



Karuna Therapeutics Reports Second Quarter 2023 Financial Results and Provides General Business Updates

August 3, 2023

On track to submit New Drug Application (NDA) for KarXT in schizophrenia with the U.S. FDA in the third quarter of 2023, with a product launch in the second half of 2024, assuming approval

Initiated the Phase 3 ADEPT-3 open label extension trial in the third quarter of 2023, and on track to commence the Phase 3 ADEPT-2 trial in the second half of 2023

Announced the appointment of Jonathan Rosin to Chief Human Resources Officer and the promotion of Jason Brown to Chief Financial Officer

\$1.4 billion in cash expected to fund operations through 2026

Conference call and webcast to take place today at 8:00 a.m. ET

BOSTON--(BUSINESS WIRE)--Aug. 3, 2023-- Karuna Therapeutics, Inc. (NASDAQ: KRTX), a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions, today announced financial results for the second quarter of 2023 and provided a general business update.

"We've made significant progress in the second quarter across our business, but most importantly in generating, analyzing, and preparing the data required for our NDA submission in schizophrenia," said Bill Meury, president and chief executive officer of Karuna Therapeutics. "Looking ahead, we remain focused on our NDA submission, which is on track for later this quarter, and building the commercial infrastructure in preparation for the potential launch of KarXT in the second half of 2024."

"Beyond the EMERGENT program, we continue to activate additional clinical trial sites to support recruitment in our ARISE trial, with data on track for the second half of 2024. We also initiated the ADEPT-3 open label extension trial in psychosis in Alzheimer's earlier this quarter, with the full Phase 3 ADEPT program expected to be underway in the coming months following the initiation of ADEPT-2, our second pivotal safety and efficacy trial in this program," added Mr. Meury.

KEY PIPELINE HIGHLIGHTS

Karuna is advancing a pipeline of novel drug candidates for the treatment of various psychiatric and neurological conditions led by KarXT (xanomeline-tropium), an oral, investigational M1/M4-preferring muscarinic agonist.

KarXT

KarXT is being evaluated in Phase 3 clinical trials as a potential treatment for schizophrenia as a monotherapy and adjunctive therapy, as well as for psychosis in Alzheimer's disease.

- Schizophrenia

- **Presented additional data analyses from the EMERGENT program evaluating KarXT in schizophrenia at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting and the 2023 Congress of the Schizophrenia International Research Society (SIRS) in the second quarter of 2023.**
 - In the EMERGENT-3 trial, KarXT demonstrated a statistically significant and clinically meaningful improvement in the Clinical Global Impression – Severity (CGI-S) score, a prespecified secondary endpoint, compared to placebo starting at week 2 and maintained such improvement throughout the trial to week 5 (-1.1 KarXT vs. -0.6 placebo; $p < 0.0001$), consistent with the EMERGENT-1 and EMERGENT-2 trials.
 - In an exploratory pooled analysis of the EMERGENT-2 and EMERGENT-3 trials, KarXT was associated with statistically significant and clinically meaningful improvements in cognitive function compared to placebo at week 5 in patients with cognitive impairment at baseline (0.41 KarXT vs. 0.13 placebo; $p < 0.01$, Cohen's $d = 0.52$) as measured by the CANTAB composite score. Additionally, there was no significant correlative relationship between changes in Positive and Negative Syndrome Scale (PANSS) total score and changes in CANTAB composite score in the KarXT group, suggesting that improvements observed in cognition were largely independent of improvements in PANSS-related symptoms.
- **Completed enrollment in the EMERGENT-5 trial in the second quarter of 2023.**
 - Topline data from the EMERGENT-4 and EMERGENT-5 trials evaluating the long-term safety of KarXT in schizophrenia are anticipated in 2024.
- **The Phase 1b trial evaluating the effect of KarXT on 24-hour ambulatory blood pressure in adults with schizophrenia completed enrollment in the second quarter of 2023.**
 - Topline data from the trial is expected in the fourth quarter of 2023.
- **The Company remains on track to submit an NDA for KarXT in schizophrenia with the FDA in the third quarter of 2023, with a launch in the second half of 2024, if approved.**

- Adjunctive treatment in schizophrenia
 - **Topline data from the ARISE trial evaluating the efficacy and safety of KarXT in schizophrenia when combined with a background antipsychotic is anticipated in the second half of 2024.**
- Psychosis in Alzheimer's disease
 - **The ADEPT-1 trial is ongoing, with the ADEPT-2 trial on track to initiate in the second half of 2023.**
 - Topline data from the ADEPT-1 and ADEPT-2 trials are anticipated in 2025.
 - **Initiated the ADEPT-3 open-label extension trial in the third quarter of 2023.**

Early-stage and discovery programs

The Karuna pipeline also includes clinical-stage candidate KAR-2618, a TRPC4/5 inhibitor for the treatment of mood and anxiety disorders, as well as pre-clinical muscarinic, TRPC4/5, and target-agnostic compounds for the treatment of psychiatric and neurological conditions.

- **The Company plans to share next steps on the development of KAR-2618 for the treatment of mood and anxiety disorders in the second half of 2023.**

BUSINESS UPDATES

- **Announced key leadership appointments.** In a separate press release, the Company today announced the appointment of Jonathan Rosin to Chief Human Resources Officer in July 2023, and the promotion of Jason Brown to Chief Financial Officer. Mr. Brown succeeds Troy Ignelzi who will remain at Karuna for a transition period through the end of the third quarter of 2023.

ANTICIPATED UPCOMING MILESTONES

- NDA submission of KarXT in schizophrenia (3Q 2023)
- Initiation of the Phase 3 ADEPT-2 trial (2H 2023)
- Topline data from the Phase 3 EMERGENT-4 trial (2024)
- Topline data from the Phase 3 EMERGENT-5 trial (2024)
- Launch of KarXT in schizophrenia, if approved (2H 2024)
- Topline data from the Phase 3 ARISE trial (2H 2024)
- Topline data from the Phase 3 ADEPT-1 trial (2025)
- Topline data from the Phase 3 ADEPT-2 trial (2025)

SECOND QUARTER 2023 FINANCIAL RESULTS

The Company reported a net loss of \$103.2 million for the second quarter of 2023, as compared to \$64.9 million for the prior year period. The increase in net loss for the quarter was driven by research and development expenses related to the Company's ongoing KarXT clinical programs, NDA-supporting activities, pre-commercialization activities, increased employee headcount across the organization, and higher stock-based compensation.

Research and development expenses were \$92.5 million for the second quarter of 2023, as compared to \$52.5 million for the prior year period. The increase in research and development expenses for the quarter was primarily driven by expenses related to the KarXT clinical programs, NDA-supporting activities, increased employee headcount, and higher stock-based compensation.

General and administrative expenses were \$27.4 million for the second quarter of 2023, as compared to \$17.8 million for the prior year period. The increase in general and administrative expenses for the quarter was primarily driven by the Company's pre-commercialization activities, increased employee headcount, and higher stock-based compensation.

The Company ended the quarter with \$1.4 billion in cash, cash equivalents, and available-for-sale investment securities compared to \$1.1 billion as of December 31, 2022. The increase was primarily the result of the completion of the Company's follow-on public offering in March 2023, which resulted in net proceeds of \$436.7 million. The Company expects that current cash, cash equivalents, and available-for-sale investment securities as of June 30, 2023 will enable the Company to fund its operating expenses and capital expenditure requirements through the end of 2026.

CONFERENCE CALL AND WEBCAST DETAILS

The second quarter 2023 financial results and business update will be discussed during a conference call and webcast today at 8:00 a.m. ET. A webcast of the live call may be accessed on the Investors section of the Karuna website at investors.karunatx.com. A replay of the webcast will be available for up to 30 days following the event.

About Karuna Therapeutics

Karuna Therapeutics is a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions. At Karuna, we understand there is a need for differentiated and more effective treatments that can help patients navigate the challenges presented by these severe and disabling disorders. Utilizing our extensive knowledge of neuroscience, we are harnessing the untapped potential of the brain in pursuit of novel pathways to develop medicines that make meaningful differences in peoples' lives. For more information, please visit www.karunatx.com.

Forward Looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E

of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations about the timing of our ongoing and planned clinical trials and regulatory filings, our goals to develop and commercialize our product candidates, our liquidity and capital resources and other statements identified by words such as “could,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “will,” “would,” or similar expressions and the negatives of those terms. Forward looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to obtain necessary funding, our ability to generate positive clinical trial results for our product candidates and other risks inherent in clinical development, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, risks relating to business interruptions resulting from the coronavirus (COVID-19) pandemic, and other risks set forth under the heading “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2022 and in our subsequent filings with the Securities and Exchange Commission. Our actual results could differ materially from the results described in or implied by such forward looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

Karuna Therapeutics, Inc.

Unaudited Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
License and other revenue	\$ -	\$ 5,278	\$ 654	\$ 5,278
Operating expenses:				
Research and development	92,490	52,487	177,957	96,293
General and administrative	27,417	17,843	51,670	32,631
Total operating expenses	119,907	70,330	229,627	128,924
Loss from operations	(119,907)	(65,052)	(228,973)	(123,646)
Other income, net:				
Interest income	16,597	490	27,942	727
Sublease income	147	147	294	286
Total other income, net	16,744	637	28,236	1,013
Net loss before income taxes	(103,163)	(64,415)	(200,737)	(122,633)
Income tax provision	—	(528)	—	(528)
Net loss attributable to common stockholders	\$ (103,163)	\$ (64,943)	\$ (200,737)	\$ (123,161)
Net loss per share, basic and diluted	\$ (2.75)	\$ (2.17)	\$ (5.55)	\$ (4.13)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	37,524,640	29,896,332	36,170,166	29,851,396

Karuna Therapeutics, Inc.

Unaudited Consolidated Balance Sheet Data

(in thousands)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and investments	\$ 1,434,477	\$ 1,124,044
Working capital	1,413,344	1,120,823
Total assets	1,472,103	1,163,334
Total stockholders' equity	\$ 1,419,563	\$ 1,126,238

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Investor:

Alexis Smith

+1 (518) 338-8990

asmith@karunatx.com

Source: Karuna Therapeutics, Inc.