



Zai Lab Announces First Quarter 2021 Financial Results

May 10, 2021

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

SHANGHAI and SAN FRANCISCO, May 10, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced financial results for the first quarter of 2021, along with recent product highlights and corporate updates.

"Zai Lab continued to execute well in all aspects of the business during the first quarter," said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. "We entered into several strategic collaborations to further strengthen our gastric and lung cancer disease strongholds; significantly bolstered our autoimmune franchise with an exclusive agreement with argenx for efgartigimod, a pipeline-in-a-product opportunity; advanced numerous clinical programs toward key data readouts; gained approval of QINLOCK by the National Medical Products Administration (NMPA), our third innovative oncology product approval in the last 15 months in China and the first commercial product in what we expect to become a world-class gastric cancer franchise; and generated solid revenue growth, in part from increased volume of ZEJULA driven by its recent inclusion on the National Reimbursement Drug List (NRDL). In addition, we recently received encouraging news on several key assets from our partners. The Biologics License Application (BLA) filing of efgartigimod in generalized myasthenia gravis (gMG) was accepted by the U.S. Food and Drug Administration (FDA). The Phase 3 pivotal LUNAR trial of Tumor Treating Fields in non-small cell lung cancer (NSCLC) was recommended to continue with reduced sample size based on an accelerated interim analysis. Bemarituzumab was granted Breakthrough Therapy Designation by the FDA as first-line treatment for gastric cancer patients who overexpress FGFR2b.

"With the completion of our recent global public offering with gross proceeds of nearly \$860 million, we significantly strengthened our capital position. This new capital will allow us to accelerate our growth by entering into additional strategic partnerships, advancing our clinical development pipeline, and scaling our commercial and R&D organizations to drive strong revenue growth and enhance our global pipeline.

"We remain on target to advance all stages of our product pipeline throughout 2021. We continue to expect approval of Nuzyra for community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) by the NMPA. We plan to file margetuximab for Her2-positive breast cancer, Tumor Treating Fields for mesothelioma and ZEJULA for late-line ovarian cancer in China. We are engaging with the NMPA on the regulatory filing strategy for efgartigimod in gMG in China. And we anticipate numerous data readouts, including for Tumor Treating Fields in liver cancer and ovarian cancer, for QINLOCK in second-line GIST, for margetuximab in gastric cancer, for CLN-081 in NSCLC and for TPX-0022 in NSCLC and gastric cancer.

"In our mission to address serious unmet medical needs for patients in China and around the world, we believe that we have built a sustainable platform that we can leverage," Dr. Du concluded. "Our team continues to deliver on our aggressive growth objectives. I believe that the future of Zai Lab has never been brighter."

Recent Product Highlights and Anticipated Milestones

Oncology

ZEJULA® (niraparib)

ZEJULA is an oral, once-daily small-molecule poly ADP-ribose polymerase (PARP) 1/2 inhibitor. It is the only PARP inhibitor approved in the United States, the European Union and mainland China (hereinafter, "China") as a monotherapy for patients with advanced ovarian cancer, regardless of their biomarker status.

Anticipated 2021 Zai Milestones

- Complete enrollment of the Phase 1b study of ZEJULA in combination with tebotelimab (PD-1 x LAG-3) in gastric cancer.
- Announce topline results of the Phase 3 PRIME study of ZEJULA in patients with first-line ovarian cancer in China in the second half.
- Submit the supplemental New Drug Application (sNDA) for late-line ovarian cancer treatment in the second half.
- Continue to explore additional indications and combination 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 cell death.

Recent Product Highlights

- In April 2021, Zai Lab partner Novocure announced an update regarding its Phase 3 pivotal LUNAR trial in stage 4 NSCLC following failure on platinum-based chemotherapy. After a review by an independent data monitoring committee (DMC), Novocure was informed by the committee that the pre-specified interim analysis for the LUNAR trial had been accelerated given the length of accrual and the number of events observed. The DMC concluded that it is likely unnecessary and possibly unethical for patients randomized to the control arm to continue accrual to 534 patients with 18 months follow-up. The DMC further recommended a reduced sample size of approximately 276 patients with 12 months follow-up. Novocure has filed an IDE supplement with the FDA and is awaiting the agency's response.
- Zai Lab has initiated the LUNAR trial in Greater China and will help accelerate the development of Tumor Treating Fields for NSCLC and other cancer patients worldwide.

Anticipated 2021 Zai Milestones

- Submit a Marketing Authorization Application (MAA) for malignant pleural mesothelioma.
- Join the global Phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer, the Phase 3 pivotal INNOVATE-3 trial in recurrent ovarian cancer and the Phase 3 pivotal METIS trial in brain metastases from non-small cell lung cancer.
- Complete enrollment of the Phase 2 pilot trial in first-line gastric adenocarcinoma.

Anticipated 2021 Partner Milestones

- Receive FDA response to IDE supplement incorporating recommended protocol changes to the Phase 3 pivotal LUNAR trial in NSCLC in the second quarter.
- Obtain final data from the Phase 2 HEPANOVA trial in advanced liver cancer in the second quarter.
- Complete the interim analysis of the Phase 3 pivotal INNOVATE-3 trial in recurrent ovarian cancer in the second half.

QINLOCK® (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor engineered to broadly inhibit KIT- and PDGFR α -mutated kinases. It is the only therapeutic approved in the United States for advanced GIST patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting.

Recent Product Highlight

- In March 2021, Zai Lab announced that the NMPA approved its New Drug Application (NDA) for QINLOCK for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. This approval is the third innovative oncology product approval Zai Lab has received in the last 15 months in China.

Anticipated 2021 Zai Milestones

- Commercial launch of QINLOCK for the treatment of fourth-line GIST in May, 2021.
- Obtain regulatory approval in Taiwan in the second half.

Anticipated 2021 Partner Milestones

- Obtain topline data from the INTRIGUE Phase 3 study of QINLOCK in patients with second-line GIST in the fourth quarter.

Odronextamab

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

Anticipated 2021 Zai Milestone

- Enroll the first patient in Greater China in the global Phase 2 potentially pivotal program, subject to feedback from the FDA.

Anticipated 2021 Partner Milestones

- Resume enrollment of the Phase 2 potentially pivotal program in B-cell non-Hodgkin lymphoma (B-NHL) in the second quarter, pending FDA approval of the updated protocol.
- Initiate confirmatory OLYMPIA Phase 3 trials in combination with chemotherapy in follicular lymphoma (FL) and diffuse

large B-cell lymphoma (DLBCL), and explore other combination opportunities.

- Initiate development of a subcutaneous formulation.

Repotrectinib

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

Anticipated 2021 Zai Milestone

- Enroll the first patient in Greater China in the global TRIDENT-1 Phase 2 registrational study in the second quarter.

Anticipated 2021 Partner Milestones

- Reach target enrollment of the ongoing TRIDENT-1 study in the ROS1-positive TKI-naïve NSCLC patient cohort. An FDA meeting is anticipated during the first quarter of 2022 to discuss topline blinded independent central review (BICR) results.
- Initiate TRIDENT-2, a Phase 1b/2 combination study in KRAS-mutant solid tumors, mid-year.
- Provide a clinical data update from the ongoing TRIDENT-1 study in the second half.
- Report initial clinical data from the Phase 1/2 CARE study in pediatric and young adult patients in the second half.

MARGENZA™ (Margetuximab)

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

Anticipated 2021 Zai Milestone

- Submit an NDA for pretreated metastatic HER2-positive breast cancer.

Anticipated 2021 Partner Milestones

- Obtain initial data from Module A of the MAHOGANY study in the third quarter.
- Complete the final overall survival analysis of the SOPHIA study, a randomized, open-label Phase 3 study evaluating margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer who have previously been treated with HER2-targeted therapies, in the third quarter.

Bemarituzumab

Bemarituzumab is a first-in-class antibody that is being developed in gastric and gastroesophageal junction cancer as a targeted therapy for tumors that overexpress FGFR2b.

Recent Product Highlight

- In April 2021, the FDA granted Breakthrough Therapy Designation for bemarituzumab as first-line treatment for patients with fibroblast growth factor receptor 2b (FGFR2b) overexpressing and human epidermal growth factor receptor 2- (HER2-) negative metastatic and locally advanced gastric and gastroesophageal junction adenocarcinoma in combination with modified FOLFOX 6, based on an FDA-approved companion diagnostic assay showing at least 10% of tumor cells overexpressing FGFR2b.

Anticipated 2021 Zai Milestone

- Initiate a pivotal Phase 3 trial in gastric cancer.

CLN-081

CLN-081 is an orally available, small-molecule, next-generation, irreversible epidermal growth factor receptor (EGFR) inhibitor designed to selectively target cells expressing mutant EGFR variants, including EGFR exon 20 insertions.

Anticipated 2021 Zai Milestone

- Enroll the first patient in Greater China in the global potentially pivotal study in the second half.

Anticipated 2021 Partner Milestone

- Provide a clinical data update from the Phase 1/2a global study.

TPX-0022

TPX-0022 is an orally bioavailable, multi-targeted kinase inhibitor with a novel three-dimensional macrocyclic structure that inhibits the MET, CSF1R (colony stimulating factor 1 receptor) and SRC kinases.

Anticipated 2021 Partner Milestones

- Provide a clinical data update from the Phase 1 SHIELD-1 study and initiate the Phase 2 portion of the SHIELD-1 study in the second half, pending FDA feedback.
- Initiate SHIELD-2, a Phase 1b/2 combination study with an EGFR targeted therapy, in the second half.

Tebotelimab

Tebotelimab is an investigational, first-in-class, bispecific, tetravalent DART molecule targeting PD-1 and LAG-3.

Anticipated 2021 Zai and Partner Milestone

- Provide a clinical update, including future development plans.

Retifanlimab

Retifanlimab is an investigational monoclonal antibody that inhibits PD-1.

Recent Product Highlight

- In January 2021, our partner Incyte announced that the FDA had accepted for Priority Review its BLA for retifanlimab in patients with pretreated advanced squamous cell anal cancer (SCAC), with a Prescription Drug User Fee Act (PDUFA) date of July 25, 2021.

Autoimmune Diseases

Efgartigimod

Efgartigimod is an antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies and block the IgG recycling process. Efgartigimod binds to the neonatal Fc receptor (FcRn), which is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from degradation.

Recent Product Highlight

- Five Clinical Trial Applications (CTAs) accepted by the NMPA.

Anticipated 2021 Zai Milestones

- Discuss with the NMPA a potential accelerated regulatory pathway for efgartigimod in gMG.
- Continue to explore and advance additional indications in coordination with argenx.
- Receive CTA approvals for additional indications.

Anticipated 2021 Partner Milestones

- Potential FDA approval with a PDUFA target action date of December 17, 2021, and global commercial launch of efgartigimod for the treatment of patients with gMG.
- Continue enrollment of the registrational ADHERE trial in chronic inflammatory demyelinating polyneuropathy (CIDP).
- Initiate clinical trials in fifth and sixth indications.

Infectious Disease

NUZYRA® (omadacycline)

NUZYRA is a once-daily oral and intravenous antibiotic for the treatment of adults with CABP and ABSSSI.

Anticipated 2021 Zai Milestone

- Potential NMPA approval and commercial launch of NUZYRA for the treatment of CABP and ABSSSI.

Sulbactam-Durlobactam (SUL-DUR)

Sulbactam-Durlobactam is a beta-lactam/beta-lactamase inhibitor combination that provides unique activity against Acinetobacter organisms,

including carbapenem-resistant strains.

Anticipated 2021 Zai and Partner Milestone

- Complete patient enrollment in the global Phase 3 ATTACK trial, with a top-line data readout anticipated in the second half.

Internal Programs with Global Rights

ZL-2309 (CDC7)

ZL-2309 is an orally active, selective and ATP-competitive cell division cycle 7 (CDC7) kinase inhibitor.

Anticipated 2021 Zai Milestone

- Initiate a biomarker-driven POC study in selected tumors.

ZL-1102 (IL-17)

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).

Anticipated 2021 Zai Milestone

- A top-line data readout is anticipated in the second half.

Business Development Updates

- In January 2021, Zai Lab announced an exclusive license agreement with argenx for the development and commercialization of efgartigimod in Greater China. Efgartigimod is an antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies and block the IgG recycling process, with potential application in myasthenia gravis, pemphigus vulgaris, immune thrombocytopenia, chronic inflammatory demyelinating polyneuropathy and several additional indications.
- In January 2021, Zai Lab expanded its collaboration with Turning Point Therapeutics with an exclusive license agreement for the development and commercialization of TPX-0022 in Greater China. TPX-0022 is a multi-targeted kinase inhibitor that targets MET, CSF1R and SRC kinases, with potential uses in treating advanced or metastatic solid tumors.

Corporate Updates

- In April 2021, Zai Lab announced the closing of a global offering of American depository shares and ordinary shares, including the full exercise of the greenshoe option, for total gross proceeds to Zai Lab of \$857.5 million. This offering was the first ever dual-tranche offering on both NASDAQ and the Hong Kong Stock Exchange.
- ZEJULA has been listed in 67 commercial health insurance plans and 52 supplemental insurance plans initiated by provincial or municipal governments since its commercial launch in January 2020 in China. Optune has also been listed in 13 supplemental insurance plans since its commercial launch in June 2020 in China.
- On May 7, 2021, Tao Fu took a new role as Chief Strategy Officer of Zai Lab, and transitioned out of his roles as President and Chief Operating Officer and resigned from the Board of Directors of Zai Lab, in order to focus on Zai Lab's corporate development and other strategic objectives.
- Zai Lab continues to expand and hire talented professionals. As of April 15, 2021, Zai Lab employed 1,354 full-time employees, including 514 and 683 employees engaged in R&D and commercial activities, respectively.

First-Quarter 2021 Financial Results

- For the three months ended March 31, 2021, net product revenues were \$20.1 million, compared to \$8.2 million for the same period in 2020. Revenues for the period were comprised of \$12.6 million for ZEJULA, compared to \$6.3 million for the same period in 2020; and \$7.1 million for Optune, compared to \$1.9 million for the same period in 2020.
- Research and Development (R&D) expenses were \$203.9 million for the three months ended March 31, 2021, compared to \$33.7 million for the same period in 2020. The increase in R&D expenses was primarily attributable to a \$62.3 million upfront payment in Zai Lab equity (fair value of the shares on the closing date of the agreement due to certain restrictions) and a \$75 million development cost-sharing payment to argenx; a \$25 million upfront payment to Turning Point; expenses related to ongoing and newly initiated late-stage clinical trials; and payroll and payroll-related expenses from increased R&D headcount.

- Selling, General and Administrative expenses (SG&A) were \$35.8 million for three months ended March 31, 2021, compared to \$18.7 million for the same period in 2020. The increase was primarily due to payroll and payroll-related expenses from increased commercial headcount and related costs, as Zai Lab continued to expand its commercial operations in China.
- For the three months ended March 31, 2021, Zai Lab reported a net loss of \$232.9 million, or a loss per share attributable to common stockholders of \$2.64, compared to a net loss of \$48.0 million, or a loss per share attributable to common stockholders of \$0.66, for the same period in 2020. The increase in the net loss was primarily attributable to payments related to new business development activities with argenx and Turning Point recorded in R&D expenses.
- As of March 31, 2021, cash and cash equivalents, short-term investments and restricted cash totaled \$1,014.2 million compared to \$1,187.5 million as of December 31, 2020. In addition, in April 2021, Zai Lab announced the closing of a global follow-on offering. The expected total proceeds to Zai Lab, including both the American depositary shares offering and the ordinary shares offering, net of underwriting fees and other offering expenses, are approximately \$818.1 million.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, May 10, 2021, 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/2374839>

Conference ID: 2374839

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; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders and infectious disease. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our 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/Zai_lab_Global.

Zai Lab Forward-Looking Statements

This press release contains references to statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding our ability to advance our product pipeline and further demonstrate our commercial and discovery capabilities, anticipated milestones for our approved products and product candidates and other statements containing words such as "aim," "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," "contemplate" 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 neither historical facts nor assurances of future performance. Forward-looking statements are based on Zai Lab's expectations and assumptions that Zai Lab believes are reasonable 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 of operations, financial condition and liquidity and the development of the industry in which Zai Lab operates 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 successfully commercialize and generate revenue from its approved products; (2) Zai Lab's ability to finance its operations and business initiatives and obtain funding for such activities, (3) Zai Lab's results of clinical and pre-clinical development of its product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's product 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 10-K for the fiscal year ended December 31, 2020, filed on March 1, 2021, 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 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

Zai Lab Limited

Unaudited Condensed Consolidated Balance Sheets

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

	As of	
	March 31, 2021	December 31, 2020
	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	1,013,420	442,116
Short-term investments	-	744,676
Accounts receivable (net of allowance of \$2 and \$1 as of March 31, 2021 and 2020, respectively)	8,815	5,165
Inventories	12,629	13,144
Prepayments and other current assets	14,321	10,935
Total current assets	1,049,185	1,216,036
Restricted cash, non-current	743	743
Investments in equity investees	1,473	1,279
Prepayments for equipment	244	274
Property and equipment, net	29,016	29,162
Operating lease right-of-use assets	16,652	17,701
Land use rights, net	7,784	7,908
Intangible assets, net	1,585	1,532
Long term deposits	910	862
Value added tax recoverable	23,698	22,141
Total assets	1,131,290	1,297,638
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	41,415	62,641
Current operating lease liabilities	5,602	5,206
Other current liabilities	45,639	30,196
Total current liabilities	92,656	98,043
Deferred income	16,657	16,858
Non-current operating lease liabilities	12,307	13,392
Total liabilities	121,620	128,293
Commitments and contingencies (Note 18)		
Shareholders' equity		
Ordinary shares (par value of \$0.00006 per share; 500,000,000 shares authorized, 88,519,172 and 74,666,725 shares issued and outstanding as of March 31, 2021 and 2020, respectively)	5	5
Additional paid-in capital	1,967,802	1,897,467
Accumulated deficit	(946,513)	(713,603)
Accumulated other comprehensive loss	(11,624)	(14,524)
Total shareholders' equity	1,009,670	1,169,345
Total liabilities and shareholders' equity	1,131,290	1,297,638

Zai Lab Limited

Unaudited Condensed Consolidated Statements of Operations

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

	Three Months Ended March 31,	
	2021	2020
	\$	\$
Revenue	20,103	8,218
Expenses:		
Cost of sales	(7,505)	(2,084)
Research and development	(203,852)	(33,742)
Selling, general and administrative	(35,838)	(18,714)
Loss from operations	(227,092)	(46,322)
Interest income	214	1,655
Interest expenses	-	(59)
Other expense, net	(6,227)	(3,125)
Loss before income tax and share of gain (loss) from equity method investment	(233,105)	(47,851)
Income tax expense	-	-
Share of gain (loss) from equity method investment	195	(137)
Net loss	(232,910)	(47,988)
Net loss attributable to ordinary shareholders	(232,910)	(47,988)
Loss per share - basic and diluted	(2.64)	(0.66)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	88,374,928	72,956,538

Zai Lab Limited

Unaudited Condensed Consolidated Statements of Comprehensive Loss

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

	Three Months Ended March 31,	
	2021	2020
	\$	\$
Net loss	(232,910)	(47,988)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	2,900	3,539
Comprehensive loss	(230,010)	(44,449)



Source: Zai Lab Limited