THERAVANCE INC
Form 8-K
January 15, 2008

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 15, 2008**

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 7.01. Regulation FD Disclosure.

The information in this Current Report is being furnished and shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

On January 15, 2008, Theravance, Inc. filed a registration statement on Form S-3 containing the following updates regarding certain aspects of its business:

Telavancin Development Status

Based on results from ATLAS 1 and ATLAS 2, our large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies in which 1,867 patients were enrolled and treated, 719 of whom were infected with methicillin resistant *Staphylococcus aureus* (MRSA), in December 2006 we submitted our first new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for telavancin for the treatment of complicated skin and skin structure infections (cSSSI) caused by Gram-positive bacteria. In October 2007, the FDA issued an approvable letter for our NDA filing. The FDA letter indicated that the telavancin application is approvable, subject to: resolution of current good manufacturing practices (cGMP) compliance issues not specifically related to telavancin at a third-party manufacturer; and submission of revised labeling or re-analyses of clinical data or additional clinical data. We are preparing a complete response to the approvable letter and believe that no additional clinical studies will need to be initiated to respond. On January 11, 2008, we announced that Anti-Infective Drugs Advisory Committee to the FDA is scheduled to meet to review our telavancin NDA for the proposed indication to treat cSSSI on February 27, 2008. Telavancin is also under review for its safety and efficacy by regulatory authorities in the European Union for the treatment of complicated skin and soft tissue infections and in Canada for the treatment of cSSSI.

In December 2007 we announced results from ATTAIN 1 and ATTAIN 2, our large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies in hospital-acquired pneumonia (HAP) in which 1,503 patients were enrolled and treated, 464 of whom were infected with MRSA. In each study, telavancin achieved its objective of non-inferiority in the all-treated and clinically evaluable patient populations. Currently, we plan to submit an NDA for the HAP indication to the FDA in 2008.

TD-1792 Development Status

In July 2007 we announced results from an approximately 200-patient study in cSSSI with TD-1792. In September 2007, we announced that we retained full ownership rights of TD-1792 as a result of Astellas decision not to exercise its right to license the compound under our telavancin collaboration arrangement. We are currently conducting further studies with TD-1792 to evaluate the potential of this compound in more serious infections such as bacteremia.

Horizon (formerly referred to as Beyond Advair) Development Status

In April 2007 the collaboration reported results from the Phase 2b clinical program, in which two long-acting beta2 agonist (LABA) product candidates, dosed once daily, achieved clinically significant increases in bronchodilation at least equivalent to that of salmeterol dosed twice daily. Based on these results, in late December 2007 the lead LABA compound in development, GW642444 (444), progressed into a 28-day Phase 2b study designed to enroll 600 patients with asthma and is planned to progress into Phase 2b studies in chronic obstructive pulmonary disease in the first half of 2008. In addition, in a recent 8-week, 650-patient Phase 2 study of the lead ICS, GW685698 (698), both doses studied (200 mcg and 400 mcg) showed improved lung function dosed once daily compared to placebo, with no adverse effect on cortisol excretion. Based on these results, three 8-week studies with 698 comprising a Phase 2b program designed to enroll a total of 1,800 patients with mild, moderate and severe asthma, began enrolling patients in late December 2007. In parallel, combination studies to enable Phase 3 studies with both 444 and 698 are scheduled to initiate in 2008.

TD-5108 Development Status

In June 2007 we announced results from our approximately 400-patient ACCORD Phase 2 clinical study in chronic constipation with TD-5108. In September 2007, we announced that we retained full ownership rights of our GI Motility Dysfunction program as a result of GSK s decision not to exercise its right to license the program under the strategic alliance. At our end-of-Phase 2 meeting with the FDA for TD-5108 in late 2007, the FDA confirmed that the TD-5108 data package from the ACCORD study was adequate to progress TD-5108 into Phase 3 efficacy and safety studies in patients with chronic idiopathic constipation (CIC). The FDA also indicated that the size of the clinical program should be consistent with the International Conference on Harmonisation (ICH) guidelines for the development of drugs for chronic use. We recently completed enrollment in a Phase 1 thorough QTc study on this compound. Our preliminary review of the electrocardiogram data from the study suggests that such data is unreliable due to problems with the conduct of the study, not with the intrinsic properties of TD-5108. We believe that lack of assay sensitivity in the active control arm of the study (moxifloxacin) renders the results uninterpretable, and that the study will need to be repeated in order to generate scientifically valid results. We currently intend to initiate a repeat of the study later this year.

Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) Development Status

The first compound in the MABA program, GSK961081, successfully completed single- and multiple-dose Phase 1 studies in healthy volunteers and commenced a Phase 2 study in late October 2007. We expect to complete and report results from this study in late 2008.

Long-Acting Muscarinic Antagonist (LAMA) Development Status

The investigational, inhaled bronchodilator GSK1160724 commenced a Phase 1 study in December 2007. We expect to complete and report results from this study in 2008. GSK currently has a competing LAMA product candidate that is further advanced in development than our LAMA product candidate, which is the second LAMA compound we delivered to GSK under this program.

Financial Update

While we are still in the process of determining final results for the fourth quarter of 2007, as of November 30, 2007, we had cash, cash equivalents and marketable securities totaling $143 million.

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 15, 2008

By: /s/ Rick E Winningham
Rick E Winningham
Chief Executive Officer