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): February 24, 2022

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 February 24, 2022, Karuna Therapeutics, Inc. announced its financial results and general corporate updates for the fourth quarter and fiscal year ended December 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 February 24, 2022
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: February 24, 2022

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

Exhibit 99.1

Karuna Therapeutics Reports Fourth Quarter and Full Year 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

Initiated 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

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

$494.0 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 for schizophrenia

BOSTON—Feb. 24, 2022—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 fourth quarter and full year ended December 31, 2021, and provided a general business update.

"We are excited by the momentum we've built in executing our comprehensive late-stage clinical program for KarXT this past year, which has laid the groundwork for additional key milestones in 2022, including topline data from the registrational Phase 3 EMERGENT-2 and EMERGENT-3 trials in schizophrenia, as well as the planned initiation of our Phase 3 program in psychosis in Alzheimer's disease," said Steve Paul, M.D., chief executive officer, president, and chairman. "Looking ahead, we are dedicated to expanding and diversifying our development efforts and capabilities to reach people living with psychiatric and neurological conditions globally, as evidenced by our strategic collaboration with Zai Lab in Greater China and the growth of our commercial organization in preparation for a potential launch in the U.S."

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, that is currently being evaluated in late-stage clinical trials as a potential treatment for schizophrenia and psychosis in Alzheimer's disease.

- **KarXT for the treatment of schizophrenia.** The EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia, includes the completed positive Phase 2 EMERGENT-1 trial and the following ongoing 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.
    - The Company anticipates topline data from EMERGENT-2 in 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.
    - The Company anticipates topline data from EMERGENT-3 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.
  - EMERGENT-5: A 52-week outpatient, open-label trial evaluating the long-term safety and tolerability of KarXT in adults with schizophrenia who were not enrolled in EMERGENT-2 or EMERGENT-3. The Company plans to increase the number of sites in the U.S. and Puerto Rico, and allow for up to 600 patients in the trial.

- **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 in adults who experience an inadequate response to current standard of care is enrolling.
- **KarXT for the treatment of psychosis in Alzheimer's disease.** The Company remains on track to initiate the Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease in mid-2022. The Company plans to share details of the Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease 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 the initiation of a Phase 1 trial of an advanced formulation of KarXT 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

- **Entered strategic collaboration with Zai Lab for the development, manufacturing, and commercialization of KarXT in Greater China in November 2021.** Under the terms of the agreement, the Company granted Zai Lab an exclusive license to develop, manufacture, and commercialize KarXT in Greater China, including mainland China, Hong Kong, Macau, and Taiwan. The Company received an upfront cash payment of $35.0 million in the fourth quarter of 2021, and is eligible to receive up to an additional $80.0 million in development and regulatory milestones. Karuna is also eligible to receive up to $72.0 million in sales milestones and low-double-digit to high-teens tiered royalties based on annual net sales of KarXT in Greater China.
- **Appointed Charmaine Lykins as Chief Commercial Officer.** Ms. Lykins joined the Company as Chief Commercial Officer, effective November 2021, bringing over 25 years of psychiatry and neuroscience-focused pharmaceutical launch experience across multiple organizations recognized as leaders in developing and commercializing medicines for central nervous system disorders.
- **COVID-19 update.** The Company continues to monitor the impact of COVID-19, and the subsequent emergence of highly contagious variants, and has taken steps to identify and mitigate the adverse impacts on its activities, including ongoing and planned clinical trials, and business operations. The Company will continue to provide relevant updates on its impact on activities as deemed appropriate.

Anticipated Upcoming Milestones

- 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)

Fourth Quarter and Full Year 2021 Financial Results

The Company reported a net loss of $28.0 million for the fourth quarter of 2021, and a net loss of $143.8 million for the year ended 2021, as compared to $24.0 million and $68.6 million for the prior year periods, respectively. The increase in net loss for the year was primarily attributable to higher operating expenses of $180.8 million compared to $71.8 million for the prior year period, driven by research and development expenses related to the Company's enrollment of the Phase 3 EMERGENT trials, NDA-supporting activities, the initiation and enrollment of the Phase 3 ARISE trial, increased employee headcount across the organization, and higher stock-based compensation expense. The increase in operating expenses was partially offset by an increase in revenue of $37.0 million related to the upfront payment and related tax gross ups for the Company's exclusive license agreement with Zai Lab for the development, manufacturing, and commercialization of KarXT in Greater China, which was signed in November 2021.

Research and development expenses were $45.1 million for the fourth quarter of 2021, and $128.2 million for the year ended 2021, as compared to $15.6 million and $43.4 million the prior year periods, respectively. The increase in research and development expenses for the year was primarily driven by expenses related to the Company's enrollment of the Phase 3 EMERGENT trials, manufacturing to support ongoing and planned clinical trials, preparation for a potential NDA submission of KarXT for schizophrenia, the initiation and enrollment of the Phase 3 ARISE trial, personnel-related costs due to the increase in employee headcount, and higher stock-based compensation expense.

General and administrative expenses were $20.1 million for the fourth quarter of 2021, and $52.6 million for the year ended 2021, as compared to $8.8 million and $28.4 million for the prior year periods, respectively. The increase in general and administrative expenses for the year was primarily due to an increase in employee headcount and higher stock-based compensation expense, an increase in professional fees, and one-time expenses related to the execution of the Company's exclusive license agreement with Zai Lab for the development, manufacturing, and commercialization of KarXT in Greater China.

The Company ended the year 2021 with $494.0 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 follow-on public offering in March 2021, as well as an upfront cash payment from Zai Lab, partially offset by cash used in operations for the year ended December 31, 2021. The Company expects that current cash, cash equivalents and available-for-sale investment securities as of December 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 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, 2021. 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
License revenue	$ 36,964	$ -	$ 36,964	$ -
Operating expenses:				
Research and development	45,092	15,584	128,200	43,408
General and administrative	20,063	8,823	52,617	28,408
Total operating expenses	65,155	24,407	180,817	71,816
Loss from operations	(28,191)	(24,407)	(143,853)	(71,816)
Other income, net:				
Impairment loss on right-of-use assets	(25)	—	(702)	—
Interest income	139	441	502	3,305
Sublease income	123	—	254	—
Total other income, net	237	441	54	3,305
Net loss before income taxes	(27,954)	(23,966)	(143,799)	(68,511)
Income tax provision	(6)	(43)	(6)	(43)
Net loss attributable to common stockholders	$ (27,960)	$ (24,009)	$ (143,805)	$ (68,554)
Net loss per share, basic and diluted	$ (0.94)	$ (0.89)	$ (4.94)	$ (2.59)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	29,688,658	26,883,923	29,138,915	26,446,006

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and investments	$ 493,991	$ 322,330
Working capital	497,121	337,746
Total assets	527,671	347,625
Total stockholders' equity	$ 502,026	$ 338,931

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