

THERAVANCE INC  
Form 8-K  
March 17, 2010

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 8-K**

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

Date of Report (Date of earliest event Reported): **March 17, 2010**

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**THERAVANCE, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**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

## Edgar Filing: THERAVANCE INC - Form 8-K

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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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:

- 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))
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**Item 8.01 Other Events.**

GlaxoSmithKline plc (GSK) is currently recruiting patients for a long-term exacerbation study in the asthma Phase 3 RELOVAIR™ clinical program. This randomized, double blind, parallel group study is designed to evaluate the safety and demonstrate the benefit of the addition of a long-acting beta2 agonist (LABA) to an inhaled corticosteroid (ICS) by utilizing an endpoint (time to first severe asthma exacerbation) that informs on both safety and efficacy. On March 10 and 11, 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as "clinical trial design") to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. It is unknown at this time what, if any, effect this FDA meeting or future FDA actions will have on the development of the RELOVAIR program. The current uncertainty regarding the FDA's position on LABAs for the treatment of asthma and the lack of consensus expressed at the recent Advisory Committee may result in increased time and cost of the asthma clinical trials in the United States for RELOVAIR and may increase the overall risk of the RELOVAIR asthma program in the United States.

**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.**

Dated: March 17, 2010

By:

/s/ Bradford J. Shafer

**Bradford J. Shafer**

**Sr. Vice President, General Counsel and Secretary**