
**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
(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))
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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.

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Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

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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: January 6, 2012

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

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EXHIBIT INDEX

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

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AMENDMENT NO. 2 TO THE LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

THIS AMENDMENT NO. 2 ("Amendment No. 2") is entered into this 6th day of January, 2012 ("Amendment Effective Date") and amends the License, Development and Commercialization Agreement dated November 7, 2005, by and between THERAVANCE INC., a Delaware corporation having its principal office at 901 Gateway Boulevard, South San Francisco, California 94080, U.S.A. ("THERAVANCE") and ASTELLAS PHARMA INC., a Japanese corporation having its principal office at 3-11, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo 130-8411, Japan ("ASTELLAS"), as previously amended July 18, 2006 (the "Agreement"). Unless otherwise specifically stated herein, capitalized terms used herein and not defined shall have the same meaning set forth in the Agreement. References to "Sections" and "Exhibits" herein shall mean the corresponding sections and exhibits set forth in the Agreement.

WHEREAS, ASTELLAS has notified THERAVANCE that ASTELLAS intends to terminate the Agreement under Section 14.03(ii) and Section 14.03(v); and

WHEREAS, the Parties have agreed to work together in transition of the Agreement in contemplation of such termination by ASTELLAS, in accordance with the Agreement as amended herein.

NOW THEREFORE, the Parties agree as follows:

1. Section 1.23 is hereby amended and restated to read as follows:

"Cost Of Goods Sold" means as applicable, either (a) the amounts paid to Third Party manufacturers for the manufacture and supply of Licensed Product to be sold hereunder or (b) the sum of the following costs to the extent directly related to Licensed Product to be sold hereunder: the cost of direct materials, direct labor, licensing costs (not including payments made pursuant to the Janssen Agreement) and manufacturing overhead related to the facility in which the Products are produced. Third Party manufacturers referred to in subsection (a) above includes THERAVANCE to the extent ASTELLAS purchased the goods from THERAVANCE. The Cost of Goods Sold shall exclude the following: corporate overhead and any allocable costs not generated in the manufacturing facility. The Cost of Goods Sold shall be calculated in a manner consistent with United States GAAP consistently applied and as generally used by the applicable Party.

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2. Section 15.01(a) is hereby amended as follows:

- (a) Section 15.01(a)(iii) is amended and restated as follows:

(iii) promptly after THERAVANCE'S request (which shall be made no later than March 31, 2012), deliver to THERAVANCE at the location specified by THERAVANCE any and all quantities of API Compound, Licensed Product and raw materials in its possession, power, custody or control subject always to ASTELLAS' right to dispose of Licensed Product which is the subject of pre-termination date orders. In addition, upon THERAVANCE's request (which shall be made no later than March 31, 2012), ASTELLAS shall use Diligent Efforts to release and transfer to THERAVANCE the unreleased Licensed Product batches manufactured by Ben Venue Laboratories ("BVL") that are identified on the four purchase orders set forth on Attachment 1 hereto ("Unreleased Licensed Product"). Two batches of the Unreleased Licensed Product are packaged with ASTELLAS labeling, and the other two batches are not packaged. THERAVANCE shall ensure that neither of the two unpackaged batches will be packaged with ASTELLAS labeling, provided, however, that in the event that a packaged batch fails to be released by both BVL and ASTELLAS, THERAVANCE (at its own cost) shall be permitted to package one of the unpackaged batches with ASTELLAS labeling (according to ASTELLAS-provided labeling and packaging standards) so long as that unpackaged batch has been released by BVL and ASTELLAS. Further, notwithstanding anything to the contrary in the Agreement, THERAVANCE acknowledges and agrees that: (a) the Unreleased Licensed Product is currently on a quality hold issued by BVL; (b) the Unreleased Licensed Product has not been released by BVL or ASTELLAS; (c) ASTELLAS makes no representations or warranties that the Unreleased Licensed Product will ever be released by BVL or by ASTELLAS (even if released by BVL); (d) any determination by ASTELLAS regarding release of the Unreleased Licensed Product to THERAVANCE shall be made in accordance with ASTELLAS' customary procedures and policies; and (e) if the Unreleased Licensed Product is not released by both BVL and ASTELLAS by December 31, 2012, ASTELLAS' obligation to transfer Unreleased Licensed Product shall terminate. THERAVANCE shall be obligated to take delivery of and purchase any quantities of Unreleased Licensed Product that it requests ASTELLAS to release hereunder, provided, however, that such Unreleased Licensed Product is first released by both BVL and Astellas. THERAVANCE shall pay for the API Compound, Licensed Product and raw materials transferred to it hereunder in an amount equal to ASTELLAS' Cost of Goods Sold for such quantities.

- (b) Section 15.01(a)(viii) is deleted in its entirety.

3. Notwithstanding the contemplated termination of the Agreement, ASTELLAS agrees to continue to perform the following activities on THERAVANCE's behalf until such activities can be transitioned to THERAVANCE or THERAVANCE's designee, but in any event no later than March 31, 2012:

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- (i) Perform those activities that are the responsibility of ASTELLAS under the Parties' "Safety Data Exchange Agreement Pertaining to Telavancin" dated October 1, 2008 ("SDEA"), upon completion of which activities by ASTELLAS, and in any event no later than March 31, 2012, the SDEA shall terminate;
- (ii) Respond to medical information inquiries with respect to Licensed Product that may be received by ASTELLAS' Medical Information Department;
- (iii) Manage the Risk Evaluation and Mitigation Strategies ("REMS") program identified in the NDA for Licensed Product;
- (iv) Manage the Pregnancy Registry identified in the NDA for Licensed Product; and

(v) sell Licensed Product in the U.S. solely in response to unsolicited purchase requests by prescribers who have demonstrated a critical medical need for a specific patient(s) ("Medically Necessary Supply Program").

For clarity, except with respect to Licensed Product supply under the Medically Necessary Supply Program, marketing and sale of Licensed Product by ASTELLAS shall cease as of the Amendment Effective Date.

The terms and conditions of the Agreement shall apply to ASTELLAS' conduct of the activities described in this Paragraph 3 as though the Agreement were in full force and effect.

4. THERAVANCE shall not encourage the sale of, or attempt to sell, Licensed Product under any ASTELLAS discount or rebate agreement that may be in effect on or after the Amendment Effective Date.

5. With respect to Licensed Product transferred to THERAVANCE hereunder that bears ASTELLAS' labeling and ASTELLAS NDC numbers ("ASTELLAS-Labeled Licensed Product"), ASTELLAS shall be liable for governmental rebate and chargeback claims associated with ASTELLAS-Labeled Licensed Product that are received on or before June 30, 2012. Thereafter, THERAVANCE shall be liable for all governmental rebate and chargeback claims associated with ASTELLAS-Labeled Licensed Product. ASTELLAS shall promptly forward to THERAVANCE any invoices for such ASTELLAS-Labeled Licensed Product rebate and chargeback claims that are THERAVANCE's financial responsibility.

6. Upon the Parties' execution of this Amendment, ASTELLAS shall execute and send to THERAVANCE the termination letter attached hereto as Attachment 2.

7. The Parties shall prepare and issue a joint press release to announce the termination of the Agreement.

In all other respects, the terms and conditions of the Agreement, and the rights and obligations of the Parties, shall remain unchanged.

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IN WITNESS WHEREOF, THERAVANCE and ASTELLAS have executed this Amendment No. 2 by their duly authorized representatives as of the Amendment Effective Date.

THERAVANCE, INC.

ASTELLAS PHARMA INC.

By:

By:

Name:

Name:

Title:

Title:

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Attachment 1
Purchase Orders

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Attachment 2
Termination Notice Letter

[ASTELLAS Letterhead]

By E-Mail and Overnight Courier

January 6, 2012

Leonard Blum
Senior Vice President, Commercial Development
Theravance, Inc.
901 Gateway Boulevard
South San Francisco, CA 94080

Re: License, Development and Commercialization Agreement Dated November 7, 2005 by and between Theravance, Inc. ("THERAVANCE") and Astellas Pharma Inc. ("ASTELLAS"), as amended July 18, 2006 and January 6, 2012 (the "Agreement")

Dear Mr. Blum:

This letter is in reference to the Agreement.

As contemplated by our recent discussions, pursuant to this letter ASTELLAS hereby terminates the Agreement under Section 14.03(ii) and Section 14.03(v) therein.

Very truly yours,

ASTELLAS PHARMA INC.

By: _____

Name: _____

Title: _____



Astellas and Theravance Announce Termination of License, Development and Commercialization Agreement for VIBATIV® (telavancin) for Injection

TOKYO, Japan and SOUTH SAN FRANCISCO, CA/January 6, 2012 — Astellas Pharma Inc. (Astellas) (Tokyo:4503) and Theravance, Inc. (NASDAQ: THRX) today announced that Astellas has exercised its right to terminate the global License, Development and Commercialization Agreement for VIBATIV® (telavancin) for injection, a bactericidal, once-daily lipoglycopeptide antibiotic discovered by Theravance. Theravance is evaluating global commercialization alternatives for VIBATIV either alone or with partners.

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.

To support a smooth transition, Astellas will transfer inventory to Theravance, manage certain clinical and regulatory activities and respond to medical inquiries with respect to VIBATIV until no later than March 31, 2012.

“We are proud of the important milestones we have achieved for patients throughout our partnership and are committed to working with Theravance to ensure a smooth transition,” said Yoshihiko Hatanaka, Chief Executive Officer of Astellas.

“We believe that VIBATIV is an important, life-saving medicine, and we appreciate Astellas’ commitment to a smooth transition. We will continue the focus on re-establishing consistent VIBATIV product supply. We will assess strategic alternatives for VIBATIV, including repartnering, and will provide updates later this year,” said Rick E Winningham, Chief Executive Officer of Theravance.

About VIBATIV

In September 2011 VIBATIV was approved in Europe for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. This approval included all member states of the EU, Norway and Iceland. VIBATIV was not approved for complicated skin and soft tissue infections in Europe.

VIBATIV was approved in Canada in September 2009 for the treatment of patients with complicated skin and skin structure infections (cSSSI) caused by susceptible strains of



certain Gram-positive bacteria, including MRSA.

VIBATIV was approved and launched in the United States in 2009 for the treatment of adult patients with cSSSI caused by susceptible Gram-positive bacteria, including *Staphylococcus aureus*, both MRSA and methicillin-susceptible (MSSA) strains. In January 2009 Theravance filed an NDA for approval of VIBATIV for treatment of patients with nosocomial pneumonia, which has not been approved.

For full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., please visit www.VIBATIV.com.

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 16,800 employees worldwide. The organization is committed to becoming a global category leader in Urology; Immunology, including Transplantation and Infectious Diseases; Oncology; Neuroscience and DM Complications and Metabolic Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

VIBATIV® is a registered trademark of Astellas Pharma Inc.

About Theravance

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. The Company’s key programs include: RELOVAIR™, LAMA/LABA (‘719/vilanterol (VI)) and MABA (Bifunctional Muscarinic Antagonist-Beta₂ Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist (PμMA) program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit the company’s web site at www.theravance.com.

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of Theravance, Inc.

RELOVAIR™ is a trademark of GlaxoSmithKline.



This press release contains certain “forward-looking” statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Theravance intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Exchange Act and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the timing of product commercialization, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning enabling capabilities of Theravance’s approach to drug discovery and its proprietary insights, and statements regarding expectations for product candidates through development and commercialization and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance to be materially different from those reflected in its forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to develop and commercialize products. These and other risks are described in greater detail under the heading “Risk Factors” contained in Theravance’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 2, 2011 and the risks discussed in our other period filings with SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements.

Contact Information:

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