

# Zai Lab Reports Full Year 2017 Financial Results and Corporate Update

2018年 5月 2日

#### -- Zai Lab to Host Conference Call and Webcast Today at 8:30 a.m. ET--

SHANGHAI, China, May 02, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, today will provide an overview of financial results for the year ended December 31, 2017 and Zai Lab's recent progress and potential upcoming milestones.

"2017 was a year of consistent and dynamic execution at Zai Lab," said Zai Lab's Chairman and Chief Executive Officer Samantha Du. "We meaningfully advanced our clinical programs and further expanded our therapeutic pipeline, completing three important business development transactions over the past twelve months. We also completed two equity financings, increased our manufacturing capabilities, and substantially expanded our team. For the remainder of 2018, we anticipate data or milestones from many of our clinical programs and are planning to launch our first commercial product in Hong Kong. We look forward to continuing our momentum towards becoming a fully integrated biopharmaceutical company, by progressing and expanding our R&D pipeline and in-house discovery efforts."

#### **Recent Highlights and Upcoming Milestones**

ZL-2306

- Recently submitted market registration application for ZL-2306 in Hong Kong, relying on approval status in the US and EU. Zai Lab plans to commercialize ZL-2306 in Hong Kong in the second half of 2018, and in Macau thereafter.
- In September 2017, Zai Lab dosed the first patient in its Phase 3 China registration trial of ZL-2306 as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. Zai Lab also expects to initiate a second Phase 3 China registration trial of ZL-2306 as a first-line maintenance therapy in patients with platinum-responsive ovarian cancer in mid-2018.
- In November 2017, Zai Lab initiated a pharmacokinetic (PK) study to establish the PK profile of ZL-2306 in Chinese patients. Enrollment is completed, with data anticipated by mid-2018.

## FPA 144

• In December 2017, Zai Lab in-licensed exclusive regional rights to FPA 144 from Five Prime Therapeutics. FPA 144 is a targeted immuno-therapy for tumors that overexpress FGFR2b, such as gastric and gastro-esophageal junction cancer. Zai Lab has submitted the CTA and plans to conduct the China portion of the global Phase I/III registrational program later this year.

## ZL-2301

 In the second quarter of 2017, Zai Lab initiated a Phase II trial of ZL-2301 as a second-line treatment for advanced hepatocellular cancer patients in China. To date, preliminary anti-tumor activity has been observed in patients treated with ZL-2301, and the drug appears to be generally well-tolerated. Phase II data from the trial are expected in the second half of 2018. Pending positive results, Zai Lab plans to start a Phase III registration trial thereafter.

## ZL-2401

• In April 2017, Zai Lab in-licensed exclusive regional rights to ZL-2401, a broad spectrum antibiotic, from Paratek Pharmaceuticals. Zai Lab has completed the technology transfer and is engaged in discussions with the SDA and key opinion leaders on Zai Lab's planned China development strategy in preparation for an NDA filing. In the US, an NDA was submitted for ZL-2401 in February 2018, and the drug is under priority review with a PDUFA date in October 2018.

## ETX2514

Zai Lab entered in to an exclusive licensing agreement and collaboration with Entasis Therapeutics for ETX2514 on April 25, 2018. ETX2514 is a novel broad-spectrum β-lactamases inhibitor and is expected to move into global Phase III clinical trials in the first quarter of 2019. Zai Lab will manage the China portion of the Phase III clinical trials.

#### ZL-3101

• Zai Lab initiated a Phase II study of ZL-3101 in eczema patients in China during the second quarter of 2017. Topline results from the Phase II study are expected to be available in the second half of 2018. Pending positive results, Zai Lab plans to start a Phase III registration trial thereafter.

#### Internal Discovery Programs

• With its in-house discovery efforts over the past two years, Zai Lab continues to focus on exploring immunotherapy and targeted approaches to treating cancer.

## **Corporate Development**

- Zai Lab continued to strengthen its financial position. In June 2017, Zai Lab completed a \$30 million Series C financing and in September 2017, Zai Lab completed its upsized public offering of American depositary shares, resulting in net proceeds of approximately \$172.5 million. This additional capital, in addition to other cash on hand, is expected to provide Zai Lab with at least a 24-month runway.
- In anticipation of commercialization of ZL-2306 in Hong Kong and other territories, Zai Lab has built a small molecule commercial drug production facility in Suzhou, China. Zai Lab is also nearing completion of a biologic pilot plant using GE's FlexFactory Platform that is capable of producing product at 1,000L scale.
- Since the date of the initial public offering last September, Zai Lab has doubled its personnel size, including several senior and key hires, and expects to have over 200 employees by the end of 2018.

## Full Year 2017 Financial Results

- As of December 31, 2017, cash and cash equivalents totaled \$229.7 million.
- Research and development expenses were \$39.3 million for the year ended December 31, 2017 compared to \$32.1 million for the same period in 2016. The increase was primarily due to higher clinical and preclinical costs, and expansion of research efforts to support internal programs.
- General and administrative expenses were \$12.0 million for the year ended December 31, 2017 compared to \$6.4 million for the same period in 2016. The increase was primarily due to the increase in payroll and payroll-related expenses due to increased headcount as Zai Lab expanded its operations, and increased costs associated with operating as a public company.
- For the year ended December 31, 2017, Zai Lab reported a net loss of \$50.4 million, or basic and diluted net loss per share attributable to common stockholders of \$2.32, compared to a net loss of \$37.5 million, or basic and diluted net loss per share attributable to common stockholders of \$3.97, for the year ended December 31, 2016.

#### **Conference Call and Webcast Information**

Zai Lab will host a live conference call and webcast today, May 2, 2018 at 8:30 a.m. Eastern Time to review its financial results and provide a general business update.

The live webcast can be accessed by visiting the Investors section of Zai Lab's website at <a href="http://ir.zailaboratory.com">http://ir.zailaboratory.com</a>. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 866-394-4355 (U.S.); 314-888-4344 (International); or 4006828609 to listen to the live conference call. The conference ID number for the live call is 5836799. A replay of the webcast will be available for on Zai Lab's website for two weeks following the live conference call.

#### 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. Zai Lab'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 global 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 trial of ZL-2306, FPA 144, ZL-2301 and ZL-3101, the commercial plans for ZL-2306, the timing of results from clinical studies of our product candidates, the ability to obtain regulatory approval for Zai Lab's product candidates and Zai Lab's cash runway. 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 From 20-F for the fiscal year ended December 31, 2017 and its other filings with the 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.

#### ZAI LAB CONTACTS:

Zai Lab Billy Cho +86 21 6163 7322 billy.cho@zailaboratory.com

Media: Justin Jackson Burns McClellan, on behalf of Zai Lab 212-213-0006, ext. 327, jjackson@burnsmc.com

Investors: Jill Steier Burns McClellan, on behalf of Zai Lab 212-213-0006, ext. 367, jsteier@burnsmc.com

## Zai Lab Limited

## Consolidated balance sheets (U.S. GAAP)

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

	As of Decen	As of December 31,	
	2016	2017	
	\$	\$	
Assets	Ŧ	Ŧ	
Current assets:			
Cash and cash equivalents	83,948,770	229,660,148	
Prepayments and other current assets	143,527	954,506	
Total current assets	84,092,297	230,614,654	
Investments in equity investees	500,000	1,650,348	
Prepayments for equipment	1,417,029	126,411	
Property and equipment	1,246,058	11,853,764	
Other non-current assets	1,651,901	5,389,051	
Total assets	88,907,285	249,634,228	
Liabilities, mezzanine equity and shareholders' (deficit) equity			
Current liabilities:			
Accounts payable	523,338	8,967,685	
Warrant liabilities	3,900,000	_	
Other payables	750,118	3,101,459	
Total current liabilities	5,173,456	12,069,144	
Deferred income	778,434	2,394,124	
Total liabilities	5,951,890	14,463,268	
Total mezzanine equity	134,507,144	_	
Total shareholders' (deficit) equity	(51,551,749)	235,170,960	
Total liabilities, mezzanine equity and shareholders' (deficit) equity	88,907,285	249,634,228	

Zai Lab Limited Consolidated statements of operations (U.S. GAAP) (In U.S. dollars ("\$") except for number of shares)

	Year ended Dec	Year ended December 31,	
	2016	2017 \$	
	\$		
Operating expenses:			
Research and development	(32,149,157)	(39,341,518)	

General and administrative	(6,380,144)	(12,049,518)
Loss from operations	(38,529,301)	(51,391,036)
Interest income	403,266	527,351
Changes in fair value of warrants	(1,920,000)	200,000
Other income, net	2,533,823	529,161
Share of loss from equity method investment		(249,652)
Net loss	(37,512,212)	(50,384,176)
Loss per share - basic and diluted	(3.97)	(2.32)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	9,439,028	21,752,757

## Zai Lab Limited

## Consolidated statements of comprehensive loss (U.S. GAAP) (In U.S. dollars ("\$") except for number of shares)

	Year ended December 31,	
	2016	2017
	\$	\$
Net loss	(37,512,212)	(50,384,176)
Other comprehensive (loss) income, net of tax of nil:		
Foreign currency translation adjustments	(594,912)	1,148,440
Comprehensive loss	(38,107,124)	(49,235,736)



Source: Zai Lab Limited