THERAVANCE INC
Form 8-K
December 16, 2013

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): December 16, 2013

THERAVANCE, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	000-30319	94-3265960
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

901 Gateway Boulevard
South San Francisco, California 94080
(650) 808-6000
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o 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.

Theravance, Inc. is reporting positive results from a Glaxo Group Limited Phase 3b efficacy and safety study of umeclidinium “UMEC”/vilanterol “VI” in patients with chronic obstructive pulmonary disease (COPD). This is a 24-week, double-dummy, parallel group, multicenter study to assess the efficacy and safety of UMEC/VI 62.5/25mcg inhalation powder administered once-daily in the new dry powder inhaler, ELLIPTA™, compared to tiotropium 18mcg administered once-daily in the HandiHaler®. A total of 905 patients with COPD were randomized 1:1 to UMEC/VI 62.5/25mcg inhalation powder or tiotropium 18mcg.

For the pre-specified primary endpoint of trough forced expiratory volume in one second (FEV1) at the end of the treatment period (Day 169), UMEC/VI 62.5/25mcg demonstrated a statistically significant change from baseline compared with tiotropium 18mcg ($p<0.001$). The magnitude of the difference between UMEC/VI 62.5/25mcg and tiotropium 18mcg was similar to the two earlier active comparator efficacy studies.

The most common reported side effects for both UMEC/VI 62.5/25mcg and tiotropium 18mcg included headache, nasopharyngitis, cough and back pain. The incidence of any on-treatment serious adverse events in both treatment arms was similar.

UMEC/VI is a combination of two investigational bronchodilator molecules -- GSK573719 or UMEC, a long-acting muscarinic antagonist (LAMA) and VI, a long-acting beta2 agonist (LABA), administered using the ELLIPTA™ inhaler. UMEC/VI is in development under the 2002 LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc.

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.

THERAVANCE, INC.

Date: December 16, 2013 By: /s/ Michael W. Aguiar
Michael W. Aguiar
Chief Financial Officer