Zai Lab Announces Second Quarter 2023 Financial Results and Corporate Updates

August 7, 2023

- *Total product revenue of $68.9 million for the second quarter of 2023, representing 45% y-o-y growth; 53% y-o-y growth at constant exchange rate*
- *VYVGART® (efgartigimod alfa injection) approved in China as first-and-only neonatal Fc receptor (FcRn) blocker for generalized myasthenia gravis (gMG); preparations for launch underway; subcutaneous efgartigimod for gMG under Biologics License Application (BLA) review*
- *Primary endpoint met in ADHERE trial of VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP)*
- *Strong balance sheet with a cash position of $876.4 million as of June 30, 2023, compared to $931.4 million as of March 31, 2023*
- *Company to host conference call and webcast on August 8, 2023, at 8:00 a.m. ET*

SHANGHAI, China and CAMBRIDGE, Mass., Aug. 07, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for the second quarter of 2023, along with recent product highlights and corporate updates.

“In the second quarter of 2023, we continued to successfully execute across our business. Our commercial products continued to deliver strong growth, with net product revenues growing 53% on a constant currency basis, and we made important progress for several late-stage and early development programs within our pipeline,” said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. “Most importantly, we gained NMPA approval of VYVGART, a first-in-class therapy that has the potential to significantly transform the lives of patients living with gMG in China, and we were able to achieve this monumental milestone on June 30th, which makes us eligible for NRDL listing in 2024. More recently, the positive data for efgartigimod in CIDP supports our confidence in its blockbuster potential across multiple indications.”

“Looking ahead, Zai Lab has the potential for significant revenue growth and margin expansion over the next five years,” said Josh Smiley, President and Chief Operating Officer of Zai Lab. “As highlighted at our 2023 Investor Day, we expect to have over 15 commercial-stage products, and at least one IND per year for global best-in-class/first-in-class assets, by the end of 2028. We expect our robust portfolio of assets to drive a revenue compound annual growth rate of over 50% from 2023 to 2028. As we launch new products and indications, we will continue to be prudent and capital efficient, prioritizing our R&D efforts and driving increased productivity across the organization. We expect that this discipline, along with our expected revenue growth, will allow us to reach corporate profitability by the end of 2025.” Mr. Smiley concluded.

Recent Product Highlights and Corporate Updates

Zai Lab has established a differentiated portfolio and pipeline of assets, including 13 in late-stage development. We have had a number of exciting developments with respect to our products and product candidates, including the following updates since our last earnings release:

Commercial Products

We continued to increase sales for each of our commercial products in the second quarter of 2023, compared to the same period in 2022, driven by increased access for ZEJULA®, QINLOCK®, and NUZYRA® as a result of their inclusion in the National Reimbursement Drug List (NRDL) and for Optune® as a result of increased supplemental insurance plan coverage.

We also received the following regulatory approvals for our commercial products during the second quarter of 2023:

- **VYVGART®:** In June 2023, we received approval from the NMPA for the BLA for VYVGART (efgartigimod alfa injection), a first-in-class FcRn antagonist, as an add on standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive. We expect to commercially launch VYVGART in mainland China later this year.
- **Optune:** In May 2023, the Taiwan Food and Drug Administration approved the Marketing Authorization Application (MAA) of Optune for the treatment of patients with glioblastoma multiforme (GBM).

Key Product Candidate Developments

We continued to advance our product candidates through our research and development and commercial operations, including the following developments with respect to our clinical trials and regulatory approvals:

Oncology

- **ZEJULA (niraparib, PARP):** In July 2023, data from the Phase 3 PRIME study were published in JAMA Oncology, supporting the utility of ZEJULA as a maintenance therapy in a broad population of Chinese patients with newly diagnosed advanced ovarian cancer and demonstrating that an individual starting dose (ISD) of 200 or 300mg based on baseline bodyweight and platelet count can bring significant benefit to patients with an improved safety and tolerability profile of ZEJULA compared to a fixed 300mg starting dose. These data demonstrate that maintenance treatment with ZEJULA can significantly prolong progression-free survival versus placebo and can reduce the risk of disease progression or death by 55% with newly diagnosed advanced ovarian cancer.

- **Tumor Treating Fields (TTFields or Optune):**

    - *Pancreatic Cancer:* In July 2023, Zai Lab partner NovoCure Limited (NovoCure) announced a favorable Independent Data Monitoring Committee recommendation to continue the Phase 3 PANOVA-3 clinical trial of TTFields therapy in pancreatic cancer. Pre-specified interim analysis concluded that the fully enrolled PANOVA-3 clinical trial should proceed to final analysis as planned. Zai Lab participated in the Greater China portion of the study.

    - *NSCLC:* In June 2023, Zai Lab and NovoCure announced the LUNAR Phase 3 clinical trial met the primary endpoint, demonstrating a statistically significant and clinically meaningful extension in overall survival for patients with metastatic NSCLC after platinum-based therapies. Zai Lab participated in the Greater China portion of the study.
        - Tumor Treating Fields therapy together with standard of care provided a statistically significant and clinically meaningful 3-month improvement in median overall survival versus standard of care with no added systemic toxicities; and
        - Tumor Treating Fields therapy together with immune checkpoint inhibitors resulted in an unprecedented 8-month improvement in median overall survival.

- **KRAZATI® (adagrasib, $KRAS^{G12C}$):**

    - In July 2023, Zai Lab completed enrollment in China for the global Phase 3 KRYSTAL-10 trial of adagrasib in combination with cetuximab vs. chemotherapy in patients with previously treated advanced $KRAS^{G12C}$-mutated colorectal cancer.
    - In June 2023, Zai Lab completed enrollment in China for the global Phase 2 KRYSTAL-7 trial of adagrasib in combination with pembrolizumab as first-line treatment for patients with advanced $KRAS^{G12C}$-mutated NSCLC.

- **Repotrectinib (ROS1/TRK):** In June 2023, Zai Lab announced that the National Medical Products Administration (NMPA) in China has accepted its New Drug Application (NDA) for repotrectinib for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC, after granting priority review in May 2023. In May 2023, Zai Lab partner Bristol Myers Squibb (BMS) announced that the NDA for repotrectinib was accepted for priority review by the FDA for the same indication, with a Prescription Drug User Fee Act (PDUFA) date of November 27, 2023.

- **Bemarituzumab (FGFR2b):** In July 2023, Zai Lab enrolled the first patient in the mainland China portion of the global Phase 3 FORTITUDE-101 study of bemarituzumab plus chemotherapy, versus placebo plus chemotherapy, in first-line gastric cancer with FGFR2b overexpression.

Autoimmune Disorders, Infectious Diseases and Neuroscience

- **VYVGART (efgartigimod, FcRn):**

    - *gMG*: In June 2023, argenx BV (argenx) announced that the FDA approved VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) injection for subcutaneous use in gMG. In July 2023, the NMPA accepted Zai Lab's BLA for efgartigimod alfa injection (subcutaneous injection) for the treatment of adult patients with gMG.

    - *CIDP*: In July 2023, Zai Lab and argenx announced positive topline results from the global registrational ADHERE study evaluating VYVGART Hytrulo in adults with CIDP. Zai Lab participated in the Greater China portion of the study. Highlights of the results include:
        - Primary endpoint met (p=0.000039); VYVGART Hytrulo demonstrated a 61% reduction (HR: 0.39 95% CI:

0.25; 0.61) in the risk of relapse versus placebo;
- 67% of patients in open-label Stage A demonstrated evidence of clinical improvement (ECI), indicating that IgG autoantibodies play a significant role in the underlying biology of CIDP; and
- Safety and tolerability profile was consistent with previous clinical trials and the confirmed safety profile of VYVGART.

- *Bullous pemphigoid (BP):* In May 2023, Zai Lab enrolled the first patient in China in the global Phase 2/3 BALLAD study of SC efgartigimod in adult patients with BP.

- **XACDURO® (SUL-DUR, Asia Pacific rights):** In May 2023, Zai Lab partner Entasis Therapeutics, Inc. (Entasis), a wholly owned subsidiary of Innoviva, Inc., announced that the FDA approved XACDURO for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus complex (Acinetobacter)*. The Company's NDA is under review at the NMPA with priority review status in China.

- **KarXT (xanomeline-trospium, M1/M4-preferring muscarinic agonist):** In June 2023, Zai Lab enrolled the first patient in the registrational bridging study in mainland China for KarXT for the treatment of patients with schizophrenia.

Corporate Updates

- **Organizational update:** In July 2023, Zai Lab promoted Yajing Chen to Chief Financial Officer (CFO), effective July 7, 2023. Dr. Chen previously served as Zai Lab's Senior Vice President and Deputy CFO, helping to oversee finance, planning and forecasting, accounting, tax, treasury, and procurement matters since joining the Company in September 2021. She is a seasoned finance executive with more than 20 years of experience in the life sciences industry as well as a Ph.D. trained scientist. She joined the Company from AstraZeneca where she held various roles of increasing responsibility from 2006 to 2021, including Chief Financial Officer for the U.S. Oncology Business Unit from 2019 to 2021 and Finance Controller of the Global Oncology Business Unit from 2016 to 2019. Her scientific background combined with her significant executive management experience, finance expertise at leading global companies, and business acumen provide a unique and valuable perspective to the Company and will help drive our next phase of growth. Dr. Chen succeeds Billy Cho, who stepped down from his role and left the Company on July 7, 2023.

- **2023 Investor Day:** Zai Lab hosted an Investor Day in New York on Tuesday, June 20, 2023.

    - Zai Lab highlighted its 5-year growth strategy, including the following goals by the end of 2028:

        - Over 15 commercial-stage products in 2028 (versus 5 today)

        - Over 8 clinical-stage global-right products in 2028 with at least one Investigational New Drug application (IND) per year (versus 3 today)

        - Revenue compound annual growth rate (CAGR) of >50% from 2023 to 2028

        - Significant revenue growth and expanding operating margins to lead to corporate profitability by the end of 2025

    - In addition, Zai Lab spotlighted multiple key programs with over $1 billion peak sales potential, starting with efgartigimod.

Anticipated Major Milestones in 2023

Oncology

Tumor Treating Fields or TTFields

- Zai Lab partner NovoCure to provide a topline data readout from the global pivotal INNOVATE-3 clinical study testing the efficacy of TTFields together with paclitaxel in platinum-resistant ovarian cancer.

KRAZATI (adagrasib, $KRAS^{G12C}$)

- Zai Lab partner Mirati Therapeutics, Inc. (Mirati) to provide a clinical data update for the global Phase 2 KRYSTAL-7 study of adagrasib in combination with pembrolizumab in first-line $KRAS^{G12C}$-mutated NSCLC. Zai Lab is participating in the study in Greater China.

- Mirati to provide an update on its multi-pronged development approach in first-line $KRAS^{G12C}$-mutated NSCLC.

- Mirati to submit a supplemental New Drug Application (sNDA) for Accelerated Approval to the FDA in third-line+ $KRAS^{G12C}$-mutated advanced colorectal cancer (CRC).

Odronextamab (CD20xCD3)

- Zai Lab partner Regeneron Pharmaceuticals, Inc. (Regeneron) to initiate confirmatory studies in follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) including in earlier lines.

- Regeneron expects to receive BLA and Marketing Authorisation Application (MAA) acceptance in relapsed/refractory FL and DLBCL.

MARGENZA™ (margetuximab, HER2)

- Potential NMPA approval of the NDA for margetuximab in third-line+ metastatic HER2+ breast cancer.

Autoimmune Disorders, Infectious Disease and Neuroscience

VYVGART (efgartigimod, FcRn)

- Zai Lab partner argenx to report topline data from the registrational Phase 3 ADDRESS trial of SC efgartigimod in pemphigus and the registrational Phase 3 ADVANCE-SC trial of SC efgartigimod in immune thrombocytopenia (ITP) in the fourth quarter of 2023. Zai Lab participated in both studies in Greater China.

- argenx to initiate a registrational study of efgartigimod in thyroid eye disease (TED) in the fourth quarter of 2023.

KarXT (xanomeline-trospium, M1/M4-preferring muscarinic agonist)

- Zai Lab partner Karuna to submit an NDA to the FDA for KarXT for the treatment of patients with schizophrenia in the third quarter of 2023.

- Karuna to initiate the Phase 3 ADEPT-2 and ADEPT-3 trials in Alzheimer's disease psychosis. Zai Lab plans to participate in these studies in Greater China.

Second Quarter 2023 Financial Results

- **Product revenues** were $68.9 million for the second quarter of 2023, compared to $47.6 million for the same period in 2022, representing 45% y-o-y growth; y-o-y growth was 53% at constant exchange rate. The increase in product revenues was primarily due to increased sales volumes and decreased negative effects from the COVID-19 pandemic. The product revenues in the second quarter of 2023, compared to the same period in 2022, included:

    - $43.0 million for ZEJULA, which increased 26% from $34.1 million; and
    - $13.7 million for Optune, which increased 18% from $11.6 million; and
    - $7.5 million for QINLOCK, which increased from $0.6 million; and
    - $4.6 million for NUZYRA, which increased from $1.3 million.

- **Research and Development (R&D) expenses** were $76.7 million for the second quarter of 2023, compared to $66.1 million for the same period in 2022. The increase in R&D expenses was primarily due to increased research activities and clinical pipeline advancement.

- **Selling, General and Administrative expenses** were $67.9 million for the second quarter of 2023, compared to $63.4 million for the same period in 2022. The increase was primarily due to higher general selling expenses to support new product launches.

- **Net loss** was $120.9 million for the second quarter of 2023, or a loss per ordinary share attributable to common stockholders of $0.13, compared to a net loss of $137.9 million for the same period in 2022, or a loss per ordinary share of $0.14. The decrease in net loss was primarily due to product revenue growing faster than net operating expenses.

- **Cash and cash equivalents, short-term investments and restricted cash** totaled $876.4 million as of June 30, 2023, compared to $931.4 million as of March 31, 2023.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, August 8, 2023, 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: https://register.vevent.com/register/BIb7d99f107c3347f29e117b2b7bc47034

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, autoimmune disorders, infectious diseases, and neuroscience. 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 and expectations under our 5-year growth strategy (including our expectations regarding our commercial-stage products, clinical-stage global-right products, revenue growth / CAGR, operating margins, and cash flow); the peak sales potential of our programs; capital allocation and investment strategy; 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. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would," and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products; (2) our ability to obtain funding for our operations and business initiatives; (3) the results of our clinical and pre-clinical development of our product candidates; (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates; (5) the effects of the COVID-19 pandemic on our business and results of operations; (6) risks related to doing business in China; and (7) 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.

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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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	859,155	1,008,470
Short-term investments	15,500	—
Accounts receivable (net of allowance for credit loss of $14 and $11 as of June 30, 2023 and December 31, 2022, respectively)	47,283	39,963
Notes receivable	20,781	8,608
Inventories, net	36,353	31,621
Prepayments and other current assets	38,433	35,674
Total current assets	1,017,505	1,124,336
Restricted cash, non-current	1,791	803
Long term investments	5,128	6,431
Prepayments for equipment	665	1,396
Property and equipment, net	56,410	57,863
Operating lease right-of-use assets	18,537	19,512
Land use rights, net	3,067	6,892
Intangible assets, net	1,690	1,511
Long-term deposits	1,580	1,396
Total assets	**1,106,373**	**1,220,140**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	67,031	65,974
Current operating lease liabilities	7,299	7,050
Other current liabilities	59,024	66,818
Total current liabilities	133,354	139,842
Deferred income	28,625	21,360
Non-current operating lease liabilities	11,755	13,343
Other non-current liabilities	325	—
Total liabilities	**174,059**	**174,545**
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 973,355,390 and 962,455,850 shares issued as of June 30, 2023 and December 31, 2022, respectively; 968,566,280 and 960,219,570 shares outstanding as of June 30, 2023 and December 31, 2022, respectively)	6	6
Additional paid-in capital	2,932,053	2,893,120
Accumulated deficit	(2,031,399)	(1,861,360)
Accumulated other comprehensive income	52,180	25,685
Treasury Stock (at cost, 4,789,110 and 2,236,280 shares as of June 30, 2023 and December 31, 2022, respectively)	(20,526)	(11,856)
Total shareholders' equity	**932,314**	**1,045,595**
Total liabilities and shareholders' equity	**1,106,373**	**1,220,140**

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	68,864	47,575	131,661	93,670
Collaboration revenue	—	601	—	1,230
Total revenues	68,864	48,176	131,661	94,900
Expenses:				
Cost of sales	(23,763)	(17,407)	(45,100)	(33,051)
Research and development	(76,682)	(66,084)	(125,153)	(119,938)
Selling, general, and administrative	(67,920)	(63,401)	(130,430)	(120,392)
Gain on sale of intellectual property	10,000	—	10,000	—

Loss from operations	(89,501)	(98,716)	(159,022)	(178,481)
Interest income	10,090	1,175	20,321	1,363
Foreign currency loss	(40,079)	(34,895)	(31,167)	(32,610)
Other expense, net	(1,405)	(5,497)	(171)	(10,378)
Loss before income tax and share of loss from equity method investment	(120,895)	(137,933)	(170,039)	(220,106)
Income tax expense	—	—	—	—
Share of loss from equity method investment	—	—	—	(221)
Net loss	(120,895)	(137,933)	(170,039)	(220,327)
Net loss attributable to ordinary shareholders	(120,895)	(137,933)	(170,039)	(220,327)
Loss per share - basic and diluted	(0.13)	(0.14)	(0.18)	(0.23)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	964,817,310	957,684,820	963,140,360	956,603,250
Loss per American Depositary Shares ("ADS") - basic and diluted	(1.25)	(1.44)	(1.77)	(2.30)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted	96,481,731	95,768,482	96,314,036	95,660,325

Zai Lab Limite
Unaudited condensed consolidated statements of comprehensive loss
(In thousands of U.S. dollars ("$"))

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	(120,895)	(137,933)	(170,039)	(220,327)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	34,908	30,325	26,495	28,132
Comprehensive loss	(85,987)	(107,608)	(143,544)	(192,195)

Zai Lab Limited
Non-GAAP Measures
(In thousands of U.S. dollars ("$"))

	Three Months Ended June 30,		Year over Year % Growth		Six Months Ended June 30,		Year over Year % Growth	
	2023	2022	As reported	At CER*	2023	2022	As reported	At CER*
Product revenue, net	68,864	47,575	45%	53%	131,661	93,670	41%	50%
Loss from operations	(89,501)	(98,716)	(9)%	(5)%	(159,022)	(178,481)	(11)%	(6)%

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

Source: Zai Lab Limited