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): December 3, 2021

ZAI LAB LIMITED
(Exact name of registrant as specified in its charter)

Cayman Islands	**001-38205**	**98-1144595**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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 8.01 Other Events.

On December 3, 2021, Zai Lab Limited issued a press release announcing that the National Reimbursement Drug List released by China's National Healthcare Security Administration has been updated to include ZEJULA (niraparib) as a first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) following a response to platinum-based chemotherapy, regardless of biomarker status. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Zai Lab Limited on December 3, 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/ Samantha Du
Samantha Du
Chief Executive Officer

Date: December 3, 2021

Zai Lab Announces Inclusion of ZEJULA® (Niraparib) in China's National Reimbursement Drug List for First-Line Ovarian Cancer

SHANGHAI, SAN FRANCISCO, and CAMBRIDGE, Mass., December 3, 2021 — Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA) has been updated to include ZEJULA (niraparib) as a first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) following a response to platinum-based chemotherapy, regardless of biomarker status.

"A key part of Zai Lab's mission is to bring transformative medicines to patients in China," said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. "The inclusion of ZEJULA in the NRDL for first-line maintenance treatment of ovarian cancer is an important step in achieving that mission. We are grateful for this action by the NHSA to make ZEJULA more accessible to Chinese patients with ovarian cancer."

"NHSA reimbursement will increase ZEJULA's availability for many patients in need across China," said William Liang, Chief Commercial Offer. "It is the only PARP inhibitor approved as monotherapy for first-line and recurrent maintenance therapy for ovarian cancer patients regardless of biomarker status in China. This action underscores ZEJULA's clinical value for a broad range of ovarian cancer patients."

In November 2021, Zai Lab announced that the Phase 3 PRIME study of ZEJULA as maintenance therapy met its primary endpoint and demonstrated a statistically significant and clinically meaningful progression-free survival (PFS) benefit with a manageable safety profile in Chinese patients with newly diagnosed advanced ovarian cancer following a response to platinum-based chemotherapy, regardless of biomarker status.

In December 2020, ZEJULA was included in the NRDL as a maintenance treatment of adult patients with platinum-sensitive, recurrent ovarian cancer.

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic cancers in China, with over 55,000 newly diagnosed cases and 37,000 deaths in China annually[1]. While platinum-based chemotherapy is effective at inducing an initial response in ovarian cancer, the disease will recur in the majority of women. New agents that prolong the duration of response following platinum-based treatment and delay the relapse of ovarian cancer will benefit patients with ovarian cancer in China.

1 *Globocan 2020.*

About ZEJULA (niraparib)

ZEJULA (niraparib) is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the maintenance treatment of adult patients with advanced and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first- and second-line platinum-based chemotherapy.

Zai Lab has completed several studies in Chinese patients with ovarian cancer:

- In November 2021, Zai Lab announced positive topline results from the company's Phase 3 PRIME study of ZEJULA as maintenance therapy for Chinese patients with first-line platinum-responsive, advanced ovarian cancer, regardless of biomarker status.
- In September 2020, Zai Lab announced that ZEJULA demonstrated a significant PFS benefit with an improved safety profile in the company's Phase 3 NORA study of ZEJULA as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer, regardless of biomarker status.
- A Phase 1 pharmacokinetic (PK) study of ZEJULA was conducted in Chinese patients with ovarian cancer.

ZEJULA is also being evaluated in China in a Phase 1b/2 study in combination with tebotelimab (PD-1 x LAG-3 DART molecule) for advanced gastric cancer, triple negative breast cancer, biliary tract cancer, and endometrial cancer.

Zai Lab has a collaboration and license agreement with GSK for the development and commercialization of ZEJULA in mainland China, Hong Kong, and Macau.

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.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements relating to our strategy and plans for ZEJULA® (niraparib) in China; clinical trial data for ZEJULA® (niraparib) in China; reimbursement administration discussions, filings, approvals, and the timing thereof; and the potential benefits, safety, and efficacy of our collaboration partners' products and investigational therapies. These forward-looking statements include, without limitation, 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 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.

More information about Zai Laboratory and its filings can be found on the SEC.gov website.

For more information, please contact:

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Zai Lab Limited