

THERAVANCE INC
Form 8-K
November 18, 2013

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: November 18, 2013
(Date of earliest event reported)

Theravance, Inc.
(Exact name of registrant as specified in its charter)
Delaware
(State or other jurisdiction
of incorporation) 000-30319
(Commission File Number) 94-3265960
(IRS Employer
Identification Number)
901 Gateway Boulevard, South San Francisco, CA
(Address of principal executive offices) 94080
(Zip Code)
650-808-6000
(Registrant's telephone number, including area code)
Not Applicable
(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 (see General Instruction A.2. below):

- ☐ 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))

o 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 November 18, 2013, GlaxoSmithKline plc (GSK) and Theravance, Inc. issued a press release announcing that the European Commission has granted marketing authorization for RELVAR(R) ELLIPTA(R), which is now licensed across 31 European countries for the following uses:

Asthma: the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate:

-- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short- acting beta2-agonists

COPD: the symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.

Relvar is a combination of the inhaled corticosteroid (ICS), fluticasone furoate "FF", and the long-acting beta2-agonist (LABA), vilanterol "VI" (FF/VI). Two strengths of FF/VI have been licensed for the treatment of asthma (92/22 mcg and 184/22 mcg) and one strength has been licensed for the treatment of COPD (92/22 mcg). Both strengths will be administered once-daily using Ellipta, a new dry powder inhaler (DPI). Under the terms of the 2002 LABA collaboration agreement, Theravance is obligated to make a milestone payment to GSK of \$15 million (USD) following marketing authorization for Relvar Ellipta from the European Commission. A further \$15 million (USD) payment to GSK will follow the launch of Relvar Ellipta in Europe. FF/VI is in development under the LABA collaboration between Glaxo Group Limited and Theravance, Inc. A copy of the press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release dated November 18, 2013

SIGNATURE

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.

Dated: November 18, 2013

THERAVANCE, INC.

By: /s/ Michael W. Aguiar

Michael W. Aguiar

Chief Financial Officer

Exhibit Index **Exhibit No.** **Description** 99.1 Press Release dated November 18, 2013