

THERAVANCE INC
Form 8-K
September 06, 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): September 6, 2013

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 (I.R.S. Employer Identification Number)
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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):

- 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 September 6, 2013, the U.S. Food and Drug Administration (FDA) posted on its website briefing documents for the September 10, 2013 Pulmonary-Allergy Drugs Advisory Committee (PADAC) meeting. The PADAC will be asked to discuss the new molecular entity New Drug Application (NDA) 203975 for umeclidinium bromide and vilanterol dry powder for inhalation (proposed trade name ANORO™ ELLIPTA™), sponsored by Glaxo Group (d/b/a GSK) for the long-term, once-daily, maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. UMEC/VI is a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium bromide (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the ELLIPTA™ inhaler. UMEC/VI is in development under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc.

The GSK Briefing Document and the FDA Briefing Document are now available at:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/>

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: September 6, 2013

By: /s/ Michael W. Aguiar
Michael W. Aguiar
Chief Financial Officer