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 04, 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)**	**(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 Select 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 4, 2021, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the third quarter ended September 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 November 4, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

KARUNA THERAPEUTICS, INC.

Date: November 4, 2021

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

Exhibit 99.1

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

Topline data from the Phase 3 EMERGENT-2 and EMERGENT-3 trials expected in mid-2022 and in the second half of 2022, respectively

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 fourth quarter of 2021

Company plans to initiate a Phase 3 program evaluating KarXT for the treatment of psychosis in elderly patients with Alzheimer's disease in mid-2022

$498.9 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—Nov. 4, 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 third quarter of 2021 and provided a general business update.

"We continue to progress our late-stage clinical programs evaluating KarXT in schizophrenia, including the ongoing enrollment in our EMERGENT program, comprised of four Phase 3 trials, with topline data from the first trial expected in mid-2022, and the Phase 3 ARISE trial, which is on track to initiate by the end of the year," said Steve Paul, M.D., chief executive officer, president and chairman. "This robust development program is a testament to our confidence in the novel mechanism of action of KarXT, as demonstrated by the compelling clinical data to date, and the promise it has to treat the multiple symptom domains of schizophrenia as both a monotherapy and an adjunctive therapy in adults who do not respond adequately to current standard of care."

"We have also advanced our efforts in dementia-related psychosis, with an initial focus on developing KarXT for Alzheimer's disease, the leading form of dementia in the U.S. Nearly half of those living with Alzheimer's disease experience symptoms of psychosis and related behavioral disturbances, such as agitation and aggression, which can negatively impact and disrupt day-to-day functioning of patients and caregivers alike. There is a dire need for an effective therapy that can alleviate these disabling symptoms," added Dr. Paul. "We look forward to building on the encouraging data seen in an earlier Phase 2 study of xanomeline in treating and preventing symptoms of psychosis in Alzheimer's disease as we progress KarXT into late-stage clinical studies in mid-2022."

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 late-stage clinical trials as a potential treatment for schizophrenia and Alzheimer's disease 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, with topline data expected 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, with topline data expected in the second half of 2022.
- 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 Phase 3 ARISE trial evaluating the safety and efficacy of KarXT compared to placebo as an adjunctive treatment for schizophrenia is on track to initiate in the fourth quarter of 2021.
- **KarXT for the treatment of psychosis in Alzheimer's disease.** The evaluation of KarXT for the treatment of dementia-related psychosis (DRP) will initially focus on psychosis in Alzheimer's disease, the most common subtype of DRP. The initial focus on the Alzheimer's disease dementia subtype reflects various strategic development, regulatory and commercial considerations, and the Company remains interested in exploring KarXT in other dementia subtypes in future development programs. Details of the Phase 3 Alzheimer's disease psychosis program will be available in the first half of 2022 prior to the program's initiation in mid-2022.
- **Discovery and early-stage pipeline.** The Company continues to advance its earlier pipeline of muscarinic receptor targeted programs and novel formulations of KarXT, including a Phase 1 trial of an advanced formulation of KarXT expected to initiate in the fourth quarter of 2021, 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 (4Q 2021)
- Initiation of the Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease (mid-2022)
- Topline data from the Phase 3 EMERGENT-2 trial (mid-2022)
- Topline data from the Phase 3 EMERGENT-3 trial (2H 2022)

Third Quarter 2021 Financial Results

The Company reported a net loss of $50.9 million for the third quarter of 2021, as compared to $18.8 million for the prior year comparable period. The increase in net loss for the quarter was due to higher research and development expenses related to the Company's enrollment of the Phase 3 EMERGENT trials, NDA-supporting activities, start-up activities related to the Phase 3 ARISE trials, increased employee headcount across the organization and higher stock-based compensation expense.

Research and development expenses were $38.8 million for the third quarter of 2021, as compared to $12.6 million the prior year comparable period. The increase in research and development expenses for the quarter was primarily driven by expenses related to the Company's enrollment of the Phase 3 EMERGENT trials, manufacturing in preparation for a potential NDA submission, start-up activities related to the Phase 3 ARISE trials, personnel-related costs due to the increase in employee headcount and higher stock-based compensation expense.

General and administrative expenses were $12.4 million for the third quarter of 2021, as compared to $6.9 million for the prior year comparable period. The increase in general and administrative expenses was primarily due to an increase in employee headcount and higher stock-based compensation expense as well as an increase in professional fees.

The Company ended the quarter with $498.9 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, partially offset by cash used in operations for the nine months ended September 30, 2021. The Company expects that current cash, cash equivalents and available-for-sale investment securities as of September 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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue	—	—	—	—
Operating expenses:				
Research and development	$ 38,775	$ 12,585	$ 83,108	$ 27,824
General and administrative	12,393	6,944	32,554	19,585
Total operating expenses	51,168	19,529	115,662	47,409
Loss from operations	(51,168)	(19,529)	(115,662)	(47,409)
Other income (loss), net:				
Impairment loss on right-of-use assets	—	—	(677)	—
Interest income	114	688	363	2,864
Sublease income	122	—	131	—
Total other income (loss), net	236	688	(183)	2,864
Net loss before income taxes	(50,932)	(18,841)	(115,845)	(44,545)
Income tax provision	—	—	—	—
Net loss attributable to common stockholders	$ (50,932)	$ (18,841)	$ (115,845)	$ (44,545)
Net loss per share, basic and diluted	$ (1.72)	$ (0.71)	$ (4.00)	$ (1.69)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	29,572,289	26,663,968	28,953,654	26,298,969

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

	September 30, 2021	**December 31, 2020**
Cash, cash equivalents and investments	$ 498,903	$ 322,330
Working capital	513,663	337,746
Total assets	540,098	347,625
Total stockholders' equity	$ 518,328	$ 338,931

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