
**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): September 28, 2021

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 2.02 Results of Operations and Financial Condition.

Kintara Therapeutics, Inc. (the “Company”) issued a press release on September 29, 2021, disclosing financial information and operating metrics for the year ended June 30, 2021, and providing a corporate update. A copy of the Company’s press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

See “Item 2.02 Results of Operation and Financial Condition” above.

The information in this Current Report on Form 8-K under Items 2.02 and 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press release of Kintara Therapeutics, Inc. issued September 29, 2021 |
| 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: September 29, 2021

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



Kintara Therapeutics Announces Fiscal Year 2021 Financial Results and Provides Corporate Update

SAN DIEGO, September 29, 2021 /PRNewswire/ -- <https://www.kintara.com/> (Nasdaq: KTRA) ("Kintara" or the "Company"), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, today announced financial results for its fiscal year ended June 30, 2021 and provided a corporate update.

CORPORATE HIGHLIGHTS AND RECENT DEVELOPMENTS

- Entered into securities purchase agreements with healthcare-focused institutional investors to raise approximately \$15 million in gross proceeds (September). Funding from this registered direct offering, which was priced at a premium to market, was consummated on September 28, 2021, and provides cash for ongoing clinical studies and corporate working capital needs.
- Bolstered patient enrollment opportunities in the U.S. by activating additional clinical trial sites for glioblastoma (GBM) patients for the VAL-083 arm of the GBM AGILE registrational study sponsored by the Global Coalition for Adaptive Research (GCAR).
 - Announced initiation of patient recruitment at first site (January)
 - Reported activation of 15 clinical sites for the GBM AGILE study (May)
 - Updated site activation to 26 clinical sites (August)

The GBM AGILE study is a revolutionary, patient-centered, adaptive platform trial for registration evaluating multiple therapies for patients with newly-diagnosed and recurrent GBM. VAL-083 currently represents the only therapeutic agent being evaluated in all subgroups of GBM AGILE (newly-diagnosed methylated MGMT, newly-diagnosed unmethylated MGMT, and recurrent patients). The study will enroll up to 150 patients in the initial evaluation (labeled 'stage 1') for the VAL-083 arm of the study at over 40 sites in the U.S. and Canada, with potential to increase to 65 clinical trial centers worldwide. The Company is forecasting that the recent financing will provide sufficient funding through stage 1, which could result in graduation to the final confirmatory stage, the potentially NDA enabling portion of the GBM AGILE study.

- Reported topline results from the Phase 2 study conducted at the MD Anderson Cancer Center that affirm the safety and efficacy of VAL-083 in two different GBM patient subtypes and support continued evaluation of VAL-083 in the GBM AGILE registrational study.
 - In September, topline Phase 2 clinical study results for VAL-083 as adjuvant therapy for newly-diagnosed GBM patients were reported demonstrating progression free survival (PFS) and overall survival (OS) of 10.0 months and 16.5 months, respectively, in efficacy evaluable patients.
 - In July, topline Phase 2 clinical study results for VAL-083 for recurrent GBM were reported demonstrating median overall survival (mOS) for the 48 efficacy evaluable
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patients initially receiving the GBM AGILE treatment dose of 30 mg/m²/day of 8.0 months.

- Continued to advance development of REM-001 for the treatment of Cutaneous Metastatic Breast Cancer (CMBC), including taking critical steps toward manufacturing sufficient quantity of drug to allow for initiation and completion of our 15-patient lead-in CMBC study.
- Joined the Russel Microcap Index effective June 28, 2021. Russell Indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. Approximately \$10.6 trillion in assets are benchmarked against Russell's U.S. Indexes.
- Enhanced leadership team by appointing Tamara A. Seymour to the Board of Directors (April). Ms. Seymour is a corporate finance veteran with three decades of experience in biotech and life sciences including roles as a Chief Financial Officer and Board member of publicly-listed companies.

"As we embark on a new fiscal year with a strengthened cash position from our recent financing, I'm extremely pleased with where the Company is positioned on the clinical and corporate development fronts," commented Saiid Zarrabian, Kintara's President and Chief Executive Officer. "Moving forward, our diversified, late-stage pipeline has multiple, significant near-term milestones, highlighted by the GCAR GBM AGILE study. We believe this registration study represents an extraordinary opportunity for the Company as it provides an optimal clinical path given its highly accelerated program as evidenced by the initiation of patient enrollment at 26 sites in less than eight months, and from a cost savings standpoint through an FDA approved registrational trial which provides Kintara the unique opportunity to enroll three separate GBM patient subtypes. We are entering a pivotal juncture in the Company's development, and I wish to extend gratitude to our longstanding shareholders for their continued support."

SUMMARY OF FINANCIAL RESULTS FOR FISCAL YEAR ENDED JUNE 30, 2021

At June 30, 2021, the Company had cash and cash equivalents of approximately \$10.5 million. For the year ended June 30, 2021, the Company reported a net loss of approximately \$38.3 million, or \$1.60 per share, compared to a net loss of approximately \$9.1 million, or \$0.87 per share, for the year ended June 30, 2020. The increase in loss for the year ended June 30, 2021 compared to the year ended June 30, 2020 was largely due to the recognition of \$16.1 million of non-cash expenses related to the acquisition of in-process research and development costs associated with the acquisition of Adgero Biopharmaceuticals Holdings, Inc. and an expanded rate of expenditures with the initiation of the GCAR study and REM-001 development.

Selected Balance Sheet Data (in thousands)

| | June 30, 2021 | June 30, 2020 |
|----------------------------|--------------------------|----------------------|
| | <u> </u> | <u> </u> |
| | \$ | \$ |
| Cash and cash equivalents | 10,537 | 2,392 |
| Working capital | 9,013 | 176 |
| Total assets | 13,543 | 2,938 |
| Total stockholders' equity | 10,581 | 263 |

Selected Statement of Operations Data (in thousands, except per share data)

For the years ended

| | June 30, | June 30, |
|---|-------------------|-----------------|
| | 2021 | 2020 |
| | \$ | \$ |
| Research and development | 11,815 | 3,630 |
| General and administrative | 9,757 | 4,514 |
| Merger costs | 500 | 1,054 |
| In-process research and development | 16,094 | - |
| Other loss (income) | 132 | (72) |
| Net loss for the period | (38,298) | (9,126) |
| Deemed dividend recognized on beneficial conversion features of Series C Preferred stock issuance | (3,181) | - |
| Series A Preferred cash dividend | (8) | (8) |
| Series B Preferred stock dividend | (17) ⁷ | (9) |
| Net loss attributable to common stockholders | (41,504) | (9,143) |
| Basic and fully diluted weighted average number of shares | 25,886 | 10,444 |
| Basic and fully diluted loss per share | (1.60) | (0.87) |

Kintara's financial statements as filed with the U.S. Securities Exchange Commission can be viewed on the Company's website at: <http://ir.kintara.com/sec-filings>.

ABOUT KINTARA

Located in San Diego, California, Kintara is dedicated to the development of novel cancer therapies for patients with unmet medical needs.

Kintara is developing two late-stage, Phase 3-ready therapeutics for clear unmet medical needs with reduced risk development programs. The two programs are VAL-083 for GBM and REM-001 for CMBC.

VAL-083 is a "first-in-class", small-molecule chemotherapeutic with a novel mechanism of action that has demonstrated clinical activity against a range of cancers, including central nervous system, ovarian and other solid tumors (e.g., NSCLC, bladder cancer, head and neck) in U.S. clinical trials sponsored by the National Cancer Institute (NCI). Based on Kintara's internal research programs and these prior NCI-sponsored clinical studies, Kintara is currently conducting clinical trials to support the development and commercialization of VAL-083 in GBM.

Kintara is also advancing its proprietary, late-stage photodynamic therapy platform that holds promise as a localized cutaneous, or visceral, tumor treatment as well as in other potential indications. REM-001 therapy, has been previously studied in four Phase 2/3 clinical trials in patients with CMBC, who had previously received chemotherapy and/or failed radiation therapy. With clinical efficacy to date of 80% complete responses of CMBC evaluable lesions, and with an existing robust safety database of approximately 1,100 patients across multiple indications, Kintara is advancing the REM-001 CMBC program to late-stage pivotal testing.

SAFE HARBOR STATEMENT

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation

Reform Act of 1995, including statements regarding the status of the Company's clinical trials and the GBM AGILE study. Any forward-looking statements contained herein are based on current expectations but are subject to a number of risks and uncertainties. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the impact of the COVID-19 pandemic on the Company's operations and clinical trials; the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in the Company's filings with the SEC, including the Company's Annual Report on Form 10-K for the year ended June 30, 2021, the Company's Quarterly Reports on Form 10-Q, and the Company's Current Reports on Form 8-K.

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