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): November 8, 2021

ZAI LAB LIMITED
(Exact name of registrant as specified in its charter)

Cayman Islands	**001-38205**	**98-1144595**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

4560 Jinke Road
Bldg. 1, Fourth Floor Pudong
Shanghai, China **201210**
(Address of principal executive offices) **(Zip Code)**

+86 21 6163 2588
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

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

* Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On November 8, 2021, Zai Lab (Shanghai) Co., Ltd., a wholly-owned subsidiary of Zai Lab Limited (the "Company"), and Blueprint Medicines Corporation ("Blueprint") entered into a license and collaboration agreement (the "Blueprint Agreement"), pursuant to which the Company obtained rights to develop and exclusively commercialize BLU-701 and BLU-945 and certain other forms thereof, including back-up compounds, in China, Macau, Hong Kong, and Taiwan (the "Licensed Territory").

Pursuant to the terms of the Blueprint Agreement, the Company will pay to Blueprint an upfront fee of $25.0 million plus milestone payments of up to an aggregate of $590.0 million upon the achievement of specified clinical, regulatory and sales milestones. Blueprint will also be eligible to receive certain royalties at tiered percentage rates ranging from the low to mid teens on annual net sales of licensed products in the Licensed Territory, subject to reduction under specified circumstances.

The Blueprint Agreement will terminate on a licensed product-by-licensed product basis and on a region-by-region basis in the Licensed Territory, upon the later to occur of (i) 12th anniversary of the date of the first commercial sale in such region, (ii) the expiration of the last valid claim within the royalty patent rights that covers the licensed product in such region, and (iii) the expiration of the last regulatory exclusivity for such licensed product in such country or region, or in its entirety upon the expiration of all payment obligations under the Blueprint Agreement. The Company may terminate the Agreement at any time after November 8, 2023 by providing 12 months' prior notice to Blueprint after the first commercial sale or nine months' prior notice prior to the first commercial sale. Either party may terminate the Agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events. In addition, Blueprint may terminate the Agreement if the Company challenges the licensed patent rights.

On November 8, 2021, the Company and Karuna Therapeutics, Inc. ("Karuna") entered into a license agreement (the "Karuna Agreement"), pursuant to which the Company and Karuna agreed to collaboratively develop KarXT in the Licensed Territory. Under the Karuna Agreement, the Company obtained from Karuna an exclusive license to develop, manufacture and commercialize KarXT in the Licensed Territory.

Pursuant to the terms of the Karuna Agreement, the Company will pay to Karuna an upfront fee of $35.0 million plus milestone payments of up to an aggregate of $152.0 million upon the achievement of specified clinical, regulatory and sales milestones. Karuna will also be eligible to receive certain royalties at tiered percentage rates ranging from the low to high teens on annual net sales of licensed products in the Licensed Territory, subject to reduction under specified circumstances.

The Karuna Agreement will terminate on a region-by-region basis and on a licensed product-by-licensed product basis in the Licensed Territory, upon the later to occur of (i) the date the last-to-expire valid claim in such region expires, (ii) the close of business of the day that is exactly 12 years after the date of the first commercial sale in such region, and (iii) the expiration date of any regulatory exclusivity in such region, or in its entirety upon the expiration of all payment obligations under the Karuna Agreement. The Company may terminate the Agreement at any time by providing 180 days' prior notice to Karuna. Either party may terminate the Agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events. In addition, Karuna may terminate the Agreement if the Company challenges the licensed patent rights.

The foregoing descriptions of the terms of the Blueprint Agreement and the Karuna Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Blueprint Agreement and the Karuna Agreement, respectively, which the Company intends to file as exhibits to a subsequent periodic report or on an amendment to this Current Report on Form 8-K.

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2021, Zai Lab Limited issued a press release announcing its financial results for the three months ended September 30, 2021. A copy of the press release is furnished as Exhibit 99.3 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.3 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 7.01 Regulation FD Disclosure.

A copy of the press releases announcing the Blueprint Agreement and the Karuna Agreement are furnished herewith as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K, respectively, and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing or this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Zai Lab Limited on November 9, 2021.
99.2	Press Release issued by Zai Lab Limited on November 9, 2021.
99.3	Press Release issued by Zai Lab Limited on November 9, 2021.
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/ Samantha Du
Samantha Du
Chief Executive Officer

Date: November 9, 2021

Zai Lab and Blueprint Medicines Announce Strategic Collaboration and License Agreement for BLU-945 and BLU-701 in Greater China

-- Zai Lab obtains exclusive rights to develop and commercialize BLU-945 and BLU-701 in Greater China --

-- Collaboration accelerates and expands global development of Blueprint Medicines' next-generation EGFR inhibitors with plans to bring clinical trials of BLU-945 and BLU-701 to Greater China --

-- Blueprint Medicines to receive $25 million upfront payment, up to $590 million in potential future milestone payments, and royalties --

CAMBRIDGE, Mass., SHANGHAI and SAN FRANCISCO, November 9, /PRNewswire/ — Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) and Blueprint Medicines Corporation (NASDAQ:BPMC) today announced 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 non-small cell lung cancer (NSCLC) in Greater China, including mainland China, Hong Kong, Macau and Taiwan. Discovered by Blueprint Medicines, BLU-945 and BLU-701 are investigational next-generation EGFR inhibitors, with first-in-class potential.

By combining Blueprint Medicines' precision therapy expertise with Zai Lab's development capabilities and established lung cancer franchise in Greater China, the collaboration aims to accelerate global development of BLU-945 and BLU-701 while addressing significant medical needs in China, where 40-50 percent of patients with NSCLC are believed to harbor EGFR mutations.[1][2][3] Blueprint Medicines will retain all rights to BLU-945 and BLU-701 in the rest of the world.

"With deep development and commercial expertise in oncology across a broad portfolio including multiple precision therapies for lung cancer, Zai Lab is the ideal partner to help us bring to China our vision for transforming the care of patients with EGFR-driven lung cancer," said Jeff Albers, Chief Executive Officer of Blueprint Medicines. "Through this collaboration, we will also propel forward our development program for BLU-945 and BLU-701 with a broad clinical trial footprint in Greater China that complements our development efforts."

"We are excited to enter into this collaboration with Blueprint Medicines, a leader in precision medicine, to bring forward two potential first-in-class EGFR inhibitors exquisitely designed to treat or prevent on-target resistance," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. "With more than 800,000 newly diagnosed lung cancer patients annually, one of the highest EGFR mutation rates in the world, and with no available therapies to address on-target resistance to early-generation EGFR therapies, we believe we have a tremendous opportunity to improve patient care in China."[1-4]

While targeted therapies have improved treatment for patients with EGFR-driven NSCLC, resistance inevitably emerges, with the T790M and C797S mutations being highly common on-target resistance mechanisms. Designed to address these challenges, BLU-945 and BLU-701 have the potential to be used either as a monotherapy or in combination, together or with other agents, to overcome or prevent on-target resistance across multiple lines of treatment. In addition, this collaboration enables opportunities to combine BLU-945 or BLU-701 with other Zai Lab lung cancer drug candidates to address off-target resistance mutations.

BLU-945 is a selective, potent EGFR tyrosine kinase inhibitor with activity against EGFR activating mutations combined with the T790M and C797S resistance mutations. It is highly selective over wild-type EGFR and off-target kinases, highlighting its potential to enable tolerable combinations. BLU-945 is currently being evaluated in the Phase 1/2 SYMPHONY trial in patients with previously treated EGFR-driven NSCLC (NCT04862780). BLU-701 is a selective, potent EGFR tyrosine kinase inhibitor with activity against EGFR activating mutations combined with the C797S resistance mutation. It has shown significant central nervous system (CNS) penetration in preclinical studies, which is meaningful because in EGFR-mutant NSCLC patients with baseline brain metastases, up to 40 percent of disease progressions involve CNS metastases.[5]

Subject to the terms of the agreement, Blueprint Medicines will receive an upfront cash payment of $25 million and will be eligible to receive up to $590 million in potential development, regulatory and sales-based milestone payments, and tiered royalties on a product-by-product basis ranging from the low-teens to mid-teens on annual net sales of BLU-945 and BLU-701 in Greater China, subject to adjustment in specified circumstances. In addition, Zai Lab will be responsible for all the development costs for BLU-945 and BLU-701 occurring in Greater China and will receive the rights to develop and exclusively commercialize BLU-945 and BLU-701 in the region.

About EGFR-Driven NSCLC in China

Lung cancer is the most commonly diagnosed cancer type and the leading cause of cancer death in China.[1] Annually, there are more than 800,000 new cases of lung cancer in China, of which approximately 85 percent are NSCLC.[1, 6]. EGFR mutations are more common in China than in the United States, occurring in 40-50 percent of NSCLC patients.[1] Third-generation EGFR-tyrosine kinase inhibitors, including osimertinib, are commonly prescribed in China and have emerged as the standard of care for the first-line setting. However, resistance inevitably emerges, leading to disease progression. There are no approved therapies for patients with disease progression following third-generation EGFR treatment.

About BLU-945 and BLU-701

Derived from Blueprint Medicines' proprietary research platform, BLU-945 and BLU-701 are investigational next-generation EGFR non-covalent tyrosine kinase inhibitors. Both treatments are specifically designed to provide comprehensive coverage of the most common activating and on-target resistance mutations, spare wild-type EGFR and other kinases to limit off-target toxicities and enable a range of combination strategies, and treat or prevent central nervous system metastases. BLU-945 is currently being evaluated in the Phase 1/2 SYMPHONY trial in patients with previously treated EGFR-driven NSCLC (NCT04862780). In addition, Blueprint Medicines plans to initiate a Phase 1/2 trial of BLU-701 in the fourth quarter of 2021.

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 disease, 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 the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

About Blueprint Medicines

Blueprint Medicines is a global precision therapy company that invents life-changing therapies for people with cancer and hematologic disorders. Applying an approach that is both precise and agile, we create medicines that selectively target genetic drivers, with the goal of staying one step ahead across stages of disease. Since 2011, we have leveraged our research platform, including expertise in molecular targeting and world-class drug design capabilities, to rapidly and reproducibly translate science into a broad pipeline of precision therapies. Today, we are delivering approved medicines directly to patients in the United States and Europe, and we are globally advancing multiple programs for genomically defined cancers, systemic mastocytosis, and cancer immunotherapy. For more information, visit www.BlueprintMedicines.com and follow us on Twitter (@BlueprintMeds) and LinkedIn.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of BLU-945 and BLU-701; the clinical development of BLU-945 and BLU-701; the potential treatment of epidermal growth factor receptor (EGFR) -driven non-small cell lung cancer (NSCLC) in Greater China; the potential of Zai Lab's commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab's collaboration arrangement with Blueprint Medicines Corporation and other risks and uncertainties associated with drug development and commercialization. These forward-looking statements may contain 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.

Cautionary Note Regarding Blueprint Medicines, Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding plans, strategies, timelines and expectations for Blueprint Medicines' current or future approved drugs and drug candidates, including timelines for marketing applications and approvals, the initiation of clinical trials or the results of ongoing and planned clinical trials; Blueprint Medicines' plans, strategies and timelines to nominate development candidates; plans and timelines for additional marketing applications for avapritinib and pralsetinib and, if approved, commercializing avapritinib and pralsetinib in additional geographies or for additional indications; the potential benefits of any of Blueprint Medicines' current or future approved drugs or drug candidates in treating patients; the potential benefits of Blueprint Medicines' collaborations; and Blueprint Medicines' strategy, goals and anticipated financial performance, milestones, business plans and focus. The words "aim," "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to the impact of the COVID-19 pandemic to Blueprint Medicines' business, operations, strategy, goals and anticipated milestones, including Blueprint Medicines' ongoing and planned research and discovery activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; Blueprint Medicines' ability and plans in continuing to establish and expand a commercial infrastructure, and successfully launching, marketing and selling current or future approved products; Blueprint Medicines' ability to successfully expand the approved indications for AYVAKIT/AYVAKYT and GAVRETO or obtain marketing approval for AYVAKIT/AYVAKYT in additional geographies in the future; the delay of any current or planned clinical trials or the development of Blueprint Medicines' current or future drug candidates; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates and gain approval of its drug candidates on a timely basis, if at all; the preclinical and clinical results for Blueprint Medicines' drug candidates, which may not support further development of such drug candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; Blueprint Medicines' ability to obtain, maintain and enforce patent and other intellectual property protection for AYVAKIT/AYVAKYT, GAVRETO or any drug candidates it is developing; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for AYVAKIT/AYVAKYT, GAVRETO or any of its current and future drug candidates; and the success of Blueprint Medicines' current and future collaborations, partnerships or licensing arrangements. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' filings with the Securities and Exchange Commission (SEC), including Blueprint Medicines' most recent Annual Report on Form 10-K, as supplemented by its most recent Quarterly Report on Form 10-Q and any other filings that Blueprint Medicines has made or may make with the SEC in the future. Any forward-looking statements contained in this press release represent Blueprint Medicines' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Blueprint Medicines explicitly disclaims any obligation to update any forward-looking statements.

Trademarks

All trademarks and registered trademarks referenced within are property of their respective owners.

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1 Zhang YL, Yuan JQ, Wang KF, et al. “The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis”. *Oncotarget*. 2016;7(48):78985-78993. doi:10.18632/oncotarget.12587

2 Zhou J, Song XB, He H, et al. “Prevalence and Clinical Profile of EGFR Mutation In Non- Small-Cell Lung Carcinoma Patients in Southwest China”. *Asian Pac J Cancer Prev*. 2016;17(3):965-71. doi: 10.7314/apjcp.2016.17.3.965. PMID: 27039821.

3 Wen S, Dai L, Wang L, et al. “Genomic Signature of Driver Genes Identified by Target Next-Generation Sequencing in Chinese Non-Small Cell Lung Cancer”. *Oncologist*. 2019 Nov;24(11):e1070-e1081. doi: 10.1634/theoncologist.2018-0572. Epub 2019 Mar 22. PMID: 30902917; PMCID: PMC6853120.

4 International Agency for Research on Cancer, Estimated New Incidence in 2020, lung, both sexes, all ages. https://gco.iarc.fr/today/online-analysis-pie?v=2020&mode=population&mode_population=countries&population=900&populations=900&key=total&sex=0&cancer=15&type=0&statistic=5&prevalence=0&population_group=0&ages_group%5B%5D=0&ages_group%5B%5D=17&nb_items=7&group_cancer=1&include_nmsc=1&include_nmsc_other=1&half_pie=0&donut=0 Accessed November 6, 2021.

5 Rangachari D, Yamaguchi N, VanderLaan PA, et al. “Brain metastases in patients with EGFR-mutated or ALK-rearranged Non-Small Cell lung cancers”. *Lung Cancer* 2015;88:108-11.

6 Govindan R, Page N, Morgensztern D, et al. “Changing epidemiology of small-cell lung cancer in the United States over the last 30 years: analysis of the surveillance, epidemiologic, and end results database.” *J Clin Oncol*. 2006 Oct 1;24(28):4539-44. doi: 10.1200/JCO.2005.04.4859. PMID: 17008692.

Exhibit 99.2

Zai Lab and Karuna Therapeutics Announce Strategic Collaboration for Development, Manufacturing, and Commercialization of KarXT in Greater China

Zai Lab obtains exclusive rights to develop and commercialize KarXT in Greater China

Karuna to receive upfront cash payment of $35 million, up to $152 million in potential near- and long-term development and commercial milestones and other payments, and low-double-digit to high-teens tiered royalties

BOSTON, SHANGHAI and SAN FRANCISCO – Nov. 9, 2021 — Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, and Karuna Therapeutics, Inc. (NASDAQ: KRTX), a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions, today announced their entry into an exclusive license agreement for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China, including mainland China, Hong Kong, Macau, and Taiwan.

KarXT is an oral, investigational M1/M4-preferring muscarinic agonist that stimulates receptors in the central nervous system implicated in various psychiatric conditions. KarXT was designed to unlock the therapeutic potential of xanomeline, which demonstrated significant benefits in reducing symptoms of psychosis in Phase 2 studies in schizophrenia and Alzheimer's disease, while ameliorating side effects seen in earlier studies. In the Phase 2 EMERGENT-1 trial, KarXT demonstrated clinically meaningful and statistically significant improvements in the primary endpoint of Positive and Negative Syndrome Scale (PANSS) total score, and in key secondary endpoints, including PANSS-positive subscore and PANSS-negative subscore, at week 5, and was generally well-tolerated.

Karuna is evaluating KarXT in late-stage clinical trials for the treatment of schizophrenia and psychosis in Alzheimer's disease. The EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia, is underway. The EMERGENT program is comprised of the previously completed Phase 2 EMERGENT-1 trial and four ongoing Phase 3 trials, with data from EMERGENT-2 and EMERGENT-3, the two Phase 3 acute efficacy and safety trials, expected in mid-2022 and in the second half of 2022, respectively. Karuna plans to initiate the Phase 3 ARISE trial evaluating KarXT as an adjunctive treatment for schizophrenia in adults who inadequately respond to atypical antipsychotics in the fourth quarter of 2021. Additionally, Karuna also plans to initiate a Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease in mid-2022 following encouraging results from the completed Phase 1b healthy elderly volunteer trial, which suggest that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile. Zai Lab will work with Karuna to design the optimal strategy to accelerate the development and regulatory timeline of KarXT in Greater China.

Under the terms of the agreement, Karuna will receive a $35 million upfront payment and is eligible to receive up to an additional $80 million in development and regulatory milestones. Karuna is also eligible to receive up to $72 million in sales milestones and low-double-digit to high-teens tiered royalties based on annual net sales of KarXT in Greater China. Zai Lab will fund substantially all development, regulatory, and commercialization activities in Greater China.

"We are thrilled to collaborate with Zai Lab, who shares our commitment to bringing transformative medicines to people living with psychiatric conditions globally," said Steve Paul, M.D., chief executive officer, president, and chairman of Karuna Therapeutics. "With their proven record of successfully developing and commercializing novel therapies in Greater China, we believe that Zai Lab is the ideal partner to expand the global footprint for KarXT alongside our ongoing efforts in the U.S., with the goal of providing meaningful treatments to millions of people living with mental illness globally."

“Our collaboration with Karuna is a significant milestone for Zai Lab, marking the expansion and diversification of our development and commercial portfolio into neuroscience, our fourth therapeutic area,” said Samantha Du, Ph.D., founder, chairperson and chief executive officer of Zai Lab. “KarXT is well positioned to serve as the anchor asset in our new neuroscience franchise. Zai Lab’s mission is to deliver innovative medicines to address unmet medical needs of patients, and we look forward to working with Karuna to bring KarXT to patients in need in Greater China as soon as possible.”

“There is a significant need for new and more effective therapies with improved safety to treat serious psychiatric conditions in Greater China,” said Gang Wang, M.D., Director of National Clinical Research Center for Mental Disorders, Dean of Beijing Anding Hospital, Capital Medical University. “Currently, more than 8 million people in Greater China are living with schizophrenia, yet fewer than half are receiving treatment, and even fewer are obtaining adequate symptom improvement from current treatment. We believe KarXT has the potential to provide a meaningful new treatment option for many patients living with schizophrenia and other conditions with disabling symptoms of psychosis.”

Goldman Sachs & Co. LLC is acting as financial advisor to Karuna Therapeutics.

About KarXT

KarXT (xanomeline-trospium) is an oral, investigational M1/M4-preferring muscarinic acetylcholine receptor agonist in development for the treatment of psychiatric and neurological conditions, including schizophrenia and dementia-related psychosis. KarXT preferentially stimulates muscarinic receptors in the central nervous system implicated in these conditions, as opposed to current antipsychotic medicines, which bind to the D_2 dopamine receptor. KarXT has the potential to usher in a new class of treatment for schizophrenia and dementia-related psychosis based on its differentiated mechanism of action.

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.

About Karuna Therapeutics

Karuna Therapeutics is a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions. At Karuna, we understand there is a need for differentiated and more effective treatments that can help patients navigate the challenges presented by these severe and disabling disorders. Utilizing our extensive knowledge of neuroscience, we are harnessing the untapped potential of the brain in pursuit of novel pathways to develop medicines that make meaningful differences in peoples’ lives. For more information, please visit www.karunatx.com.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of KarXT; the clinical development of KarXT; the potential treatment of schizophrenia and dementia-related psychosis; the potential of Zai Lab's commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab's collaboration arrangement with Karuna Therapeutics, Inc. and other risks and uncertainties associated with drug development and commercialization. These forward-looking statements may contain 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.

Karuna Therapeutics Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the potential benefits and results that may be achieved through our collaboration with Zai Lab, our ongoing and planned clinical trials and regulatory filings, our goals to develop and commercialize our product candidates, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to obtain necessary funding, our ability to generate positive clinical trial results for our product candidates and other risks inherent in clinical development, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, risks relating to business interruptions resulting from the coronavirus (COVID-19) pandemic, and other risks set forth under the heading "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

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Zai Lab Announces Third Quarter 2021
Financial Results and Corporate Updates

— 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, SAN FRANCISCO, and CAMBRIDGE, Mass., November 9, 2021 — 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® 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 strong 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® (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 Milestones

- 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 PDGFRα-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 600mg 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 600mg 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 Milestones

- 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 trospium, 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, infectious disease, 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 the company, 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, 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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Zai Lab Limited

Zai Lab Limited

Unaudited Condensed Consolidated balance sheets

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

	As of	
	September 30, 2021	December 31, 2020
	$	$
Assets		
Current assets:		
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	1,619,087	1,216,036
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	23,390	22,141
Total assets	**1,728,079**	**1,297,638**
Liabilities and shareholders’ equity		
Current liabilities:		
Accounts payable	51,406	62,641
Current operating lease liabilities	6,312	5,206
Other current liabilities	54,292	30,196
Total current liabilities	112,010	98,043
Deferred income	17,487	16,858
Non-current operating lease liabilities	10,652	13,392
Total liabilities	**140,149**	**128,293**
Shareholders’ equity		
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)	(3,533)	—
Total shareholders’ equity	**1,587,930**	**1,169,345**
Total liabilities and shareholders’ equity	**1,728,079**	**1,297,638**

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 30,		Nine Months Ended September 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	(59,002)	(27,874)	(149,254)	(70,346)
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	(13,580)	11,958	(12,401)	11,267
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	(340)	(265)	(548)	(671)
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)