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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 6, 2021

Zai Lab Limited
(Exact name of registrant as specified in its charter)

Cayman Islands	**001-38205**	**98-1144595**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

4560 Jinke Road
Bldg. 1, Fourth Floor, Pudong, Shanghai, China **201210**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code: +86 21 6163 2588

Not applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing one Ordinary Shares, par value $0.00006 per share	**ZLAB**	**The Nasdaq Global Market**
Ordinary shares, par value $0.00006 per share*	**9688**	**The Stock Exchange of Hong Kong Limited**

* Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement

Summary

On January 6, 2021 (U.S. time), Zai Lab Limited (the "Company") entered into a collaboration and license agreement (the "Collaboration Agreement") with argenx BV ("Argenx") pursuant to which Zai Auto Immune (Hong Kong) Limited ("Zai Auto Immune"), a wholly-owned subsidiary of the Company, received an exclusive license to develop and commercialize products containing Argenx's proprietary antibody fragment, known as efgartigimod, in mainland China, Hong Kong, Macau and Taiwan. On the same date, as partial consideration for the exclusive license granted by Argenx to Zai Auto Immune under the Collaboration Agreement, the Company entered into a share issuance agreement ("Share Issuance Agreement") with Argenx pursuant to which the Company has agreed to issue 568,182 ordinary shares, par value US$0.00006 per share (the "Subscription Shares") to Argenx in full satisfaction of the $75 million upfront payment under the Collaboration Agreement.

The transaction for the issuance of the Subscription Shares to Argenx under the Share Issuance Agreement has been approved by the boards of directors of both companies and is expected to close in January 2021, subject to approval by the Listing Committee of the Hong Kong Stock Exchange of the listing of the shares to be issued by the Company to Argenx on the Hong Kong Stock Exchange, and satisfaction of other customary closing conditions (the "Closing").

The terms of the Collaboration and License Agreement are further summarized below.

Collaboration and License Agreement

On January 06, 2021 (U.S. time), Zai Auto Immune entered into the Collaboration Agreement with Argenx, pursuant to which Zai Auto Immune received an exclusive license under relevant patents and know-how to develop and commercialize Argenx's proprietary antibody fragment, efgartigimod (the "Licensed Compound") and biopharmaceutical products containing the Licensed Compound (the "Licensed Products") in mainland China, Hong Kong, Macau and Taiwan (the "Territory"). Under the Collaboration Agreement, Zai Auto Immune may participate in Argenx's global phase 3 trials for Licensed Products by enrolling patients in the Territory.

Pursuant to the Collaboration Agreement, Zai Auto Immune will be responsible for the development of the Licensed Compound and Licensed Products in the Territory in accordance with a development plan to support the regulatory approval of the Licensed Product in the Territory.

For each Licensed Product that is approved in the Territory, Zai Auto Immune will have the right to commercialize such Licensed Product in the Territory, during which Argenx is eligible to receive tiered royalties (mid-teen to low-twenties on a percentage basis and subject to customary reductions) based on annual net sales of all Licensed Products in the Territory. Zai Auto Immune's royalty obligations will continue on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis until the last to occur of (i) expiration of the last valid claim of a licensed patent that covers such Licensed Product in such jurisdiction, (ii) expiration of regulatory exclusivity in such jurisdiction for such Licensed Product and (iii) twelve years from the first commercial sale of such Licensed Product in such jurisdiction.

In partial consideration of the license granted to Zai Auto Immune, a $75 million upfront payment will be made to Argenx through the issuance by the Company of 568,182 Subscription Shares calculated at a price of $132.00 per share. In addition, Zai Auto Immune will make a guaranteed non-creditable, non-refundable development cost-sharing payment of $75 million to Argenx, and a cash payment of $25 million upon the first regulatory approval of a Licensed Product by the U.S. Food and Drug Administration for Myasthenia Gravis.

The Collaboration Agreement contains customary representations, warranties and covenants by the parties. Unless terminated earlier pursuant to its terms, the agreement will continue in effect on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis until expiration of the royalty term for such Licensed Product in such jurisdiction. The Collaboration Agreement may be terminated by either party upon the other party's uncured material breach, bankruptcy, insolvency or similar event. In addition, Zai Auto Immune may terminate the

Collaboration Agreement for any or no reason upon 180 days' prior written notice of Argenx. If Zai Auto Immune or any of its affiliates or sublicensees challenges a patent licensed by Argenx under the Collaboration Agreement as invalid, unenforceable or otherwise not patentable, Argenx will have the right to immediately terminate the Collaboration Agreement, subject to certain exceptions. In addition, if a force majeure event is specific to Zai Auto Immune and persists for a specified period of time, Argenx will have the right to terminate the Collaboration Agreement upon notice to Zai Auto Immune.

* * *

The foregoing description of the terms of the Collaboration Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreement, which the Company intends to file as an exhibit to a subsequent periodic report or on an amendment to this Current Report on Form 8-K.

* * *

The representations and warranties and other statements in the agreements (1) speak only as to the date on which they were made, and may be modified or qualified by confidential schedules or other disclosures, agreements or understandings among the parties, which the parties believe are not required by the securities laws to be publicly disclosed, and (2) may be subject to a different materiality standard than the standard that is applicable to disclosures to investors. Moreover, it was advised that information concerning the subject matter of the representations and warranties and other statements made in the various agreements would likely change after the execution date of such agreements, and subsequent information may or may not be fully reflected in the Company's public disclosures. Accordingly, investors should not rely upon representations and warranties and other statements in the various agreements as factual characterizations of the actual state of affairs of the Company. Investors should instead look to disclosures contained in the Company's reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Item 3.02. Unregistered Sales of Equity Securities.

The disclosure set forth under Item 1.01 with respect to the issuance of the Subscription Shares, consisting of 568,182 ordinary shares of the Company, pursuant to the Share Subscription Agreement is incorporated by reference into this Item 3.02. Based upon the outstanding ordinary shares of the Company as of January 5, 2021, the Subscription Shares upon issuance will represent less than 1% of the outstanding ordinary shares of the Company.

The issuance of shares pursuant to the Share Issuance Agreement will be made in reliance upon Regulation S under the Securities Act of 1933, as amended (the "Securities Act") to Argenx, a non-U.S. person and will be restricted securities under the Securities Act.

Item 7.01 Regulation FD Disclosure.

On January 6, 2021 (U.S. time), the Company issued a press release announcing the above-described transactions. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing or this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 6, 2021.
104	The cover page of this Current Report on Form 8-K is formatted in Inline XBRL

SIGNATURES

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

ZAI LAB LIMITED

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

Dated: January 6, 2021

Exhibit Index

Exhibit 99.1—Press Release

argenx and Zai Lab Announce Strategic Collaboration for Efgartigimod in Greater China

- Collaboration to expand and accelerate global development of efgartigimod; expected to allow argenx to more rapidly advance new potential indications into clinical development each year
- Zai Lab granted exclusive rights to develop and commercialize efgartigimod in Greater China
- argenx to receive $75 million in upfront Zai Lab equity and $100 million in near-term milestone and other payments

Regulated Information/Inside Information

Breda, the Netherlands, Shanghai and San Francisco – Jan. 6, 2021 – argenx SE (Euronext & NASDAQ: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, and Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced an exclusive license agreement for the development and commercialization of efgartigimod in Greater China, including mainland China, Hong Kong, Taiwan and Macau.

“Through this collaboration with Zai Lab, we are expanding our global footprint in one of the world’s fastest growing markets and reaching more people living with severe autoimmune diseases. By leveraging Zai Lab’s strong local expertise within Greater China and proven development capabilities, we aim to provide broad access to efgartigimod in these important markets as well as accelerate the number of autoimmune indications in clinical development,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “We believe that Zai Lab is the ideal partner for us ahead of our first potential approval of efgartigimod in generalized myasthenia gravis (gMG) in the U.S. and we are aligned in our mutual passion to bring potential innovative immunology therapies to patients in need.”

“argenx is building a leading immunology company and we are excited to collaborate with them during this important time. Efgartigimod is being evaluated in a broad range of autoimmune diseases and we look forward to bringing this potentially first-in-class product to patients in Greater China,” said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. “This collaboration also significantly expands and strengthens our pipeline in severe autoimmune diseases, where there is an urgent and serious need for new therapeutic options.”

“There are an estimated 200,000 people living with MG in China,” said Dr. Harald Reinhart, Chief Medical Officer for Autoimmune and Infectious Diseases, Zai Lab. “The unmet medical need is significant for these patients, with very limited treatment options. We believe efgartigimod has a promising profile that, if approved, can potentially change the treatment paradigm not only of gMG but of other autoimmune diseases.”

Under the terms of the agreement, Zai Lab obtains the exclusive right to develop and commercialize efgartigimod in Greater China. Zai Lab will recruit Chinese patients to argenx’s global registrational trials for the development of efgartigimod. Additionally, this agreement is expected to allow argenx to accelerate efgartigimod development by initiating multiple Phase 2 proof-of-concept trials in new autoimmune indications.

argenx will receive $175 million in collaboration payments, comprised of a $75 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132.00 per share, $75 million as a guaranteed non-creditable, non-refundable development cost-sharing payment, and an additional $25 million milestone payment upon approval of efgartigimod in the U.S. argenx is also eligible to receive tiered royalties (mid-teen to low-twenties on a percentage basis) based on annual net sales of efgartigimod in Greater China.

About Efgartigimod

Efgartigimod is an investigational 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. Blocking FcRn reduces IgG antibody levels, representing a logical potential therapeutic approach for several autoimmune diseases known to be driven by disease-causing IgG antibodies, including: myasthenia gravis (MG), a chronic disease that causes muscle weakness; pemphigus vulgaris (PV), a chronic disease characterized by severe blistering of the skin; immune thrombocytopenia (ITP), a chronic bruising and bleeding disease; and chronic inflammatory demyelinating polyneuropathy (CIDP), a neurological disease leading to impaired motor function.

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx is evaluating efgartigimod in multiple serious autoimmune diseases, and cusatuzumab in hematological cancers in collaboration with Janssen. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, and Japan. For more information, visit www.argenx.com and follow us on LinkedIn at https://www.linkedin.com/company/argenx/.

About Zai Lab

Zai Lab (NASDAQ:ZLAB; HKEX: 9688) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer and infectious and autoimmune diseases to patients in China and around the world. We aim to address significant unmet medical needs in large, fast-growing segments of the pharmaceutical market. 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 drug candidates. We have also built an in-house team with strong drug discovery and translational research capabilities and are establishing a pipeline of proprietary drug 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 on Linkedin at https://www.linkedin.com/company/zai-lab/mycompany/ and Twitter at www.twitter.com/ZaiLab_Global.

argenx Contacts

Media:

Kelsey Kirk
KKirk@argenx.com

Investors:

Beth DelGiacco
bdelgiacco@argenx.com

Joke Comijn (EU)
jcomijn@argenx.com

Zai Lab Contacts

Billy Cho, CFO
+86 137 6151 2501
billy.cho@zailaboratory.com

Media: Ryo Imai / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006 ext. 315 / 364
rimai@burnsmc.com / rflamm@burnsmc.com

Investors: Mike Zanoni
Endurance Advisors, on behalf of Zai Lab
610-442-8570
mzanoni@enduranceadvisors.com

argenx Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, forward-looking statements. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, intends, may, will, or should, and include statements argenx makes concerning the therapeutic potential of its product candidates; the intended results of its strategy; the expected benefits of the collaboration with Zai Lab; its and its collaboration partners' clinical development and regulatory plans, including the timing, design and outcome of ongoing and planned clinical trials and the timing and outcome of regulatory filings and approvals; and the timing and progress of commercialization activities. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including the effects of the COVID-19 pandemic, the inherent uncertainties associated with preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing efgartigimod in Greater China. 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.