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May 3, 2022

### **VIA EDGAR**

U.S. Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549

Attention: Tracie Mariner

Kevin Vaughn Jason Drory Jeffrey Gabor

Re: Zai Lab, Ltd.

Form 10-K for Fiscal Year Ended December 31, 2021

Filed March 1, 2022 File No. 001-38205

### Ladies and Gentlemen:

On behalf of Zai Lab, Ltd. (the "Company"), we are hereby providing the following response to the comment letter from the staff of the Division of Corporate Finance, Office of Life Science (the "Staff") of the Securities and Exchange Commission (the "Commission") dated April 19, 2022 related to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 (the "Form 10-K"). To assist your review, we have presented the text of the Staff's comment in italics below. The response and information described below are based upon information provided to us by the Company.

## Form 10-K for Fiscal Year Ended December 31, 2021

# Disclosures Relating to our Chinese Operations, page ii

1. Please provide prominent disclosure here discussing whether your auditor is subject to the determinations announced by the PCAOB on December 16, 2021 and whether and how the Holding Foreign Companies Accountable Act (the "HFCAA") and related regulations will affect your company, including disclosing that you were identified by the Commission under the HFCAA. Also, disclose that the United States Senate passed the Accelerating Holding Foreign Companies Accountable Act, which, if enacted, would decrease the number of non-inspection years from three years to two, thus reducing the time period before your securities may be prohibited from trading or delisted.

### **Response to Comment 1:**

The Company acknowledges the Staff's comment and advises the Staff that it will provide prominent disclosure of such information at the onset of Part 1 of the Company's Form 10-Q for the quarter ending March 31, 2022. Unless there are changes in relevant law or regulations, or in interpretations thereof that would necessitate changes to the below, we will add the following disclosure in response to this comment:

Because the majority of our operations are in mainland China and our auditor has been located in mainland China, a jurisdiction where the U.S. Public Company Accounting Oversight Board ("PCAOB") is currently unable to conduct inspections without the approval of Chinese authorities, there have been concerns regarding oversight of the audits of our financial statements filed with the SEC. In March 2022, SEC staff conclusively identified us under the Holding Foreign Companies Accountable Act ("HFCAA") as an issuer that uses an auditor that the PCAOB is unable to inspect or investigate completely. Although in April 2022 our Audit Committee approved the engagement of KPMG LLP ("KPMG"), a U.S. auditor that is subject to inspection by the PCAOB, as our independent public accounting firm for the fiscal year ending December 31, 2022, KPMG is in the process of concluding its standard client evaluation procedures, including obtaining approval from the Hong Kong Stock Exchange to audit the Company's consolidated financial statements submitted to the Hong Kong Stock Exchange. If for any reason we continue to fail to meet the audit requirements of the HFCAA for three consecutive years, the HFCAA requires the SEC to prohibit the trading of our securities on a national securities exchange, including Nasdaq, or on over-the-counter markets in the United States. In addition, the U.S. Senate and U.S. House of Representatives have each passed bills, which, if enacted, would decrease the number of non-inspection years from three consecutive years to two, thus reducing the time period before our securities may be prohibited from trading on a U.S. securities exchange or delisted from Nasdaq. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including our independent registered public accounting firm, are required to be registered with the PCAOB and to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and applicable professional standards. Because our current auditor is located in mainland China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of Chinese authorities, our auditor is not currently inspected by the PCAOB.

PCAOB inspections of auditors located outside of mainland China and Hong Kong have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the PCAOB's inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in mainland China and Hong Kong prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors are deprived of the benefits of PCAOB inspections, which could result in limitations or restrictions on our access to the U.S. capital markets.

Furthermore, in recent years, the U.S. Congress and regulatory authorities have continued to express concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. As part of this continued focus on access to audit and other information currently protected by national law, in particular under Chinese law, the United States enacted the HFCAA in December 2020. The HFCAA requires the SEC to identify issuers that have filed an annual report with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that the PCAOB has determined it is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction (a "Commission-Identified Issuer"). Under the HFCAA, if the SEC conclusively identifies an issuer as a Commission-Identified Issuer for three consecutive years, the SEC is required to prohibit the trading of the issuer's securities on a national securities exchange or through any other method that is within the jurisdiction of the SEC to regulate, including over-the-counter markets in the United States. Our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for three consecutive years, and this ultimately could result in our ADSs being delisted.

Furthermore, in June 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act ("AHFCAA"), which, if enacted, would amend the HFCAA and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years (as opposed to the three years under the HFCAA). In February 2022, the U.S. House of Representatives passed the America Creating Opportunities for Manufacturing Pre-Eminence in Technology and Economic Strength (COMPETES) Act of 2022 (the "America COMPETES Act"), which similarly would amend the HFCAA to shorten the number of non-inspection years from three years to two years. The America COMPETES Act, however, includes a broader range of legislation than the AHFCA Act in response to the U.S. Innovation and Competition Act passed by the U.S. Senate in 2021. The U.S. House of Representatives and the U.S. Senate will need to agree on amendments to these respective bills to allow the legislature to pass their amended bills before the President can sign the bill into law. It is unclear if or when either of these bills will be signed into law.

In September 2021, the PCAOB adopted PCAOB Rule 6100, Board Determinations Under the Holding Foreign Companies Accountable Act, which provides a framework for the PCAOB to use when determining whether the PCAOB is unable to inspect or investigate completely a registered public accounting firm located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction for the purposes of the HFCAA. PCAOB Rule 6100 establishes the manner of the PCAOB's determinations; the factors the PCAOB will evaluate and the documents and information it will consider when assessing whether a determination is warranted; the form, public availability, effective date, and duration of such determinations; and the process by which the PCAOB will reaffirm, modify or vacate any such determinations. In November 2021, the SEC announced that it had approved Rule 6100.

In December 2021, the SEC adopted amendments to finalize rules implementing the submission and disclosure requirements in the HFCAA for Commission-Identified Issuers, which became effective on January 10, 2022. In addition, the PCAOB issued a Determination Report, pursuant to PCAOB Rule 6100, which found that the PCAOB is unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by Chinese authorities in those jurisdictions. The SEC began to identify Commission-Identified Issuers for fiscal years beginning after December 18, 2020. A Commission-Identified Issuer will be required to comply with the submission and disclosure requirements in the annual report for each year in which it was so identified. If an issuer is identified as a Commission-Identified Issuer based on its annual report for the fiscal year ended December 31, 2021, the issuer will be required to comply with the submission or disclosure requirements in its annual report for the fiscal year ended December 31, 2022.

In March 2022, SEC staff conclusively identified the Company as a Commission-Identified Issuer. In April 2022 the Audit Committee of our Board of Directors approved the engagement of KPMG, an auditor located in the United States that is inspected by the PCAOB, as our independent registered public accounting firm for the fiscal year ending December 31, 2022 for the annual consolidated financial statements of the Company filed with the SEC and the Company's internal controls over financial reporting in accordance with the Exchange Act. KPMG will also be engaged to audit the consolidated financial statements of the Company for the year ending December 31, 2022 submitted to the Hong Kong Stock Exchange in accordance with the Rules Governing the Listing of Securities of the Hong Kong Stock Exchange, subject to the Company's receipt of the approval from the Hong Kong Stock Exchange and the FRC. Even though such approval is expected to be administrative in nature, if such approval is rejected by the Hong Kong Stock Exchange or the FRC, or, for some reason, we are not able to enter into an engagement agreement with KPMG, the Company would need to engage another auditor that is inspected by the PCAOB in order to comply with the audit requirements of the HFCAA. Additionally, even if KPMG is approved as our auditor by the Hong Kong Stock Exchange and the FRC, there remains a risk that the CSRC or another Chinese governmental agency could limit or prohibit our ability to use KPMG as our auditor. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

While we understand that there appears to be ongoing, constructive dialogue among the CSRC, the SEC and the PCAOB regarding permitting the inspection of PCAOB-registered accounting firms in China, there can be no assurance that the U.S. and Chinese governments ultimately reach an agreement on these matters, or that we will be able to comply with requirements imposed by U.S. regulators, Nasdaq, the CSRC, or other Chinese regulators. If for any reason we continue to be identified as a Commission-Identified Issuer that uses an auditor not subject to PCAOB inspection for three consecutive years or, if the AHFCAA or the America COMPETES Act is passed, two consecutive years, our ADSs may be delisted from Nasdaq as a result. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. Further, we may be prohibited from listing our ADSs on another U.S. securities exchange. The market price of our ordinary shares and/or ADSs could be adversely affected as a result of anticipated negative impacts of such legislative or executive actions upon, as well as negative investor sentiment toward, companies with significant operations in mainland China and Hong Kong that are listed in the United States, regardless of whether such actions are implemented and regardless of our actual operating performance.

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We hope that the foregoing has been responsive to the Staff's comments. If you have any questions about this letter or require any further information, please call my office at (617) 235-4961.

Very truly yours,

/s/ Thomas J. Danielski

Thomas J. Danielski

cc: F. Ty Edmondson Billy Cho