

**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, 2021**

**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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>American Depositary Shares, each representing 1 Ordinary Share, par value \$0.00006 per share</b>	<b>ZLAB</b>	<b>The Nasdaq Global Market</b>
<b>Ordinary Shares, par value \$0.00006 per share*</b>	<b>9688</b>	<b>The Stock Exchange of Hong Kong Limited</b>

\* 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, 2021, Zai Lab Limited issued a press release announcing its financial results for the three months ended June 30, 2021. 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**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by Zai Lab Limited on August 9, 2021.</a>
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, 2021



## Zai Lab Announces Second Quarter 2021 Financial Results and Corporate Updates

— Company to Host Conference Call and Webcast on August 10, 2021, at 8:00 a.m. EDT

SHANGHAI and SAN FRANCISCO, August 9, 2021 — Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced financial results for the second quarter of 2021, along with recent product highlights and corporate updates.

“Consistent with our past track record, Zai Lab continued to execute with speed and quality across the organization during the second quarter,” said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. “We successfully launched QINLOCK, the first product in what we hope will become a world-class gastric cancer franchise, in China; generated strong revenue growth from ZEJULA and Optune; and entered into strategic collaborations with Mirati, MacroGenics and Schrödinger to further strengthen our disease strongholds in oncology and our global pipeline.

“We anticipate achieving multiple regulatory milestones across our product pipeline throughout 2021, including the potential approval of NUZYRA for community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) by the NMPA. We also continue to make progress in numerous regulatory activities, and we anticipate a discussion with the NMPA in the near future on the filing strategy for efgartigimod. In addition, we anticipate many important data readouts and updates in the remainder of this year, including for Tumor Treating Fields in ovarian cancer, for QINLOCK in second-line GIST, for margetuximab in gastric cancer, for CLN-081 in non-small cell lung cancer (NSCLC), for TPX-0022 in NSCLC and gastric cancer, for adagrasib in NSCLC and colorectal cancer, and for other product candidates in our global pipeline.

“We are focused more than ever on our mission to build a leading global biopharmaceutical company addressing the unmet medical needs of patients in China and around the world, Dr. Du concluded.

### **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 once-daily PARP inhibitor approved in the United States, the European Union and mainland China (hereinafter, “China”) as a monotherapy maintenance treatment for patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy, regardless of their biomarker status.*

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### *Recent Product Highlight*

- Zai Lab has made significant progress in recent months in the number of hospitals that list ZEJULA as an approved medicine. From the date of National Reimbursement Drug List (NRDL) implementation on March 1, 2021 to June 30, 2021, the number of hospitals listing ZEJULA has increased sevenfold to more than 800.

### *Anticipated 2021 Zai Milestones*

- Complete enrollment of the Phase 1b study of ZEJULA in combination with tebotelimab in gastric cancer.
- Announce topline results of the Phase 3 PRIME study of ZEJULA in Chinese patients with first-line ovarian cancer.
- Seek NRDL inclusion for a first-line ovarian cancer indication.
- Continue to explore additional indications and combination opportunities.

### **Tumor Treating Fields**

*Tumor Treating Fields (TTFields) are electric fields tuned to specific frequencies to disrupt cell division.*

### *Recent Product Highlights*

- In July 2021, Zai Lab partner Novocure announced the final results from its Phase 2 pilot HEPANOVA trial in liver cancer testing the safety and efficacy of TTFields together with sorafenib for the treatment of advanced hepatocellular cancer. In 21 evaluable patients, HEPANOVA showed a 76% disease control rate, 9.5% objective response rate and 5.8 months of progression free survival in a patient population with poor prognosis and limited exposure to study treatments. In patients who completed at least 12 weeks (n=11) of TTFields treatment, the disease control rate was 91% with an 18% objective response rate. Novocure is actively designing a Phase 3 pivotal trial that contemplates TTFields together with the current standard of care, including immunotherapy.
- In May 2021, Zai Lab partner Novocure announced that the U.S. Food and Drug Administration (FDA) approved the Investigational Device Exemption (IDE) supplement incorporating the independent data monitoring committee's recommended protocol changes for its Phase 3 pivotal LUNAR trial in NSCLC, reducing the enrollment requirement to 276 patients with 12 months follow-up following the enrollment of the last patient. Novocure now anticipates last patient enrollment in the LUNAR trial in the fourth quarter of 2021, with final data available in 2022.

- In April 2021, 26 presentations on TTFIELDS at the American Association for Cancer Research (AACR) Annual Meeting 2021 suggested the broad applicability of TTFIELDS.
- In April and May 2021, Zai Lab initiated the pivotal Phase 3 LUNAR trial in NSCLC and the pivotal Phase 3 METIS trial in brain metastases from NSCLC, respectively, in Greater China.
- Zai Lab held extensive campaigns for Optune in Standardized Multi-Department Treatment programs in hospitals.
- Optune has been listed in 14 regional customized commercial health insurance plans offered by provincial or municipal governments (or “supplemental insurance plans”) since its commercial launch in China in the third quarter of 2020.

#### *Anticipated 2021 Zai Milestones*

- Submit a Marketing Authorization Application (MAA) for malignant pleural mesothelioma.
- Join the global Phase 3 pivotal PANOVA-3 trial for TTFIELDS in locally advanced pancreatic cancer and the Phase 3 pivotal INNOVATE-3 trial for TTFIELDS in recurrent ovarian cancer.
- Complete enrollment of the Phase 2 pilot trial in first-line gastric adenocarcinoma.

#### *Anticipated 2021 Partner Milestone*

- Complete the interim analysis of the Phase 3 pivotal INNOVATE-3 trial for TTFIELDS in recurrent ovarian cancer.

#### **QINLOCK® (ripretinib)**

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

#### *Recent Product Highlights*

- In July 2021, QINLOCK was included in the Chinese Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of Gastrointestinal Stromal Tumors 2021 for second-line treatments for advanced GIST patients.

- In June 2021, Deciphera presented the intra-patient dose escalation data from the INVICTUS Phase 3 study of QINLOCK in GIST patients. The exploratory analysis showed that dose escalation to QINLOCK 150 mg BID after disease progression on QINLOCK 150 mg QD may be able to offer substantial additional clinical benefit with a tolerable safety profile.
- In May 2021, Zai Lab launched QINLOCK in China, our third innovative oncology product launch in China in the last 16 months. Zai Lab has held multiple national launch events for QINLOCK across China since its approval. QINLOCK is listed in two supplemental insurance plans.

#### *Anticipated 2021 Partner Milestones*

- Obtain topline data from the INTRIGUE Phase 3 study of QINLOCK in patients with second-line GIST in the fourth quarter.
- Initiate a Phase 1b/2 study in combination with the MEK inhibitor binimetinib in imatinib-refractory or -intolerant GIST patients.

#### **Adagrasib**

*Adagrasib is a highly selective and potent oral small-molecule inhibitor of KRAS<sup>G12C</sup> for treating KRAS-G12C-mutated NSCLC, colorectal cancer (CRC), pancreatic cancer and other solid tumors.*

#### *Recent Product Highlight*

- In June 2021, Zai Lab partner Mirati announced that the FDA granted Breakthrough Therapy Designation to adagrasib for the potential treatment of NSCLC patients who harbor the KRAS<sup>G12C</sup> mutation following prior systemic therapy.

#### *Anticipated 2021 Partner Milestones*

- Mirati plans to present updated NSCLC data in the second half of 2021 and submit an NDA in the United States for adagrasib in the fourth quarter of 2021 for the potential treatment of patients with NSCLC who harbor the KRAS<sup>G12C</sup> mutation following prior systemic therapy.
- Mirati plans to present new CRC data from the Phase 1/2 KRYSTAL-01 study evaluating adagrasib in combination with cetuximab (ERBITUX®) in second-line patients with a KRAS<sup>G12C</sup> mutation and as a monotherapy in patients who have received three or more lines of therapy.

#### **Odronextamab**

*Odronextamab is a 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 May 2021, Zai Lab partner Regeneron resumed the enrollment of patients with follicular lymphoma and diffuse large B-cell lymphoma in the potentially pivotal Phase 2 program.

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*Anticipated 2021 Zai Milestone*

- Enroll the first patient in Greater China in the global, potentially pivotal Phase 2 program.

*Anticipated 2021 Partner Milestone*

- Initiate development of a subcutaneous formulation.

**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 Highlight*

- In May 2021, Zai Lab enrolled the first patient in Greater China in the global registrational Phase 2 TRIDENT-1 study for both the ROS1+ advanced NSCLC and the NTRK+ advanced solid tumor cohorts.

*Anticipated 2021 Partner Milestones*

- Reach enrollment of 50 patients from both the Phase 1 and Phase 2 portions of the TRIDENT-1 study in the ROS1-positive TKI-naïve NSCLC patient cohort. Zai Lab partner Turning Point Therapeutics has announced that they anticipate an FDA meeting during the first quarter of 2022 to discuss topline blinded independent central review (BICR) results for that cohort.
- Initiate TRIDENT-2, a Phase 1b/2 combination study in KRAS-mutant solid tumors.
- Provide a clinical data update from the ongoing TRIDENT-1 study.
- Report initial clinical data from the Phase 1/2 CARE study in pediatric and young adult patients.

**MARGENZA™ (Margetuximab)**

*MARGENZA is an Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2 (HER2).*

*Anticipated 2021 Zai Milestone*

- Submit an NDA for pretreated metastatic HER2-positive breast cancer around year-end.

*Anticipated 2021 Partner Milestones*

- Obtain initial data from Module A of the MAHOGANY study in the third quarter.



- Complete the final overall survival analysis of the SOPHIA study, a randomized, open-label Phase 3 study evaluating margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer who have previously been treated with HER2-targeted therapies, in the third quarter.

### **Bemarituzumab**

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

#### *Recent Product Highlight*

- In April 2021, Zai Lab partner Amgen was granted Breakthrough Therapy Designation by the FDA for bemarituzumab as first-line treatment for patients with FGFR2b overexpression in HER2-negative metastatic and locally advanced gastric and gastroesophageal adenocarcinoma in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin).

#### *Anticipated 2021 Partner Milestone*

- Initiate a registrational Phase 3 study in gastric cancer in the fourth quarter.
- Plan for clinical development in other FGFR2b+ solid tumors, including squamous cell NSCLC.

### **CLN-081**

*CLN-081 is an orally available, small-molecule, next-generation, irreversible epidermal growth factor receptor (EGFR) inhibitor designed to selectively target cells expressing mutant EGFR variants, including EGFR exon 20 insertions.*

#### *Recent Product Highlight*

- In June 2021, Zai Lab partner Cullinan announced Phase 1/2a interim data of CLN-081 in NSCLC EGFR exon 20 patients. CLN-081 continued to demonstrate acceptable overall safety and tolerability, with an encouraging GI toxicity profile.

#### *Anticipated 2021 Partner Milestone*

- Initiate a potentially registrational Phase 2b clinical trial.

### **TPX-0022**

*TPX-0022 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.*

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#### *Recent Product Highlight*

- In August and June 2021, Zai Lab partner Turning Point Therapeutics was granted Fast Track Designation and Orphan Drug Designation, respectively, by the FDA for TPX-0022 in gastric cancer.

#### *Anticipated 2021 Partner Milestones*

- Provide a clinical data update from the dose-finding portion of the Phase 1 SHIELD-1 study and initiate the Phase 2 portion of the SHIELD-1 study, pending FDA feedback.
- Initiate SHIELD-2, a Phase 1b/2 combination study with an epidermal growth factor receptor- (EGFR-) targeted therapy.

#### **Tebotelimab**

*Tebotelimab is an investigational, first-in-class, bispecific, tetravalent DART molecule targeting PD-1 and LAG-3.*

#### *Recent Product Highlight*

- Zai Lab expanded the Phase 1b/2 study of tebotelimab in combination with ZEJULA into new indications in Greater China. In June and July 2021, Zai Lab enrolled the first patients in the biliary tract cancer and triple negative breast cancer cohorts, respectively.

#### *Anticipated 2021 Zai and Partner Milestone*

- Provide a clinical update, including future development plans.

#### **Autoimmune Diseases**

##### **Efgartigimod**

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

#### *Recent Product Highlights*

- In July 2021, Zai Lab partner argenx announced plans to develop two new indications for efgartigimod: myositis and bullous pemphigoid.
- In June 2021, Zai Lab partner argenx announced that The Lancet Neurology published pivotal trial results from the Phase 3 ADAPT trial of efgartigimod for the treatment of adults with generalized myasthenia gravis (gMG).
- To date, five Clinical Trial Applications (CTAs) have been approved by the NMPA.

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#### *Anticipated 2021 Zai Milestones*

- Discuss with the NMPA a potential accelerated regulatory pathway for efgartigimod in gMG.
- Continue to explore and advance additional indications in coordination with argenx.
- Enroll the first patients in Greater China in the global pivotal Phase 3 trials of the subcutaneous formulation in primary immune thrombocytopenia (ITP) and pemphigus vulgaris (PV).
- Expect CTA submissions for additional indications.

#### *Anticipated 2021 Partner Milestones*

- Potential FDA approval, with a Prescription Drug User Fee Act (PDUFA) target action date of December 17, 2021, and global commercial launch of efgartigimod for the treatment of patients with gMG.
- Initiate clinical trials in myositis and bullous pemphigoid.

#### ***Infectious Disease***

##### **NUZYRA® (omadacycline)**

*NUZYRA is a once-daily oral and intravenous antibiotic for the treatment of adults with CABP and ABSSSI.*

#### *Recent Product Highlight*

- In June 2021, Zai Lab partner Paratek Pharmaceuticals announced the sNDA approval from the FDA of the NUZYRA oral-only dosing regimen for the treatment of CABP.

#### *Anticipated 2021 Zai Milestone*

- Potential NMPA approval and commercial launch of NUZYRA for the treatment of CABP and ABSSSI.

##### **Sulbactam-Durlobactam (SUL-DUR)**

*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 July 2021, Zai Lab and its partner Entasis Therapeutics completed patient enrollment in the global registrational Phase 3 ATTACK clinical trial.

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*Anticipated 2021 Zai and Partner Milestone*

- Announce the top-line data readout of the global registrational Phase 3 ATTACK clinical trial early in the fourth quarter.

**Clinical Programs with Global Rights**

**ZL-1102 (IL-17 Nanobody)**

*ZL-1102 is a novel human nanobody targeting IL-17 with high affinity and avidity. Unlike other anti-IL-17 products, ZL-1102 is being developed as a topical treatment for chronic plaque psoriasis (CPP).*

*Anticipated 2021 Zai Milestone*

- Announce the top-line data readout of the global Phase 1 study.

**ZL-1201 (CD47)**

*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 2021 Zai Milestone*

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

**Simurosertib, ZL-2309 (CDC7)**

*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 2021 Zai Milestone*

- Initiate a Phase 2 proof-of-concept study by year-end.

**Business Development Updates**

- In July 2021, Zai Lab and Schrödinger, Inc. announced a global discovery, development and commercialization collaboration focused on a novel DNA damage repair target in oncology. Schrödinger is a recognized leader in providing physics-based computational software platforms used in drug discovery. The research program will be conducted jointly by the scientific teams of the two companies. Following the selection of a development candidate, Zai Lab will assume primary responsibility for global development, manufacturing and commercialization in the program. This initiative will complement Zai's existing discovery efforts in the DNA damage response pathway in addition to potential combinations with existing Zai Lab products such as the PARP inhibitor ZEJULA and ZL-2309.

- In June 2021, Zai Lab and Mirati announced that the companies entered into a collaboration and license agreement for adagrasib, a small-molecule KRASG12C inhibitor, in Greater China. Under the terms of the agreement, Zai Lab obtains the right to research, develop, manufacture and exclusively commercialize adagrasib in Greater China. Zai Lab will support accelerated enrollment in key global, registration-enabling clinical trials of adagrasib in patients with cancer who have a KRASG12C mutation.
- In June 2021, Zai Lab and MacroGenics announced that the companies entered into an exclusive collaboration and license agreement involving up to four immuno-oncology molecules. The first collaboration program covers a lead research molecule that incorporates MacroGenics' DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors. The second collaboration program covers a target to be designated by MacroGenics. For both molecules, Zai receives commercial rights in Greater China, Japan, and Korea, and MacroGenics receives commercial rights in all other territories. For the lead molecule, Zai Lab receives an option to convert the regional arrangement into a global 50/50 profit share upon reaching a predefined clinical milestone. Zai Lab also obtains exclusive, global licenses from MacroGenics to develop, manufacture and commercialize two additional molecules.

### **Corporate Updates**

- Zai Lab plans to host a virtual R&D Day on September 22, 2021, to provide a comprehensive update on our business and expanding pipeline across oncology, autoimmune and infectious diseases. Additional details will be announced at a later date.
- Zai Lab continues to strengthen and expand its team. New hires include Danielle Halstrom, Senior Vice President, Global Head of Communications, and Jean Wang, PhD, Senior Vice President, Small Molecule CMC.
- As of June 30, 2021, Zai Lab employed 1,600 full-time employees, including 594 and 832 employees engaged in research & development (R&D) and commercial activities, respectively.
- We continue to invest in our global organization and facilities. During September, we plan to expand our presence in the United States by opening a clinical development and business facility in Cambridge, MA, to tap into the Boston area biopharmaceutical ecosystem. This facility complements our growing R&D and business center in the San Francisco Bay area.

### **Second-Quarter 2021 Financial Results**

- For the three months ended June 30, 2021, net product revenues were \$36.9 million, compared to \$11.0 million for the same period in 2020. Revenues for the period were comprised of \$23.4 million for ZEJULA, compared to \$7.5 million for the same period in 2020; \$9.5 million for Optune, compared to \$3.5 million for the same period in 2020; and \$4.0 million for QINLOCK, compared to nil for the same period in 2020.

- R&D expenses were \$142.2 million for the three months ended June 30, 2021, compared to \$68.3 million for the same period in 2020. The increase in R&D expenses was primarily attributable to a \$65 million upfront payment to Mirati and a \$25 million upfront payment to MacroGenics; expenses related to ongoing and newly initiated late-stage clinical trials; and payroll and payroll-related expenses from increased R&D headcount.
- Selling, General and Administrative expenses (SG&A) were \$54.4 million for three months ended June 30, 2021, compared to \$23.8 million for the same period in 2020. The increase was primarily due to payroll and payroll-related expenses from increased commercial headcount and expanded commercial activities in China.
- For the three months ended June 30, 2021, Zai Lab reported a net loss of \$163.3 million, or a loss per share attributable to common stockholders of \$1.76, compared to a net loss of \$80.6 million, or a loss per share attributable to common stockholders of \$1.08, for the same period in 2020. The increase in the net loss was primarily attributable to payments related to new business development activities with Mirati and MacroGenics recorded in R&D expenses.
- As of June 30, 2021, cash and cash equivalents, short-term investments and restricted cash totaled \$1,767.3 million compared to \$1,187.5 million as of December 31, 2020.

#### **Conference Call and Webcast Information**

Zai Lab will host a live conference call and webcast today, August 10, 2021, at 8:00 a.m. EDT. Listeners can 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/7290113>

Conference ID: 7290113

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 an innovative, research-based, commercial-stage biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders and infectious disease. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order 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 in order to impact human health worldwide.

For additional information about the company, please visit [www.zailaboratory.com](http://www.zailaboratory.com) or follow us at [www.twitter.com/ZaiLab\\_Global](https://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, date 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 investigational therapies; the anticipated benefits and potential of investments, collaborations and business development activities; our future financial and operating results; and 2021 financial guidance. These forward-looking statements include, without limitation, statements containing 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 statements of historical fact nor are they 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. Actual results may differ materially from those indicated by such 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 finance our operations and business initiatives and obtain funding for such activities, (3) our results of 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 and (6) the risk factors identified in our most recent annual or quarterly report 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.

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**For more information, please contact:**

ZAI LAB CONTACTS:

**Zai Lab**

Billy Cho, CFO

+86 137 6151 2501

[billy.cho@zailaboratory.com](mailto:billy.cho@zailaboratory.com)

Media: Ryo Imai / Robert Flamm, Ph.D.

Burns McClellan, on behalf of Zai Lab

212-213-0006 ext. 315 / 364

[rimai@burnsmc.com](mailto:rimai@burnsmc.com) / [rflamm@burnsmc.com](mailto:rflamm@burnsmc.com)

Investors: Mike Zanoni

Endurance Advisors, on behalf of Zai Lab

610-442-8570

[mzanoni@enduranceadvisors.com](mailto:mzanoni@enduranceadvisors.com)



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	
	June 30, 2021 \$	December 31, 2020 \$
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	1,766,573	442,116
Short-term investments	—	744,676
Accounts receivable (net of allowance of \$5 and \$1 as of June 30, 2021 and December 31, 2020, respectively)	18,029	5,165
Inventories	11,114	13,144
Prepayments and other current assets	12,887	10,935
<b>Total current assets</b>	<b>1,808,603</b>	<b>1,216,036</b>
Restricted cash, non-current	743	743
Investments in equity investees	1,070	1,279
Prepayments for equipment	1,846	274
Property and equipment, net	31,642	29,162
Operating lease right-of-use assets	17,015	17,701
Land use rights, net	7,849	7,908
Intangible assets, net	1,733	1,532
Long term deposits	891	862
Value added tax recoverable	23,823	22,141
<b>Total assets</b>	<b>1,895,215</b>	<b>1,297,638</b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	125,621	62,641
Current operating lease liabilities	6,371	5,206
Other current liabilities	61,925	30,196
<b>Total current liabilities</b>	<b>193,917</b>	<b>98,043</b>
Deferred income	17,632	16,858
Non-current operating lease liabilities	11,968	13,392
<b>Total liabilities</b>	<b>223,517</b>	<b>128,293</b>
<b>Shareholders' equity</b>		
Ordinary shares (par value of \$0.00006 per share; 500,000,000 shares authorized, 94,758,189 and 87,811,026 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively)	6	5
Additional paid-in capital	2,799,318	1,897,467
Accumulated deficit	(1,109,837)	(713,603)
Accumulated other comprehensive loss	(16,865)	(14,524)
Treasury Stock (at cost, 6,086 and nil shares as of June 30, 2021 and December 31, 2020, respectively)	(924)	—
<b>Total shareholders' equity</b>	<b>1,671,698</b>	<b>1,169,345</b>
<b>Total liabilities and shareholders' equity</b>	<b>1,895,215</b>	<b>1,297,638</b>

## 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,	
	2021 \$	2020 \$	2021 \$	2020 \$
Revenue	36,935	10,995	57,038	19,213
Expenses:				
Cost of sales	(10,868)	(2,896)	(18,373)	(4,980)
Research and development	(142,224)	(68,307)	(346,076)	(102,049)
Selling, general and administrative	(54,414)	(23,758)	(90,252)	(42,472)
Loss from operations	(170,571)	(83,966)	(397,663)	(130,288)
Interest income	244	1,227	458	2,882
Interest expenses	—	(55)	—	(114)
Other income (expense), net	7,406	2,434	1,179	(691)
Loss before income tax and share of gain (loss) from equity method investment	(162,921)	(80,360)	(396,026)	(128,211)
Income tax expense	—	—	—	—
Share of loss from equity method investment	(403)	(269)	(208)	(406)
Net loss	(163,324)	(80,629)	(396,234)	(128,617)
Net loss attributable to ordinary shareholders	(163,324)	(80,629)	(396,234)	(128,617)
Loss per share - basic and diluted	(1.76)	(1.08)	(4.37)	(1.74)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	93,045,531	74,738,563	90,723,132	73,847,551

**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)**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Net loss	(163,324)	(80,629)	(396,234)	(128,617)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	(5,241)	(1,173)	(2,341)	2,366
Comprehensive loss	<u>(168,565)</u>	<u>(81,802)</u>	<u>(398,575)</u>	<u>(126,251)</u>