's Phase 2 study

Barriers to Competition

VAL-083

GBM Orphan drug designation in US and EU
- Seven years market exclusivity after approval in US
- 10 years market exclusivity after approval in Europe

Fourteen patent families
- Claims to methods of use, dosing and administration, combinations, manufacturing, analytical methods, and methods of synthesis

Fourteen US granted patents and forty-five patents granted worldwide
- Expiry dates range from 2031 to 2038

Ovarian Cancer Orphan Drug Designation in US

REM-001

New Chemical Entity
- Five years data exclusivity after approval in US
- 8+2+1 Regime in Europe

Combination Product Regulatory Pathway
- REM-001 and Laser Device

Follow-on Indication Orphan Drug Designations in US
- Basal cell carcinoma nevus syndrome (BCCNS)
- Hemodialysis access grafts

Upcoming Milestones/Value Inflection Events

Q1 2021

- Commence Enrollment - GCAR GBM AGILE International Registrational Study ✓

Q2 2021

- AACR Posters – Data updates for Phase 2 GBM Studies ✓
- Top Line Results - Phase 2 Recurrent GBM Study ✓

Q3 2021

- Top Line Results - Phase 2 Newly Diagnosed Adjuvant GBM Study ✓

Q4 2021

- First site in Canada – GCAR GBM AGILE International Registrational Study ✓

Q1 2022

- First site in the EU – GCAR GBM AGILE International Registrational Study

Q2 2022

- Initiate 15-patient CMBC confirmatory trial

Q2 2023

- Top line results from 15-patient CMBC confirmatory trial

By end of 2023

- Top line results 12 months after last patient randomized - GCAR GBM AGILE International Registrational Study



Seasoned Biopharma Leadership Team

Robert Hoffman
President and CEO
Chair, Board of Directors

CEO of Kintara from November 2021, Chair of Board from June 2018; Board member of Aslan Pharmaceuticals, Antibe Therapeutics, and Saniona; previously served as Senior Vice President and Chief Financial Officer of Heron Therapeutics from April 2017 to October 2020; part of the founding management team of Arena Pharmaceuticals in 1997, serving in various roles until 2015, including Senior Vice President, Finance and Chief Financial Officer

Saiid Zarrabian
Head of Strategic Partnerships
Member, Board of Directors

CEO of Kintara from November 2017 - November 2021; previously served as Chairman and Board Member of La Jolla Pharmaceutical Company; as President of the Protein Production Division of Intrexon Corporation; as CEO and member of the Board of Cytellect, Inc; as President and COO of Senomyx, Inc.; as COO of Pharmacoepia, Inc. and as President & COO of its MSI Division

Greg Johnson
(Acting) Head of Operations

Acting head of operations since January 2018; 29 years of international clinical research and drug development experience; 10 years at MedGenesis Therapeutix Inc. initially as COO, then President and CFO; 15 years at PRA International (now ICON) in a variety of senior roles in four different countries; M.Sc. in Clinical Research; Fellow of the Institute of Clinical Research (FICR)

Scott Prail
CFO

CFO of Kintara since January 2013; previously consulted with multiple companies including Kintara; served as Director of Finance for Inflazyme Pharmaceuticals; worked at PricewaterhouseCoopers LLP for four years and completed a CPA in 1996

Dennis Brown
CSO

Kintara founder, and Chief Scientific Officer since January 2013; served as a member of Board of Directors from February 2013 to April 2018; more than 30 years of successful drug discovery and development experience; B.A. in Biology and Chemistry, M.S. in Cell Biology, Ph.D. in Radiation and Cancer Biology

Scientific Advisory Boards

GBM Scientific Advisory Board



Dr. John de Groot Groot (PI for Kintara/VAL-083 in GBM AGILE)
University of California San Francisco
Division Chief Neuro Oncology Division, Department of Neurological Surgery



Dr. Timothy Cloughesy (Overall PI for GBM AGILE)
David Geffen School of Medicine (UCLA)
Professor of Neurology



UCLA Brain Research Institute and Jonsson Comprehensive Cancer Center
Member



Dr. Napoleone Ferrara
University of California, San Diego
World renowned scientist and Distinguished Professor of Pathology and a
Distinguished Adjunct Professor of Ophthalmology and Pharmacology



Dr. David Reardon
Dana-Farber Cancer Institute
Clinical Director of the Center for Neuro-Oncology
Harvard Medical School
Professor of Medicine



Dr. Nicholas Butowski
UCSF Medical Center
Neuro-oncologist
Brain Tumor Center
Director of Translational Research in Neuro-Oncology and Researcher



CMBC Scientific Advisory Board



Mario Lacouture, MD
Memorial Sloan Kettering Cancer Center
Director, Oncodermatology Program
Leading expert in treatment of cutaneous metastases in cancer



Thomas S. Mang, PhD
University at Buffalo (UB) School of Dental Medicine*
Director of Research for Oral and Maxillofacial Surgery Department
Recognized PDT expert and prior clinical work with REM-001 Therapy



Stephen B. Solomon, MD
Memorial Sloan Kettering Hospital
Chairman, Interventional Radiology and Co-Director,
Image-Guided Intervention
Specializes in image-guided interventions in cancer



Leonard A. Farber, MD
Weill Cornell Hospital*
Radiation Oncologist
Specialties include adult radiation oncology for breast cancer patients
Experience in treating CMBC and recurrent basal cell carcinoma

*Prior affiliations

Investment Highlights

- Late-stage oncology company with two highly de-risked assets for underserved indications
- VAL-083
 - Initiated GBM AGILE International Registrational Study: January 2021 with VAL-083 as the only trial arm enrolling all three GBM AGILE patient subtypes
 - Accelerated clinical pathway with strong regulatory support and 31 sites enrolling in Kintara arm
 - >\$1B market opportunity¹
- REM-001 — Light activated cancer therapy diversifies late-stage oncology pipeline
 - 80% complete responses across four clinical trials to date in CMBC
 - 15-Patient confirmatory study initiation planned for Q2 2022, prior to Phase 3 trial
 - \$500M market opportunity²
- Significant upcoming milestones/value inflection events
 - Q1 2022: First site in the EU – GCAR GBM AGILE International Registrational Study
 - Q2 2022: Initiate 15-patient CMBC confirmatory trial
 - Q2 2023: Top line results from 15-patient CMBC confirmatory trial
 - By end of 2023: Top line results from GCAR GBM AGILE Study 12 months after last patient randomized

¹GlobalData November 2018

²Charles River Associates April 2018

