## 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 11, 2011

### 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 January 11, 2011, Rick E Winningham, Chairman and Chief Executive Officer of Theravance, Inc. ("Theravance"), presented information about Theravance at the 29th Annual J.P. Morgan Healthcare Conference, in San Francisco, CA. A copy of the slides presented are furnished as Exhibit 99.1 and incorporated herein by reference.

#### ITEM 9.01 Financial Statements and Exhibits.

d)	Exhibits.
----	-----------

(

Exhibit

Exhibit 99.1 Slide Presentation dated January 11, 2011

Description

#### 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 11, 2011

By: /s/ Michael W. Aguiar

Michael W. Aguiar Chief Financial Officer



Theravance<sup>®</sup> Medicines That Make a Difference<sup>®</sup>



# 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 forward-looking 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 goals and timing of clinical studies and product commercialization, 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 forwardlooking 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 preclinical 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 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 October 29, 2010 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.

# **Theravance – Advancing Key Programs**

RELOVAIR™	<ul> <li>In collaboration with GlaxoSmithKline</li> <li>Targeted to be next-generation combination LABA+ICS</li> <li>Large global Phase 3 programs in COPD and asthma ongoing</li> </ul>
MABA	<ul> <li>In collaboration with GlaxoSmithKline</li> <li>Muscarinic antagonist and ß<sub>2</sub>-agonist pharmacology in a single molecule</li> <li>Phase 2b COPD study of GSK961081 initiated in December 2010</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>Plan to progress into further Phase 2 dose-ranging in 2011</li> </ul>
Diverse Product Pipeline	<ul> <li>VIBATIV<sup>™</sup> (telavancin) approved in U.S. and Canada for cSSSI</li> <li>Targeting "best-in-class" medicines in respiratory, bacterial infections, gastrointestinal disease, pain &amp; cognitive disorders</li> </ul>
RELOVAIR is a trademark of Glaxo Group Limit	ed and mark is intended for U.S. and subject to FDA approval. VIBATIV is a trademark of Astellas Pharma Inc.

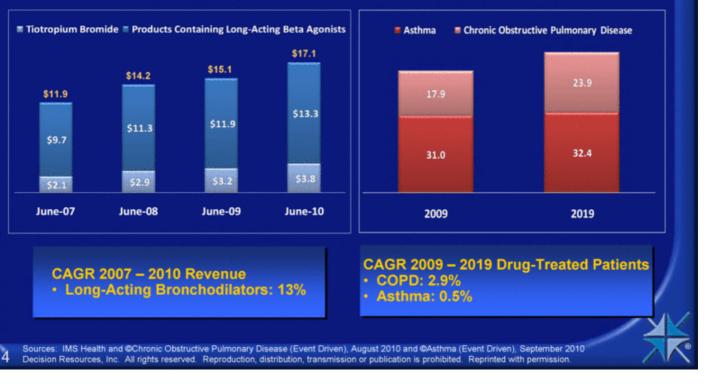
# Significant Respiratory Market Opportunity

### Significant Revenue Growth Recently

Global Sales of Products Containing Long-Acting Bronchodilators (\$B) 12-Month Periods Ending

### Forecast Patient Growth Driven by COPD

Drug-Treated Patients with Asthma & COPD in G7 Countries (M)



# RELOVAIR<sup>™</sup> with GSK Goal: Once-Daily LABA + ICS for COPD & Asthma

### Targeted to be next-generation combination COPD/asthma products

- Currently Seretide/Advair<sup>®</sup> is GSK's largest product ~£5.0B/~\$7.8B in '09
  - ~50% COPD
  - ~50% Asthma

### Initiated Phase 3 program in asthma in March '10 and in COPD in October '09

- 13 Phase 3 studies are progressing with the novel once-daily LABA, vilanterol trifenatate (VI), and the novel once-daily ICS, fluticasone furoate (FF)
  - 5 studies in COPD
  - 8 studies in Asthma
- Theravance would receive royalties of 15% on first \$3B of annual net sales and 5% thereafter for approved LABA and LABA+ICS
- Theravance has <u>no</u> cost obligation through NDA/MAA

Positive Phase 2b results in 3,000 COPD and asthma patients

# RELOVAIR<sup>™</sup> Phase 3 Programs in COPD and Asthma Status of 13 Registrational Studies

Phase 3a Study	Status
COPD Studies	
12-month exacerbation study	Enrollment complete; study ongoing
12-month exacerbation study	Enrollment complete; study ongoing
6-month efficacy and safety study	Enrollment complete; study ongoing
6-month efficacy and safety study	Enrollment complete; study ongoing
Detailed lung function profile study	Completed
Asthma Studies	
Exacerbation study	Enrollment complete; study ongoing
12-month safety study	Enrollment complete; study ongoing
Hypothalamic-Pituitary-Adrenal (HPA) axis study	Completed
24-week head-to-head study of RELOVAIR <sup>™</sup> vs. Advair®/Seretide	Recruiting
24-week high-dose combination efficacy study	Recruiting
12-week low-dose combination efficacy study	Recruiting
24-week fluticasone furoate vs. fluticasone propionate	Recruiting
12-week vilanterol trifenatate vs. salmeterol	Recruiting

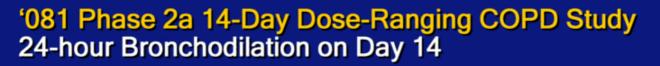
### RELOVAIR™ Phase 3 programs in COPD and asthma have now enrolled over 9,000 patients

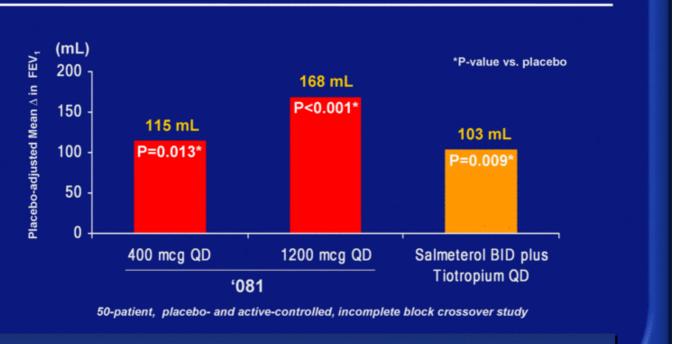
RELOVAIR is a trademark of Glaxo Group Limited. Mark intended for U.S. and subject to FDA approval.

6

# MABA Advanced to Phase 2b Dual Pharmacology in a Single Molecule

- Muscarinic antagonist and ß<sub>2</sub>-agonist pharmacology in a single molecule
  - Potential for triple therapy with an inhaled corticosteroid (ICS) in a single inhaler for the treatment of COPD
- Discovered through Theravance's insights on secondary binding clefts on both the ß<sub>2</sub> and muscarinic receptors
- Strategic Alliance with GSK
  - Theravance has no cost obligation on the program
  - Potential milestone payments
  - Single-agent average percentage royalty rate low double-digits to mid-teens
- Positive topline Phase 2a clinical results with GSK961081 ('081)





'081 QD bronchodilation comparable to salmeterol BID + tiotropium QD Change in heart rate comparable to or lower than salmeterol BID + tiotropium QD

# MABA Phase 2b Study in COPD Goal and Design

Goal: To evaluate the dose response, dose interval, safety and efficacy of GSK961081 ('081) administered QD and BID in COPD patients

### Design

- Multicenter, randomized, double-blind, double-dummy, parallel-group, placebo- and 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: 50 mcg BID
  - Placebo
- 425 randomized patients
- Efficacy Endpoints
  - Primary: Change from baseline in a.m. trough FEV<sub>1</sub> on Day 29
  - Secondary: Includes serial FEV<sub>1</sub> measures and use of albuterol rescue medication.

9

# TD-1211 for OIC Goal: Once-Daily, Orally-Administered PµMA

Targeted to be a best-in-class, once-a-day, orally-administered, peripherally selective, multivalent antagonist of the mu opioid receptor (PµMA), for the treatment of opioid-induced constipation (OIC)

- Theravance-discovered novel, multivalent compound designed to alleviate gastrointestinal side effects of opioid therapy without affecting analgesia
- Potential OIC Market Opportunity in U.S. could be >500M treatment days (TD) annually\*
  - 3.9B TD on non-injectable opioids\*
  - ~40% of patients on chronic opioids have constipation\*
  - 45% of OIC patients using laxatives still report <3 BM per week\*</li>
- TD-1211 achieved positive Phase 2 Proof-of-Concept

# TD-1211 Phase 2 Study in Patients Suffering from Opioid-Induced Constipation

- Double-blind, placebo-controlled, dose-escalation study, two U.S. sites
- 70 patients requiring chronic opioid therapy for non-cancer pain
  - ≤ 5 Spontaneous Bowel Movements (SBMs) during 2-week baseline
  - At least one additional symptom of constipation
- 2-week baseline followed by 2-week treatment period and 1-week follow-up
  - 3 days in unit after first dose (fasted for the first dose)
  - Daily electronic Patient Reported Outcome (ePRO) diary to collect bowel movement (BM), symptom and quality-of-life metrics
- Primary endpoint: Change from baseline in average number of SBMs per week over 2-week treatment period
  - Pre-Defined Proof-of-Concept: Lower bound of the 95% CI > 1

## TD-1211 Phase 2 Results Primary Efficacy Endpoint: Change from Baseline in Average Number of SBMs per Week

### EA LOCF Population\*

		TD-1211					
	Placebo (N=14)	0.25 mg (N=8)	0.75 mg (N=8)	2 mg (N=7)	5 mg (N=16)	10 mg (N=14)	
Baseline	1.7	1.0	1.2	1.1	1.1	1.4	
Treatment Period	3.3	2.4	2.1	2.1	4.3	6.3	
Change from Baseline	1.6	1.4	0.9	0.9	3.2	4.9	
95% CI for Mean	(0.6, 2.5)	(0.1, 2.7)	(0.0, 1.8)	(-0.5, 2.4)	(1.5, 5.0)	(3.1, 6.7)	

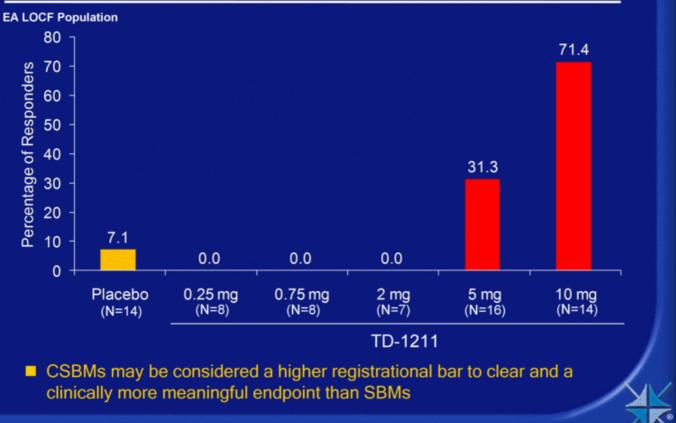
\*Efficacy Analysis (EA) Last Observation Carried Forward (LOCF) Population

Pre-Defined Proof-of-Concept: Lower bound of the 95% CI > 1

Dose-dependent increase in SBMs per week

5 mg and 10 mg Doses Achieved Positive Phase 2 Proof-of-Concept

# TD-1211 Phase 2 Results Responder Analysis: ≥ 3 CSBMs per week



## TD-1211 Phase 2 Results Safety Summary

- No Serious Adverse Events (SAEs) reported
- No evidence of CNS opioid withdrawal or analgesic interference
- Most adverse events (AEs) were mild/moderate
  - Early onset (Day 1 or Day 2)
  - Majority of GI-related AEs resolved within a few days
- No clinically significant changes in laboratory tests, ECGs, vital signs, physical exam

Theravance retains sole ownership of TD-1211 and intends to progress it into further Phase 2 work in 2011

# VIBATIV<sup>™</sup> (telavancin)



- Launched in the U.S. for the treatment of cSSSI caused by susceptible Gram+ pathogens including *Staphylococcus aureus/*MRSA
  - Dual mechanism of action
  - Bactericidal, once-daily injectable antibiotic approved for adults
- Commercialized in partnership with Astellas
- Phase 3 results in nosocomial pneumonia (NP) published in Clinical Infectious Diseases in December 2010
  - Recent FDA communications: ATTAIN studies do not meet new NP draft guidance
- cSSTI and NP under review in Europe
- For full Prescribing Information, including Boxed Warning and Medication Guide for VIBATIV<sup>™</sup>, please visit <u>www.VIBATIV.com</u>.



# **Financial Position**

- Cash as of September 30, 2010: ~\$193M
  - GSK's investment of ~\$129M through a private placement in November '10
- Projected 2010 expenses
  - Approximately \$80M to \$85M for R&D + G&A
  - Excludes SFAS 123(R) stock option expenses
- Access to development funding
  - GSK pays all RELOVAIR<sup>™</sup> and MABA program development costs
  - Potential MABA milestone payments from GSK
  - Potential VIBATIV<sup>™</sup> milestone payments from Astellas
- Royalties from sales of VIBATIV<sup>™</sup>

16 RELOVAIR is a trademark of Glaxo Group Limited and mark is intended for U.S. and subject to FDA approval. VIBATIV is a trademark of Astellas Pharma Inc For full Prescribing Information and Medication Guide for VIBATIV™ please visit www.VIBATIV.com.

# 2011: RELOVAIR<sup>™</sup> and Advance Pipeline

	Stage of Dev	elopment		
	Ph 1	Ph 2	Ph 3	NDA/MAA
RESPIRATORY				
RELOVAIR™ (LABA/ICS): COPD				
RELOVAIR™ (LABA/ICS): Asthma				
GSK961081 (MABA): COPD				
BACTERIAL INFECTIONS				
Telavancin: cSSTI and NP (EU)			-	
TD-1792 (Glycopeptide-Cephalosporin Heterodin	mer): Serious Gram+ In	fections		
GASTROINTESTINAL DISEASE				
TD-5108 (velusetrag, 5-HT4 agonist): GI Motility	Dysfunction			
TD-8954 (5-HT4 agonist): GI Motility Dysfunctio	n an			
TD-8954 (5-HT4 agonist): GI Motility Dysfunctio	n			
	n			
CNS/PAIN	n and a second sec			
CNS/PAIN TD-1211 (PµMA): Opioid-Induced Constipation	n and a second sec			

# Theravance®

Medicines That Make a Difference®



# VIBATIV<sup>TM</sup> (telavancin) Important Safety Information

Fetal Risk Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment.

Nephrotoxicity New onset or worsening renal impairment occurred in patients who received VIBATIV. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV presus discontinuing and initiating therapy with an alternative agent should be assessed. Clinical cure rates in telavancin-treated patients were lower in patients with baseline CrCI s50 mL/min compared to those with CrCI >50 mL/min. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate/severe renal impairment. ng

Geriatric Use Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Infusion Related Reactions VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intraveno infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome"-like reactions including: flushing of the upper body, urticaria, pruritus, or rash. nous

Clostridium difficile-Associated Diarrhea Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use.

Development of Drug Resistant Bacteria Prescribing VIBATIV in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. As with other antibacterial drugs, use of VIBATIV may result in overgrowth of nonsusceptible organisms, including fungi.

QTc Prolongation Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV prolonged the QTc interval. Use of VIBATIV should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

Coagulation Test Interference VIBATIV does not interfere with coagulation, but does interfere with certain tests used to monitor coagulation such as prothrombin time, international normalized ratio, activated partial thromosplastin time, activated clotting time, and coagulation based factor Xa tests. Blood samples for these coagulation tests should be collected as close as possible prior to a patient's next dose of VIBATIV.

Adverse Reactions
The most common adverse reactions (≥10% of patients treated with VIBATIV) observed in the Phase III cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy

In the Phase III cSSSI clinical trials, serious adverse events were reported in 7% of patients treated with VIBATIV and most commonly included renal, respiratory, or cardiac events. Serious adverse events were reported in 5% of vancomycin-treated patients, and most commonly included cardiac, respiratory, or infectious events.

For full Prescribing Information, including Boxed Warning and Medication Guide, please visit www.VIBATIV.com

VIBATIV is a trademark of Astellas Pharma Inc. 19