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): August 5, 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**	**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**	**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 August 5, 2021, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the second quarter ended June 30, 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 August 5, 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: August 5, 2021

KARUNA THERAPEUTICS, INC.

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

Exhibit 99.1

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

All Phase 3 trials in the EMERGENT clinical program evaluating KarXT for the treatment of psychosis in adults with schizophrenia are enrolling

Topline data from the Phase 3 EMERGENT-2 trial expected mid-2022

On track to initiate the Phase 3 ARISE trial evaluating KarXT in adults with schizophrenia who inadequately respond to current standard of care in the second half of 2021

Plan to initiate a Phase 2 trial evaluating KarXT in dementia-related psychosis in the first half of 2022

$543.6 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— August 5, 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 second quarter of 2021 and provided a general business update.

“The second quarter was an exciting one for Karuna as we’ve made important progress in advancing our mid- and late-stage clinical trials studying our lead asset, KarXT, across multiple indications to drive innovation in the treatment of schizophrenia and dementia-related psychosis,” said Steve Paul, M.D., chief executive officer, president and chairman. “All four Phase 3 trials in the EMERGENT program evaluating KarXT in schizophrenia are now enrolling, with completion of the first trial, EMERGENT-2, expected mid-2022. We also plan to evaluate KarXT in adults with schizophrenia who inadequately respond to atypical antipsychotics in a Phase 3 trial initiating later this year.”

“We plan to advance KarXT into a Phase 2 clinical trial for the treatment of dementia-related psychosis in the first half of 2022 following encouraging results from our completed Phase 1b healthy elderly volunteer trial which suggest that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile,” Dr. Paul commented further. “We are pleased with the breadth of milestones we’ve achieved in the first half of 2021, including significant growth across our organization, all of which we believe contribute to laying a strong foundation for the company as we seek to push the boundaries of neuroscience to transform mental illness.”

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, which is currently being evaluated in mid- and late-stage clinical trials as a potential treatment for schizophrenia and dementia-related psychosis.

- **KarXT for the treatment of psychosis in adults with schizophrenia.** The EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia, is underway. The EMERGENT program includes the completed positive Phase 2 EMERGENT-1 trial and four ongoing Phase 3 trials, including:
    - 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.
        - Enrollment for this trial began in December 2020. The Company anticipates reporting topline data mid-2022.
    - 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.
        - Enrollment for this trial began in the second quarter of 2021.
    - 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.
        - Enrollment for this trial began in the first quarter of 2021.
    - 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.
        - Enrollment for this trial began in the second quarter of 2021.
- **KarXT for the treatment of schizophrenia in adults who experience an inadequate response to current standard of care.** The Company is on track to initiate the Phase 3 ARISE trial evaluating the safety and efficacy of KarXT compared to placebo as an adjunctive treatment in adults with schizophrenia who have an inadequate response to their current antipsychotic therapy in the second half of 2021.
    - The Phase 3, six-week, 1:1 randomized, double-blind, placebo-controlled trial will enroll approximately 400 adults with schizophrenia who have not achieved an adequate response to current atypical antipsychotic treatment. Participants in this trial will continue their currently prescribed atypical antipsychotic therapy at the same dose or regimen schedule as prior to entry in the study, and will receive a flexible dose of KarXT or placebo based on tolerability and clinical response as determined by a clinician. The primary outcome measure of the trial is change in Positive and Negative Syndrome Scale (PANSS) total score of KarXT compared to placebo at Week 6. Upon completion of the trial at week 6, participants will have the opportunity to enroll in a 52-week outpatient, open-label extension trial evaluating the long-term safety and tolerability of KarXT when dosed with antipsychotic treatment.

- **KarXT for the treatment of dementia-related psychosis.** The Company announced results from the multi-cohort, placebo-controlled Phase 1b trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers in the second quarter of 2021. Results from the trial suggest that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile, and support the advancement of KarXT into a Phase 2 trial. The Company plans to initiate the Phase 2 trial evaluating KarXT in dementia-related psychosis in the first half of 2022.
- **Discovery and early-stage pipeline.** The Company continues to advance its earlier pipeline of muscarinic receptor targeted programs and novel formulations, as well as its artificial intelligence-based target agnostic discovery program for treating psychiatric and neurological conditions.

Business Updates

- **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.

Anticipated Upcoming Milestones

- Initiation of the Phase 3 ARISE trial (2H 2021)
- Initiation of the Phase 2 trial evaluating KarXT for the treatment of dementia-related psychosis (1H 2022)
- Topline data from the Phase 3 EMERGENT-2 trial (mid-2022)

Second Quarter 2021 Financial Results

The Company reported a net loss of $34.4 million for the second quarter of 2021, as compared to $17.0 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, increased employee headcount across the organization and higher stock-based compensation expense.

Research and development expenses were $24.1 million for the second quarter of 2021, as compared to $10.8 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, manufacturing in preparation for a potential NDA submission, personnel-related costs due to the increase in employee headcount and higher stock-based compensation expense.

General and administrative expenses were $10.4 million for the second quarter of 2021, as compared to $7.0 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in employee headcount and higher stock-based compensation expense.

The Company ended the quarter with $543.6 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 in March 2021. The Company expects that current cash, cash equivalents and available-for-sale investment securities as of June 30, 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 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, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	—	—	—	—
Operating expenses:				
Research and development	$ 24,147	$ 10,819	$ 44,333	$ 15,239
General and administrative	10,384	7,006	20,161	12,641
Total operating expenses	34,531	17,825	64,494	27,880
Loss from operations	(34,531)	(17,825)	(64,494)	(27,880)
Other income (loss), net:				
Impairment loss on right-of-use assets	—	—	(677)	—
Interest income	106	779	249	2,176
Sublease income	9	—	9	—
Total other income (loss), net	115	779	(419)	2,176
Net loss before income taxes	(34,416)	(17,046)	(64,913)	(25,704)
Income tax provision	—	—	—	—
Net loss attributable to common stockholders	$ (34,416)	$ (17,046)	$ (64,913)	$ (25,704)
Net loss per share, basic and diluted	$ (1.17)	$ (0.65)	$ (2.27)	$ (0.98)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	29,482,511	26,186,493	28,639,210	26,114,464

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and investments	$543,628	$322,330
Working capital	556,789	337,746
Total assets	577,188	347,625
Total stockholders' equity	$560,338	$338,931

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