# 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 7, 2019**

# 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**<br>**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 November 7, 2019, Karuna Therapeutics, Inc. (the "Company") announced its financial results and general corporate updates for the third quarter ended September 30, 2019. 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 Form8-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 (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 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 7, 2019.

SIGNATURES

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 7, 2019

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

**Exhibit 99.1**

**Karuna Therapeutics Reports Third Quarter 2019 Financial Results and Provides General Business Update**

- *Phase 2 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia remains on track with topline data expected in late 2019*
- *Phase 1b clinical trials for the treatment of psychosis in Alzheimer's disease and pain on track to commence by the end of 2019*
- *Cash, cash equivalents and short-term investment balance of $161.6 million to fund development of novel CNS pipeline*

**BOSTON, Mass., November 7, 2019** – Karuna Therapeutics, Inc. (Nasdaq: KRTX), a clinical-stage biopharmaceutical company primarily focused on developing novel therapies to address disabling neuropsychiatric conditions, today announced financial results for the third quarter 2019 and provided a general business update.

"At Karuna our mission is to develop first-in-class therapeutics that dramatically improve the lives of people living with schizophrenia, Alzheimer's disease and pain," stated Steve Paul, M.D., chief executive officer, president and chairman of Karuna Therapeutics. "It has been a very productive quarter as we work towards this mission and look forward to presenting the results of our Phase 2 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia later this year. KarXT offers a new mechanism of action with the potential for not only improved efficacy, but safety and tolerability as well. If approved, KarXT could substantially improve the treatment paradigm for people suffering from this debilitating and potentially fatal disease."

**Business Highlights**

- **KarXT for the treatment of acute psychosis in patients with schizophrenia.** KarXT, a proprietary oral modulator of muscarinic receptors, is the Company's lead product candidate that combines xanomeline, a novel muscarinic agonist, with trospium, an FDA approved muscarinic antagonist that does not appreciably cross the blood-brain-barrier, to preferentially stimulate muscarinic receptors in the central nervous system (CNS).
    - **Phase 2 topline results expected in late 2019.** Karuna has completed enrollment of a multi-site, double-blind, placebo-controlled, inpatient Phase 2 clinical trial of KarXT in 182 schizophrenia patients with acute psychosis. The trial's primary endpoint is the change from baseline in Positive and Negative Syndrome Score (PANSS) total scores for KarXT compared to placebo treated patients. In addition to reporting topline efficacy results, Karuna will also provide an overview of the drug's safety and tolerability. Secondary endpoints include changes in PANSS Marder Factor (including the negative symptom factor), cognitive battery and the clinical global impression severity scale (CGI-S). The Phase 2 clinical trial design represents the same fundamental design and primary endpoint utilized in the previous third-party xanomeline Phase 2 trial in psychosis in schizophrenia, as well as in pivotal trials for several currently approved antipsychotic medicines.
    - **Blinded Phase 2 safety data and Independent Safety Monitoring Committee (ISMC) suggests KarXT continues to offer improved tolerability compared to xanomeline.** The Phase 2 trial uses a flexible-dose design with the potential to escalate the dose after the first week of treatment based solely on the tolerability experienced by each individual patient. The

low dose of KarXT in the Phase 2 study is equivalent to the high dose in the previous third-party xanomeline-alone Phase 2 trials in Alzheimer's disease and schizophrenia. Approximately 90% of patients in Karuna's Phase 2 trial escalated to the highest dose (125mg/30mg twice daily) and less than 5% of patients who dose-escalated have subsequently de-escalated back to the 100mg/20mg twice daily dose level. The early termination rate has been approximately 20-25%, which is lower than the 38% early termination reported in a meta-analysis of 167 placebo-controlled studies in schizophrenia patients with acute psychosis. Additionally, the ISMC completed review of the unblinded safety and tolerability data at three prespecified intervals and each time recommended the trial continue without modification.

- **Advancing CNS pipeline with two Phase 1b clinical programs initiating by the end of 2019.** The Company's pipeline is built on the therapeutic potential of KarXT and the established link between muscarinic receptor stimulation in the CNS and its ability to impact a wide range of disorders including schizophrenia, Alzheimer's disease psychosis and various forms of pain.
    - **Phase 1b clinical trial of KarXT in healthy elderly volunteers.** Expanding upon the two previously completed Phase 1 trials that demonstrated the tolerability of KarXT in healthy volunteers, this trial will investigate the safety and tolerability of KarXT in elderly volunteers. Xanomeline-alone was previously studied by a third party in a placebo-controlled, double-blind Phase 2 clinical trial in 343 Alzheimer's patients that reported both the reduction of emergence and remission of psychotic symptoms and suggested cognitive benefits.
    - **Phase 1b clinical trial of KarXT in experimentally induced pain.** Preclinical data published in peer-reviewed scientific journals link the stimulation of muscarinic receptors, and specifically xanomeline, to analgesic benefits. Xanomeline has demonstrated robust activity in several animal models of different types of pain including post-operative, inflammatory and neuropathic pain.
- **Karuna added to the Russell 2000 and 3000 Indexes.** In September, Karuna was added to the Russell 2000 and 3000 Indexes as part of the FTSE Russell's quarterly update. The Russell U.S. Indexes are widely used by investment managers and institutional investors for passive funds and investment products and as benchmarks for active investment strategies.
- **Continued recruitment of top talent across key functional areas.** Karuna has recently expanded its Senior Discovery Team with the addition of James E. Audia, Ph.D. and James A. Monn, Ph.D. As Karuna pursues development of KarXT for additional indications it is also scaling up discovery efforts to expand its product pipeline. "Dr. Audia and Dr. Monn are very accomplished scientific leaders and drug discovery experts who join Karuna at an exciting time," said Steve Paul, M.D., chief executive officer, president and chairman of Karuna. "Their decades long careers will support our early discovery programs focused on developing novel therapies to address disabling neuropsychiatric conditions." Dr. Audia joins as head of medicinal chemistry and senior adviser. He brings over 20 years of medicinal chemistry experience in both the pharmaceutical and biotechnology industries, having most recently served as the chief scientific officer at Constellation Pharmaceuticals and prior to that as distinguished Lilly scholar at Eli Lilly. Dr. Monn joins Karuna as a vice president of medicinal chemistry and brings over 20 years of drug discovery experience as a senior research fellow at Eli Lilly.

**Third Quarter 2019 Financial Results**

The Company reported a net loss of $9.0 million for the third quarter 2019 as compared to $6.2 million for the prior year period. The increase in net loss for the year was due to increased research and development expenses, as well as an increase in general and administrative expenses primarily related to investments in the Company's infrastructure as a publicly traded company.

Research and development expenses for the third quarter 2019 were $5.8 million as compared to $1.4 million for the prior year period. The increase in research and development expenses was primarily driven by increased spending related to the Company's Phase 2 clinical trial for the treatment of schizophrenia, Phase 1b trial in experimentally induced pain, increased personnel-related costs due to the increase in employee headcount, as well as expenses associated with consulting fees and our discovery programs.

General and administrative expenses were $4.1 million for the third quarter 2019 as compared to $1.1 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in employee headcount inclusive of the impact of stock-based compensation and higher costs related to the support of business operations as a publicly traded company.

The Company ended the quarter with $161.6 million in cash, cash equivalents and short-term investments compared to $13.9 million as of December 31, 2018. The increase was primarily the result of the completion of the Company's initial public offering which generated $93.0 million in net proceeds and Series B Preferred Stock Financing which generated net proceeds of $74.8 million. The Company expects that current cash, cash equivalents, and short-term investments as of September 30, 2019, will enable the Company to fund its operating expenses and capital expenditure requirements into the second half of 2021. This includes multiple clinical and development milestones including a Phase 3 clinical trial of KarXT in psychosis related to schizophrenia.

**About Karuna**

Karuna is an innovative clinical-stage biopharmaceutical company primarily focused on developing novel therapies to address disabling neuropsychiatric conditions characterized by significant unmet medical need. Karuna is currently conducting a Phase 2 clinical trial of its lead product candidate, KarXT (Karuna-Xanomeline-Trospium), for the treatment of acute psychosis in patients with schizophrenia. Karuna also plans to initiate clinical trials of KarXT to evaluate its potential therapeutic benefit in other central nervous system disorders, including psychosis in Alzheimer's disease, as well as pain.

**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 our cash resources, the timing of advancing of our planned clinical trials, interim trial results, our goals to develop and commercialize our 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 costs and timing of establishing, equipping, 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, and other risks set forth under the heading "Risk Factors" of our Quarterly Report on Form 10-Q for the third quarter ended September 30, 2019. 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.

**Investor Contact:**
Chris Brinzey
Westwicke, an ICR Company
+1 339 970-2843
chris.brinzey@westwicke.com

**Media Contact:**
Jenn Gordon
GlobalHealthPR
+1 202 587-2580
jgordon@globalhealthpr.com

**Karuna Therapeutics, Inc.**
**Unaudited Statements of Operations**
(in thousands, except share and per share data)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue | — | — | — | — |
| Operating expenses: | | | | |
| Research and development | $ 5,793 | $ 1,417 | $ 19,544 | $ 4,816 |
| General and administrative | 4,103 | 1,056 | 16,995 | 1,548 |
| Total operating expenses | 9,896 | 2,473 | 36,539 | 6,364 |
| Loss from operations | (9,896) | (2,473) | (36,539) | (6,364) |
| Other income (expense): | | | | |
| Interest income (expense) | — | 192 | 11 | (396) |
| Interest income | 858 | — | 1,425 | — |
| Accretion of debt discount | — | (1,324) | (945) | (1,996) |
| Change in fair value of derivative | — | (2,633) | (135) | (429) |
| Total other income (expense), net | 858 | (3,765) | 356 | (2,821) |
| Net loss before income taxes | (9,038) | (6,238) | (36,183) | (9,185) |
| Income tax provision | — | — | — | — |
| Net loss attributable to common stockholders | $ (9,038) | $ (6,238) | $ (36,183) | $ (9,185) |
| Net loss per share, basic and diluted | $ (0.39) | $(1,247,600) | $ (4.67) | $(4,592,500) |
| Weighted average common shares outstanding used in computing net loss per share, basic and diluted | 22,907,349 | 5 | 7,755,137 | 2 |

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

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 161,605 | $ 13,887 |
| Working capital | 162,395 | 14,400 |
| Total assets | 164,227 | 15,857 |
| Redeemable convertible preferred stock | — | 41,965 |
| Total stockholders' equity (deficit) | $ 162,530 | $ (29,922) |