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

November 6, 2025

– Zocilurtatug pelitecan (zoci, DLL3 ADC) (formerly ZL-1310) data presented at Triple Meeting in October continues to demonstrate first- and best-in-class potential, supporting the recent initiation of the global registrational study in 2L+ ES-SCLC

– Advancing other high-potential global programs, including initiation of a global Phase 1 study for ZL-1503 (IL-13xIL-31R bispecific antibody) and a planned IND submission for ZL-6201 (LRRC15 ADC) by year-end 2025

– KarXT was recently included in China's national-level treatment guidelines, underscoring the urgent need for novel therapies in schizophrenia; launch preparations are underway

– Total revenues grew 14% y-o-y to $116.1 million in the third quarter of 2025, operating loss improved by 28% y-o-y to $48.8 million, and by 42% to $28.0 million on an adjusted basis[1]; revising total revenue guidance for the full year 2025 to at least $460 million

Conference call and webcast today, November 6, 2025, at 8:00 a.m. ET (9:00 p.m. HKT)

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 6, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced financial results for the third quarter of 2025, along with recent product highlights and corporate updates.

"Zai Lab is entering the next phase of our growth, powered by the rapid advancement of our global pipeline and supported by a commercially profitable and scalable business in China," said Dr. Samantha Du, Founder, Chairperson, and CEO of Zai Lab. "With zoci moving into pivotal development less than two years after IND and multiple differentiated global programs progressing in parallel, we are demonstrating the speed, scientific rigor, and global ambition of our R&D engine. At the same time, our commercial platform in China remains strong, with new products and indications – including KarXT, povetacicept and VYVGART – broadening our long-term growth profile. Together, we are building a company that will make a lasting difference for patients and create long-term value for our shareholders."

"This quarter, we continued to deepen the foundations of the VYVGART launch," said Josh Smiley, President and COO of Zai Lab. "In gMG, we are seeing steady new patient starts and increasing treatment duration, supported by updated treatment guidelines and real-world experience. While adoption is building gradually, physician confidence continues to grow and reinforces the long-term potential of VYVGART as a new standard of care in the treatment of this chronic disease. Looking ahead, we are preparing for our next expected launch for KarXT in schizophrenia. We remain focused on disciplined execution as we position for the significant opportunities ahead, supported by a growing regional business and a rapidly progressing, global pipeline."

[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.

Recent Pipeline Highlights

Below are key product updates since our last earnings release:

Oncology Pipeline

- **Zocilurtatug Pelitecan (zoci, DLL3 ADC) (formerly ZL-1310):**

  – In October 2025, Zai Lab initiated a global registrational study of zocilurtatug pelitecan monotherapy in second-line+ extensive-stage small cell lung cancer (ES-SCLC).

  – In October 2025, Zai Lab presented updated Phase 1 results at the AACR-NCI-EORTC International Conference, demonstrating a best overall response rate of 68% at the 1.6 mg/kg dose in second-line extensive-stage small cell lung cancer. The estimated median duration of response (DoR) of 6.1 months across all doses and all lines of therapy is highly encouraging for a monotherapy in this heavily pre-treated and difficult-to-treat patient population. Meaningful activity in patients with brain metastases was also observed, including an 80% response rate in patients with untreated brain metastases. The data also demonstrated a well-tolerated safety profile at 1.6 mg/kg, with Grade ≥ 3 treatment-related adverse events of 13%, no Grade ≥2 interstitial lung disease, and no drug discontinuations. Together, these results reinforce zoci's best-in-class potential and support the initiation of the global registrational study.

- **Tumor Treating Fields (TTFields)**: In August 2025, Zai Lab announced that the China National Medical Products Administration (NMPA) has granted Innovative Medical Device Designation for TTFields for patients with pancreatic cancer

based on the positive results from the Phase 3 PANOVA-3 trial. We plan to submit for regulatory approval in China in the fourth quarter of 2025.

- **Bemarituzumab (FGFR2b)**: In November 2025, Zai Lab partner Amgen announced FORTITUDE-102, a Phase 1b/3 study of bemarituzumab plus chemotherapy and nivolumab in patients with first-line gastric cancer, was stopped.

Immunology Pipeline

- **ZL-1503 (IL-13/IL-31R)**: In November 2025, Zai Lab initiated a global Phase 1/1b study to evaluate safety, tolerability and pharmacokinetics of ZL-1503 in healthy volunteers and participants with moderate to severe atopic dermatitis.
- **Efgartigimod (FcRn)**:

  – *Sjogren's disease:* In September 2025, Zai Lab joined the registrational UNITY study of efgartigimod subcutaneous given by prefilled syringe in Sjogren's disease in Greater China (mainland China, Hong Kong, Macau and Taiwan, collectively).

  – *Seronegative gMG*: In August 2025, Zai Lab partner argenx announced topline data from the pivotal ADAPT SERON study of VYVGART in patients with AChR-Ab seronegative gMG. The study met its primary endpoint (p-value=0.0068) and it is the first global phase 3 study to demonstrate clinically meaningful improvements in disease activity across all three subtypes – MuSK+, LRP4+, triple seronegative. Zai Lab participated in the global Phase 3 study in Greater China, enabling a potential China regulatory submission.

- **Xanomeline-Trospium (or KarXT) (M1/M4-agonist)**: In September 2025, the "China Schizophrenia Prevention and Treatment Guidelines (2025 Edition)" were officially released, and KarXT was included for the first time, marking the first national-level guideline globally to include KarXT. The guidelines emphasize KarXT's broad efficacy across all three symptom domains (positive, negative, and cognitive symptoms) and its unique safety profile, supporting long-term adherence and functional recovery. China's NMPA accepted the New Drug Application (NDA) for the treatment of schizophrenia in January 2025.
- **Povetacicept:** In September 2025, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to povetacicept for the treatment of IgA nephropathy (IgAN). Subsequently, the FDA also granted a rolling review of the Biologics License Application (BLA) submission for povetacicept for this indication. Vertex has completed full enrollment of the Phase 3 study, including the interim analysis cohort for potential accelerated approval in the U.S. Zai Lab participated in the global Phase 3 RAINIER study in patients with IgAN in Greater China.

Third Quarter 2025 Financial Results

- **Product revenue, net** was $115.4 million in the third quarter of 2025, compared to $101.8 million for the same period in 2024, representing 13% y-o-y growth, 14% y-o-y growth at constant exchange rate (CER). This increase was primarily driven by increased sales for NUZYRA and XACDURO, partially offset by softer sales for ZEJULA:

  – **VYVGART and VYVGART Hytrulo** were $27.7 million in the third quarter of 2025 which includes a $2.4 million reduction following a voluntary price adjustment on Hytrulo ahead of National Reimbursement Drug List (NRDL) negotiation, compared to $26.5 million in the second quarter of 2025. Sales grew 4.6% quarter over quarter driven by an extension of duration of therapy and increased market penetration.

  – **ZEJULA** was $42.4 million in the third quarter of 2025, compared to $48.2 million for the same period in 2024. Sales were softer due to evolving competitive dynamics within the PARPi class.

  – **XACDURO**, which was launched in the fourth quarter of 2024, was $6.4 million in the third quarter of 2025.

  – **NUZYRA** was $15.4 million in the third quarter of 2025, compared to $10.0 million for the same period in 2024. This growth was supported by increased market coverage and penetration.

- **Research and Development (R&D) expenses** were $47.9 million in the third quarter of 2025, compared to $66.0 million for the same period in 2024, primarily due to a decrease in licensing fees in connection with upfront and milestone payments.
- **Selling, General and Administrative expenses** were $70.1 million in the third quarter of 2025, compared to $67.2 million for the same period in 2024. This increase was primarily driven by higher general selling expenses to support the growth of NUZYRA and VYVGART, partially offset by decreases in selling expenses related to ZEJULA.
- **Loss from operations** was $48.8 million in the third quarter of 2025, $28.0 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 $36.0 million in the third quarter of 2025, or a loss per ordinary share attributable to stockholders of $0.03 (or loss per American Depositary Share (ADS) of $0.33), compared to a net loss of $41.7 million for the same period in 2024, or a loss per ordinary share of $0.04 (or loss per ADS of $0.42). These decreases in net loss were primarily due to increased product revenue and decreased operating expenses.
- **Cash and cash equivalents, short-term investments, and current restricted cash** totaled $817.2 million as

of September 30, 2025, compared to $832.3 million as of June 30, 2025.

Anticipated Major Milestones in the Fourth Quarter of 2025 and Full Year 2026

Expected Clinical Developments and Data Readouts

Global Pipeline

Zocilurtatug Pelitecan (zoci, DLL3 ADC) (formerly ZL-1310)

- *Second-Line+ ES-SCLC:* Zai Lab to present updated data on intracranial activity from the ongoing Phase 1 study in the first half of 2026.
- *First-Line ES-SCLC*: Zai Lab to provide data readout from the Phase 1 study evaluating zoci combination therapy (with atezolizumab and/or chemotherapy) in the first half of 2026 and advance into a registrational study in 2026 based on emerging data. Zai Lab also plans to initiate a Phase 1 study to explore zoci in a novel combination in 2026.
- *Other neuroendocrine carcinomas*: Zai Lab to provide data readout from the global Phase 1/2 study in patients with selected solid tumors in the first half of 2026 and advance into a registrational-enabling cohort in 2026.

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

- Zai Lab to provide the initial data readout from the global Phase 1/1b study in healthy volunteers and participants with moderate to severe atopic dermatitis in 2026.

ZL-6201 (LRRC15 ADC)

- Zai Lab to submit an Investigational New Drug application to the FDA for a global Phase 1 study for patients with sarcoma and potentially other LRRC15-positive solid tumors in the fourth quarter of 2025.

Upcoming Potential NMPA Submissions

- **Tumor Treating Fields (TTFields)** in first-line pancreatic cancer in the fourth quarter of 2025
- **Efgartigimod (FcRn)** for prefilled syringe in generalized myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP) in the fourth quarter 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

Regional Pipeline

Efgartigimod (FcRn)

- *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.
- *Myositis:* Zai Lab partner argenx to provide topline results from the global Phase 2/3 ALKIVIA study evaluating three myositis subsets (immune-mediated necrotizing myopathy (IMNM), anti-synthetase syndrome (ASyS) and dermatomyositis (DM)) in the second half of 2026. Zai Lab participated in the study in Greater China.
- *Thyroid eye disease (TED):* Zai Lab partner argenx to provide topline results from two registrational UplighTED studies in the second half of 2026. Zai Lab participated in the studies in Greater China.

Povetacicept (APRIL/BAFF)

- *Primary membranous nephropathy (pMN)*: Zai Lab to join the global pivotal Phase 2/3 OLYMPUS study of povetacicept in pMN in Greater China in the fourth quarter of 2025.
- *IgAN*: Zai Lab partner Vertex will conduct an interim analysis of the global Phase 3 RAINIER study following 36 weeks of treatment. Vertex expects to submit the first module of the IgAN BLA to the FDA before the end of 2025 and plans to complete the full BLA submission in the first half of 2026 for potential accelerated approval in the U.S.

VRDN-003 (anti-IGF-1R, subcutaneous)

- Zai Lab to initiate a registrational study in TED in Greater China in the fourth quarter of 2025.
- Viridian to provide topline results from global registrational REVEAL-1 study in active TED patients in the first quarter of 2026 and global registrational REVEAL-2 study in chronic TED in the second quarter of 2026. Zai Lab, through its license

agreement with Zenas, obtained a sublicense to the Viridian anti-IGF-1R antibody and is proceeding with clinical development.

Full-Year 2025 Outlook

Zai Lab is revising total revenue guidance for the full year 2025 to at least $460 million.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, November 6, 2025, 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 of registration links are as follows:

- For webcast (preferred): https://edge.media-server.com/mmc/p/svanah67
- For dial-in: https://register-conf.media-server.com/register/BIc22945ac95b04071a1d7c0d81eb32021

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)

	September 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	717,155	449,667
Restricted cash, current	100,000	100,000
Short-term investments	—	330,000
Accounts receivable (net of allowance for credit losses of $25 as of both September 30, 2025 and December 31, 2024, respectively)	85,377	85,178
Notes receivable	19,628	4,233
Inventories, net	67,135	39,875
Prepayments and other current assets	43,653	41,527
Total current assets	1,032,948	1,050,480
Restricted cash, non-current	1,115	1,114
Property and equipment, net	48,868	47,961
Operating lease right-of-use assets	15,751	21,496
Land use rights, net	2,852	2,907
Intangible assets, net	55,278	56,027
Other non-current assets	2,128	5,768
Total assets	**1,158,940**	**1,185,753**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	99,706	100,906
Current operating lease liabilities	5,496	8,048
Short-term debt	203,026	131,711
Other current liabilities	51,541	58,720
Total current liabilities	359,769	299,385
Deferred income	28,061	31,433
Non-current operating lease liabilities	10,840	13,712
Other non-current liabilities	325	325
Total liabilities	**398,995**	**344,855**
Commitments and contingencies		
Shareholders' equity		
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 1,113,299,160 and 1,082,614,740 shares issued as of September 30, 2025 and December 31, 2024, respectively; 1,105,865,950 and 1,077,702,540 shares outstanding as of September 30, 2025 and December 31, 2024, respectively)	7	7
Additional paid-in capital	3,327,557	3,264,295
Accumulated deficit	(2,578,211)	(2,453,083)
Accumulated other comprehensive income	39,645	50,515
Treasury Stock (at cost, 7,433,210 and 4,912,200 shares as of September 30, 2025 and December 31, 2024, respectively)	(29,053)	(20,836)
Total shareholders' equity	**759,945**	**840,898**
Total liabilities and shareholders' equity	**1,158,940**	**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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues				
Product revenue, net	115,361	101,847	330,095	289,102
Collaboration revenue	734	418	2,464	816
Total revenues	116,095	102,265	332,559	289,918
Expenses				
Cost of product revenue	(46,764)	(36,569)	(128,219)	(105,336)
Cost of collaboration revenue	(119)	(348)	(531)	(433)
Research and development	(47,928)	(65,982)	(159,271)	(182,252)
Selling, general, and administrative	(70,106)	(67,219)	(204,566)	(216,123)
Loss from operations	(48,822)	(67,853)	(160,028)	(214,226)
Interest income	8,345	9,029	25,794	28,017
Interest expenses	(1,400)	(745)	(3,848)	(1,350)
Foreign currency gains	6,422	14,457	9,909	8,281
Other income (expense), net	(508)	3,441	3,045	3,859
Loss before income tax	(35,963)	(41,671)	(125,128)	(175,419)
Income tax expense	—	—	—	—
Net loss	(35,963)	(41,671)	(125,128)	(175,419)
Loss per share - basic and diluted	(0.03)	(0.04)	(0.11)	(0.18)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	1,102,072,680	981,687,390	1,091,690,340	976,941,030

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	(35,963)	(41,671)	(125,128)	(175,419)
Other comprehensive loss, net of tax of nil:				
Foreign currency translation adjustments	(6,703)	(14,503)	(10,870)	(9,356)
Comprehensive loss	(42,666)	(56,174)	(135,998)	(184,775)

Zai Lab Limited
Non-GAAP Measures
(unaudited)
($ 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	
	2025	2024	As reported	At CER*	2025	2024	As reported	At CER*
Product revenue, net	115,361	101,847	13%	14%	330,095	289,102	14%	15%
Loss from operations	(48,822)	(67,853)	(28)%	(28)%	(160,028)	(214,226)	(25)%	(25)%

* *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,	
	2025	2024	2025	2024

GAAP loss from operations	(48,822)	(67,853)	(160,028)	(214,226)
Plus: Depreciation and amortization expenses	3,901	2,871	11,094	8,824
Plus: Share-based compensation	16,923	16,795	49,696	53,413
Adjusted loss from operations	(27,998)	(48,187)	(99,238)	(151,989)

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