Karuna Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Result and Provides General Business Updates

February 23, 2023

Topline data from Phase 3 EMERGENT-3 trial anticipated in the first quarter of 2023

On track to submit New Drug Application (NDA) for KarXT in schizophrenia to the U.S. Food & Drug Administration (FDA) in mid-2023

Announced exclusive global license agreement for investigational TRPC4/5 inhibitors, including lead clinical-stage candidate KAR-2618 (formerly GFB-887), in the first quarter of 2023

$1.1 billion in cash is expected to fund operations through the end of 2025

BOSTON--(BUSINESS WIRE)--Feb. 23, 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 fourth quarter and full year ended December 31, 2022, and provided a general business update.

"A great deal was accomplished in 2022, which is a testament to the hard work and skill of our employees," said Bill Meury, president and chief executive officer of Karuna Therapeutics. "We announced positive data from our Phase 3 EMERGENT-2 trial of KarXT in schizophrenia, further confirming the results seen in our earlier registrational trial, EMERGENT-1. We also initiated ADEPT-1, our Phase 3 trial evaluating KarXT for the treatment of psychosis in Alzheimer's disease, the third potential indication for KarXT, and scaled our in-house capabilities to support our planned transition to a fully integrated R&D and commercial organization."

"Our development and regulatory priorities for 2023 are to continue to execute our late-stage development programs with KarXT, which most notably include announcing the results from the Phase 3 EMERGENT-3 trial of KarXT in schizophrenia next month, as well as submitting our New Drug Application to the Food & Drug Administration for KarXT by the middle of the year," Mr. Meury added. "We will also continue to focus on pre-commercialization activities needed to support the potential launch of KarXT in schizophrenia next year, as well as grow our pipeline organically and inorganically, as evidenced by our exclusive license agreement for TRPC4/5 compounds for the treatment of mood and anxiety disorders announced earlier this month."

Pipeline Highlights
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 medicine with a novel mechanism of action mediated via muscarinic cholinergic receptors, that is being evaluated in Phase 3 clinical trials as a potential treatment for schizophrenia as a monotherapy and adjunctive therapy, as well as psychosis in Alzheimer's disease. The pipeline also consists of clinical-stage candidate KAR-2618 (formerly GFB-887), 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.

KarXT in schizophrenia:

- The EMERGENT program: The clinical program evaluating KarXT for the treatment of schizophrenia as a monotherapy consists of the completed positive registrational EMERGENT-1 and EMERGENT-2 trials, one Phase 3 trial evaluating the efficacy and safety of KarXT (EMERGENT-3), and two Phase 3 trials evaluating the long-term safety of KarXT (EMERGENT-4 & EMERGENT-5).
    - **Results from the Phase 3 EMERGENT-2 trial in schizophrenia were presented at the 2022 Neuroscience Education Institute and the 2022 American College of Neuropsychopharmacology Annual Meeting in the fourth quarter of 2022.** The presentations included new efficacy analyses on pre-specified secondary endpoint measures. In the trial, KarXT demonstrated statistically significant reduction in Clinical Global Impression-Severity (CGI-S) score when compared to placebo at Week 5 ($p<0.0001$). Additionally, a greater proportion of patients in the KarXT arm had a $\geq$30% reduction in Positive and Negative Syndrome Scale (PANSS) compared to placebo at Week 5 ($p<0.0001$).
    - **Topline data from the Phase 3 EMERGENT-3 trial is anticipated in the first quarter of 2023.**
    - **The Company remains on track to submit an NDA for KarXT in schizophrenia with the U.S. FDA in mid-2023.**

- The ARISE program: The Phase 3 clinical program evaluating KarXT as an adjunctive treatment for schizophrenia consists of the ARISE trial, a six-week outpatient trial evaluating the efficacy and safety of KarXT compared to placebo, and ARISE-2, an optional open-label extension trial of ARISE evaluating the long-term safety of KarXT.
    - **Topline data from the Phase 3 ARISE trial is anticipated in the first half of 2024.**

- The Company plans to initiate a Phase 1B open-label clinical trial to evaluate the effect of KarXT on 24-hour ambulatory blood pressure in adults with schizophrenia.
    - **The Company is on track to initiate the trial early in the second quarter of 2023.**

KarXT for the treatment of psychosis in Alzheimer's disease:

- The ADEPT program: The Phase 3 clinical program evaluating KarXT for the treatment of psychosis related to Alzheimer's disease consists of the ongoing ADEPT-1 trial and two planned trials evaluating the efficacy and long-term safety of KarXT (ADEPT-2 & ADEPT-3).
    - **The Company is on track to initiate the Phase 3 ADEPT-2 trial in the second half of 2023.**
    - **Topline data from the Phase 3 ADEPT-1 & ADEPT-2 trials are anticipated in 2025.**

Business Updates

- **Announced exclusive global license agreement for Goldfinch Bio's investigational TRPC4/5 product candidates in the first quarter of 2023.** The Company obtained an exclusive global license to develop, manufacture, and commercialize multiple TRPC4/5 investigational therapies, including lead clinical-stage candidate KAR-2618 (formerly GFB-887). The Company made a $15 million upfront payment to GFB (ABC), LLC, assignee of the Goldfinch Bio assignment estate, in the first quarter of 2023. The Company is also obligated to pay up to $520 million in milestone payments for each licensed TRPC4/5 candidate, of which $410 million are related to regulatory approval and commercial sales milestones, as well as a flat low-single-digit royalty on any potential global net sales of each licensed product.
    - Details on the planned development of KAR-2618 (formerly GFB-887) for the treatment of mood and anxiety disorders will be shared in the second half of 2023.

- **Strengthened corporate governance and executive leadership team in the first quarter of 2023.** Effective January 2023, the Company appointed Bill Meury as President and Chief Executive Officer, and as a member of the Board of Directors, succeeding former Chief Executive Officer, President and Chairman of the Board, Steve Paul, M.D. At this time, Dr. Paul transitioned to Chief Scientific Officer and President of Research & Development, and Christopher Coughlin assumed the role of Chairman of the Board. In February 2023, the Company announced the appointment of Will Kane as Chief Commercial Officer.

Anticipated Upcoming Milestones

- Topline data from the Phase 3 EMERGENT-3 trial (1Q 2023)
- NDA submission of KarXT in schizophrenia (mid-2023)
- Initiation of the Phase 3 ADEPT-2 trial (2H 2023)
- Initiation of the Phase 3 ADEPT-3 trial (2023)
- Topline data from the Phase 3 ARISE trial (1H 2024)
- Topline data from the Phase 3 ADEPT-1 trial (2025)
- Topline data from the Phase 3 ADEPT-2 trial (2025)

Fourth Quarter and Full Year 2022 Financial Results

The Company reported a net loss of $76.2 million for the fourth quarter of 2022, and a net loss of $276.3 million for the year ended 2022, as compared to $28.0 million and $143.8 million for the prior year periods, respectively. The increase in net loss for the year was primarily attributable to higher operating expenses of $300.3 million compared to $180.8 million for the prior year period, driven by research and development expenses related to the Company's enrollment of the Phase 3 EMERGENT & ARISE trials, NDA-supporting activities, the initiation and enrollment of the Phase 3 ADEPT-1 trial, increased employee headcount across the organization, and higher stock-based compensation expense. The Company recognized licensing revenue of $5.3 million for the fourth quarter of 2022, and $10.6 million for the year ended 2022, as compared to $37.0 million for the fourth quarter and year ended 2021. The licensing revenue for the year ended 2022 is related to development milestones and related tax gross ups associated with our License Agreement with Zai Lab (Shanghai) Co., Ltd.

Research and development expenses were $66.0 million for the fourth quarter of 2022, and $224.2 million for the year ended 2022, as compared to $45.1 million and $128.2 million the prior year periods, respectively. The increase in research and development expenses for the year was primarily driven by expenses related to the Company's enrollment of the Phase 3 EMERGENT & ARISE trials, manufacturing to support ongoing and planned clinical trials, preparation for a potential NDA submission of KarXT for schizophrenia, the initiation and enrollment of the Phase 3 ADEPT-1 trial, personnel-related costs due to the increase in employee headcount, and higher stock-based compensation expense.

General and administrative expenses were $24.3 million for the fourth quarter of 2022, and $76.1 million for the year ended 2022, as compared to $20.1 million and $52.6 million for the prior year periods, respectively. The increase in general and administrative expenses for the year was primarily due to an increase in employee headcount and higher stock-based compensation expense and an increase in professional fees.

The Company ended the year 2022 with $1.1 billion in cash, cash equivalents, and available-for-sale investment securities compared to $494.0 million as of December 31, 2021. The increase was the result of the completion of the Company's follow-on public offering in August 2022. Based on the Company's current operating plan, the Company expects that current cash, cash equivalents and available-for-sale investment securities as of December 31, 2022, will enable the Company to fund its operating expenses and capital expenditure requirements through 2025. The Company anticipates that total operating expenses will be $430-$470 million, which includes up to $70 million in non-cash stock compensation expense, for the full year 2023.

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, 2022. 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
License and other revenue	$ 5,278	$ 36,964	$ 10,637	$ 36,964
Operating expenses:				
Research and development	66,004	45,092	224,247	128,200
General and administrative	24,310	20,063	76,066	52,617
Total operating expenses	90,314	65,155	300,313	180,817
Loss from operations	(85,036)	(28,191)	(289,676)	(143,853)
Other income, net:				
Interest income	9,567	139	14,178	502
Sublease income	147	123	580	254
Impairment loss on right-of-use assets	—	(25)	—	(702)
Total other income, net	9,714	237	14,758	54
Net loss before income taxes	(75,322)	(27,954)	(274,918)	(143,799)
Income tax provision	(890)	(6)	(1,418)	(6)
Net loss attributable to common stockholders	$ (76,212)	$ (27,960)	$ (276,336)	$ (143,805)
Net loss per share, basic and diluted	$ (2.22)	$ (0.94)	$ (8.74)	$ (4.94)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	34,406,182	29,688,658	31,629,013	29,138,915

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 1,124,044	$ 493,991
Working capital	1,120,823	497,121
Total assets	1,163,334	527,671
Total stockholders' equity	$ 1,126,238	$ 502,026

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