

**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 9, 2022

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

Cayman Islands
(State or other jurisdiction of
incorporation or organization)

001-38205
(Commission
File Number)

98-1144595
(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

(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 2.02 Results of Operations and Financial Condition.

On November 9, 2022, Zai Lab Limited issued a press release announcing its financial results for the three months ended September 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, 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 November 9, 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/ Billy Cho

Billy Cho

Chief Financial Officer

Date: November 9, 2022



Zai Lab Announces Third Quarter 2022 Financial Results and Corporate Updates

- Revenue of \$57.5 million for the third quarter of 2022, representing a 33% increase y-o-y and a 19% increase q-o-q; continued revenue growth led by ZEJULA
- Regional strategic collaboration for TIVDAK® (tisotumab vedotin) strengthens Zai Lab’s leadership in developing and providing access to medicine to treat women’s cancer in China
- Strong balance sheet with a cash position of \$1.12 billion
- Company to host a conference call and webcast on November 10, 2022, at 8:00 a.m. ET

SHANGHAI and CAMBRIDGE, Mass., November 9, 2022 -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced financial results for the third quarter of 2022, along with recent product highlights and corporate updates.

“Zai Lab’s third quarter was marked by a new regional and highly synergistic collaboration, strong revenue growth across our commercial products, and significant progress toward achieving our remaining 2022 corporate priorities,” said Dr. Samantha Du, Founder, Chairperson and CEO, of Zai Lab. “The company’s strategic positioning with respect to its targeted disease areas provides a robust and synergistic platform to benefit patients in Greater China and around the world as we continue to increase our sales and developmental efforts. Looking ahead, we expect this momentum to be bolstered by our late-stage development candidates that are progressing through pivotal studies and regulatory submissions. As one example, we reached an agreement with the NMPA on the development plan for a bridging study for KarXT in schizophrenia in China. In addition, our recently announced strategic collaboration with Seagen for the license of TIVDAK strengthens our ability to address unmet medical needs in women’s cancer. TIVDAK is the first and only ADC approved in the U.S. for the treatment of adult patients with recurrent or metastatic cervical cancer. Zai Lab is progressing this asset in pivotal studies in China.”

Recent Product Developments and Anticipated Milestones

Oncology

ZEJULA® (Niraparib)

ZEJULA is an oral, once-daily small-molecule poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor. It is the only PARP inhibitor approved in the United States, the European Union, and China as a first-line maintenance monotherapy for patients with advanced ovarian cancer, regardless of their biomarker status.

Recent Product Highlights

- Throughout this year, the U.S. Food and Drug Administration (FDA) has been reviewing data on PARP inhibitors, and other companies have issued Dear HCP Letters in the U.S. as a result of ongoing discussions with the FDA. In September 2022, Zai Lab partner GlaxoSmithKline (GSK) disclosed that it was in discussions with the FDA to discuss overall survival (OS) data from GSK’s ENGOT-OV16/NOVA phase III clinical trial for adult patients with recurrent ovarian cancer irrespective of the gBRCA mutation. Zai Lab does not expect the FDA’s discussions with GSK to impact its approval from the NMPA for ZEJULA in China. The NMPA’s full approval of ZEJULA in the recurrent ovarian cancer setting is based on a separate study, the NORA study, which is a Phase 3 randomized, double-blind, placebo-controlled study of ZEJULA that the Company independently conducted in China. While the NORA study is not fully mature, to date, favorable trends have been observed in OS irrespective of gBRCA mutation status. We expect to present this data at a future scientific congress. As a result, the Company does not anticipate that its second-line all-comer label in China will be affected by the FDA’s discussions with GSK. The Company also does not expect a change in its first-line label for ZEJULA; the FDA’s discussions with GSK do not apply to this indication.

Tumor Treating Fields

Tumor Treating Fields (TTFields) are electric fields that disrupt cancer cell division. Optune and Optune Lua, commercial TTFields devices, are approved or marketed in certain countries or regions for the treatment of newly diagnosed and recurrent glioblastoma and malignant pleural mesothelioma.

Recent Product Highlight

- As of September 30, 2022, Optune has been listed in 72 regional customized commercial health insurance plans guided by provincial or municipal governments (or supplemental insurance plans) since its commercial launch in China in the third quarter of 2020, compared to 25 supplemental insurance plans as of September 30, 2021.

Anticipated 2022 / Early 2023 Partner and Zai Milestones

- Last patient enrollment anticipated in the Phase 3 pivotal METIS study evaluating the efficacy and safety of stereotactic radiosurgery plus TTFields compared to stereotactic radiosurgery alone in patients with brain metastases resulting from Non-small Cell Lung Cancer (NSCLC).
- Top-line results from the Phase 3 pivotal LUNAR study in NSCLC in the early first quarter of 2023. Zai Lab joined the global LUNAR study in April 2021.

QINLOCK® (Ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor engineered to broadly inhibit KIT- and PDGFR α -mutated kinases. It is the only therapeutic approved in the United States and China for advanced gastrointestinal stromal tumor (GIST) patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting.

Recent Product Highlights

- As of September 30, 2022, QINLOCK has been listed in 96 supplemental insurance plans since its commercial launch in China in May 2021, compared to 28 supplemental insurance plans as of September 30, 2021.
- In August 2022, the recommendation level of QINLOCK for second-line treatments for advanced GIST patients was advanced from Level III to Level II (1A evidence) in the Chinese Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of GIST 2022.

Anticipated 2022 Zai Milestone

- Seek National Reimbursement Drug List (NRDL) inclusion for a fourth-line GIST indication.

Adagrasib

Adagrasib is a highly selective and potent oral small-molecule inhibitor of KRAS^{G12C} for treating KRAS^{G12C}-mutated NSCLC, colorectal cancer (CRC), pancreatic cancer, and other solid tumors.

Recent Product Highlights

- In September 2022, Zai Lab partner Mirati Therapeutics, Inc. (Mirati) presented results from KRYSTAL-1, a multicohort Phase 1/2 study evaluating adagrasib with or without cetuximab in patients with advanced CRC harboring a KRAS^{G12C} mutation at the European Society for Medical Oncology (ESMO) Congress 2022.
 - Of the evaluable patients in the adagrasib monotherapy cohort (n=43), the investigator assessed confirmed objective response rate (ORR) was 19% (8/43) and the disease control rate (DCR) was 86% (37/43). The median duration of response (DOR) was 4.3 months (95% CI, 2.3–8.3) and median PFS was 5.6 months (95% CI, 4.1–8.3).
 - Of the evaluable patients in the adagrasib plus cetuximab combination cohort (n=28), the investigator assessed confirmed ORR was 46% (13/28) and the DCR was 100% (28/28). The median DOR was 7.6 months (95% CI 5.7–NE) and median PFS was 6.9 months (95% CI, 5.4–8.1).
 - The prognosis for patients with CRC has historically been poor in later lines of therapy with response rates of approximately 1-2% and median PFS of approximately 2 months in patients with late-line CRC; patients with KRAS^{G12C}-mutated CRC tend to have even worse outcomes than the broader CRC patient population.

- In the overall subset of patients with KRAS^{G12C}-mutated CRC evaluated in this study, adagrasib was found to be well-tolerated as a monotherapy and in combination with cetuximab. The majority of observed treatment-related adverse events (TRAEs) were grade 1-2 (59%); no grade 5 TRAEs were observed.
- In August 2022, Zai Lab treated the first patient in Greater China for the global Phase 2 KRYSTAL-7 study of adagrasib in combination with pembrolizumab in first-line KRAS^{G12C}-mutated NSCLC patients.

Anticipated 2022 Partner Milestones

- Potential FDA approval and commercial launch in the United States for adagrasib as the treatment for patients with NSCLC harboring the KRAS^{G12C} mutation who have received at least one prior systemic therapy; Prescription Drug User Free Act (PDUFA) target action date of December 14, 2022.
- Update for the Phase 2 KRYSTAL-7 study of adagrasib in combination with pembrolizumab in first-line KRAS^{G12C}-mutated NSCLC in the fourth quarter of 2022.
- Additional clarity on the regulatory pathway of adagrasib monotherapy in first-line KRAS^{G12C}-mutated NSCLC.

Bemarituzumab

Bemarituzumab is a potential first-in-class antibody that is being developed in gastric and gastroesophageal junction (GEJ) cancer as a targeted therapy for tumors that overexpress FGFR2b.

Recent Product Highlight

- Zai Lab partner Amgen continues to enroll patients in several studies of bemarituzumab, including:
 - FORTITUDE-101, a Phase 3 study of bemarituzumab plus chemotherapy, versus placebo plus chemotherapy in first-line gastric cancer with FGFR2b overexpression.
 - FORTITUDE-102, the Phase 3 portion of the 1b/3 study of bemarituzumab plus chemotherapy and nivolumab versus chemotherapy and nivolumab in first-line gastric cancer with FGFR2b overexpression.

Anticipated 2022 / Early 2023 Zai Milestone

- Initiate a registrational study of bemarituzumab in first-line advanced gastric and GEJ cancer in Greater China.

Odronextamab

Odronextamab is a bispecific antibody designed to trigger tumor killing by linking and activating a cytotoxic T-cell (binding to CD3) to a lymphoma cell (binding to CD20).

Anticipated 2022 Zai Milestone

- Complete enrollment in China in a potentially pivotal Phase 2 study in B-Cell Non-Hodgkin Lymphoma (B-NHL).

Anticipated 2022 Partner Milestone

- Report additional results from the potentially pivotal Phase 2 study in B-NHL.

Repotrectinib

Repotrectinib is a next-generation tyrosine kinase inhibitor (TKI) designed to effectively target ROS1 and TRK A/B/C, with the potential to treat TKI-naïve or TKI-pretreated patients.

Recent Product Highlights

- In October 2022, Zai Lab partner Turning Point Therapeutics (a wholly owned subsidiary of Bristol Myers Squibb Company) provided a clinical data update from the global, registrational Phase 1/2 TRIDENT-1 study of repotrectinib at the 34th EORTC-NCI-AACR (ENA) Symposium 2022.
 - Repotrectinib continued to demonstrate meaningful clinical activity in patients with ROS1+ advanced NSCLC, who were TKI-naïve or TKI-pretreated, including with ROS1 G2032R resistance mutation. Durable responses and intracranial efficacy were observed in both TKI-naïve and TKI-pretreated patients.

- Repotrectinib also continued to show clinical activity in patients with NTRK+ advanced solid tumors who were TKI-naïve or TKI-pretreated, and responses were seen across diverse tumor types.
- Safety is well characterized, manageable with known protocols, and signals potential compatibility with long-term use.
- In October 2022, Zai Lab completed enrollment in China in all cohorts of the registrational Phase 1/2 TRIDENT-1 study.

Anticipated Early 2023 Zai Milestone

- Discuss regulatory pathway with the National Medical Products Administration (NMPA) at a pre-NDA meeting.

CLN-081

CLN-081 is an orally available, irreversible epidermal growth factor receptor (EGFR) inhibitor that selectively targets cells expressing EGFR exon 20 insertion mutations while sparing cells expressing wild type EGFR.

Anticipated 2022 Partner Milestone

- Initiate a pivotal study following the completion of a pharmacokinetic (PK) food effect study.

BLU-945

BLU-945 is a selective and potent investigational inhibitor of the activating EGFR L858R mutation and on-target T790M and C797S resistance mutations, for the potential treatment of EGFR-driven NSCLC.

Recent Product Highlight

- In November 2022, Zai Lab partner Blueprint Medicines presented an update on the Phase 1/2 SYMPHONY trial data supporting plans to develop BLU-945 in combination with osimertinib in first-line EGFR L858R mutation-positive NSCLC.

Autoimmune Disorders

VYVGART® (Efgartigimod)

Efgartigimod is an antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) autoantibodies and block the IgG recycling process. It binds to the neonatal Fc receptor (FcRn), which is widely expressed throughout the body and plays a central role in rescuing IgG from degradation.

Recent Product Highlights

- As of November 1, 2022, VYVGART (efgartigimod alfa-fcab) has been listed in 10 supplemental insurance plans in China.
- In September 2022, Zai Lab partner argenx announced the submission of a BLA to the FDA for subcutaneous (SC) efgartigimod for the treatment of generalized myasthenia gravis (gMG) in adult patients.
- In September 2022, argenx also announced that the European Commission (EC) has granted marketing authorization for VYVGART as an add-on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive.

Anticipated 2022 / Early 2023 Zai Milestones

- Launch the proof-of-concept trials in two autoimmune renal diseases.
- Continue to explore and advance additional indications in coordination with argenx.

Anticipated Early 2023 Partner Milestone

- Report topline data from the registrational ADHERE trial of SC efgartigimod for chronic inflammatory demyelinating polyneuropathy (CIDP) in the first quarter of 2023.

Infectious Disease

NUZYRA (Omadacycline)

NUZYRA is a once-daily oral and intravenous antibiotic for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). Zai Lab led the China development and obtained approval by the NMPA in December 2021.

Anticipated 2022 Zai Milestone

- Seek NRDL inclusion for CABP and ABSSSI indications.

Sulbactam-Durlobactam (SUL-DUR, Asia Pacific Rights)

Sulbactam-Durlobactam is a beta-lactam/beta-lactamase inhibitor combination that provides unique activity against Acinetobacter organisms, including carbapenem-resistant strains.

Anticipated 2022 / Early 2023 Zai Milestone

- Submit an NDA to the NMPA.

Neuroscience

KarXT

KarXT combines xanomeline, a novel muscarinic agonist, with trospium, an approved muscarinic antagonist. In November 2021, Zai partnered with Karuna Therapeutics, Inc. (Karuna) to develop KarXT in Greater China for the treatment of schizophrenia and possibly other indications like dementia-related psychosis.

Recent Product Highlights

- In September, 2022, Zai Lab obtained agreement from the NMPA on the development plan of a bridging study in schizophrenia in China.
- In October 2022, Zai Lab partner Karuna announced that data from the Phase 3 EMERGENT-2 trial of KarXT in schizophrenia was shared at the 35th European College of Neuropsychopharmacology (ECNP) Congress in Vienna, Austria. A poster presentation and symposium included previously reported efficacy and safety data, as well as new additional safety data from the trial.
- Karuna initiated the Phase 3 ADEPT-1 study evaluating KarXT as a treatment for psychosis in Alzheimer's disease in the third quarter of 2022.
- Karuna completed enrollment in the Phase 3 EMERGENT-3 trial in schizophrenia in the fourth quarter of 2022.

Anticipated Early 2023 Partner Milestone

- Report topline data from the Phase 3 EMERGENT-3 trial in schizophrenia in the first quarter of 2023.

Global R&D Autoimmune Disorder Programs

ZL-1102 (IL-17 Human VH Antibody Fragment, Global Rights)

ZL-1102 is a novel human VH antibody fragment (Humabody®) targeting the IL-17A cytokine with high affinity and avidity. Unlike other anti-IL-17 products, ZL-1102 is being developed as a topical treatment for mild-to-moderate chronic plaque psoriasis (CPP).

Recent Product Highlight

- In September 2022, Zai Lab presented results of the Phase 1 proof-of-concept study for ZL-1102 at the 2022 European Academy of Dermatology and Venereology Congress (EADV) in Milan, Italy.

Anticipated 2022 / Early 2023 Zai Milestone

- Initiate a global Phase 2 study for CPP.

Global R&D Oncology Programs

Recent Highlight

- In November 2022, Zai Lab presented data from its internal oncology pipeline at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in Boston, Mass. These presentations focus on two key global discovery programs: ZL-1211, an anti-CLDN18.2 antibody, and ZL-1218, an anti-CCR8 antibody.

Corporate Updates

- In September 2022, Zai Lab entered into a collaboration and license agreement with Seagen, Inc. for the development and commercialization of TIVDAK in Greater China. 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 and is an important addition to our oncology portfolio.
- In the second half of 2022, Zai Lab has continued to enhance its global leadership team. For example, Dr. Peter Huang joined the Company from Zentaris Pharmaceutical in November as Chief Scientific Officer (CSO). Dr. Huang brings to the Company an extensive scientific background and strong leadership and research and development experience, including over 16 years working within the biopharmaceutical industry. Dr. Huang will be a key member of the Company's executive management team and is responsible for leading and overseeing the Company's discovery efforts and translational medicine. In addition, Alette Verbeek joined the Company from Novartis in October as SVP, Head of Global Strategic Partnering. She is our first employee based in Europe and is responsible, among other things, for leading our European business development efforts.
- In November 2022, The Stock Exchange of Hong Kong Limited ("Hong Kong Stock Exchange") approved the Company's transition from a listing under Chapter 18A of the Listing Rules of the Hong Kong Stock Exchange (Biotech Companies) to a general listing under Rule 8.05(3) of the Listing Rules (Qualifications for Listing), as the Company has satisfied applicable revenue and market capitalization requirements for listing outside of Chapter 18A. As a result of this approval, the "B" marker will be removed from the Company's stock short name on the Hong Kong Stock Exchange, effective November 11, 2022.

Third-Quarter 2022 Financial Results

- For the three months ended September 30, 2022, total revenues were \$57.5 million, compared to \$43.1 million for the same period in 2021. Net product revenues for the period were \$39.2 million for ZEJULA, compared to \$28.2 million for the same period in 2021; \$10.7 million for Optune, compared to \$10.7 million for the same period in 2021; \$5.5 million for QINLOCK, compared to \$4.3 million for the same period in 2021, and \$1.5 million for NUZYRA, compared to nil for the same period in 2021.
- Research and Development (R&D) expenses were \$99.5 million for the three months ended September 30, 2022, compared to \$55.1 million for the same period in 2021. The increase in R&D expenses was primarily due to the \$30.0 million upfront payment for the new collaboration and license agreement with Seagen in the third quarter of 2022, increased expenses related to ongoing and newly initiated clinical trials, and higher payroll and payroll-related expenses from increased R&D headcount and share-based compensation.
- Selling, General and Administrative (SG&A) expenses were \$66.6 million for the three months ended September 30, 2022, compared to \$59.0 million for the same period in 2021. The increase was primarily due to payroll and payroll-related expenses from increased commercial and general and administrative headcount and share-based compensation as Zai Lab continued to enhance infrastructure and commercial operations in anticipation of new drug approvals and launches. We expect our net product revenue to exceed cost of goods sold and commercial expenses in 2023.
- Net loss was \$161.2 million for the three months ended September 30, 2022, compared to \$96.4 million for the same period in 2021. The increase in net loss was primarily due to a \$30.0 million upfront payment for the new collaboration and license agreement with Seagen and an increase in foreign exchange loss of \$36.7 million, which is a non-cash adjustment. Net loss per ordinary share during the three months ended September 30, 2022 was \$0.17, compared to \$0.10 for the same period in 2021. Net loss per ADS during the three months ended September 30, 2022, was \$1.68, compared to \$1.01 for the same period in 2021.

- As of September 30, 2022, cash and cash equivalents, short-term investments, and restricted cash totaled \$1,120.3 million, which we expect will provide us with cash runway through 2025.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, November 10, 2022, at 8:00 a.m. ET. Listeners may access the live webcast by visiting the Company's website at <http://ir.zailaboratory.com>. Participants must register in advance of the conference call. Details are as follows:

Registration Link: <https://register.vevent.com/register/BI98db73679f254c8eb1024c9df5ea85a8>

All participants must use the link provided above to complete the online registration process in advance of the conference call. Upon registering, each participant will receive a dial-in number, Direct Event passcode, and a unique access PIN, which can be used to join the conference call.

A replay will be available shortly after the call and can be accessed by visiting the Company's website at <http://ir.zailaboratory.com>.

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.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements relating to our strategy and plans; potential of and expectations for our business and pipeline programs; capital allocation and investment strategy; clinical development programs; clinical trial data, data readouts, and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our collaboration partners' products and of our pipeline therapies; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; financial guidance, including our projections for the number of marketed products we will have in the future; key data readouts and regulatory filings across our entire portfolio; and our plans to initiate or continue existing clinical trials for our other products and product candidates. 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 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.

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

For more information, please contact:

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Zai Lab Limited

Zai Lab Limited

Unaudited condensed consolidated balance sheets

(In thousands of U.S. dollars ("\$\$") except for number of shares and per share data)

	September 30, 2022	December 31, 2021
	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	1,119,476	964,100
Short-term investments	—	445,000
Accounts receivable (net of allowance for credit loss of \$8 and \$11 as of September 30, 2022 and December 31, 2021, respectively)	27,736	47,474
Notes receivable	10,251	7,335
Inventories, net	29,131	18,951
Value added tax recoverable - current	1,080	—
Prepayments and other current assets	22,157	18,021
Total current assets	1,209,831	1,500,881
Restricted cash, non-current	803	803
Long term investments (including the fair value measured investment of \$3,316 and \$15,383 as of September 30, 2022 and December 31, 2021, respectively)	3,316	15,605
Prepayments for equipment	4,068	989
Property and equipment, net	50,528	43,102
Operating lease right-of-use assets	20,269	14,189
Land use rights, net	6,824	7,811
Intangible assets, net	1,540	1,848
Long-term deposits	1,329	870
Value added tax recoverable	6	23,858
Total assets	1,298,514	1,609,956
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	90,112	126,163
Current operating lease liabilities	6,980	5,927
Other current liabilities	58,456	60,811
Total current liabilities	155,548	192,901
Deferred income	23,205	27,486
Non-current operating lease liabilities	13,892	9,613
Total liabilities	192,645	230,000
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 961,829,720 and 955,363,980 shares issued as of September 30, 2022 and December 31, 2021, respectively; 959,724,940 and 954,981,050 shares outstanding as of September 30, 2022 and December 31, 2021, respectively)	6	6
Additional paid-in capital	2,877,361	2,825,948
Accumulated deficit	(1,799,591)	(1,418,074)
Accumulated other comprehensive income (loss)	39,549	(23,645)
Treasury Stock (at cost, 2,104,780 and 382,930 shares as of September 30, 2022 and December 31, 2021, respectively)	(11,456)	(4,279)
Total shareholders' equity	1,105,869	1,379,956
Total liabilities and shareholders' equity	1,298,514	1,609,956

Zai Lab Limited

Unaudited condensed consolidated statements of operations

(In thousands of U.S. dollars ("\$\$") except for number of shares and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Revenues:				
Product revenue, net	56,963	43,103	150,633	100,141
Collaboration revenue	577	—	1,806	—
Total revenues	57,540	43,103	152,439	100,141
Expenses:				
Cost of sales	(20,044)	(12,162)	(53,094)	(30,535)
Research and development	(99,524)	(55,144)	(219,462)	(401,220)
Selling, general, and administrative	(66,555)	(59,002)	(186,947)	(149,254)
Loss from operations	(128,583)	(83,205)	(307,064)	(480,868)
Interest income	3,872	713	5,235	1,171
Other income (expenses), net	(36,479)	(13,580)	(79,467)	(12,401)
Loss before income tax and share of loss from equity method investment	(161,190)	(96,072)	(381,296)	(492,098)
Income tax expense	—	—	—	—
Share of loss from equity method investment	—	(340)	(221)	(548)
Net loss	(161,190)	(96,412)	(381,517)	(492,646)
Net loss attributable to ordinary shareholders	(161,190)	(96,412)	(381,517)	(492,646)
Loss per share - basic and diluted	(0.17)	(0.10)	(0.40)	(0.53)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	959,085,960	950,354,320	957,439,910	921,748,380
Loss per American Depositary Shares ("ADS") - basic and diluted	(1.68)	(1.01)	(3.98)	(5.34)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted	95,908,596	95,035,432	95,743,991	92,174,838

Note: Basic and diluted net loss per ordinary share, weighted average number of ordinary shares for the three and nine months ended September 30, 2021, respectively, have been retrospectively adjusted as a result of the Share Subdivision and the ADS Ratio Change that became effective on March 30, 2022. The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company.

Zai Lab Limited**Unaudited condensed consolidated statements of comprehensive loss****(In thousands of U.S. dollars ("\$\$") except for number of shares and per share data)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Net loss	(161,190)	(96,412)	(381,517)	(492,646)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	35,062	1,741	63,194	(600)
Comprehensive loss	(126,128)	(94,671)	(318,323)	(493,246)