Zai Lab Limited
再鼎醫藥有限公司*
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 9688)

OVERSEAS REGULATORY ANNOUNCEMENT
BUSINESS UPDATE

This announcement is made by Zai Lab Limited (the "**Company**") pursuant to Rule 13.10B of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited.

The Company filed a Form 8-K on September 27, 2022 (U.S. Eastern Time) with the U.S. Securities and Exchange Commission to announce that Zai Lab (Hong Kong) Limited, a wholly-owned subsidiary of the Company, and Seagen Inc. ("**Seagen**") entered into a collaboration and license agreement (the "**Agreement**"), pursuant to which the Company and Seagen agreed to collaboratively develop and commercialize TIVDAK® (tisotumab vedotin). Under the Agreement, the Company obtained from Seagen an exclusive license to develop and commercialize TIVDAK in mainland China, Hong Kong, Macau, and Taiwan (collectively, the "**Licensed Territory**").

Pursuant to the terms of the Agreement, the Company will pay Seagen an upfront payment of US$30.0 million, as well as development and regulatory milestone payments of up to an aggregate of US$78.0 million upon the achievement of specified development and regulatory milestones and sales milestones payments of up to an aggregate of US$185.0 million upon the achievement of specified sales milestones. Seagen will also be eligible to receive certain royalties at tiered percentage rates ranging from mid-teens to low twenties on annual net sales of licensed products in the Licensed Territory, subject to reduction under specified circumstances.

The Agreement will remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last licensed product. The Agreement contains customary provisions for termination by either party, including in the event of a material breach by the other party that remains uncured, by the Company for convenience, for certain bankruptcy events, and by Seagen upon a challenge of the licensed patent rights.

For further details, please refer to the attached Form 8-K.

The Company's shareholders and potential investors are advised not to place undue reliance on this announcement and to exercise caution in dealing in securities in the Company.

By order of the Board
Zai Lab Limited
Samantha Du
Director, Chairperson, and
Chief Executive Officer

Hong Kong, September 27, 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. Samantha Du as a director, and Dr. Kai-Xian Chen, Dr. John Diekman, Ms. Nisa Leung, Mr. William Lis, Mr. Leon O. Moulder, Jr., Mr. Peter Wirth, Mr. Scott W. Morrison, and Richard Gaynor, M.D. as independent directors.

* *For identification only*

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): September 23, 2022

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**	**201210**
314 Main Street **4th Floor, Suite 100** **Cambridge, MA, USA** **(Address of principal executive offices)**	**02142** **(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 10 Ordinary Shares, par value $0.000006 per share	**ZLAB**	**The Nasdaq Global Market**
Ordinary Shares, par value $0.000006 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 September 23, 2022, Zai Lab (Hong Kong) Limited, a wholly-owned subsidiary of Zai Lab Limited (the "Company"), and Seagen Inc. ("Seagen") entered into a collaboration and license agreement (the "Agreement"), pursuant to which the Company and Seagen agreed to collaboratively develop and commercialize TIVDAK® (tisotumab vedotin). Under the Agreement, the Company obtained from Seagen an exclusive license to develop and commercialize TIVDAK in mainland China, Hong Kong, Macau, and Taiwan (collectively, the "Licensed Territory").

Pursuant to the terms of the Agreement, the Company will pay Seagen an upfront payment of $30.0 million, as well as development and regulatory milestone payments up to an aggregate of $78.0 million upon the achievement of specified development and regulatory milestones and sales milestone payments of up to an aggregate of $185.0 million upon the achievement of specified sales milestones. Seagen will also be eligible to receive certain royalties at tiered percentage rates ranging from mid-teens to low twenties on annual net sales of licensed products in the Licensed Territory, subject to reduction under specified circumstances.

The Agreement will remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last licensed product. The Agreement contains customary provisions for termination by either party, including in the event of a material breach by the other party that remains uncured, by the Company for convenience, for certain bankruptcy events, and by Seagen upon a challenge of 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.

A copy of the press release announcing the Agreement 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Zai Lab Limited on September 27, 2022
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/ F. Ty Edmondson
F. Ty Edmondson
Chief Legal Officer & Corporate Secretary

Date: September 27, 2022

Exhibit 99.1

Seagen and Zai Lab Announce Regional Strategic Collaboration and License Agreement for TIVDAK® (tisotumab vedotin-tftv)

-- Zai Lab Obtains Exclusive Rights to Develop and Commercialize TIVDAK, an FDA-approved First-in-Class Antibody-Drug Conjugate (ADC), in Mainland China, Hong Kong, Macau, and Taiwan --

-- Zai Lab will Leverage its Leadership in Women's Cancer in China to Commercialize and Expand Patient Access to TIVDAK --

-- Collaboration Supports Regional Patient Enrollment for InnovaTV 301, a Global Phase 3 Trial of TIVDAK in Patients with Recurrent or Metastatic Cervical Cancer --

SHANGHAI, CAMBRIDGE, Mass., and BOTHELL, Wash. -- (BUSINESS WIRE) -- September 27, 2022 — Zai Lab Limited (Nasdaq: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage global biopharmaceutical company, and Seagen Inc. (Nasdaq: SGEN), a world leader and pioneer in antibody-drug conjugate (ADC) therapies today announced an exclusive collaboration and license agreement for the development and commercialization of TIVDAK® (tisotumab vedotin-tftv) in mainland China, Hong Kong, Macau, and Taiwan. TIVDAK is the first and only ADC approved in the U.S. for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

Under the terms of the agreement, Seagen will receive an upfront payment of $30 million, as well as development, regulatory, and commercial milestone payments, and tiered royalties on net sales of TIVDAK in the Zai Lab territory. Based on the existing TIVDAK co-development and co-commercialization collaboration between Seagen and Genmab (Nasdaq: GMAB), all upfront, milestone payments, and royalties will be shared 50/50 with Genmab.

In 2021, the U.S. Food and Drug Administration (FDA) granted accelerated approval for TIVDAK for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. As verification and description of clinical benefit in the U.S., and to support further global regulatory applications, a confirmatory phase 3 open-label, randomized, global clinical trial (https://clinicaltrials.gov/ct2/show/NCT04697628), innovaTV 301, is ongoing.

"This agreement enables us to leverage Zai Lab's strong expertise in developing and commercializing innovative medicines in the licensed territory," said Natasha Hernday, EVP Corporate Development and Alliance Management, Seagen. "We are delighted to collaborate with Zai Lab, including on the phase 3 innovaTV 301 trial, an important component of expanding the availability of TIVDAK to recurrent or metastatic cervical cancer patients around the world. TIVDAK is also under evaluation and development in early trials for first-line cervical cancer and certain other solid tumors."

"Zai Lab has a significant presence treating women's cancers in China, and TIVDAK is an important addition to our oncology commercial portfolio. Treatments for cervical cancer remain a significant unmet need in China with approximately 110,000 new cases annually[1], and currently there are few effective therapeutic options available," said William Liang, Chief Commercial Officer, President of Greater China at Zai Lab. "We look forward to this collaboration with Seagen to make TIVDAK available for patients in China as we expand our oncology portfolio."

"Following progression on first-line standard of care therapy, there are limited treatment options, and chemotherapy has low objective response rates with poor outcomes," said Dr. Lingying Wu, Director of the Department of Gynecologic Oncology, National Cancer Center / National Clinical Research Center for Cancer / Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College. "This represents one of the biggest challenges faced by gynecologic oncologists with significant unmet needs for new therapies. We believe TIVDAK could become an important treatment option for patients with cervical cancer in China, as it demonstrated clinically meaningful, durable responses with a tolerable safety profile."

About Cervical Cancer in China
Cervical cancer remains one of the leading causes of cancer death in women in China and globally. An estimated 110,000 new cases of cervical cancer occur annually in China[1]. Treatment options are limited for patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. TIVDAK is currently not approved in this region and is well positioned to provide a new option for previously treated advanced cervical cancer patients who currently have limited treatment options and poor outcomes.

About TIVDAK (tisotumab vedotin-tftv)
TIVDAK (tisotumab vedotin-tftv) is an ADC composed of Genmab's human monoclonal antibody directed to tissue factor (TF) and Seagen's ADC technology that utilizes a protease-cleavable linker that covalently attaches the microtubule-disrupting agent monomethyl auristatin E (MMAE) to the antibody. Nonclinical data suggests that the anticancer activity of TIVDAK is due to the binding of the ADC to TF expressing cancer cells, followed by internalization of the ADC-TF complex, and release of MMAE via proteolytic cleavage. MMAE disrupts the microtubule network of actively dividing cells, leading to cell cycle arrest and apoptotic cell death. In vitro, TIVDAK also mediates antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity.

TIVDAK® (tisotumab vedotin-tftv) for injection, for intravenous use, 40 mg Important Safety Information

Adverse Reactions
Serious adverse reactions occurred in 43% of patients; the most common (≥3%) were ileus (6%), hemorrhage (5%), pneumonia (4%), peripheral neuropathy (PN), sepsis, constipation, and pyrexia (each 3%). Fatal adverse reactions occurred in 4% of patients who received TIVDAK, including septic shock, pneumonitis, sudden death, and multisystem organ failure (each 1%).

Adverse reactions leading to permanent discontinuation occurred in 13% of patients receiving TIVDAK; the most common (≥3%) were PN (5%) and corneal adverse reactions (4%). Adverse reactions leading to dose interruption occurred in 47% of patients; the most common (≥3%) were PN (8%), conjunctival adverse reactions (4%), and hemorrhage (4%). Adverse reactions leading to dose reduction occurred in 23% of patients; the most common (≥3%) were conjunctival adverse reactions (9%) and corneal adverse reactions (8%).

In the InnovaTV 204 study, the most common (≥25%) adverse reactions, including laboratory abnormalities, were hemoglobin decreased (52%), fatigue (50%), lymphocytes decreased (42%), nausea (41%), PN (39%), alopecia (39%), epistaxis (39%), conjunctival adverse reactions (37%), hemorrhage (32%), leukocytes decreased (30%), creatinine increased (29%), dry eye (29%), prothrombin international normalized ratio increased (26%), activated partial thromboplastin time prolonged (26%), diarrhea (25%), and rash (25%).

Please see full prescribing information for TIVDAK at https://seagendocs.com/Tivdak_Full_Ltr_Master.pdf.

About the Seagen and Genmab Collaboration
TIVDAK (tisotumab vedotin) is being co-developed and co-commercialized by Genmab and Seagen under an agreement in which the companies, with respect to certain major markets, including China, share costs and

profits for the product on a 50/50 basis, including upfront payments, future milestones and royalties received under the collaboration and licensing agreement with Zai Lab.

About Seagen
Seagen is a global biotechnology company that discovers, develops and commercializes transformative cancer medicines to make a meaningful difference in people's lives. Seagen is headquartered in the Seattle, Washington area, and has locations in California, Canada, Switzerland and the European Union. For more information on the company's marketed products and robust pipeline, visit www.seagen.com and follow @SeagenGlobal on Twitter.

About Zai Lab
Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases, and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, including our products, business activities and partnerships, research, and other events or developments, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Seagen Forward-Looking Statements
Certain of the statements made in this press release are forward looking, such as those, among others, relating to the therapeutic potential of TIVDAK, its efficacy, safety and therapeutic uses, the innovaTV 301 clinical trial, the potential of the innovaTV 301 trial to serve as a confirmatory trial in the U.S. and support further global regulatory applications, and the TIVDAK clinical development program. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include without limitation the possibility that the innovaTV 301 trial and other clinical trials may fail to establish sufficient efficacy; the risk that adverse events, newly emerging safety signals or adverse regulatory actions may occur; the risk of delays, setbacks or failures in clinical development activities for a variety of reasons, including without limitation the inherent difficulty and uncertainty of pharmaceutical product development; possible required modifications to clinical trials; the inability to provide information and institute safety mitigation measures as may be required by the FDA or other regulatory authorities from time to time; failure to properly conduct or manage clinical trials; and failure of clinical results to support continued development or regulatory approvals. More information about the risks and uncertainties faced by Seagen is contained under the caption "Risk Factors" included in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the Securities and Exchange Commission. Seagen disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Zai Lab Forward-Looking Statements
This press release contains forward-looking statements relating to our future expectations, plans, and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of TIVDAK (tisotumab vedotin-tftv); the clinical development of TIVDAK; the potential treatment of recurrent or metastatic cervical cancer in mainland China, Hong Kong, Macau and Taiwan; the potential of Zai Lab's commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab's collaboration arrangement with Seagen; and other risks and uncertainties associated with drug development and commercialization. All statements, other than statements of historical fact, included in this press release are forward-looking statements and can be identified by 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 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. We may not actually achieve the plans, carry out the

intentions or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by 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 obtain funding for our operations and business initiatives, (3) the results of our 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, including any government actions or lockdown measures taken in response, on our business and general economic, regulatory, and political conditions, (6) risks related to doing business in China and (7) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the 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.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC's website at www.sec.gov.

Reference:
1. Globocan 2020.

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