THERAVANCE INC
Form 8-K
January 06, 2012

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): **January 6, 2012**

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 1.01 Entry into a Material Definitive Agreement.

On January 6, 2012, Theravance, Inc. (Theravance) and Astellas Pharma Inc. (Astellas) entered into an amendment to the License, Development and Commercialization Agreement for VIBATIV® (telavancin) for injection, a bactericidal, once-daily lipoglycopeptide antibiotic discovered by Theravance. The amendment provides, among other things, that upon termination of the Agreement, Astellas will transfer inventory to Theravance and, to support a smooth transition, manage certain clinical and regulatory activities and respond to medical inquiries with respect to VIBATIV® until no later than March 31, 2012. This general description of the amendment is subject to the specific terms and conditions contained in the amendment.

A copy of the form of amendment is filed as Exhibit 10.1 to this report and is incorporated herein by reference.

Item 1.02 Termination of a Material Definitive Agreement.

On January 6, 2012, Theravance and Astellas announced that Astellas has exercised its right to terminate the global License, Development and Commercialization Agreement for VIBATIV® (telavancin) for injection dated November 7, 2005, as amended (the Agreement). The termination of the Agreement is effective as of January 6, 2012.

Under the terms of the Agreement, Theravance granted Astellas an exclusive license to develop and commercialize VIBATIV® worldwide in consideration for an upfront payment and potential milestone and royalty payments. Theravance was responsible for substantially all costs to develop and obtain U.S. regulatory approval for VIBATIV® for the treatment of complicated skin and skin structure infections (cSSSI) and nosocomial-pneumonia and to manufacture drug product for the first six months of commercialization in the U.S., and Astellas was responsible for substantially all other costs associated with commercialization of VIBATIV® , which includes seeking regulatory approval for VIBATIV® outside of the U.S., commercializing VIBATIV® following regulatory approval, and supplying drug product for commercialization.

The rights granted to Astellas ceased upon termination of the Agreement and Astellas has stopped promotional sales efforts. Pursuant to the terms of the Agreement, there are no termination payments required by either party and Astellas is entitled to a ten-year, 2% royalty on net sales of VIBATIV®. This general description of the termination provisions of the Agreement is subject to the specific terms and conditions contained in the Agreement.

Due to manufacturing issues at the single-source supplier of drug product, VIBATIV® is currently subject to critical product shortages and regional supply outages. If these issues at the manufacturer are not promptly resolved, obtaining supply would require identifying and qualifying an alternative manufacturer, which could take 12 to 24 months.

A copy of the press release 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 10.1	Form of Amendment to License, Development and Commercialization Agreement between Theravance, Inc. and Astellas Pharma Inc.
Exhibit 99.1	Press Release dated January 6, 2012

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: January 6, 2012

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

EXHIBIT INDEX

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