

**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): March 1, 2023

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 March 1, 2023, Zai Lab Limited issued a press release announcing its financial results for the year ended December 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**

Exhibit No.	Description
99.1	Press Release issued by Zai Lab Limited on March 1, 2023.
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: March 1, 2023



Zai Lab Announces Full-Year 2022 Financial Results and Recent Corporate Updates

- Total revenue of \$215.0 million for 2022, representing a 49.0% increase y-o-y; ZEJULA[®] achieved 55.2% y-o-y growth
- Strong balance sheet with a cash position of \$1.0 billion as of December 31, 2022
- Company to host conference call and webcast on March 2, 2023, at 8:00 a.m. EST

SHANGHAI and CAMBRIDGE, Mass., March 1, 2023 -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced full-year 2022 financial results, along with recent product highlights and corporate updates.

“In 2022, our four marketed products each had substantial sales growth, and we made exciting progress across our pipeline globally,” said Dr. Samantha Du, Founder, Chief Executive Officer, and Chairperson of the Board of Directors of Zai Lab. “Our pipeline assets continued to demonstrate potential global best-in-class and/or first-in-class profile with numerous positive late-stage data readouts announced during the year, including adagrasib in non-small cell lung cancer, KarXT in schizophrenia, and efgartigimod in primary immune thrombocytopenia and generalized myasthenia gravis. We are also pleased to have contributed to several successful registrational studies, including the Tumor Treating Fields LUNAR study and the repotrectinib TRIDENT-1 study. We are also pleased to have added QINLOCK and NUZYRA to China’s National Reimbursement Drug List (NRDL) in 2023. We further deepened our women’s cancer franchise through our strategic collaboration with Seagen for TIVDAK. And, we continued to significantly enhance our talented global team.”

“Zai Lab is already a leading global biotech with relevant scale, a world-class pipeline, and a growing commercial portfolio in China. We expect to achieve commercial profitability this year, and we are preparing to launch at least 8 additional products and achieve overall corporate profitability by the end of 2025,” Dr. Du continued. “We will continue to invest in research and development as we seek to advance our product pipeline, including our internal discovery activities, and accelerate medicines to patients in need. We also aim to strengthen our portfolio and strategic positioning with potentially transformative assets and partnerships.”

“We believe that the global regulatory environment will continue to be supportive of innovative biopharmaceutical companies like Zai Lab,” Dr. Du concluded. “We will continue to build on our success in pursuit of our overall goal of improving human health, in China and globally.”

2023 Strategic Priorities

Zai Lab will focus on the following strategic priorities in 2023 to drive innovation in China and beyond:

Regulatory and Commercial

- BLA approval by China’s National Medical Products Administration (NMPA) and commercial launch for efgartigimod alfa injection for the treatment of adult patients with generalized myasthenia gravis (gMG)
- NDA submission to the NMPA for repotrectinib for ROS1+ advanced non-small cell lung cancer (NSCLC)
- BLA submission to the NMPA for subcutaneous (SC) efgartigimod for gMG in mid-2023
- ZEJULA becoming the leader in PARP inhibitors sales for ovarian cancer in China
- A significant increase in sales of QINLOCK and NUZYRA following their inclusion on the NRDL

Research and Clinical Development

- Topline data readouts of the SC efgartigimod study for chronic inflammatory demyelinating polyneuropathy (CIDP) in the second quarter of 2023, and for pemphigus and immune thrombocytopenia (ITP) in the second half of 2023
- Full data readout of the Tumor Treating Fields LUNAR study in NSCLC in the first half of 2023

- Clinical data update for adagrasib in combination with pembrolizumab in first-line KRAS^{G12C}-mutated NSCLC in the second half of 2023
- Complete enrollment in the global Phase 3 innovaTV 301 study of TIVDAK in second- and third-line cervical cancer in the first half of 2023
- Join the global Phase 3 FORTITUDE-101 study of bemarituzumab in first-line gastric cancer in China in mid-2023
- Initiate a bridging study of KarXT for schizophrenia in China in mid-2023
- Initiate a global Phase 2 study for ZL-1102 (IL-17 Humabody[®]) in chronic plaque psoriasis (CPP)
- Initiate a global Phase 1 study for ZL-1218 (CCR8) in the first half of 2023

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 (FDA), the European Union (EMA), and mainland China (NMPA) as a first-line maintenance monotherapy for patients with advanced ovarian cancer, regardless of their biomarker status.

Recent Product Highlights

- In February 2023, Zai Lab received the complete approval of ZEJULA in first-line ovarian cancer maintenance treatment by the NMPA. The complete approval was based on the data of Phase 3 PRIME study in Chinese patients.
- In December 2022, Zai Lab presented new interim overall survival (OS) data in Chinese patients with platinum-sensitive recurrent ovarian cancer (PSROC) from the Phase 3 NORA study for ZEJULA at the European Society for Medical Oncology (ESMO) Virtual Plenary.
 - Median OS (mOS) was numerically longer for patients receiving ZEJULA regardless of biomarker status, at 46.3 months compared to 43.4 months in the placebo group [HR=0.82; 95% CI, 0.56-1.21].
 - Based on the OS analysis adjusted for subsequent PARP inhibitor therapy, mOS for patients receiving ZEJULA was 46.3 months compared to 34.3 months in the placebo group [HR=0.69; 95% CI, 0.45-1.07].
 - No new safety issues were identified based on long-term follow-up.

Anticipated 2023 Zai Milestone

- Present final OS analysis of the Phase 3 NORA study.

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, including the United States, Greater China (mainland China, Hong Kong, Macau, and Taiwan), Europe, and Japan, for the treatment of newly diagnosed and recurrent glioblastoma and malignant pleural mesothelioma.

Recent Product Highlights

- In March 2023, NovoCure Ltd. announced that the last patient has been enrolled in the pivotal METIS study evaluating the efficacy of TTFields therapy following stereotactic radiosurgery (SRS) for treatment of patients with brain metastases resulting from NSCLC. Zai Lab participated in the study in Greater China.
- In February 2023, NovoCure announced that the last patient has been enrolled in the pivotal PANOVA-3 study evaluating the efficacy of TTFields together with nab-paclitaxel and gemcitabine for treatment of patients with locally advanced pancreatic cancer. Zai Lab participated in the study in Greater China.

- In January 2023, Zai Lab and NovoCure announced that the pivotal LUNAR study for patients with stage 4 NSCLC who progressed during or after platinum-based therapy met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in OS for patients treated with TTFIELDS and standard therapies (either immune checkpoint inhibitor or docetaxel) versus standard therapies alone.
- As of December 31, 2022, Optune had been listed in 87 regional customized commercial health insurance plans guided by provincial or municipal governments (or supplemental insurance plans) since its commercial launch in mainland China for the treatment of glioblastoma in the third quarter of 2020, up from 33 such plans as of December 31, 2021.
- In November 2022, the Marketing Authorization Application (MAA) for malignant pleural mesothelioma was accepted by the NMPA.

Anticipated 2023 Partner and Zai Milestones

- Present data from the LUNAR study in NSCLC at a future medical conference.
- Provide topline data readout from the pivotal INNOVATE-3 clinical study testing the efficacy of TTFIELDS together with paclitaxel in platinum-resistant ovarian cancer in the second half of 2023.

QINLOCK® (ripretinib)

QINLOCK is an orally administered 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 mainland China for the treatment of 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

- In January 2023, the NRDL released by China's National Healthcare Security Administration (NHSA) was updated to include QINLOCK for advanced GIST patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting.
- In January 2023, Zai Lab partner Deciphera Pharmaceuticals, Inc. (Deciphera) presented additional data from the planned exploratory analysis from the INTRIGUE Phase 3 clinical study of QINLOCK using circulating tumor DNA (ctDNA) for second-line GIST patients. Patients with mutations in *KIT* exon 11 and 17 and/or 18 and the absence of mutations in *KIT* exon 9, 13, and/or 14 (also referred to as patients with mutations in *KIT* exon 11 and 17/18) derived substantially improved clinical benefit with QINLOCK versus sunitinib. Deciphera plans to initiate the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in *KIT* exon 11 and 17/18 in the second half of 2023.

TIVDAK® (tisotumab vedotin)

TIVDAK is an antibody-drug conjugate (ADC) composed of Genmab's human monoclonal antibody directed against cell surface tissue factor (TF) and Seagen's ADC technology that utilizes a protease-cleavable linker that covalently attaches the microtubule-disrupting agent monomethyl auristatin E (MMAE) to the antibody.

Recent Product Highlight

- In February 2023, Zai Lab dosed the first patient in China for the global Phase 3 confirmatory innovaTV 301 study in second- or third-line recurrent or metastatic (r/m) cervical cancer.

Anticipated 2023 Partner and Zai Milestone

- Complete global patient enrollment for the innovaTV 301 study in the first half of 2023, with potential for topline data readout by year-end 2023.

Anticipated 2023 Partner Milestones

- Clinical data update for the innovaTV 207 study in head and neck cancer in the first half of 2023.
- Clinical data update for the innovaTV 205 study in first-line+ r/m cervical cancer in the second half of 2023.

KRAZATI™ (adagrasib)

KRAZATI™ 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 December 2022, Zai Lab partner Mirati Therapeutics, Inc. (Mirati) announced that the FDA has granted Breakthrough Therapy Designation (BTD) to adagrasib in combination with cetuximab in patients with KRAS^{G12C}-mutated, advanced CRC whose cancer has progressed following prior treatment with chemotherapy and an anti-VEGF therapy. This designation is supported by results from the Phase 1b cohort of the KRYSTAL-1 trial. Zai Lab is participating in the KRYSTAL-10 Phase 3 trial in patients with second-line KRAS^{G12C}-mutated CRC.
- In December 2022, Mirati announced that the FDA has granted accelerated approval for KRAZATI™, a targeted treatment option for adult patients with KRAS^{G12C}-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy.
- In December 2022, Mirati reported results from the KRYSTAL-7 Phase 2 trial and KRYSTAL-1 Phase 1b cohort evaluating adagrasib concurrently combined with pembrolizumab in patients for the treatment of first-line NSCLC harboring a KRAS^{G12C} mutation across all PD-L1 subgroups. These results are the first to demonstrate the tolerability and feasibility of a concurrent combination regimen of a KRAS^{G12C} inhibitor and a PD-1/L1 checkpoint inhibitor.

Anticipated 2023 Partner and Zai Milestones

- Provide a clinical data update for adagrasib in combination with pembrolizumab in first-line KRAS^{G12C}-mutated NSCLC in the second half of 2023.
- Initiate Phase 3 studies in first-line KRAS^{G12C}-mutated NSCLC in 2023.

Anticipated 2023 Partner Milestones

- Submit the supplemental New Drug Application (sNDA) in third-line+ KRAS^{G12C}-mutated advanced CRC by year end 2023, and move forward with Accelerated Approval pathway.
- Provide a clinical data update for pancreatic cancer and other solid tumors in the second quarter of 2023.

Bemarituzumab

Bemarituzumab is a potential first-in-class humanized monoclonal antibody that is in clinical development as a targeted therapy for gastric and gastroesophageal junction cancer patients whose tumors overexpress FGFR2b.

Recent Product Highlight

- Zai Lab partner Amgen Inc. 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, Phase 3 portion of a Phase 1b/3 study of bemarituzumab plus chemotherapy and nivolumab versus chemotherapy and nivolumab in first-line gastric cancer with FGFR2b overexpression.

Anticipated 2023 Zai Milestones

- Join the global Phase 3 FORTITUDE-101 study in first-line gastric cancer in China in mid-2023.
- Join the global Phase 3 FORTITUDE-102 study in first-line gastric cancer in China.

Odronextamab

Odronextamab is an investigational bispecific monoclonal 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

- In December 2022, Zai Lab partner Regeneron announced positive first interim data from the ELM-2 Phase 2 trial in patients with heavily pre-treated, relapsed/refractory (R/R) follicular lymphoma (FL) and R/R diffuse large B-cell lymphoma (DLBCL). The data were presented at the 64th American Society of Hematology Annual Meeting.

Anticipated 2023 Zai Milestone

- Complete enrollment in China in the registrational global ELM-2 Phase 2 trial in B-Cell Non-Hodgkin Lymphoma (B-NHL) in the first quarter of 2023.

Anticipated 2023 Partner Milestones

- Initiate confirmatory studies in FL and DLBCL, including in earlier lines in the first half of 2023.
- Submit a Biologics License Application (BLA) for R/R DLBCL and R/R FL in the second half of 2023.

Repotrectinib

Repotrectinib is an investigational next-generation tyrosine kinase inhibitor (TKI) designed to effectively target ROS1 and TRK A/B/C in TKI-naïve or TKI-pretreated cancer patients.

Anticipated 2023 Zai Milestones

- Discuss regulatory pathway with the NMPA at a pre-NDA meeting in the first quarter of 2023.
- Submit an NDA to the NMPA for ROS1+ advanced NSCLC in 2023.

Zipalertinib (previously CLN-081)

Zipalertinib is an orally available small molecule designed as a next-generation, irreversible epidermal growth factor receptor (EGFR) inhibitor in development for the treatment of patients with EGFR exon 20 insertion NSCLC.

Recent Product Highlight

- Zai Lab partner Taiho Pharmaceuticals (which acquired Cullinan Pearl in 2022) initiated a pivotal study of zipalertinib in patients with EGFR exon 20 insertion NSCLC progressing after prior systemic therapy in the fourth quarter of 2022.

MARGENZA™ (margetuximab)

MARGENZA is an investigational, immune-enhancing monoclonal antibody that targets human epidermal growth factor receptor 2 (HER2)-positive tumors, including certain types of breast and gastroesophageal cancers.

Anticipated 2023 Zai Milestone

- Potential China NDA approval by the NMPA in third-line+ metastatic HER2-positive breast cancer in 2023.

BLU-945

BLU-945 is a potential next-generation investigational oral EGFR inhibitor designed to selectively target the EGFR L858R activating mutation as well as C797X and T790M on-target resistance mutations, while being highly selective against wild-type EGFR. BLU-945 is in development for the potential treatment of EGFR-mutant NSCLC.

Anticipated 2023 Partner Milestone

- Provide an initial clinical data update on SYMPHONY trial expansion of BLU-945 in combination with osimertinib in first-line EGFR L858R-positive NSCLC in the second half of 2023.

Retifanlimab

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

Recent Product Update

- Based on the shifting competitive landscape, Zai Lab has terminated the collaboration with Incyte for the development and commercialization of retifanlimab in Greater China, effective January 11, 2023. Zai Lab will continue to support Incyte with the transition of on-going clinical trials, such as the China portion of the Phase 3 global study for NSCLC and the Phase 1 global study for endometrial cancer.

Internal Oncology R&D Programs (Global Rights)

Recent Update

- ZL-1211 (Claudin18.2) translational and clinical biomarker data will be presented in a poster at the upcoming American Association for Cancer Research (AACR) conference in April 2023.

Anticipated 2023 Zai Milestone

- Initiate a global Phase 1 study for ZL-1218 (CCR8) in the first half of 2023.

Autoimmune Disorders

VYVGART® (efgartigimod)

Efgartigimod is an investigational antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies 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 February 2023, Zai Lab initiated enrollment of two proof-of-concept trials in autoimmune renal diseases.
- As of December 31, 2022, efgartigimod had been listed in 15 supplemental insurance plans in China.
- In November 2022, Zai Lab partner argenx announced the FDA has accepted for priority review a BLA for SC efgartigimod for the treatment of adult patients with gMG.

Anticipated 2023 Zai Milestones

- Potential BLA approval by the NMPA for efgartigimod alfa injection for the treatment of adult patients with gMG in China.
- Potential BLA submission to the NMPA for SC efgartigimod for the treatment of adult patients with gMG in mid-2023.
- Join the global Phase 2/3 BALLAD study in adult patients with bullous pemphigoid in China.
- Continue to explore and advance additional indications in coordination with argenx.

Anticipated 2023 Partner Milestones

- Potential BLA approval by the FDA for SC efgartigimod for gMG in the first half of 2023, with the Prescription Drug User Fee Act (PDUFA) date of June 20, 2023.
- Report topline data from the registrational ADHERE trial of SC efgartigimod for CIDP in the second quarter of 2023.
- Report topline data from the registrational Phase 3 ADDRESS trial of SC efgartigimod in pemphigus and the registrational Phase 3 ADVANCE-SC trial of SC efgartigimod in ITP in the second half of 2023.

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

ZL-1102 is a 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 2023 Zai Milestone

- Initiate a global Phase 2 study for CPP.

Infectious Disease

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

Sulbactam-Durlobactam is a combination of a beta-lactam antibiotic (sulbactam) and a beta-lactamase inhibitor (durlobactam) for the treatment of serious infections caused by Acinetobacter, including multi-drug and carbapenem-resistant strains.

Recent Product Highlights

- In February 2023, China's NMPA accepted the NDA for SUL-DUR for the treatment of infections caused by *Acinetobacter baumannii*, including multidrug-resistant and carbapenem-resistant (CRAB) strains. Previously, in January 2023, the NMPA granted priority review status to the NDA for SUL-DUR.
- In November 2022, Zai Lab partner Entasis Therapeutics announced that the FDA accepted the NDA for SUL-DUR for priority review with an action date of May 29, 2023.

Anticipated 2023 Partner Milestone

- Potential NDA approval by the FDA.

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) in both hospital and community settings.

Recent Product Highlight

- In January 2023, the NRDL released by China's NHTA was updated to include NUZYRA for the treatment of adults with CABP and ABSSSI for intravenous (IV) formulation.

Neuroscience

KarXT

KarXT (xanomeline-trospium) is an oral, investigational M1/M4-preferring muscarinic acetylcholine receptor agonist in development for the treatment of psychiatric and neurological conditions, including schizophrenia and dementia-related psychosis.

Anticipated 2023 Zai Milestone

- Initiate a bridging study for the treatment of patients with schizophrenia in China in mid-2023.

Anticipated 2023 Partner Milestones

- Report topline data from the Phase 3 EMERGENT-3 trial in schizophrenia in the first quarter of 2023.
- Submit an NDA to the FDA for KarXT in schizophrenia in mid-2023.
- Initiate the Phase 3 ADEPT-2 trial in Alzheimer's disease psychosis in the second half of 2023.

Corporate Updates

- In January 2023, Michel Vounatsos was appointed to Zai Lab's Board of Directors. Mr. Vounatsos brings to the Board extensive global leadership and management experience in the biopharmaceutical industry, including more than 25 years of service at leading companies. His expertise includes significant commercial experience in China and worldwide.

- In the fourth quarter of 2022, Zai Lab continued to enhance its global leadership team. In December 2022, Zai Lab appointed Rafael G. Amado, M.D. as President, Head of Global Oncology Research and Development. Dr. Amado joined the Company from Allogene Therapeutics and brings to Zai Lab deep expertise in the field of oncology and significant global biopharmaceutical R&D leadership.
- In 2022, we established our ESG Trust for Life strategy, which includes three commitments: improve human health, create better outcomes, and act right now with ethical business practices and strong corporate governance. As part of our corporate strategy, and the actions taken in support of our corporate goals, we seek to continue to develop and integrate our Trust for Life strategy into our business and operations.

Financial Results for Full-Year 2022

- Total revenues for 2022 were \$215.0 million, an increase of 49.0% compared to 2021. This included total revenues of \$62.6 million for the fourth quarter of 2022, an increase of 41.7% compared to the fourth quarter of 2021.
- Product revenues for 2022 were \$145.2 million for ZEJULA, an increase of 55.2% y-o-y; \$47.3 million for Optune, an increase of 21.6% y-o-y; \$15.0 million for QINLOCK, an increase of 28.7% y-o-y; and \$5.2 million for NUZYRA, compared to close to zero in 2021.
- Research and Development (R&D) expenses were \$286.4 million in 2022, compared to \$573.3 million for the same period in 2021. This decrease was primarily due to lower upfront payment for new licensing agreements, partially offset by higher payroll and payroll-related expenses from increased R&D headcount and an increase in expenses related to ongoing and newly initiated late-stage clinical trials. Excluding upfront payment for new licensing agreements, R&D expenses were \$256.4 million in 2022, compared to \$252.0 million in 2021.
- Selling, General and Administrative (SG&A) expenses were \$259.0 million in 2022, compared to \$218.8 million for the same period in 2021. This increase was primarily due to higher payroll and payroll-related expenses from increased headcount, as Zai Lab continued to expand and invest in its commercial operations in China and infrastructure in the United States in anticipation of substantial growth over the next few years.
- Zai Lab reported a net loss of \$443.3 million, or a loss per share attributable to common stockholders of \$0.46, for 2022, compared to a net loss of \$704.5 million, or a loss per share attributable to common stockholders of \$0.76, for 2021. The decrease in the net loss was primarily attributable to payments related to new business development activities.
- As of December 31, 2022, cash and cash equivalents, short-term investments and restricted cash totaled \$1,009.3 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, March 2, 2023, 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/BI7e1f2dd4243c461585564c4b7dd866a6>

All participants must use the link provided above to complete the online registration process in advance of the conference call. Dial-in details will be in the confirmation email which the participant will receive upon registering.

A replay will be available shortly after the call and can be accessed by visiting the Company's website.

About Zai Lab

Zai Lab (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, 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 and related clinical trials; 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 products and product candidates and those of our collaboration partners; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; and financial guidance. 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 COVID-19 pandemic on our business and results of operations; (6) risks related to doing business in China; and (7) other factors identified in our most recent annual report 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

Consolidated Balance Sheets

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

	December 31,	
	2022	2021
	\$	\$
Assets		
Current assets		
Cash and cash equivalents	1,008,470	964,100
Short-term investments	—	445,000
Accounts receivable (net of allowance for credit loss of \$11 as of December 31, 2022 and 2021, respectively)	39,963	47,474
Notes receivable	8,608	7,335
Inventories, net	31,621	18,951
Prepayments and other current assets	35,674	18,021
Total current assets	1,124,336	1,500,881
Restricted cash, non-current	803	803
Long-term investments (including the fair value measured investment of \$6,431 and \$15,383 as of December 31, 2022 and 2021, respectively)	6,431	15,605
Prepayments for equipment	1,396	989
Property and equipment, net	57,863	43,102
Operating lease right-of-use assets	19,512	14,189
Land use rights, net	6,892	7,811
Intangible assets, net	1,511	1,848
Long-term deposits	1,396	870
Value added tax recoverable	—	23,858
Total assets	1,220,140	1,609,956
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	65,974	126,163
Current operating lease liabilities	7,050	5,927
Other current liabilities	66,818	60,811
Total current liabilities	139,842	192,901
Deferred income	21,360	27,486
Non-current operating lease liabilities	13,343	9,613
Total liabilities	174,545	230,000
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized, 962,455,850 and 955,363,980 shares issued as of December 31, 2022 and 2021, respectively; 960,219,570 and 954,981,050 shares issued and outstanding as of December 31, 2022 and 2021, respectively)	6	6
Additional paid-in capital	2,893,120	2,825,948
Accumulated deficit	(1,861,360)	(1,418,074)
Accumulated other comprehensive income (loss)	25,685	(23,645)
Treasury stock (at cost, 2,236,280 and 382,930 shares as of December 31, 2022 and 2021, respectively)	(11,856)	(4,279)
Total shareholders' equity	1,045,595	1,379,956
Total liabilities and shareholders' equity	1,220,140	1,609,956

Zai Lab Limited

Consolidated Statements of Operations

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

	Year Ended December 31,		
	2022	2021	2020
	\$	\$	\$
Revenues			
Product revenue, net	212,672	144,105	48,958
Collaboration revenue	2,368	207	—
Total revenues	<u>215,040</u>	<u>144,312</u>	<u>48,958</u>
Expenses			
Cost of sales	(74,018)	(52,239)	(16,736)
Research and development	(286,408)	(573,306)	(222,711)
Selling, general and administrative	(258,971)	(218,831)	(111,312)
Loss from operations	<u>(404,357)</u>	<u>(700,064)</u>	<u>(301,801)</u>
Interest income	14,582	2,190	5,120
Interest expenses	—	—	(181)
Foreign currency (loss) gain	(56,403)	4,661	21,659
Other income (expenses), net	3,113	(10,201)	7,417
Loss before income tax and share of loss from equity method investment	<u>(443,065)</u>	<u>(703,414)</u>	<u>(267,786)</u>
Income tax expense	—	—	—
Share of loss from equity method investment	(221)	(1,057)	(1,119)
Net loss	<u>(443,286)</u>	<u>(704,471)</u>	<u>(268,905)</u>
Loss per share — basic and diluted	(0.46)	(0.76)	(0.35)
Weighted-average shares used in calculating net loss per ordinary share — basic and diluted	958,067,140	929,921,120	776,677,430
Loss per American Depositary Shares (“ADS”) - basic and diluted	(4.63)	(7.58)	(3.46)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted	95,806,714	92,992,112	77,667,743

Note: Basic and diluted net loss per ordinary share, weighted average number of ordinary shares for the year ended December 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**Consolidated Statements of Comprehensive Loss****(In thousands of U.S. dollars (“\$”) except for number of shares and per share data)**

	Year Ended December 31,		
	2022	2021	2020
	\$	\$	\$
Net loss	(443,286)	(704,471)	(268,905)
Other comprehensive income (loss), net of tax of nil:			
Foreign currency translation adjustments	49,330	(9,121)	(19,144)
Comprehensive loss	(393,956)	(713,592)	(288,049)