

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 05, 2022

Karuna Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38958
(Commission File Number)

27-0605902
(IRS Employer
Identification No.)

99 High Street, Floor 26
Boston, Massachusetts
(Address of Principal Executive Offices)

02110
(Zip Code)

Registrant's Telephone Number, Including Area Code: 857 449-2244

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001	KRTX	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 5, 2022, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the first quarter ended March 31, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

- 99.1 [Press Release issued by Karuna Therapeutics, Inc., dated May 5, 2022](#)
 - 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KARUNA THERAPEUTICS, INC.

Date: May 5, 2022

By: /s/ Troy Ignelzi
Troy Ignelzi
Chief Financial Officer

Karuna Therapeutics Reports First Quarter 2022 Financial Results and Provides General Business Update

Completed enrollment in the Phase 3 EMERGENT-2 trial evaluating KarXT for the treatment of schizophrenia in the second quarter of 2022

Topline data from the Phase 3 EMERGENT-2 and EMERGENT-3 trials expected in the third quarter of 2022 and in the first quarter of 2023, respectively

On track to initiate Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease in mid-2022

Company to host webcast event highlighting KarXT clinical programs, with a primary focus on the Phase 3 program in psychosis in Alzheimer's disease, in late-May

\$443.2 million in cash expected to fund operations for at least 12 months following the potential New Drug Application (NDA) submission of KarXT for schizophrenia

BOSTON—May 5, 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 first quarter of 2022 and provided a general business update.

“We have made significant progress advancing our comprehensive late-stage clinical programs for KarXT, most notably with the completion of enrollment of our registrational Phase 3 EMERGENT-2 trial in schizophrenia in the second quarter,” said Steve Paul, M.D., chief executive officer, president, and chairman. “I am incredibly proud of our accomplishments, as within 18 months we have advanced KarXT into six Phase 3 clinical trials in schizophrenia, including the Phase 3 EMERGENT-2 trial which is on track for data mid-year, specifically in the third quarter.”

“The growth of our organization, and the continued progression and expansion of our development efforts, as seen through our ongoing Phase 3 schizophrenia programs evaluating KarXT as a monotherapy and adjunctive therapy, as well as the planned initiation of our Phase 3 program in psychosis in Alzheimer's disease mid-year, is a testament to our belief that KarXT has the potential to offer a new, potentially transformative therapy for people living with serious mental illness,” Dr. Paul added. “This is an exciting time for Karuna as we look ahead to important milestones this year and work towards our mission of developing and delivering important medicines for people living with serious psychiatric and neurological conditions.”

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 in 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 trial and the following ongoing Phase 3 trials:
 - **EMERGENT-2:** A five-week inpatient trial evaluating the efficacy and safety of KarXT compared to placebo in 246 adults with schizophrenia in the U.S.
 - The Company completed enrollment of EMERGENT-2 in the second quarter of 2022, and anticipates topline data in the third quarter of 2022.
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- o **EMERGENT-3:** A five-week inpatient trial evaluating the efficacy and safety of KarXT compared to placebo in 246 adults with schizophrenia in the U.S. and Ukraine.
 - The Company anticipates topline data in the first quarter of 2023. The company continues to enroll patients at clinical trial sites in the U.S., and is not enrolling patients at clinical trial sites in the Ukraine at this time due to the Ukraine-Russia conflict.
- o **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.
- o **EMERGENT-5:** A 52-week outpatient, open-label trial evaluating the long-term safety and tolerability of KarXT in adults with schizophrenia in the U.S. and Puerto Rico who were not enrolled in EMERGENT-2 or EMERGENT-3.
- **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.
- **KarXT for the treatment of psychosis in Alzheimer’s disease.** The Company remains on track to initiate the Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer’s disease in mid-2022.
- **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.

Business Updates

- **The Company plans to host a webcast event highlighting KarXT clinical programs on Wednesday, May 25, 2022.** The webcast event will highlight progress across the ongoing and planned KarXT clinical programs, with a primary focus on the planned Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer’s disease.

Anticipated Upcoming Milestones

- Initiation of the Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer’s disease (mid-2022)
- Topline data from the Phase 3 EMERGENT-2 trial (3Q 2022)
- Topline data from the Phase 3 EMERGENT-3 trial (1Q 2023)

First Quarter 2022 Financial Results

The Company reported a net loss of \$58.2 million for the first quarter of 2022, as compared to \$30.5 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.

Research and development expenses were \$43.8 million for the first quarter of 2022, as compared to \$20.2 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 enrollment of the Phase 3 EMERGENT and ARISE trials, manufacturing to support ongoing and planned clinical trials, as well as for a future potential NDA submission and 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 \$14.8 million for the first quarter of 2022, as compared to \$9.8 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 \$443.2 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 March 31, 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 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, 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

	Three Months Ended March 31,	
	2022	2021
License revenue	\$ -	\$ -
Operating expenses:		
Research and development	43,806	20,186
General and administrative	14,788	9,777
Total operating expenses	58,594	29,963
Loss from operations	(58,594)	(29,963)
Other income (loss), net:		
Impairment loss on right-of-use assets	—	(677)
Interest income	237	143
Sublease income	139	—
Total other income (loss), net	376	(534)
Net loss before income taxes	(58,218)	(30,497)
Income tax provision	—	—
Net loss attributable to common stockholders	\$ (58,218)	\$ (30,497)
Net loss per share, basic and diluted	\$ (1.95)	\$ (1.10)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	29,805,961	27,786,538

Karuna Therapeutics, Inc.
Unaudited Consolidated Balance Sheet Data

	March 31, 2022	December 31, 2021
Cash, cash equivalents and investments	\$ 443,187	\$ 493,991
Working capital	448,716	497,121
Total assets	474,474	527,671
Total stockholders' equity	\$ 453,688	\$ 502,026

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