



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

November 12, 2024

- Strong growth in net product revenue of 47% y-o-y to reach \$101.8 million for the third quarter of 2024
- Positive China bridging study of KarXT in schizophrenia; expected regulatory submission in early 2025
- Global Phase 1 data of ZL-1310 (DLL3 ADC) suggests best-in-class potential in extensive-stage SCLC
- Three product launches in mainland China expected by the end of 2024, and up to four potential regulatory submissions to the NMPA in the next six months
- Strong balance sheet with a cash position¹ of \$716.1 million as of September 30, 2024, compared to \$730.0 million as of June 30, 2024

Conference call and webcast today, November 12, at 8:00 a.m. ET (9:00 p.m. HKT)

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 12, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for the third quarter of 2024, along with recent product highlights and corporate updates.

"In the third quarter, we delivered strong commercial results, maintained financial discipline, and continued to advance our global pipeline of innovative medicines," said Dr. Samantha Du, Founder, Chairperson, and Chief Executive Officer of Zai Lab. "The launch of VYVGART[®] has been a great success, and we are well-positioned to support the ongoing needs of many patients living with generalized myasthenia gravis (gMG). Our late-stage pipeline is progressing well. The China bridging study of KarXT for schizophrenia had positive results for all study endpoints, and we expect a China submission in early 2025. The FORTITUDE-102 study, which evaluates bemarituzumab in gastric cancer, has completed enrollment. Additionally, promising data from our global Phase 1 study of ZL-1310 – a potential best-in-class DLL3-targeted ADC being developed globally for small cell lung cancer (SCLC) – has shown preliminary breakthrough antitumor activity. We believe we are on track to drive substantial value for our business over the next few years."

"Our net product revenues in the third quarter grew 47% y-o-y, driven by the continued strong uptake of VYVGART," said Josh Smiley, President and Chief Operating Officer of Zai Lab. "VYVGART in gMG, is on track to be a blockbuster launch in its first year on China's National Reimbursement Drug List (NRDL). The VYVGART franchise has tremendous potential. In addition to evaluating a variety of additional indications, we expect to launch the subcutaneous formulation of VYVGART (VYVGART Hytrulo) for gMG and chronic inflammatory demyelinating polyneuropathy (CIDP) in the fourth quarter. Our late-stage programs including bemarituzumab for gastric cancer and KarXT for schizophrenia present high potential opportunities that will further drive growth. Meanwhile, we had significant improvement in net loss, driven by our continued efforts to improve efficiency and exercise financial discipline. We are well positioned for future growth and profitability, supported by our current commercial portfolio and advancing global and late-stage pipeline."

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

Third-Quarter 2024 Financial Results

- **Product revenue, net** was \$101.8 million in the third quarter of 2024, compared to \$69.2 million for the same period in 2023, representing 47% y-o-y growth, 46% y-o-y growth at constant exchange rate (CER). This increase was primarily driven by increased sales for VYVGART and was also supported by increased sales for ZEJULA[®] and NUZYRA[®].
 - **VYVGART** was \$27.3 million in the third quarter of 2024, compared to \$4.9 million for the same period in 2023, driven by increased sales since its launch in September 2023 and listing on NRDL for the treatment of gMG effective January 1, 2024.
 - **ZEJULA** was \$48.2 million in the third quarter of 2024, an increase of 16% y-o-y from \$41.6 million for the same period in 2023. ZEJULA sales remained strong as it continued to be the leading PARP inhibitor in hospital sales for ovarian cancer in mainland China.
 - **NUZYRA** was \$10.0 million in the third quarter of 2024, an increase of 82% y-o-y compared to \$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 \$66.0 million in the third quarter of 2024, compared to \$58.8 million for the same period in 2023. This increase was primarily due to increased upfront and milestone fees for our license and collaboration agreements, partially offset by decreased clinical trial expenses and personnel costs as a result of ongoing resource prioritization and efficiency efforts.
- **Selling, General and Administrative expenses** were \$67.2 million in the third quarter of 2024, compared to \$68.6 million

for the same period in 2023. This decrease was primarily driven by decreased personnel costs as a result of ongoing resource prioritization and efficiency efforts, partially offset by increased general selling expenses primarily for VYVGART.

- **Loss from operations** was \$67.9 million in the third quarter of 2024, \$48.2 million when adjusted to exclude non-cash expenses including depreciation, amortization, and share-based compensation. A reconciliation of loss from operations (GAAP) to adjusted loss from operations (non-GAAP) is included at the end of this release.
- **Net loss** was \$41.7 million in the third quarter of 2024, or a loss per ordinary share attributable to common stockholders of \$0.04 (or loss per American Deposit Share (ADS) of \$0.42), compared to a net loss of \$69.2 million for the same period in 2023, or a loss per ordinary share of \$0.07 (or loss per ADS of \$0.71).
- **Cash and cash equivalents, short-term investments, and current restricted cash** totaled \$716.1 million as of September 30, 2024, compared to \$730.0 million as of June 30, 2024.

Corporate Updates

Below are key corporate updates since our last earnings release:

- **Organizational Update:** In September 2024, the Company appointed Prista Charuworn, M.D., as Vice President, Immunology, Global R&D. Dr. Charuworn is an accomplished gastroenterologist with extensive experience and leadership in clinical development in hepatology and immunology. She reports to Rafael Amado, M.D., President of Global Research and Development, and is responsible for leading and advancing the R&D strategy and execution of our immunology therapeutic area as well as our neuroscience and infectious disease assets. She previously held key leadership roles in clinical development at Amgen, AstraZeneca and Gilead.

Recent Pipeline Highlights

Below are key product updates since our last earnings release:

Oncology Pipeline

- **Global Pipeline – ZL-1310 (DLL3 ADC):** In October 2024, Zai Lab presented data from a Phase 1 study of ZL-1310 in extensive-stage SCLC (ES-SCLC) after platinum-based therapy. The data, from the ongoing Part 1a monotherapy dose-escalation portion of the study, included results from 25 patients across four dose cohorts (0.8 mg/kg, 1.6mg/kg, 2.0 mg/kg, 2.4 mg/kg). Findings from this study suggest that ZL-1310 delivers anti-tumor activity across multiple dose levels with an overall response rate of 74%. It was well tolerated across all dose levels with the majority of treatment emergent adverse events being Grade 1 or 2.
- **Bemarituzumab (FGFR2b):** In October 2024, Zai Lab and partner Amgen completed patient enrollment for the global Phase 3 FORTITUDE-102 study of bemarituzumab in combination with chemotherapy and a checkpoint inhibitor in first-line gastric cancer.

Immunology, Neuroscience, and Infectious Disease Pipeline

- **Efgartigimod (FcRn):** In November 2024, China's National Medical Products Administration (NMPA) approved the supplemental Biologics License Application (sBLA) for the subcutaneous formulation of efgartigimod, under the brand name VYVGART Hytrulo, for the treatment of adult patients with CIDP. It is the first and only NMPA-approved treatment for patients with CIDP in China. The product is to be administered as a single subcutaneous injection per week (1,000 mg fixed dose) delivered over 30 to 90 seconds.
- **Xanomeline and Trospium Chloride (KarXT) (M1/M4-agonist):**
 - In October 2024, Zai Lab announced positive topline results from the Phase 3 bridging study evaluating the safety and efficacy of KarXT in schizophrenia in China. The study met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 9.2-point reduction in the Positive and Negative Syndrome Scale (PANSS) total score compared to placebo at Week 5 (-16.9 KarXT vs. -7.7 placebo, p=0.0014). The study also met all secondary efficacy endpoints. Zai Lab expects to submit a New Drug Application to the NMPA for KarXT for the treatment of schizophrenia in early 2025.
 - In October 2024, Zai Lab partner Bristol Myers Squibb (BMS) announced new topline results from the Phase 3 EMERGENT-4 and EMERGENT-5 open-label trials evaluating the long-term efficacy, safety and tolerability of KarXT in adults with schizophrenia over 52 weeks of treatment. In the analysis, KarXT was associated with continued improvements in symptoms of schizophrenia across all efficacy measures. KarXT continued to see a lack of weight gain, and it was not associated with movement disorders or metabolic changes. In September 2024, BMS announced that the U.S. FDA approved KarXT, under the brand name COBENFY™, for the treatment of adult patients with schizophrenia.
- **Global Pipeline – ZL-1503 (IL-13/IL-31):** In September 2024, Zai Lab presented pre-clinical data of ZL-1503, an IL-13/IL-31 bi-specific antibody, at the European Academy of Dermatology and Venerology Congress (EADV) 2024. The presentation discussed the potential of ZL-1503 as a novel treatment for moderate-to-severe atopic dermatitis, as well as other diseases involving the IL-13 and IL-31 pathways.

Anticipated Major Milestones in 2024 and 2025

Expected Commercial Launches in China by the End of 2024

- **XACDURO (SUL-DUR)** for the treatment of adult patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.
- **VYVGART Hytrulo (efgartigimod alfa injection (subcutaneous injection))** as an add on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive and for the treatment of adult patients with CIDP.
- **AUGTYRO (reprotrectinib, ROS1/TRK)** for the treatment of adult patients with locally advanced or metastatic *ROS1*+ NSCLC.

Upcoming Potential NMPA Submissions

- **Xanomeline and Trospium Chloride (KarXT) (M1/M4-agonist)**: NDA submission in schizophrenia in early 2025.
- **TTFields (Tumor Treating Fields)**: Marketing Authorization Application (MAA) submission in second-line+ NSCLC following progression on or after platinum-based chemotherapy. Zai Lab partner Novocure announced that TTFields was approved by the FDA under the brand name Optune Lua® for the treatment of metastatic NSCLC in October 2024.
- **Tisotumab Vedotin (Tissue Factor ADC)**: BLA submission in recurrent or metastatic cervical cancer following progression on or after chemotherapy.
- **Reprotrectinib (ROS1/TRK)**: supplementary NDA submission in *NTRK*+ solid tumors.

Expected Clinical Development and Data Readouts in 2024 and 2025

Efgartigimod (FcRn)

- Zai Lab partner argenx to provide topline data from the Phase 2/3 ALKIVIA study evaluating efgartigimod across three myositis subsets (immune-mediated necrotizing myopathy, anti-synthetase syndrome, and dermatomyositis) by the end of 2024. Zai Lab to join the Phase 3 portion of this study in the fourth quarter of 2024.
- Zai Lab to continue to work with argenx to explore the potential of efgartigimod to treat other IgG-mediated autoimmune indications by joining several studies in Greater China, including:
 - The global registrational studies of efgartigimod alfa injection given by prefilled syringe in Thyroid Eye Disease (TED) in the fourth quarter of 2024.
 - The global registrational Phase 3 studies in seronegative gMG and ocular MG in early 2025 aiming to expand the label into broader MG populations.
 - The global registrational Phase 3 study in Sjogren's disease in the second half of 2025.

Bemarituzumab (FGFR2b)

- Zai Lab partner Amgen to provide a data readout from the Phase 3 FORTITUDE-101 study of bemarituzumab combined with chemotherapy versus chemotherapy alone in first-line gastric cancer. We are participating in the study in Greater China.

TTFields

- Zai Lab partner 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)

- Zai Lab to enroll patients into dose expansion in the ongoing global Phase 1 study for ZL-1310 monotherapy for second-line+ ES-SCLC in 2024, and initiate dose escalation for the first-line setting, in combination with atezolizumab and platinum-based chemotherapy in 2025.
- Zai Lab to initiate a global Phase 1 study to explore ZL-1310 in other neuroendocrine tumors in 2025.

ZL-6301 (ROR1 ADC)

- Zai Lab to initiate a global Phase 1 study in solid tumors in 2025.

ZL-1503 (IL-13/IL-31)

- Zai Lab to submit an Investigational New Drug Application to the FDA in 2025.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, November 12, 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/Ble3071c05888e4577aa901f5de0f00669>

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

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.twitter.com/Zai_Lab_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. We have also presented a measure of adjusted loss from operations that adjusts GAAP loss from operations to exclude the impact of certain non-cash expenses including depreciation, amortization, and share-based compensation. These adjusted growth rates and adjusted loss from operations are non-GAAP measures. We believe that these non-GAAP measures are important for an understanding of the performance of our business operations and financial results and provide investors with an additional perspective on trends. Although we believe the non-GAAP financial measures enhance investors' understanding of our business and performance, these non-GAAP financial measures should not be considered an exclusive alternative to accompanying GAAP financial measures.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements relating to our strategy and plans; potential of and expectations for our business and pipeline programs; our goals, objectives, and priorities and our expectations under our growth strategy (including our expectations regarding our commercial products and launches, clinical stage products, revenue growth, profitability, and cash flow); clinical development programs and related clinical trials; clinical trial data, data readouts, and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our products and product candidates and those of our collaboration partners; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; and financial guidance, including with respect to our planned sources and uses of cash and our expected path to profitability. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would," and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products; (2) our ability to obtain funding for our operations and business initiatives; (3) the results of our clinical and pre-clinical development of our product candidates; (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates; (5) risks related to doing business in China; and (6) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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

Zai Lab Limited

Unaudited Condensed Consolidated Balance Sheets

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

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	616,086	790,151
Restricted cash, current	100,000	—
Short-term investments	—	16,300

Accounts receivable (net of allowance for credit losses of \$14 and \$17 as of September 30, 2024 and December 31, 2023, respectively)	49,970	59,199
Notes receivable	19,278	6,134
Inventories, net	39,548	44,827
Prepayments and other current assets	35,667	22,995
Total current assets	860,549	939,606
Restricted cash, non-current	1,118	1,113
Long term investments	3,153	9,220
Prepayments for equipment	32	111
Property and equipment, net	50,765	53,734
Operating lease right-of-use assets	12,833	14,844
Land use rights, net	3,012	3,069
Intangible assets, net	51,669	13,389
Long-term deposits	975	1,209
Value added tax recoverable	1,240	—
Total assets	985,346	1,036,295
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	120,652	112,991
Current operating lease liabilities	6,585	7,104
Short-term debt	112,994	—
Other current liabilities	46,084	82,972
Total current liabilities	286,315	203,067
Deferred income	24,924	28,738
Non-current operating lease liabilities	6,113	8,047
Other non-current liabilities	325	325
Total liabilities	317,677	240,177
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 989,268,370 and 977,151,270 shares issued as of September 30, 2024 and December 31, 2023, respectively; 984,356,170 and 972,239,070 shares outstanding as of September 30, 2024 and December 31, 2023, respectively)	6	6
Additional paid-in capital	3,031,628	2,975,302
Accumulated deficit	(2,371,399)	(2,195,980)
Accumulated other comprehensive income	28,270	37,626
Treasury Stock (at cost, 4,912,200 shares as of both September 30, 2024 and December 31, 2023)	(20,836)	(20,836)
Total shareholders' equity	667,669	796,118
Total liabilities and shareholders' equity	985,346	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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues				
Product revenue, net	101,847	69,228	289,102	200,889
Collaboration revenue	418	—	816	—
Total revenues	102,265	69,228	289,918	200,889
Expenses				
Cost of product revenue	(36,569)	(25,479)	(105,336)	(70,579)
Cost of collaboration revenue	(348)	—	(433)	—
Research and development	(65,982)	(58,767)	(182,252)	(183,920)
Selling, general, and administrative	(67,219)	(68,552)	(216,123)	(198,982)
Gain on sale of intellectual property	—	—	—	10,000

Loss from operations	(67,853)	(83,570)	(214,226)	(242,592)
Interest income	9,029	9,172	28,017	29,493
Interest expense	(745)	—	(1,350)	—
Foreign currency gains (losses)	14,457	4,852	8,281	(26,315)
Other income, net	3,441	394	3,859	223
Loss before income tax	(41,671)	(69,152)	(175,419)	(239,191)
Income tax expense	—	—	—	—
Net loss	(41,671)	(69,152)	(175,419)	(239,191)
Loss per share - basic and diluted	(0.04)	(0.07)	(0.18)	(0.25)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	981,687,390	968,767,730	976,941,030	965,060,570

Zai Lab Limited

Unaudited Condensed Consolidated Statements of Comprehensive Loss (in thousands of \$)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	(41,671)	(69,152)	(175,419)	(239,191)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	(14,503)	(4,228)	(9,356)	22,267
Comprehensive loss	(56,174)	(73,380)	(184,775)	(216,924)

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Non-GAAP Measures (\$ in thousands)

Growth on a Constant Exchange Rate (CER) Basis

	Three Months Ended September 30,		Year over Year % Growth		Nine Months Ended September 30,		Year over Year % Growth	
	2024	2023	As reported	At CER*	2024	2023	As reported	At CER*
Product revenue, net	101,847	69,228	47%	46%	289,102	200,889	44%	45%
Loss from operations	(67,853)	(83,570)	(19)%	(20)%	(214,226)	(242,592)	(12)%	(11)%

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

Reconciliation of Loss from Operations (GAAP) to Adjusted Loss from Operations (Non-GAAP)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP loss from operations	(67,853)	(83,570)	(214,226)	(242,592)
Plus: Depreciation and amortization expenses	2,871	1,918	8,824	6,570
Plus: Share-based compensation	16,795	21,992	53,413	59,164
Adjusted loss from operations	(48,187)	(59,660)	(151,989)	(176,858)

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