



Zai Lab Announces Financial Results for Six Months Ended June 30, 2020 and Corporate Updates

August 13, 2020

-- Company to Host Conference Call and Webcast Today at 8:00 a.m. EDT --

-- Recent highlights include successful ZEJULA and Optune commercial launches, NMPA approval for Optune, two highly strategic collaboration deals and three NDAs accepted with priority review --

SHANGHAI and SAN FRANCISCO, Aug. 13, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), an innovative commercial-stage biopharmaceutical company, today announced financial results for the six months ended June 30, 2020 and corporate updates.

"This year we have continued to build Zai Lab's leadership through strong execution. Highlights include two successful commercial launches in China, NMPA approval for Optune, two highly strategic collaboration deals, three NDAs accepted with priority review, 15 clinical trial authorizations approved and eight trial initiations across our innovative pipeline which now includes 14 clinical stage assets," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. "We were able to overcome headwinds brought on by the COVID-19 pandemic, launching both ZEJULA and Optune in under six weeks from regulatory approval and gaining immediate support from the medical, patient and payor communities. Our clinical pipeline continues to strengthen with the addition of two key late-stage assets, REGN1979 and Repotrectinib. With our broad and differentiated pipeline, we remain confident that Zai Lab can become a leading global biopharma company, leveraging our capabilities and network to drive the next wave of innovations with transformative impact on patients with significant unmet medical needs. Over the next three years, we expect to have a steady stream of approvals and commercial product launches in Greater China across multiple therapeutic areas, establish transformative partnerships, expand our global footprint, and advance our internally discovered global pipeline into the pivotal stage."

Key Product Highlights and Near Term Milestones

Oncology

ZEJULA® (Niraparib)

ZEJULA is an oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor. It is the only once-daily PARP inhibitor approved in the US as monotherapy for all-comer patients in the first-line and recurrent maintenance treatment settings.

- In May 2020, Zai Lab announced positive topline results from the NORA Phase 3 study of ZEJULA as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer.
- In April 2020, the China National Medical Products Administration (NMPA) granted priority review to the supplemental New Drug Application (sNDA) for ZEJULA (niraparib) for first-line ovarian cancer maintenance treatment.
- Since the commercial launch in January 2020 in China, ZEJULA has been included for regional reimbursement in one province and six cities. It has also been listed in 16 commercial health insurances and four supplemental insurance initiated by provincial or municipal governments.

Near-term Milestones

- Detailed presentation at an upcoming global medical conference of the NORA Phase 3 study of ZEJULA as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer expected in second half of 2020.
- Initiate registrational bridging trial for late-line ovarian cancer treatment in second half of 2020.
- Collaborate with our partner GSK to study additional indications and combinations for niraparib.

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 cell death.

- In August 2020, Optune Lua™ launched for the treatment of malignant pleural mesothelioma (MPM) in Hong Kong.

- In May 2020, the China NMPA approved Optune® for the treatment of newly diagnosed and recurrent glioblastoma.

Near-term Milestones

- Join global Phase 3 pivotal trials in non-small cell lung cancer, locally advanced pancreatic cancer and brain metastases in mainland China, Hong Kong, Macau and Taiwan by early 2021.
- File Marketing Authorization Application (MAA) for MPM in China in first half of 2021.
- Announce clinical data readout of the Phase 2 pilot trial in first-line gastric adenocarcinoma in 2021.
- Partner milestones:
 - Interim analysis of Phase 3 pivotal LUNAR trial in non-small cell lung cancer expected in 2021.
 - Interim analysis of Phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer expected in 2021.
 - Interim analysis of Phase 3 pivotal INNOVATE-3 trial in recurrent ovarian cancer expected in 2021.
 - Data from Phase 2 pilot HEPANOVA trial in advanced liver cancer expected in 2021.

Ripretinib

Ripretinib is a KIT and PDGFR α kinase switch control inhibitor for the treatment of KIT and/or PDGFR α -driven cancers, including gastrointestinal stromal tumors (GIST), systemic mastocytosis, and other cancers. It is the only therapeutic approved in the US for advanced GIST patients who have received three or more lines of treatment in the all-comer setting.

- In August 2020, the China NMPA granted Priority Review to the New Drug Application (NDA) for ripretinib for the treatment of adult patients with advanced GIST.
- In July 2020, the China NMPA accepted the NDA submission of ripretinib for advanced GIST.
- In July 2020, Zai Lab received the Clinical Trial Authorization (CTA) approval for the registrational bridging study of ripretinib in patients with second-line GIST.

Near-term Milestones

- Initiate the bridging trial for second-line GIST in second half of 2020.

Odronextamab (REGN1979)

Odronextamab is an investigational bispecific monoclonal antibody that is designed to trigger tumor killing by linking and activating a cytotoxic T-cell (binding to CD3) to a lymphoma cell (binding to CD20).

- In April 2020, Zai Lab announced a strategic collaboration with Regeneron for the development and exclusive commercialization of odronextamab in oncology in mainland China, Hong Kong, Taiwan and Macau.

Near-term Milestones

- Enroll first Chinese patient into the potentially registrational global Phase 2 program by early 2021.

Repotrectinib

Repotrectinib is a next-generation tyrosine kinase inhibitor (TKI) designed to effectively target ROS1 and TRK A/B/C with potential to treat TKI-naïve or TKI-pretreated patients.

- In July 2020, Zai Lab announced an exclusive license agreement with Turning Point Therapeutics for the development and commercialization of repotrectinib in mainland China, Hong Kong, Taiwan and Macau.

Near-term Milestones

- Enroll first Chinese patient into the global TRIDENT-1 Phase 2 study by early 2021.
- Partner milestone: Early interim data from initial patients in the TRIDENT-1 Phase 2 study in third quarter of 2020.

Margetuximab

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

Near-term Milestones

- Enroll first Chinese patient into the global Phase 2/3 MAHOGANY study as a front-line treatment for advanced gastric and gastroesophageal junction cancer in second half of 2020.
- Partner milestone: The Prescription Drug User Fee Act (PDUFA) target action date for the Biologics License Application (BLA) for margetuximab in combination with chemotherapy as a treatment for patients with metastatic HER2-positive breast cancer is December 18, 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 May 2020, the China NMPA granted priority review to the NDA for omadacycline for the treatment of CABP and ABSSSI.

Durlobactam

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

- In May 2020, the first Chinese patient was enrolled into the global Phase 3 ATTACK trial of Sulbactam-Durlobactam (SUL-DUR) for Acinetobacter infections.

Internal Programs with Global Rights

ZL-1201

ZL-1201 is a humanized, IgG4 monoclonal antibody engineered to reduce effector function, that specifically targets CD47. Its therapeutic potential will be assessed in both solid tumors and hematological malignancies, in both mono and combination opportunities.

- In June 2020, first-in-human dosing was achieved in the Phase 1 study.

ZL-1102

ZL-1102 is a novel human nanobody targeting IL-17 with high affinity and avidity. Unlike other anti-IL-17 products, ZL-1102 is being developed as a topical treatment for chronic plaque psoriasis (CPP).

- In July 2020, first-in-human dosing was achieved in the Phase 1 study.

Other Upcoming Milestones

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

- Enroll first Chinese patient into the global Phase 1 basket trial in second half of 2020.
- Zai Lab's partner MacroGenics is expanding enrollment of the combination of tebotelimab and margetuximab in a cohort of patients with advanced HER2-positive tumors.

Retifanlimab – an anti-PD-1 monoclonal antibody.

- Initiate potentially registration-enabling 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 retifanlimab with platinum-based chemotherapy in first-line metastatic squamous and non-squamous non-small cell lung cancer in second half of 2020.

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

- Zai Lab's partner Five Prime Therapeutics expects the topline results of the Phase 2 FIGHT study by the end of 2020 or in early 2021.

Business Development

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

Corporate Update

- Zai Lab continues to expand its US presence to enhance internal drug discovery, clinical development and business development, with the opening of a 20,000 sq. ft new research facility in Menlo Park, CA and the expansion of our office in Boston, MA.
- Zai Lab continues to expand and hire talented professionals. As of June 2020, Zai Lab employed 859 full-time employees, with 366 and 377 employees engaged in R&D and commercial activities, respectively.
- Zai Lab appointed several executives with extensive experience in R&D, regulatory affairs and alliance management including Dr. Karl Hsu, Senior Vice President (SVP) of Clinical Research and Early Development; Angela Jiang, SVP of Regulatory Affairs; and Petter Veiby, Head of Alliance Management and Business Development Search & Evaluation. Valeria Fantin, Chief Scientific Officer, will leave Zai Lab by September 25, 2020 to pursue a new opportunity.

First-Half 2020 Financial Results

- For the six months ended June 30, 2020, net product revenues were \$19.2 million, compared to \$3.4 million for the same period in 2019. Revenues for the period were comprised of \$13.8 million in sales of ZEJULA and \$5.4 million in sales of Optune, respectively. Launched in January 2020, ZEJULA's revenue in mainland China was the main driver for the first half of 2020 given Optune was commercially available at the end of June.
- R&D expenses were \$102.0 million for the six months ended June 30, 2020, compared to \$58.9 million for the same period in 2019. The increase in R&D expenses were primarily attributable to increased fees in connection with the upfront and milestone payments for new licensing and strategic collaboration agreements, 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 \$42.5 million for the six months ended June 30, 2020 compared to \$29.5 million for the same period in 2019. 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 six months ended June 30, 2020, Zai Lab reported a net loss of \$128.6 million, or a net loss per share attributable to common stockholders of \$1.74, compared to a net loss of \$83.3 million, or net loss per share attributable to common stockholders of \$1.37, for the same period in 2019.
- As of June 30, 2020, cash and cash equivalents, restricted cash and short-term investments totaled \$464.1 million.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, August 13, 2020 at 8:00 a.m. ET. 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 are as follows:

Registration Link: <http://apac.directeventreg.com/registration/event/7077004>

Conference ID: 7077004

All participants must use the link provided above to complete the online registration process in advance of the conference call. Upon registering, each participant will receive a dial-in number, Direct Event passcode, and a unique access PIN, which can be used to join the conference call.

A replay will be available shortly after the call and can be accessed by visiting the Company's website at <http://ir.zailaboratory.com>.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune diseases to patients in China and around the world. To quickly target the large, fast-growing segments of China's pharmaceutical market and address unmet medical needs, Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates. Zai Lab has also built an in-house team with strong drug discovery and translational research capabilities, aiming to establish a global pipeline of proprietary drug candidates against targets in our focus areas. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its portfolio in order to impact human health worldwide.

For additional information about the Company, please visit www.zailaboratory.com or follow us at [www.twitter.com/ZaiLab_Global](https://twitter.com/ZaiLab_Global).

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 generate revenue from its drug candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, 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 thousands of U.S. dollars ("\$\$") except for number of shares)

	As of	
	December 31, 2019	June 30, 2020
	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	75,932	258,604
Short-term investments	200,000	205,000
Accounts receivable (net of allowance of nil and \$2 as of Dec 31, 2019 and June 30, 2020, respectively)	3,791	7,024
Inventories, net	6,005	6,569
Prepayments and other current assets	6,736	7,684
Total current assets	292,464	484,881
Restricted cash, non-current	510	510
Investments in equity investees	2,398	1,991
Prepayments for equipment	440	383
Property and equipment, net	21,353	21,017
Operating lease right-of-use assets	15,071	13,929

Land use rights	7,655	7,416
Intangible assets, net	1,148	1,216
Long term deposits	377	712
Value added tax recoverable	13,737	16,159
Total assets	355,153	548,214
Liabilities and shareholders' equity		
Current liabilities:		
Short-term borrowings	6,450	4,238
Accounts payable	22,660	32,392
Current operating lease liabilities	4,351	4,175
Other current liabilities	13,174	15,750
Total current liabilities	46,635	56,555
Deferred income	2,881	15,736
Non-current operating lease liabilities	10,977	10,457
Total liabilities	60,493	82,748
Shareholders' equity		
Ordinary shares (par value of US\$0.00006 per share; 83,333,333 shares authorized, 68,237,247 and 74,882,338 shares issued and outstanding as of December 31, 2019 and June 30, 2020, respectively)	4	4
Additional paid-in capital	734,734	1,031,791
Accumulated deficit	(444,698)	(573,315)
Accumulated other comprehensive income	4,620	6,986
Total shareholders' equity	294,660	465,466
Total liabilities and shareholders' equity	355,153	548,214

Zai Lab Limited

Unaudited condensed consolidated statements of operations

(In thousands of U.S. dollars ("\$\$") except for number of shares and per share data)

	For the six months ended	
	June 30,	
	2019	2020
	\$	\$
Revenue	3,420	19,213
Expenses:		
Cost of sales	(882)	(4,980)
Research and development	(58,928)	(102,049)
Selling, general and administrative	(29,489)	(42,472)
Loss from operations	(85,879)	(130,288)
Interest income	3,365	2,882
Interest expense	(137)	(114)
Other expense, net	(307)	(691)
Loss before income tax and share of loss from equity method investment	(82,958)	(128,211)
Income tax expense	—	—
Share of loss from equity method investment	(316)	(406)
Net loss	(83,274)	(128,617)
Net loss attributable to ordinary shareholders	(83,274)	(128,617)
Loss per share - basic and diluted	(1.37)	(1.74)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	60,919,842	73,847,551

Zai Lab Limited

Unaudited condensed consolidated statements of comprehensive loss

(In thousands of U.S. dollars ("\$\$"))

	For the six months ended June 30,	
	2019	2020
	\$	\$
Net loss	(83,274)	(128,617)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	563	2,366
Comprehensive loss	<u>(82,711)</u>	<u>(126,251)</u>



Source: Zai Lab Limited