THERAVANCE INC
Form 8-K/A
December 02, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K/A

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 2, 2011**

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.

On November 17, 2011, Theravance, Inc. (Theravance) filed a Current Report on Form 8-K with the Securities and Exchange Commission (the SEC) disclosing that we were informed by Astellas Pharma US, Inc. (Astellas), the exclusive licensee of VIBATIV® (telavancin for injection) pursuant to the License, Development and Commercialization Agreement with Theravance, Inc. dated November 7, 2005, as amended, that on November 16, 2011 Astellas distributed a letter to wholesalers and distributors of VIBATIV® advising them of an issue that occurred at the third party manufacturer of VIBATIV® drug product. This manufacturer informed Astellas that it had notified the United States Food and Drug Administration (FDA) of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer s facility which remain within expiry, including current batches of VIBATIV®.

In the November 16, 2011 letter, Astellas communicated that it had decided to voluntarily place a hold on distribution of VIBATIV® to wholesalers until more information becomes available. Also, Astellas communicated that the duration of the distribution hold is difficult to predict and may result in product shortages.

On November 19, 2011, Astellas third party manufacturer of VIBATIV® drug product announced the voluntary shutdown of manufacturing and distribution at its facility due to significant manufacturing and quality concerns. According to its announcement, the manufacturer notified the FDA as soon as it made the decision to shut down. Further, the manufacturer s announcement reported that manufacturing and distribution of all products from the facility are currently on hold; however, products already in distribution will remain on the market until further analysis is complete.

On December 2, 2011, we were informed by Astellas that it had distributed letters to wholesalers and distributors of VIBATIV® and Healthcare Professionals advising them that Astellas voluntary distribution hold has now resulted in critical product shortages and regional supply outages. In these letters, Astellas recommended that no new patients should be initiated on VIBATIV® therapy until the production issue is resolved unless sufficient supply is available at the Healthcare Professional s institution.

A copy of the letters are filed as Exhibit 99.1 and Exhibit 99.2 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
Exhibit 99.1	Astellas Pharma US, Inc. Letter to Wholesalers and Distributors of VIBATIV® (telavancin for injection) dated December 2, 2011
Exhibit 99.2	Astellas Pharma US, Inc. Letter to Healthcare Professionals dated December 2, 2011

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 2, 2011

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

EXHIBIT INDEX

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