

**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): June 1, 2021

ZAI LAB LIMITED

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation or organization)

001-38205
(Commission
File Number)

98-1144595
(I.R.S. Employer
Identification No.)

4560 Jinke Road
Bldg. 1, Fourth Floor Pudong
Shanghai, China
(Address of principal executive offices)

201210
(Zip Code)

+86 21 6163 2588
(Registrant's Telephone Number, Including Area Code)

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
American Depositary Shares, each representing 1 Ordinary Share, par value \$0.00006 per share	ZLAB	The Nasdaq Global Market
Ordinary Shares, par value \$0.00006 per share*	9688	The Stock Exchange of Hong Kong Limited

* Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited

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 May 28, 2021, Zai Lab Limited (the “Company”) and Mirati Therapeutics, Inc. (“Mirati”) entered into a collaboration and license agreement (the “Agreement”), pursuant to which Zai Lab (Hong Kong) Limited, a wholly-owned subsidiary of the Company (“Zai HK”), and Mirati agreed to collaboratively develop MRTX849 (adagrasib) in China, Macau, Hong Kong and Taiwan (the “Licensed Territory”). Under the Agreement, Zai HK received from Mirati the right to research, develop, manufacture and exclusively commercialize adagrasib in all indications in the Licensed Territory, with Mirati retaining exclusive rights for the development, manufacturing and commercialization of adagrasib outside the Licensed Territory and certain co-commercialization, manufacture, and development rights in the Licensed Territory.

Pursuant to the terms of the Agreement, Zai HK will pay to Mirati an upfront fee of \$65.0 million plus milestone payments of up to an aggregate of \$273.0 million upon the achievement of specified clinical, regulatory and sales milestones. Mirati will also be eligible to receive certain royalties at tiered percentage rates ranging from the high teens to low twenties percent on annual net sales of licensed products in the Licensed Territory, subject to reduction under specified circumstances.

The Agreement will terminate on a licensed product-by-licensed product basis and on a region-by-region basis in the Licensed Territory, upon the later to occur of (i) the date of expiration of the last valid claim covering such licensed product in such region, (ii) the date that is 10 years after the date of the first commercial sale in such region and (iii) the expiration date of any regulatory exclusivity for such licensed product in such region, or for a co-commercialized product on the date the parties agree to terminate such co-commercialization, or in its entirety upon the expiration of all payment obligations under this Agreement. Zai HK may terminate the Agreement at any time by providing 12 months’ prior notice to Mirati. Either party may terminate the Agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events. In addition, Mirati may terminate the Agreement if Zai HK challenges the licensed patent rights.

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, which the Company intends to file as an exhibit to a subsequent periodic report or on an amendment to this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On June 1, 2021 (U.S. time), the Company issued a press release announcing the above-described transactions. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and shall not be deemed to be “filed” for purposes of Section 18 of 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 or the Exchange Act, except as expressly set forth by specific reference in such filing or this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Joint press release issued on June 1, 2021.
104	The cover page of this Current Report on Form 8-K is formatted in Inline XBRL

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.

ZAI LAB LIMITED

By: /s/ Billy Cho
Billy Cho
Chief Financial Officer

Date: June 1, 2021



**Mirati Therapeutics and Zai Lab Enter Into a Collaboration to
Develop and Commercialize *adagrasib* in Greater China**

- Zai Lab obtains the right to develop and exclusively commercialize *adagrasib* in mainland China, Hong Kong, Macau and Taiwan
- Mirati to receive an upfront payment of \$65 million, up to approximately \$273 million in potential milestone payments and high-teen- to low-twenties-percent tiered royalties
- Agreement will accelerate enrollment in key global, registration-enabling clinical trials investigating *adagrasib* in patients with KRASG12C mutations

SAN DIEGO, SHANGHAI and SAN FRANCISCO – June 1, 2021 – Mirati Therapeutics, Inc. (NASDAQ: MRTX), a clinical-stage targeted oncology company, and Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced the companies have entered into a collaboration and license agreement for *adagrasib*, a small-molecule KRASG12C inhibitor, in Greater China (mainland China, Hong Kong, Macau and Taiwan).

“We believe Zai Lab is an ideal partner to enable us to expand and accelerate Mirati’s global *adagrasib* development,” said Charles M. Baum, M.D., Ph.D., president and chief executive officer, Mirati Therapeutics, Inc. “Zai Lab has an established record of rapid and high quality development and commercialization of innovative oncology product candidates in China. Their capabilities position Mirati to further develop *adagrasib* for patients with cancer who harbor the KRASG12C mutation around the world.”

“We are delighted to collaborate with Mirati to bring *adagrasib* to patients in need in Greater China as soon as possible,” said Samantha Du, Ph.D., founder, chairperson, and chief executive officer of Zai Lab. “Lung cancer is the most common cancer in China, and we aim to make *adagrasib* an important product in our growing lung cancer franchise. We are also excited about the potential of *adagrasib* to treat colorectal, pancreatic and other cancers characterized by KRASG12C mutations.”

Under the terms of the agreement, Zai Lab obtains the right to research, develop, manufacture and exclusively commercialize *adagrasib* in Greater China. Zai Lab will support accelerated enrollment in key global, registration-enabling clinical trials of *adagrasib* in patients with cancer who have a KRASG12C mutation.

Mirati has an option to co-commercialize in Greater China and retains full and exclusive rights to *adagrasib* in all countries outside of Greater China. Mirati will receive a \$65 million upfront payment, with the potential to receive up to an additional \$273 million in development, regulatory and sales-based milestone payments. Mirati is also eligible to receive high-teen- to low-twenties-percent tiered royalties based on annual net sales of *adagrasib* in Greater China.

About Adagrasib (MRTX849)

Adagrasib is an investigational, highly selective, and potent oral small-molecule inhibitor of KRAS^{G12C} that is optimized to sustain target inhibition, an attribute that could be important to treat KRAS^{G12C} mutated cancers, which regenerates every 24-48 hours. Studies of *adagrasib* have shown that the drug has a long half-life and extensive tissue distribution and is well tolerated. *Adagrasib* has shown single-agent responses in non-small cell lung cancer (NSCLC), colorectal cancer, pancreatic cancer, and other solid tumors with KRAS^{G12C} mutations. *Adagrasib* is also being evaluated in several clinical trials in combination with other anticancer therapies with strong scientific rationale in patients with advanced solid tumors. Registration-enabling studies are ongoing in NSCLC and colorectal cancer. For more information visit [Mirati.com/science](https://www.mirati.com/science).

About NSCLC and Colorectal Cancer in China

KRAS^{G12C} is the most common KRAS mutation in non-small cell lung cancer (NSCLC). The mutation is a biomarker of poor prognosis in Chinese patients with NSCLC. Lung cancer consists of NSCLC in approximately 85% of cases and small cell lung cancer (SCLC) in approximately 15% of cases. According to the World Health Organization, the incidence of lung cancer in China in 2020 was 815,563 cases, with 714,699 deaths.

Colorectal cancer (CRC) is the second most commonly diagnosed cancer type in China. According to the World Health Organization, the incidence of colorectal cancer in China in 2020 was 550,628 cases, with 283,751 deaths.

About Mirati Therapeutics Inc.

Mirati Therapeutics Inc. is a clinical-stage biotechnology company whose mission is to discover, design and deliver breakthrough therapies to transform the lives of patients with cancer and their loved ones. The company is relentlessly focused on bringing forward therapies that address areas of high unmet need, including lung cancer, and advancing a pipeline of novel therapeutics targeting the genetic and immunological drivers of cancer. Mirati is using its scientific expertise to develop novel solutions in two registration-enabling programs: *adagrasib* (MRTX849), an investigational small molecule, potent and selective KRAS^{G12C} inhibitor, as monotherapy and in combination with other agents, and *sitravatinib*, an investigational spectrum-selective inhibitor of receptor tyrosine kinases in combination with checkpoint inhibitor therapies. Mirati is also advancing its differentiated preclinical portfolio, including MRTX1133, an investigational KRAS^{G12D} inhibitor, and other oncology discovery programs. Unified for patients, Mirati's vision is to unlock the science behind the promise of a life beyond cancer.

For more information about Mirati Therapeutics Inc., visit us at [Mirati.com](https://www.mirati.com) or follow us on [Twitter](#) and [LinkedIn](#).

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer and infectious and autoimmune diseases to patients in China and around the world. We aim to address significant unmet medical needs in large, fast-growing segments of the pharmaceutical market. Our experienced team has secured partnerships with leading global biopharmaceutical companies to generate a broad pipeline of potentially innovative, marketed products and product candidates. We have also built an in-house team with strong drug discovery and translational research capabilities and are establishing a pipeline of proprietary drug candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to positively impact human health worldwide.

Mirati Therapeutics Forward Looking Statements

This press release contains forward-looking statements regarding the business of Mirati Therapeutics, Inc. (“Mirati”). Any statement describing Mirati’s goals, expectations, financial or other projections, intentions or beliefs, development plans and the commercial potential of Mirati’s drug development pipeline, including without limitation *adagrasib* (MRTX849), *sitravatinib* and MRTX1133, is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to risks and uncertainties, particularly those challenges inherent in the process of discovering, developing and commercialization of new drug products that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs.

Mirati’s forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Mirati’s forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Mirati. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Mirati’s programs are described in additional detail in Mirati’s quarterly reports on Form 10-Q and annual reports on Form 10-K, which are on file with the U.S. Securities and Exchange Commission (the “SEC”) available at the SEC’s Internet site (www.sec.gov). These forward-looking statements are made as of the date of this press release, and Mirati assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects and plans for developing and commercializing *adagrasib* in Greater China and other statements containing 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 Zai Lab’s 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) Zai Lab’s ability to successfully commercialize and generate revenue from its approved products; (2) Zai Lab’s ability to finance its operations and business initiatives and obtain funding for such activities, (3) Zai Lab’s results of clinical and pre-clinical development of its product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab’s 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. Zai Lab anticipates that subsequent events and developments will cause Zai Lab’s expectations and assumptions to change and undertakes 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 Zai Lab’s views as of any date subsequent to the date of this press release.

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