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 04, 2023

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**	**02110**
(Address of Principal Executive Offices)	**(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 May 4, 2023, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the first quarter ended March 31, 2023. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current 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 4, 2023
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: May 4, 2023

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

Karuna Therapeutics Reports First Quarter 2023 Financial Results and Provides General Business Updates

Announced positive topline data from the Phase 3 EMERGENT-3 trial of KarXT in schizophrenia in the first quarter of 2023

On track to submit New Drug Application (NDA) for KarXT in schizophrenia with the U.S. FDA in the third quarter of 2023, with a launch in the second half of 2024, if approved

Phase 3 ADEPT-2 and ADEPT-3 trials of KarXT in psychosis in Alzheimer's disease to initiate in the second half of 2023

$1.5 billion in cash expected to fund operations through 2026

Conference call and webcast to take place today at 8:00 a.m. ET

BOSTON—May 4, 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 first quarter of 2023 and provided a general business update.

"We've had a very strong start to the year," said Bill Meury, president and chief executive officer of Karuna Therapeutics. "We announced positive data from EMERGENT-3, our third consecutive registrational trial of KarXT in schizophrenia, which further reinforces KarXT's potential to be a completely novel and differentiated treatment for people living with schizophrenia. On the regulatory front, we remain on track to submit our NDA mid-year – specifically the third quarter – following an encouraging pre-NDA meeting with the FDA last month. We've also made significant progress advancing EMERGENT-4 and 5, our Phase 3 open-label trials evaluating the long-term safety of KarXT in schizophrenia, which will provide valuable information for both the NDA and medical education pre- and post-launch, with data to share next year."

"As we continue to build the infrastructure to support the potential commercialization of KarXT in schizophrenia, we maintain a sharp focus on the execution of our ARISE program evaluating KarXT as an adjunctive treatment for schizophrenia, with anticipated topline data from the Phase 3 ARISE trial in the second half of 2024, as we activate additional sites to support recruitment in the study. We remain on track for the ADEPT program evaluating KarXT in psychosis in Alzheimer's disease and expect topline data from the Phase 3 ADEPT-1 & 2 trials in 2025," Mr. Meury added. "Beyond KarXT, we continue to grow our pipeline both organically and inorganically, most notably with our exclusive global in-license agreement for TRPC4/5 inhibitors for the treatment of mood and anxiety disorders announced in February, and we look forward to sharing next steps in the program later this year."

KEY PIPELINE HIGHLIGHTS

Karuna is advancing a pipeline of novel drug candidates for the treatment of various psychiatric and neurological conditions led by KarXT (xanomeline-trospium), an oral, investigational M1/M4-preferring muscarinic agonist.

KarXT

KarXT is being evaluated in Phase 3 clinical trials as a potential treatment for schizophrenia as a monotherapy and adjunctive therapy, as well as for psychosis in Alzheimer's disease.

- Schizophrenia
  - **Announced positive results from the Phase 3 EMERGENT-3 trial in schizophrenia in the first quarter of 2023.** The trial met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 8.4-point reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-20.6 KarXT vs. -12.2 placebo; p<0.0001) at week 5. KarXT was generally well tolerated, with a side effect profile substantially consistent with prior trials of KarXT.
  - **Additional data analyses from the EMERGENT-2 and EMERGENT-3 trials to be presented at upcoming medical congresses in the second quarter of 2023.** Presentations will highlight additional new efficacy and safety data from EMERGENT-3 and data from the cognitive exploratory endpoint analyses from EMERGENT-2 and EMERGENT-3.
  - **Topline data from the EMERGENT-4 and EMERGENT-5 trials evaluating the long-term safety of KarXT in schizophrenia are anticipated in 2024.** EMERGENT-4 completed enrollment in the fourth quarter of 2022, and EMERGENT-5 is estimated to complete enrollment in the second quarter of 2023.
  - **The Phase 1b trial evaluating the effect of KarXT on 24-hour ambulatory blood pressure in adults with schizophrenia initiated in the second quarter of 2023.** Topline data from the trial is expected in the fourth quarter of 2023.
  - **The Company remains on track to submit an NDA for KarXT in schizophrenia with the FDA in the third quarter of 2023 following the completion of a pre-NDA meeting in the second quarter of 2023.**

- Adjunctive treatment in schizophrenia
  - **The Company now anticipates topline data from the Phase 3 ARISE trial in the second half of 2024.** The Company is increasing the number of sites in the trial, including additional clinical trial sites in Europe, to support recruitment.

- Psychosis in Alzheimer's disease
  - **Topline data from the Phase 3 ADEPT-1 trial is anticipated in 2025.**
  - **The Company is on track to initiate the Phase 3 ADEPT-2 and ADEPT-3 trials in the second half of 2023.** Topline data from the Phase 3 ADEPT-2 trial is anticipated in 2025.

Early-stage and discovery programs
The Karuna pipeline also includes clinical-stage candidate KAR-2618, 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.

- **Announced exclusive global license of TRPC4/5 inhibitors, including lead clinical-stage candidate KAR-2618, in the first quarter of 2023.** The Company plans to share next steps on the development of KAR-2618 for the treatment of mood and anxiety disorders in the second half of 2023.

ANTICIPATED UPCOMING MILESTONES

- NDA submission of KarXT in schizophrenia (3Q 2023)
- Initiation of the Phase 3 ADEPT-2 trial (2H 2023)
- Initiation of the Phase 3 ADEPT-3 trial (2H 2023)
- Topline data from the Phase 3 EMERGENT-4 trial (2024)
- Topline data from the Phase 3 EMERGENT-5 trial (2024)
- Launch of KarXT in schizophrenia, if approved (2H 2024)
- Topline data from the Phase 3 ARISE trial (2H 2024)
- Topline data from the Phase 3 ADEPT-1 trial (2025)
- Topline data from the Phase 3 ADEPT-2 trial (2025)

FIRST QUARTER 2023 FINANCIAL RESULTS

The Company reported a net loss of $97.6 million for the first quarter of 2023, as compared to $58.2 million for the prior year period. The increase in net loss for the quarter was primarily attributable to higher operating expenses of $109.7 million compared to $58.6 million for the prior year period, driven by expenses related to the EMERGENT, ARISE and ADEPT clinical programs, NDA-supporting activities, the $15.0 million upfront license payment for Goldfinch Bio's TRPC4/5 channel candidates, increased employee headcount across the organization, and higher stock-based compensation expense. Operating expenses were slightly offset by higher interest income driven by the increase in cash equivalents and short-term investments, as well as higher interest rates. The Company recognized licensing revenue of $0.7 million for the first quarter of 2023 associated with sales of clinical drug supply to Zai Lab (Shanghai) Co., Ltd. No license revenue was recognized for the prior year period.

Research and development expenses were $85.5 million for the first quarter of 2023, as compared to $43.8 million for the prior year period. The increase in research and development expenses for the quarter was primarily driven by the EMERGENT, ARISE and ADEPT clinical programs, NDA-supporting activities, the upfront license payment for Goldfinch Bio's TRPC4/5 channel candidates, 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 first quarter of 2023, as compared to $14.8 million for the prior year period. The increase in general and administrative expenses for the quarter was primarily driven by an increase in pre-commercialization activities, professional fees, employee headcount, and higher stock-based compensation expense.

The Company ended the quarter with $1.5 billion in cash, cash equivalents, and available-for-sale investment securities compared to $1.1 billion as of December 31, 2022. The increase was primarily the result of the completion of the Company's follow-on public offering in March 2023, which resulted in net proceeds of $436.7 million. The Company expects that current cash, cash equivalents, and available-for-sale investment securities as of March 31, 2023 will enable the Company to fund its operating expenses and capital expenditure requirements through the end of 2026.

CONFERENCE CALL AND WEBCAST DETAILS

The first quarter 2023 financial results and business update will be discussed during a conference call and webcast today at 8:00 a.m. ET. A webcast of the live call may be accessed on the Investors section of the Karuna website at investors.karunatx.com. A replay of the webcast will be available for up to 30 days following the event.

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, 2022 and in our subsequent filings with the Securities and Exchange Commission. 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 March 31,	
	2023	**2022**
License and other revenue	$ 654	$ —
Operating expenses:		
Research and development	85,467	43,806
General and administrative	24,253	14,788
Total operating expenses	109,720	58,594
Loss from operations	(109,066)	(58,594)
Other income, net:		
Interest income	11,345	237
Sublease income	147	139
Total other income, net	11,492	376
Net loss before income taxes	(97,574)	(58,218)
Income tax provision	—	—
Net loss attributable to common stockholders	$ (97,574)	$ (58,218)
Net loss per share, basic and diluted	$ (2.80)	$ (1.95)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	34,800,643	29,805,961

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 1,474,454	$ 1,124,044
Working capital	1,482,522	1,120,823
Total assets	1,516,168	1,163,334
Total stockholders' equity	$ 1,488,135	$ 1,126,238

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