## 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): February 16, 2012

### 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 (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 contained in this Item 7.01 and in the accompanying exhibit 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 February 16, 2012, Theravance, Inc. (the "Company") will present at an investor conference the positive topline results from a Phase 2b efficacy and safety study of GSK961081 ('081) administered once daily or twice daily for 28 days to 436 patients with moderate to severe chronic obstructive pulmonary disease (COPD). '081, previously known as TD-5959, is an investigational inhaled compound that is a single molecule functioning as both a muscarinic antagonist and a beta<sub>2</sub> receptor agonist (MABA). '081 was discovered by Theravance and is currently being developed by GlaxoSmithKline (GSK) under license from Theravance. Progression into Phase 3 development is dependent upon successful completion of ongoing Phase 3-enabling studies. Members of the Company's management will discuss the results and present a slide presentation at the Leerink Swann Healthcare Conference, New York, at 9:30 a.m. Eastern Standard Time.

A copy of the slide presentation is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

Description

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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.

Date: February 16, 2012

Exhibit

THERAVANCE, INC.

Description

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

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#### EXHIBIT INDEX

Exhibit 99.1 Slide Presentation at Leerink Swann Healthcare Conference Dated February 16, 2012

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Exhibit 99.1



## Safe Harbor

This presentation 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 forwardlooking statements contained in Section 21E of the Exchange Act and the Private Securities Litigation Reform Act of 1995. The words "may", "will", "should", "could", "would", "plan", "anticipate", "believe", "estimate", "intend", "goal," "project", "potential", "expect", "consistent", "supportive", "target" and "promising" and similar expressions are intended to identify such forward-looking statements. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates, statements concerning enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning expectations for product candidates through development and commercialization and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this presentation 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 difficulties in commencing or completing clinical studies, risks related to the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, 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 November 2, 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.



Medicines that make a **difference** 

# Theravance – Advancing Key Programs

RELOVAIR™	<ul> <li>In collaboration with GlaxoSmithKline</li> <li>Targeted to be a once-daily combination LABA+ICS</li> <li>Reported initial outcomes from pivotal Phase 3 studies in COPD and asthma</li> <li>GSK intends to commence global regulatory filings in COPD and asthma from mid-2012</li> </ul>
LAMA/LABA	<ul> <li>In collaboration with GlaxoSmithKline</li> <li>Targeted to be a once-daily dual bronchodilator, LAMA + LABA</li> <li>Phase 3a development program for GSK573719/vilanterol expected to complete in 2012</li> </ul>
MABA	<ul> <li>In collaboration with GlaxoSmithKline</li> <li>Muscarinic antagonist/B<sub>2</sub>-agonist in a single molecule</li> <li>Positive topline results from a Phase 2b COPD study of GSK961081</li> </ul>
ΡμΜΑ	<ul> <li>Targeted to be a once-daily, orally-administered therapy for OIC</li> <li>TD-1211 achieved positive Phase 2 Proof-of-Concept</li> <li>Phase 2b program in opioid-induced constipation initiated in July 2011</li> </ul>
Diverse Product Pipeline	<ul> <li>VIBATIV® (telavancin) approved in the U.S., Canada and the European Union</li> <li>Targeting "best-in-class" medicines in respiratory, bacterial infections, pain, gastrointestinal disease, cognitive disorders &amp; attention deficit hyperactivity disorder</li> </ul>
Theravance	3

on and Medication Guide for VIBATIV®

# RELOVAIR™ & Diverse Pipeline: Building Long-Term Value

THERAPEUTIC AREA	DEVELOPMENT STATUS				
Program	Phase 1	Phase 2	Phase 3	FILED	
RESPIRATORY					
RELOVAIR™ (LABA/ICS): COPD			REGULATO	DRY SUBMISSION PLANNED	
RELOVAIR™ (LABA/ICS): Asthma			REGULATO	ORY SUBMISSION PLANNED	
GSK573719/Vilanterol (LAMA/LABA): COPD					
GSK961081 (MABA): COPD					
TD-4208 (LAMA): COPD					
BACTERIAL INFECTIONS					
TD-1792 (Glycopeptide-Cephalosporin Heteroo	limer): Serious Gram+ Infecti	ons			
CNS/PAIN					
TD-1211 (PµMA): Opioid-Induced Constipation					
TD-9855 (MARIN): ADHD					
GASTROINTESTINAL DISEASE					
TD-5108 (velusetrag, 5-HT4 agonist): GI Motili	ty Dysfunction				
TD-8954 (5-HT4 agonist): GI Motility Dysfuncti	on				
COGNITIVE DISORDERS			Pre-Proof-of	f-Concept	
TD-5108 (5-HT4 agonist): Alzheimer's Disease			Demonstrated Pro	oof-of-Concept	
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Theravance					

# MABA (GSK961081) Program

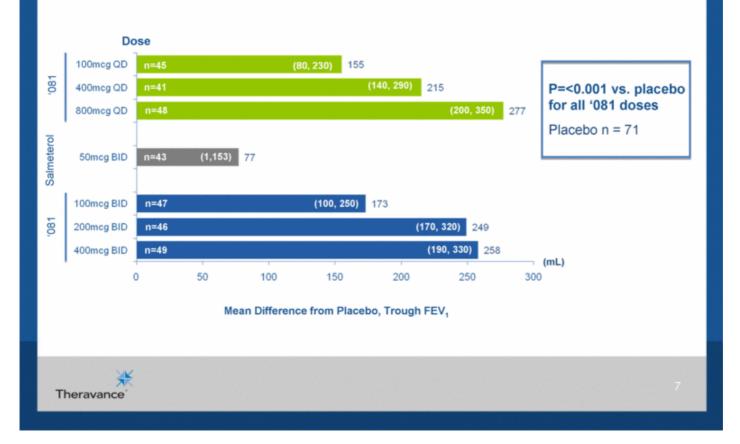
- Muscarinic antagonist and B<sub>2</sub>-agonist in a single molecule
  - Potential for monotherapy and triple mechanism in a single inhaler when combined with an inhaled corticosteroid (ICS) for the treatment of COPD
- Discovered through Theravance's insights on secondary binding sites on both the B<sub>2</sub> and muscarinic receptors
- Theravance has no cost obligation on the program
- All doses of GSK961081 ('081) achieved primary endpoint in Phase 2b study in COPD
- Evaluating '081 initially as BID fixed-dose combination with fluticasone propionate (FP) outside the US
  - Efficient pathway to market
  - In the US, further discussion with FDA is required
- QD/BID and Phase 3 timing dependent upon successful completion of Phase 3 enabling studies

# MABA Phase 2b Study in COPD

Goal and Design

## A Goal: To evaluate the dose response, dose interval, safety and efficacy of GSK961081 ('081 and previously known as TD-5959) administered QD and BID in patients with moderate to severe COPD Design Multicenter, randomized, double-blind, double-dummy, parallel-group, placeboand active-controlled ↗ 4-week treatment period Doses/Eight arms ↗ '081: 100 mcg, 400 mcg, and 800 mcg QD '081: 100 mcg, 200 mcg, and 400 mcg BID Salmeterol, an active control: 50 mcg BID ↗ Placebo 436 randomized and treated patients Efficacy Endpoints Primary: Change from baseline in a.m. trough FEV<sub>1</sub> on Day 29 ス Secondary: Weighted mean FEV₁ (0-24hr) on Day 28 and serial FEV₁ on Days 1 and 28 Theravance

## '081 Phase 2b 28-Day COPD Dose-Ranging Study Achieved Primary Endpoint: Trough Bronchodilation on Day 29



# MABA Phase 2b Positive Results in COPD

### Summary

### Efficacy

- '081 QD/BID achieved statistically significant difference from placebo in mean change from baseline in morning trough FEV<sub>1</sub> on Day 29
- Weighted mean FEV<sub>1</sub> (0-24hr) on Day 28 and serial FEV<sub>1</sub> on Day 1 and Day 28, demonstrated statistically significant differences vs. placebo for all doses of '081 at all time points except one (100mcg QD at 12h on Day 1)
- All '081 doses produced numerically greater improvements in bronchodilation compared to salmeterol\*

### Safety

- ↗ '081 was generally well-tolerated
- Incidences of adverse events (AEs) and drug-related AEs were similar across treatments with no apparent dose-related effect
- Most frequently reported AEs were headache, cough, and dysgeusia
- One serious AE was reported (biliary colic) in the 400mcg QD '081 treatment group, but was not considered related to study drug

\*No prespecified comparison versus '081 was conducted in this study





Theravance Medicines that make a difference®

# THANK YOU

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