Zai Lab Announces Second Quarter 2025 Financial Results and Recent Corporate Updates

August 7, 2025

- *Total revenues grew 9% y-o-y to $110.0 million for the second quarter of 2025; reaffirming full-year 2025 revenue guidance of $560 million to $590 million*
- *VYVGART reached record patient utilization in the second quarter; updated national guidelines elevate VYVGART's role as a treatment for both acute and maintenance gMG*
- *Operating loss improved by 28% year-over-year to $54.9 million for the second quarter of 2025, and by 37% to $34.2 million on an adjusted basis[1]; on track to achieve profitability[1] in the fourth quarter of 2025*
- *ZL-1310 (DLL3 ADC) data presented at ASCO 2025 showed a 67% ORR across all doses (n=33) and 79% at 1.6mg/kg (n=14) in 2L ES-SCLC, with a differentiated safety profile; registrational study to be initiated in the second half of 2025*
- *The success of the global Phase 3 FORTITUDE-101 study of bemarituzumab highlighted its potential as a first-line treatment for gastric cancer patients with FGFR2b overexpression; China regulatory submission expected in the second half of 2025*
- *EAACI Congress 2025 presentation of ZL-1503 (IL-13/IL-31R) underscores its promising potential as a novel treatment option for moderate-to-severe atopic dermatitis*

Conference call and webcast today, August 7, 2025, *at 8:00 a.m. ET (8:00 p.m. HKT)*

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 7, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for the second quarter of 2025, along with recent product highlights and corporate updates.

"Zai Lab is entering a pivotal period – defined by innovation, scale and strong execution," said Dr. Samantha Du, Founder, Chairperson, and CEO of Zai Lab. "We are making meaningful progress throughout our business – expanding patient impact, accelerating global innovation, and operating with financial discipline. Updated ASCO data for ZL-1310 (DLL3 ADC) reaffirm its best-in-class potential in second-line SCLC, and we are moving swiftly into pivotal development while exploring opportunities in first-line SCLC and other neuroendocrine carcinomas. We were also encouraged by positive data for bemarituzumab in first-line gastric cancer and by emerging preclinical results for our IL-13/IL-31 bispecific antibody in atopic dermatitis, reinforcing both our near-term commercial opportunities and the potential of our global pipeline, respectively. With multiple launches ahead, a robust pipeline, and profitability[1] within reach, Zai Lab is executing on its vision to become a leading global biopharma company."

"VYVGART continues to lead our commercial momentum, with record patient utilization driven by longer treatment durations and growing adoption in the maintenance setting," said Josh Smiley, President and COO of Zai Lab. "The July update to national MG guidelines further strengthens VYVGART's role in both acute and chronic care, and we expect momentum to accelerate in the second half. We are also preparing for several high-impact launches – including KarXT and bemarituzumab – that, together with pipeline-in-a-product assets like VYVGART and povetacicept, will fuel our next wave of growth. With a *28%* year-over-year reduction in operating loss and a *37%* improvement on an adjusted basis, we are on track to achieve profitability[1] in the fourth quarter. Backed by a strong cash position[2], a growing commercial business, and an advancing global pipeline, Zai Lab is well equipped to deliver long-term shareholder value."

1 Refers to adjusted income (loss) from operations (non-GAAP), calculated as GAAP income (loss) from operations adjusted to exclude certain non-cash expenses, including depreciation, amortization, and share-based compensation. For additional information on this adjusted profitability measure, refer to the "Non-GAAP Measures" section.

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

Second Quarter 2025 Financial Results

- **Product revenue, net** was $109.1 million in the second quarter of 2025, compared to $100.1 million for the same period in 2024, representing 9% y-o-y growth, 10% y-o-y growth at constant exchange rate (CER). This increase was primarily driven by increased sales for VYVGART, XACDURO, and NUZYRA, partially offset by softer sales for ZEJULA:
    - **VYVGART and VYVGART Hytrulo** were $26.5 million in the second quarter of 2025, compared to $18.1 million in the first quarter of 2025. Sales grew 46% quarter over quarter driven by an extension of duration of therapy and

increasing market penetration.

- **ZEJULA** was $41.0 million in the second quarter of 2025, compared to $45.0 million for the same period in 2024. Sales were softer due to evolving competitive dynamics within the PARPi class.

- **XACDURO,** which was launched since the fourth quarter of 2024, was $4.6 million in the second quarter of 2025.

- **NUZYRA** was $14.3 million in the second quarter of 2025, compared to $12.3 million for the same period in 2024. This growth was supported by increasing market coverage and penetration.

- **Research and Development (R&D) expenses** were $50.6 million in the second quarter of 2025, compared to $61.6 million for the same period in 2024. The decrease reflects reduced personnel and clinical trial costs, driven by ongoing resource prioritization and efficiency efforts.

- **Selling, General and Administrative expenses** were $71.0 million in the second quarter of 2025, compared to $79.7 million for the same period in 2024. The decrease was primarily driven by reduced personnel costs because of resource prioritization and efficiency efforts.

- **Loss from operations** was $54.9 million in the second quarter of 2025, $34.2 million when adjusted to exclude certain 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 $40.7 million in the second quarter of 2025, or a loss per ordinary share attributable to common stockholders of $0.04 (or loss per American Deposit Share (ADS) of $0.37), compared to a net loss of $80.3 million for the same period in 2024, or a loss per ordinary share of $0.08 (or loss per ADS of $0.82). These decreases in net loss were primarily due to product revenue growing faster than net operating expenses.

- **Cash and cash equivalents, short-term investments, and current restricted cash** totaled $832.3 million as of June 30, 2025, compared to $857.3 million as of March 31, 2025.

Recent Pipeline Highlights

Below are key product updates since our last earnings release:

Oncology Pipeline

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

  - In June 2025, Zai Lab presented positive data from an ongoing, global Phase 1a/1b clinical trial of ZL-1310 for the treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. In second-line (2L) SCLC, objective response rate (ORR) was 67% across all dose levels (n=33) and 79% at 1.6 mg/kg dose (n=14). ZL-1310 demonstrated a well-tolerated safety profile at target doses of less than 2.0 mg/kg, with Grade ≥3 treatment-related adverse events (TRAEs) of 6%, no Grade ≥2 interstitial lung disease, and no drug discontinuations.

  - In May 2025, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to ZL-1310 for treatment of ES-SCLC.

- **Bemarituzumab (FGFR2b)**: In June 2025, Zai Lab announced the Phase 3 FORTITUDE-101 clinical trial evaluating first-line bemarituzumab plus chemotherapy (mFOLFOX6) met its primary endpoint of overall survival (OS) at a pre-specified interim analysis. At the interim analysis, bemarituzumab plus chemotherapy significantly improved OS in patients with FGFR2b overexpression compared to chemotherapy alone. The most common treatment-emergent adverse events (>25%) in patients treated with bemarituzumab plus chemotherapy were reduced visual acuity, punctate keratitis, anemia, neutropenia, nausea, corneal epithelium defect and dry eye. While ocular events were consistent with the Phase 2 experience and observed in both arms, they occurred with greater frequency and severity in the Phase 3 bemarituzumab arm. Detailed results from FORTITUDE 101 will be shared at a future medical meeting. Zai Lab plans to move rapidly toward regulatory submission in China in the second half of 2025.

- **Tumor Treating Fields (TTFields)**: In May 2025, Zai Lab partner Novocure presented results from the Phase 3 PANOVA-3 trial for pancreatic cancer as a late-breaking oral presentation at the 2025 ASCO Annual Meeting. The data demonstrated that TTFields therapy, when added to standard of care, achieved an OS benefit supported by significantly improved quality

of life and extended pain-free survival, a key outcome for patients with pancreatic cancer. Zai Lab participated in the study in Greater China (mainland China, Hong Kong, Macau and Taiwan, collectively) and plans to file for regulatory approval in China in the second half of 2025.

Immunology Pipeline

- **Efgartigimod (FcRn)**: In July 2025, the China Guidelines for the Diagnosis and Treatment of Myasthenia Gravis (MG) (2025) was published, emphasizing the importance of Minimal Symptom Expression (MSE), as the primary treatment goal in MG. The guidelines have highlighted VYVGART's ability to achieve MSE rapidly and provide durable benefit. VYVGART is now recommended for early use in mild-to-moderate and highly active patients, and for sustained long-term treatment to maximize potential benefit.

- **ZL-1503 (IL-13/IL-31R):** In June 2025, Zai Lab announced new preclinical data highlighting the potential of ZL-1503 as a promising treatment for moderate-to-severe atopic dermatitis and other IL-13 and IL-31-driven diseases. Its favorable preclinical safety profile, prolonged half-life and durable suppression of both inflammatory and pruritogenic pathways support the continued advancement of ZL-1503 toward clinical development.

Anticipated Major Milestones in 2025 and the First Half of 2026

Upcoming Potential NMPA Submissions

- **Bemarituzumab (FGFR2b)** in first-line gastric cancer in the second half of 2025

- **Tumor Treating Fields (TTFields)** in first-line pancreatic cancer in the second half of 2025

- **Efgartigimod (FcRn)** for prefilled syringe in generalized myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP) in the second half of 2025

Upcoming Potential NMPA Approvals

- **Xanomeline-Trospium (or KarXT) (M1/M4-agonist)** in schizophrenia

- **Tisotumab Vedotin (Tissue Factor ADC)** in recurrent or metastatic cervical cancer following progression on or after chemotherapy

- **Repotrectinib (ROS1/TRK)** in *NTRK*+ solid tumors

Expected Clinical Developments and Data Readouts

Global Pipeline

ZL-1310 or Zocilurtatug pelitecan (DLL3 ADC)

- *Second-Line ES-SCLC:* Zai Lab to provide data update and to initiate a global registrational study of ZL-1310 monotherapy in the second half of 2025.

- *First-Line ES-SCLC*: Zai Lab to provide data readout for dose escalation of ZL-1310 doublet in combination with atezolizumab.

- *Other neuroendocrine carcinomas*: Zai Lab to provide data readout from the global Phase 1/2 study in patients with selected solid tumors.

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

- Zai Lab to advance into a global Phase 1 study in moderate-to-severe atopic dermatitis in the second half of 2025.

ZL-6201 (LRRC15 ADC)

- Zai Lab to advance into global Phase 1 development for patients with sarcoma and potentially other LRRC15-positive solid tumors, such as breast cancer and other malignancies.

Regional Pipeline

Bemarituzumab (FGFR2b)

- Zai Lab partner Amgen to provide detailed results from the Phase 3 FORTITUDE-101 study of bemarituzumab combined

with chemotherapy versus chemotherapy alone in first-line gastric cancer at an upcoming medical meeting. Zai Lab participated in the study in Greater China.

- Zai Lab partner Amgen to provide potential data readout from the Phase 1b/3 FORTITUDE-102 study of bemarituzumab plus chemotherapy and nivolumab versus chemotherapy and nivolumab in first-line gastric cancer. Zai Lab participated in the study in Greater China.

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

- Zai Lab partner Bristol Myers Squibb to provide data readout from the Phase 3 ADEPT-2 study of KarXT in Alzheimer's Disease Psychosis in the second half of 2025. Zai Lab participated in the study in Greater China.

Efgartigimod (FcRn)

- *Lupus Nephritis (LN)*: Zai Lab and partner argenx to provide topline results from the Phase 2 study in LN in the fourth quarter of 2025.

- *Seronegative gMG*: Zai Lab partner argenx to provide topline results from the global Phase 3 ADAPT-SERON study in seronegative gMG in the second half of 2025. Zai Lab participated in the study in Greater China.

- *Ocular myasthenia gravis:* Zai Lab partner argenx to provide topline results from the global Phase 3 ADAPT-OCULUS study in the first half of 2026. Zai Lab participated in the study in Greater China.

- *Sjogren's disease:* Zai Lab to join the registrational UNITY study of efgartigimod subcutaneous given by prefilled syringe in Sjogren's disease in Greater China in the third quarter of 2025.

Povetacicept (APRIL/BAFF)

- *Primary Membranous Nephropathy (pMN)*: Zai Lab plans to partner with Vertex to execute the global pivotal Phase 2/3 study of povetacicept in pMN in Greater China. The study is expected to start in the second half of 2025.

- *IgA Nephropathy (IgAN)*: Zai Lab partner Vertex will conduct an interim analysis of the global Phase 3 RAINIER study following 36 weeks of treatment with the potential to file for U.S. accelerated approval in the first half of 2026.

VRDN-003 (IGF-1R, subcutaneous)

- Zai Lab to initiate a registrational study in thyroid eye disease in Greater China in the second half of 2025.

- Zai Lab partner Viridian to provide topline results from the global registrational REVEAL-1 and REVEAL-2 studies in the first half of 2026.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, August 7, 2025, 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 of registration links are as follows:

- For webcast: https://edge.media-server.com/mmc/p/5xsbgbn3
- For dial-in: https://register-conf.media-server.com/register/BI52be4f1f4178480fa60b0d17b5c6ae3d

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 worldwide.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at https://x.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. 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, which we refer to as “profitability.” These adjusted growth rates and adjusted loss from operations are non-GAAP financial measures. We believe that these non-GAAP financial measures are important for an understanding of the performance of our business operations and financial results and provide investors with an additional perspective on operational trends and greater transparency into our historical and projected operating performance. 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 the corresponding GAAP financial measures.

Zai Lab Forward-Looking Statements

This press release contains certain forward-looking statements, including statements relating to our strategy and plans; potential of and expectations for our business, commercial products, 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 profitability and timeline to profitability; our future financial and operating results; and financial guidance, including with respect to our capital allocation and investment strategy 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,” “poised,” “positioned,” “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 such 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)

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	732,159	449,667
Restricted cash, current	100,111	100,000
Short-term investments	—	330,000
Accounts receivable (net of allowance for credit losses of $26 and $25 as of June 30, 2025 and December 31, 2024, respectively)	88,499	85,178
Notes receivable	10,843	4,233
Inventories, net	61,700	39,875
Prepayments and other current assets	40,750	41,527
Total current assets	1,034,062	1,050,480
Restricted cash, non-current	1,114	1,114
Property and equipment, net	50,160	47,961
Operating lease right-of-use assets	16,787	21,496
Land use rights, net	2,860	2,907
Intangible assets, net	56,519	56,027
Other non-current assets	2,599	5,768
Total assets	**1,164,101**	**1,185,753**
Liabilities and shareholders’ equity		
Current liabilities		
Accounts payable	107,357	100,906
Current operating lease liabilities	5,584	8,048
Short-term debt	174,509	131,711
Other current liabilities	44,051	58,720
Total current liabilities	331,501	299,385

Deferred income	29,233	31,433
Non-current operating lease liabilities	11,307	13,712
Other non-current liabilities	325	325
Total liabilities	**372,366**	**344,855**
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 1,104,032,910 and 1,082,614,740 shares issued as of June 30, 2025 and December 31, 2024, respectively; 1,099,112,890 and 1,077,702,540 shares outstanding as of June 30, 2025 and December 31, 2024, respectively)	7	7
Additional paid-in capital	3,308,491	3,264,295
Accumulated deficit	(2,542,248)	(2,453,083)
Accumulated other comprehensive income	46,348	50,515
Treasury Stock (at cost, 4,920,020 and 4,912,200 shares as of June 30, 2025 and December 31, 2024, respectively)	(20,863)	(20,836)
Total shareholders' equity	**791,735**	**840,898**
Total liabilities and shareholders' equity	**1,164,101**	**1,185,753**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenues				
Product revenue, net	109,085	100,106	214,735	187,255
Collaboration revenue	892	398	1,729	398
Total revenues	109,977	100,504	216,464	187,653
Expenses				
Cost of product revenue	(43,003)	(35,148)	(81,455)	(68,767)
Cost of collaboration revenue	(217)	(85)	(412)	(85)
Research and development	(50,614)	(61,625)	(111,343)	(116,270)
Selling, general, and administrative	(71,038)	(79,710)	(134,460)	(148,904)
Loss from operations	(54,895)	(76,064)	(111,206)	(146,373)
Interest income	8,843	9,330	17,449	18,988
Interest expenses	(1,262)	(492)	(2,449)	(605)
Foreign currency gains (losses)	2,837	(4,108)	3,488	(6,176)
Other income (expense), net	3,750	(8,943)	3,553	418
Loss before income tax	(40,727)	(80,277)	(89,165)	(133,748)
Income tax expense	—	—	—	—
Net loss	(40,727)	(80,277)	(89,165)	(133,748)
Loss per share - basic and diluted	(0.04)	(0.08)	(0.08)	(0.14)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	1,091,933,150	975,937,790	1,086,413,130	974,541,780

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Net loss	(40,727)	(80,277)	(89,165)	(133,748)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	(2,955)	3,605	(4,167)	5,147
Comprehensive loss	(43,682)	(76,672)	(93,332)	(128,601)

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

Growth on a Constant Exchange Rate (CER) Basis

	Three Months Ended June 30,		Year over Year % Growth		Six Months Ended June 30,		Year over Year % Growth	
	2025	2024	As reported	At CER*	2025	2024	As reported	At CER*
Product revenue, net	109,085	100,106	9%	10%	214,735	187,255	15%	16%
Loss from operations	(54,895)	(76,064)	(28)%	(28)%	(111,206)	(146,373)	(24)%	(24)%

* *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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
GAAP loss from operations	(54,895)	(76,064)	(111,206)	(146,373)
Plus: Depreciation and amortization expenses	3,735	2,941	7,193	5,953
Plus: Share-based compensation	16,973	18,638	32,773	36,618
Adjusted loss from operations	(34,187)	(54,485)	(71,240)	(103,802)

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