Karuna Therapeutics Reports Second Quarter 2022 Financial Results and Provides General Business Updates

August 8, 2022

Met primary and key secondary endpoints in Phase 3 EMERGENT-2 trial of KarXT in schizophrenia

The Company plans to submit a New Drug Application (NDA) with the U.S. Food & Drug Administration (FDA) in mid-2023

Topline data from the Phase 3 EMERGENT-3 trial and Phase 3 ARISE trial of KarXT in schizophrenia expected in the first quarter of 2023 and first half of 2024, respectively

Phase 3 ADEPT-1 trial of KarXT in psychosis related to Alzheimer's disease to initiate in the third quarter of 2022

$407.4 million in cash expected to fund operations for at least 12 months following the potential New Drug Application (NDA) submission of KarXT for schizophrenia

Management to host conference call and webcast at 8:00 a.m. ET to discuss Phase 3 EMERGENT-2 trial topline results

BOSTON--(BUSINESS WIRE)--Aug. 8, 2022-- 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 2022 and provided a general business update.

In a separate press release issued today, the Company announced positive results from the Phase 3 EMERGENT-2 trial evaluating the efficacy, safety and tolerability of its lead investigational therapy, KarXT (xanomeline-trospium), in adults with schizophrenia. The trial met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 9.6-point reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-21.2 KarXT vs. -11.6 placebo; p<0.0001) at Week 5 (Cohen's d effect size of 0.61). KarXT also met key secondary endpoints in the Phase 3 EMERGENT-2 trial, demonstrating a statistically significant reduction in both positive symptoms (e.g., hallucinations or delusions) and negative symptoms (e.g., difficulty enjoying life or withdrawal from others) of schizophrenia as measured by the PANSS positive, PANSS negative and PANSS negative Marder factor subscales. KarXT was generally well tolerated, with a side effect profile substantially consistent with prior trials of KarXT in schizophrenia.

"It is an incredibly exciting time for Karuna; with two positive, registrational trials in hand for KarXT, we are another step closer to potentially providing the first new class of medicine in more than 50 years to the millions of people worldwide living with schizophrenia," said Steve Paul, M.D., chief executive officer, president, and chairman of Karuna Therapeutics. "People living with serious mental illness are in dire need of medicines that work differently than current treatments in order to find relief from burdensome symptoms. We plan to submit a New Drug Application in schizophrenia in mid-2023, and will simultaneously continue to progress the ARISE and ADEPT clinical trial programs to explore KarXT's potential in additional indications."

Pipeline Updates

Karuna is advancing a pipeline of novel drug candidates for the treatment of various psychiatric and neurological conditions. The clinical pipeline is led by KarXT (xanomeline-trospium), an oral investigational antipsychotic with a novel mechanism of action mediated via muscarinic cholinergic receptors, that is currently being evaluated in ongoing and planned late-stage clinical trials as a potential treatment for schizophrenia and psychosis related to Alzheimer's disease.

- **KarXT for the treatment of schizophrenia.** The EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia, includes the completed positive Phase 2 EMERGENT-1 and Phase 3 EMERGENT-2 trials, and the following ongoing Phase 3 trials:
  - EMERGENT-3: A five-week inpatient trial evaluating the efficacy and safety of KarXT compared to placebo in 246 adults with schizophrenia currently being conducted in the U.S.
    - The Company anticipates topline data in the first quarter of 2023.
  - EMERGENT-4: A 52-week outpatient, open-label extension trial evaluating the long-term safety and tolerability of KarXT in adults with schizophrenia who completed EMERGENT-2 or EMERGENT-3.
  - EMERGENT-5: A 52-week outpatient, open-label trial evaluating the long-term safety and tolerability of KarXT in adults with schizophrenia conducted in the U.S. and Puerto Rico who were not enrolled in EMERGENT-2 or EMERGENT-3.
  - The Company expects to submit an NDA for KarXT in schizophrenia with the U.S. FDA in mid-2023.

- **KarXT for the treatment of schizophrenia in adults who experience an inadequate response to current standard of care.** The Phase 3 ARISE trial evaluating the safety and efficacy of KarXT compared to placebo as an adjunctive treatment for schizophrenia in adults who experience an inadequate response to current standard of care is enrolling.
  - The Company anticipates topline data in the first half of 2024.

- **KarXT for the treatment of psychosis related to Alzheimer's disease.** The ADEPT program, the clinical program

evaluating KarXT for the treatment of psychosis related to Alzheimer's disease, will consist of three Phase 3 trials:

- **ADEPT-1**: A trial evaluating the efficacy and safety of KarXT compared to placebo in adults with moderate to severe psychosis related to Alzheimer's disease. This trial will consist of a 12-week, single-blind treatment period, followed by a 26-week, double-blind, randomized withdrawal period. Patients who meet the response criteria in the single-blind treatment period will enter the double-blind treatment period and will be randomized to receive KarXT or placebo.
  - The ADEPT-1 trial is on track to initiate in the third quarter of 2022.
- **ADEPT-2**: A 12-week trial evaluating the acute efficacy and safety of KarXT compared to placebo in adults with psychosis related to Alzheimer's disease.
  - The ADEPT-2 trial is expected to initiate in 2023.
- **ADEPT-3:** A 52-week outpatient, open-label extension trial evaluating the long-term safety and tolerability of KarXT in adults who completed ADEPT-1 or ADEPT-2.
  - The ADEPT-3 trial is expected to initiate in 2023.

- **Discovery and early-stage pipeline.** The Company continues to advance its novel formulations of KarXT, earlier pipeline of muscarinic receptor targeted programs, and its artificial intelligence-based target agnostic drug discovery program for treating psychiatric and neurological conditions.

Anticipated Upcoming Milestones

- Initiate the Phase 3 ADEPT-1 trial (3Q 2022)
- Topline data from the Phase 3 EMERGENT-3 trial (1Q 2023)
- Initiate the Phase 3 ADEPT-2 trial (2023)
- Initiate the Phase 3 ADEPT-3 trial (2023)
- NDA submission of KarXT in schizophrenia (mid-2023)
- Topline data from the Phase 3 ARISE trial (1H 2024)

Second Quarter 2022 Financial Results

The Company reported a net loss of $64.9 million for the second quarter of 2022, as compared to $34.4 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 enrollment of the Phase 3 EMERGENT and ARISE trials, NDA-supporting activities, increased employee headcount across the organization, and higher stock-based compensation expense. The Company recognized licensing revenue of $5.3 million for the second quarter of 2022 related to a development milestone and related tax gross ups associated with our License Agreement with Zai Lab (Shanghai) Co., Ltd. There was no license revenue in the prior year period.

Research and development expenses were $52.5 million for the second quarter of 2022, as compared to $24.1 million the prior year period. The increase in research and development expenses for the quarter was primarily driven by expenses related to the Company's Phase 3 EMERGENT, ARISE and ADEPT trials, manufacturing to support ongoing and planned clinical trials, as well as for a planned NDA submission and potential commercialization of KarXT for schizophrenia, personnel-related costs due to the increase in employee headcount, and higher stock-based compensation expense.

General and administrative expenses were $17.8 million for the second quarter of 2022, as compared to $10.4 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in employee headcount.

The Company ended the quarter with $407.4 million in cash, cash equivalents and available-for-sale investment securities compared to $494.0 million as of December 31, 2021. The Company expects that current cash, cash equivalents and available-for-sale investment securities as of June 30, 2022 will enable the Company to fund its operating expenses and capital expenditure requirements for at least 12 months following the potential NDA submission of KarXT for the treatment of psychosis in adults with schizophrenia.

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 serious mental illness. 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, 2021. 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
License revenue	$ 5,278	$ —	$ 5,278	$ —
Operating expenses:				
Research and development	52,487	24,147	96,293	44,333
General and administrative	17,843	10,384	32,631	20,161
Total operating expenses	70,330	34,531	128,924	64,494
Loss from operations	(65,052)	(34,531)	(123,646)	(64,494)
Other income (loss), net:				
Interest income	490	106	727	249
Sublease income	147	9	286	9
Impairment loss on right-of-use assets	—	—	—	(677)
Total other income (loss), net	637	115	1,013	(419)
Net loss before income taxes	(64,415)	(34,416)	(122,633)	(64,913)
Income tax provision	(528)	—	(528)	—
Net loss attributable to common stockholders	$ (64,943)	$ (34,416)	$ (123,161)	$ (64,913)
Net loss per share, basic and diluted	$ (2.17)	$ (1.17)	$ (4.13)	$ (2.27)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	29,896,332	29,482,511	29,851,396	28,639,210

Karuna Therapeutics, Inc.
Unaudited Consolidated Balance Sheet Data
(in thousands)

	June 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 407,414	$ 493,991
Working capital	400,313	497,121
Total assets	433,556	527,671
Total stockholders' equity	$ 405,409	$ 502,026

View source version on businesswire.com: https://www.businesswire.com/news/home/20220808005231/en/

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