

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report: September 15, 2011
(Date of earliest event reported)

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
(IRS Employer
Identification Number)

**901 Gateway Boulevard, South San Francisco,
CA**
(Address of principal executive offices)

94080
(Zip Code)

650-808-6000
(Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if changed since last report)

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:

- 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 September 15, 2011, Astellas Pharma Europe Ltd., subsidiary of Tokyo based Astellas Pharma Inc. and Theravance, Inc. (the "Company") issued a press release announcing that the European Commission has granted marketing authorization for VIBATIV(R) (telavancin hydrochloride) for the treatment of adults with nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. 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

99.1 [Press Release of Theravance, Inc. dated September 15, 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.

Dated: September 15, 2011

THERAVANCE, INC.

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

Exhibit Index

Exhibit No.

Description

99.1

Press Release of Theravance, Inc. dated September 15, 2011

Astellas and Theravance Announce European Marketing Authorization for VIBATIV® for Nosocomial Pneumonia Caused by MRSA

New Treatment Option for Adult Patients with Nosocomial Pneumonia, Including Critically Ill Patients with Ventilator-Associated Pneumonia

SOUTH SAN FRANCISCO, CA -- (Marketwire - September 15, 2011) - Astellas Pharma Europe Ltd., a subsidiary of Tokyo based Astellas Pharma Inc., and Theravance, Inc. (NASDAQ: THRX) announced today that the European Commission has granted marketing authorization for VIBATIV® (telavancin hydrochloride), following the Committee for Human Medicinal Products' (CHMP) positive opinion in May 2011.(1) VIBATIV®, discovered by Theravance, Inc., is a bactericidal, once-daily injectable lipoglycopeptide antibacterial agent with a dual mechanism of action against Gram-positive bacteria, including resistant pathogens such as methicillin-resistant Staphylococcus aureus (MRSA).

The VIBATIV® marketing authorization from the European Commission is granted for the treatment of adults with nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. The marketing authorization for VIBATIV® is valid in all Member States of the European Community, and Norway and Iceland. Launch plans are under review by Astellas.

"The approval of VIBATIV® can provide European healthcare professionals with a new, effective hospital antibiotic option for patients with hospital-acquired pneumonia caused by MRSA," said Ken Jones, President and CEO of Astellas Pharma Europe.

"We are extremely excited about the European approval of VIBATIV® for the treatment of nosocomial pneumonia caused by MRSA," said Rick E Winningham, Theravance's Chief Executive Officer. "This is a significant milestone for the collaboration, marking the first approval for this indication. I believe VIBATIV® will be a valuable new therapy option for physicians in Europe treating this life-threatening infection."

Reference:

1. VIBATIV® European Marketing Authorization 14 September 2011. Available at <http://ec.europa.eu/health/documents/community-register/html/register.htm.txt>
Accessed 14 September 2011

About VIBATIV®

VIBATIV® is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby VIBATIV® both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. VIBATIV® is approved in the United States and in Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius and S. constellatus) and Enterococcus faecalis (vancomycin-susceptible isolates only). VIBATIV® is approved in Europe for the treatment of adults with nosocomial pneumonia including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. VIBATIV® has not been approved for the treatment of patients with nosocomial pneumonia in the United States and Canada or complicated skin and soft tissue infections in Europe.

VIBATIV® Important Safety Information (U.S.)

Fetal Risk

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV®. Avoid use of VIBATIV® during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV® treatment.

Nephrotoxicity

New onset or worsening renal impairment occurred in patients who received VIBATIV®. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV® prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV® versus discontinuing and initiating therapy with an alternative agent should be assessed. Clinical cure rates in telavancin-treated patients were lower in patients with baseline CrCl \leq 50 mL/min compared to those with CrCl $>$ 50 mL/min. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate/severe renal impairment.

Geriatric Use

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Infusion Related Reactions

VIBATIV® is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome"-like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

Clostridium difficile-Associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use.

Development of Drug Resistant Bacteria

Prescribing VIBATIV® in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. As with other antibacterial drugs, use of VIBATIV® may result in overgrowth of nonsusceptible organisms, including fungi.

QTc Prolongation

Caution is warranted when prescribing VIBATIV® to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV® prolonged the QTc interval. Use of VIBATIV® should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

Coagulation Test Interference

VIBATIV® does not interfere with coagulation, but does interfere with certain tests used to monitor coagulation such as prothrombin time, international normalized ratio, activated partial thromboplastin time, activated clotting time, and coagulation based factor Xa tests. Blood samples for these coagulation tests should be collected as close as possible prior to a patient's next dose of VIBATIV®.

Adverse Reactions

The most common adverse reactions ($\geq 10\%$ of patients treated with VIBATIV®) observed in the Phase 3 cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy urine.

In the Phase 3 cSSSI clinical trials, serious adverse events were reported in 7% of patients treated with VIBATIV® and most commonly included renal, respiratory, or cardiac events. Serious adverse events were reported in 5% of vancomycin-treated patients, and most commonly included cardiac, respiratory, or infectious events.

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

About the ATTAIN I and II Clinical Studies

Patients with nosocomial pneumonia suspected or proven to be caused by Gram-positive bacteria were enrolled in the ATTAIN program. This included ATTAIN I and ATTAIN II, two large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies, in which 1,503 patients were enrolled and treated either with VIBATIV® 10 mg/kg IV once daily or vancomycin 1 g IV every 12hr (the protocols allowed vancomycin dosage to be modified per site-specific guidelines). For patients with suspected or proven polymicrobial infections involving Gram-negative and/or anaerobic bacteria in addition to the Gram-positive organisms for which study medication therapy was used, aztreonam and piperacillin-tazobactam were allowed. The objective of each study was non-inferiority of VIBATIV® versus vancomycin in clinical cure rate at the test-of-cure visit. Determination of clinical cure was based upon physician-judged resolution of clinical signs and symptoms of nosocomial pneumonia. In both studies, VIBATIV® achieved the objective of non-inferiority compared to vancomycin.

About the VIBATIV® Collaboration

In November 2005, Theravance entered into a collaboration arrangement with Astellas Pharma Inc. for the development and commercialization of VIBATIV® worldwide except Japan. In July 2006, Theravance and Astellas expanded the collaboration to include Japan. Under the terms of the collaboration, Theravance is responsible for substantially all the costs to develop and obtain U.S. regulatory approval for telavancin for its initial indications. Theravance collaborates with Astellas in marketing in the United States for the first three years following approval.

About Astellas Pharma Inc.

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 16,000 employees worldwide. The organisation is committed to becoming a global category leader in Urology, Immunology including Transplantation and Infectious Diseases, Oncology, Neuroscience, DM Complications and Metabolic Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

About Astellas Pharma Europe Ltd.

Astellas Pharma Europe Ltd., located in the UK, is a European subsidiary of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. The organisation is committed to becoming a global company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. Astellas Pharma Europe Ltd. is responsible for 21 affiliate offices located across Europe, the Middle East and Africa, an R&D site and three manufacturing plants. The company employs approximately 4000 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

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. Theravance'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 Theravance'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 concerning the timing of potential regulatory approval of product candidates, 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. 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 August 3, 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.

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