

LIGAND PHARMACEUTICALS INC
Form 8-K
May 18, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): May 13, 2010

LIGAND PHARMACEUTICALS INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

001-33093
(Commission
File Number)

77-0160744
(I.R.S. Employer
Identification No.)

11085 North Torrey Pines Road, Suite 300, La Jolla, California, 92037

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(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 Events.

On May 13, 2010, Pfizer Inc. (NYSE: PFE) announced in a Form 10-Q filed with the U.S. Securities and Exchange Commission that it is in the process of withdrawing its New Drug Applications (NDA s) with the U.S. Food and Drug Administration (FDA) relating to Fablyn (lasofoxifene tartrate). As previously disclosed, Fablyn is a selective estrogen receptor modulator (SERM) product candidate that resulted from a collaboration between Pfizer and Ligand Pharmaceuticals Incorporated (the Company or Ligand) formed to develop therapies for osteoporosis. Pfizer submitted an NDA to the FDA and a marketing authorization application (MAA) to the European Medicines Agency (EMEA) for Fablyn for the treatment of osteoporosis in December 2007 and January 2008, respectively, and in February 2009, Pfizer received approval from the European Commission for Fablyn tablets. Under the terms of the Company s agreement with Pfizer, Ligand is entitled to receive royalty payments on worldwide net sales of lasofoxifene for any indication. Pfizer has indicated that it is exploring strategic options for Fablyn, including out-licensing or sale.

Other product candidates, Viviant and Aprela, resulting from the Company s collaboration arrangements with Pfizer remain under development. Two approvable letters were received by Wyeth (now Pfizer) in April and December 2007 from the FDA for Viviant (bazedoxifene) for the prevention of post-menopausal osteoporosis that set forth the additional requirements for approval. In May 2008, Wyeth received an approvable letter from the FDA for the treatment of post-menopausal osteoporosis. Pfizer has been systematically working to address the FDA s concerns. In February 2008, the FDA advised Wyeth that it expects to convene an advisory committee to review the pending NDAs for both the treatment and prevention indications. In April 2009, Wyeth received approval in the EU for CONBRIZA (the EU trade name for Viviant) for the treatment of post-menopausal osteoporosis in women at increased risk of fracture.

Pfizer is also developing Aprela (bazedoxifene/conjugated estrogens) for the treatment of menopausal vasometer symptoms and an NDA is planned in 2H 2010.

SIGNATURES

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

LIGAND PHARMACEUTICALS INCORPORATED

Date: May 18, 2010

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