

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 8-K/A**

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**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**

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**THERAVANCE, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**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)

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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 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

<u>Exhibit</u>	<u>Description</u>
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

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**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**

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**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 December 2, 2011
Exhibit 99.2	Astellas Pharma US, Inc. Letter to Healthcare Professionals dated December 2, 2011

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Astellas Pharma US, Inc.

**VIBATIV® (telavancin for injection) — Critical Supply Shortage**

December 2, 2011

Dear Wholesales/Distributor:

This letter is a follow up to our communication dated November 16, 2011 advising you of an issue that 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. made a decision to voluntarily place a hold on distribution of VIBATIV to wholesalers and distributors. The duration of the distribution hold is difficult to predict and has now resulted in critical product shortages and regional supply outages. As a precaution against these potential supply issues Astellas has recommended that **no new patients should be initiated on VIBATIV therapy** until this production issue is resolved (please see attached letter to Health Care Professionals).

We are working diligently with the third party manufacturer to resolve these issues and resume distribution of VIBATIV as soon as possible. We will continue to keep you informed of new information as it becomes available. In the meantime, please contact your Trade Director if you should have any questions.

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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Astellas Pharma US, Inc.

**VIBATIV® (telavancin for injection) — Critical shortage**

December 2, 2011

Dear Healthcare Professional:

This communication is a follow up to our initial communication dated November 16, 2011 advising 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. As a result, there is a critical shortage of VIBATIV.

The duration of the distribution hold is difficult to predict and has now resulted in critical product shortages and regional supply outages. **While Astellas is not withdrawing the product from the market, we recommend that patients not be initiated on VIBATIV therapy unless sufficient supply is available at your institution.**

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.

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

**011K-022-4628-1**



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.

Sincerely,

M. Joyce Rico, MD  
Vice President, Medical Affairs  
Astellas Pharma Global Development, Inc.

**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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