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): November 23, 2020

LIGAND PHARMACEUTICALS INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-33093**	**77-0160744**
(State or other jurisdiction of incorporation or organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

3911 Sorrento Valley Boulevard, Suite 110	
San Diego	
CA	**92121**
(Address of principal executive offices)	*(Zip Code)*

(858) 550-7500

(Registrant's Telephone Number, Including Area Code)

N/A

(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:

☐ 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(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	LGND	The Nasdaq Global Market

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 8.01 Other Events.

On November 23, 2020, Ligand Pharmaceuticals Incorporated (“Ligand” or the “Company”) announced clinical and regulatory progress by multiple partners utilizing antibodies from its OmniAb® discovery platform. Two large multinational pharmaceutical companies with a license to OmniAb have reached clinical-development milestones with their programs. The progress by these companies resulted in a total of $4.5 million in milestone payments being earned by Ligand.

In addition, CStone Pharmaceuticals (“CStone”) recently announced that China’s National Medical Products Administration has accepted for review CStone’s New Drug Application (“NDA”) for sugemalimab (CS1001), an OmniAb-derived anti-PD-L1 monoclonal antibody used in combination with chemotherapy for the first-line treatment of advanced squamous and non-squamous non-small cell lung cancer (“NSCLC”). This marks the first regulatory submission by CStone for sugemalimab. Last month, CStone announced a major financial and commercial partnership with Pfizer to commercialize sugemalimab in greater China. Ligand is entitled to a 3% royalty on worldwide commercial sales of sugemalimab.

CStone also announced that positive clinical data based on a pre-planned interim analysis of the GEMSTONE-302 clinical study were disclosed in an oral presentation at European Society for Medical Oncology (ESMO) Asia Virtual Congress 2020 on November 21, 2020. The GEMSTONE-302 trial is the first randomized, double-blind, Phase 3 study of an anti-PD-L1 monoclonal antibody plus platinum-based chemotherapy as first-line treatment for stage IV squamous or non-squamous NSCLC. The results showed sugemalimab plus chemotherapy as first-line treatment for advanced NSCLC demonstrated statistically significant and clinically meaningful benefit in progression free survival (PFS) compared to chemotherapy across PD-L1 expression levels and histologies. Specifically, sugemalimab in combination with chemotherapy reduced the risk of disease progression or death by 50% and produced an objective response rate (ORR) of 61.4%. The combination therapy was well-tolerated with no new safety signals detected.

Forward-Looking Statements

This report contains forward-looking statements by Ligand that involve risks and uncertainties and reflect Ligand's judgment as of the date of this report. These forward-looking statements include, without limitation, statements regarding: the potential that any OmniAb-derived antibodies will receive regulatory approval or whether Ligand will receive any OmniAb royalty revenue thereafter; and the potential that CS1001 could be approved to treat lung cancer patients. Actual events or results may differ from Ligand’s expectations due to risks and uncertainties inherent in Ligand’s business, including, without limitation: regulatory authorities such as China’s National Medical Products Administration or the FDA may not agree with CStone’s interpretation of the results from the Phase 3 clinical trial; CS1001 may not be approved for lung cancer or any other indication and Ligand may not receive any additional payments or royalties from the development of CS1001; Ligand may not generate expected revenues under its existing OmniAb license agreements; Ligand's partners may terminate any of its agreements or development or commercialization of any of its products; the OmniAb platform faces specific risks, including the fact that no product using antibodies from the platform has been approved by the FDA or similar regulatory agency; unexpected adverse side effects or inadequate therapeutic efficacy of Ligand’s or Ligand’s partners’ product(s) could delay or prevent regulatory approval or commercialization; and other risks described in Ligand’s prior filings with the SEC. The failure to meet expectations with respect to any of the foregoing matters may reduce Ligand's stock price. Ligand disclaims any intent or obligation to update these forward-looking statements after the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

SIGNATURES

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

LIGAND PHARMACEUTICALS INCORPORATED

Date: November 23, 2020

By: /s/ Charles S. Berkman
Name: Charles S. Berkman
Title: Senior Vice President, General Counsel and Secretary