Zai Lab Announces Financial Results and Corporate Updates for Twelve Months Ended December 31, 2021

March 1, 2022

Company to Host Conference Call and Webcast on March 2, 2022, at 8:00 a.m. EST

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., March 01, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced financial results for the twelve months ended December 31, 2021, along with recent product highlights and corporate updates.

“2021 marked another year of strong growth and execution for Zai Lab in all areas of our business,” said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. “We significantly expanded our portfolio of potential first-in-class and/or best-in-class assets. We made meaningful advances with our global pipeline of 11 assets, including achieving proof of concept for ZL-1102, our internally developed anti-IL-17A Humabody® for chronic plaque psoriasis with global rights. Through business development, we deepened our world-class gastric and lung cancer franchises with four additional promising drug candidates; we bolstered our autoimmune franchise with efgartigimod, a pipeline-in-a-product opportunity; and we expanded into neuroscience with an exciting anchor asset KarXT. We achieved additional regulatory submissions and approvals, including our first non-oncology approval with NUZYRA®. Our commercial execution is gaining strong momentum for our four marketed products. We are pleased to have ZEJULA included in the NRDL for first-line ovarian cancer maintenance treatment, and we expect that ZEJULA can become the leading PARP inhibitor in ovarian cancer in China given its unique label for ovarian cancer patients regardless of biomarker status. Lastly, we grew our talented global team both in the United States and China, building a solid foundation for continuing growth and excellent execution.”

Other Recent Achievements

Clinical Development

- Positive topline results were announced for SUL-DUR in *Acinetobacter* infections from the global Phase 3 ATTACK trial.
- Zai Lab initiated clinical trials for efgartigimod in mainland China (China) for primary immune thrombocytopenia (ITP), chronic inflammatory demyelinating polyneuropathy (CIDP), pemphigus, and pharmacokinetics.

Regulatory

- Feedback from the China National Medical Products Administration (NMPA) provided clarity on the accelerated pathway for potential regulatory approval for efgartigimod for generalized myasthenia gravis (gMG) in China.
- Zai Lab partner argenx BV (argenx) received approval for efgartigimod for gMG in the United States.
- The U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) filed by Zai Lab partner Mirati Therapeutics, Inc. (Mirati) for adagrasib in second-line NSCLC in the United States.
- The NMPA accepted the NDA filed by Zai Lab for margetuximab in HER2-positive breast cancer in China.

Business Development

- Zai Lab and Karuna Therapeutics, Inc. entered into an exclusive license agreement for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China.
- Zai Lab and Blueprint Medicines Corporation (Blueprint) entered into an exclusive collaboration and license agreement for the development and commercialization of BLU-945 and BLU-701 for the treatment of patients with epidermal growth factor receptor (EGFR) -driven NSCLC in Greater China.

Commercial

- The NMPA approved the NDA for NUZYRA (omadacycline). NUZYRA was launched in China in December 2021.

“We have set clear strategic priorities for 2022 to position ourselves to lead the next wave of biopharma innovation,” Dr. Du continued. “We will plan to expedite bringing medicines to patients by accelerating important data readouts and regulatory filings across our entire portfolio. We plan to file the NDA for efgartigimod in China in mid-2022, subject to ongoing discussion with the NMPA, and initiate a registrational study in China for bemarituzumab in first-line advanced gastric and gastroesophageal junction (GEJ) cancer. We will continue to invest in R&D and advance our internal

pipeline of assets with global rights. We plan to move ZL-1102, our anti-IL-17A Humabody®, into full global development and submit up to two Investigational New Drug Applications (INDs) for compounds with global rights in 2022. We intend to leverage our leading position in China to accelerate our growing revenue base and to source innovation internally and externally with potentially transformative assets and partnership opportunities. Our mission is to build a leading global biopharmaceutical company.

"Looking ahead, we aim to have at least 15 marketed products approved in more than 30 indications by 2025," Dr. Du concluded. "We believe that the regulatory environment will continue to be supportive of innovative biopharma companies like Zai Lab. We are also confident in the long-term market potential of our differentiated world-class portfolio designed to address significant unmet medical needs and to create significant value for all of our constituents, including our shareholders. For example, we are presently forecasting that peak-year sales of the assets currently in our lung and GI cancer franchises could generate up to a combined total of $2.5 to $3 billion through 2030.[1,2] We remain as committed as ever to continuing to invest in internal R&D and extending our track record of execution in pursuit of our overall goal of improving human health globally."

Recent Product Highlights and Anticipated Milestones

Oncology

ZEJULA® (niraparib)

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

Recent Product Highlights

- In December 2021, Zai Lab announced that the NRDL released by China's National Healthcare Security Administration (NHSA) has been updated to include ZEJULA as a first-line maintenance treatment of adult patients with advanced ovarian cancer following a response to platinum-based chemotherapy, regardless of biomarker status.

- In November 2021, Zai Lab announced that the Phase 3 PRIME study of ZEJULA as maintenance therapy met its primary endpoint. ZEJULA demonstrated a statistically significant and clinically meaningful progression-free survival (PFS) benefit with a tolerable safety profile in Chinese patients with newly diagnosed advanced ovarian cancer following a response to platinum-based chemotherapy, regardless of biomarker status.

Anticipated 2022 Zai Milestones

- Present the clinical data of the Phase 3 PRIME study at the 2022 Society of Gynecologic Oncology (SGO) annual meeting.

- Continue to explore combination opportunities.

Tumor Treating Fields

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

Recent Product Highlights

- In January 2022, Zai Lab announced that the first patient was treated in Greater China in Novocure's Phase 3 pivotal PANOVA-3 clinical trial testing the efficacy of TTFields together with nab-paclitaxel and gemcitabine for the treatment of patients with locally advanced pancreatic cancer.

- As of January 31, 2022, Optune has been listed in 33 regional customized commercial health insurance plans guided by provincial or municipal governments (or "supplemental insurance plans") since its commercial launch in China in the third quarter of 2020.

- In December 2021, Zai Lab submitted the Marketing Authorization Application (MAA) for malignant pleural mesothelioma to the NMPA.

Anticipated 2022 Partner and Zai Milestones

- Novocure anticipates topline data from the Phase 3 pivotal LUNAR clinical trial testing the efficacy of TTFields together with physician's choice immune-checkpoint inhibitor or docetaxel for the treatment of patients with stage 4 NSCLC by year end 2022.

- Novocure anticipates an independent Data Monitoring Committee (DMC) will conduct a pre-specified interim analysis for Novocure's Phase 3 pivotal INNOVATE-3 clinical study testing the efficacy of TTFields together with paclitaxel in platinum-resistant ovarian cancer in the second quarter of 2022.

- In partnership with Novocure, Zai Lab anticipates data from the Phase 2 pilot EF-31 clinical trial testing the safety and

efficacy of TTFields together with chemotherapy in the treatment of patients with gastric cancer in 2022.

QINLOCK® (ripretinib)

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

Recent Product Highlights

- In November 2021, Zai Lab partner Deciphera announced that the European Commission approved QINLOCK for the treatment of fourth-line GIST.
- As of January 31, 2022, QINLOCK has been listed in 52 supplemental insurance plans since its commercial launch in China in May 2021.

Adagrasib

Adagrasib is a highly selective and potent oral small-molecule inhibitor of KRAS^{G12C} for treating KRAS^{G12C}-mutated NSCLC, colorectal cancer (CRC), pancreatic cancer and other solid tumors.

Recent Product Highlights

- The FDA accepted the adagrasib NDA for the treatment of patients with NSCLC harboring the KRAS^{G12C} mutation who have received at least one prior systemic therapy, with a Prescription Drug User Fee Act (PDUFA) date of December 14, 2022.
- In January 2022, Zai Lab partner Mirati announced positive results from a Phase 2 cohort of the KRYSTAL-1 study evaluating adagrasib in patients with KRAS^{G12C}-mutated gastrointestinal (GI) cancers. Results showed that adagrasib demonstrated significant clinical activity and broad disease control.

Anticipated 2022 Zai Milestone

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

Anticipated 2022 Partner Milestones

- Provide a clinical data update from the Phase 2 registration-enabling NSCLC cohort of the KRYSTAL-1 study at a medical conference during the first half of 2022.
- Potential FDA approval, with a PDUFA target action date of December 14, 2022, and commercial launch.

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

- Zai Lab partner Amgen has initiated two registrational Phase 3 programs for bemarituzumab in first-line advanced gastric and GEJ cancer.

Anticipated 2022 Zai Milestone

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

Anticipated 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.

Odronextamab

Odronextamab is a bispecific antibody designed to trigger tumor killing by linking and activating a cytotoxic T-cell (binding to CD3) to a lymphoma cell (binding to CD20).

Anticipated 2022 Partner and Zai Milestone

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

Anticipated 2022 Partner Milestones

- Submit a Biologics License Application (BLA) to the FDA in the second half of 2022.
- Initiate dosing with a subcutaneous formulation, the Phase 3 OLYMPIA program, and studies of additional combinations in 2022.

Repotrectinib

Repotrectinib is a next-generation tyrosine kinase inhibitor (TKI) designed to effectively target ROS1 and TRK A/B/C, with the potential to treat TKI-naïve or TKI-pretreated patients.

Recent Product Highlights

- In February 2022, Zai Lab announced that the Center for Drug Evaluation (CDE) of the NMPA granted Breakthrough Therapy Designation for repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 TKI.
- In January 2022, Zai Lab partner Turning Point Therapeutics, Inc. (Turning Point) announced that data from ROS1-positive TKI-naïve NSCLC patients in the Phase 1 portion of the TRIDENT-1 trial continued to demonstrate best-in-class potential.

Anticipated 2022 Partner Milestones

- Report topline blinded independent central review (BICR) results, including both objective response rate and duration of response, from all of the ROS1-positive NSCLC cohorts from TRIDENT-1 in the second quarter of 2022.
- Discuss the topline BICR data with the FDA at a pre-NDA meeting in the second quarter of 2022.
- Provide a clinical data update from the NTRK-positive advanced solid tumor cohorts from TRIDENT-1 in the second half of 2022.

CLN-081

CLN-081 is an orally available, small-molecule, irreversible epidermal growth factor receptor (EGFR) inhibitor that selectively targets cells expressing EGFR exon 20 insertion mutations while sparing cells expressing wild type EGFR, in development by Cullinan Pearl, a subsidiary of Cullinan Oncology, Inc., for the treatment of patients with EGFR exon 20 insertion NSCLC.

Recent Product Highlight

- In January 2022, Zai Lab partner Cullinan Oncology announced that the FDA has granted Breakthrough Therapy Designation for CLN-081 for the treatment of patients with locally advanced or metastatic NSCLC harboring EGFR exon 20 insertion mutations who have previously received platinum-based systemic chemotherapy.

Anticipated 2022 Zai Milestone

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

Anticipated 2022 Partner Milestone

- Provide a regulatory update in the first quarter of 2022.

Elzovantinib (TPX-0022)

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

Recent Product Highlights

- In January 2022, Zai Lab partner Turning Point announced that the company has received clearance from the FDA for the company's IND application for the combination of elzovantinib and aumolertinib in EGFR-mutant MET-amplified advanced NSCLC.
- In December 2021, Zai Lab partner Turning Point announced that the FDA agreed with the company's plan to proceed to

the potentially registrational Phase 2 MET-amplified gastric/GEJ cancer expansion cohorts of SHIELD-1 after determination of the recommended Phase 2 dose. Based on guidance from the FDA, Turning Point plans to submit data to the FDA from the Phase 2 trial and to discuss whether the study is potentially registrational.

Anticipated 2022 Partner Milestones

- Provide a clinical data update from the Phase 1 SHIELD-1 study in the second half of 2022.
- Initiate the Phase 2 portion of the SHIELD-1 study in the second half of 2022, pending FDA feedback on data from the intermediate dose level.
- Initiate the Phase 1b/2 SHIELD-2 combination study of elzovantinib and aumolertinib in mid-2022.

MARGENZA™ (Margetuximab)

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

Recent Product Highlight / Update

- In January 2022, Zai Lab announced that the NMPA has accepted the NDA for review of margetuximab for patients with pretreated metastatic HER2-positive breast cancer.
- As previously disclosed and based on a review of the clinical data and the changing treatment landscape, we have decided to no longer participate in Cohort B of the Phase 2/3 MAHOGANY study. In November 2021, MacroGenics announced a decision to discontinue enrollment of Cohort A of the MAHOGANY study.

Tebotelimab

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

Recent Product Update

- As previously disclosed and based on a review of the clinical data, Zai Lab has decided to terminate company-sponsored studies of tebotelimab in melanoma and hepatocellular carcinoma and a basket study of tebotelimab in combination with niraparib.

BLU-945

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

Recent Product Highlights

- Zai Lab partner Blueprint presented new preclinical data supporting the development of BLU-701 and BLU-945 combination therapy in EGFR-driven NSCLC at the British Thoracic Oncology Group annual conference.
- Multiple abstracts were accepted for presentation at the American Association for Cancer Research (AACR) annual meeting, including initial Phase 1/2 SYMPHONY trial dose escalation data for BLU-945 in EGFR-driven NSCLC.

Anticipated 2022 Partner Milestone

- Present initial Phase 1/2 SYMPHONY trial data for BLU-945 in EGFR-driven NSCLC in the second quarter of 2022.

BLU-701

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

Recent Product Highlight

- Zai Lab partner Blueprint Medicines announced the treatment of the first patient in the Phase 1/2 HARMONY trial of BLU-701 in EGFR-driven NSCLC.

Anticipated 2022 Partner Milestone

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

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

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

Anticipated 2022 Zai Milestone

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

ZL-1201 (CD47 Inhibitor, Global Rights)

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

Anticipated 2022 Zai Milestones

- Determine a recommended Phase 2 dose in the ongoing Phase 1 trial in mid-2022.
- Present preclinical data of ZL-1201 in combination with standard of care therapeutic antibodies in hematologic and solid tumor models at the 2022 AACR annual meeting.

Other Internal R&D Programs (Global Rights)

Anticipated 2022 Zai Milestone

- Present preclinical data of ZL-1211 (Claudin18.2), ZL-2201 (DNA-PK), and ZL-1218 (CCR8) at the 2022 AACR annual meeting.

Autoimmune Diseases

VYVGART™ (Efgartigimod)

Efgartigimod is an antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) autoantibodies 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 from degradation.

Recent Product Highlights

- The last Chinese patients have been enrolled in the global registrational Phase 3 ADDRESS study of efgartigimod in patients with pemphigus vulgaris (PV) or pemphigus foliaceus (PF) and the global registrational Phase 3 ADVANCE-SC study of efgartigimod in patients with ITP, respectively.
- In January 2022, Zai Lab partner argenx announced the approval of VYVGART™ inJapan for the treatment of gMG, the first and only FcRn blocker approved in Japan.
- In December 2021, Zai Lab partner argenx announced that the FDA approved VYVGART™ for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. With this regulatory milestone, VYVGART is the first and only FDA-approved FcRn blocker.
- At the end of 2021, Zai Lab partner argenx initiated the registrational trial of SC efgartigimod for bullous pemphigoid.
- In November 2021, Zai Lab announced that the first patient was dosed in the Greater China portion of the global registrational ADHERE study of efgartigimod in patients with CIDP.
- In November 2021, Zai Lab announced that the first patient was treated in the Greater China portion of the global registrational Phase 3 ADDRESS study of efgartigimod in patients with PV/PF.
- In November 2021, Zai Lab announced that the first patient was treated in the Greater China portion of the global registrational Phase 3 ADVANCE-SC study of efgartigimod in patients with ITP.

Anticipated 2022 Zai Milestones

- Submit an NDA to the NMPA for gMG in mid-2022.
- Launch proof-of-concept trials in two autoimmune renal diseases in 2022.

- Continue to explore and advance additional indications in coordination with argenx.

Anticipated 2022 Partner Milestones

- Initiate the registrational trial of SC efgartigimod for idiopathic inflammatory myopathy (myositis) in the first quarter of 2022. An interim analysis of data from the first 40 patients of each subtype (immune-mediated necrotizing myopathy, anti-synthetase syndrome and dermatomyositis) is planned.
- Report topline data of SC efgartigimod for gMG in the first quarter of 2022.
- Report topline data of intravenous efgartigimod for ITP in the second quarter of 2022.
- Report topline data of SC efgartigimod for PV/PF in the fourth quarter of 2022.
- Initiate proof-of-concept trials in two new autoimmune conditions: primary Sjogren's syndrome in the second half of 2022 and COVID-19-mediated postural orthostatic tachycardia syndrome in mid-2022.

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

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

Recent Product Highlight

- Recent transcriptome analysis of ZL-1102 showed a clear differential effect, with downregulated genes enriched in the immune response pathway and a decrease in K16 marker expression.

Anticipated 2022 Zai Milestone

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

Infectious Disease

NUZYRA (omadacycline)

NUZYRA is a once-daily oral and intravenous antibiotic for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

Recent Product Highlight

- In December 2021, Zai Lab announced the NMPA approval and commercial launch of NUZYRA for the treatment of CABP and ABSSSI as a Category 1 innovative drug. The product is locally manufactured in China.

Anticipated 2022 Zai Milestone

- Seek NRDL inclusion for CABP and ABSSSI indications.

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

Sulbactam-Durlobactam is a beta-lactam/beta-lactamase inhibitor combination that provides unique activity against Acinetobacter *organisms, including carbapenem-resistant strains.*

Anticipated 2022 Zai Milestone

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

Anticipated 2022 Partner Milestone

- Submit an NDA to the FDA in mid-2022.

Neuroscience

KarXT

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

Anticipated 2022 Zai Milestones

- Initiate a bridging study.

- Seek regulatory discussion with the NMPA on the required China program in schizophrenia.

Anticipated 2022 Partner Milestones

- Announce details of the Phase 3 program in psychosis in Alzheimer's disease in the first half of 2022 and initiate the study in mid-2022.

- Report topline data from the Phase 3 EMERGENT-2 trial in mid-2022.

Corporate Updates

- In February 2022, Zai Lab announced that it will seek shareholder approval of a proposed share subdivision of its ordinary shares, whereby each issued and unissued ordinary share will be subdivided into ten ordinary shares of the company. The company believes that the proposed share subdivision would increase the trading liquidity of the ordinary shares on The Stock Exchange of Hong Kong, lower the investment barrier and attract more investors to trade in the ordinary shares. Each American Depositary Share of Zai Lab currently represents the right to receive one fully paid ordinary share. If the proposed share subdivision is approved and effected, each American Depositary Share will represent the right to receive ten fully paid ordinary shares.

- In December 2021, Zai Lab announced the promotion of Harald Reinhart, M.D., to President and Head of Global Development, Neuroscience, Autoimmune and Infectious Diseases.

- In November 2021, Zai Lab announced the appointment to its Board of Directors of Richard Gaynor, M.D. Dr. Gaynor is the President and Chief of Research and Development of BioNTech US.

- Zai Lab continues to strengthen and expand its team. New hires since November 2021 include Linda Liu, Ph.D., Senior Vice President, Biologics Discovery; Hua Gong, Ph.D., Senior Vice President, Translational Medicine; and Jing Cao, Ph.D., Vice President, Program Management, Neuroscience, Autoimmune and Infectious Diseases.

- As of January 31, 2022, Zai Lab employed 1,951 full-time employees, including 788 and 945 employees engaged in R&D and commercial activities, respectively.

Full Year 2021 Financial Results

- Net product revenues for the full year of 2021 were $144.1 million, compared to $49.0 million in 2020. Product revenues for the period were $93.6 million for ZEJULA, compared to $32.2 million in 2020; $38.9 million for Optune, compared to $16.4 million in 2020; and $11.6 million for QINLOCK, compared to $0.4 million in 2020. Note that there was a negative $7.5 million nonrecurring adjustment to revenue in the fourth quarter of 2021 as a one-time compensation to distributors for ZEJULA sold at the 2021 price that remained in the distribution channel before the NRDL implementation.

- Research and Development (R&D) expenses were $573.3 million for 2021, compared to $222.7 million for the same period in 2020. The increase in R&D expenses in 2021 was primarily attributable to upfront payment for eight new licensing agreements, expenses related to ongoing and newly initiated late-stage clinical trials, and higher payroll and payroll-related expenses from increased R&D headcount. Excluding upfront payment for new licensing agreements, core R&D expenses were $252.0 million in 2021, compared to $139.2 million in 2020.

- Selling, General and Administrative (SG&A) expenses were $218.8 million for 2021, compared to $111.3 million for the same period in 2020. The increase was primarily due to payroll and payroll-related expenses from increased commercial headcount, as Zai Lab continued to expand and invest in its commercial operations in China in anticipation of substantial topline growth over the next few years.

- For the full year 2021, Zai Lab reported a net loss of $704.5 million, or a loss per share attributable to common stockholders of $7.58, compared to a net loss of $268.9 million, or a loss per share attributable to common stockholders of $3.46, for the same period in 2020. The increase in the net loss was primarily attributable to payments related to new business development activities.

- Excluding upfront payments for new licensing agreements, our cash used in operating activity and purchase of property and equipment and intangible assets was approximately $309.2 million in 2021, compared to approximately $143.2 million in 2020.

- As of December 31, 2021, cash and cash equivalents, short-term investments and restricted cash totaled $1,409.9 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 tomorrow, March 2, 2022, at 8:00 a.m. ET. Listeners may access the live webcast by visiting the Company's website at http://ir.zailaboratory.com. Participants must register in advance of the conference call. Details are as follows:

Registration Link: http://apac.directeventreg.com/registration/event/5968327

Conference ID: 5968327

All participants must use the link provided above to complete the online registration process in advance of the conference call. Upon registering, each participant will receive a dial-in number, Direct Event passcode and a unique access PIN, which can be used to join the conference call.

A replay will be available shortly after the call and can be accessed by visiting the Company's website at http://ir.zailaboratory.com.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies 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 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; clinical trial data, data readouts and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety and efficacy of our collaboration partners' products and of our pipeline therapies; the anticipated benefits and potential of investments, collaborations and business development activities; our future financial and operating results; and financial guidance, including our projections for the number of marketed products we will have in the future; our revenue projections for our current lung and GI cancer franchises; the impact of the inclusion of ZEJULA and/or our other marketed products in the NRDL; our plans to accelerate important data readouts and regulatory filings across our entire portfolio; our plans to file the NDA for efgartigimod in China and for our other products and product candidates in China and elsewhere; our plans to initiate a registrational study in China for bemarituzumab in first-line advanced gastric and gastroesophageal junction (GEJ) cancer or to initiate or continue existing clinical trials for our other products and product candidates. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other similar expressions.
Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products; (2) our ability to obtain funding for our operations and business initiatives, (3) the results of our clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory and political conditions, (6) risks related to doing business in China and (7) the other 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 about our SEC filings, please go to www.SEC.gov.

For more information, please contact:

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Zai Lab Limited
Audited Consolidated Balance Sheets
(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	As of	
	December 31, 2021	**December 31, 2020**
	$	**$**
Assets		
Current assets:		
Cash and cash equivalents	964,100	442,116
Short-term investments	445,000	744,676
Accounts receivable (net of allowance for credit loss of $11 and $1 as of December 31, 2021 and 2020, respectively)	47,474	5,165
Notes receivable	7,335	—
Inventories	18,951	13,144
Prepayments and other current assets	18,021	10,935
Total current assets	1,500,881	1,216,036
Restricted cash, non-current	803	743
Long term investments (including the fair value measured investment of $15,383 and nil as of December 31, 2021 and 2020, respectively)	15,605	1,279
Prepayments for equipment	989	274
Property and equipment, net	43,102	29,162
Operating lease right-of-use assets	14,189	17,701
Land use rights, net	7,811	7,908
Intangible assets, net	1,848	1,532
Long-term deposits	870	862
Value added tax recoverable	23,858	22,141
Total assets	**1,609,956**	**1,297,638**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	126,163	62,641
Current operating lease liabilities	5,927	5,206
Other current liabilities	60,811	30,196
Total current liabilities	192,901	98,043
Deferred income	27,486	16,858
Non-current operating lease liabilities	9,613	13,392
Total liabilities	**230,000**	**128,293**
Shareholders' equity		
Ordinary shares (par value of $0.00006 per share; 500,000,000 shares authorized, 95,536,398 and 87,811,026 shares issued and outstanding as of December 31, 2021 and 2020, respectively)	6	5
Additional paid-in capital	2,825,948	1,897,467
Accumulated deficit	(1,418,074)	(713,603)
Accumulated other comprehensive loss	(23,645)	(14,524)
Treasury Stock (at cost, 38,293 and nil shares as of December 31, 2021 and 2020, respectively)	(4,279)	—
Total shareholders' equity	**1,379,956**	**1,169,345**
Total liabilities and shareholders' equity	**1,609,956**	**1,297,638**

Zai Lab Limited
Audited Consolidated Statements of Operations
(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Year ended December 31,	
	2021	2020
	$	$
Revenues:		
Product Revenue	144,105	48,958
Collaboration Revenue	207	—
Total Revenues	144,312	48,958
Expenses:		
Cost of sales	(52,239)	(16,736)
Research and development	(573,306)	(222,711)
Selling, general and administrative	(218,831)	(111,312)
Loss from operations	(700,064)	(301,801)
Interest income	2,190	5,120
Interest expenses	—	(181)
Other (expenses) income, net	(5,540)	29,076
Loss before income tax and share of loss from equity method investment	(703,414)	(267,786)
Income tax expense	—	—
Share of loss from equity method investment	(1,057)	(1,119)
Net loss	(704,471)	(268,905)
Net loss attributable to ordinary shareholders	(704,471)	(268,905)
Loss per share - basic and diluted	(7.58)	(3.46)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	92,992,112	77,667,743

Zai Lab Limited
Audited Consolidated Statements of Comprehensive Loss
(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Year ended December 31,	
	2021	2020
	$	$
Net loss	(704,471)	(268,905)
Other comprehensive loss, net of tax of nil:		
Foreign currency translation adjustments	(9,121)	(19,144)
Comprehensive loss	(713,592)	(288,049)

[1] Based on aggregating, on selected asset-by-asset basis, forecasted sales in the peak year between now and 2030.

[2] Our forecasts are based on certain estimates and assumptions, including from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. The sources of such estimates and assumptions cannot guarantee the accuracy or completeness of such information. While we are not aware of any misstatements regarding the third-party information and we believe that each of these studies and publications is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and our other filings with the Securities and Exchange Commission. These and other factors could cause results to differ materially from those expressed in the estimates and assumptions made by third parties and by us.

Source: Zai Lab Limited