Zai Lab Announces Full-Year 2023 Financial Results and Recent Corporate Updates

February 27, 2024

- *Total product revenue of $266.7 million for Full-Year 2023, representing 25% y-o-y growth; 31% y-o-y growth at constant exchange rate (CER)*
- *VYVGART® (efgartigimod alfa injection) was launched in September 2023 in China and we estimate that nearly 1,000 patients were treated through the fourth quarter before its listing on China's National Reimbursement Drug List (NRDL)*
- *We estimate that nearly 1,000 new patients were treated with VYVGART in January 2024 alone; expect VYVGART product sales to exceed $70.0 million in 2024*
- *Regulatory reviews ongoing for sulbactam-durlobactam, efgartigimod SC and repotrectinib; up to four new regulatory submissions expected in 2024*
- *Strong balance sheet with a cash position of $807.6 million as of December 31, 2023, compared to $1.0 billion as of December 31, 2022*
- *Company to host conference call and webcast on February 28, 2024, at 8:00 a.m. ET (9:00 p.m. HKT)*

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 27, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for full-year 2023, along with recent product highlights and corporate updates.

"We made excellent progress on several key strategic priorities in 2023, notably the launch of VYVGART in China for generalized myasthenia gravis (gMG) in September and the drug's successful inclusion on China's NRDL for this indication effective January 1, 2024," said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. "The launch is off to an impressive start with more patients treated with VYVGART in January than the last four months of 2023 combined, fueled by high physician adoption and increased patient access as hospitals add VYVGART to formularies. Looking ahead, we expect strong commercial performance across our portfolio this year, and are preparing for three new potential launches in 2024. We are also excited by the progress of our late-stage pipeline and our growing global early-stage development efforts. We are on track to achieve the objectives outlined in our five-year strategic plan and to position Zai Lab as a high-growth, profitable and innovative biotech company."

"We are focused on achieving three corporate objectives," said Josh Smiley, President and Chief Operating Officer of Zai Lab. "First, we seek to accelerate top-line growth supported by multiple launches of new products and indications over the next two to three years. Second, we aim to reach corporate profitability by the end of 2025 through revenue growth and continued focus on efficiency and productivity. Third, we are committed to building a global portfolio through our internal discovery activities and strategic business development. These corporate objectives capture our vision for Zai Lab, where we lead with innovation, grow with purpose, and deliver on our mission of improving patient lives globally," Mr. Smiley concluded.

Full-Year 2023 Financial Results

- **Product revenue** was $266.7 million in 2023, compared to $212.7 million in 2022, representing 25% y-o-y growth and 31% 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, partially offset by an increase in sales rebates to distributors and the effects on hospital and physician practices from the recent industry-wide anti-corruption enforcement efforts in China in the second half of 2023.
    - Sales rebates to distributors resulting from price reductions in connection with NRDL listings were $13.0 million in 2023, up from $5.3 million in 2022, driven by an increased number of new and renewed NRDL listings.

Key Highlights by Commercial Products

ZEJULA®

- $168.8 million in 2023, which increased 16% y-o-y from $145.2 million in 2022.
- The increase was driven by increased hospital sales in first-line ovarian cancer and duration of treatment prolongment, partially offset by sales rebates in connection with the renewal in the NRDL.
- ZEJULA continues to be the leading PARP inhibitor in hospital sales for ovarian cancer in China, in its third year on the NRDL.

- ZEJULA's NRDL listing was renewed for the maintenance treatment of adult patients with first-line and recurrent ovarian cancer, effective January 1, 2024.

VYVGART®

- $10.0 million in 2023, compared to nil in 2022.
- We successfully launched VYVGART for the treatment of adult patients with gMG, who are anti-acetylcholine receptor (AChR) antibody positive, in September 2023.
- We estimate that nearly 1,000 patients were treated from launch through the fourth quarter of 2023.
- VYVGART was added to the NRDL for the treatment of gMG, effective January 1, 2024.
- We estimate that nearly 1,000 new patients were treated in January 2024 alone driven by positive physician and patient reception as well as increased patient access as VYVGART is added to hospital formularies.
- We are expecting more than $70.0 million in VYVGART revenue in 2024.

OPTUNE®

- $47.0 million in 2023, which was relatively flat compared to $47.3 million in 2022.
- Continued growth in supplemental insurance coverage was offset by the effects of industry-wide anti-corruption efforts.

QINLOCK®

- $19.2 million in 2023, which increased 29% y-o-y from $15.0 million in 2022.
- Growth was supported by its inclusion in the NRDL in the first quarter of 2023 for the fourth-line treatment of advanced gastrointestinal stromal tumors (GIST), partially offset by sales rebates in connection with the NRDL listing.

NUZYRA®

- $21.7 million in 2023, which increased by 316% y-o-y from $5.2 million in 2022.
- Growth was driven by the initial inclusion of NUZYRA (IV formulation) for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) in the NRDL in the first quarter of 2023.
- The oral formulation of NUZYRA was added to the NRDL for these indications, effective January 1, 2024, which we expect to further increase patient access.

- **Research and Development (R&D) expenses** were $265.9 million for 2023, compared to $286.4 million for 2022. This decrease was primarily due to decreased upfront and milestone payments for our license and collaboration agreements, partially offset by an increase in personnel compensation and related costs.

- **Selling, General and Administrative expenses** were $281.6 million for 2023, compared to $259.0 million for 2022. This increase was primarily due to higher general selling expenses related to commercial operations to support the launch of VYVGART, partially offset by a decrease in professional services fees.

- **Net loss** was $334.6 million for 2023, or a loss per ordinary share attributable to common stockholders of $0.35 (or loss per American Deposit Share ("ADS") of $3.46), compared to a net loss of $443.3 million for 2022, or a loss per ordinary share of $0.46 (or loss per ADS of $4.63). The decrease in net loss was primarily due to product revenue growing faster than net operating expenses, increased interest income, and decreased foreign currency loss.

- **Cash and cash equivalents, short-term investments and restricted cash** totaled $807.6 million as of December 31, 2023, compared to $1.0 billion as of December 31, 2022.

2024 Strategic Priorities

Zai Lab will focus on the following strategic priorities in 2024 to drive innovation in China and beyond:

Commercial Execution

- Drive VYVGART ramp-up in gMG in its first year of NRDL inclusion and increase access via hospital listing
- Maintain ZEJULA leadership position in ovarian cancer in China
- Continue to grow supplemental insurance coverage for OPTUNE GIO® in glioblastoma (GBM)
- Successfully launch additional products (up to 3) from our innovative pipeline

Clinical Data and Regulatory Actions

- Potential China approvals:
  - Sulbactam-durlobactam in infections caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex
  - Efgartigimod SC in gMG
  - Repotrectinib in ROS1-positive NSCLC
- Planned China submissions:
  - Efgartigimod SC in chronic inflammatory demyelinating polyneuropathy (CIDP)
  - Adagrasib in second-line+ NSCLC
  - Tisotumab vedotin in second-line+ cervical cancer
  - Tumor Treating Fields in second-line+ NSCLC
- Key clinical data readouts:
  - Tumor Treating Fields in first-line brain metastases from NSCLC (METIS) and first-line locally advanced pancreatic cancer (PANOVA-3)
  - Adagrasib in first-line NSCLC and second-line+ NSCLC

Clinical Development

- Join the global Phase 3 registrational study of efgartigimod in thyroid eye disease (TED) in Greater China[1]
- Join the global Phase 3 ADEPT-2 and ADEPT-3 studies of xanomeline-trospium (or KarXT) in Alzheimer's disease psychosis (ADP) in Greater China
- Complete enrollment in the China bridging Phase 3 study of xanomeline-trospium (or KarXT) in schizophrenia
- Advance ZL-1102 (IL-17 Humabody®) into global Phase 2 development in chronic plaque psoriasis (CPP)
- Enroll patients in the global Phase 1 study for ZL-1310 (DLL3 ADC) in small cell lung cancer (SCLC)

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

Recent Pipeline Highlights

Below are key product updates since our last earnings release:

Oncology Pipeline

- **Tumor Treating Fields:**
  - In January 2024, Zai Lab partner Novocure announced that the U.S. Food and Drug Administration (FDA) had accepted for filing its Premarket Approval (PMA) application seeking approval for the use of Tumor Treating Fields therapy together with standard systemic therapies for the treatment of NSCLC, following progression on or after platinum-based therapy. We are preparing a similar submission for this indication, with a goal to submit a Marketing Authorization Application (MAA) to the National Medical Products Administration (NMPA) in 2024.

- **Repotrectinib (ROS1/TRK):**
  - In February 2024, Zai Lab partner Bristol-Myers Squibb (BMS) announced that, based on the results of the TRIDENT-1 trial, the FDA has accepted its supplemental NDA (sNDA) for repotrectinib for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity. The application was granted priority review status, with a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2024.
  - In November 2023, BMS announced that, based on results from the TRIDENT-1 trial, the FDA approved repotrectinib for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC. The New Drug Application (NDA) that Zai Lab submitted to the NMPA for this indication is under priority review.

- **Adagrasib ($KRAS^{G12C}$)**
  - In February 2024, Zai Lab partner BMS announced that, based on the results of the KRYSTAL-1 trial, the FDA has accepted its sNDA for adagrasib in combination with cetuximab for the treatment of patients with previously treated $KRAS^{G12C}$-mutated locally advanced or metastatic colorectal cancer (CRC). The application was granted priority review status, with a PDUFA goal date of June 21, 2024. We are participating in the global confirmatory Phase 3 KRYSTAL-10 study in second-line $KRAS^{G12C}$-mutated CRC in Greater China.

- **Bemarituzumab (FGFR2b):**
  - Zai Lab has joined the global Phase 3 FORTITUDE-102 study of bemarituzumab in combination with nivolumab and chemotherapy in first-line gastric or GEJ cancer in Greater China. We expect the first patient in Greater China to be treated in the first quarter of 2024.

- **ZL-1310 (DLL3 ADC):**

- Zai Lab is currently enrolling patients in the United States and China in the global Phase 1 study in relapsed and refractory second-line+ SCLC who have progressed after platinum-based treatment.

Autoimmune Disorders, Infectious Disease, and Neuroscience Pipeline

- **Efgartigimod (FcRn):**
  - In February 2024, argenx announced that the FDA has accepted the supplemental Biologics License Application (sBLA) for efgartigimod SC for the treatment of CIDP with priority review. The application has been granted a PDUFA goal date of June 21, 2024.
  - We plan to submit an sBLA to the NMPA for efgartigimod SC in CIDP in the first half of 2024.

- **Xanomeline-Trospium (or KarXT) (M1/M4-agonist):**
  - In November 2023, Karuna announced that the FDA has accepted its NDA for xanomeline-trospium for the treatment of schizophrenia in adults. The application has been granted a PDUFA goal date of September 26, 2024. We continue to enroll patients in the registrational bridging study in mainland China, and we expect to complete the study this year.
  - In November 2023, Karuna announced positive results from its Phase 1b open-label, eight-week inpatient trial evaluating the effect of xanomeline-trospium on 24-hour ambulatory blood pressure in adults with schizophrenia demonstrating that xanomeline-trospium was not associated with increases in blood pressure.

Anticipated Major Milestones in 2024

Oncology

Tumor Treating Fields

- Zai Lab to submit an MAA to the NMPA in second-line+ NSCLC, following progression on or after platinum-based therapy.
- Zai Lab partner Novocure to provide a topline data readout from the phase 3 METIS clinical trial in brain metastases from NSCLC 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 fourth quarter 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.

Adagrasib ($KRAS^{G12C}$)

- Zai Lab to submit an NDA to the NMPA in second-line+ $KRAS^{G12C}$-mutated NSCLC.
- Zai Lab to join the global Phase 3 KRYSTAL-7 study in first-line $KRAS^{G12C}$-mutated NSCLC with Tumor Proportion Score (TPS) ≥ 50% in Greater China in the second half of 2024.
- Zai Lab partner Mirati, a BMS company, to provide a clinical data update for the global confirmatory Phase 3 KRYSTAL-12 study in second-line+ $KRAS^{G12C}$-mutated NSCLC. We are participating in the study in Greater China.
- Mirati to provide a clinical data update for the global Phase 2 KRYSTAL-17 study in first-line $KRAS^{G12C}$-mutated NSCLC with TPS < 50%.

Tisotumab Vedotin (Tissue Factor ADC)

- Zai Lab to submit an NDA to the NMPA in second-line+ cervical cancer.

Neuroscience, Autoimmune Disorders, and Infectious Diseases (NSAiID)

Efgartigimod (FcRn)

- Potential NMPA approval of the sBLA for efgartigimod SC in gMG.
- Zai Lab to submit an sBLA to the NMPA for efgartigimod SC in CIDP in the first half of 2024.
- Zai Lab partner argenx to initiate a registrational study of efgartigimod in TED. Zai Lab plans to participate in the study in Greater China in the second half of 2024.

Sulbactam-Durlobactam (SUL-DUR)

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

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

- Zai Lab to complete patient enrollment in the China bridging study in schizophrenia in the fourth quarter of 2024.
- Zai Lab to join the global Phase 3 ADEPT-2 and ADEPT-3 studies in ADP in Greater China in mid-year.
- Zai Lab partner Karuna to report topline 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 mid-year.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast tomorrow, February 28, 2024, at 8:00 a.m. ET (9:00 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/BIa1fd72e50c9e4117b696c49bdfa9f83b

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.

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

	December 31,

	2023	2022
Assets		
Current assets		
Cash and cash equivalents	790,151	1,008,470
Short-term investments	16,300	—
Accounts receivable (net of allowance for credit loss of $17 and $11 as of December 31, 2023 and 2022, respectively)	59,199	39,963
Notes receivable	6,134	8,608
Inventories, net	44,827	31,621
Prepayments and other current assets	22,995	35,674
Total current assets	939,606	1,124,336
Restricted cash, non-current	1,113	803
Long-term investments	9,220	6,431
Prepayments for equipment	111	1,396
Property and equipment, net	53,734	57,863
Operating lease right-of-use assets	14,844	19,512
Land use rights, net	3,069	6,892
Intangible assets, net	13,389	1,511
Long-term deposits	1,209	1,396
Total assets	**1,036,295**	**1,220,140**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	112,991	65,974
Current operating lease liabilities	7,104	7,050
Other current liabilities	82,972	66,818
Total current liabilities	203,067	139,842
Deferred income	28,738	21,360
Non-current operating lease liabilities	8,047	13,343
Other non-current liabilities	325	—
Total liabilities	**240,177**	**174,545**
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized, 977,151,270 and 962,455,850 shares issued as of December 31, 2023 and 2022, respectively; 972,239,070 and 960,219,570 shares issued and outstanding as of December 31, 2023 and 2022, respectively)	6	6
Additional paid-in capital	2,975,302	2,893,120
Accumulated deficit	(2,195,980)	(1,861,360)
Accumulated other comprehensive income	37,626	25,685
Treasury stock (at cost, 4,912,200 and 2,236,280 shares as of December 31, 2023 and 2022, respectively)	(20,836)	(11,856)
Total shareholders' equity	**796,118**	**1,045,595**
Total liabilities and shareholders' equity	**1,036,295**	**1,220,140**

Zai Lab Limited
Consolidated Statements of Operations
(in thousands of $, except for number of shares and per share data)

	Year Ended December 31,		
	2023	2022	2021
Revenues			
Product revenue, net	266,719	212,672	144,105
Collaboration revenue	—	2,368	207
Total revenues	266,719	215,040	144,312
Expenses			
Cost of sales	(95,816)	(74,018)	(52,239)
Research and development	(265,868)	(286,408)	(573,306)
Selling, general and administrative	(281,608)	(258,971)	(218,831)
Gain on sale of intellectual property	10,000	—	—
Loss from operations	(366,573)	(404,357)	(700,064)
Interest income	39,797	14,582	2,190

Foreign currency (loss) gain	(14,850)	(56,403)	4,661
Other income (expense), net	7,006	3,113	(10,201)
Loss before income tax and share of loss from equity method investment	(334,620)	(443,065)	(703,414)
Income tax expense	—	—	—
Share of loss from equity method investment	—	(221)	(1,057)
Net loss	(334,620)	(443,286)	(704,471)
Loss per share — basic and diluted	(0.35)	(0.46)	(0.76)
Weighted-average shares used in calculating net loss per ordinary share — basic and diluted	966,394,130	958,067,140	929,921,120

Note: Basic and diluted net loss per ordinary share, weighted average number of ordinary shares for the year ended December 31, 2021 have been retrospectively adjusted as a result of the Share Subdivision that became effective on March 30, 2022.

Zai Lab Limited
Consolidated Statements of Comprehensive Loss
(in thousands of $)

	Year Ended December 31,		
	2023	**2022**	**2021**
Net loss	(334,620)	(443,286)	(704,471)
Other comprehensive income (loss), net of tax of nil:			
Foreign currency translation adjustments	11,941	49,330	(9,121)
Comprehensive loss	**(322,679)**	**(393,956)**	**(713,592)**

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

	Year Ended December 31,		Year over Year % Growth	
	2023	**2022**	**As reported**	**At CER***
Product revenue, net	266,719	212,672	25%	31%
Loss from operations	(366,573)	(404,357)	(9)%	(7)%

** 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.*

View source version on businesswire.com: https://www.businesswire.com/news/home/20240227802106/en/

For more information:

Investor Relations:
Christine Chiou / Lina Zhang
+1 (917) 886-6929 / +86 136 8257 6943
christine.chiou1@zailaboratory.com / lina.zhang@zailaboratory.com

Media:
Shaun Maccoun / Xiaoyu Chen
+1 (415) 317-7255 / +86 185 0015 5011
shaun.maccoun@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Source: Zai Lab Limited