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 8, 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 1.01. Entry into a Material Definitive Agreement

On November 8, 2021, Karuna Therapeutics, Inc. ("Karuna") and Zai Lab (Shanghai) Co., Ltd ("Zai") entered into a license agreement (the "Agreement"), pursuant to which Karuna granted to Zai the right to exclusively develop, manufacture and commercialize KarXT (xanomeline-trospium) in Greater China, including mainland China, Hong Kong, Macau, and Taiwan (the "Licensed Territory").

Under the terms of the Agreement, Karuna will receive a $35 million upfront payment and is eligible to receive up to an additional $80 million in development and regulatory milestone payments. Karuna is also eligible to receive up to $72 million in sales milestone payments and low double-digit to high-teens tiered royalties based on annual net sales of KarXT in the Licensed Territory, subject to reduction under specified circumstances. Zai will fund substantially all development, regulatory, and commercialization activities in the Licensed Territory.

The Agreement will expire upon the latest of the following dates with respect to the last licensed product in any region in the Licensed Territory: (i) the date of expiration of the last valid claim covering such licensed product in such region, (ii) the date that is a specific period after the date of the first commercial sale of such licensed product in such region and (iii) the expiration date of any regulatory exclusivity for such licensed product in such region. Subject to the terms of the Agreement, Zai may terminate the Agreement for convenience by providing written notice to Karuna, which termination will be effective following a prescribed notice period. In addition, Karuna may terminate the Agreement under specified circumstances if Zai or certain other parties challenge Karuna's patent rights or if Zai or its affiliates fail to complete certain development activities with respect to the licensed product for a specified period of time, subject to specified exceptions. Either party may terminate the Agreement for the other party's uncured material breach of the Agreement, with a customary notice and cure period, or insolvency. After termination or expiration of the Agreement, Karuna is entitled to retain a worldwide, exclusive, and perpetual license from Zai to exploit the licensed product (which license would be non-exclusive after expiration (but not termination) of the Agreement), subject to a reasonable royalty to be agreed by the parties if the Agreement is terminated for Karuna's uncured material breach.

The foregoing description of the terms of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed with the Securities and Exchange Commission as an exhibit to Karuna's Annual Report on Form 10-K for the year ending December 31, 2021.

Item 7.01. Regulation FD Disclosure.

On November 9, 2021, Karuna and Zai issued a joint press release announcing the Agreement. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 7.01 by reference. The information contained in Item 7.01 of this Current 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 (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	Joint Press Release issued by Karuna Therapeutics, Inc., dated November 9, 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: November 9, 2021

KARUNA THERAPEUTICS, INC.

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

Exhibit 99.1

Karuna Therapeutics and Zai Lab Announce Strategic Collaboration for Development, Manufacturing, and Commercialization of KarXT in Greater China

Zai Lab obtains exclusive rights to develop and commercialize KarXT in Greater China

Karuna to receive upfront cash payment of $35 million, up to $152 million in potential near- and long-term development and commercial milestones and other payments, and low-double-digit to high-teens tiered royalties

BOSTON, SHANGHAI and SAN FRANCISCO – Nov. 9, 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, and Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced their entry into an exclusive license agreement for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China, including mainland China, Hong Kong, Macau, and Taiwan.

KarXT is an oral, investigational M1/M4-preferring muscarinic agonist that stimulates receptors in the central nervous system implicated in various psychiatric conditions. KarXT was designed to unlock the therapeutic potential of xanomeline, which demonstrated significant benefits in reducing symptoms of psychosis in Phase 2 studies in schizophrenia and Alzheimer's disease, while ameliorating side effects seen in earlier studies. In the Phase 2 EMERGENT-1 trial, KarXT demonstrated clinically meaningful and statistically significant improvements in the primary endpoint of Positive and Negative Syndrome Scale (PANSS) total score, and in key secondary endpoints, including PANSS-positive subscore and PANSS-negative subscore, at week 5, and was generally well-tolerated.

Karuna is evaluating KarXT in late-stage clinical trials for the treatment of schizophrenia and psychosis in Alzheimer's disease. The EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia, is underway. The EMERGENT program is comprised of the previously completed Phase 2 EMERGENT-1 trial and four ongoing Phase 3 trials, with data from EMERGENT-2 and EMERGENT-3, the two Phase 3 acute efficacy and safety trials, expected in mid-2022 and in the second half of 2022, respectively. Karuna plans to initiate the Phase 3 ARISE trial evaluating KarXT as an adjunctive treatment for schizophrenia in adults who inadequately respond to atypical antipsychotics in the fourth quarter of 2021. Additionally, Karuna also plans to initiate a Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease in mid-2022 following encouraging results from the 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. Zai Lab will work with Karuna to design the optimal strategy to accelerate the development and regulatory timeline of KarXT in Greater China.

Under the terms of the agreement, Karuna will receive a $35 million upfront payment and is eligible to receive up to an additional $80 million in development and regulatory milestones. Karuna is also eligible to receive up to $72 million in sales milestones and low-double-digit to high-teens tiered royalties based on annual net sales of KarXT in Greater China. Zai Lab will fund substantially all development, regulatory, and commercialization activities in Greater China.

“We are thrilled to collaborate with Zai Lab, who shares our commitment to bringing transformative medicines to people living with psychiatric conditions globally,” said Steve Paul, M.D., chief executive officer, president, and chairman of Karuna Therapeutics. “With their proven record of successfully developing and commercializing novel therapies in Greater China, we believe that Zai Lab is the ideal partner to expand the global footprint for KarXT alongside our ongoing efforts in the U.S., with the goal of providing meaningful treatments to millions of people living with mental illness globally.”

“Our collaboration with Karuna is a significant milestone for Zai Lab, marking the expansion and diversification of our development and commercial portfolio into neuroscience, our fourth therapeutic area,” said Samantha Du, Ph.D., founder, chairperson and chief executive officer of Zai Lab. “KarXT is well positioned to serve as the anchor asset in our new neuroscience franchise. Zai Lab’s mission is to deliver innovative medicines to address unmet medical needs of patients, and we look forward to working with Karuna to bring KarXT to patients in need in Greater China as soon as possible.”

“There is a significant need for new and more effective therapies with improved safety to treat serious psychiatric conditions in Greater China,” said Gang Wang, M.D., Director of National Clinical Research Center for Mental Disorders, Dean of Beijing Anding Hospital, Capital Medical University. “Currently, more than 8 million people in Greater China are living with schizophrenia, yet fewer than half are receiving treatment, and even fewer are obtaining adequate symptom improvement from current treatment. We believe KarXT has the potential to provide a meaningful new treatment option for many patients living with schizophrenia and other conditions with disabling symptoms of psychosis.”

Goldman Sachs & Co. LLC is acting as financial advisor to Karuna Therapeutics.

About KarXT

KarXT (xanomeline-trospium) is an oral, investigational M1/M4-preferring muscarinic acetylcholine receptor agonist in development for the treatment of psychiatric and neurological conditions, including schizophrenia and dementia-related psychosis. KarXT preferentially stimulates muscarinic receptors in the central nervous system implicated in these conditions, as opposed to current antipsychotic medicines, which bind to the D_2 dopamine receptor. KarXT has the potential to usher in a new class of treatment for schizophrenia and dementia-related psychosis based on its differentiated mechanism of action.

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.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Karuna Therapeutics 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 the potential benefits and results that may be achieved through our collaboration with Zai Lab, our ongoing and planned clinical trials and regulatory filings, 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 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, 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.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of KarXT; the clinical development of KarXT; the potential treatment of schizophrenia and dementia-related psychosis; the potential of Zai Lab’s commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab’s collaboration arrangement with Karuna Therapeutics, Inc. and other risks and uncertainties associated with drug development and commercialization. These forward-looking statements may contain words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” “would” and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products; (2) our ability to finance our operations and business initiatives and obtain funding for such activities, (3) our results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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