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 6, 2021

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)**	**(I.R.S. Employer Identification No.)**

99 High Street, 26th Floor **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**	**The 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 6, 2021, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the first quarter ended March 31, 2021. 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 6, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Date: May 6, 2021

KARUNA THERAPEUTICS, INC.

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

Karuna Therapeutics Reports First Quarter 2021 Financial Results and Provides General Business Update

Three Phase 3 trials – EMERGENT-2, EMERGENT-3 and EMERGENT-4 – evaluating KarXT for the treatment of psychosis in adults with schizophrenia are currently enrolling

On track to complete third cohort in Phase 1b trial evaluating KarXT in healthy elderly volunteers in the second quarter of 2021

Patents granted on co-formulation compositions of KarXT, extending exclusivity through 2039

$571.3 million in cash expected to fund operations, including multiple milestones, for at least 12 months following the potential New Drug Application (NDA) submission of KarXT in schizophrenia

BOSTON— May 6, 2021— 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 2021 and provided a general business update.

“This year is off to a very productive start, with the advancement of our early- and late-stage clinical programs, most notably the initiation and ongoing enrollment of three Phase 3 trials in our EMERGENT program, the clinical program evaluating KarXT, our lead product candidate, in schizophrenia,” said Steve Paul, M.D., chief executive officer, president and chairman. “We believe KarXT represents a major advance in the treatment of neuropsychiatric conditions, such as schizophrenia and dementia-related psychosis, where symptoms of psychosis are prominent and disabling. We look forward to furthering our journey to improve the lives of those living with these conditions.”

Pipeline Updates

KarXT (xanomeline-trospium) is an oral investigational antipsychotic with a novel mechanism of action mediated via muscarinic cholinergic receptors. KarXT is currently being evaluated as a potential treatment for psychiatric disorders, including schizophrenia and dementia-related psychosis.

- **KarXT for the treatment of psychosis in adults with schizophrenia.** The U.S. Food & Drug Administration has indicated that the previously completed positive Phase 2 five-week, inpatient safety and efficacy trial (EMERGENT-1), one successful Phase 3 efficacy and safety trial, and additional safety data would be acceptable to support a New Drug Application (NDA) filing in schizophrenia.
    - **The Phase 3 EMERGENT-2, EMERGENT-3 and EMERGENT-4 trials are currently enrolling.** The Phase 3 EMERGENT-5 trial remains on track to initiate in the second quarter of 2021.
    - The EMERGENT program includes the following 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.
        - 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.

- EMERGENT-4: A 52-week outpatient, open-label extension trial evaluating the long-term safety and tolerability of KarXT in 350 adults with schizophrenia who completed EMERGENT-2 or EMERGENT-3.
- EMERGENT-5: A 52-week outpatient, open-label trial evaluating the long-term safety and tolerability of KarXT in 400 adults with schizophrenia in the U.S. in patients who were not enrolled in EMERGENT-2 or EMERGENT-3.

- **KarXT for the treatment of schizophrenia in adults who experience an inadequate response to standard of care.** The Company plans to initiate a Phase 2 trial evaluating the potential of KarXT to improve symptoms of schizophrenia in adults who have not achieved an adequate response on their current antipsychotic treatment. This trial will evaluate the safety and efficacy of KarXT when dosed with background antipsychotic treatment, and is expected to initiate in the second half of 2021.
  - **Data highlighting the antipsychotic activity of xanomeline in combination with an atypical antipsychotic in pre-clinical models of psychosis will be presented at the 2021 American Society of Clinical Psychopharmacology in June.** The poster presentation will include data demonstrating xanomeline's, the active ingredient in KarXT, augmentation of ineffective doses of an atypical antipsychotic in a pre-clinical model.
- **KarXT for the treatment of dementia-related psychosis.** The multi-cohort, placebo-controlled Phase 1b dose-ranging trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers is ongoing.
  - **Data from Cohort 3 of the Phase 1b trial in healthy elderly volunteers is expected in the second quarter of 2021.** Based on interim data from Cohorts 1 and 2, previously reported in the first quarter of 2021, the Company believes that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile, providing a path to a Phase 2 trial evaluating KarXT in dementia-related psychosis. Cohort 3 will serve to further refine the dose range of xanomeline and trospium and the titration protocol. Planning for this Phase 2 trial in dementia-related psychosis has commenced and the Company expects to provide further guidance following the completion of Cohort 3 later this year.

Business Updates

- **The Company completed a successful follow-on offering in the first quarter of 2021.** The follow-on public offering resulted in net proceeds of $270.0 million after deducting underwriting discounts and commissions, and other offering related expenses.
- **The United States Patent and Trademark Office (USPTO) granted two patents in the first quarter of 2021, with September 2039 patent expiration dates and the potential for patent term extension.** The USPTO granted US Patent Nos. 10,933,020 and 10,925,832 related to compositions and methods for treating disorders ameliorated by muscarinic receptor activation.
- **COVID-19 update.** The Company continues to monitor the impact of COVID-19 on operations and will provide relevant updates on its impact on activities as deemed appropriate.

First Quarter 2021 Financial Results

The Company reported a net loss of $30.5 million for the first quarter of 2021, as compared to $8.7 million for the prior year period. The increase in net loss for the quarter was due to higher research and development expenses related to the Company's preparation, initiation and enrollment of the Phase 3 clinical trials within its EMERGENT program, NDA-supporting activities such as manufacturing, and increased employee headcount across the organization.

Research and development expenses were $20.2 million for the first quarter of 2021, as compared to $4.4 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 preparation, initiation and enrollment of the Phase 3 clinical trials within the EMERGENT program, expenses related to manufacturing in preparation for a potential NDA submission, increased spend on the Company's discovery programs and increased personnel-related costs due to the increase in employee headcount.

General and administrative expenses were $9.8 million for the first quarter of 2021, as compared to $5.6 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 $571.3 million in cash, cash equivalents and available-for-sale investment securities compared to $322.3 million as of December 31, 2020. The increase was the result of the completion of the Company's public offering. The Company expects that current cash, cash equivalents and available-for-sale investment securities as of March 31, 2021, 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 advancing of our planned clinical trials and regulatory filings, our goals to develop and commercialize our product candidates, our identification of additional 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, 2020. 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,	
	2021	2020
Revenue	—	—
Operating expenses:		
Research and development	$ 20,186	$ 4,420
General and administrative	9,777	5,635
Total operating expenses	29,963	10,055
Loss from operations	(29,963)	(10,055)
Other income (loss), net:		
Impairment loss on right-of-use assets	(677)	—
Interest income	143	1,397
Total other income (loss), net	(534)	1,397
Net loss before income taxes	(30,497)	(8,658)
Income tax provision	—	—
Net loss attributable to common stockholders	$ (30,497)	$ (8,658)
Net loss per share, basic and diluted	$ (1.10)	$ (0.33)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	27,786,538	26,042,434

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

	March 31, 2021	December 31, 2020
Cash, cash equivalents and investments	$571,295	$ 322,330
Working capital	583,390	337,746
Total assets	593,264	347,625
Total stockholders' equity	$584,914	$ 338,931

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