

LIGAND PHARMACEUTICALS INC

Form 8-K

December 18, 2018

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): December 17, 2018

LIGAND PHARMACEUTICALS INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

Delaware

001-33093

77-0160744

(State or other jurisdiction of (Commission File Number) (I.R.S. Employer

incorporation or organization)

Identification No.)

3911 Sorrento Valley Boulevard, Suite 110 92121

San Diego, CA

(Zip Code)

(Address of principal executive offices)

(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))

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.

On December 17, 2018, Ligand Pharmaceuticals Incorporated (“Ligand”) entered into a development funding and royalties agreement (the “Royalty Agreement”) with Palvella Therapeutics, Inc. (“Palvella”), pursuant to which Ligand will receive certain payments at specified milestones, as well as royalties on any future net sales of PTX-022, a product candidate being developed to treat pachyonychia congenita (“PC”). Ligand paid Palvella an upfront payment of \$10.0 million, which Palvella is required to use to fund the development of PTX-022. Ligand will not incur any expenses to develop or commercialize PTX-022.

PC is a serious, chronically debilitating genetic disorder that results in malformation of the skin and severely limits the mobility and quality-of-life of those affected. Palvella’s PTX-022 program has received Fast Track and Orphan Drug designations for treatment of PC from the U.S. Food and Drug Administration (“FDA”). PC affects up to 10,000 people in the U.S. and no FDA-approved therapies exist to treat the disorder.

Pursuant to the Royalty Agreement, Ligand will receive up to \$8.0 million of milestone payments upon the achievement by Palvella of certain regulatory milestones for PTX-002 and corporate and financing milestones. In addition to the milestone payments, Palvella will pay Ligand tiered royalties from 5.0% to 9.8% based on aggregate annual worldwide net sales of any PTX-022 products, if approved, subject to Palvella’s right to reduce the royalty rates by making payments in certain circumstances.

Unless earlier terminated, the Royalty Agreement will continue for as long as payments are due or payable under the Royalty Agreement. Ligand may terminate the Royalty Agreement for any or no reason upon 90 days prior written notice to Palvella. In addition, Ligand may terminate the Royalty Agreement in the event of an uncured material breach by Palvella.

The foregoing description of certain terms contained in the Royalty Agreement does not purport to be complete and is qualified in its entirety by reference to the copy of the Royalty Agreement to be filed with the Company’s Annual Report on Form 10-K for the period ending December 31, 2018 and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

d) Exhibits.

To be filed with Ligand’s Annual Report on Form 10-K for the period ending December 31, 2018.

Exhibit No.	Description
10.1	Development Funding and Royalties Agreement, dated December 17, 2018, by and between Ligand Pharmaceuticals Incorporated and Palvella Therapeutics, Inc.

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 comments regarding Palvella’s planned clinical development program for PTX-022; the potential for future regulatory and financing milestones as well as royalties from net sales of PTX-022, if approved; the possibility that PTX-022 will show clinical benefit to treat patients with PC; and the size of the PC patient population. Actual events or results may differ from Ligand’s expectations. For example, the development of PTX-022 is entirely dependent on Palvella’s success and Ligand will

have no ability to direct the development program; Palvella may abandon the development

of PTX-022 under certain circumstances; there can be no assurance that Palvella will be able to successfully develop PTX-022, including initiation of a Phase 2/3 clinical trial that supports filing a new drug application (“NDA”) to the FDA; the FDA could require additional clinical trials than the planned clinical trials and the Phase 2/3 clinical trial may not be able to serve as a sufficient basis for an NDA filing with the FDA; Palvella’s planned Phase 2/3 clinical trial could fail to reach its primary endpoints or show sufficient safety or efficacy to continue development or submit an NDA to the FDA; the FDA could rescind Fast Track or Orphan Drug designations previously granted to PTX-022; and even if approved, Palvella may not successfully launch PTX-022. Many of these risks also apply to the other programs which comprise Ligand’s shots-on-goal portfolio. The failure to meet expectations with respect to any of the foregoing matters may reduce Ligand's stock price. Additional information concerning these and other important risk factors affecting Ligand (including Ligand’s current reliance on revenues based on sales of Promacta® and Kyprolis®, and various risks to which Ligand’s Captiso® cyclodextrin operations are subject) can be found in Ligand's prior periodic filings with the Securities and Exchange Commission (including its Form 10-K filed on March 1, 2018), available at www.sec.gov, as updated by future period reports filed with the Securities and Exchange Commission. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this report. 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

By: /s/ Charles Berkman

Date: December 18, 2018 Name: Charles Berkman

Title: Senior Vice President, General Counsel and Secretary