FORM 8-K

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THERAVANCE INC

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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: January 26, 2009
(Date of earliest event reported)

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)**	**(IRS Employer Identification Number)**

901 Gateway Boulevard, South San Francisco, CA	**94080**
(Address of principal executive offices)	**(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 7.01. Regulation FD Disclosure

The information contained in this Item 7.01 and in the accompanying exhibits shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference

in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

On January 26, 2009 Theravance, Inc. announced that it submitted a New Drug Application to the U.S. Food and Drug Administration for telavancin, a novel, bactericidal, once-daily injectable investigational antibiotic for the proposed indication to treat nosocomial pneumonia (also known as hospital-acquired pneumonia, or HAP) caused by Gram-positive bacteria such as methicillin-resistant Staphylococcus aureus. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release of Theravance, Inc. dated January 26, 2009

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: January 26, 2009

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 January 26, 2009

Theravance Submits U.S. NDA for Telavancin for the Treatment of Hospital-Acquired Pneumonia

SOUTH SAN FRANCISCO, CA -- (Marketwire - January 26, 2009) - Theravance, Inc. (NASDAQ: THRX) announced today that it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for telavancin, a novel, bactericidal, once-daily injectable investigational antibiotic, for the proposed indication to treat nosocomial pneumonia (also known as hospital-acquired pneumonia, or HAP) caused by Gram-positive bacteria such as methicillin-resistant Staphylococcus aureus (MRSA).

"The submission of the telavancin NDA for HAP is another important milestone for the telavancin program," said Rick E Winningham, Chief Executive Officer. "There is a significant unmet medical need in HAP. MRSA pneumonia is becoming an increasingly serious health threat as the incidence of infection is growing and bacterial resistance is evolving, mortality rates are high and there are few treatment options. We look forward to working closely with the FDA on their review of our HAP NDA submission."

About Telavancin

Telavancin is a bactericidal, once-daily injectable investigational antibiotic with a multifunctional mechanism of action. Telavancin was discovered by Theravance in a research program dedicated to finding new antibiotics for serious infections due to Staphylococcus aureus, including MRSA, and other Gram-positive bacteria. Telavancin inhibits the formation of the bacterial cell wall and disrupts bacterial cell membrane function. Theravance believes the additive mechanisms of action seen with telavancin speed bacterial killing while also reducing the risks of inducing resistance to telavancin or cross-resistance with other antibiotics. Telavancin has been studied in two Phase 3 programs, one in complicated skin and skin structure infections (cSSSI) and one in HAP, both of which demonstrated non-inferiority in the all-treated (AT) and clinically evaluable (CE) patient populations versus vancomycin. Theravance believes these clinical programs comprise the largest global studies ever conducted in patients with confirmed MRSA infections. The FDA is currently reviewing the telavancin marketing application for the treatment of cSSSI.

About ATTAIN 1 and ATTAIN 2 Clinical Studies

The telavancin NDA is based on data from two large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies, ATTAIN 1 and ATTAIN 2, in which 1,503 patients were enrolled and treated, 464 of whom were infected with MRSA. Patients with HAP suspected or proven to be caused by Gram-positive bacteria were randomized (1:1) to receive either telavancin 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, piperacillin-tazobactam, and/or metronidazole was allowed. The objective of each study was non-inferiority of telavancin 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 HAP.

In both studies, telavancin achieved the objective of non-inferiority in the all-treated (AT) and clinically evaluable (CE) patient populations. In the ATTAIN studies, 82% of telavancin-treated patients and 81% of those who received vancomycin experienced one or more treatment-emergent adverse events. The most common adverse events were diarrhea, constipation, anemia and renal adverse events. With regard to changes in the QTc interval, there were similar proportions of patients in each group who experienced a post-baseline maximum value of greater than 500 milliseconds or a maximum change from baseline of greater than 60 milliseconds.

About the Telavancin Collaboration

In November 2005, Theravance entered into a collaboration arrangement with Astellas Pharma Inc. for the development and commercialization of telavancin worldwide except Japan. In July 2006, Theravance and Astellas expanded the collaboration to include Japan. Under the terms of the collaboration, Theravance will lead the development of and U.S. regulatory activities for telavancin for the treatment of cSSSI and HAP, and will collaborate substantially with Astellas in marketing in the United States for the first three years. Astellas will lead all other development, regulatory, manufacturing, sales and marketing activities.

About Theravance

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. 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 gastrointestinal motility dysfunction. The company's key programs include: telavancin for the treatment of serious Gram-positive bacterial infections with Astellas Pharma Inc., the Horizon program and Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) program with GlaxoSmithKline plc, and the Gastrointestinal Motility Dysfunction program. By leveraging its proprietary insight of multivalency toward drug discovery focused primarily on validated targets, Theravance is pursuing a next generation 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.

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 regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates (including with respect to telavancin statements regarding any expectation that regulatory authorities will approve telavancin on the basis of existing preclinical and clinical data or at all) and the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights. 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 the potential that results of clinical or preclinical studies indicate product candidates are unsafe or ineffective, delays or failure to achieve regulatory approvals, risks of relying on third-party manufacturers for the supply of our 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 Item 1A of Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 6, 2008 and the risks discussed in our other periodic filings with the 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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