Karuna Therapeutics Reports Second Quarter 2020 Financial Results and Business Highlights

August 5, 2020

On track to initiate Phase 3 trials within the EMERGENT program, the clinical program evaluating KarXT for the treatment of acute psychosis in patients with schizophrenia, by the end of 2020

Topline data from Phase 1b trial in healthy elderly volunteers expected by the end of 2020

Plans to initiate Phase 2 trial evaluating KarXT as adjunctive therapy with standard of care for the treatment of psychosis in patients with schizophrenia who remain symptomatic on existing therapies

$367.6 million in cash, cash equivalents and short-term investments expected to fund multiple milestones, including the Phase 3 program to NDA submission, and operations for at least the next three years

BOSTON--(BUSINESS WIRE)--Aug. 5, 2020-- Karuna Therapeutics, Inc. (NASDAQ: KRTX), an innovative clinical-stage biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with disabling and potentially fatal neuropsychiatric disorders, today announced financial results for the second quarter of 2020 and provided a general business update.

"We've made tremendous progress in advancing our clinical development programs evaluating KarXT in neuropsychiatric disorders, including schizophrenia and dementia-related psychosis, where the standards of care are simply insufficient," said Steve Paul, M.D., chief executive officer, president and chairman of Karuna Therapeutics. "We remain focused on initiating Phase 3 trials within our EMERGENT program following a successful End-of-Phase 2 meeting with the FDA in the second quarter. This important next step brings us closer to providing a new, unique and differentiated treatment option to patients with schizophrenia."

Dr. Paul continued: "Our commitment to discover and develop more effective treatments for neuropsychiatric disorders is not only underscored by our clinical-stage programs, but also the expansion of our drug discovery efforts. These discovery efforts have enabled us to broaden our approach to CNS drug discovery and development with the goal of enhancing Karuna's pipeline of novel drug candidates for treating a wide range of neuropsychiatric disorders."

Pipeline Updates
KarXT, a proprietary oral modulator of muscarinic cholinergic receptors, is Karuna's lead product candidate combining xanomeline, a novel muscarinic agonist, with trospium, a U.S. Food & Drug Administration (FDA) approved muscarinic antagonist that does not appreciably cross the blood-brain-barrier, to preferentially stimulate muscarinic receptors in the central nervous system (CNS). KarXT is currently being evaluated as a potential treatment for neuropsychiatric disorders, including schizophrenia and dementia-related psychosis.

- **KarXT in schizophrenia:** The Company previously announced a positive outcome of its End-of-Phase 2 meeting with the FDA for KarXT for the treatment of acute psychosis in patients with schizophrenia. The outcome of the meeting supports the progression of KarXT into Phase 3 development. The formal minutes from the meeting also confirmed that the completed Phase 2 trial, along with one successful Phase 3 efficacy and safety trial, and additional safety data to meet regulatory requirements, would be acceptable to support a New Drug Application (NDA) filing.
    - **The Company is on track to initiate the first Phase 3 trial within its EMERGENT program, the clinical program evaluating KarXT for the treatment of acute psychosis in adults with schizophrenia, by the end of 2020.** The EMERGENT program includes the completed positive Phase 2 clinical trial (EMERGENT-1) and additional planned efficacy and safety trials to support an NDA filing, including:
        - **EMERGENT-2:** A five-week inpatient trial evaluating the efficacy and safety of KarXT in adults with schizophrenia. The EMERGENT-2 trial design shares many characteristics with the completed EMERGENT-1 trial, including duration of treatment, primary endpoint and patient population. EMERGENT-2 is a 1:1 randomized, flexible-dose, double-blind, placebo-controlled trial enrolling approximately 250 adults in the U.S., and will evaluate the change in Positive and Negative Syndrome Scale (PANSS) total score at Week 5 of KarXT versus placebo as the primary outcome measure. EMERGENT-2 is expected to commence by the end of 2020.
        - **EMERGENT-3:** A five-week inpatient trial evaluating the safety and efficacy of KarXT in adults with schizophrenia. This trial will share characteristics of the completed EMERGENT-1 trial and planned EMERGENT-2 trial, including duration of treatment, patient population and primary outcome measure. Details of the EMERGENT-3 trial will be finalized by the end of 2020, with initiation expected in the first half of 2021.
        - **EMERGENT-4:** A 52-week, outpatient, open-label long-term safety and tolerability extension trial of EMERGENT-2 and EMERGENT-3.
        - **EMERGENT-5:** A 52-week, outpatient, open-label long-term trial evaluating the safety of KarXT in adults with schizophrenia who have not been enrolled in the EMERGENT-2 or EMERGENT-3 trials. This trial is expected to commence the first half of 2021.
    - **The Company plans to initiate a Phase 2 trial evaluating KarXT as an adjunctive therapy with standard of**

care for the treatment of psychosis in patients with schizophrenia who remain symptomatic on existing therapies. The Company previously planned to initiate a Phase 1b trial assessing potential Drug-Drug Interactions with a selection of currently marketed antipsychotics in healthy volunteers, but based on multiple considerations, including the evaluation of existing preclinical and clinical data supporting the potential of KarXT to augment traditional antipsychotic drugs, the Company will move forward directly to initiate a Phase 2 trial. The trial will evaluate the efficacy and safety of KarXT when dosed in conjunction with background antipsychotic treatment and its potential to improve symptoms in patients who had not achieved an adequate response on their current antipsychotic treatment.

        - **Data evaluating KarXT as an adjunctive therapy is intended to support a supplemental NDA filing assuming the successful development of KarXT as a monotherapy for the treatment of adults with schizophrenia.** The Company plans to initiate this trial following the initiation of the Phase 3 trials within the EMERGENT program.
    - **The use of KarXT for the treatment of negative and cognitive symptoms in patients with schizophrenia remains of interest.** The Company will collect data on the potential benefit of KarXT on negative and cognitive symptoms of schizophrenia as part of the EMERGENT program and the Company's adjunctive therapy trial. The Company continues to evaluate the timing of potential trial designs specifically directed towards the negative and cognitive symptoms of schizophrenia.
- **KarXT in dementia-related psychosis:** The multi-cohort, placebo-controlled, inpatient Phase 1b trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers is ongoing. The trial is designed to demonstrate safety and tolerability of KarXT in healthy elderly volunteers with the goal of selecting the most appropriate dose and dose-titration schedule to carry forward into future studies in patients with dementia-related psychosis.
    - **Topline data from the Phase 1b trial is anticipated by the end of 2020.** Due to the particular vulnerability of the elderly population to COVID-19, the Company continues to monitor the ongoing COVID-19 pandemic and may elect to pause recruitment in this trial out of an abundance of caution for the health and safety of the elderly volunteers.
- **KarXT in pain:** As previously announced, the Company will not move forward to develop KarXT in pain.

Business Updates

- **The Company recently announced a drug discovery collaboration with PsychoGenics, a phenotypic drug discovery platform company, to identify potential novel drug candidates for the treatment of severe neuropsychiatric disorders.** The multi-year drug discovery collaboration leverages behavioral and physiological phenotypic screening and machine learning to identify novel neuropsychiatric treatments. Under the terms of the agreement, Karuna will provide an upfront payment to PsychoGenics for access to its proprietary platforms. Both parties are eligible to receive payments upon reaching pre-specified development, regulatory and commercial milestones, as well as royalties on net sales, for products developed under the agreement.
- **Recruitment of top talent remains a key organizational priority to meet corporate and product development objectives.** The Company continues to grow its leadership team with the addition of new strategic hires across functional areas, including Clinical Operations, Regulatory and Commercial.

Second Quarter 2020 Financial Results

The Company reported a net loss of $17.0 million for the second quarter of 2020, as compared to $15.1 million for the prior year period. The increase in net loss for the period was due to higher research and development expenses related to preparation for the initiation of the Company's Phase 3 clinical trials within its EMERGENT program but was partially offset by lower general and administrative stock compensation expense.

Research and development expenses were $10.8 million for the second quarter of 2020, as compared to $6.8 million for the prior year period. The increase in research and development expenses for the period was primarily driven by expenses related to the preparation for the initiation of the Company's Phase 3 clinical trials within its EMERGENT program, including CRO start-up costs and clinical trial material manufacturing. In addition, the Company had additional expenses related to its Phase 1b trials in healthy elderly volunteers and experimentally induced pain, increased personnel-related costs due to the increase in employee headcount, as well as expenses associated with consulting fees and the Company's discovery programs.

General and administrative expenses were $7.0 million for the second quarter of 2020, as compared to $8.3 million for the prior year period. The decrease in general and administrative expenses was primarily due to the acceleration of option awards as a result of the Company's IPO and was partially offset by increased expenses related to increased employee headcount and higher costs related to the support of business operations as a publicly traded company.

The Company ended the quarter with $367.6 million in cash, cash equivalents, and short-term investments compared to $389.4 million as of December 31, 2019. The Company expects that its current cash, cash equivalents, and short-term investments as of June 30, 2020 will enable the Company to fund its operating expenses and capital expenditure requirements for at least the next three years. This includes multiple potential clinical and development milestones, including an NDA submission of KarXT for the treatment of acute psychosis in patients with schizophrenia, pending the outcomes of the Company's planned clinical trials. Additional activities which may be funded include the completion of the Phase 1b and potential Phase 2 trial for the treatment of dementia-related psychosis and continued investment into pipeline expansion, including evaluating KarXT as an adjunctive therapy in patients with schizophrenia.

About Karuna

Karuna is a clinical-stage biopharmaceutical company committed to developing and delivering first-in-class therapies with the potential to transform

the lives of people with CNS disorders – which remain among the most disabling and potentially fatal disorders worldwide. Galvanized by the understanding that today's neuropsychiatric patients deserve better, Karuna's mission is to harness the untapped potential of the brain's complex biology in pursuit of novel therapeutic pathways that will advance the standard of care. For more information, please visit 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 our cash resources, the timing of advancing of our planned clinical trials and regulatory filings, interim trial results, our goals to develop and commercialize our product candidates, our identification of additional product candidates, 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, 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, 2019 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. 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,	
	2020	2019	2020	2019
Revenue	—	—	—	—
Operating expenses:				
Research and development	$ 10,819	$ 6,784	$ 15,239	$ 13,751
General and administrative	7,006	8,286	12,641	12,892
Total operating expenses	17,825	15,070	27,880	26,643
Loss from operations	(17,825)	(15,070)	(27,880)	(26,643)
Other income (expense):				
Interest income	779	452	2,176	567
Interest income, net	—	—	—	11
Accretion of debt discount	—	(522)	—	(945)
Change in fair value of derivative	—	—	—	(135)
Total other income (expense), net	779	(70)	2,176	(502)
Net loss before income taxes	(17,046)	(15,140)	(25,704)	(27,145)
Income tax provision	—	—	—	—
Net loss attributable to common stockholders	$ (17,046)	$ (15,140)	$ (25,704)	$ (27,145)
Net loss per share, basic and diluted	$ (0.65)	$ (146.02)	$ (0.98)	$ (507.76)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	26,186,493	103,684	26,114,464	53,460

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 367,585	$ 389,397
Working capital	370,787	389,748
Total assets	377,816	393,024
Total stockholders' equity	$ 371,803	$ 389,916

View source version on businesswire.com: https://www.businesswire.com/news/home/20200805005318/en/

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