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): November 13, 2024

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

Cayman Islands	**001-38205**	**98-1144595**
(State or other jurisdiction of incorporation)	**(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	**02142**
(Address of principal executive offices)	**(Zip Code)**

+86 21 6163 2588
+1 857 706 2604
(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 8.01 Other Events.

Zai Lab Limited (the "Company") is filing certain updated risk factors disclosure applicable to its business for the purpose of supplementing and updating disclosures contained in the Company's prior public filings, including those discussed under the heading "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on February 27, 2024. The supplemental updated risk factors are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Updated Risk Factors
104	The cover page of this report 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 and Corporate Secretary

Date: November 13, 2024

Exhibit 99.1

Updated Risk Factors

Risks Related to Our Business and Industry

We, our employees, and our contracted third parties are subject to laws and government regulations relating to privacy and data protection that have required us to modify certain of our policies and procedures with respect to the collection and processing of personal data, and future laws and regulations may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

We, our employees, and our contracted third parties are subject to data privacy and security laws in the various jurisdictions in which we operate, obtain, or store personally identifiable information, including in mainland China, the United States, and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

We could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims under the laws described, as well as for alleged unfair or deceptive practices. If our operations are found to be in violation of any of the privacy laws, rules, or regulations that apply to us, we could be subject to penalties, including civil penalties, damages, injunctive relief, and other penalties, which could adversely affect our ability to operate our business and our financial results. We will continue to review these and all future privacy and other laws and regulations to assess whether additional procedural safeguards are warranted, which may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

While we maintain and enforce policies and practices designed so that we and our employees comply with such data privacy and security laws in the various jurisdictions in which we operate, we have identified, and may in the future identify, instances of non-compliance with such policies and practices by our employees. Such non-compliance may result in a material adverse effect on our business, reputation, or operations, and our policies and practices may not prevent such an incident from having a material adverse impact in the future. In addition, our employees and contracted third parties may become subject to regulatory actions involving privacy issues related to data collection and use practices and other data privacy laws and regulations. Such regulatory actions may result in criminal or civil penalties, convictions or sanctions, which may materially adversely affect our business and reputation. Such investigations of our employees and contracted third parties could also lead to allegations against, or investigations into, the Company and the Company's practices with respect to such data and privacy laws and regulations.

If we fail to maintain our licenses or other intellectual property-related agreements for our products or product candidates or if we otherwise experience disruptions to or disputes relating to our business relationships, we could lose the ability to continue the development and commercialization of our products and product candidates and such disputes could cause us to use substantial resources.

Our business relies, in large part, on our ability to develop and commercialize products and product candidates from third parties in accordance with our license and collaboration agreements and other intellectual property-related agreements. If we fail to maintain such licenses or other intellectual-property-related agreements that are relevant to our products and product candidates, we may be unable to develop and commercialize the affected products or product candidates, and our business, results of operations, financial condition, and prospects

could be materially harmed. If we fail to comply with our obligations under such agreements or if our licensors or collaboration partners fail to comply with obligations under such agreements or other agreements from which our rights are based, we may be unable to successfully develop and commercialize the affected products or product candidates, and our business, results of operations, financial condition, and prospects could be materially harmed.

Failure to meet obligations under any of the aforementioned agreements may result in termination of same by the other contracting party. Even though we may exercise all rights and remedies available to us and otherwise seek to preserve our rights, we may not be able to do so in a timely manner, at an acceptable cost, or at all. Any uncured, material breach under such agreements could result in loss of our rights and may lead to a complete termination of our rights to the applicable products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, we have had, and may in the future have, disputes regarding our rights under license, collaboration, or other intellectual-property related agreement, including but not limited to:

- the scope of rights granted under such agreement;
- the use of intellectual property rights under such agreement;
- the satisfaction of diligence obligations under such agreement;
- the ownership of inventions or know-how resulting from such agreement; and
- the payments due under such agreement.

Such dispute may disrupt our business relationships or otherwise hinder our ability to successfully develop and commercialize the affected products or product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Such disputes may also require or result in substantial costs and diversion of resources, including the consumption of significant management and other personnel time, to defend or assert our contractual rights or interpretation or to settle or litigate such disputes. Any such settlements of contractual disputes, and the negotiations in connection therewith, could have a material adverse effect on our business, reputation, financial condition, results of operations, and prospects.

In addition, the resolution of any disputed contractual interpretation of any of the foregoing agreements could result in a narrower interpretation of the scope of our rights or increase our financial or other obligations and thereby may prevent or impair our ability to maintain our current agreement on commercially acceptable terms. Accordingly, we may be unable to successfully develop and commercialize the affected products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Doing Business in China

We may be exposed to liabilities under anti-corruption, anti-bribery, and anti-fraud laws in China and the United States, including the U.S. Foreign Corrupt Practices Act, and any allegation, investigation, or determination that we, or our employees and contracted third parties, have violated such laws could have a material adverse effect on our business or reputation.

We, our employees, and our contracted third parties are subject to anti-corruption laws in China and the United States, including the FCPA, which generally prohibit, among other things, making improper payments to government officials for the purpose of obtaining or retaining business, and Chinese laws governing competition, which prohibit commercial bribery. In addition, we, our employees, and our contracted third parties are subject to

laws targeted at medical insurance and other fraud in China and the United States. Although we have implemented controls and procedures to promote compliance with such laws, failures to comply, due to either our own deliberate, negligent, or inadvertent acts or those of others, including our employees and contracted third parties, may harm our business and reputation and may cause us to incur criminal or civil liabilities, penalties, sanctions, and/or other significant expenses, which may have a material adverse effect on our results of operations, financial condition, prospects, ability to raise capital or continue to offer our securities, and the market price of our securities. For example, under certain circumstances, a pharmaceutical company's products may not be purchased by public medical institutions if that pharmaceutical company is involved in a criminal investigation or administrative proceeding related to bribery.

In addition, Chinese authorities have become increasingly active in enforcing laws affecting the pharmaceutical industry. Specifically, the Chinese authorities have recently increased anti-bribery and anti-fraud efforts to address improper payments and other benefits received by physicians, staff, hospital administrators, and other individuals in connection with the sales, marketing, and purchase of pharmaceutical products. The scope and intensity of such recent anti-corruption and medical insurance fraud enforcement efforts in China have led to increased uncertainty in the healthcare industry, which have impacted and may continue to impact hospital and physician practices. Such uncertainty, and related evaluations and adjustments by hospitals and physicians and other market participants, may adversely affect our business and results of operations.

Furthermore, we have been, and may in the future be, involved in inquiries or investigations by Chinese authorities as part of these enforcement efforts. Although we have not experienced a material adverse impact to the Company from such an inquiry or investigation to date, there can be no such assurance that such inquiries or investigations will not have a material adverse effect on our business, reputation, or operations in the future. For example, there have been public reports of recent investigations by Chinese authorities in relation to alleged medical insurance fraud and potential violations of China's data privacy and other laws by a number of persons affiliated with AstraZeneca. Certain of our former and current employees were formerly employed with AstraZeneca. Some of our current and former employees in our ZEJULA® sales team are under criminal investigations by Chinese authorities in their personal capacity and have been detained for questioning or otherwise under police compulsory measures in connection with alleged medical insurance fraud, a crime under Chinese law that can be prosecuted only against individuals and not against companies. Such investigations, allegations, and the reporting thereof, and any potential enforcement actions, formal convictions, or administrative penalties or fines in connection therewith, may materially adversely affect our business and reputation. In addition, such investigations may lead to additional allegations or findings or may implicate or expand to additional employees. While we are not currently aware of any allegations or investigations into actions which may result in the criminal liability of the Company, there can be no assurance that such allegations or investigations will not result in a material adverse effect on our business.

Risks Related to Intellectual Property

If we are unable to obtain and maintain protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends, in part, on our ability to protect our products, product candidates, and technologies from competition by obtaining, maintaining, and enforcing our intellectual property rights. We seek to protect our products and product candidates as well as technologies that we consider commercially important through intellectual property rights, such as patents and trade secrets.

We do not own or hold an exclusive license to patent rights in all of the territories in which we plan to commercialize certain of our products and product candidates. Further, we cannot predict whether patent applications that we hold rights to or any of our other owned or in-licensed pending patent applications will result in the issuance of patents that effectively protect our products, product candidates, and technologies, or whether our issued patents will effectively exclude competitors. It is also possible that we do not identify and/or secure patent rights to certain patentable aspects of our products, product candidates, or technologies. If we do not secure patent rights with respect to our products, product candidates, and technologies, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, license, or defend all necessary or desirable patent rights at a reasonable cost or in a timely manner, and patents may be invalidated, in whole or in part, and thereby rendered unenforceable. In addition, our licenses may not provide us with exclusive rights to products and product candidates in all relevant fields of use and in all territories in a manner which we may wish to develop or commercialize products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future have issued or do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or in-licensed patent rights. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit the scope and/or duration of patent protection for our product(s) or product candidate(s). Consequently, we may not be able to exclude others from using certain technology without compensating us or possibly may be unable to exclude a competitor from commercializing a competitive product which may materially adversely impact our sales and may also cause us to reduce, more than we otherwise might, the price at which we sell our products. For example, granted claims in two Chinese patents that pertain to certain aspects related to Optune have been the subject of a successful invalidation proceeding, which is currently being appealed. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology, products or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, the term of a patent is finite and generally expires 20 years from its earliest non-provisional filing date provided that associated fees are timely paid. Given the amount of time required for the development, testing, and regulatory review of products and new product candidates, patents protecting such products and product candidates might expire before or shortly after such products or product candidates are commercialized. For example, certain of our in-licensed patents related to Optune will be expiring over the next two years. As a result, the patent rights we hold may be insufficient to protect our products and product candidates from competitors' products, including those that are generic.

Moreover, in the case of any patent rights that are jointly owned by us and another party, if we are unable to obtain an exclusive license or otherwise limit the other party's right to license such patent rights to a third party, such patent rights may be licensed to third parties, including our competitors. In addition, we may need the cooperation of any joint owner of such jointly-owned patent to enforce it against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our owned or in-licensed patents could be found invalid or unenforceable if challenged in court or before the U.S. Patent and Trademark Office or other foreign authority.

We or our licensors or collaboration partners may become involved in patent litigation against third parties, for example, to enforce our patent rights, to invalidate patents held by such third parties, or to defend against such claims. Further, third parties could claim that we infringed, misappropriated, or otherwise violated their intellectual property rights or that a patent we or our licensors or collaboration partners have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are common, and there are numerous grounds upon which a party can assert invalidity or unenforceability of a patent. In addition to court proceedings, in certain jurisdictions, parties may initiate legal proceedings before administrative bodies to assert challenges to intellectual property rights, including patent rights. Such proceedings could result in revocation, cancellation, or amendment to the scope of our patent rights and could negatively affect our business.

The outcome of any such proceeding is generally unpredictable. Furthermore, even if we are successful in defending against such challenges, the cost to us of any patent litigation or similar proceeding could be substantial, and it may consume significant management and other personnel time.

An adverse result in any litigation or other intellectual property proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one or more of our products or product candidates, we may lack sufficient patent coverage of our products or product candidates to prevent others from marketing competing products. Any of these outcomes could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, granted claims in two Chinese patents that pertain to certain aspects related to Optune have been the subject of a successful invalidation proceeding, which is currently being appealed.