

**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): May 10, 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**
(Address of principal executive offices)

201210
(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 May 10, 2022, Zai Lab Limited issued a press release announcing its financial results for the three months ended March 31, 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**

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release issued by Zai Lab Limited on May 10, 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: May 10, 2022



**Zai Lab Announces First Quarter 2022
Financial Results and Corporate Updates**

— Company to Host Conference Call and Webcast on May 11, 2022, at 8:00 a.m. ET

SHANGHAI, SAN FRANCISCO, and CAMBRIDGE, Mass., May 10, 2022 — Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced financial results for the first quarter of 2022, along with recent product highlights and corporate updates.

“Our first-quarter results reflect Zai’s solid foundation and track record of consistent execution, and were marked by progress across the entire portfolio,” said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. “Today, Zai’s broad, proprietary pipeline consists of 11 assets with global rights. Building upon last year’s proof of concept achievement for ZL-1102, our anti-IL-17A Humabody® for chronic plaque psoriasis, Zai recently unveiled preclinical data from four key oncology programs at the 2022 AACR Annual Meeting. With these assets just beginning to enter first-in-human and proof-of-concept clinical studies, we are in the exciting early days of demonstrating Zai’s commitment to its in-house discovery and translational research. And of course, this proprietary pipeline complements the advancements within our later-stage partnered pipeline, which is expected to produce numerous pivotal study readouts throughout 2022.”

“At the beginning of this year, we established 2022 strategic priorities that aim to position Zai to lead the next wave of biopharma innovation. I am pleased to say we continue to progress toward achieving these priorities, including progress toward filing the NDA for efgartigimod in China in mid-2022, initiation of a registrational study for bemarituzumab in first-line gastric cancer in Greater China, topline data readout for KarXT from its Phase 3 EMERGENT-2 trial in the third quarter of 2022, and continued investment in R&D to advance our proprietary pipeline with global rights, including moving ZL-1102 into full global development.

“Importantly, our commercial team continues to drive significant growth with our four marketed products in Greater China. We remain very confident in the underlying strengths of our business despite the challenges due to the COVID situation in certain regions in China, current macro and geopolitical headwinds. The fundamental drivers of value at Zai Lab are further strengthened by our expanding leadership team and global talent, the steps we have taken to facilitate access to global capital markets, and our track record of consistent execution in bringing global first and best-in-class medicines to patients in China and beyond. Looking forward, we at Zai Lab remain committed in pursuit of our overall vision of improving human health worldwide, and to build a leading global biopharmaceutical company.”

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 China as a monotherapy for patients with advanced ovarian cancer, regardless of their biomarker status.

Recent Product Highlight

- In March 2022, Zai Lab presented positive results from the Phase 3 PRIME study of ZEJULA (niraparib) as maintenance therapy at the Society of Gynecologic Oncology (SGO) Annual Meeting. In the PRIME study, median progression-free survival (mPFS) was significantly longer for patients treated with niraparib compared to placebo: 24.8 months versus 8.3 months, hazard ratio (HR), 0.45; $p < 0.001$. Other pre-specified efficacy results included:
 - gBRCAmut patients: mPFS was not reached vs. 10.8 months; HR and 95% CI: 0.40 (0.23, 0.68).
 - Non-gBRCAmut patients: mPFS was 19.3 months vs. 8.3 months; HR and 95% CI: 0.48 (0.34, 0.67).
 - Overall survival (OS) data was still immature (percentage of death in niraparib and placebo groups are 14.5% vs. 21.7%); there was a trend in favor of niraparib at the data cut-off.

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 March 2022, Zai Lab partner Novocure announced the presentation of updated results by Dr. David Tran, Chief of the Division of Neuro-Oncology at the McKnight Brain Institute at the University of Florida, from the investigator-initiated phase 2 pilot 2-THE-TOP clinical trial testing the safety and preliminary efficacy of TTFields together with pembrolizumab and temozolomide for the treatment of adult patients with newly diagnosed glioblastoma (GBM). These preliminary results, which are based on a median follow-up time on 16.8 months, compare outcomes for 26 patients in the ongoing 2-THE-TOP trial. For patients in the 2-THE-TOP trial:
 - mPFS was 12.1 months, compared with 7.9 months for the matched-control patients in EF-14 (hazard ratio=0.46, $p=0.033$).
 - mOS was 25.2 months, compared with 15.9 months for the matched-control patients in EF-14 (hazard ratio=0.38, $p=0.020$).

- Of the 15 patients in 2-THE-TOP with measurable target lesions, six (40%) achieved partial to complete response and eight (53%) had stable disease.
- In March 2022, Zai Lab partner Novocure announced the results of a pre-specified interim analysis for the phase 3 pivotal INNOVATE-3 study evaluating the safety and efficacy of TTFIELDS together with paclitaxel for the treatment of patients with platinum-resistant ovarian cancer. An independent data monitoring committee (DMC) reviewed the safety data for all platinum-resistant ovarian cancer patients enrolled in the trial. The pre-specified interim analysis concluded that the INNOVATE-3 study should proceed to the final analysis as planned. Data will be reviewed in 2023, following an 18-month follow-up period.
- As of March 31, 2022, Optune has been listed in 37 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.

Anticipated 2022 Partner and Zai Milestones

- Topline data anticipated from the Phase 3 pivotal LUNAR clinical trial testing the efficacy of TTFIELDS together with physician’s choice immune-checkpoint inhibitor or docetaxel for the treatment of patients with stage 4 non-small cell lung cancer (NSCLC) by year end 2022.
- Last patient enrollment anticipated in the Phase 3 pivotal METIS clinical trial testing the efficacy and safety of stereotactic radiosurgery plus TTFIELDS compared to stereotactic radiosurgery alone in patients with brain metastases resulting from NSCLC.
- Report topline data from the Phase 2 pilot EF-31 clinical trial testing the safety and efficacy of TTFIELDS together with chemotherapy in the treatment of patients with gastric cancer in 2022.

QINLOCK® (Ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor engineered to broadly inhibit KIT- and PDGFRα-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 March 31, 2022, QINLOCK has been listed in 58 supplemental insurance plans since its commercial launch in China in May 2021.

Adagrasib

Adagrasib is a highly selective and potent oral small-molecule inhibitor of KRASG12C for treating KRASG12C-mutated NSCLC, colorectal cancer (CRC), pancreatic cancer and other solid tumors.

Anticipated 2022 Zai Milestone

- Enroll first patients in Greater China in Mirati Therapeutics, Inc. (Mirati)'s global, potentially registrational trials in NSCLC and CRC.

Anticipated 2022 Partner Milestones

- Two oral presentations at the upcoming 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. Presentations to include full results from the registration-enabling Phase 2 cohort of the KRYSTAL-1 study evaluating adagrasib in patients with pre-treated NSCLC harboring a KRASG12C mutation and late-breaking data on adagrasib in patients with KRASG12C-mutated NSCLC with active and untreated central nervous system metastases.
- Tolerability and ORR update for the Phase 2 KRYSTAL-7 study of adagrasib in combo with pembrolizumab in first line KRASG12C-mutated NSCLC in the second half of 2022.
- Additional clarity on the regulatory pathway of adagrasib monotherapy in first line KRASG12C-mutated NSCLC, and next steps for tumors other than NSCLC in the second half of 2022.
- Potential FDA approval and commercial launch for adagrasib as treatment for patients with NSCLC harboring the KRASG12C mutation who have received at least one prior systemic therapy; 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 has initiated a Phase 1b study (FORTITUDE-103) of bemarituzumab plus oral chemotherapy regimens in first line gastric cancer with FGFR2b overexpression.
- Zai Lab partner Amgen is enrolling patients for a Phase 1b study (FORTITUDE-201) of bemarituzumab monotherapy and in combination with docetaxel for the treatment of squamous NSCLC 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.

Anticipated 2022 Partner Milestone

- Planning is underway for a signal-seeking basket study in other solid tumors.

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).

Recent Product Highlight

- Zai Lab partner Regeneron announced that odronextamab received Fast Track designation from the FDA in follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL).

Anticipated 2022 Partner and Zai Milestone

- Complete enrollment in the potentially pivotal Phase 2 study in B-NHL.

Anticipated 2022 Partner Milestones

- Report additional results from the potentially pivotal Phase 2 study in B-NHL, and submit a Biologics License Application (BLA) to the FDA in the second half of 2022.
- Initiate dosing with a subcutaneous formulation, the Phase 3 OLYMPIA program, and studies of additional combinations in 2022.

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 April 2022, Zai Lab and Turning Point Therapeutics, Inc. (Turning Point) announced positive topline results for repotrectinib within the China region from the previously disclosed Phase 1/2 TRIDENT-1 study dataset, as reported by Blinded Independent Central Review (BICR).
 - In TKI-naïve patients in China (EXP-1: n=11), the confirmed objective response rate (cORR) was 91% (95% CI: 59,100).
 - In TKI-pretreated patients in China, the cORR was 67% in those treated with 1 TKI and platinum-based chemotherapy (EXP-2: n=3); the cORR was 50% in those treated with two TKIs globally (EXP-3: n=4); the cORR was 36% in those treated with 1 TKI (EXP-4: n=11).

- In April 2022, Zai Lab partner Turning Point announced positive topline results from the registrational TRIDENT-1 study across all four ROS1-positive advanced NSCLC cohorts, as reported by BICR.
 - In TKI-naïve patients (EXP-1: n=71), the cORR was 79% (95% CI: 68, 88).
 - In TKI-pretreated patients, the cORR was 42% in those treated with 1 TKI and platinum-based chemotherapy (EXP-2: n=26); the cORR was 28% in those treated with two TKIs (EXP-3: n=18); the cORR was 36% in those treated with 1 TKI (EXP-4: n=56).
 - In TKI-pretreated patients with an identified ROS1 G2032R solvent front mutation, the cORR was 59% (n=10/17; 95% CI: 33, 82).
- In March 2022, Zai Lab partner Turning Point announced that the company has achieved its enrollment target of 40 patients in the EXP-6 cohort of the phase 1/2 registrational TRIDENT-1 study. EXP-6 is comprised of NTRK-positive TKI-pretreated advanced solid tumor patients.

Anticipated 2022 Zai Milestones

- Complete enrollment in the phase 1/2 registrational TRIDENT-1 study.
- Discuss the regulatory pathway with the National Medical Products Administration (NMPA) at a pre-NDA meeting in the fourth quarter of 2022.

Anticipated 2022 Partner Milestones

- Discuss the topline BICR data with the FDA at a pre-NDA meeting in the second quarter of 2022.
- Anticipate providing a detailed update from TRIDENT-1 utilizing BICR analyses, including intracranial activity, at an upcoming medical conference in the second half of 2022.
- Provide a clinical data update from the NTRK-positive advanced solid tumor cohorts from TRIDENT-1 in the second half of 2022.

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 March 2022, Zai Lab partner Cullinan Oncology announced the clinical and regulatory updates for CLN-081 in NSCLC EGFR exon 20 patients. Key highlights of 100mg BID dose level in the ongoing Phase 1/2a study:
 - Of 39 response evaluable patients, 16 achieved a confirmed partial response for a 41% cORR.

- No patients have experienced Grade 3 or greater treatment-related diarrhea or rash.
- Promising response durability previously observed in initial phase 1 patient cohort (n=13) with estimated median response duration > 15 months and mPFS of 12 months.

Anticipated 2022 Zai Milestone

- Enroll the first patient in Greater China in the Phase 2a potentially pivotal study in NSCLC.

Anticipated 2022 Partner Milestones

- Updated CLN-081 data accepted for oral presentation at the ASCO 2022 Annual Meeting.
- Initiate a pivotal study in the second half of 2022 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 in the second half of 2022.
- Initiate the Phase 2 portion of the SHIELD-1 study in the second half of 2022, pending FDA feedback on data from the intermediate dose level.
- Initiate the Phase 1b/2 SHIELD-2 combination study of elzovantinib and aumolertinib in mid-2022.

Retifanlimab

Retifanlimab is an investigational monoclonal antibody that inhibits PD-1.

Recent Product Update

- As previously disclosed and based on a review of the clinical data and the changing treatment landscape, we have decided to complete and close trial enrollment for the study of retifanlimab in MSI-H/dMMR endometrial cancer in Greater China.

Anticipated 2022 Partner and Zai Milestone

- Complete enrollment in the global Phase 3 PODIUM-304 study evaluating retifanlimab in combination with platinum-based chemotherapy in patients with first-line metastatic NSCLC.

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 potential treatment of EGFR-driven NSCLC.

Recent Product Highlights

- In April 2022, Zai Lab's partner Blueprint Medicines Corporation announced the proof-of-concept data from the Phase 1/2 SYMPHONY clinical trial of BLU-945 in advanced EGFR-driven NSCLC patients at the 2022 American Association for Cancer Research (AACR) Annual Meeting. The preliminary trial results showed early evidence of safety and clinical activity consistent with preclinical data, supporting plans to expand development of BLU-945 in combination with multiple agents including osimertinib.
- Blueprint Medicines is initiating a cohort in the ongoing Phase 1/2 SYMPHONY trial assessing BLU-945 in combination with osimertinib in patients with second-line or later EGFR-mutant NSCLC.

Anticipated 2022 Partner Milestones

- Present initial clinical data from the dose escalation cohort of the Phase 1/2 SYMPHONY trial evaluating BLU-945 in combination with osimertinib in the second half of 2022.
- 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.

Recent Product Highlight

- Zai Lab's partner Blueprint Medicines presented preclinical data at the AACR Annual Meeting in April 2022 demonstrating potent antitumor activity of BLU-945 and BLU-701 on models of L858R-driven disease, with or without on-target resistance, supporting the development of both investigational agents in combination in the first- and second-line EGFR-driven NSCLC settings.

Anticipated 2022 Partner Milestone

- Present initial Phase 1/2 HARMONY trial data for BLU-701 in EGFR-driven NSCLC in the second half of 2022.

Internal R&D Oncology Programs

Recent Highlights

- In April 2022, Zai Lab presented new data from the internal oncology discovery portfolio at the 2022 AACR Annual Meeting.
 - First preview of preclinical data for ZL-1218, an anti-CCR8 antibody, in an oral presentation.
 - Poster presentations featured ZL-1201 (anti-CD47 antibody) for advanced hematologic malignancies and solid tumors, ZL-1211 (anti-CLDN18.2 antibody) for gastric and pancreatic cancer and ZL-2201 (DNA-PK inhibitor) for solid tumors.

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

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

Anticipated 2022 Zai Milestone

- Initiate a Phase 2 proof-of-concept study in the second quarter of 2022.

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.

Anticipated 2022 Zai Milestone

- Determine a recommended Phase 2 dose in the ongoing Phase 1 trial in mid-2022.

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 May 2022, Zai Lab partner argenx announced positive topline data from the Phase 3 ADVANCE trial of efgartigimod for the treatment of primary immune thrombocytopenia (ITP). ADVANCE met its primary endpoint demonstrating a significantly higher proportion of patients with chronic ITP receiving efgartigimod (17/78; 21.8%) compared to placebo (2/40; 5%) achieved a sustained platelet response ($p=0.0316$). Key platelet-derived secondary endpoints also demonstrated statistical significance.
- In April 2022, Zai Lab partner argenx announced interim results from the ongoing Phase 3 ADAPT+ study, an open-label, extension study evaluating the long-term efficacy, safety, and tolerability of efgartigimod for the treatment of adults with generalized myasthenia gravis (gMG). Interim data suggest that efgartigimod provides consistent improvement over multiple treatment cycles with a safety profile as seen in the Phase 3 ADAPT study.
- In March 2022, Zai Lab partner argenx announced positive topline data from the Phase 3 ADAPT-SC study evaluating subcutaneous (SC) efgartigimod for the treatment of gMG. SC efgartigimod achieved the primary endpoint of total IgG reduction from baseline at Day 29, demonstrating statistical noninferiority to the intravenous (IV) formulation of efgartigimod in gMG patients.

Anticipated 2022 Zai Milestones

- Submit the NDA to the NMPA for gMG in mid-2022.
- Launch proof-of-concept trials in two autoimmune renal diseases in 2022.
- Continue to explore and advance additional indications in coordination with argenx.

Anticipated 2022 Partner Milestones

- Initiate the registrational ALKIVIA trial in the second 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 SC efgartigimod in gMG by the end of 2022.

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).

Anticipated 2022 Zai Milestone

- Initiate a global Phase 2 study for CPP in the second half of 2022.

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 National Reimbursement Drug List (NRDL) inclusion for CABP and ABSSSI indications.
- Submit Zai Lab's plan for post-approval studies in the second half of 2022.

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.

Recent Product Highlight

- In April 2022, Zai Lab partner Entasis Therapeutics presented top-line data from the pivotal Phase 3 ATTACK trial at the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) Annual Conference in Lisbon.

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 mid-2022.

Neuroscience

KarXT

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

Anticipated 2022 Zai Milestones

- Seek regulatory agreement with the NMPA on a China program in schizophrenia in mid-2022.
- Initiate the bridging study program.

Anticipated 2022 Partner Milestones

- The Phase 3 EMERGENT-2 trial completed enrollment in the second quarter of 2022. Topline data from the trial anticipated in the third quarter of 2022.
- Initiate Phase 3 program evaluating KarXT as a treatment for psychosis in Alzheimer's disease in mid-2022. Details of the program to be shared in the first half of 2022.

Corporate Updates

- In April 2022, Zai Lab announced that the Audit Committee of its Board of Directors has approved the engagement of KPMG LLP (KPMG) as Zai Lab's independent registered public accounting firm. KPMG will be engaged to audit the annual consolidated financial statements of Zai Lab and its subsidiaries filed with the U.S. Securities and Exchange Commission and our internal controls over financial reporting for the fiscal year ending December 31, 2022. Zai Lab expects that this transition to an audit firm located in the United States and subject to inspection by the Public Company Accounting Oversight Board (PCAOB) enables Zai Lab to comply with the audit requirements of the Holding Foreign Companies Accountable Act and, if so, will facilitate its continued listing on Nasdaq.
- In March 2022, the shareholders of Zai Lab approved a one-to-ten share subdivision, effective March 30, 2022. The one-to-ten share subdivision will increase the number of ordinary shares of Zai Lab in issue and reduce the nominal value and trading price of each ordinary share. The Board of Directors of the Company believes that this will increase the trading liquidity of the ordinary shares, lower the investment barrier, and will attract more investors to trade in the ordinary shares. The share subdivision did not result in any change to the number of outstanding American Depositary Shares (ADSs) of the Company.
- Zai Lab continues to strengthen and expand its global leadership team. In March 2022, Zai Lab announced the appointment of Josh Smiley as its Chief Operating Officer (COO), effective in August 2022. Mr. Smiley brings over 26 years of experience working within the biopharmaceutical industry, including experience leading finance, corporate strategy, business development, venture capital, and the Global Business Services operations at Eli Lilly and Co (Lilly).

- As of March 31, 2022, Zai Lab employed 1,999 full-time employees, including 825 and 950 employees engaged in R&D and commercial activities, respectively.

First-Quarter 2022 Financial Results

- For the three months ended March 31, 2022, total revenues were \$46.7 million, compared to \$20.1 million for the same period in 2021. Product revenues for the period were \$29.6 million for ZEJULA, compared to \$12.6 million for the same period in 2021; \$12.8 million for Optune, compared to \$7.1 million for the same period in 2021; \$3.0 million for QINLOCK, compared to \$0.4 million for the same period in 2021, and \$0.7 million for NUZYRA, compared to nil for the same period in 2021.
- Research and Development (R&D) expenses were \$53.9 million for the three months ended March 31, 2022, compared to \$203.9 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 late-stage clinical trials and higher payroll and payroll-related expenses from increased R&D headcount. Excluding upfront payment for new licensing agreements, core R&D expenses were \$53.9 million for the three months ended March 31, 2022, compared to \$41.6 million for the same period in 2021.
- Selling, General and Administrative (SG&A) expenses were \$57.0 million for the three months ended March 31, 2022, compared to \$35.8 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 substantial topline growth over the next few years.
- Net Loss was \$82.4 million for the three months ended March 31, 2022 compared to \$232.9 million for the same period in 2021, primarily due to no upfront payment for new licensing agreements. Net loss per ordinary share during the three months ended March 31, 2022 was \$0.09, compared to \$0.26 for the same period in 2021. Net loss per ADS during the three months ended March 31, 2022 was \$0.86, compared to \$2.64 for the same period in 2021.
- As of March 31, 2022, cash and cash equivalents, short-term investments and restricted cash totaled \$1,313.0 million compared to \$1,409.9 million as of December 31, 2021.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, May 11, 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: <http://apac.directeventreg.com/registration/event/5185688>

Conference ID: 5185688

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 (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing, and commercializing our portfolio to impact human health worldwide.

For additional information about Zai Lab, including information on our products, business activities and partnerships, research, or other events or developments that may be of interest to investors, 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; our key data readouts and regulatory filings across our entire portfolio; our plans to file the NDA for efgartigimod in China and for our other products and product candidates in China and elsewhere; 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 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.

For more information about our SEC filings, please go to 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)

| | As of | |
|---|------------------|----------------------|
| | March 31, 2022 | December 31, 2021 |
| | \$ | \$ |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | 846,957 | 964,100 |
| Short-term investments | 465,274 | 445,000 |
| Accounts receivable (net of allowance for credit loss of \$10 and \$11 as of March 31, 2022 and December 31, 2021, respectively) | 33,394 | 47,474 |
| Notes receivable | 10,848 | 7,335 |
| Inventories | 20,288 | 18,951 |
| Prepayments and other current assets | 16,490 | 18,021 |
| Total current assets | 1,393,251 | 1,500,881 |
| Restricted cash, non-current | 803 | 803 |
| Long term investments (including the fair value measured investment of \$8,444 and \$15,383 as of March 31, 2022 and December 31, 2021, respectively) | 8,444 | 15,605 |
| Prepayments for equipment | 4,978 | 989 |
| Property and equipment, net | 45,227 | 43,102 |
| Operating lease right-of-use assets | 16,986 | 14,189 |
| Land use rights, net | 7,774 | 7,811 |
| Intangible assets, net | 1,745 | 1,848 |
| Long-term deposits | 941 | 870 |
| Value added tax recoverable | 20,766 | 23,858 |
| Total assets | 1,500,915 | 1,609,956 |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Accounts payable | 98,161 | 126,163 |
| Current operating lease liabilities | 6,795 | 5,927 |
| Other current liabilities | 49,956 | 60,811 |
| Total current liabilities | 154,912 | 192,901 |
| Deferred income | 26,896 | 27,486 |
| Non-current operating lease liabilities | 11,099 | 9,613 |
| Total liabilities | 192,907 | 230,000 |
| Shareholders' equity | | |
| Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 957,035,440 and 955,363,980 shares issued as of March 31, 2022 and December 31, 2021, respectively; 956,637,360 and 954,981,050 shares outstanding as of March 31, 2022 and December 31, 2021, respectively) | 6 | 6 |
| Additional paid-in capital | 2,838,655 | 2,825,948 |
| Accumulated deficit | (1,500,468) | (1,418,074) |
| Accumulated other comprehensive loss | (25,838) | (23,645) |
| Treasury Stock (at cost, 398,080 and 382,930 shares as of March 31, 2022 and December 31, 2021, respectively) | (4,347) | (4,279) |
| Total shareholders' equity | 1,308,008 | 1,379,956 |
| Total liabilities and shareholders' equity | 1,500,915 | 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 March 31, | |
|--|-------------------------------------|------------------|
| | 2022 | 2021 |
| | \$ | \$ |
| Revenues: | | |
| Product revenue, net | 46,095 | 20,103 |
| Collaboration revenue | 629 | — |
| Total revenues | 46,724 | 20,103 |
| Expenses: | | |
| Cost of sales | (15,643) | (7,505) |
| Research and development | (53,854) | (203,852) |
| Selling, general and administrative | (56,991) | (35,838) |
| Loss from operations | (79,764) | (227,092) |
| Interest income | 188 | 214 |
| Other expenses, net | (2,597) | (6,227) |
| Loss before income tax and share of loss from equity method investment | (82,173) | (233,105) |
| Income tax expense | — | — |
| Share of income (loss) from equity method investment | (221) | 195 |
| Net loss | (82,394) | (232,910) |
| Net loss attributable to ordinary shareholders | (82,394) | (232,910) |
| Loss per share - basic and diluted | (0.09) | (0.26) |
| Weighted-average shares used in calculating net loss per ordinary share - basic and diluted (Note) | 955,499,030 | 883,749,280 |
| Loss per American Depositary Shares (“ADS”) (Note) - basic and diluted | (0.86) | (2.64) |
| Weighted-average ADS used in calculating net loss per ADS - basic and diluted | 95,549,903 | 88,374,928 |

Note: Basic and diluted net loss per ordinary share, weighted average number of ordinary shares for the three months ended March 31, 2021 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 March 31, | |
|---|-------------------------------------|------------------|
| | 2022 | 2021 |
| | \$ | \$ |
| Net loss | (82,394) | (232,910) |
| Other comprehensive (loss) income, net of tax of nil: | | |
| Foreign currency translation adjustments | (2,193) | 2,900 |
| Comprehensive loss | <u>(84,587)</u> | <u>(230,010)</u> |