



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

November 9, 2021

-- Broad Product Pipeline Expands Both Vertically and Horizontally with Three New Potential First-in-Class or Best-in-Class Medicines

-- Company to Host Conference Call and Webcast on November 10, 2021, at 8:00 a.m. EST

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced financial results for the third quarter of 2021, along with recent product highlights and corporate updates.

"In the third quarter of 2021, we continued to deliver strong growth and performance," said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. "We made important advances across our broad, innovative product portfolio and recently added three new potentially transformative medicines. Our agreement with Blueprint Medicines for two promising lung cancer drug candidates presents opportunities to further deepen our potentially world-class lung cancer franchise. Our partnership with Karuna Therapeutics allows us to expand into neuroscience with an exciting anchor asset. Neuroscience is a disease area with a large patient population and significant unmet medical needs."

Notable updates across our business in the quarter included:

- Our three marketed products—ZEJULA, OPTUNE, and QINLOCK—achieved solid revenue growth, driven by strong demand and commercial execution.
- ZEJULA received approval and was launched for first-line ovarian cancer in Hong Kong.
- QINLOCK received approval and was launched for fourth-line GIST in Taiwan.
- Positive Phase 1/2 results for adagrasib in colorectal cancer and potentially registration-enabling Phase 2 topline results in non-small-cell lung cancer were announced.
- Encouraging updated Phase 2 data for repotrectinib and Phase 1 data for elzovantinib (TPX-0022) in advanced cancer patients with relevant genomic alterations were announced.
- Enrollment of our clinical trial of Tumor Treating Fields in gastric cancer was completed; a topline data readout of this Phase 2 pilot trial is expected in the first half of 2022.
- Regulatory filings are being prepared for Tumor Treating Fields in malignant pleural mesothelioma and for margetuximab in HER2-positive breast cancer.
- A positive meeting with the NMPA on efgartigimod suggests the potential for an accelerated pathway for regulatory approval for generalized myasthenia gravis (gMG) in China. Subject to United States Food and Drug Administration (FDA) approval and further discussion with the NMPA, we expect to file the New Drug Application (NDA) in China by the first half of 2022. Our partner argenx anticipates a decision by the FDA on their regulatory filing of efgartigimod for gMG during the fourth quarter.
- ZL-1102, Zai Lab's internally developed anti-IL-17A Humabody<sup>®</sup> for plaque psoriasis, achieved proof of concept and will now advance into global clinical development.
- Positive topline results were announced for sulbactam-durlobactam (SUL-DUR) in *Acinetobacter* infections from the global Phase 3 ATTACK trial.

"We have had a very productive year and built a stronger pipeline with depth and breadth," Dr. Du concluded. "With 28 products in our innovative pipeline, we expect our fourth quarter and 2022 to be rich in milestones to unlock significant value in our business."

### Recent Product Highlights and Anticipated Milestones

#### Oncology

##### ZEJULA<sup>®</sup> (niraparib)

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

#### *Recent Product Highlight*

- In August 2021, Zai Lab announced that the Hong Kong Department of Health has approved its post-approval variation for ZEJULA as a maintenance treatment for adult patients with high-grade serous epithelial ovarian cancer who are in a complete response or partial response to first-line platinum-based chemotherapy. Unlike other PARP inhibitors approved in Hong Kong for this setting, ZEJULA does not require BRCA mutation or other biomarker testing prior to administration.

#### *Anticipated 2021 Zai Milestones*

- Announce topline results of the Phase 3 PRIME study of ZEJULA in Chinese patients as a first-line maintenance treatment of ovarian cancer.
- Seek National Reimbursement Drug List (NRDL) inclusion for a first-line ovarian cancer indication.
- Continue to explore additional indications and combination opportunities.

#### **Tumor Treating Fields**

*Tumor Treating Fields (TTFields) is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and potentially causing cancer cell death.*

#### *Recent Product Highlights*

- In October 2021, Zai Lab partner Novocure announced that the final patient has been enrolled in the Phase 3 pivotal INNOVATE-3 trial for the treatment of recurrent ovarian cancer.
- In October 2021, Zai Lab and partner Novocure announced that the final patient has been enrolled in the Phase 2 pilot trial of TTFields in combination with chemotherapy as a first-line treatment in patients with gastric adenocarcinoma. Final data collection is expected in the first half of 2022.
- In September 2021, Zai Lab partner Novocure announced a clinical trial collaboration with Roche to develop TTFields together with Roche's anti-PD-L1 therapy atezolizumab for the first-line treatment of metastatic pancreatic cancer.
- In September 2021, Zai Lab partner Novocure announced the FDA has granted breakthrough designation to the NovoTTF-200T System, a TTFields delivery system, for use with atezolizumab and bevacizumab for the first-line treatment of patients with unresectable or metastatic liver cancer. The designation offers Novocure an opportunity to interact with FDA experts through several program options to address regulatory topics efficiently as they arise during the premarket review phase and allows for prioritized review of regulatory submissions.
- Optune has been listed in 25 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 / Early 2022 Zai Milestone*

- Prepare for the Marketing Authorization Application (MAA) submission for malignant pleural mesothelioma.
- Join the global Phase 3 pivotal PANOVA-3 trial for TTFields in locally advanced pancreatic cancer.

#### *Anticipated 2021 Partner Milestone*

- Complete enrollment of Phase 3 pivotal LUNAR trial for TTFields in non-small-cell lung cancer (NSCLC).

#### **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 November 2021, Zai Lab partner Deciphera announced top-line results from the INTRIGUE Phase 3 clinical study of QINLOCK in patients with GIST previously treated with imatinib. The study did not meet the primary endpoint of improved progression-free survival compared with the standard of care, sunitinib. Zai Lab does not anticipate that the INTRIGUE study results will have a material effect on the current operations of the company.
- In September 2021, Zai Lab announced that the Taiwan Food and Drug Administration has approved its NDA for

QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

- QINLOCK has been listed in 28 supplemental insurance plans since its commercial launch in China in May 2021.

#### *Anticipated 2021 Partner Milestones*

- Potential European Medicines Agency (EMA) approval for QINLOCK.
- 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 G12C for treating KRAS-G12C-mutated NSCLC, colorectal cancer (CRC), pancreatic cancer and other solid tumors.*

#### *Recent Product Highlights*

- In November 2021, Mirati announced that preliminary results from the Phase 1b cohort of the KRYSTAL-1 study evaluating adagrasib plus pembrolizumab in eight patients with KRAS G12C-mutated first-line NSCLC support moving forward with a 400 mg BID dose of adagrasib with full dose pembrolizumab, which will be evaluated in the ongoing Phase 2 KRYSTAL-7 study.
- In September 2021, Zai Lab partner Mirati announced positive topline results from the potentially registrational Phase 2 KRYSTAL-1 study, evaluating adagrasib in a patient cohort with advanced NSCLC harboring the KRAS G12C mutation following prior systemic therapy. Adagrasib 600 mg BID demonstrated an objective response rate (ORR) of 43% and a disease control rate of 80%, based on central independent review as of June 15, 2021. The median follow-up was nine months. The safety and tolerability profile was consistent with previously reported findings for adagrasib in patients with advanced NSCLC.
- In September 2021, Zai Lab partner Mirati announced results from a cohort of the Phase 1/2 KRYSTAL-1 study evaluating adagrasib at the 600 mg BID dose as both monotherapy and in combination with cetuximab in patients with heavily pretreated colorectal cancer harboring a KRAS G12C mutation. Results showed that adagrasib alone and with cetuximab demonstrated significant clinical activity and broad disease control in these patients.

#### *Anticipated 2021 Partner Milestone*

- Mirati has announced their intention to file an NDA for adagrasib monotherapy in advanced NSCLC following prior systemic therapy in the United States by the end of 2021.

#### **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*

- In October 2021, Zai Lab announced that the first patient was treated in the Greater China portion of the global, potentially pivotal Phase 2 program.

#### *Anticipated 2021 / 2022 Partner Milestones*

- Initiate studies with a subcutaneous formulation in the fourth quarter of 2021.
- Initiate broader Phase 3 programs 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 October 2021, Zai Lab partner Turning Point provided early clinical data from the NTRK-positive TKI-naïve and TKI-pretreated advanced solid tumor cohorts (EXP-5 and EXP-6) of the ongoing TRIDENT-1 Phase 1/2 study of its lead drug candidate repotrectinib.

- Confirmed ORR of 48% in patients with NTRK+ TKI-pretreated advanced solid tumors.
  - Confirmed ORR of 62% in NTRK+ TKI-pretreated advanced solid tumor patients with solvent front mutations.
  - Confirmed ORR of 41% in patients with NTRK+ TKI-naive advanced solid tumors.
- In October 2021, Zai Lab partner Turning Point provided a clinical data update from the ongoing TRIDENT-1 study. Repotrectinib demonstrated clinical activity across multiple ROS1+ TKI-pretreated NSCLC cohorts, with confirmed ORRs of 30-39% in the TRIDENT-1 study. In ROS1+ TKI-pretreated NSCLC patients with G2032R solvent-front mutations, repotrectinib demonstrated a confirmed ORR of 53%.
- In October 2021, Zai Lab partner Turning Point announced the presentation of early clinical data from the ongoing Phase 1/2 CARE study in pediatric and young adult patients with advanced solid tumors harboring ALK, ROS1 or NTRK alterations.
- In October 2021, Zai Lab partner Turning Point announced that the FDA granted a second breakthrough therapy designation to repotrectinib for the treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with one or two prior TRK tyrosine kinase inhibitors, with or without prior chemotherapy, and have no satisfactory alternative treatments.
- In August 2021, Zai Lab partner Turning Point announced the initiation of the first cohort of its Phase 1b/2 TRIDENT-2 combination study of repotrectinib in combination with MEK-inhibitor trametinib in KRAS G12D-mutated advanced solid tumors.

#### *Anticipated 2021 / 2022 Partner Milestone*

- Anticipate discussing next steps towards registration of repotrectinib in patients with NTRK-positive TKI-pretreated advanced solid tumors at a Type B meeting with the FDA in the fourth quarter of 2021.
- Anticipate reporting topline blinded independent central review (BICR) data from all of the ROS1-positive NSCLC cohorts from TRIDENT-1 and discussing the BICR data with the FDA at a pre-NDA meeting in the second quarter of 2022.

#### **MARGENZA® (Margetuximab)**

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

#### *Recent Product Highlight*

- In October 2021, Zai Lab announced that the bridging study of margetuximab plus chemotherapy in advanced, previously treated HER2+ breast cancer met its primary endpoint, with acceptable safety and tolerability. The study showed that efficacy of this combination in Chinese patients was consistent with that seen in the global population in the SOPHIA trial conducted by Zai Lab partner MacroGenics.

#### *Anticipated 2021 / Early 2022 Zai Milestone*

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

#### **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 Highlights*

- In November 2021, Zai Lab partner Amgen announced the registrational Phase 3 program has initiated for bemarituzumab in first-line advanced gastric and gastroesophageal junction adenocarcinoma. The program will explore bemarituzumab in combination with either backbone chemotherapy or chemotherapy plus a checkpoint inhibitor.
- In September 2021, Zai Lab announced that the Center for Drug Evaluation (CDE) of the NMPA granted Breakthrough Therapy designation for bemarituzumab for first-line treatment for patients with FGFR2b-overexpressing and human epidermal growth factor receptor 2 (HER2) -negative metastatic and locally advanced gastric and gastroesophageal junction (GEJ) cancers in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin).

#### *Anticipated Early 2022 Partner Milestone*

- Initiate a Phase 1b signal-seeking study of bemarituzumab alone and in combination with chemotherapy for the treatment of advanced, refractory squamous NSCLC by the first quarter of 2022. Planning is underway for signal-seeking studies in

other solid tumors.

### **Elzovantinib (TPX-0022)**

*Elzovantinib (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.*

#### *Recent Product Highlight*

- In October 2021, Zai Lab partner Turning Point provided a clinical data update from the dose-finding portion of the Phase 1 SHIELD-1 study. Elzovantinib demonstrated a confirmed ORR of 36% and 33%, respectively, in MET TKI-naïve NSCLC and gastric/GEJ cancer patients harboring genetic alterations in MET in the SHIELD-1 study.

#### *Anticipated 2021 / 2022 Partner Milestones*

- Explore an additional intermediate dose level in at least 6-10 patients as recommended by the FDA, with the intention of revising the SHIELD-1 study into a potentially registrational Phase 1/2 study. Turning Point plans to initiate the Phase 2 portion of the SHIELD-1 study pending FDA feedback in 2022.
- Anticipate FDA feedback on the development path for elzovantinib in gastric/GEJ cancer in the fourth quarter of 2021.
- Initiate SHIELD-2, a Phase 1b/2 combination study with an epidermal growth factor receptor (EGFR) -targeted therapy in mid-2022, pending filing of an investigational new drug (IND) application by the FDA.

### **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, including gastric cancer, triple negative breast cancer and biliary tract cancer. In addition, Zai Lab enrolled the first patient in the endometrial cancer cohort in October 2021.

#### *Anticipated First Half 2022 Zai and Partner Milestone*

- Provide an update regarding ongoing studies and plans for the next stage of development.

### **BLU-945**

*BLU-945 is a selective and potent inhibitor of EGFR activating mutations combined with the acquired T790M and C797S mutations, common on-target resistance mechanisms, for the potential treatment of EGFR-positive NSCLC.*

#### *Recent Product Highlight*

- The global Phase 1/2 trial of BLU-945 in treatment-resistant EGFR-driven NSCLC was initiated in the second quarter of 2021.

#### *Anticipated Early 2022 Partner Milestone*

- Present preclinical data supporting combination of BLU-945 and BLU-701 in EGFR-driven NSCLC at a medical conference.

### **BLU-701**

*BLU-701 is a selective and potent inhibitor of EGFR activating mutations combined with the acquired C797S mutation, a common on-target resistance mechanism, for the potential treatment of EGFR-positive NSCLC.*

#### *Anticipated 2021 Partner Milestone*

- Initiate Phase 1 trial of BLU-701 in EGFR-driven NSCLC in the fourth quarter of 2021.

### **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 2021 / Early 2022 Zai Milestone*

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

### **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 2021 / Early 2022 Zai Milestone*

- Initiate a Phase 2 biomarker-driven proof-of-concept study.

## **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.*

*Anticipated 2021 Zai Milestones*

- Enroll first patients in Greater China in the global pivotal Phase 3 trials of the subcutaneous formulation in primary immune thrombocytopenia (ITP), chronic inflammatory demyelinating polyneuropathy (CIDP) and pemphigus.
- Continue to explore and advance additional indications in coordination with our partner argenx.

*Anticipated 2021 / Early 2022 Partner Milestones*

- Potentially obtain FDA approval, with a Prescription Drug User Fee Act (PDUFA) target action date of December 17, 2021, and undertake global commercial launch of efgartigimod for the treatment of patients with gMG.
- Initiate clinical trials in bullous pemphigoid by the end of 2021 and myositis in the first quarter of 2022, respectively.

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

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

*Recent Product Highlight*

- In October 2021, Zai Lab announced that ZL-1102 achieved proof-of-concept in the Phase 1b psoriasis study. Topical therapy with ZL-1102 resulted in clinical improvement in local PASI score, the PASI elements erythema and scaling, target lesion size and responder rates in patients with mild-to-moderate chronic plaque psoriasis. Consistent improvement was seen over time.

*Anticipated 2022 Zai Milestone*

- Advance into global full development.

## **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).*

*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 October 2021, Zai Lab and partner Entasis announced the positive topline data readout of the global registrational Phase 3 ATTACK clinical trial in *Acinetobacter* infections. An NDA submission to the FDA is planned for mid-2022.
  - SUL-DUR first to achieve statistical non-inferiority in 28-day all-cause mortality in carbapenem-resistant *Acinetobacter* (CRAB) patients.
  - Statistically significant difference in clinical cure at Test of Cure vs. colistin.
  - Favorable safety profile with statistically significant reduction in nephrotoxicity.

## **Neuroscience**

## KarXT

*KarXT combines xanomeline, a novel muscarinic agonist, with tropium, an approved muscarinic antagonist, to preferentially stimulate muscarinic receptors in the central nervous system for potential treatment of schizophrenia and dementia-related psychosis.*

### Recent Product Highlights

- Began enrollment in all Phase 3 EMERGENT trials for the treatment of schizophrenia.
- Published Phase 2 EMERGENT-1 data in *New England Journal of Medicine*.

### Anticipated 2021 Partner Milestones

- Initiate the Phase 3 ARISE trial evaluating KarXT in adults with schizophrenia who inadequately respond to current standard of care.
- Advance a new formulation of KarXT into clinical development.

### Corporate Updates

- In October 2021, Zai Lab announced the appointment of Scott Morrison to its Board of Directors.
- In September 2021, Zai Lab held a Virtual R&D Day for analysts and investors to provide an in-depth look at its product portfolio, pipeline and global operations.
- In September 2021, Zai Lab announced that it will expand its operations in the United States and establish a key presence in the Cambridge biotechnology hub. Business operations to be headquartered in the new Cambridge office include alliance management, business development, and legal and governance functions.
- Zai Lab continues to strengthen and expand its team. New hires during the third quarter include Mehrdad Mobasher, M.D., M.P.H., Senior Vice President, Global Head of Late-stage Development; Yajing Chen, Ph.D., Senior Vice President, Deputy Chief Financial Officer; and Jim Massey, Chief Sustainability Officer.
- As of September 30, 2021, Zai Lab employed 1,864 full-time employees, including 713 and 944 employees engaged in R&D and commercial activities, respectively.

### Third-Quarter 2021 Financial Results

- For the three months ended September 30, 2021, net product revenues were \$43.1 million, compared to \$14.7 million for the same period in 2020. Revenues for the period were comprised of \$28.1 million for ZEJULA, compared to \$8.5 million for the same period in 2020; \$10.7 million for Optune, compared to \$6.0 million for the same period in 2020; and \$4.3 million for QINLOCK, compared to \$0.2 million for the same period in 2020.
- Research and Development (R&D) expenses were \$55.1 million for the three months ended September 30, 2021, compared to \$58.1 million for the same period in 2020. The decrease in R&D expenses was primarily attributable to lower upfront payments for new licensing agreements, partially offset by the increase of 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 \$59.0 million for three months ended September 30, 2021, compared to \$27.9 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 September 30, 2021, Zai Lab reported a net loss of \$96.4 million, or a loss per share attributable to common stockholders of \$1.01, compared to a net loss of \$63.7 million, or a loss per share attributable to common stockholders of \$0.84, for the same period in 2020. The increase in the net loss was primarily attributable to increased expenses related to expanded commercial activities.
- As of September 30, 2021, cash and cash equivalents, short-term investments and restricted cash totaled \$1,569.2 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 on November 10, 2021, 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/9666772>

Conference ID: 9666772

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 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.

### For more information, please contact:

#### ZAI LAB CONTACTS:

Investor Relations: Ron Aldridge / Lina Zhang

+1 (781) 434-8465 / +86 136 8257 6943

[ronald.aldridge@zailaboratory.com](mailto:ronald.aldridge@zailaboratory.com) / [lina.zhang@zailaboratory.com](mailto:lina.zhang@zailaboratory.com)

Media: Danielle Halstrom / Xiaoyu Chen

+1 (215) 280-3898 / +86 185 0015 5011

[danielle.halstrom@zailaboratory.com](mailto:danielle.halstrom@zailaboratory.com) / [xiaoyu.chen@zailaboratory.com](mailto:xiaoyu.chen@zailaboratory.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	
	September 30, 2021	December 31, 2020
	\$	\$
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	1,398,498	442,116
Short-term investments	170,000	744,676
Accounts receivable (net of allowance for credit loss of \$6 and \$1 as of September 30, 2021 and December 31, 2020, respectively)	21,018	5,165
Inventories	12,494	13,144



Prepayments and other current assets	17,077	10,935
Total current assets	<u>1,619,087</u>	<u>1,216,036</u>
Restricted cash, non-current	743	743
Long term investments (including the fair value measured investments of \$20,070 and nil as of September 30, 2021 and December 31, 2020, respectively)	20,801	1,279
Prepayments for equipment	1,129	274
Property and equipment, net	37,087	29,162
Operating lease right-of-use assets	15,514	17,701
Land use rights, net	7,749	7,908
Intangible assets, net	1,678	1,532
Long-term deposits	901	862
Value added tax recoverable	<u>23,390</u>	<u>22,141</u>
<b>Total assets</b>	<b><u>1,728,079</u></b>	<b><u>1,297,638</u></b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	51,406	62,641
Current operating lease liabilities	6,312	5,206
Other current liabilities	<u>54,292</u>	<u>30,196</u>
Total current liabilities	112,010	98,043
Deferred income	17,487	16,858
Non-current operating lease liabilities	<u>10,652</u>	<u>13,392</u>
<b>Total liabilities</b>	<b><u>140,149</u></b>	<b><u>128,293</u></b>
<b>Shareholders' equity</b>		
Ordinary shares (par value of \$0.00006 per share; 500,000,000 shares authorized, 95,273,589 and 87,811,026 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively)	6	5
Additional paid-in capital	2,812,830	1,897,467
Accumulated deficit	(1,206,249)	(713,603)
Accumulated other comprehensive loss	(15,124)	(14,524)
Treasury Stock (at cost, 27,722 and nil shares as of September 30, 2021 and December 31, 2020, respectively)	<u>(3,533)</u>	<u>—</u>
<b>Total shareholders' equity</b>	<b><u>1,587,930</u></b>	<b><u>1,169,345</u></b>
<b>Total liabilities and shareholders' equity</b>	<b><u>1,728,079</u></b>	<b><u>1,297,638</u></b>

## Zai Lab Limited

### Unaudited Condensed Consolidated statements of operations

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

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2021	2020	2021	2020
	\$	\$	\$	\$
Revenue	43,103	14,651	100,141	33,864
Expenses:				
Cost of sales	(12,162)	(4,934)	(30,535)	(9,914)
Research and development	(55,144)	(58,100)	(401,220)	(160,149)
Selling, general and administrative	<u>(59,002)</u>	<u>(27,874)</u>	<u>(149,254)</u>	<u>(70,346)</u>
Loss from operations	(83,205)	(76,257)	(480,868)	(206,545)
Interest income	713	866	1,171	3,748
Interest expenses	—	(43)	—	(157)
Other (expenses) income, net	<u>(13,580)</u>	<u>11,958</u>	<u>(12,401)</u>	<u>11,267</u>
Loss before income tax and share of loss from equity method investment	(96,072)	(63,476)	(492,098)	(191,687)
Income tax expense	—	—	—	—
Share of loss from equity method investment	<u>(340)</u>	<u>(265)</u>	<u>(548)</u>	<u>(671)</u>
Net loss	(96,412)	(63,741)	(492,646)	(192,358)
Net loss attributable to ordinary shareholders	(96,412)	(63,741)	(492,646)	(192,358)
Loss per share - basic and diluted	(1.01)	(0.84)	(5.34)	(2.59)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	95,035,432	75,436,646	92,174,838	74,381,115

Zai Lab Limited

Unaudited Condensed Consolidated statements of comprehensive loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	\$	\$	\$	\$
Net loss	(96,412)	(63,741)	(492,646)	(192,358)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	1,741	(9,901)	(600)	(7,535)
Comprehensive loss	(94,671)	(73,642)	(493,246)	(199,893)



Source: Zai Lab Limited