

**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  
(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 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**

Exhibit 99.1

**Description**

Astellas Pharma US, Inc. Letter to Wholesalers and Distributors of VIBATIV® (telavancin for injection) dated November 16,

**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**

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Astellas Pharma US, Inc. Letter to Wholesalers and Distributors of VIBATIV® (telavancin for injection) dated November 16, 2011



Astellas Pharma US, Inc.

**Important Update Regarding the Availability of VIBATIV® (telavancin for injection)**

November 16, 2011

Dear Customer:

This communication is to advise you of an issue that has occurred at the third party manufacturer of VIBATIV. The manufacturer has informed Astellas that they have notified the United States Food and Drug Administration of an ongoing investigation related to their production equipment and processes. The notification includes all products manufactured at their facility which remain within expiry, including current batches of VIBATIV.

Based on this information and our ongoing commitment to patient safety, Astellas Pharma US, Inc. has decided to voluntarily place a hold on distribution of VIBATIV to wholesalers until more information is available. Astellas is not withdrawing the product from the market and we are not requesting that our distributors and wholesalers stop selling the product.

Astellas is not aware of any adverse reactions or safety issues with the use of VIBATIV related to manufacturing concerns. We will continue to carefully evaluate the situation and inform you as new information becomes available.

The duration of the distribution hold is difficult to predict and may result in product shortages. When initiating or continuing VIBATIV therapy, Astellas recommends checking with the dispensing pharmacy for availability of VIBATIV.

Adverse reactions or quality problems experienced with the use of this product may be reported to Astellas Pharma US, Inc. at 1-800-727-7003 or FDA at

**Astellas Pharma US, Inc.**

Three Parkway North, Deerfield, IL 60015-2537

Tel: 1-800-888-7704 Fax: 1-800-688-6668

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1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

We are committed to resolving this issue and will continue to provide you with updates as new information becomes available. For information on the use of VIBATIV, please read the full U.S. prescribing information at [www.vibativ.com/PrescribingInformation.aspx](http://www.vibativ.com/PrescribingInformation.aspx) or contact Astellas Medical Information at 1-800-727-7003.

For product availability information, please do not hesitate to contact your Astellas Trade Account Director.

Sincerely,

Kenton Stewart  
Vice President Health Systems

**Astellas Pharma US, Inc.**

Three Parkway North, Deerfield, IL 60015-2537

Tel: 1-800-888-7704 Fax: 1-800-688-6668

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