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 5, 2020

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.)**

33 Arch Street, Suite 3110 **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 November 5, 2020, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the third quarter ended September 30, 2020. 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 5, 2020

SIGNATURE

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 5, 2020

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

Karuna Therapeutics Reports Third Quarter 2020 Financial Results and Provides General Business Update

On track to initiate first Phase 3 trial within the EMERGENT program by the end of 2020

Topline data from Phase 1b trial in healthy elderly volunteers expected early in the second quarter of 2021

$344.9 million in cash, cash equivalents and investment securities expected to fund multiple milestones, including progressing KarXT to NDA submission, and operations for at least the next three years

BOSTON – Nov. 5, 2020 – Karuna Therapeutics, Inc. (NASDAQ: KRTX), an innovative clinical-stage biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with disabling and potentially fatal neuropsychiatric disorders, today announced financial results for the third quarter of 2020 and provided a general business update.

"The end of this year will be transformative for Karuna as we initiate our Phase 3 EMERGENT program and transition to a late-stage clinical biotech company," said Steve Paul, M.D., chief executive officer, president and chairman of Karuna Therapeutics. "We continue to grow the organization to support our corporate and development objectives, and remain focused on simultaneously advancing our discovery efforts and early- and late-stage clinical programs evaluating KarXT in neuropsychiatric disorders."

Pipeline Updates

KarXT, a proprietary oral modulator of muscarinic cholinergic receptors, is Karuna's lead product candidate combining xanomeline, a novel muscarinic agonist, with trospium, a U.S. Food & Drug Administration (FDA) approved muscarinic antagonist that does not appreciably cross the blood-brain-barrier, to preferentially stimulate muscarinic receptors in the central nervous system (CNS). KarXT is currently being evaluated as a potential treatment for neuropsychiatric disorders, including schizophrenia and dementia-related psychosis.

- **KarXT in schizophrenia:** The Company remains on track to initiate EMERGENT-2, the first Phase 3 trial within the Company's EMERGENT clinical program evaluating KarXT for the treatment of acute psychosis in adults with schizophrenia, by the end of 2020. The Company plans to initiate the remaining Phase 3 trials within the EMERGENT program in the first half of 2021.
    - **Data highlighting details of efficacy, tolerability and safety from the Company's completed Phase 2 trial (EMERGENT-1) will be presented at the American College of Neuropsychopharmacology Annual Meeting scheduled for December.** The presentation will include both efficacy and safety data, including new data on the duration of treatment emergent adverse events of KarXT versus placebo.
    - **The Company plans to initiate a Phase 2 trial evaluating KarXT for the treatment of psychosis in patients with schizophrenia who have an**

inadequate response to current standard of care therapies. The trial will evaluate the efficacy and safety of KarXT when dosed in conjunction with background antipsychotic treatment and its potential to improve symptoms in patients who had not achieved an adequate response on their current antipsychotic treatment given the unique mechanism of action of KarXT in comparison to existing standard of care therapies. The Company plans to start this trial following the initiation of the Phase 3 trials within the EMERGENT program.

- **An exploratory endpoint analysis evaluating the impact of KarXT on cognition in the EMERGENT-1 trial was presented at the European College of Neuropsychopharmacology Annual Meeting in September**. The analysis demonstrated trends towards improvements in cognition for patients receiving KarXT relative to placebo, with larger benefits seen in patients with greater cognitive impairment at baseline. The Company plans to collect data on the potential benefit of KarXT on negative and cognitive symptoms of schizophrenia as part of the EMERGENT program and the Company's trial evaluating KarXT in patients who have an inadequate response to current standard of care therapies, and will continue to evaluate the timing and design of potential trials specifically directed towards the negative and cognitive symptoms of schizophrenia.

- **KarXT in dementia-related psychosis:** The multi-cohort, placebo-controlled, inpatient Phase 1b trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers is ongoing, with results anticipated early in the second quarter of 2021. The trial is designed to assess the safety and tolerability of KarXT in healthy elderly volunteers with the goal of selecting the most appropriate dose and dose-titration schedule to carry forward into future studies in patients with dementia-related psychosis.

Business Updates

- **Laurie Olson appointed to Board of Directors.** In August 2020, the Company's Board of Directors elected Laurie Olson as a director and as a member of its nominating and corporate governance committee. Ms. Olson is a seasoned pharmaceutical executive with more than 30 years of commercial and corporate strategy experience, most recently serving as the Executive Vice President, Strategy and Commercial Operations at Pfizer Inc.

- **COVID-19 update.** The Company continues to monitor the impact of COVID-19 across all ongoing and planned clinical trials and will provide updates on enrollment and completion timelines as deemed appropriate.

Third Quarter 2020 Financial Results

The Company reported a net loss of $18.8 million for the third quarter of 2020, as compared to $9.0 million for the prior year period. The increase in net loss for the period was due to higher research and development expenses related to the Company's preparation for the initiation of the Phase 3 clinical trials within its EMERGENT program as well as higher general and administrative expense.

Research and development expenses were $12.6 million for the third quarter of 2020, as compared to $5.8 million for the prior year period. The increase in research and development expenses for the period was primarily driven by expenses related to the Company's preparation for the initiation of the Phase 3 clinical trials within its EMERGENT program, including CRO start-up costs and clinical trial material manufacturing. The Company also had additional expenses related to its Phase 1b trial in healthy elderly volunteers, increased personnel-related costs due to the increase in employee headcount, as well as expenses associated with the Company's discovery programs.

General and administrative expenses were $6.9 million for the third quarter of 2020, as compared to $4.1 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in personnel-related expenses.

The Company ended the quarter with $344.9 million in cash, cash equivalents, and available-for-sale investment securities compared to $389.4 million as of December 31, 2019. The Company expects that its current cash, cash equivalents, and available-for-sale investment securities as of September 30, 2020 will enable the Company to fund its operating expenses and capital expenditure requirements for at least the next three years. This includes multiple potential clinical and development milestones, including an NDA submission of KarXT for the treatment of acute psychosis in patients with schizophrenia pending the outcomes of the Company's planned EMERGENT clinical trials and the completion of the Phase 1b healthy elderly trial. Additional activities which may be funded include the initiation of the potential Phase 2 trial for the treatment of dementia-related psychosis and continued investment into pipeline expansion, including evaluating KarXT in patients with schizophrenia who have an inadequate response to standard of care therapies.

About Karuna

Karuna is a clinical-stage biopharmaceutical company committed to developing and delivering first-in-class therapies with the potential to transform the lives of people with CNS disorders – which remain among the most disabling and potentially fatal disorders worldwide. Galvanized by the understanding that today's neuropsychiatric patients deserve better, Karuna's mission is to harness the untapped potential of the brain's complex biology in pursuit of novel therapeutic pathways that will advance the standard of care. For more information, please visit 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, 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, 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, 2019 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	—	—	—	—
Operating expenses:				
Research and development	$ 12,585	$ 5,793	$ 27,824	$ 19,544
General and administrative	6,944	4,103	19,585	16,995
Total operating expenses	19,529	9,896	47,409	36,539
Loss from operations	(19,529)	(9,896)	(47,409)	(36,539)
Other income, net:				
Interest income	688	858	2,864	1,425
Interest income, net	—	—	—	11
Accretion of debt discount	—	—	—	(945)
Change in fair value of derivative	—	—	—	(135)
Total other income, net	688	858	2,864	356
Net loss before income taxes	(18,841)	(9,038)	(44,545)	(36,183)
Income tax provision	—	—	—	—
Net loss attributable to common stockholders	$ (18,841)	$ (9,038)	$ (44,545)	$ (36,183)
Net loss per share, basic and diluted	$ (0.71)	$ (0.39)	$ (1.69)	$ (4.67)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	26,663,968	22,907,349	26,298,969	7,755,137

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents and investments	$ 344,897	$ 389,397
Working capital	356,101	389,748
Total assets	364,436	393,024
Total stockholders' equity	$ 357,259	$ 389,916

Investors
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