



Zai Lab Announces Financial Results for Full Year Ended December 31, 2019 and Corporate Updates

March 19, 2020

-- Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT

SHANGHAI, China and SAN FRANCISCO, March 19, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced financial results for the twelve months ended December 31, 2019 and corporate updates.

"Coinciding with the celebration of our five-year anniversary, 2019 was a year of many important achievements for Zai Lab," said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. "Some key milestones achieved include the marketing approval obtained for ZEJULA® in China and our submissions for regulatory approval in China for Optune® and omadacycline in China. We also entered into licensing collaborations with Deciphera and Incyte, expanded our commercial platform in China, launched commercial activities for ZEJULA and Optune in Hong Kong and further enhanced our in-house R&D capabilities. We are proud of our global reputation as a biotech pioneer and a partner-of-choice in China, and we continued to deliver exceptional execution across global and local clinical development, regulatory affairs, business development and operational expansion. Despite the challenges caused by the coronavirus (COVID-19) in China and globally, we expect 2020 to be another pivotal year for us as we continue to advance our clinical pipeline and further demonstrate our commercial and discovery capabilities. The proceeds from our recent financing positions us well to execute our key strategic initiatives towards becoming a leading global biopharma company."

Key Product Highlights and Expected Milestones

Oncology

ZEJULA® (niraparib)

ZEJULA is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor.

- In March 2020, Zai Lab announced that the China National Medical Products Administration (NMPA) has accepted its supplemental New Drug Application (sNDA) for ZEJULA for first-line maintenance treatment of patients with ovarian cancer.
- Based on IQVIA data, ZEJULA was the leading PARP inhibitor with market share in Hong Kong of 71% by value for 2019. ZEJULA was also ranked amongst the top 5 oncology drugs launches in Hong Kong after 2014 behind Keytruda®, Opdivo®, Tecentriq® and Tagrisso® based on first full-year revenue.
- In February 2020, Zai Lab dosed the first patient in the Phase 1b study of niraparib with MGD013, a first-in-class PD1/LAG-3 bispecific antibody, in advanced or metastatic gastric cancer.
- In February 2020, Zai Lab terminated the Phase 3 study of niraparib as first-line maintenance treatment of patients with small-cell lung cancer due to changes in the treatment landscape in China.
- In January 2020, Zai Lab launched ZEJULA in China.
- In December 2019, Zai Lab announced that the China NMPA approved the NDA for ZEJULA as maintenance treatment of patients with recurrent ovarian cancer. This approval represents the fastest approval time by the NMPA in 2019 for a locally manufactured, category 1 oncology drug.
- In November 2019, Zai Lab completed enrollment of the China Phase 3 PRIME study of ZEJULA in patients with first-line ovarian cancer.

Expected Milestones

- Initiate registrational bridging trial for late-line ovarian cancer treatment in second half of 2020
- Expect final clinical data from the NORA study, the pivotal trial for maintenance therapy of Chinese patients with recurrent ovarian cancer in first half of 2020

- Continue to collaborate with our Partner GSK on additional indications and opportunities

Tumor Treating Fields

Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and potentially causing cancer cells to die.

- In January 2020, Zai Lab announced that the first patient has been enrolled in a Phase 2 pilot clinical trial evaluating the safety and efficacy of Tumor Treating Fields in combination with chemotherapy as first-line treatment in patients with gastric adenocarcinoma.
- In September 2019, the NMPA accepted the Marketing Authorization Application (MAA) of Optune, a Tumor Treating Fields delivery system for the treatment of glioblastoma (GBM).

Expected Milestones

- Potential China GBM MAA approval with trial waiver in first half of 2020
- Complete enrollment of the Phase 2 pilot clinical trial in first-line gastric adenocarcinoma in 2020
- File MAA for malignant pleural mesothelioma in China
- *Partner Milestone:* Novocure to announce interim results from Phase 3 pivotal LUNAR trial in patients with non-small cell lung cancer in second half of 2020

Ripretinib

Ripretinib is an investigational KIT and PDGFR α kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFR α -driven cancers, including gastrointestinal stromal tumors (GIST), systemic mastocytosis, and other cancers.

- In November 2019, Zai Lab received the Clinical Trial Authorization (CTA) approval for the registrational bridging study of ripretinib in patients with advanced GIST. The previously announced positive top-line data from the pivotal Phase 3 INVICTUS clinical study of ripretinib in patients with advanced GIST will support the NDA package of ripretinib in China.

Expected Milestones

- Submit NDA to the China NMPA for advanced GIST in 2020
- Initiate bridging trial for second-line GIST in second half of 2020

Margetuximab

Margetuximab is an Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2 (HER2).

- In February 2020, Zai Lab announced that the first patient has been dosed in the registrational bridging study of margetuximab, in combination with chemotherapy, for the treatment of patients with metastatic HER2-positive breast cancer.
- In February 2020, Zai Lab received CTA approval for the Phase 2/3 MAHOGANY study, a clinical trial of margetuximab in combination with a checkpoint inhibitor, with or without chemotherapy, as first-line treatment for patients with advanced HER2-positive gastric cancer and gastroesophageal junction (GEJ) cancer.

Expected Milestones

- Enroll first Chinese patient in second half of 2020 in the global Phase 2/3 MAHOGANY initiated by MacroGenics
- *Partner Milestone:* MacroGenics expects final overall survival (OS) data from the Phase 3 SOPHIA study in HER2+ metastatic breast cancer by year end of 2020. MacroGenics also anticipates a Prescription Drug User Fee Act (PDUFA) date by the end of 2020

Infectious Disease

NUZYRA® (Omadacycline)

NUZYRA is a once-daily oral and intravenous antibiotic for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

- In March 2020, Zai Lab entered into a contract sales agreement with Hanhui, a leading local pharmaceutical company with a strong commercial presence in antibiotics. The agreement allows us to leverage Hanhui's existing infrastructure to optimize an anticipated future commercial launch of omadacycline in China given that omadacycline is a broad spectrum antibiotic in both the hospital and community setting.
- In February 2020, Zai Lab announced that the NMPA has accepted its NDA with Category 1 new drug designation for NUZYRA for the treatment of CABP and ABSSSI.
- In February 2020, Zai Lab submitted a request for Priority Review to the NMPA for patients developing CABP in the context of coronavirus infection.

Durlobactam (ETX2514)

Durlobactam is a beta-lactamase inhibitor which – in combination with sulbactam – provides unique activity against Acinetobacter organisms, including carbapenem-resistant strains (CRAB).

- In March 2020, Zai Lab's partner Entasis Therapeutics announced it expects top-line results of the global Phase 3 ATTACK (Acinetobacter Treatment Trial Against Colistin) registrational trial in early 2021.

Expected Milestones

- Enroll first Chinese patient into the global Phase 3 ATTACK trial in first half of 2020

Other Upcoming Milestones

MGD013 – a first-in-class, bispecific PD-1 x LAG-3 DART molecule

- Enroll first Chinese patient to the global Phase 1 basket trial in second half of 2020

INCMGA0012 – an anti-PD-1 monoclonal antibody

- Initiate pivotal study in second-line MSI-high endometrial cancer in China in second half of 2020
- Enroll first Chinese patient into the Incyte-sponsored global Phase 3 study of INCMGA0012 with platinum-based chemotherapy in first-line metastatic squamous and non-squamous non-small cell lung cancer in China in second half of 2020

FPA144 – a first-in-class antibody for tumors that overexpress FGFR2b

- Zai Lab's partner Five Prime Therapeutics expects futility results from the Phase 3 FIGHT trial in gastric and GEJ cancer in mid-2020

Discovery

- Submit two global Investigational New Drug (IND) applications in 2020
- Research facilities located in Menlo Park, California scheduled to open in mid-2020

Business Development

- Continue to pursue bolt-on and transformational business development opportunities

Corporate Highlights

- In January 2020, Zai Lab announced the closing of an underwritten public offering of 5,500,000 American depositary shares ("ADSs") at a price of \$47.50 per ADS. In addition, the underwriters fully exercised their option to purchase an additional 500,000 ADSs at the public offering price. Total proceeds, net of underwriting fees and other offering expenses, were \$281.3 million.
- In January 2020, Zai Lab announced the appointment of Lonnie Moulder, formerly chief executive officer of TESARO, to its Board of Directors.
- In December 2019, Zai Lab announced the appointment of Timothy Yap, M.D., Ph.D., to its Scientific Advisory Board.
- Zai Lab continues to expand its U.S. presence to enhance internal drug discovery and business development, with the securing of a lease for a larger facility in San Francisco and the opening of a Boston office.

- Zai Lab continues to expand and hire talented professionals. As of February 2020, Zai Lab employed 733 full-time employees, with 293 and 340 employees engaged in R&D and commercial activities, respectively.

Full-Year 2019 Financial Results

- Revenues for the full year of 2019 were \$13.0 million, compared to \$0.1 million in 2018. Revenues for the period were comprised of \$6.6 million in sales of ZEJULA in Hong Kong and Macau, and \$6.4 million of in sales of Optune in Hong Kong.
- R&D expenses were \$142.2 million for 2019, compared to \$120.3 million for 2018. The increase in R&D expenses was primarily attributable to ongoing and newly initiated late-stage clinical trials, payroll and payroll-related expenses from increased R&D headcount and expansion of research efforts to support internal development programs.
- Selling, General & Administrative expenses were \$70.2 million for 2019, compared to \$21.6 million for 2018. The increase was primarily due to payroll and payroll-related expenses from increased commercial headcount and related costs as Zai Lab expanded its commercial operations in China.
- For the full year of 2019, Zai Lab reported a net loss of \$195.1 million, or net loss per share attributable to common stockholders of \$3.03, compared to a net loss of \$139.1 million, or net loss per share attributable to common stockholders of \$2.64, for the full year of 2018.
- As of December 31, 2019, cash and cash equivalents, short-term investment and restricted cash totaled \$276.4 million. In addition, in January 2020, Zai Lab announced the closing of an underwritten public offering with total proceeds, net of underwriting fees and other offering expenses, of approximately \$281.3 million.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, March 19, 2020 at 8:30 a.m. EDT to review its financial results and provide a general business update.

The live webcast and a replay may be accessed by visiting the Company's website at <http://ir.zailaboratory.com>. Alternatively, please call (866) 5194004 (U.S.), +65 67135090 (International), 4006208038 (China), +852 30186771 (Hong Kong), or +44 2036214779 (United Kingdom) to listen to the live conference call. The conference ID number for the live call is 8093543. Telephone replay will be available shortly after the call. To access the replay, please call (855) 4525696 (U.S.). The conference ID number for the replay is 8093543.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a China and U.S.-based innovative commercial stage 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 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 contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding our ability to advance our clinical pipeline and further demonstrate our commercial and discovery capabilities, expected milestones for our products and product candidates and other statements containing words such as "anticipates", "believes", "expects", "plan" 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 statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's 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. 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) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to commercialize and generate revenue from its drug candidates, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2018 and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and 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. These forward-looking statements should not be relied upon as representing Zai Lab's views as of any date subsequent to the date of this press release.

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Zai Lab Limited

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Unaudited condensed consolidated balance sheets

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

	As of December 31,	
	2018	2019
	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	62,951,607	75,932,037
Short-term investments	200,350,000	200,000,000
Accounts receivable	89,708	3,791,407
Inventories	3,822	6,004,932
Prepayments and other current assets	5,749,260	6,735,917
Total current assets	269,144,397	292,464,293
Restricted cash, non-current	—	510,218
Investments in equity investees	3,149,855	2,397,655
Prepayments for equipment	275,853	439,604
Property and equipment, net	20,494,482	21,353,437
Operating lease right-of-use assets	—	15,071,292
Land use rights	—	7,655,115
Intangible assets, net	321,566	1,147,797
Long term deposits	556,738	377,128
Value added tax recoverable	8,044,258	13,736,949
Total assets	301,987,149	355,153,488
Liabilities and shareholders' equity		
Current liabilities:		
Short-term borrowings	3,642,616	6,450,503
Accounts payable	37,432,035	22,659,600
Current operating lease liabilities	—	4,350,765
Other current liabilities	7,766,843	13,174,389
Total current liabilities	48,841,494	46,635,257
Deferred income	2,063,942	2,881,351
Non-current operating lease liabilities	—	10,976,846
Total liabilities	50,905,436	60,493,454
Shareholders' equity		
Ordinary shares (par value of US\$0.00006 per share; 83,333,333 shares authorized, 58,006,967 and 68,237,247 shares issued and outstanding as of December 31, 2018 and 2019, respectively)	3,481	4,094
Additional paid-in capital	498,043,011	734,733,914
Accumulated deficit	(249,626,508)	(444,697,632)
Accumulated other comprehensive income	2,661,729	4,619,658

Total shareholders' equity	251,081,713	294,660,034
Total liabilities and shareholders' equity	301,987,149	355,153,488

Zai Lab Limited

Unaudited condensed consolidated statements of operations

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

	For the year ended December 31,	
	2018	2019
	\$	\$
Revenue	129,452	12,984,751
Cost of sales	(43,590)	(3,748,806)
Gross profit	85,862	9,235,945
Operating expenses:		
Research and development	(120,278,023)	(142,221,056)
Selling, general and administrative	(21,575,921)	(70,210,828)
Loss from operations	(141,768,082)	(203,195,939)
Interest income, net	3,220,962	7,939,230
Other income, net	58,776	937,785
Loss before income tax and share of loss from equity method investment	(138,488,344)	(194,318,924)
Income tax expense	—	—
Share of loss from equity method investment	(586,551)	(752,200)
Net loss	(139,074,895)	(195,071,124)
Net loss attributable to ordinary shareholders	(139,074,895)	(195,071,124)
Loss per share - basic and diluted	(2.64)	(3.03)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	52,609,810	64,369,490

Zai Lab Limited

Unaudited condensed consolidated statements of comprehensive loss

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

	For the year ended December 31,	
	2018	2019
	\$	\$
Net loss	(139,074,895)	(195,071,124)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	2,211,821	1,957,929
Comprehensive loss	(136,863,074)	(193,113,195)



Source: Zai Lab Limited