# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER**
**PURSUANT TO RULE 13A-16 OR 15D-16**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the month of September 2019**

**Commission Filing Number: 001-38205**

# ZAI LAB LIMITED
**(Translation of registrant's name into English)**

**4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210**
**(Address of principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

## EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release issued September 3, 2019. |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ZAI LAB LIMITED**

By: /s/ Billy Cho
Name: Billy Cho
Title: Chief Financial Officer

Date: September 3, 2019

**Exhibit 99.1**

**Zai Lab Announces Financial Results and Corporate Update for the Six Months Ended June 30, 2019**

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

SHANGHAI, China and SAN FRANCISCO, Sep. 3, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (“Zai Lab” or “the Company”) (NASDAQ: ZLAB), a China and U.S.-based innovative commercial-stage biopharmaceutical company, today announced financial results for the six months ended June 30, 2019 and provided a corporate update.

“During the first half of 2019 we continued to make significant progress toward our objective of becoming a fully integrated global biopharmaceutical company. Our portfolio currently includes ten clinical assets, nine of which are in late stage, targeting over 20 indications,” said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. “We launched our two lead oncology products, ZEJULA® and Optune® in Hong Kong and ZEJULA in Macau. We submitted applications for marketing approval in China for both of these therapeutics and have built a full commercial platform. Other late-stage product candidates, such as margetuximab, ripretinib, bemarituzumab, omadacycline and sulbactam-durlobactam, continue to advance in clinical development and hit significant milestones through efforts by Zai Lab and our strategic partners. As always, we constantly search for novel and potentially best-in-class clinical candidates that would both complement our pipeline across key indications and address unmet medical needs in Greater China. So far this year, we entered into two collaborative agreements, one with Deciphera on an advanced clinical-stage gastrointestinal cancer drug candidate ripretinib and the other with Incyte on a potential globally competitive anti-PD-1 antibody, INCMGA0012, which may be combined with several of our other oncology candidates. With a growing pipeline and execution progress, Zai Lab has established a global reputation as a China biotech pioneer. Zai Lab is already an integrated biopharma with nearly 600 employees across six offices in Greater China and the U.S. With proven global and local clinical development, regulatory and business development expertise, we also look forward to demonstrating our commercial and discovery capabilities in the near future. The proceeds from our recent financing positions us to execute on all of our top initiatives as we continue to build and expand our business. We expect the upcoming months to potentially be transformative for Zai Lab as we prepare for the marketing approvals for ZEJULA and Optune in China.”

**Recent Pipeline and Product Highlights**

Oncology

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

- In August 2019, Zai Lab announced publication of “Phase I Pharmacokinetic Study of Niraparib in Chinese Patients with Epithelial Ovarian Cancer” in *The Oncologist*, demonstrating that the pharmacokinetic (PK) profile of niraparib in Chinese patients were comparable to that of patients evaluated in GSK’s global PK study.

- In July 2019, our partner GSK (formerly Tesaro) announced positive top-line results of the pivotal Phase 3 PRIMA study of ZEJULA as first line maintenance in patients with ovarian cancer. The study met its primary endpoint of a statistically significant improvement in progression free survival (PFS) for women regardless of biomarker status.

- In June 2019, GSK announced the U.S. Food and Drug Administration's (FDA) acceptance of the supplemental New Drug Application (NDA) for ZEJULA in late-stage ovarian cancer based on the results of the QUADRA study. The application was granted priority review with a PDUFA action date of October 24, 2019.

- In June 2019, Zai Lab announced receipt of marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer.

- In January 2019, Zai Lab announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has granted priority review status to the NDA for niraparib for the maintenance treatment of adult patients with recurrent epithelial, ovarian, fallopian tube or primary peritoneal ovarian cancer who are in a complete or partial response to platinum-based chemotherapy. NMPA acceptance of the NDA was announced in December 2018, more than one year ahead of expectations.

- In January 2019, Zai Lab announced that it completed patient enrollment in its pivotal clinical trial of niraparib, which is in development for second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer.

***Optune®***, a Tumor Treating Fields delivery system that uses electric fields tuned to specific frequencies to disrupt cancer cell division, inhibiting tumor growth and causing affected cancer cells to die.

- In August 2019, the NMPA granted Innovative Medical Device Designation for Optune, which will allow the Company to take advantage of an expedited approval process for Optune.

- In May 2019, our partner Novocure received the U.S. FDA approval for the NovoTTF-100L™ System in combination with chemotherapy for the first-line treatment of unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM). NovoTTF-100L, the first treatment for MPM approved by the U.S. FDA in more than 15 years, is a non-invasive, antimitotic cancer treatment that delivers Tumor Treating Fields to the region of the tumor.

- In March 2019, Novocure initiated a Phase 3 clinical trial of Tumor Treating Fields in patients with recurrent ovarian cancer. Novocure's Tumor Treating Fields is currently in late stage clinical development for four solid tumor indications including non-small cell lung cancer, brain metastases, pancreatic and ovarian cancers.

- In February 2019, Optune was launched in Hong Kong for patients with GBM.

***Margetuximab***, an investigational, Fc-optimized monoclonal antibody (mAb) that targets human epidermal growth factor receptor 2 (HER2).

- In February and June 2019, our partner MacroGenics announced positive top-line results from its SOPHIA Phase 3 study of margetuximab in patients with HER2-positive metastatic breast cancer and presented the primary analysis at the American Society of Clinical Oncology (ASCO) in June 2019. The trial met the first sequential primary endpoint of prolongation of PFS in patients treated with the combination of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy.

- In January 2019, MacroGenics presented updated clinical data from a combination study of margetuximab plus pembrolizumab in gastric cancer at the 2019 ASCO Gastrointestinal Cancers Symposium. Based on these positive data, MacroGenics and Zai Lab plan to initiate a global registrational clinical trial of margetuximab in combination with checkpoint inhibitor molecules, including INCMGA0012 (anti-PD-1 mAb) and MGD013 (bispecific PD-1 x LAG-3 molecule) in first line patients with HER2-positive gastric or gastroesophageal junction cancer in 2019.

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

- In August 2019, our partner Deciphera announced positive top-line data from the pivotal Phase 3 INVICTUS clinical study of ripretinib in patients with fourth-line and fourth-line plus GIST. The study met its primary endpoint of a significantly improved median PFS of 6.3 months compared to 1.0 month in the placebo arm, and the risk of disease progression or death was reduced by 85% (HR of 0.15, $p<0.0001$) compared to placebo.

- In June 2019, Zai Lab entered into an exclusive license agreement with Deciphera for the right to develop and commercialize ripretinib in Greater China.

***INCMGA0012***, an investigational mAb that inhibits PD-1, currently being evaluated as a monotherapy in registrational trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer.

- In July 2019, Zai Lab announced a collaboration and license agreement with Incyte for the development and commercialization of INCMGA0012 in Greater China. The collaboration enables Zai Lab to rapidly explore the potential of a competitive anti PD-1 as both monotherapy and combination therapy, unlocking the full potential of the Company's pipeline.

***Bemarituzumab***, a first-in-class isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immunotherapy for tumors that overexpress FGFR2b.

- Enrollment in the pivotal FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment (FIGHT) trial continues ahead of projections due to FGFR2b biomarker prevalence that has remained steady at more than 30%.

- Our partner Five Prime Therapeutics plans to pause enrollment in the fourth quarter of 2019 and conduct an early futility analysis for the FIGHT trial by the first half of 2020.

Infectious Disease

**NUZYRA® (*Omadacycline)***, 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 July 2019, enrollment of the CDE-requested bridging trial in China was completed ahead of schedule. Zai Lab also completed the bioequivalence, PK and microbiology studies on time.

***Sulbactam-durlobactam***, a novel, broad-spectrum and potent inhibitor of Class A, C, and D β-lactamases. This is a novel IV antibiotic for the treatment of infections caused by carbapenem-resistant Acinetobacter.

- In May 2019, Zai Lab received Clinical Trial Application (CTA) acceptance from the NMPA to initiate a Phase 3 clinical trial for the treatment of carbapenem-resistant Acinetobacter baumannii infections in China. The Acinetobacter Treatment Trial Against Colistin (ATTACK) study is a global Phase 3 clinical trial that will enroll approximately 300 patients from 18 countries. Zai Lab will be responsible for patient enrollment in China, and potentially provide early access for patients in Asia-pacific countries. Entasis Therapeutics will be responsible for patient enrollment in the U.S. and Europe.

**Recent Corporate Developments**

- In July 2019, Dr. Alex A. Adjei, M.D., Ph.D., a world-renowned clinical scientist from the Mayo Clinic, with expertise in drug development, cancer pharmacology and early phase clinical trials, joined Zai Lab's Scientific Advisory Board (SAB). Dr. Adjei will advise Zai Lab as it continues to expand the clinical trials of the multiple innovative molecules in its oncology pipeline.

- In June 2019, Zai Lab appointed Valeria Fantin, Ph.D., as Chief Scientific Officer to further enhance internal discovery capabilities and continue to grow its U.S. presence. Dr. Fantin will lead the Company's internal drug discovery effort on a global basis and is directly reporting to Dr. Samantha Du.

- In May 2019, Zai Lab raised $216.2 million, net of underwriting fees, in a public offering of American Depositary Shares, each representing one ordinary share of the Company.

- In February 2019, Immuno-Oncology Pioneer, Lieping Chen, M.D., Ph.D., from the Yale School of Medicine, joined Zai Lab's SAB. Dr. Chen will advise Zai Lab as it continues to progress its internally-developed oncology pipeline.

- Zai Lab continues to expand its U.S. presence to enhance internal drug discovery efforts. As of July 31, 2019, our U.S. R&D center in the San Francisco Bay Area has approximately 10 employees and is growing.

- Zai Lab continues to expand its platform, particularly its R&D and commercial teams. As of July 31, 2019, Zai Lab employed 577 full-time employees, with 247 and 246 employees engaged in R&D and commercial activities, respectively.

**Anticipated Upcoming Milestones**

*ZEJULA*®

- GSK to present PRIMA data at an upcoming medical conference
- Potential U.S. FDA approval for ovarian cancer late line treatment in the fourth quarter of 2019
- Potential China NDA approval for ovarian cancer second-line maintenance therapy
- Potential China commercial launch
- Completion of enrollment of China Phase 3 clinical trial for ovarian cancer first-line maintenance therapy (PRIME)
- China second-line ovarian cancer Phase 3 clinical trial (NORA) to reach target events by the fourth quarter of 2019 with readout in the first half of 2020
- Zai Lab to present data from PRIME and NORA studies at Asian Society of Gynecologic Oncology (ASGO) 2019
- Continued enrollment of the China small cell lung cancer (SCLC) Phase 3 clinical trial
- Initiate trials in other key indications in China.

*Optune*®

- Potential China GBM MAA approval with trial waiver
- Potential China commercial launch
- Initiate exploratory trial in China for gastric cancer with first patient in by the end of 2019
- Prepare trials in other key indications in China

*Margetuximab*

- Initiate bridging trial of heavily pretreated HER2-positive metastatic breast cancer patients in China
- MacroGenics to present the results from a pre-specified interim overall survival (OS) analysis and submit a Biologics License Application (BLA) to the U.S. FDA in the fourth quarter of 2019
- Potential China CTA approval for the planned global gastric cancer and join MacroGenics to initiate the global registrational trial in combination with checkpoint inhibitor molecules, including INCMGA 0012 and MGD013, for patients with gastric or gastroesophageal junction cancer in 2019

*Ripretinib*

- Deciphera to present INVICTUS data at an upcoming medical conference
- Deciphera to submit NDA to the U.S. FDA for fourth-line and fourth-line plus GIST by the first quarter of 2020
- Discussions with the NMPA for an accelerated approval for fourth-line and fourth-line plus GIST, leveraging the INVICTUS data
- Potential China CTA approval for INTRIGUE trial for second-line GIST patients and contribute Chinese patients to the global registrational study

*Brivanib*

- Potential CTA approval to initiate a combination study of brivanib and a checkpoint inhibitor in the treatment of second-line hepatocellular cancer

*NUZYRA®*

- Complete the Phase 3 clinical trial in China and submit China NDA for two major indications: CABP and ABSSSI

*Sulbactam-durlobactam*

- Initiate ATTACK global Phase 3 registrational study in China with Entasis

*Discovery*

- Announce one to two global investigational new drug (IND) applications by 2020

**First Half 2019 Financial Results**

- For the six months ended June 30, 2019, net revenues were $3.4 million, reflecting the commercial launch of our two lead oncology products in Hong Kong, with $1.9 million and $1.5 million from ZEJULA and Optune, respectively.

  Since the Hong Kong launch of ZEJULA in October 2018, it has rapidly gained market share in the region despite being launched more than two years behind LYNPARZA. Based on IQVIA* (formerly IMS) data, ZEJULA is now the market leading PARP inhibitor with market share in Hong Kong of 66% in the second quarter of 2019.

  Officially launched in February 2019, Optune’s revenue has ramped ahead of expectations, with strong momentum generated for the second half of the year.

- R&D expenses were $58.9 million for the six months ended June 30, 2019 compared to $34.6 million for the same period in 2018. The increase in R&D expenses was primarily attributable to an increase in licensing fees, ongoing and newly initiated late-stage clinical trials, headcount and payroll and payroll-related expenses, and expansion of research efforts to support internal programs.

- Selling, general and administrative expenses were $29.5 million for the six months ended June 30, 2019 compared to $6.4 million for the same period in 2018. The increase was primarily attributable to an increase in payroll and payroll-related expenses as Zai Lab continued to expand its commercial operations in China.

- For the six months ended June 30, 2019, Zai Lab reported a net loss of $83.3 million, or a net loss per share attributable to common stockholders of $1.37, compared to a net loss of $41.5 million, or net loss per share attributable to common stockholders of $0.83, for the same period in 2018.

- As of June 30, 2019, cash and cash equivalents and short-term investments totaled $393.2 million. This includes net proceeds of $216.2 million obtained in a public offering of American Depositary Shares in May 2019.

** IQVIA Hong Kong Pharmaceutical Audit QTR 2Q2019 data*

**Conference Call and Webcast Information**

Zai Lab will host a live conference call and webcast today, September 3, 2019 at 8:30 a.m. EDT 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 http://ir.zailaboratory.com. 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) 519-4004 (U.S.); +65 67135090 (International); +852 30186771 (Hong Kong); 4006208038 (China) to listen to the live conference call. The conference ID number for the live call is 6785308. A replay of the webcast will be available for on Zai Lab's website for two weeks following the live conference call. The conference ID for the replay is 6785308.

**About Zai Lab**

Zai Lab (NASDAQ: ZLAB) is a Shanghai-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 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 our product candidates, the timing of commercial launch of ZEJULA and Optune in China, 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, 2018 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:**
Billy Cho
Zai Lab, CFO
+86 21 6163 7322
billy.cho@zailaboratory.com

Media: Ryo Imai / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006
rimai@burnsmc.com / rflamm@burnsmc.com

Investors: Lee Roth
Burns McClellan, on behalf of Zai Lab
212-213-0006, ext. 331, lroth@burnsmc.com

**Zai Lab Limited**

**Condensed consolidated balance sheets (U.S. GAAP)**

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

| | As of June 30, 2019 | As of December 31, 2018 |
|---|---|---|
| | $ | $ |
| **Assets** | | |
| **Current assets:** | | |
| Cash and cash equivalents | 91,602,489 | 62,951,607 |
| Short-term investments | 301,600,000 | 200,350,000 |
| Accounts receivable | 2,483,131 | 89,708 |
| Inventories | 141,103 | 3,822 |
| Prepayments and other current assets | 5,971,200 | 5,749,260 |
| Total current assets | 401,797,923 | 269,144,397 |
| Investments in equity investees | 2,833,568 | 3,149,855 |
| Prepayments for equipment | — | 275,853 |
| Property and equipment | 21,906,317 | 20,494,482 |
| Operating lease right-of-use assets | 7,698,765 | — |
| Intangible assets | 663,667 | 321,566 |
| Long-term deposits | 389,773 | 556,738 |
| Value added tax recoverable | 11,170,490 | 8,044,258 |
| **Total assets** | **446,460,503** | **301,987,149** |
| **Liabilities and shareholders' equity** | | |
| **Current liabilities:** | | |
| Short-term borrowing | 5,818,436 | 3,642,616 |
| Accounts payable | 27,725,527 | 37,432,035 |
| Current operating lease liabilities | 2,899,075 | — |
| Other payables | 9,526,288 | 7,766,843 |
| Total current liabilities | 45,969,326 | 48,841,494 |
| Deferred income | 2,514,473 | 2,063,942 |
| Non-current operating lease liabilities | 4,646,586 | — |
| **Total liabilities** | **53,130,385** | **50,905,436** |
| **Total shareholders' equity** | **393,330,118** | **251,081,713** |
| **Total liabilities and shareholders' equity** | **446,460,503** | **301,987,149** |

**Zai Lab Limited**

**Condensed consolidated statements of operations (U.S. GAAP)**

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

| | For the six months ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| | $ | $ |
| Revenue | 3,420,183 | — |
| Cost of sales | (881,774) | — |
| Gross profit | 2,538,409 | — |
| Operating expenses: | | |
| Research and development | (58,928,465) | (34,632,256) |
| Selling, general and administrative | (29,488,857) | (6,364,088) |
| Loss from operations | (85,878,913) | (40,996,344) |
| Interest income | 3,505,043 | 407,977 |
| Interest expense | (276,768) | — |
| Other expenses, net | (320,258) | (695,618) |
| Loss before income tax and share of loss from equity method investment | (82,970,896) | (41,283,985) |
| Income tax expense | — | — |
| Share of loss from equity method investment | (302,827) | (206,443) |
| Net loss | (83,273,723) | (41,490,428) |
| Net loss attributable to ordinary shareholders | (83,273,723) | (41,490,428) |
| Loss per share - basic and diluted | (1.37) | (0.83) |
| Weighted-average shares used in calculating net loss per ordinary share - basic and diluted | 60,919,842 | 50,041,672 |

**Zai Lab Limited**

**Condensed consolidated statements of comprehensive loss (U.S. GAAP)**

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

| | For the six months ended June 30, | |
|---|---|---|
| | **2019** | **2018** |
| | **$** | **$** |
| Net loss | (83,273,723) | (41,490,428) |
| Other comprehensive income, net of tax of nil: | | |
| Foreign currency translation adjustments | 563,065 | 418,389 |
| **Comprehensive loss** | **(82,710,658)** | **(41,072,039)** |