Karuna Therapeutics Reports Second Quarter 2019 Financial Results and Provides General Business Update

August 8, 2019

- *Completed multiple financings in 2019, including initial public offering, raising $184.7 million to fund clinical development of novel CNS pipeline*
- *Results from Phase 2 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia remains on track to report data in late 2019*
- *Two programs to initiate clinical trials by the end of 2019, including programs for the treatment of psychosis in Alzheimer's disease and pain*

BOSTON--(BUSINESS WIRE)--Aug. 8, 2019-- Karuna Therapeutics, Inc. (Nasdaq: KRTX), a clinical-stage biopharmaceutical company primarily focused on developing novel therapies to address disabling neuropsychiatric conditions, today announced financial results for the second quarter 2019 and provided a general business update.

"This has been a transformative year for Karuna," stated Steve Paul, M.D., chief executive officer, president and chairman of Karuna Therapeutics. "Having successfully completed multiple financings, including our successful initial public offering, we are well positioned to achieve our mission of developing first-in-class therapeutics that dramatically improve the lives of people living with schizophrenia, Alzheimer's disease and pain. Having spent most of my career developing products targeting these therapeutic areas, I understand the limitations of currently marketed therapies and the importance of the work we are doing to bring novel products that address the unmet need to patients. Our CNS pipeline is built on the broad therapeutic potential of our lead product candidate KarXT and we remain on track to announce topline results of our Phase 2 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia in late 2019. We also continue to advance additional product candidates towards the clinic, initiating clinical trials evaluating KarXT's potential therapeutic benefit in psychosis in Alzheimer's disease and pain management."

Recent Business Highlights

- **Successfully completed multiple financings.** In June 2019, the Company successfully priced the initial public offering (IPO) of common stock, including the full exercise of the underwriters' over-allotment option, raising gross proceeds of $102.6 million. The IPO was preceded by the completion of a $82.1 million multi-tranche Series B financing round in March and April 2019, including the issuance of $7.1 million in shares upon conversion of debt into equity. These two financings have strengthened the Company's balance sheet and provided it with funding to significantly drive pipeline advancement, clinical programs and operations through at least mid-2021.
- **Phase 2 topline results of KarXT for the treatment of acute psychosis in patients with schizophrenia anticipated in late 2019.** KarXT, a proprietary oral modulator of muscarinic receptors, is the Company's lead product candidate that combines xanomeline, a novel muscarinic agonist, with trospium, an approved muscarinic antagonist, to preferentially stimulate muscarinic receptors in the central nervous system (CNS). Karuna is conducting a 180 patient, multi-site, double-blind, placebo-controlled, inpatient Phase 2 clinical trial of KarXT in patients with schizophrenia with acute psychosis. The clinical trial's primary endpoint is the change from baseline in Positive and Negative Syndrome Score (PANSS) total scores for KarXT compared to placebo treated patients. Secondary endpoints include changes in PANSS Marder Factor (including the negative symptom factor), cognitive battery and the clinical global impression (CGI-S) scores. The clinical trial design of the Phase 2 trial represents the same fundamental design and primary endpoint utilized in the previous xanomeline Phase 2 trial in psychosis in schizophrenia, and the same design used in pivotal trials for several currently approved antipsychotic medicines.
- **Independent Safety Monitoring Committee (ISMC) completes third and final pre-specified review of KarXT Phase 2 trial.** As part of the Phase 2 clinical trial protocol, the Company included the ISMC to actively monitor the safety and tolerability of KarXT given the focus on demonstrating the treatment's improved tolerability profile and the dosing of patients at higher xanomeline doses than were previously tested in Phase 2 studies with xanomeline-alone. The ISMC established three prescribed intervals to evaluate the unblinded safety data of KarXT. Following the third and final review, the ISMC recommended the trial continue without modification. This is the same recommendation received following the first two ISMC reviews during the first half of 2019. Further supporting the tolerability of KarXT, approximately 90% of patients in the Phase 2 trial have escalated to the highest dose (125mg/30mg BID) and the early termination rate has been observed to be 20-25%.
- **Advancing CNS pipeline with two clinical programs initiating by the end of 2019.** The Company's pipeline is built on the broad therapeutic potential of KarXT and the established link between muscarinic receptor stimulation in the CNS and its ability to impact a wide range of disorders including schizophrenia, Alzheimer's disease and various forms of pain. The Company plans to initiate a Phase 1b clinical trial of KarXT in experimentally induced pain and a Phase 1b clinical trial in healthy elderly volunteers later this year.
- **Granted additional patents on KarXT.** The Company was recently granted new methods of use and medicament patents

that expand the intellectual property portfolio surrounding KarXT. The Company now has four issued US and one issued European patent covering KarXT.

Second Quarter Financial Results

The Company reported a net loss of $15.1 million for the second quarter 2019 as compared to $0.5 million for the prior year period. The increase in net loss for the year was due to increased research and development expenses, as well as an increase in general and administrative expenses primarily related to investments in the Company's infrastructure as a publicly traded company.

Research and development expenses for the second quarter 2019 were $6.8 million as compared to $2.2 million for the prior year period. The increase in research and development expenses was primarily driven by increased spending related to the Company's Phase 2 clinical trial for the treatment of schizophrenia, increases in formulation development activities, as well as increased personnel-related costs due to the increase in employee headcount.

General and administrative expenses were $8.3 million for the second quarter 2019 as compared to $0.3 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in employee headcount inclusive of the impact of stock-based compensation and higher costs related to the support of business operations as a publicly traded company.

The Company ended the quarter with $75.3 million in cash, cash equivalents and short-term investments compared to $13.9 million as of December 31, 2018. The increase was primarily the result of the completion of the Company's Series B Preferred Stock Financing, from which the Company received aggregate net proceeds of $74.8 million. On July 2, 2019, subsequent to quarter end, the Company closed its initial public offering of its common stock ("IPO") resulting in the issuance of 6,414,842 shares and net proceeds of approximately $93.2 million after deducting underwriting discounts and commissions of $7.2 million and estimated offering expenses of approximately $2.3 million. The Company's existing cash on hand combined with the expected net proceeds of the IPO results in a proforma cash balance on June 30, 2019 of $168.5 million. Upon closing of the IPO, there were 23,412,754 common shares outstanding.

About Karuna

Karuna is an innovative clinical-stage biopharmaceutical company primarily focused on developing novel therapies to address disabling neuropsychiatric conditions characterized by significant unmet medical need. Karuna is currently conducting a Phase 2 clinical trial of its lead product candidate, KarXT (Karuna-Xanomeline-Trospium), for the treatment of acute psychosis in patients with schizophrenia. Karuna also plans to initiate clinical trials of KarXT to evaluate its potential therapeutic benefit in other central nervous system disorders, including psychosis in Alzheimer's disease, as well as pain.

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, interim trial results, our goals to develop and commercialize our 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 costs and timing of establishing, equipping, 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, and other risks set forth under the heading "Risk Factors" of our Quarterly Report on Form 10-Q for the second quarter ended June 30, 2019. 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 Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue	-	-	-	-
Operating expenses:				
Research and development	$ 6,784	$ 2,175	$ 13,751	$ 3,399
General and administrative	8,286	256	12,892	492
Total operating expenses	15,070	2,431	26,643	3,891
Loss from operations	(15,070)	(2,431)	(26,643)	(3,891)
Other income (expense):				
Interest income (expense)	-	(307)	11	(588)
Interest income	452	-	567	-
Accretion of debt discount	(522)	(85)	(945)	(672)
Change in fair value of derivative	-	2,284	(135)	2,204
Total other income (expense), net	(70)	1,892	(502)	944
Net loss before income taxes	(15,140)	(539)	(27,145)	(2,947)
Income tax provision	-	-	-	-
Net loss attributable to common stockholders	$ (15,140)	$ (539)	$(27,145)	$ (2,947)
Net loss per share, basic and diluted	$ (146.02)		$(507.76)	

Weighted average common shares outstanding used in computing net loss per share, basic and diluted	103,684	53,460

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

	June 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 75,299	$ 13,887
Working capital	76,773	14,400
Total assets	79,357	15,857
Redeemable convertible preferred stock	123,892	41,965
Total stockholders' equity (deficit)	$ (46,989)	$ (29,922)

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