

THERAVANCE INC
Form 8-K
November 17, 2011

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): **November 16, 2011**

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)

901 Gateway Boulevard
South San Francisco, California 94080

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(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))
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Item 8.01 Other Events.

On November 16, 2011, 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, distributed a letter to wholesalers and distributors of VIBATIV® (telavancin for injection) advising them of an issue that has occurred at the third party manufacturer of VIBATIV®. The third party manufacturer informed Astellas that they have notified the United States Food and Drug Administration (FDA) of an ongoing investigation related to their production equipment and processes. The notification includes 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 has 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.

A copy of the letter is filed as Exhibit 99.1 to this report and is 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 November 16, 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: November 17, 2011

By:

/s/ Michael W. Aguiar

Michael W. Aguiar
Chief Financial Officer

EXHIBIT INDEX

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