
**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): August 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**

201210

(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 August 9, 2022, Zai Lab Limited issued a press release announcing its financial results for the three months ended June 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 August 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: August 9, 2022



Zai Lab Announces Second Quarter 2022 Financial Results and Corporate Updates

- *Key pipeline milestones achieved including the BLA acceptance of efgartigimod by China's NMPA and positive topline results for the KarXT Phase 3 EMERGENT-2 trial*
- *Continued revenue growth led by ZEJULA; strong balance sheet with a cash position of \$1.26 billion*
- *Company to host a conference call and webcast on August 10, 2022, at 8:00 a.m. ET*

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

“We executed well in the second quarter and delivered strong results,” said Dr. Samantha Du, Founder, Chairperson and CEO, of Zai Lab. “Despite the challenging operating environment, Zai has continued to achieve all of our corporate priorities, including the BLA acceptance for efgartigimod by China’s NMPA. With the positive topline readout from the Phase 3 EMERGENT-2 trial in schizophrenia earlier this week, we believe KarXT could be a very important treatment option as the first new class of medicine in over half a century for the many patients suffering from schizophrenia in China and globally. I’m also excited that our pipeline continues to mature and demonstrate first and best-in-class potential. In addition, there were positive data readouts for adagrasib, CLN-081, repotrectinib, efgartigimod, ZEJULA and Tumor Treating Fields in the second quarter. Importantly, our commercial operations remain resilient in the face of the ongoing pandemic situation in certain regions in China. For the remainder of the year, we are on track to deliver our remaining 2022 corporate priorities, including an NDA submission to the NMPA for sulbactam-durlobactam, advancing ZL-1102 (anti-IL-17A Humabody®) into full global development, as well as seeking NRDL inclusion for QINLOCK and NUZYRA. We are also very pleased to welcome Josh Smiley as our COO at this exciting time given his operational expertise, global experience, and deep understanding of Zai Lab and our industry.”

“I am thrilled to be joining Zai Lab at such a pivotal time in the company’s history,” said Josh Smiley, COO of Zai Lab. “Zai is working toward becoming a leading global biotech company, leveraging its commercial success in Asia and its development of global products. The advancement of Zai’s proprietary research pipeline and the diversification of its portfolio beyond its traditional strength in oncology present tremendous opportunities. I am looking forward to working with the great team and helping scale the company both in China and in the United States.”

Recent Product Highlights 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 mainland China (hereinafter, “China”) as a monotherapy for patients with advanced ovarian cancer, regardless of their biomarker status.

Recent Product Highlight

- In June 2022, Zai Lab presented a new prespecified subgroup analysis from the Phase 3 PRIME study for niraparib in patients in China with ovarian cancer at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. This analysis examined 384 newly diagnosed stage III or IV ovarian cancer patients enrolled in the PRIME study who experienced a complete response (CR) or partial response (PR) to first-line platinum-based chemotherapy.
 - In the CR group: The median progression-free survival (mPFS) was 29.4 months for niraparib vs 8.3 months for placebo (HR=0.45; 95% confidence interval [CI], 0.32–0.61; P<0.001).
 - In the PR group: The mPFS was 19.3 months for niraparib versus 8.3 months for placebo (HR=0.45; 95% CI, 0.23–0.86; P=0.014).

- The safety profile of niraparib was consistent with previous clinical trials, with no new safety issues identified in this subgroup analysis.

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 Highlights

- In June 2022, Zai Lab and Novocure announced the EF-31 phase 2 pilot study, evaluating the safety and efficacy of TTFields together with standard-of-care (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as a first-line treatment in patients with gastric cancer, met its primary endpoint of objective response rate (ORR) with supportive signals across secondary endpoints.
- As of June 30, 2022, Optune has been listed in 50 regional customized commercial health insurance plans guided by provincial or municipal governments (or “supplemental insurance plans”).

Anticipated 2022 Partner and Zai Milestone

- Last patient enrollment anticipated in the Phase 3 pivotal METIS clinical trial evaluating the efficacy and safety of stereotactic radiosurgery plus TTFields compared to stereotactic radiosurgery alone in patients with brain metastases resulting from NSCLC.

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 Highlight

- As of June 30, 2022, QINLOCK has been listed in 73 supplemental insurance plans since its commercial launch in China in May 2021.

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 July 2022, Zai Lab treated the first patient in Greater China for the global Phase 3 KRYSTAL-12 study of adagrasib in patients with KRAS^{G12C}-mutated advanced NSCLC.
- In June 2022, Zai Lab treated the first patient in Greater China for the global Phase 3 KRYSTAL-10 study of the combination of adagrasib and cetuximab in patients with KRAS^{G12C}-mutated advanced CRC.
- In June 2022, Zai Lab partner Mirati Therapeutics, Inc. (Mirati) presented the following information at the 2022 ASCO Annual Meeting:
 - Mirati reported full results from the registration-enabling Phase 2 cohort of the KRYSTAL-1 study evaluating adagrasib in patients with previously treated NSCLC harboring a KRAS^{G12C} mutation; these results were concurrently published in the New England Journal of Medicine. This presentation included results from a retrospective subgroup analysis from the Phase 2 NSCLC cohort of the KRYSTAL-1 study evaluating adagrasib in patients with KRAS^{G12C}-mutated NSCLC and stable, previously treated CNS metastases.
 - Summary of clinical results from the Phase 2 registration-enabling study (n=112): initial results showed that the ORR was 43%, the disease control rate (DCR) was 80%, the median duration of response (mDOR)

was 8.5 months (95% CI: 6.2 – 13.8), the mPFS was 6.5 months (95% CI: 4.7 – 8.4). With a January 15, 2022 data cutoff, the median overall survival (mOS) was 12.6 months (95% CI: 9.2 – 19.2).

- Central nervous system (CNS)-specific activity was evaluated in a subset analysis of stable, previously treated CNS metastases (n=33): results revealed an intracranial (IC) ORR of 33% (11/33).
- In addition, Mirati reported updated findings from a pooled analysis from the KRYSTAL-1 study, including the registrational Phase 2 and Phase 1/1b NSCLC cohorts.
 - Pooled analysis of KRYSTAL-1 NSCLC cohorts (n=132): initial results showed that the ORR was 44% and the DCR was 81%. The mDOR was 12.5 months and the mPFS was 6.9 months. With a January 15, 2022 data cutoff, the mOS was 14.1 months.
- In June 2022, Mirati also announced the results of a prospective analysis from the Phase 1b cohort of the KRYSTAL-1 study evaluating IC responses of adagrasib in patients with KRAS^{G12C}-mutated advanced NSCLC with active and untreated CNS metastases.
 - CNS-specific activity in active and untreated CNS metastases (n=19): results showed an IC ORR of 32% (6/19).

Anticipated 2022 Partner Milestones

- Tolerability and ORR update for the Phase 2 KRYSTAL-7 study of adagrasib in combo 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, and next steps for tumors other than NSCLC.
- Potential FDA (Food and Drug Administration) 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.

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 Highlights

- Zai Lab partner Amgen reported that the final analysis of the FIGHT study, a Phase 2 randomized, double-blind, controlled study evaluating bemarituzumab and modified FOLFOX6 (mFOLFOX6) in patients with previously untreated advanced gastric and GEJ cancer was completed. These results continued to demonstrate that bemarituzumab + mFOLFOX6 improves the clinical outcome of patients with FGFR2b expressing tumors with no new safety concerns. A greater survival benefit was observed with increasing FGFR2b expression levels.
- Zai Lab partner Amgen has initiated a Phase 1b/2 study (FORTITUDE-301), evaluating the safety and efficacy of bemarituzumab monotherapy in solid tumors with FGFR2b overexpression.

Anticipated 2022 Zai Milestone

- Initiate a registrational study of bemarituzumab in first-line advanced gastric and GEJ cancer in Greater China in the fourth quarter of 2022.

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 Partner and Zai Milestone

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

Anticipated 2022 Partner Milestone

- Report additional results from a potentially pivotal Phase 2 study in B-NHL, and submit a Biologics License Application (BLA) to the FDA.

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 July 2022, Zai Lab partner Turning Point Therapeutics, Inc. (Turning Point) announced receipt of positive feedback from the FDA at a pre-New Drug Application (NDA) meeting completed within the second quarter. The FDA agreed with Turning Point's plan to provide data for ROS1+ TKI-naïve and TKI-pretreated advanced NSCLC patients with at least six months of follow-up from the first post-baseline scan at the time of NDA submission.
- In June 2022, the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted two Breakthrough Therapy Designations (BTDs) to repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and one prior line of platinum-based chemotherapy and for those with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and no chemotherapy or immunotherapy.
- In May 2022, Zai Lab and Turning Point announced that the FDA granted an eighth regulatory designation, and third BTD, to repotrectinib, for the treatment of patients with ROS1-positive metastatic NSCLC who have been previously treated with one ROS1 TKI and who have not received prior platinum-based chemotherapy.

Anticipated 2022 Zai Milestones

- Complete enrollment in all cohorts of the phase 1/2 registrational TRIDENT-1 study.
- Discuss regulatory pathway with the NMPA at a pre-NDA meeting in the fourth quarter of 2022.

Anticipated 2022 Partner Milestones

- Anticipate providing a detailed update from TRIDENT-1 utilizing BICR analyses, including intracranial activity, at an upcoming medical conference.
- Provide a clinical data update from the NTRK-positive advanced solid tumor cohorts from TRIDENT-1.

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.

Recent Product Highlight

- In June 2022, Zai Lab partner Cullinan Oncology presented updated data from the Phase 1/2a study in NSCLC patients with EGFR exon 20 insertion mutations at the 2022 ASCO Annual Meeting. Of the 39 patients in the 100 mg BID dose group:
 - 16 (41%) had a confirmed PR.
 - The estimated mDOR was greater than 21 months.
 - mPFS was 12 months.
 - The safety profile of CLN-081 was amenable for long-term treatment.

Anticipated 2022 Partner Milestone

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

Elzovantinib (TPX-0022)

Elzovantinib is an orally bioavailable, multi-targeted kinase inhibitor with a novel three-dimensional macrocyclic structure that inhibits the MET, CSF1R (colony stimulating factor 1 receptor) and SRC kinases.

Anticipated 2022 Zai Milestone

- Enroll the first patient in Greater China in the Phase 1 expansion portion of the global Phase 1/2 SHIELD-1 study.

Anticipated 2022 Partner Milestones

- Provide a clinical data update from the Phase 1 SHIELD-1 study.
- Initiate the Phase 2 portion of the SHIELD-1 study, pending FDA feedback on data from the intermediate dose level.

BLU-945

BLU-945 is a selective and potent investigational inhibitor of EGFR harboring either the activating L858R or exon 19 deletion mutations combined with the acquired T790M and C797S mutations, common on-target resistance mutations to first-generation EGFR inhibitors and osimertinib, respectively, for the potential treatment of EGFR-driven NSCLC.

Recent Product Highlight

- In June 2022, Zai Lab received a Clinical Trial Application (CTA) approval from the NMPA for the BLU-945 monotherapy cohort of the global Phase 1/2 SYMPHONY study in Greater China.

Anticipated 2022 Partner Milestones

- Present updated BLU-945 monotherapy data and initial dose escalation data for BLU-945 in combination with osimertinib from the Phase 1/2 SYMPHONY trial in EGFR-mutant NSCLC.
- Initiate additional cohorts in the Phase 1/2 SYMPHONY trial for BLU-945 in combination with other agents across multiple patient populations, including early line therapy.

BLU-701

BLU-701 is a selective and potent investigational inhibitor of EGFR harboring either the activating L858R or exon 19 deletion mutations combined with the acquired C797S mutation, a common on-target resistance mutation to osimertinib, for potential treatment of EGFR-driven NSCLC.

Anticipated 2022 Partner Milestone

- Present initial clinical data from the Phase 1/2 HARMONY trial of BLU-701 in EGFR-mutant NSCLC.

Autoimmune Diseases

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

- In July 2022, Zai Lab announced the NMPA accepted the BLA for efgartigimod alfa injection for the treatment of adult patients with generalized myasthenia gravis (gMG) in China.
- In June 2022, efgartigimod was introduced to the Hainan Bo'ao Lecheng International Medical Tourism Pilot Zone, and in July 2022, the first Chinese patient was treated with efgartigimod.

Anticipated 2022 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 2022 Partner Milestones

- Initiate the registrational ALKIVIA trial in the third quarter of 2022 for three subtypes of idiopathic inflammatory myopathies (myositis), including immune-mediated necrotizing myopathy, anti-synthetase syndrome, and dermatomyositis; interim analysis planned of first 30 patients of each subtype.
- Submit a BLA to the FDA for subcutaneous (SC) efgartigimod in gMG.

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 Milestones

- Seek NRDL inclusion for CABP and ABSSSI indications.
- Submit Zai Lab's plan for post-approval studies.

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 Zai Milestone

- Submit an NDA to the NMPA in the fourth quarter of 2022.

Anticipated 2022 Partner Milestone

- Submit an NDA to the FDA in the third quarter of 2022.

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 Highlight

- In August 2022, Zai Lab partner Karuna announced positive topline results from its Phase 3 EMERGENT-2 trial evaluating the efficacy, safety, and tolerability of KarXT in adults with schizophrenia. The trial met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 9.6-point reduction in the Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-21.2 KarXT vs. -11.6 placebo, $p < 0.0001$) at Week 5. KarXT also demonstrated an early and sustained statistically significant reduction of symptoms, as assessed by PANSS total score, starting at Week 2 and maintained such reduction through all timepoints in the trial.
 - The trial also met its key secondary endpoints, demonstrating statistically significant reductions in positive and negative symptoms of schizophrenia, as measured by the PANSS positive, PANSS negative and PANSS Marder negative subscales.
 - KarXT was generally well tolerated, with a side effect profile substantially consistent with prior trials of KarXT in schizophrenia.

Anticipated 2022 Zai Milestone

- Seek regulatory agreement with the NMPA on a China program in schizophrenia.

Anticipated 2022 Partner Milestone

- Initiate the Phase 3 ADEPT-1 study evaluating KarXT as a treatment for psychosis in Alzheimer’s disease in the third quarter of 2022.

Global R&D 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

- The results of the Phase 1 proof-of-concept study, evaluating the efficacy and safety of ZL-1102 in patients with mild-to-moderate CPP, have been accepted for an oral presentation at EADV (European Academy of Dermatology and Venereology) annual meeting on September 7-10, 2022.

Anticipated 2022 Zai Milestone

- Initiate a global Phase 2 study for CPP in the fourth quarter of 2022.

Simurosertib, ZL-2309 (CDC7 Inhibitor, Global Rights)

Simurosertib, or ZL-2309, is an oral selective inhibitor of CDC7, a protein kinase with key roles in DNA replication and in bypassing DNA damage response.

Recent Product Update

- Based on an extensive review of the data collected from previously completed studies, Zai Lab has decided to terminate enrollment for the study of simurosertib.

ZL-1201 (CD47 Inhibitor, Global Rights)

ZL-1201 is a humanized, IgG4 monoclonal antibody, engineered to reduce effector function, that specifically targets CD47. Its therapeutic potential will be assessed in both solid tumors and hematological malignancies and in both monotherapy and combination opportunities.

Recent Product Updates

- In July 2022, Zai Lab determined a recommended Phase 2 dose in the ongoing Phase 1 trial.
- Based on a review of the competitive landscape, Zai Lab has decided to deprioritize ZL-1201 for internal development but will pursue out-licensing opportunities.

Corporate Updates

- In June 2022, Zai Lab completed the voluntary conversion of its secondary listing status in Hong Kong to a primary listing on the Main Board of The Hong Kong Stock Exchange. Zai Lab is now a dual-primary listed company, with its ordinary shares traded on the Hong Kong Stock Exchange and its American Depositary Shares traded on the Nasdaq Global Market.
- In June and July 2022, Zai Lab’s ordinary shares have been included in the Shenzhen- and Shanghai-Hong Kong Stock Connect programs, respectively. These Stock Connect programs permit eligible investors in mainland China to invest in the Company.
- Zai Lab engaged KPMG LLP as the company’s auditor, effective May 31, 2022. The engagement of this U.S. auditor, which is subject to full inspection and review by the Public Company Accounting Oversight Board, was a natural progression of Zai Lab’s global growth. With a principal executive office in Cambridge, Massachusetts and significant operations and a majority of the company’s Board and executives in the United States, Zai Lab may be audited by KPMG in the United States. As a result, we believe that we will be in compliance with the requirements of the Holding

Foreign Companies Accountable Act (HFCAA) beginning with our annual report for the fiscal year ending December 31, 2022, and that we will not be conclusively identified under the HFCAA in 2023 or going forward. The company expects, therefore, its Nasdaq listing to continue uninterrupted. Our full statement on the appointment of KPMG can be found on the Investors section of the Zai Lab website.

- Zai Lab has continued to enhance its corporate governance and leadership team. In July 2022, the Board of Directors appointed John Diekman to be Lead Independent Director. In light of the additional responsibilities of the Lead Independent Director, Mr. Diekman stepped down as Chair of the Audit Committee, although he will continue to serve as a member of the Audit Committee, and Scott Morrison has been appointed Chair of the Audit Committee. Also, Josh Smiley joined the Company as Chief Operating Officer, effective August 1. He will report directly to the Chief Executive Officer and will be a key member of the executive committee.
- As of June 30, 2022, Zai Lab employed 2,063 full-time employees, including 861 and 968 employees engaged in R&D and commercial activities, respectively.

Second-Quarter 2022 Financial Results

- For the three months ended June 30, 2022, total revenues were \$48.2 million, compared to \$36.9 million for the same period in 2021. Product revenues for the period were \$34.1 million for ZEJULA, compared to \$23.4 million for the same period in 2021; \$11.6 million for Optune, compared to \$9.5 million for the same period in 2021; \$0.6 million for QINLOCK, compared to \$4.0 million for the same period in 2021, and \$1.3 million for NUZYRA, compared to nil for the same period in 2021.
 - QINLOCK and NUZYRA are scheduled to enter negotiations with the National Healthcare Security Administration (NHS) regarding potential inclusion in the NRDL, and in June 2022, the Company lowered the selling price for these products. Accordingly, the Company accrued \$2.9 million of sales rebates as compensation to distributors for those products previously sold at the price prior to the reduction during the three months ended June 30, 2022.
- Research and Development (R&D) expenses were \$66.1 million for the three months ended June 30, 2022, compared to \$142.2 million for the same period in 2021. The decrease in R&D expenses was primarily due to no upfront payment for new licensing agreements, partially offset by increased expenses related to ongoing and newly initiated clinical trials and higher payroll and payroll-related expenses from increased R&D headcount. Excluding upfront payments for new licensing agreements, core R&D expenses were \$51.7 million for the same period in 2021.
- Selling, General and Administrative (SG&A) expenses were \$63.4 million for the three months ended June 30, 2022, compared to \$54.4 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, as Zai Lab continued to expand and invest in its commercial operations in China in anticipation of strong topline growth over the next few years.
- Net loss was \$137.9 million for the three months ended June 30, 2022, compared to \$163.3 million for the same period in 2021. The decrease in net loss was primarily due to no upfront payments for new licensing agreements partially offset by an increase in foreign exchange loss of \$42.2 million, which is a non-cash adjustment. Net loss per ordinary share during the three months ended June 30, 2022 was \$0.14, compared to \$0.18 for the same period in 2021. Net loss per ADS during the three months ended June 30, 2022 was \$1.44, compared to \$1.76 for the same period in 2021.
- As of June 30, 2022, cash and cash equivalents, short-term investments, and restricted cash totaled \$1,256.9 million, compared to \$1,313.0 million as of March 31, 2022.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, August 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/BI462e47de1af64af599432ab5c90a148b>

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; our revenue projections for our current lung cancer and GI cancer franchises; 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.

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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)

	June 30, 2022	December 31, 2021
	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	680,820	964,100
Short-term investments	575,274	445,000
Accounts receivable (net of allowance for credit loss of \$8 and \$11 as of June 30, 2022 and December 31, 2021, respectively)	27,054	47,474
Notes receivable	10,968	7,335
Inventories, net	23,339	18,951
Value added tax recoverable - current	219	—
Prepayments and other current assets	17,973	18,021
Total current assets	1,335,647	1,500,881
Restricted cash, non-current	803	803
Long term investments (including the fair value measured investment of \$2,827 and \$15,383 as of June 30, 2022 and December 31, 2021, respectively)	2,827	15,605
Prepayments for equipment	4,542	989
Property and equipment, net	46,419	43,102
Operating lease right-of-use assets	18,596	14,189
Land use rights, net	7,286	7,811
Intangible assets, net	1,673	1,848
Long-term deposits	947	870
Value added tax recoverable	37	23,858
Total assets	1,418,777	1,609,956
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	108,443	126,163
Current operating lease liabilities	6,824	5,927
Other current liabilities	53,610	60,811
Total current liabilities	168,877	192,901
Deferred income	24,775	27,486
Non-current operating lease liabilities	12,960	9,613
Total liabilities	206,612	230,000
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 960,520,140 and 955,363,980 shares issued as of June 30, 2022 and December 31, 2021, respectively; 958,494,830 and 954,981,050 shares outstanding as of June 30, 2022 and December 31, 2021, respectively)	6	6
Additional paid-in capital	2,857,202	2,825,948
Accumulated deficit	(1,638,401)	(1,418,074)
Accumulated other comprehensive income (loss)	4,487	(23,645)
Treasury Stock (at cost, 2,025,310 and 382,930 shares as of June 30, 2022 and December 31, 2021, respectively)	(11,129)	(4,279)
Total shareholders' equity	1,212,165	1,379,956
Total liabilities and shareholders' equity	1,418,777	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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Revenues:				
Product revenue, net	47,575	36,935	93,670	57,038
Collaboration revenue	601	—	1,230	—
Total revenues	48,176	36,935	94,900	57,038
Expenses:				
Cost of sales	(17,407)	(10,868)	(33,051)	(18,373)
Research and development	(66,084)	(142,224)	(119,938)	(346,076)
Selling, general, and administrative	(63,401)	(54,414)	(120,392)	(90,252)
Loss from operations	(98,716)	(170,571)	(178,481)	(397,663)
Interest income	1,175	244	1,363	458
Other income (expenses), net	(40,392)	7,406	(42,988)	1,179
Loss before income tax and share of loss from equity method investment	(137,933)	(162,921)	(220,106)	(396,026)
Income tax expense	—	—	—	—
Share of loss from equity method investment	—	(403)	(221)	(208)
Net loss	(137,933)	(163,324)	(220,327)	(396,234)
Net loss attributable to ordinary shareholders	(137,933)	(163,324)	(220,327)	(396,234)
Loss per share - basic and diluted	(0.14)	(0.18)	(0.23)	(0.44)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	957,684,820	930,455,310	956,603,250	907,231,320
Loss per American Depositary Shares (“ADS”) - basic and diluted	(1.44)	(1.76)	(2.30)	(4.37)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted	95,768,482	93,045,531	95,660,325	90,723,132

Note: Basic and diluted net loss per ordinary share, weighted average number of ordinary shares for the three and six months ended June 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Net loss	(137,933)	(163,324)	(220,327)	(396,234)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	30,325	(5,241)	28,132	(2,341)
Comprehensive loss	(107,608)	(168,565)	(192,195)	(398,575)