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): November 03, 2022

Karuna Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38958**	**27-0605902**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 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 November 3, 2022, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the third quarter ended September 30, 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 November 3, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

KARUNA THERAPEUTICS, INC.

Date: November 3, 2022

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

Exhibit 99.1

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

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

Phase 3 EMERGENT-3 trial completed enrollment in the fourth quarter of 2022, with topline data anticipated in the first quarter of 2023

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

$1.2 billion in cash is expected to fund operations through the end of 2025

BOSTON—November 3, 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 third quarter of 2022 and provided a general business update.

"The third quarter was truly a transformational time for Karuna, marked by the positive results from the Phase 3 EMERGENT-2 trial and further diversification of our pipeline through the initiation of ADEPT-1, our Phase 3 trial in psychosis in Alzheimer's disease, the third therapeutic area we're evaluating with KarXT," said Steve Paul, M.D., chief executive officer, president, and chairman. "The work our team has accomplished this quarter illustrates and underscores our ongoing commitment to developing and delivering transformational medicines – such as KarXT, a true 'pipeline in a product' – to 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 medicine with a novel mechanism of action mediated via muscarinic cholinergic receptors, that is currently being evaluated in ongoing Phase 3 clinical trials as a potential treatment for schizophrenia as a monotherapy and adjunctive therapy, as well as psychosis in Alzheimer's disease.

KarXT for the treatment of schizophrenia:

- The EMERGENT program: The clinical program evaluating KarXT for the treatment of schizophrenia as a monotherapy. The EMERGENT program consists of the completed positive registrational EMERGENT-1 and EMERGENT-2 trials, one ongoing Phase 3 trial evaluating the efficacy and safety of KarXT (EMERGENT-3), and two ongoing Phase 3 trials evaluating the long-term safety of KarXT (EMERGENT-4 and EMERGENT-5).
  - **Positive results from the Phase 3 EMERGENT-2 trial in schizophrenia announced in August 2022.** 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. KarXT also met key secondary endpoints, demonstrating a statistically significant reduction in both positive symptoms and negative symptoms of schizophrenia, as measured by the PANSS positive, PANSS negative and PANSS negative Marder factor subscales, compared to placebo. KarXT was generally well tolerated, with the most common treatment emergent adverse events (TEAEs) all rated mild to moderate in severity, consistent with prior trials.

        - **Results from the EMERGENT-2 trial were presented at the 35th European College of Neuropsychopharmacology (ECNP) Annual Congress in October.** The poster and symposium presentation included previously reported efficacy and safety data, as well as additional new safety analysis from the trial. The additional analysis highlighted that common cholinergic TEAEs associated with KarXT were mild to moderate in severity, time limited, and resolved with repeated dosing, consistent with prior trials.
        - **Additional data analyses from the EMERGENT-2 trial to be presented at the Neuroscience Education Institute Congress, held November 3-6, 2022.** The poster presentation will highlight efficacy and safety data from EMERGENT-2, including additional pre-specified secondary efficacy endpoints that have not been previously disclosed.
    - **The Company completed enrollment in the Phase 3 EMERGENT-3 trial in the fourth quarter of 2022 and anticipates topline data in the first quarter of 2023.** EMERGENT-3 is a five-week inpatient trial evaluating the efficacy and safety of KarXT compared to placebo in 256 adults with schizophrenia in the U.S. and Ukraine.
    - **The Company remains on track to submit an NDA for KarXT in schizophrenia with the U.S. FDA in mid-2023.**

- The PENNANT trial: A planned three-year, open-label, outpatient Phase 3b trial evaluating the long-term safety, tolerability, and efficacy of KarXT as a monotherapy in up to 380 adults with schizophrenia in the U.S. Data from the trial will provide insight into the long-term use of KarXT over a period of multiple years.
    - **The Company expects to initiate the Phase 3b PENNANT trial in the fourth quarter of 2022.**

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

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. The ADEPT program consists of the ongoing ADEPT-1 trial, a Phase 3 trial evaluating the efficacy and safety of KarXT compared to placebo, and the planned ADEPT-2 and ADEPT-3 trials evaluating the efficacy and long-term safety of KarXT.
    - **The Company initiated the ADEPT-1 trial in the third quarter of 2022, with topline data anticipated in 2025.**
    - **The Company plans to initiate the ADEPT-2 and ADEPT-3 trials in 2023. Topline data from the ADEPT-2 trial is anticipated in 2025.**

Discovery and early-stage pipeline:

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

Corporate Updates

- **The United States Patent and Trademark Office (USPTO) granted two additional patents with anticipated patent expiration dates out to 2039 and the potential for patent term extension.** The USPTO granted US Patent Nos. 11,452,692 and 11,471,413 in September and October 2022, respectively.

Anticipated Upcoming Milestones

- Initiation of the Phase 3 PENNANT trial (4Q 2022)
- Topline data from the Phase 3 EMERGENT-3 trial (1Q 2023)
- Initiation of the Phase 3 ADEPT-2 trial (2023)
- Initiation of 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)
- Topline data from the Phase 3 ADEPT-1 trial (2025)
- Topline data from the Phase 3 ADEPT-2 trial (2025)

Third Quarter 2022 Financial Results

The Company reported a net loss of $77.0 million for the third quarter of 2022, as compared to $50.9 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 $62.0 million for the third quarter of 2022, as compared to $38.8 million for 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, activities to support the Company's 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 $19.1 million for the third quarter of 2022, as compared to $12.4 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in employee headcount and an increase in stock-based compensation expense.

The Company ended the quarter with $1.2 billion in cash, cash equivalents and available-for-sale investment securities compared to $494.0 million as of December 31, 2021. The increase was primarily the result of the completion of the Company's public offering in August 2022, which resulted in net proceeds of $819.1 million. The Company expects that current cash, cash equivalents and available-for-sale investment securities as of September 30, 2022, will enable to Company to fund operating expenses and capital expenditure requirements through the end of 2025.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
License and other revenue	$ 81	$ —	$ 5,359	$ —
Operating expenses:				
Research and development	61,950	38,775	158,243	83,108
General and administrative	19,125	12,393	51,756	32,554
Total operating expenses	81,075	51,168	209,999	115,662
Loss from operations	(80,994)	— (51,168)	(204,640)	(115,662)
Other income (loss), net:				
Interest income	3,884	114	4,611	363
Sublease income	147	122	433	131
Impairment loss on right-of-use assets	—	—	—	(677)
Total other income (loss), net	4,031	236	5,044	(183)
Net loss before income taxes	(76,963)	(50,932)	(199,596)	(115,845)
Income tax provision	—	—	(528)	—
Net loss attributable to common stockholders	$ (76,963)	$ (50,932)	$ (200,124)	$ (115,845)
Net loss per share, basic and diluted	$ (2.38)	$ (1.72)	$ (6.52)	$ (4.00)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	32,349,111	29,572,289	30,693,117	28,953,654

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

	September 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 1,192,034	$ 493,991
Working capital	1,178,933	497,121
Total assets	1,228,412	527,671
Total stockholders' equity	$ 1,183,955	$ 502,026

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