



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

May 8, 2025

– Total revenues grew 22% y-o-y to \$106.5 million for the first quarter of 2025; reaffirming full-year 2025 revenue guidance of \$560 million to \$590 million

– Operating loss improved significantly, declining 20% year-over-year to \$56.3 million for the first quarter of 2025, and 25% to \$37.1 million on an adjusted basis¹; on track to achieve profitability¹ in the fourth quarter of 2025

– ZL-1310 (DLL3 ADC) is advancing rapidly, with upcoming ASCO 2025 data presentation in ES-SCLC; initiation of registrational study in ES-SCLC expected in the second half of 2025

– AACR 2025 presentations of ZL-6201 (LRRC15 ADC) and ZL-1222 (PD-1/IL-12) underscore the promising potential of Zai Lab's internally developed next-generation oncology therapies

– Strong balance sheet with a cash position² of \$857.3 million as of March 31, 2025, compared to \$879.7 million as of December 31, 2024

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

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 8, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for the first quarter of 2025, along with recent product highlights and corporate updates.

"In the first quarter, we continued to advance both our global pipeline and commercial business," said Dr. Samantha Du, Founder, Chairperson, and CEO of Zai Lab. "We are rapidly expanding our global portfolio, having recently presented promising data for two next-generation oncology therapies at AACR, and we look forward to presenting updated results for ZL-1310 (DLL3 ADC) at the 2025 ASCO Annual Meeting. We remain on track to initiate a pivotal study for ZL-1310 in SCLC this year, with the goal of securing FDA approval in 2027. In parallel, we are also exploring opportunities in first-line SCLC and other neuroendocrine tumors to unlock the full potential of this important global asset. On the commercial front, we continued to expand patient access for key products and are leveraging our existing infrastructure to support upcoming launches and our next wave of blockbuster opportunities. With a strong foundation in place, we are well positioned to drive growth and profitability, and to further our mission of becoming a leading global biopharmaceutical company."

"2025 marks a transformational year for Zai Lab, and we are executing against the key objectives we set at the start of the year," said Josh Smiley, President and COO of Zai Lab. "Following a seasonal slowdown of VYVGART early in the year, we saw patient volumes rebound in March and April, and we anticipate a return to strong sequential growth throughout the rest of the year. Looking ahead, our late-stage pipeline, including bemarituzumab and KarXT, is expected to fuel the next wave of topline growth alongside VYVGART. At the same time, we continue to strengthen our financial position, achieving a 20% year-over-year reduction in operating loss and a 25% year-over-year reduction in adjusted operating loss¹, keeping us on track to achieve profitability¹ in the fourth quarter of 2025. With a strong cash position,² a growing commercial business and an expanding global portfolio, Zai Lab is poised to capitalize on multiple upcoming catalysts and drive 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.

First Quarter 2025 Financial Results

- **Product revenue, net** was \$105.7 million in the first quarter of 2025, compared to \$87.1 million for the same period in 2024, representing 21% y-o-y growth, 23% y-o-y growth at constant exchange rate (CER). This increase was primarily driven by increased sales for VYVGART, ZEJULA, and NUZYRA.
 - **VYVGART and VYVGART Hytrulo** were \$18.1 million in the first quarter of 2025, compared to \$13.2 million for the same period in 2024. Although quarter over quarter growth was impacted by seasonality, sales grew year over year driven by increasing market coverage and penetration since VYVGART's launch in September 2023 and listing on China's National Reimbursement Drug List (NRDL) for the treatment of generalized Myasthenia Gravis (gMG) effective January 1, 2024.

- **ZEJULA** was \$49.5 million in the first quarter of 2025, compared to \$45.5 million for the same period in 2024. ZEJULA sales remained strong as it continued to be the leading PARP inhibitor in hospital sales for ovarian cancer in mainland China.
- **NUZYRA** was \$15.1 million in the first quarter of 2025, compared to \$9.9 million for the same period in 2024. This growth was supported by increasing market coverage and penetration.
- **Research and Development (R&D) expenses** were \$60.7 million in the first quarter of 2025, compared to \$54.6 million for the same period in 2024. This increase was primarily due to upfront fees totaling \$20.0 million for our license and collaboration agreements. Other R&D expenses decreased as a result of resource prioritization and efficiency efforts.
- **Selling, General and Administrative expenses** were \$63.4 million in the first quarter of 2025, compared to \$69.2 million for the same period in 2024. This decrease was primarily driven by decreased personnel costs as a result of resource prioritization and efficiency efforts.
- **Loss from operations** was \$56.3 million in the first quarter of 2025, \$37.1 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 \$48.4 million in the first quarter of 2025, or a loss per ordinary share attributable to common stockholders of \$0.04 (or loss per American Deposit Share (ADS) of \$0.45), compared to a net loss of \$53.5 million for the same period in 2024, or a loss per ordinary share of \$0.05 (or loss per ADS of \$0.55). 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 \$857.3 million as of March 31, 2025, compared to \$879.7 million as of December 31, 2024.

Recent Pipeline Highlights

Below are key product updates since our last earnings release:

Oncology Pipeline

- **ZL-1310 (DLL3 ADC):**
 - *Second-Line+ Extensive-Stage SCLC (ES-SCLC):* In April 2025, Zai Lab announced that updated data from an ongoing, global Phase 1a/1b clinical trial of ZL-1310 for the treatment of ES-SCLC, will be presented during a poster session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The updated results will include additional patients and follow-up from the ongoing trial.
 - *Other neuroendocrine tumors:* In April 2025, Zai Lab initiated a global Phase 1/2 study in patients with selected solid tumors, exploring its therapeutic potential beyond ES-SCLC.
- **Tisotumab Vedotin (TIVDAK, Tissue Factor ADC):** In March 2025, China's National Medical Products Administration (NMPA) accepted the Biologics License Application (BLA) for TIVDAK for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy. Zai Lab will leverage its commercial footprint of ZEJULA in women's cancer to accelerate patient access to this therapy in China if approved.
- **Tumor Treating Fields (TTFields):** In April 2025, Zai Lab partner Novocure announced that the additional results from the Phase 3 PANOVA-3 trial for pancreatic cancer will be presented as a late-breaking oral presentation at the 2025 ASCO Annual Meeting. 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 2025.
- **Repotrectinib (ROS1/TRK):** In April 2025, China's NMPA accepted the supplemental New Drug Application for repotrectinib for patients with *NTRK*-positive solid tumors. Repotrectinib has the potential to become a next-generation TKI that can be used across a broad range of *NTRK* fusion-positive solid tumors for both TKI-naïve and TKI-pretreated patients.
- **ZL-6201 (LRRC15 ADC):** In April 2025, Zai Lab presented new data at the American Association for Cancer Research (AACR) Annual Meeting 2025. The findings demonstrate that ZL-6201 efficiently internalizes within and kills tumor cells, while also exhibiting a strong bystander killing effect in the tumor microenvironment where the target is often

expressed. Based on these findings, Zai Lab plans to initiate Investigational New Drug (IND)-enabling studies of ZL-6201 as a potential treatment for patients with sarcoma and other LRRC15-positive solid tumors, such as breast cancer and other malignancies, in 2025.

- **ZL-1222 (PD-1/IL-12):** In April 2025, Zai Lab presented data at the AACR Annual Meeting 2025, marking the first public disclosure of this global asset. Findings from preclinical studies demonstrate its potent anti-tumor activity in both anti-PD-1 sensitive and resistant tumor models, with improved systemic safety. These results indicate its potential to benefit patients who are unresponsive or resistant to the current immuno-oncology therapies.

Immunology Pipeline

- **Efgartigimod (FcRn):** In April 2025, Zai Lab partner argenx announced the U.S. Food and Drug Administration (FDA) approved VYVGART Hytrulo prefilled syringe (PFS) for self-injection in gMG and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). It is the third administration option providing additional flexibility and convenience for patients. Zai Lab plans to submit the Chemical Manufacturing and Control (CMC) variation for PFS for these indications in China in 2025.
- **ZL-1102 (IL-17 Humabody®):** Zai Lab has decided to discontinue the global Phase 2 clinical trial of ZL-1102 following a comprehensive review of the data from interim analysis from the first 40 enrolled participants and the subsequent recommendation of the independent Data and Safety Monitoring Board.
- **Povetacicept (APRIL/BAFF):** Zai Lab partner Vertex has completed enrollment of the interim analysis cohort in the global Phase 3 RAINIER study of povetacicept in IgA nephropathy. Zai Lab participated in the study in Greater China.

Anticipated Major Milestones in 2025

Upcoming Potential NMPA Submissions

- **Bemarituzumab (FGFR2b):** BLA submission in first-line gastric cancer.
- **Tumor Treating Fields (TTFields):** Marketing Authorization Application submissions in first-line pancreatic cancer.
- **Efgartigimod (FcRn):** submission for the CMC variation for PFS in gMG and CIDP.

Expected Clinical Developments and Data Readouts

Global Pipeline

ZL-1310 (DLL3 ADC)

- **Second-Line+ ES-SCLC:** Zai Lab to present updated data at the 2025 ASCO Annual Meeting on June 2, 2025. Zai Lab plans to initiate a pivotal study in the second half of 2025.
- **First-Line ES-SCLC:** Zai Lab to provide a data readout for dose escalation of ZL-1310 doublet in combination with atezolizumab.

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

- Zai Lab to provide a preclinical data update and advance into a global Phase 1 study in moderate-to-severe atopic dermatitis.

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 data readout from the Phase 3 FORTITUDE-101 study of bemarituzumab combined with chemotherapy versus chemotherapy alone in first-line gastric cancer in the second quarter of 2025. Zai Lab participated in the study in Greater China.
- Zai Lab partner Amgen to provide data readout from the Phase 3 FORTITUDE-102 study of bemarituzumab plus

chemotherapy and nivolumab versus chemotherapy and nivolumab in first-line gastric cancer in the second half of 2025. Zai Lab participated in the study in Greater China.

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

- Zai Lab partner Bristol Myers Squibb (BMS) 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)

- *Seronegative gMG*: Zai Lab partner argenx to provide topline results from the Phase 3 ADAPT-SERON study in seronegative gMG. Zai Lab participated in the study in Greater China.
- *Lupus Nephritis (LN)*: Zai Lab to provide topline results from the Phase 2 study in LN.

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.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, May 8, 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/pwq4a9of>
- For dial-in: <https://register-conf.media-server.com/register/Blb40d2ed331c84e39982d7fe2b6ed496f>

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 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 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 accompanying 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 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," "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)

	March 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	757,263	449,667
Restricted cash, current	100,000	100,000
Short-term investments	—	330,000
Accounts receivable (net of allowance for credit losses of \$22 and \$25 as of March 31, 2025 and December 31, 2024, respectively)	76,555	85,178
Notes receivable	11,118	4,233
Inventories, net	53,054	39,875
Prepayments and other current assets	43,878	41,527
Total current assets	1,041,868	1,050,480
Restricted cash, non-current	1,113	1,114
Property and equipment, net	49,654	47,961
Operating lease right-of-use assets	19,081	21,496
Land use rights, net	2,882	2,907
Intangible assets, net	56,198	56,027
Other non-current assets	2,534	5,768
Total assets	1,173,330	1,185,753
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	103,017	100,906
Current operating lease liabilities	6,574	8,048
Short-term debt	173,405	131,711
Other current liabilities	36,811	58,720
Total current liabilities	319,807	299,385
Deferred income	30,126	31,433
Non-current operating lease liabilities	12,319	13,712
Other non-current liabilities	325	325
Total liabilities	362,577	344,855
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 1,089,076,400 and 1,082,614,740 shares issued as of March 31, 2025 and December 31, 2024, respectively; 1,084,164,200 and 1,077,702,540 shares outstanding as of March 31, 2025 and December 31, 2024, respectively)	7	7
Additional paid-in capital	3,283,800	3,264,295
Accumulated deficit	(2,501,521)	(2,453,083)

Accumulated other comprehensive income	49,303	50,515
Treasury Stock (at cost, 4,912,200 shares as of both March 31, 2025 and December 31, 2024)	(20,836)	(20,836)
Total shareholders' equity	810,753	840,898
Total liabilities and shareholders' equity	1,173,330	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 March 31,	
	2025	2024
Revenues		
Product revenue, net	105,650	87,149
Collaboration revenue	837	—
Total revenues	106,487	87,149
Expenses		
Cost of product revenue	(38,452)	(33,619)
Cost of collaboration revenue	(195)	—
Research and development	(60,729)	(54,645)
Selling, general, and administrative	(63,422)	(69,194)
Loss from operations	(56,311)	(70,309)
Interest income	8,606	9,658
Interest expenses	(1,187)	(113)
Foreign currency gains (losses)	651	(2,068)
Other (expense) income, net	(197)	9,361
Loss before income tax	(48,438)	(53,471)
Income tax expense	—	—
Net loss	(48,438)	(53,471)
Loss per share - basic and diluted	(0.04)	(0.05)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	1,080,825,300	973,145,760

Zai Lab Limited

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

	Three Months Ended March 31,	
	2025	2024
Net loss	(48,438)	(53,471)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	(1,212)	1,542
Comprehensive loss	(49,650)	(51,929)

Zai Lab Limited

Non-GAAP Measures

(unaudited)

(\$ in thousands)

Growth on a Constant Exchange Rate (CER) Basis

	Three Months Ended		Year over Year %	
	March 31,		Growth	
	2025	2024	As reported	At CER*
Product revenue, net	105,650	87,149	21%	23%
Loss from operations	(56,311)	(70,309)	(20)%	(20)%

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

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

Three Months Ended March 31,

	2025	2024
GAAP loss from operations	(56,311)	(70,309)
Plus: Depreciation and amortization expenses	3,458	3,012
Plus: Share-based compensation	15,800	17,980
Adjusted loss from operations	<u>(37,053)</u>	<u>(49,317)</u>

View source version on [businesswire.com](https://www.businesswire.com/news/home/20250508272596/en/): <https://www.businesswire.com/news/home/20250508272596/en/>

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