Zai Lab Announces Financial Results and Corporate Progress for the Six Months ended June 30, 2018

August 30, 2018

SHANGHAI, China, Aug. 30, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited ("Zai Lab" or the "Company") (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced financial results for the six months ended June 30, 2018, and provided a corporate update.

"The first half of 2018 has been a period of tremendous progress for Zai Lab, marked by the continued advancement of our clinical programs, expansion of our therapeutic pipeline, preparation for our commercial launch and strengthening of our management team," said Dr. Samantha Du, Zai Lab's Chief Executive Officer. "For ZL-2306 (niraparib), we continue to enroll patients in three separate pivotal trials in China targeting ovarian and small cell lung cancer, and are exploring additional indications by planning to initiate several more trials in the remainder of the year. The goal of our comprehensive clinical development program is to establish ZL-2306 (niraparib) as the leading PARP inhibitor in China. In addition, we continue to advance our multiple late-stage clinical programs in both oncology and infectious diseases. The past six months also marked the exciting transition of Zai Lab to a commercial stage company. In anticipation of the launch of ZL-2306 (niraparib) in Hong Kong later this year and in China, we started building our sales and marketing team, and importantly, appointed industry veteran William Liang as Chief Commercial Officer. In addition, we appointed Yong-Jiang Hei, M.D., Ph.D., as our Chief Medical Officer (CMO) for oncology to lead and advance our oncology pipeline. As we approach our upcoming clinical and commercial milestones throughout the remainder of 2018, we believe that Zai Lab is well-positioned to continue our positive momentum."

Recent Clinical Highlights

ZL-2306 (niraparib)

- In August 2018, Zai Lab announced the early completion of an open-label study to evaluate the pharmacokinetic (PK) profile of ZL-2306 (niraparib) made in China in Chinese ovarian cancer patients. The study demonstrated a comparable PK profile of Chinese patients who were administered ZL-2306 to the PK profile of patients evaluated in Tesaro's clinical trials using product manufactured outside of China. These results support the regulatory review of ZL-2306 (niraparib) in China.

- In August 2018, Zai Lab enrolled the first patient in its Phase III registration trial of ZL-2306 (niraparib) as a first-line maintenance therapy in small cell lung cancer (SCLC) in China. This will be the first clinical trial of ZL-2306 (niraparib) in this type of cancer.

- In June 2018, Zai Lab dosed the first patient in its Phase III China registration trial of ZL-2306 (niraparib) for first-line maintenance therapy of patients with platinum-responsive ovarian cancer.

FPA144 (bemarituzumab)

- In May 2018, Zai Lab received clinical trial application (CTA) approval from China's National Drug Administration (CNDA) to enroll Chinese patients in the Phase I/III FIGHT (FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment) global registrational trial, evaluating FPA144 (bemarituzumab) in combination with a modified FOLFOX chemotherapy regimen. Zai Lab received CTA approval three months ahead of schedule.

ZL-2401 (omadacycline)

- In April 2018, Zai Lab's bridging approach leveraging the Phase III ZL-2401 (omadacycline) studies conducted abroad was accepted by China's Center for Drug Evaluation (CDE). An agreement was reached with CDE for the Company's proposal to conduct a truncated clinical program for approval in China. Zai Lab obtained CTA approval from CNDA within three and a half months of submitting its application and is ready to implement the requested China studies in the fourth quarter of 2018.

ZL-3101 (Fugan)

- In August 2018, results of a Phase II study evaluating ZL-3101 (Fugan), a natural product in patients with mild to moderate atopic dermatitis, received four months ahead of schedule, showed ZL-3101 was safe and well-tolerated, but did not show signs of efficacy over placebo. The Company elected to discontinue further development of ZL-3101 (Fugan) based on

these findings and shift related resources to other programs.

Recent Business & Corporate Developments

- In August 2018, Zai Lab appointed Yong-Jiang Hei, M.D., Ph.D., as its CMO, Oncology. Dr. Hei is a seasoned industry expert with over 20 years of experience in clinical development in oncology and will support the strategic development and expansion of the Company's growing oncology clinical pipeline. Most notably, he served at Amgen, Inc. for approximately 10 years in multiple roles of increasing responsibility in oncology global development. Dr. Qi Liu will transition to an advisory role.

- In August 2018, Zai Lab appointed Kai-Xian Chen, Ph.D., to its Board of Directors. Professor Chen is a globally recognized scientist and widely regarded as a pioneer in the field of interdisciplinary healthcare research. In connection with Professor Chen's appointment, Marietta Wu, Ph.D. retired from the Board of Directors.

- In June 2018, Zai Lab appointed William Liang as Chief Commercial Officer. William brings more than two decades of experience in the pharmaceutical industry, with expertise in commercial launch, strategy and operations. Prior to joining Zai Lab, William served as Vice President at AstraZeneca heading up the Oncology Business Unit in China.

- In June 2018, Zai Lab completed construction of a biologics pilot facility using GE Healthcare's Flex Factory platform technology. The facility is capable of supporting biologics drug products for clinical and non-clinical development of Zai Lab's drug candidates.

- In May 2018, Zai Lab entered into an exclusive worldwide agreement with Crescendo Biologics for ZL-1102, a topical, innovative antibody for potential application in inflammatory indications, including psoriasis.

- In April 2018, Zai Lab entered into an exclusive license agreement in Asia-Pacific, and a global development agreement, with Entasis Therapeutics (Entasis) for ETX2514, a novel broad-spectrum intravenous inhibitor of β-lactamases, for the treatment of a variety of serious multidrug-resistant (MDR) infections. In combination with sulbactam, ETX2514 is particularly active against MDR *Acinetobacter baumannii* infections.

- Zai Lab continues to expand its platform and human resources. As of June 30, 2018, Zai Lab employed 182 full-time employees, including 37 employees with M.D. or Ph.D. degrees. Currently, approximately 85% of the Company's employees are engaged in R&D activities. Employee mix is projected to change as the Company continues to build out its commercial team.

- Zai Lab has, from time to time, evaluated partnership opportunities and may, in the future, make acquisitions of, or investments in, companies that Zai Lab believes have products or capabilities that are a strategic or commercial fit with Zai Lab's current drug candidates and business or otherwise offer opportunities for the Company.

Upcoming Milestones

ZL-2306 (niraparib)

- On September 23, 2018, the design of the Phase III study of ZL-2306 (niraparib) as maintenance therapy in first line platinum-responsive small cell lung cancer (SCLC) patients will be presented at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer (WCLC).

- On September 21, 2018, results from a Phase I PK and safety study of ZL-2306 (niraparib) in Chinese patients with epithelial ovarian cancer (OC) will be presented at the 21st Annual Meeting of Chinese Society of Clinical Oncology (CSCO).

- Zai Lab plans to begin commercializing ZL-2306 (niraparib) as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer in Hong Kong during the fourth quarter of 2018, and in Macau thereafter.

ZL-2401 (omadacycline)

- Zai Lab expects to initiate a bioequivalence and PK bridging study in China to demonstrate comparability in the PK profile of Chinese patients administered with ZL-2401 (omadacycline) to non-Chinese patients, in preparation for its New Drug Application (NDA) submission in China. This program is expected to start in the fourth quarter of 2018.

- Paratek Pharmaceuticals has a Prescription Drug User Fee Act (PDUFA) action date set in October 2018 for its NDA for once-daily oral and intravenous formulations of omadacycline for the treatment of community-acquired bacterial pneumonia

(CABP) and acute skin and skin structure infections (ABSSSI). On August 8, 2018, Antimicrobials Drug Advisory Committee of the U.S. FDA voted in favor of the approval of IV and oral omadacycline.

FPA144 (bemarituzumab)

- In collaboration with Five Prime, Zai Lab plans to initiate patient dosing in the China portion of the randomized, controlled Phase III portion of the Phase I/III FIGHT global registration trial in the fourth quarter of 2018.

ETX2514

- In collaboration with Entasis, Zai Lab plans to initiate patient dosing in the Asia-Pacific portion of the Phase III global registration trial of ETX2514 for MDR *Acinetobacter* pneumonia and bloodstream infections in 2019.

ZL-2301 (brivanib)

- Data from a Phase II trial of ZL-2301 (brivanib) as a second-line treatment for advanced hepatocellular cancer patients in China are expected in the second half of 2018.

- On September 22, 2018, preliminary study results from the Phase II trial of ZL-2301 (brivanib) in advanced HCC patients with systemic treatment failure or intolerance will be presented at the 21st Annual Meeting of Chinese Society of Clinical Oncology (CSCO).

ZL-2302

- In the fourth quarter of 2018, Zai Lab plans to initiate Phase I clinical trials in China of ZL-2302 for the treatment of patients with non-small cell lung cancer (NSCLC) who have ALK mutations and developed crizotinib resistance and/or brain metastasis.

Financial Results for the Six Months Ended June 30, 2018

- As of June 30, 2018, cash and cash equivalents and short-term investments totaled $177.7 million.

- Research and development expenses were $34.6 million for the six months ended June 30, 2018 compared to $20.9 million for the same period in 2017. The increase was primarily due to higher clinical and preclinical costs from the advancement of the Company's expanded pipeline, and expansion of research efforts to support internal programs.

- General and administrative expenses were $6.4 million for the six months ended June 30, 2018 compared to $4.0 million for the same period in 2017. The increase was primarily due to the increase in payroll and payroll-related expenses as a result of the increased headcount from expanded operations, and increased costs associated with operating as a public company.

- For the six months ended June 30, 2018, Zai Lab reported a net loss of $41.5 million, or basic and diluted net loss per share attributable to common stockholders of $0.83, compared to a net loss of $24.4 million, or basic and diluted net loss per share attributable to common stockholders of $2.30, for the same period in 2017.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The company's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Zai Lab Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the timing of the initiation, progress and scope of the clinical trials of ZL-2306, ZL-2401, FPA144, ETX2514, ZL-2301 and ZL-2302, the commercial plans for ZL-2306, the timing of results from clinical studies of our product candidates and the ability to obtain regulatory approval for Zai Lab's product candidates. You can identify forward-looking statements because they contain words such as "anticipate" and "expected." Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2017 and its other filings with the U.S. Securities and Exchange Commission. Zai Lab undertakes no obligation to publicly 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.

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Zai Lab Limited

Consolidated balance sheets (U.S. GAAP)

(In U.S. dollars ("$") except for number of shares)

	As of June 30, 2018	As of December 31, 2017
	$	$
Assets		
Current assets:		
Cash and cash equivalents	127,715,473	229,660,148
Short term investment	50,000,000	—
Prepayments and other current assets	4,690,984	954,506
Total current assets	182,406,457	230,614,654
Investments in equity investees	3,500,600	1,650,348
Prepayments for equipment	927,154	126,411
Property and equipment	19,466,017	11,853,764
Other non-current assets	4,512,146	5,389,051
Total assets	**210,812,374**	**249,634,228**
Liabilities and shareholders' equity		
Current liabilities:		
Short term borrowing	755,675	—
Accounts payable	5,726,571	8,967,685
Other payables	3,776,643	3,101,459
Total current liabilities	10,258,889	12,069,144
Deferred income	1,622,225	2,394,124
Total liabilities	**11,881,114**	**14,463,268**
Total shareholders' equity	**198,931,260**	**235,170,960**
Total liabilities and shareholders' equity	**210,812,374**	**249,634,228**

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Consolidated statements of operations (U.S. GAAP)

(In U.S. dollars ("$") except for number of shares)

	For the six months ended June 30,	
	2018	2017
	$	$
Operating expenses:		

Research and development	(34,632,256)	(20,873,605)
General and administrative	(6,364,088)	(4,040,996)
Loss from operations	(40,996,344)	(24,914,601)
Interest income	407,977	285,466
Changes in fair value of warrants	—	200,000
Other income (expenses), net	(695,618)	9,652
Loss before income tax and share of loss from equity method investment	(41,283,985)	(24,419,483)
Income tax expense	—	—
Share of loss from equity method investment	(206,443)	—
Net loss	(41,490,428)	(24,419,483)
Loss per share - basic and diluted	(0.83)	(2.30)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	50,041,670	10,630,041

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Consolidated statements of comprehensive loss (U.S. GAAP)

(In U.S. dollars ("$") except for number of shares)

	For the six months ended June 30,	
	2018	**2017**
	$	**$**
Net loss	(41,490,428)	(24,419,483)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	418,389	376,574
Comprehensive loss	(41,072,039)	(24,042,909)

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