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

May 8, 2024

- *Net product revenue of $87.1 million for the first quarter of 2024, representing 39% y-o-y growth; 43% y-o-y growth at constant exchange rate (CER)*
- *VYVGART® (efgartigimod alfa injection) sales of $13.2 million for the first quarter of 2024, driven by increased patient access; an estimated 2,700 new patients were treated with VYVGART in the first quarter of 2024*
- *Regulatory reviews ongoing for sulbactam-durlobactam for ABC, efgartigimod SC for gMG, and repotrectinib for ROS1+ NSCLC; sBLA submitted for efgartigimod SC in CIDP*
- *Strong balance sheet with a cash position[1] of $750.8 million as of March 31, 2024, compared to $806.5 million as of December 31, 2023*
- *Company to host conference call and webcast on May 9, 2024, at 8:00 a.m. ET (8:00 p.m. HKT)*

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 8, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for the first quarter of 2024, along with recent product highlights and corporate updates.

“Our first quarter results demonstrate strong commercial execution and pipeline progress across our potential first- and best-in-class product portfolio,” said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. “The launch of VYVGART is off to an impressive start with $13.2 million of sales in the first quarter. Looking ahead, we expect to accelerate commercial performance for the remainder of the year and are preparing for three new potential launches in 2024. We are also excited by the progress of our late-stage pipeline and we are on track to achieve the objectives outlined in our five-year strategic plan, including significant revenue growth and profitability by the end of 2025.”

“Our net revenues grew 39% y-o-y or 43% y-o-y at CER in the first quarter, driven by strong execution with the launch of VYVGART and uptake of our existing portfolio,” said Josh Smiley, President and Chief Operating Officer of Zai Lab. “With VYVGART’s launch in gMG at the end of last year, and multiple new products and indications expected to launch over the near-term, we are now entering a period of robust growth for Zai Lab. Our significant growth, coupled with our focus on driving efficiencies and productivity across the organization, will drive the evolution of Zai Lab into a profitable, high growth business by the end of 2025. Furthermore, we will continue to focus on expanding our global portfolio through our internal discovery activities and strategic business development,” Mr. Smiley concluded.

First-Quarter 2024 Financial Results

- **Product revenue** was $87.1 million in the first quarter of 2024, compared to $62.8 million for the same period in 2023, representing 39% y-o-y growth and 43% y-o-y growth at CER. This increase was primarily driven by increased sales volumes, including from the launch of VYVGART last September and decreased sales rebates to distributors resulting from price reductions in connection with listings on China’s National Reimbursement Drug List (NRDL) for certain products. This revenue growth included the following:
  - **ZEJULA®**: $45.5 million in the first quarter of 2024, an increase of 7% y-o-y from $42.7 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®**: $13.2 million in the first quarter of 2024, compared to nil for the same period in 2023, driven by 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 generalized myasthenia gravis (gMG) in September 2023 and was subsequently included for first-time NRDL listing effective, January 1, 2024.
  - **OPTUNE** (Tumor Treating Fields): $12.5 million in the first quarter of 2024, a decrease of 6% y-o-y from $13.3 million for the same period in 2023. Although revenue declined y-o-y for OPTUNE, it increased 49% versus the fourth quarter of 2023, with continued recovery of patient volume expected throughout 2024.
  - **QINLOCK®**: $6.1 million in the first quarter of 2024, an increase of 367% y-o-y from $1.3 million for the same period in 2023, driven by its inclusion in the NRDL in the first quarter of 2023 for the fourth-line treatment of advanced gastrointestinal stromal tumors (GIST).
  - **NUZYRA®**: $9.9 million in the first quarter of 2024, an increase of 81% y-o-y from $5.5 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 $54.6 million in the first quarter of 2024, compared to $48.5 million for the same period in 2023. This increase was primarily due to increased clinical trial expenses related to newly initiated studies and progress of existing studies, partially offset by a decrease in milestone fees for our licensed products.

- **Selling, General and Administrative expenses** were $69.2 million in the first quarter of 2024, compared to $62.5 million for the same period in 2023. This increase was primarily driven by higher general selling expenses and headcount growth associated with the VYVGART launch.

- **Net loss** was $53.5 million in the first quarter of 2024, or a loss per ordinary share attributable to common stockholders of $0.05 (or loss per American Deposit Share (ADS) of $0.55), compared to a net loss of $49.1 million for the same period in 2023, or a loss per ordinary share of $0.05 (or loss per ADS of $0.51).

- **Cash and cash equivalents, short-term investments, and current restricted cash** totaled $750.8 million as of March 31, 2024, compared to $806.5 million as of December 31, 2023.

Corporate Update

- In April 2024, Andrew Zhu joined Zai Lab as our Chief Commercial Officer in Greater China[2]. Mr. Zhu's rich experience in building innovative business models and resource integration will help us further enhance our commercial operations and drive sales and profit growth across Greater China. He joins us from Simcere Zaiming, where he most recently served as Chief Operating Officer responsible for the commercial and pharmaceutical business. He previously served in various operational, sales, and marketing leadership roles at leading global biopharmaceutical companies, including AstraZeneca, Roche, Sanofi, and Bristol Myers Squibb (BMS).

Recent Pipeline Highlights

Below are key product updates since our last earnings release:

Oncology Pipeline

- **Tumor Treating Fields:**
  - In March 2024, Zai Lab partner Novocure announced positive topline results from the Phase 3 METIS clinical trial for brain metastases from non-small cell lung cancer (NSCLC). The primary endpoint was met with Tumor Treating Fields therapy and supportive care demonstrating a significant improvement in time to intracranial progression versus supportive care alone (21.9 months median versus 11.3 months, respectively). These results will be presented as a late-breaking abstract at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on June 3. We are participating in the Greater China portion of the METIS trial.

- **Bemarituzumab (FGFR2b):**
  - We are enrolling patients in Greater China for the global Phase 3 FORTITUDE-101 and FORTITUDE-102 studies:
    - FORTITUDE-101 is a Phase 3 study of bemarituzumab plus chemotherapy in first-line gastric cancer.
    - FORTITUDE-102 is a Phase 1b/3 study of bemarituzumab plus chemotherapy and nivolumab in first-line gastric cancer.

- **Tisotumab Vedotin (Tissue Factor ADC):**
  - In April 2024, Zai Lab partner Pfizer Inc. and Genmab A/S announced that the U.S. Food and Drug Administration (FDA) approved the supplemental Biologics License Application (sBLA) granting full approval for tisotumab vedotin (or TIVDAK®) for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. We are participating in the global Phase 3 innovaTV 301 trial and extension study in Greater China.

- **Adagrasib ($KRAS^{G12C}$):**
  - We are evaluating the clinical data of the global Phase 3 KRYSTAL-12 study evaluating adagrasib in previously treated patients with $KRAS^{G12C}$-mutated NSCLC as we decide on next steps in the development of this product across indications.

- **ZL-1310 (DLL3 ADC):**
  - In March 2024, Zai Lab presented findings from preclinical studies highlighting the therapeutic potential of ZL-1310 at the European Lung Cancer Congress (ELCC) 2024.
  - We are enrolling patients in the United States and Greater China in the global Phase 1 study in relapsed and refractory second-line+ small cell lung cancer (SCLC) who have progressed after platinum-based treatment.

- **ZL-1218 (CCR8):**
  - We are enrolling patients in the United States, Europe, and Greater China in the global Phase 1 study of ZL-1218

as a single agent and in combination with pembrolizumab in patients with advanced solid tumor malignancies.

Autoimmune Disorders, Infectious Disease, and Neuroscience Pipeline

- **Efgartigimod (FcRn):**
  - In April 2024, Zai Lab submitted an sBLA for efgartigimod SC for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to the National Medical Products Administration (NMPA).

- **Xanomeline-Trospium (or KarXT) (M1/M4-agonist):**
  - In April 2024, Zai Lab partner BMS presented new interim long-term data from the Phase 3 EMERGENT program at the Annual Congress of the Schizophrenia International Research Society (SIRS).
    - In the new interim analysis of long-term efficacy data from the Phase 3 EMERGENT-4 open-label extension trial, KarXT was associated with significant improvement in symptoms of schizophrenia across all efficacy measures at 52 weeks.
    - In the new pooled interim long-term safety and metabolic outcomes from the Phase 3 EMERGENT-4 and EMERGENT-5 trials, KarXT demonstrated a favorable long-term metabolic profile where most patients experienced stability or improvements on metabolic parameters over 52 weeks of treatment.
  - We are enrolling patients in a registrational bridging study in mainland China.

Anticipated Major Milestones in 2024

Oncology

Repotrectinib

- Potential NMPA approval of our NDA for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC.

Tumor Treating Fields

- Zai Lab to submit a Marketing Authorization Application (MAA) to the NMPA in second-line+ NSCLC, following progression on or after platinum-based therapy.
- 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.

Neuroscience, Autoimmune Disorders, and Infectious Diseases (NSAiID)

Efgartigimod (FcRn)

- Potential NMPA approval of the BLA for efgartigimod SC for gMG.
- We plan to join in the registrational study of efgartigimod SC in Thyroid Eye Disease (TED) in Greater China in the second half of 2024.

Sulbactam-Durlobactam (SUL-DUR)

- Potential NMPA approval of our NDA for infections caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (ABC).

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

- Zai Lab to complete patient enrollment in the China bridging study in schizophrenia.
- Zai Lab to join the global Phase 3 ADEPT-2 and ADEPT-3 studies in Alzheimer's disease with psychosis in Greater China in mid-year.
- 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.

ZL-1102 (IL-17 Humabody®)

- Zai Lab to initiate a global Phase 2 study in mild-to-moderate chronic plaque psoriasis in the second quarter of 2024.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, May 9, 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/BIb8622a7cf98e46cd9bc9198a5f105c36

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, 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.

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

[2] Mainland China, Hong Kong, Macau, and Taiwan (collectively, Greater China).

Zai Lab Limited
Unaudited Condensed Consolidated Balance Sheets
(in thousands of U.S. dollars ($), except for number of shares and per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	650,780	790,151
Restricted cash, current	100,000	—
Short-term investments	—	16,300
Accounts receivable (net of allowance for credit losses of $18 and $17 as of March 31, 2024 and December 31, 2023, respectively)	60,422	59,199

Notes receivable	15,363	6,134
Inventories, net	37,851	44,827
Prepayments and other current assets	24,224	22,995
Total current assets	888,640	939,606
Restricted cash, non-current	1,114	1,113
Long term investments	14,109	9,220
Prepayments for equipment	89	111
Property and equipment, net	52,386	53,734
Operating lease right-of-use assets	15,187	14,844
Land use rights, net	3,034	3,069
Intangible assets, net	12,398	13,389
Long-term deposits	1,480	1,209
Total assets	**988,437**	**1,036,295**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	88,121	112,991
Current operating lease liabilities	7,536	7,104
Short-term debts	48,273	—
Other current liabilities	48,176	82,972
Total current liabilities	192,106	203,067
Deferred income	26,297	28,738
Non-current operating lease liabilities	7,540	8,047
Other non-current liabilities	325	325
Total liabilities	**226,268**	**240,177**
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 978,197,710 and 977,151,270 shares issued as of March 31, 2024 and December 31, 2023, respectively; 973,285,510 and 972,239,070 shares outstanding as of March 31, 2024 and December 31, 2023, respectively)	6	6
Additional paid-in capital	2,993,282	2,975,302
Accumulated deficit	(2,249,451)	(2,195,980)
Accumulated other comprehensive income	39,168	37,626
Treasury Stock (at cost, 4,912,200 shares as of both March 31, 2024 and December 31, 2023)	(20,836)	(20,836)
Total shareholders' equity	**762,169**	**796,118**
Total liabilities and shareholders' equity	**988,437**	**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 March 31,	
	2024	**2023**
Revenue	87,149	62,797
Expenses		
Cost of sales	(33,619)	(21,337)
Research and development	(54,645)	(48,472)
Selling, general, and administrative	(69,194)	(62,510)
Loss from operations	(70,309)	(69,522)
Interest income	9,658	10,232
Interest expenses	(113)	—
Foreign currency (losses) gains	(2,068)	8,912
Other income, net	9,361	1,234
Loss before income tax	(53,471)	(49,144)
Income tax expense	—	—
Net loss	(53,471)	(49,144)
Loss per share - basic and diluted	(0.05)	(0.05)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	973,145,760	961,444,780

Zai Lab Limited
Unaudited condensed consolidated statements of comprehensive loss
(in thousands of $)

	Three Months Ended March 31,	
	2024	**2023**
Net loss	(53,471)	(49,144)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	1,542	(8,413)
Comprehensive loss	(51,929)	(57,557)

Zai Lab Limited
Non-GAAP Measures
(in thousands of $)

	Three Months Ended March 31,		Year over Year % Growth	
	2024	**2023**	**As reported**	**At CER***
Revenue	87,149	62,797	39%	43%
Loss from operations	(70,309)	(69,522)	1%	3%

** 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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