Zai Lab Announces Third Quarter 2023 Financial Results and Recent Corporate Updates

November 7, 2023

- *Total product revenue of $69.2 million for the third quarter of 2023, representing 22% y-o-y growth; 27% y-o-y growth at constant exchange rate (CER)*
- *VYVGART® (efgartigimod alfa injection) achieved $4.9 million sales since its commercial launch in September in China*
- *Strong balance sheet with a cash position of $822.2 million as of September 30, 2023, compared to $876.4 million as of June 30, 2023*
- *Company to host conference call and webcast on November 8, 2023, at 8:00 a.m. ET*

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

“During the third quarter, we achieved important milestones, including the successful launch of VYVGART in China for patients with generalized myasthenia gravis (gMG) and the positive pivotal trial readout for efgartigimod in chronic inflammatory demyelinating polyneuropathy (CIDP),” said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. “These developments underscore our unwavering commitment to delivering innovative medicines to patients in need. With new drug applications under review by the National Medical Products Administration (NMPA) and multiple ongoing pivotal trials evaluating drugs with significant market potential, we are well-positioned to accelerate our pipeline and to expand our portfolio of commercial assets as we work to elevate patient care worldwide.”

“Our commercial team navigated macro-level challenges in the third quarter to achieve y-o-y net product revenue growth of 27% on a constant currency basis,” said Josh Smiley, President and Chief Operating Officer of Zai Lab. “ZEJULA® continues to be the leading PARP inhibitor in hospital sales for ovarian cancer in China, and there is exciting momentum with the launch of VYVGART, a potentially paradigm changing therapy for patients living with gMG in China. At least seven additional product launches in the next two to three years are expected to support meaningful revenue growth, and this growth, combined with enhanced operational efficiencies, will help lead us to profitability,” Mr. Smiley concluded.

Third Quarter 2023 Financial Results

- **Product revenues** were $69.2 million for the third quarter of 2023, compared to $57.0 million for the same period in 2022, representing 22% y-o-y growth and 27% y-o-y growth at CER. This increase was primarily driven by increased sales volumes, the launch of VYVGART, and decreased negative effects from the COVID-19 pandemic. Our revenue growth was slowed by the effects on hospital and physician practices from the recent industry-wide anti-corruption enforcement efforts in China. Product revenues in the third quarter of 2023, compared to the same period in 2022, included:
  - $41.6 million for ZEJULA, which increased from $39.2 million, as ZEJULA, which is in its third year on the NRDL, continued to be the leading PARP inhibitor in hospital sales for ovarian cancer in China;
  - $11.6 million for Optune, which increased from $10.7 million, supported by increased patient access to this product in the private-pay market;
  - $5.7 million for QINLOCK, which increased from $5.5 million, supported by the NRDL listing in March 2023;
  - $5.5 million for NUZYRA, which increased from $1.5 million, supported by the NRDL listing in March 2023; and
  - $4.9 million for VYVGART, compared to nil, due to the launch of VYVGART in September 2023.
- **Research and Development (R&D) expenses** were $58.8 million for the third quarter of 2023, compared to $99.5 million for the same period in 2022. This decrease was primarily due to a decrease in licensing fees in connection with decreased upfront and milestone payments for our licensed and collaboration agreements.
- **Selling, General and Administrative expenses** were $68.6 million for the third quarter of 2023, compared to $66.6 million for the same period in 2022. This increase was primarily due to higher general selling expenses to support new product launches, partially offset by a decrease in professional services fees.
- **Net loss** was $69.2 million for the third quarter of 2023, or a loss per ordinary share attributable to common stockholders of $0.07, compared to a net loss of $161.2 million for the same period in 2022, or a loss per ordinary share of $0.17. The

decrease in net loss was primarily due to increase of product revenue, the decrease of licensing fees, and the shift from foreign currency loss to gain.

- **Cash and cash equivalents, short-term investments and restricted cash** totaled $822.2 million as of September 30, 2023, compared to $876.4 million as of June 30, 2023.

Recent Product Highlights and Corporate Updates

Below are key product and corporate updates since our last earnings release:

Commercial Products

- **VYVGART (efgartigimod, FcRn):** In September 2023, we launched VYVGART as an add-on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive in mainland China, increasing our number of commercial products to five. We are in the negotiation process for VYVGART's inclusion on the National Reimbursement Drug List (NRDL) to help support increased patient access for this therapy.

- **ZEJULA (niraparib, PARP):** In September 2023, we conducted the final overall survival (OS) analysis for the Phase 3 NORA study in Chinese patients with platinum-sensitive recurrent ovarian cancer, which supports the NMPA's approval of ZEJULA for patients with recurrent ovarian cancer in China. The final OS results showed that niraparib maintenance treatment in the recurrent setting provides a favorable trend in OS irrespective of gBRCA mutation status compared with placebo. We expect to present detailed results at an upcoming medical conference.

Oncology Pipeline

- **KRAZATI® (adagrasib, KRASG12C):**

  - *First-line non-small cell lung cancer (NSCLC):* In October 2023, Zai Lab partner Mirati Therapeutics, Inc. (Mirati) announced updated results from the KRYSTAL-7 Phase 2 study evaluating adagrasib combined with pembrolizumab in first-line $KRAS^{G12C}$-mutated NSCLC at the European Society of Medical Oncology Congress (ESMO) 2023. The results demonstrate a manageable safety profile and early signs of durability of adagrasib in combination with a checkpoint inhibitor in the first-line NSCLC setting. We are participating in the study in mainland China, Hong Kong, Macau and Taiwan (collectively, Greater China).

  - *Second-line+ NSCLC*: In September 2023, Mirati presented two-year follow-up data from a pooled analysis of the Phase 1/1b Cohort and Phase 2 Cohort A for the KRYSTAL-1 study in previously treated patients with $KRAS^{G12C}$-mutated NSCLC at the 2023 World Conference on Lung Cancer (WCLC). In the pooled analysis, adagrasib demonstrated durable efficacy and a manageable long-term safety profile. We are participating in the ongoing confirmatory Phase 3 KRYSTAL-12 study in previously treated patients with $KRAS^{G12C}$-mutated NSCLC in Greater China.

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

  - *NTRK-positive solid tumors*: In August 2023, the Center for Drug Evaluation (CDE) of the NMPA granted Breakthrough Therapy Designation (BTD) for repotrectinib for the treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with TRK tyrosine kinase inhibitors (TKIs). This BTD was supported by data from both global and Chinese patients enrolled in the Phase 1/2 TRIDENT-1 study.

  - *ROS1-positive NSCLC*: In August 2023, Zai Lab partner Bristol Myers Squibb (BMS) announced updated results from the registrational TRIDENT-1 study, demonstrating that repotrectinib continued to demonstrate high response rates and durable responses, including robust intracranial responses, in patients with ROS1-positive locally advanced or metastatic NSCLC who were TKI-naïve or previously treated with one TKI and no chemotherapy. We are participating in the study in Greater China.

    - Based on results from the TRIDENT-1 trial, the U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) submitted by BMS for repotrectinib in ROS1-positive NSCLC and granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) goal date of November 27, 2023.

    - The NDA we submitted to the NMPA for repotrectinib in ROS1-positive NSCLC has been accepted with priority review.

- **TIVDAK® (tisotumab vedotin):** In October 2023, Zai Lab partner Seagen Inc. and Genmab A/S presented results from the Phase 3 innovaTV 301 randomized global trial at the ESMO 2023 Congress in recurrent or metastatic cervical cancer patients with disease progression on or after front-line therapy. TIVDAK demonstrated superior OS, progression-free survival (PFS) and objective response rate, compared to chemotherapy alone, and there were no new safety signals. We are participating in the global trial and extension study in Greater China.

- **Odronextamab (CD20xCD3):** In September 2023, Zai Lab partner Regeneron announced that the FDA has accepted for Priority Review the Biologics License Application (BLA) for odronextamab to treat adult patients with relapsed/refractory (R/R) follicular lymphoma (FL) or R/R diffuse large B-cell lymphoma (DLBCL), who have progressed after at least two prior systemic therapies, with a PDUFA goal date of March 31, 2024. In August 2023, the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application for odronextamab for the same indications.

- **ZL-1211 (Claudin18.2):** Based on a review of the competitive landscape and market opportunity, we decided to terminate ZL-1211 for internal development.

- **Tumor Treating Fields:** In August 2023, Zai Lab partner NovoCure Limited announced that the Phase 3 INNOVATE-3 clinical trial of TTFields together with paclitaxel in patients with platinum-resistant ovarian cancer did not meet its primary endpoint of OS at the final analysis. We did not participate in this study.

Autoimmune Disorders, Infectious Disease, and Neuroscience Pipeline

- **Efgartigimod (FcRn):** In September 2023, the CDE of China's NMPA granted BTD for efgartigimod alfa injection (subcutaneous injection) (efgartigimod SC) in CIDP. This BTD was supported by positive data from both global and Chinese patients enrolled in the ADHERE study.

- **KarXT (xanomeline-trospium, M1/M4-agonist):**

    - *Schizophrenia:* In September 2023, Zai Lab partner Karuna Therapeutics, Inc. (Karuna) announced that it had submitted an NDA to the FDA for the treatment of schizophrenia, supported by data from three positive registrational trials. We continue to enroll patients in the registrational bridging study in mainland China.

    - *Alzheimer's disease psychosis (ADP)* : Karuna initiated the Phase 3 ADEPT-2 and ADEPT-3 trials in ADP in the third quarter. We plan to participate in these studies in Greater China next year.

Corporate Update

- **Organizational update:** In September 2023, Zai Lab appointed Robert J. Brown, M.D. as Chief Medical Officer, Oncology. Dr. Brown is an oncology drug development leader, with more than 16 years of translational, research, and clinical development expertise in the areas of oncology, immunology, and neurology. Dr. Brown reports to Dr. Rafael Amado, President, Head of Global Oncology Research and Development at Zai Lab, and provides strategic leadership and support with respect to the clinical development of our oncology pipeline.

Anticipated Major Milestones in 2023 / 2024

Oncology

ZEJULA (niraparib, PARP)

- Zai Lab to present the final OS analysis for the Phase 3 NORA study in Chinese patients with platinum-sensitive recurrent ovarian cancer at an upcoming medical conference in 2024.

Tumor Treating Fields

- NovoCure to submit a Premarket Approval Application with the FDA in second-line+ NSCLC post-platinum progression by the end of 2023.

- NovoCure to provide a topline data readout from the phase 3 METIS clinical trial in brain metastases in the first quarter of 2024. We are participating in the study in Greater China.

- NovoCure to provide a topline data readout from the phase 3 PANOVA-3 clinical trial in locally advanced pancreatic cancer in the second half of 2024. We are participating in the study in Greater China.

Repotrectinib (ROS1/TRK)

- Potential NMPA approval of the NDA in locally advanced or metastatic ROS1-positive NSCLC in 2024.

KRAZATI (adagrasib, KRAS^{G12C})

- Zai Lab to submit an NDA to the NMPA in second-line+ KRAS^{G12C}-mutated NSCLC in 2024.

Bemarituzumab (FGFR2b)

- Zai Lab to join the global Phase 3 FORTITUDE-102 study of bemarituzumab in combination with nivolumab and chemotherapy in first-line gastric or gastroesophageal junction cancer in Greater China in the first half of 2024.

ZL-1310 (DLL3 ADC)

- Zai Lab to initiate a global Phase 1 study in relapsed and refractory second-line+ small cell lung cancer (SCLC) who have progressed after platinum-based treatment in the first quarter of 2024.

Autoimmune Disorders, Infectious Disease, and Neuroscience

Efgartigimod (FcRn)

- argenx to report topline data from the registrational Phase 3 ADVANCE-SC trial of efgartigimod SC in immune thrombocytopenia (ITP) in the fourth quarter of 2023. We are participating in the study in Greater China.
- argenx to report topline data from the registrational Phase 3 ADDRESS trial of efgartigimod SC in pemphigus around year-end 2023. We are participating in the study in Greater China.
- argenx to file the supplemental BLA in CIDP by the end of 2023.
- argenx to initiate a registrational study of efgartigimod in thyroid eye disease (TED) in the fourth quarter of 2023. We plan to participate in the program in Greater China in 2024.
- Potential NMPA approval of the supplemental BLA for efgartigimod SC in gMG in 2024.

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

- Karuna to launch KarXT for the treatment of schizophrenia, if approved by the FDA, in the second half of 2024.

XACDURO® (Sulbactam-Durlobactam)

- Potential NMPA approval of the NDA in infections caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex in 2024.

ZL-1102 (IL-17 Humabody®)

- Zai Lab to initiate a global Phase 2 study in chronic plaque psoriasis in 2024.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, November 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/BI87a7a83f6a6441279fddbaae217dd092

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; 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.

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Unaudited Condensed Consolidated Balance Sheets

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	788,806	1,008,470
Short-term investments	31,600	—
Accounts receivable (net of allowance for credit loss of $12 and $11 as of September 30, 2023 and December 31, 2022, respectively)	41,596	39,963
Notes receivable	23,679	8,608
Inventories, net	44,229	31,621
Prepayments and other current assets	29,821	35,674
Total current assets	959,731	1,124,336
Restricted cash, non-current	1,792	803
Long term investments	4,466	6,431
Prepayments for equipment	144	1,396
Property and equipment, net	55,282	57,863
Operating lease right-of-use assets	16,398	19,512
Land use rights, net	3,057	6,892
Intangible assets, net	1,568	1,511

Long-term deposits	1,256	1,396
Total assets	**1,043,694**	**1,220,140**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	55,020	65,974
Current operating lease liabilities	6,886	7,050
Other current liabilities	62,990	66,818
Total current liabilities	124,896	139,842
Deferred income	27,686	21,360
Non-current operating lease liabilities	9,808	13,343
Other non-current liabilities	325	—
Total liabilities	**162,715**	**174,545**
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 973,930,280 and 962,455,850 shares issued as of September 30, 2023 and December 31, 2022, respectively; 969,037,150 and 960,219,570 shares outstanding as of September 30, 2023 and December 31, 2022, respectively)	6	6
Additional paid-in capital	2,954,362	2,893,120
Accumulated deficit	(2,100,551)	(1,861,360)
Accumulated other comprehensive income	47,952	25,685
Treasury Stock (at cost, 4,893,130 and 2,236,280 shares as of September 30, 2023 and December 31, 2022, respectively)	(20,790)	(11,856)
Total shareholders' equity	**880,979**	**1,045,595**
Total liabilities and shareholders' equity	**1,043,694**	**1,220,140**

Zai Lab Limited

Unaudited Condensed Consolidated Statements of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product revenue, net	69,228	56,963	200,889	150,633
Collaboration revenue	—	577	—	1,806
Total revenues	69,228	57,540	200,889	152,439
Expenses:				
Cost of sales	(25,479)	(20,044)	(70,579)	(53,094)
Research and development	(58,767)	(99,524)	(183,920)	(219,462)
Selling, general, and administrative	(68,552)	(66,555)	(198,982)	(186,947)
Gain on sale of intellectual property	—	—	10,000	—
Loss from operations	(83,570)	(128,583)	(242,592)	(307,064)
Interest income	9,172	3,872	29,493	5,235
Foreign currency gain (loss)	4,852	(40,442)	(26,315)	(73,052)
Other income (expense), net	394	3,963	223	(6,415)
Loss before income tax and share of loss from equity method investment	(69,152)	(161,190)	(239,191)	(381,296)
Income tax expense	—	—	—	—
Share of loss from equity method investment	—	—	—	(221)
Net loss	(69,152)	(161,190)	(239,191)	(381,517)
Net loss attributable to ordinary shareholders	(69,152)	(161,190)	(239,191)	(381,517)
Loss per share - basic and diluted	(0.07)	(0.17)	(0.25)	(0.40)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	968,767,730	959,085,960	965,060,570	957,439,910
Loss per American Depositary Shares ("ADS") - basic and diluted	(0.71)	(1.68)	(2.48)	(3.98)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted	96,876,773	95,908,596	96,506,057	95,743,991

Zai Lab Limited

Unaudited condensed consolidated statements of comprehensive loss

(In thousands of $)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	(69,152)	(161,190)	(239,191)	(381,517)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	(4,228)	35,062	22,267	63,194
Comprehensive loss	(73,380)	(126,128)	(216,924)	(318,323)

Zai Lab Limited

Non-GAAP Measures

(In thousands of $)

	Three Months Ended September 30,		Year over Year % Growth		Nine Months Ended September 30,		Year over Year % Growth	
	2023	**2022**	**As reported**	**At CER***	**2023**	**2022**	**As reported**	**At CER***
Product revenue, net	69,228	56,963	22%	27%	200,889	150,633	33%	41%
Loss from operations	(83,570)	(128,583)	(35)%	(33)%	(242,592)	(307,064)	(21)%	(17)%

** 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