Zai Lab Announces Second Quarter 2024 Financial Results and Recent Corporate Updates

August 6, 2024

– Net product revenue of $100.1 million for the second quarter of 2024, representing 45% y-o-y growth; 47% y-o-y growth at constant exchange rate (CER)

– VYVGART® (efgartigimod alfa injection) sales of $23.2 million for the second quarter of 2024; raising full-year VYVGART revenue guidance to exceed $80.0 million

– Expansion of Zai Lab's global oncology pipeline with a next generation ROR1 antibody-drug conjugate (ADC) program

– Three product approvals in China including XACDURO® for HABP/VABP, efgartigimod SC for gMG, and AUGTYRO™ for ROS1+ NSCLC; expect at least four regulatory submissions to the NMPA within next 12 months including KarXT for schizophrenia

– Strong balance sheet with a cash position[1] of $730.0 million as of June 30, 2024, compared to $750.8 million as of March 31, 2024

– Company to host conference call and webcast on August 7, 2024, at 8:00 a.m. ET (8:00 p.m. HKT)

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 6, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for the second quarter of 2024, along with recent product highlights and corporate updates.

"In the second quarter, we achieved impressive commercial growth, maintained financial discipline, and made significant strides across our product portfolio, highlighting our capability to execute on our strategic objectives," said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. "The success of VYVGART underscores the urgent need for effective and safe treatments for patients living with generalized myasthenia gravis. We will continue to prioritize resources and focus investments on high-value initiatives with the potential to significantly improve human health. Recently, we expanded our global oncology pipeline with a next generation ROR1 ADC program, ZL-6301. Additionally, the progress of our pipeline, including efgartigimod, bemarituzumab, KarXT and our three global clinical-stage assets, keeps us on track to achieve the goals outlined in our five-year strategic plan."

"Our net product revenues grew 45% y-o-y in the second quarter, driven by the successful commercialization of VYVGART," said Josh Smiley, President and Chief Operating Officer of Zai Lab. "In 2024, we will maintain our focus on the strong execution of VYVGART's launch in generalized myasthenia gravis while also preparing for the anticipated launches of several new products and indications in the near future. Our efforts to build a stronger and more efficient organization, coupled with our innovative pipeline, position us for substantial topline growth and set us on the path to achieve profitability by the end of 2025."

1 Cash position includes cash and cash equivalents, current restricted cash, and short-term investments.

Second-Quarter 2024 Financial Results

- **Product revenue, net** was $100.1 million in the second quarter of 2024, compared to $68.9 million for the same period in 2023, representing 45% y-o-y growth and 47% y-o-y growth at CER. This increase was primarily driven by increased sales for VYVGART since its launch in September 2023 and China's National Reimbursement Drug List (NRDL) listing in January 2024, and increased sales for ZEJULA and NUZYRA. Primary drivers of this revenue growth included the following:
    - **ZEJULA®:** $45.0 million in the second quarter of 2024, an increase of 5% y-o-y from $43.0 million for the same period in 2023, driven by increased hospital sales in first-line ovarian cancer and increased duration of treatment and supported by the renewal of ZEJULA's NRDL listing for the maintenance treatment of adult patients with first-line and recurrent ovarian cancer, effective January 1, 2024.
    - **VYVGART®:** $23.2 million in the second quarter of 2024, compared to $0.1 million for the same period in 2023, driven by its NRDL listing for the treatment of generalized myasthenia gravis (gMG) effective January 1, 2024 and positive physician and patient reception as well as increased patient access as VYVGART is added to hospital formularies. VYVGART was launched for the treatment of gMG in September 2023.
    - **NUZYRA®:** $12.3 million in the second quarter of 2024, an increase of 165% y-o-y compared to $4.6 million for the same period in 2023, driven by the NRDL listings for the IV formulation of NUZYRA for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) in the first quarter of 2023 and the oral formulation for these indications in the first quarter

of 2024.

- **Research and Development (R&D) expenses** were $61.6 million in the second quarter of 2024, compared to $76.7 million for the same period in 2023. This decrease was primarily due to decreased milestone fees for our license and collaboration agreements, partially offset by increased clinical trial expenses related to newly initiated studies and progress of existing studies.

- **Selling, General and Administrative expenses** were $79.7 million in the second quarter of 2024, compared to $67.9 million for the same period in 2023. This increase was primarily driven by higher general selling expenses and headcount growth primarily to support VYVGART.

- **Net loss** was $80.3 million in the second quarter of 2024, or a loss per ordinary share attributable to common stockholders of $0.08 (or loss per American Deposit Share (ADS) of $0.82), compared to a net loss of $120.9 million for the same period in 2023, or a loss per ordinary share of $0.13 (or loss per ADS of $1.25).

- **Cash and cash equivalents, short-term investments, and current restricted cash** totaled $730.0 million as of June 30, 2024, compared to $750.8 million as of March 31, 2024.

Corporate Updates

Below are key corporate updates since our last earnings release:

- **Business Development:** In July 2024, Zai Lab entered into a strategic partnership and global license agreement with MabCare Therapeutics. Through this collaboration, the Company expanded its global oncology pipeline with a next generation ADC targeting ROR1, ZL-6301. ZL-6301 has the potential to be used in the treatment of solid tumors where ROR1 is commonly expressed and in hematological malignancies where ROR1 is a validated target. ZL-6301 has demonstrated an encouraging pre-clinical profile, and it is currently in the IND-enabling stage. Zai Lab plans to focus on advancing its global development.

- **Organizational Update:** In June 2024, Zai Lab appointed Dr. Rafael Amado as President, Head of Global Research and Development, expanding his role to encompass R&D efforts across all of our therapeutic areas upon the retirement of Dr. Harald Reinhart at the end of June. This leadership transition allows for continued momentum and a strategic focus on our pipeline.

Recent Pipeline Highlights

Below are key product updates since our last earnings release:

Oncology Pipeline

- **Niraparib (PARP):** In July 2024, Zai Lab announced that data of a Zai-supported study published in *Cell* provides new insights with potential to improve treatment of HRD-positive ovarian cancers, including through neoadjuvant monotherapy with niraparib and a combination of niraparib and ZL-1218, an investigational CCR8 antibody.

- **Bemarituzumab (FGFR2b):**

– In June 2024, Zai Lab and partner Amgen completed enrollment for the global Phase 3 FORTITUDE-101 study of bemarituzumab plus chemotherapy in first-line gastric cancer.

– The enrollment is ongoing for the global Phase 3 FORTITUDE-102 study of bemarituzumab plus chemotherapy and nivolumab in first-line gastric cancer in mainland China, Hong Kong, Macau, and Taiwan (collectively, Greater China).

- **AUGTYRO ™(Repotrectinib) (ROS1/TRK):**

– In May 2024, China's National Medical Products Administration (NMPA) approved the New Drug Application (NDA) for repotrectinib for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC. The approval was based on the global TRIDENT-1 study that evaluated repotrectinib in TKI naïve and TKI-pretreated patients with *ROS1*-positive NSCLC. We participated in the Greater China portion of this study.

– In June 2024, Zai Lab partner Bristol Myers Squibb (BMS) announced that the U.S. Food and Drug Administration (FDA) had granted accelerated approval of AUGTYRO for the treatment of patients with *NTRK*-positive locally advanced or metastatic solid tumors.

- **ZL-1310 (DLL3 ADC):** The enrollment in the United States and Greater China is ongoing for the global Phase 1 study in relapsed and refractory second-line+ small cell lung cancer (SCLC) who have progressed on or after platinum-based chemotherapy.

- **ZL-1218 (CCR8):** The enrollment in the United States, Europe, and Greater China is ongoing for the global Phase 1 study of ZL-1218 as a single agent and in combination with pembrolizumab in patients with advanced solid tumor malignancies.

Immunology, Neuroscience, and Infectious Disease Pipeline

- **Efgartigimod (FcRn):**

– In July 2024, the NMPA approved the Biologics License Application (BLA) for efgartigimod alfa injection (subcutaneous injection) (efgartigimod SC) as an add on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive. This approval will provide additional flexibility and optionality for gMG patients in mainland China.

– In May 2024, the NMPA accepted the supplemental Biologics License Application (sBLA) with priority review for efgartigimod SC in chronic inflammatory demyelinating polyneuropathy (CIDP). In June 2024, Zai Lab partner argenx announced that the FDA approved VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for this indication. We participated in the global ADHERE Study, the largest clinical trial to date studying CIDP.

- **XACDURO® (Sulbactam-Durlobactam or SUL-DUR):** In May 2024, the NMPA approved the NDA for XACDURO for the treatment of adult patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

- **Xanomeline-Trospium (KarXT) (M1/M4-agonist):** In July 2024, Zai Lab joined the global Phase 3 ADEPT-2 study in Alzheimer's disease with psychosis in Greater China.

- **ZL-1102 (IL-17 Humabody®):** In May 2024, Zai Lab dosed the first patient in a global Phase 2 study evaluating the efficacy and safety of ZL-1102 for the treatment of chronic plaque psoriasis (CPP).

Anticipated Major Milestones in 2024 and the First Half of 2025

Potential Regulatory Submissions to the NMPA

- **TTFields:** Marketing Authorization Application (MAA) submission in second-line+ NSCLC following progression on or after platinum-based chemotherapy in the fourth quarter of 2024.

- **Tisotumab Vedotin (Tissue Factor ADC):** BLA submission in recurrent or metastatic cervical cancer following progression on or after chemotherapy.

- **Repotrectinib (ROS1/TRK):** supplementary NDA (sNDA) submission in *NTRK*+ solid tumors.

- **Xanomeline-Trospium (KarXT) (M1/M4-agonist):** NDA submission in schizophrenia.

Expected Clinical Development and Data Readouts

Efgartigimod (FcRn)

- Zai Lab to join the registrational study of efgartigimod SC given by prefilled syringe in Thyroid Eye Disease (TED) in Greater China in the fourth quarter of 2024.

- argenx to provide topline data from the Phase 2/3 ALKIVIA study evaluating efgartigimod across three myositis subsets (immune-mediated necrotizing myopathy (IMNM), anti-synthetase syndrome (ASyS), and dermatomyositis (DM)) in the fourth quarter of 2024. Zai Lab to join the Phase 3 portion of this study in the fourth quarter of 2024.

- Zai Lab to join the global registrational Phase 3 studies in seronegative gMG and ocular MG in early 2025, aiming to expand the label into broader MG populations.

Xanomeline-Trospium (KarXT) (M1/M4-agonist)

- Zai Lab to complete patient enrollment of the China registrational bridging study in schizophrenia, with topline data expected by the end of 2024.

- BMS to report data from the EMERGENT-4 and EMERGENT-5 trials evaluating the long-term safety for treatment of schizophrenia in the second half of 2024.

TTFields

- Novocure to provide a topline data readout from the Phase 3 PANOVA-3 clinical trial in locally advanced pancreatic cancer in the fourth quarter of 2024. We are participating in the study in Greater China.

ZL-1310 (DLL3 ADC)

- Potential dose escalation data from the global Phase 1 study in relapsed and refractory second-line+ SCLC at the end of 2024 or early 2025.

ZL-1218 (CCR8)

- Present the preliminary clinical PK and PD analysis of the global Phase 1 study in solid tumors at 2024 European Society for Medical Oncology (ESMO) in September 2024.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, August 7, 2024, at 8:00 a.m. ET (8:00 p.m. HKT). Listeners may access the live webcast by visiting the Company's website at http://ir.zailaboratory.com. Participants must register in advance of the conference call.

Details are as follows:

Registration Link: https://register.vevent.com/register/BIaccafead4b094cf191720bf5d03048c6

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

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

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Non-GAAP Measures

In addition to results presented in accordance with GAAP, we disclose growth rates that have been adjusted to exclude the impact of changes due to the translation of foreign currencies into U.S. dollars, which are non-GAAP measures. We believe that these non-GAAP measures are important for an understanding of the performance of our business operations and financial results and provide investors with an additional perspective on trends. Although we believe the non-GAAP financial measures enhance investors' understanding of our business and performance, these non-GAAP financial measures should not be considered an exclusive alternative to accompanying GAAP financial measures.

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; our goals, objectives, and priorities and our expectations under our growth strategy (including our expectations regarding our commercial products and launches, clinical stage products, revenue growth, profitability, and cash flow); clinical development programs and related clinical trials; clinical trial data, data readouts, and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our products and product candidates and those of our collaboration partners; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; and financial guidance, including with respect to our planned sources and uses of cash and our expected path to profitability. 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) risks related to doing business in China; and (6) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC's website at www.SEC.gov.

Zai Lab Limited

Unaudited Condensed Consolidated Balance Sheets

(in thousands of U.S. dollars ($), except for number of shares and per share data)

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	630,048	790,151

Restricted cash, current	100,000	—
Short-term investments	—	16,300
Accounts receivable (net of allowance for credit losses of $20 and $17 as of June 30, 2024 and December 31, 2023, respectively)	69,635	59,199
Notes receivable	8,102	6,134
Inventories, net	41,846	44,827
Prepayments and other current assets	20,292	22,995
Total current assets	869,923	939,606
Restricted cash, non-current	1,116	1,113
Long term investments	4,073	9,220
Prepayments for equipment	46	111
Property and equipment, net	50,613	53,734
Operating lease right-of-use assets	13,102	14,844
Land use rights, net	2,991	3,069
Intangible assets, net	44,063	13,389
Long-term deposits	1,441	1,209
Total assets	**987,368**	**1,036,295**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	127,344	112,991
Current operating lease liabilities	7,581	7,104
Short-term debt	70,298	—
Other current liabilities	46,495	82,972
Total current liabilities	251,718	203,067
Deferred income	25,343	28,738
Non-current operating lease liabilities	5,803	8,047
Other non-current liabilities	325	325
Total liabilities	**283,189**	**240,177**
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 986,310,340 and 977,151,270 shares issued as of June 30, 2024 and December 31, 2023, respectively; 981,398,140 and 972,239,070 shares outstanding as of June 30, 2024 and December 31, 2023, respectively)	6	6
Additional paid-in capital	3,011,964	2,975,302
Accumulated deficit	(2,329,728)	(2,195,980)
Accumulated other comprehensive income	42,773	37,626
Treasury Stock (at cost, 4,912,200 shares as of both June 30, 2024 and December 31, 2023)	(20,836)	(20,836)
Total shareholders' equity	**704,179**	**796,118**
Total liabilities and shareholders' equity	**987,368**	**1,036,295**

Zai Lab Limited

Unaudited Condensed Consolidated Statements of Operations

(in thousands of $, except for number of shares and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenues				
Product revenue, net	100,106	68,864	187,255	131,661
Collaboration revenue	398	—	398	—
Total revenues	100,504	68,864	187,653	131,661
Expenses				
Cost of product revenue	(35,148)	(23,763)	(68,767)	(45,100)
Cost of collaboration revenue	(85)	—	(85)	—
Research and development	(61,625)	(76,682)	(116,270)	(125,153)
Selling, general, and administrative	(79,710)	(67,920)	(148,904)	(130,430)
Gain on sale of intellectual property	—	10,000	—	10,000
Loss from operations	(76,064)	(89,501)	(146,373)	(159,022)
Interest income	9,330	10,090	18,988	20,321

Interest expense	(492)	—	(605)	—
Foreign currency losses	(4,108)	(40,079)	(6,176)	(31,167)
Other (expenses) income, net	(8,943)	(1,405)	418	(171)
Loss before income tax	(80,277)	(120,895)	(133,748)	(170,039)
Income tax expense	—	—	—	—
Net loss	(80,277)	(120,895)	(133,748)	(170,039)
Loss per share - basic and diluted	(0.08)	(0.13)	(0.14)	(0.18)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	975,937,790	964,817,310	974,541,780	963,140,360

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Unaudited Condensed Consolidated Statements of Comprehensive Loss

(in thousands of $)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net loss	(80,277)	(120,895)	(133,748)	(170,039)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	3,605	34,908	5,147	26,495
Comprehensive loss	(76,672)	(85,987)	(128,601)	(143,544)

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Non-GAAP Measures

(in thousands of $)

	Three Months Ended June 30,		Year over Year % Growth		Six Months Ended June 30,		Year over Year % Growth	
	2024	**2023**	**As reported**	**At CER***	**2024**	**2023**	**As reported**	**At CER***
Product revenue, net	100,106	68,864	45%	47%	187,255	131,661	42%	45%
Loss from operations	(76,064)	(89,501)	(15)%	(15)%	(146,373)	(159,022)	(8)%	(8)%

** The growth rates at CER were calculated assuming the same foreign currency exchange rates were in effect for the current and prior year periods.*

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