

LIGAND PHARMACEUTICALS INC
Form 8-K
November 25, 2015

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 19, 2015

LIGAND PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

001-33093
(Commission

77-0160744
(I.R.S. Employer

of Incorporation)

File Number)

Identification No.)

11119 North Torrey Pines Road, Suite 200, La Jolla, California 92037

(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))

Item 8.01 Other Information.

On November 19, 2015, Ligand Pharmaceuticals Incorporated (Ligand) entered into a License Agreement and a Supply Agreement with Vireo Health, LLC (Vireo) granting Vireo an exclusive right in certain states within the United States and certain global territories to use Captisol® in Vireo s development and commercialization of pharmaceutical-grade cannabinoid-based products. Vireo operates in the medical-model cannabis industry with an established team of licensed physicians, pharmaceutical chemists, and personnel with appropriate legal, regulatory, financial and operational experience. Vireo has received state licenses to operate fully-integrated pharmaceutical-grade medical cannabis businesses in New York and Minnesota. Vireo is planning to expand as additional states conduct their licensure processes, and it also plans to seek appropriate federal or other pharmaceutical regulatory authorities approval for marketing products with Captisol in the United States and multiple other countries.

Under the License Agreement, Ligand will receive an upfront payment and could also potentially receive milestone payments, plus tiered royalties from 4% to 10% on net sales for products that use the Captisol technology. Ligand will also receive revenue from any shipment of Captisol to Vireo for clinical and commercial use.

The ability to use Captisol, a patented cyclodextrin solubilizing agent used in numerous drugs approved by the U.S. Food and Drug Administration (the FDA), may help scientists and physicians at Vireo overcome formulation hurdles unique to cannabinoid-based products. Vireo believes that peer-reviewed scientific literature supports the utility and potential for significant benefits of using cyclodextrins with cannabinoids, illustrating improved solubility, chemical stability and bioavailability. Vireo s goal is to incorporate Captisol into cannabinoid-based medicines in order to design novel, patent-protected, FDA-approved dosage formats that have been previously unavailable to physicians, caregivers and patients. Possible methods of administration include oral, nasal, topical and nebulized delivery.

Vireo s territories include states of the United States in which Vireo or its affiliates have a valid state license, certification or approval to produce and/or dispense cannabis included or derived medicines, and countries where Vireo is seeking or plans to seek federal pharmaceutical regulatory authority approval. Notwithstanding any state law, Ligand s agreements with Vireo and its conduct pursuant to those agreements may be challenged under United States federal law. Defending such charges could involve significant legal expenses and any violation could result in substantial penalties and fines. Either party may terminate the agreements or key provisions or geographies thereunder for breach, bankruptcy of the other party, or convenience.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements by Ligand that involve risks and uncertainties and reflect Ligand s judgment as of the date of this release. Words such as plans, believes, expects, anticipates, and will, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding: Vireo s development and commercialization plans, the potential for Captisol to improve solubility, chemical stability or bioavailability in Vireo s drug candidates, the possibility of state or Federal enforcement of laws involving cannabinoids, and Vireo s plans to expand its licensure procedures to other territories. Actual events or results may differ from Ligand s expectations. For example, the federal government could choose to enforce existing federal laws prohibiting cannabinoids, states which currently permit medical-model cannabinoids could prohibit the use, sale and development of such products in the future, the FDA may reject any new drug application involving cannabinoids, or Vireo may change its development plans away from FDA-approved drug candidates. Additional information concerning these and other risk factors affecting Ligand can be found in prior press releases available at www.ligand.com as well as in Ligand s public periodic filings with the Securities and Exchange Commission available at

www.sec.gov. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|-------------|--|
| 99.1 | License Agreement, dated November 19, 2015, between CyDex Pharmaceuticals, Inc. and Vireo Health, LLC. |
| 99.2 | Supply Agreement, dated November 19, 2015, between CyDex Pharmaceuticals, Inc. and Vireo Health, LLC. |

Confidential treatment has been requested for portions of this exhibit. These portion have been omitted and submitted separately to the Securities and Exchange Commission.

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.

LIGAND PHARMACEUTICALS INCORPORATED

Date: November 25, 2015

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