

**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): January 11, 2021**

**Zai Lab Limited**

(Exact name of registrant as specified in its charter)

**Cayman Islands**  
(state or other jurisdiction  
of incorporation)

**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)

**Registrant's telephone number, including area code: +86 21 6163 2588**

**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 (see General Instruction A.2. below):

- 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:

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
<b>American Depositary Shares, each representing one Ordinary Shares, par value \$0.00006 per share</b>	<b>ZLAB</b>	<b>The Nasdaq Global Market</b>
<b>Ordinary shares, par value \$0.00006 per share*</b>	<b>9688</b>	<b>The Stock Exchange of Hong Kong Limited</b>

\* 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

### License Agreement

On January 10, 2021 (U.S. time), Zai Lab (Shanghai) Co., Ltd., a wholly-owned subsidiary of Zai Lab Limited (“Zai Shanghai”), entered into a license agreement (the “License Agreement”) with Turning Point Therapeutics, Inc. (“Turning Point”) pursuant to which Zai Shanghai received an exclusive license to develop and commercialize products containing Turning Point’s drug candidate, TPX-0022, as an active ingredient (the “Licensed Product”) in mainland China, Hong Kong, Macau and Taiwan (the “Territory”). Pursuant to the License Agreement, Zai Shanghai will be responsible for conducting the development and commercialization activities in the Territory related to the Licensed Products. Zai Shanghai may, at its election and expense, subject to specified exceptions, participate in future global clinical studies of the Licensed Products through clinical trial sites in the Territory. In addition, Turning Point will also have a first right to negotiate a license outside the Territory to a potential drug candidate from one of Zai Shanghai’s pipeline programs if Zai Shanghai files an investigational new drug application for the drug candidate.

Pursuant to the terms of the License Agreement, Zai Shanghai will pay to Turning Point a \$25 million upfront payment, plus up to approximately \$336 million in potential development, regulatory and sales-based milestone payments. Turning Point will also be eligible to receive tiered royalties (mid-teen to low-twenties on a percentage basis and subject to customary reductions) based on annual net sales of all Licensed Products in the Territory. Zai Shanghai’s royalty obligations will continue on a region-by-region and Licensed Product-by-Licensed Product basis until the last to occur of (i) the expiration of the last-to-expire licensed patent claims in such region, (ii) the expiry of the regulatory exclusivity for the Licensed Product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the first commercial sale of the Licensed Product in such region.

The License Agreement contains customary representations, warranties and covenants by the parties. Unless terminated earlier pursuant to its terms, the License Agreement will continue in effect until expiration of the last royalty term with respect to any Licensed Product in any region in the Territory. The License Agreement may be terminated for customary reasons, including upon mutual written agreement and upon the other party’s uncured material breach, bankruptcy, insolvency or similar event. In addition, Zai Shanghai may terminate the License Agreement for any or no reason by providing written notice to Turning Point, which termination will be effective following a prescribed notice period.

Subject to specified exceptions, during the term of the License Agreement, Zai Shanghai has agreed that neither it nor its affiliates, its licensees and its sublicensees will conduct any development, manufacturing and commercialization activities with specified products that would compete with the Licensed Products in or outside the Territory, and Turning Point has agreed that neither it nor its affiliates, its licensees and its sublicensees of Licensed Products will conduct any development, manufacturing and commercialization activities with such competing products in the Territory, other than manufacturing activities in support of activities outside the Territory.

\* \* \*

*The foregoing description of the terms of the License Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such 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.*

\* \* \*

*The representations and warranties and other statements in the agreements (1) speak only as to the date on which they were made, and may be modified or qualified by confidential schedules or other disclosures, agreements or understandings among the parties, which the parties believe are not required by the securities laws to be publicly disclosed, and (2) may be subject to a different materiality standard than the standard that is applicable to disclosures to investors. Moreover, it was advised that information concerning the subject matter of the representations and warranties and other statements made in the various agreements would likely change after the execution date of such agreements, and subsequent information may or may not be fully reflected in the Company’s public disclosures. Accordingly, investors should not rely upon representations and warranties and other statements in the various agreements as factual characterizations of the actual state of affairs of the Company. Investors should instead look to disclosures contained in the Company’s reports under the Securities Exchange Act of 1934, as amended (the “Exchange Act”).*

## Item 7.01 Regulation FD Disclosure.

On January 11, 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.

Exhibit No.	Description
99.1	<a href="#">Press Release, dated January 11, 2021.</a>
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  
Name: Billy Cho  
Title: Chief Financial Officer

Dated: January 11, 2021

Exhibit 99.1— [Press Release](#)

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## TURNING POINT AND ZAI LAB BROADEN COLLABORATION

### *Zai Lab Secures Exclusive Right to Develop and Commercialize TPX-0022, Turning Point's MET/SRC/CSF1R Inhibitor, in Greater China*

### *Turning Point to Receive \$25 Million Upfront, with Up to Approximately \$336 Million in Potential Milestone Payments and Royalties*

**SAN DIEGO, SHANGHAI and SAN FRANCISCO, Jan. 11, 2021** – Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, and Zai Lab (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced an expansion of their collaboration.

Under the terms of the new agreement, Zai Lab will obtain exclusive rights to develop and commercialize TPX-0022, Turning Point's MET, SRC and CSF1R inhibitor, in Greater China, which includes mainland China, Hong Kong, Macau and Taiwan. Turning Point will receive a \$25 million upfront payment, with up to approximately \$336 million in potential development, regulatory and sales-based milestone payments. Turning Point will also be eligible to receive mid-teen- to low-twenty-percent royalties based on annual net sales of TPX-0022 in Greater China. In addition, Turning Point will have the right of first negotiation to develop and commercialize an oncology drug candidate discovered by Zai Lab.

This agreement builds on Zai Lab and Turning Point's existing relationship under the exclusive licensing agreement announced by the companies in July 2020, under which Zai Lab gained the exclusive right to develop and commercialize Turning Point's lead drug candidate, repotrectinib, in Greater China.

"The higher incidence of MET-driven cancers – particularly in gastric and lung cancer – in Asian countries led us to initiate the development of TPX-0022 in Greater China following our encouraging initial data from the Phase 1 SHIELD-1 study," said Athena Countouriotis, M.D., president and chief executive officer of Turning Point. "We have great confidence in Zai Lab as our partner to advance this important drug candidate in a key region of the world. Zai Lab also has a promising discovery pipeline and we are pleased to receive the right of first negotiation for a drug candidate from Zai's discovery pipeline."

Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab, said, "Turning Point has assembled a formidable pipeline of next-generation oncology target therapies, and we are very pleased to broaden our global collaboration and strategic partnership. We believe TPX-0022 is a promising drug candidate that is also highly synergistic with our portfolio in gastric and lung cancer."

Jin Li, M.D., Professor, Chairman of Chinese Society of Clinical Oncology Foundation and Director of Department of Oncology, Tongji University Shanghai East Hospital said, "The initial safety and efficacy data for TPX-0022 are promising, and its novel mechanism to target MET, SRC and CSF1R encourages us to investigate its therapeutic potential further. We are particularly interested in the early but promising findings in patients with MET-driven gastric cancer and look forward to advancing the study of TPX-0022 in this area of high unmet need in China."

Initial data from the SHIELD-1 study reported in a late-breaker oral presentation at the EORTC-NCI-AACR symposium highlighted preliminary clinical activity, including objective responses across multiple tumor types and a generally tolerable safety profile.

#### **About TPX-0022**

TPX-0022 is an orally bioavailable multi-targeted kinase inhibitor with a novel three-dimensional macrocyclic structure that inhibits the MET, CSF1R (colony stimulating factor 1 receptor) and SRC kinases. TPX-0022 has completed IND-enabling studies and cleared its IND. During the second half of 2019, Turning Point initiated the SHIELD-1 Phase 1 clinical trial of TPX-0022 for the treatment of advanced or metastatic solid tumors with abnormal MET/HGF or CSF1R/SCF1R signaling.

MET is a receptor tyrosine kinase that binds with high affinity to hepatocyte growth factor (HGF). MET alterations, including point mutations, amplifications, fusions, exon 14 skipping, and the generation of HGF-MET autocrine loops have been reported in many cancers. MET amplification has been detected in up to 20 percent of non-small cell lung cancer patients with EGFR mutations who acquired resistance to Iressa (gefitinib), Tarceva (erlotinib) or Tagrisso (osimertinib) treatment. SRC is a kinase involved in the MET signaling pathway. Inhibition of SRC has the potential to reduce or abolish the upregulation of HGF. Targeting CSF1R leads to the modulation of tumor-associated macrophages (TAMs), a type of immune cell that suppresses the T-cell mediated anti-tumor immune response, which is a promising therapeutic strategy for TPX-0022 as a single agent or in combination with standard of care chemotherapy and immunotherapy in various solid tumors.

## **About Turning Point Therapeutics Inc.**

Turning Point Therapeutics is a clinical-stage precision oncology company with a pipeline of internally discovered investigational drugs designed to address key limitations of existing cancer therapies. The company's lead drug candidate, repotrectinib, is a next-generation kinase inhibitor targeting the ROS1 and TRK oncogenic drivers of non-small cell lung cancer and advanced solid tumors. Repotrectinib, which is being studied in a registrational Phase 2 study called TRIDENT-1 in adults and a Phase 1/2 study in pediatric patients, has shown antitumor activity and durable responses among kinase inhibitor treatment-naïve and pre-treated patients. The company's pipeline of drug candidates also includes TPX-0022, targeting MET, CSF1R and SRC, which is in a Phase 1 study called SHIELD-1 in patients with advanced or metastatic solid tumors harboring genetic alterations in MET; RET-inhibitor TPX-0046, which is in a Phase 1/2 study of patients with advanced or metastatic solid tumors harboring genetic alterations in RET; and ALK-inhibitor TPX-0131, which is in IND-enabling studies. Turning Point's next-generation kinase inhibitors are designed to bind to their targets with greater precision and affinity than existing therapies, with a novel, compact structure that has demonstrated an ability to potentially overcome treatment resistance common with other kinase inhibitors. The company is driven to develop therapies that mark a turning point for patients in their cancer treatment.

For more information, visit [www.tptherapeutics.com](http://www.tptherapeutics.com).

## **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. 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 drug 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 impact human health worldwide.

For additional information about the company, please visit [www.zailaboratory.com](http://www.zailaboratory.com) or follow us on LinkedIn at <https://www.linkedin.com/company/zai-lab/mycompany/> and Twitter at [www.twitter.com/ZaiLab\\_Global](https://www.twitter.com/ZaiLab_Global).

## **Turning Point Therapeutics Forward Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of Turning Point Therapeutics' drug candidates repotrectinib and TPX-0022, the results, conduct, progress and timing of Turning Point Therapeutics' SHIELD-1 clinical study of TPX-0022, including the potential to advance the development of TPX-0022 in Greater China, the potential to further expand the relationship with Zai Lab and the potential to receive milestone and royalty payments from Zai Lab. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans", "will", "believes," "anticipates," "expects," "intends," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Turning Point Therapeutics' current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Turning Point Therapeutics' business in general, risks and uncertainties related to the impact of the COVID-19 pandemic to Turning Point's business and the other risks described in Turning Point Therapeutics' filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Turning Point Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

## **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 of and plans for commercializing repotrectinib and TPX-0022 in Greater China. 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 obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, and its other filings with the 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 publicly 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.

For more information, please contact:

### **CONTACTS:**

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