THERAVANCE INC
Form 8-K
December 15, 2009

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): **December 15, 2009**

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 8.01 Other Events.

Today at the Deutsche Bank 2009 Biotech Boston Confab, Michael W. Aguiar, Senior Vice President and Chief Financial Officer of Theravance, Inc. will discuss individual study mortality data from the telavancin ATTAIN studies. The New Drug Application for telavancin for the treatment of nosocomial pneumonia (NP) due to resistant Gram-positive pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA), which contains data from the ATTAIN studies, is currently under review by the U.S. Food and Drug Administration (FDA). These individual study data are being provided at this time in conjunction with the posting of data from study 0015 on www.clinicaltrials.gov and the expected posting of data from study 0019 in the near future. The additional data on www.clinicaltrials.gov include patient flow, efficacy and safety data for the time window for treatment and follow-up specified in the protocols of the ATTAIN studies.

Summary of In-Window Vital Status Safety Population

	Study 0015		Study 0019		Total	
	Telavancin 10 mg/kg (N=372)	**Vancomycin (N=374)**	**Telavancin 10 mg/kg (N=379)**	**Vancomycin (N=378)**	**Telavancin 10 mg/kg (N=751)**	**Vancomycin (N=752)**
Total Deaths	80 (21.5%)	62 (16.6%)	70 (18.5%)	78 (20.6%)	150 (20.0%)	140 (18.6%)
Difference (95% CI)*	4.9% (-0.7%, 10.6%)		-2.2% (-7.8%, 3.5%)		1.4% (-2.6%, 5.3%)	

* Point estimate (95% confidence interval (CI) on the treatment difference (telavancin minus vancomycin) in mortality rate.

The pooled analysis is stratified by study.

Theravance has collected additional mortality data subsequent to the close of the studies which extend beyond the time window specified in the protocols. These data were requested by the FDA in the Complete Response letter that we received on November 23, 2009 as part of the FDA s evaluation of all-cause mortality as the primary endpoint in the treatment of NP. The Complete Response letter requested that we submit all available all-cause mortality data but did not identify any specific time period, statistical analysis or patient population. The telavancin NP clinical trials evaluated clinical response as the primary endpoint, consistent with current draft FDA guidelines for antibacterial clinical trial design in NP, and all-cause mortality as a secondary endpoint. The results of the updated mortality analyses are consistent with the reported results of the ATTAIN studies. We plan to submit the updated data and analyses in a response to the Complete Response letter shortly and to disclose the top line results after our response has been accepted for filing by the FDA.

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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: December 15, 2009 By: /s/ Michael W. Aguiar

Michael W. Aguiar
Chief Financial Officer

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