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): August 16, 2021

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.)*

5980 Horton Street, Suite 405 **Emeryville** **CA**	**94608**
(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 Information

On August 16, 2021, 2021, Ligand Pharmaceuticals Incorporated ("Ligand") announced that its partner Travere Therapeutics, Inc. ("Travere") announced positive topline interim results from the ongoing pivotal Phase 3 PROTECT Study of sparsentan, an investigational product candidate for the treatment of IgA nephropathy ("IgAN"). The PROTECT Study met its pre-specified interim primary efficacy endpoint with statistical significance, demonstrating a greater than threefold reduction of proteinuria from baseline after 36 weeks of treatment, compared to the active control irbesartan ($p<0.0001$). Preliminary results from the interim analysis suggest that to date in the study, sparsentan has been generally well-tolerated and consistent with the observed safety profile to date. Based on the results from the interim analysis, Travere plans to submit an application for accelerated approval in the U.S. in the first half of 2022 and also plans to submit an application for conditional marketing authorization in Europe.

Under a license agreement with Travere for sparsentan, Ligand is entitled to receive a net $5.9 million milestone upon NDA submission, other potential milestone payments and net royalties of 9% on future worldwide sales by Travere.

To maintain integrity in the ongoing study, Travere is providing limited data from the interim analyses. In the PROTECT Study, a total of 404 patients with persistent proteinuria despite active ACE or ARB treatment, were randomized 1:1 to receive once daily oral doses of either sparsentan or irbesartan, the active control. The study protocol provided for an unblinded analysis to evaluate the interim efficacy endpoint – the change in proteinuria (urine protein-to-creatinine ratio, or "UPCR") at Week 36 from baseline – following the first approximately 280 patients reaching 36 weeks of treatment. After 36 weeks of treatment, patients receiving sparsentan experienced a 49.8 percent mean reduction of proteinuria from baseline after 36 weeks, more than threefold the mean reduction in proteinuria from baseline of 15.1 percent for irbesartan-treated patients ($p=0.0001$).

The secondary endpoints of the PROTECT Study include the rate of change in estimated glomerular filtration rate ("eGFR") following the initiation of randomized treatment over 58-week and 110-week periods, as well as the rate of change in eGFR over 52-week and 104-week periods following the first six weeks of randomized treatment. Travere said they believe that preliminary eGFR data available at the time of the interim analysis are indicative of a potential clinically meaningful treatment effect after two years of treatment. Consistent with the PROTECT Study protocol, patients will continue in a blinded manner in the PROTECT Study to fully assess the treatment effect on eGFR slope over 110 weeks in the confirmatory endpoint analysis. Topline results from the confirmatory endpoint analysis are expected in the second half of 2023.

A preliminary review of the interim safety results indicate sparsentan has been generally well-tolerated and consistent with the previously observed safety profile with no new safety signals emerging.

Travere is also evaluating sparsentan for the treatment of focal segmental glomerulosclerosis ("FSGS") in the ongoing pivotal Phase 3 DUPLEX Study and remains on track to provide a regulatory update during the third quarter of 2021.

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 timing and amount of milestone payments Ligand expects; the potential to receive royalties, and the potential royalty term, from future worldwide sales of sparsentan, if approved by the U.S. Food and Drug Administration ("FDA") or other regulatory agencies; Travere's expectations around the timeline for submitting an application for accelerated approval regulatory submissions for sparsentan in IgAN based on the available data set from the PROTECT interim analysis, the potential for sparsentan to become the first medicine approved for both FSGS and IgAN and references to the efficacy, safety and tolerability profile of sparsentan based on the preliminary data from the PROTECT Study interim analysis. Actual events or results may differ from Ligand's expectations due to risks and uncertainties inherent in Ligand's business, including, without limitation: the FDA may not accept

Travere's NDA submission for review; the risk that the Phase 3 PROTECT Study of sparsentan in IgAN will not demonstrate that sparsentan is safe or effective or serve as a basis for accelerated approval of sparsentan as planned; the FDA may not agree with Travere's interpretation of results from the PROTECT trial or other clinical trial data; the FDA may request additional data in connection with its review of the sparsentan NDA; Ligand is dependent on Travere on the development and, if approved, commercialization of sparsentan and Travere may not generate net sales to generate royalties payable to Ligand; 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: August 16, 2021

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