



## Theravance Reports First Quarter 2011 Financial Results

**SOUTH SAN FRANCISCO, CA/April 28, 2011** – Theravance, Inc. (NASDAQ: THRX) reported today its financial results for the quarter ended March 31, 2011. Revenue for the first quarter of 2011 was \$6.3 million. Net loss for the first quarter of 2011 was \$22.7 million or \$0.28 per share. Cash, cash equivalents and marketable securities totaled \$293.8 million as of March 31, 2011.

“I’m pleased with the continued progress of our key programs,” said Rick E Winningham, Chief Executive Officer. “In early 2011, GSK and Theravance announced the progression of the LAMA/LABA program into Phase 3 and initiated the Phase 3b outcomes study for RELOVAIR™, both in COPD. GSK also initiated other studies in the Phase 3b COPD program with RELOVAIR™. We continue to work diligently in advancing our pipeline and look forward to reporting on the further developments of these programs.”

### Program Highlights

#### Respiratory Programs

##### *Phase 3a Programs with RELOVAIR™*

The Phase 3a programs with RELOVAIR™ in chronic obstructive pulmonary disease (COPD) and asthma are progressing and have now enrolled over 10,000 patients out of an expected 11,000 patients in total. RELOVAIR™ is an investigational once-daily medicine that combines fluticasone furoate (FF, an inhaled corticosteroid or ICS) and vilanterol (VI, a long-acting beta<sub>2</sub> agonist or LABA) for the treatment of patients with COPD or asthma.

The Phase 3a pivotal program in COPD consists of five studies, including two 12-month exacerbation studies, two six-month efficacy and safety studies, and a detailed lung function profile study.

The Phase 3a asthma program consists of eight studies to determine the safety and efficacy of RELOVAIR™ in asthma patients who remain uncontrolled on current treatment. These studies include an exacerbation study, a 12-month safety study (which also supports the COPD program), a 12-week low-dose combination efficacy study, a 24-week high-dose combination efficacy study, a 24-week head-to-head study of RELOVAIR™ versus Advair®/Seretide®, a 24-week study of FF versus fluticasone propionate (FP), a 12-week study of VI versus salmeterol, and a hypothalamic-pituitary-adrenal (HPA) axis study.

##### *Phase 3b Program with RELOVAIR™ in COPD*

In early February 2011, GSK and Theravance announced the start of a large Phase 3b outcomes study with RELOVAIR™ in COPD. This is a study of 16,000 patients to assess the potential for RELOVAIR™ to improve survival in patients with moderate COPD and a history of, or at risk for, cardiovascular disease. This Phase 3b study is an outcomes trial across 1,100 global sites and will run alongside the existing COPD program. The results are not required for the regulatory submission and will not form part of the initial New Drug Application (NDA)/Marketing Authorization Application (MAA).



The primary objective is to evaluate prospectively the effect of the combination (FF/VI, 100/25mcg) compared with placebo on patient survival. Secondary objectives will evaluate rate of decline in lung function, as well as cardiovascular endpoints including cardiovascular death, heart attacks and strokes.

This study will evaluate the clinical outcomes of patients receiving standard cardiovascular care (including cardiovascular medications) versus patients receiving FF/VI in addition to receiving standard cardiovascular care (including cardiovascular medications).

This is a four-arm, multicenter, randomized, double-blind, parallel-group study, with treatment administered once daily via a new dry powder inhaler. The total duration of the study will be determined by the number of events in the study, with each patient being treated for between 15 and 44 months based on current estimates.

In addition to the outcomes study, GSK recently initiated four Phase 3b studies. Three of these studies are 12-week studies that will evaluate the 24-hour pulmonary function profile of RELOVAIR™ once daily compared with Advair®/Seretide® twice daily in patients with COPD. These studies are targeted to enroll approximately 500 patients per study. The fourth study is a 24-week study to evaluate the effect of RELOVAIR™ once-daily on arterial wall stiffness compared with placebo and vilanterol in patients with COPD. The estimated enrollment for this study is 410 patients.

#### *LAMA/LABA Combination (GSK573719/Vilanterol or '719/VI)*

In early February 2011, GSK and Theravance announced the initiation of the Phase 3 program for the once-daily LAMA/LABA dual bronchodilator '719/VI which will evaluate over 5,000 patients globally. '719/VI combines two bronchodilators currently under development - '719, a long-acting muscarinic antagonist (LAMA) and VI, a LABA. These molecules act through two mechanisms: antagonism of acetylcholine muscarinic receptors and agonism of beta<sub>2</sub> adrenoreceptors. This investigational medicine will be administered using a new dry powder inhaler.

The LAMA/LABA Phase 3 program consists of seven studies which include a 52-week study to evaluate the long term safety and tolerability of '719 (125mcg) alone, as well as the combination '719/VI (125/25mcg), two large pivotal studies that will compare improvements in lung function between '719/VI, its components and placebo, two studies to compare the combination and its components to tiotropium and two studies to assess the effect of '719/VI on exercise endurance. The Phase 3 program will investigate two doses of '719 (125mcg and 62.5mcg) and '719/VI (125/25mcg and 62.5/25mcg). All seven studies have been initiated and are enrolling patients.

#### *Inhaled Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist (MABA)*

In December 2010, GSK and Theravance announced that the first patient had started treatment with GSK961081 ('081) in a Phase 2b study in patients with moderate to severe COPD. '081 is a single molecule bifunctional bronchodilator with both muscarinic antagonist and beta<sub>2</sub> receptor agonist (MABA) activities. The study is progressing and enrollment is in line with expectations. The primary objective of this study is to evaluate dose response, dose interval, efficacy, and safety of '081 by studying once-daily (QD) doses (100mcg, 400mcg, and 800mcg), twice-daily (BID) doses (100mcg, 200mcg, and 400mcg), the active comparator salmeterol (50mcg BID) and placebo over a 28-day period. The overall aim of this Phase 2b study is to evaluate the safety and



efficacy of '081 administered both once daily and twice daily over a 28-day period to allow the selection of a well-tolerated and efficacious dose and dosing interval.

### Central Nervous System (CNS)/Pain Program

#### *Oral Peripheral Mu Opioid Receptor Antagonist (PμMA) – TD-1211*

The PμMA program in opioid-induced constipation (OIC) is progressing. TD-1211 is an investigational once-daily, orally-administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed to alleviate gastrointestinal side effects of opioid therapy without affecting analgesia. We intend to initiate a Phase 2 dose-optimization study of TD-1211 around mid-year.

## **Financial Results**

### Revenue

Revenue was \$6.3 million for the first quarter of 2011 compared with \$5.7 million for the same period in 2010, an increase of \$0.6 million. The increase in the first quarter of 2011 was due to higher royalty revenue of \$0.6 million earned from VIBATIV™ net sales of \$3.5 million compared to royalty revenues in the same period of 2010 which were immaterial.

### Research and Development

Research and development expense for the first quarter of 2011 increased to \$20.5 million compared with \$20.4 million for the same period in 2010. The increase in the first quarter of 2011 was primarily due to higher employee and facilities related expenses, partially offset by lower external expenses. Total external research and development expense was \$3.2 million during the first quarter of 2011 compared with \$4.2 million for the same period in 2010. Total research and development stock-based compensation expense for the first quarter of 2011 was \$3.1 million compared with \$2.5 million for the same period in 2010.

### General and Administrative

General and administrative expense for the first quarter of 2011 increased to \$7.2 million from \$6.5 million for the same period in 2010. The increase in the first quarter of 2011 was primarily due to higher employee-related expenses partially offset by lower external costs. Total general and administrative stock-based compensation expense for the first quarter of 2011 was \$2.4 million compared with \$2.0 million for the same period in 2010.

### Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled \$293.8 million as of March 31, 2011, a decrease of \$15.8 million during the first quarter. This decrease was primarily due to cash used in operations.



## Conference Call and Webcast Information

As previously announced, the Company has scheduled a conference call to discuss this announcement beginning at 5:00 p.m. Eastern Daylight Time. To participate in the live call by telephone, please dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting the company's web site at [www.theravance.com](http://www.theravance.com). To listen to the live call, please go to the web site 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call will be available on the company's web site for 30 days through May 28, 2011. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on May 5, 2011 by dialing (800) 642-1687 from the U.S., or (706) 645-9291 for international callers, and entering confirmation code 54391737.

## About Theravance

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. The Company's key programs include: RELOVAIR™, LAMA/LABA ('719/vilanterol (VI)) and MABA (Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist), each partnered with GlaxoSmithKline plc, and our oral Peripheral Mu Opioid Receptor Antagonist (PμMA) program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit the company's web site at [www.theravance.com](http://www.theravance.com).

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RELOVAIR™ is a trademark of GlaxoSmithKline group of companies.

This press release contains and the conference call will contain 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. Examples of such statements include statements relating to the timing of clinical studies, data analysis 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, and statements regarding 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 press release and the conference call 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, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 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.

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**THERAVANCE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
	(unaudited)	
Revenue	\$ 6,331	\$ 5,714
Operating expenses:		
Research and development (1)	20,464	20,351
General and administrative (1)	7,169	6,476
Total operating expenses	<u>27,633</u>	<u>26,827</u>
Loss from operations	(21,302)	(21,113)
Interest and other income	145	94
Interest expense	(1,510)	(1,517)
Net loss	<u>\$ (22,667)</u>	<u>\$ (22,536)</u>
Basic and diluted net loss per share	<u>\$ (0.28)</u>	<u>\$ (0.35)</u>
Shares used in computing basic and diluted net loss per share	<u>80,854</u>	<u>64,921</u>

(1) Amounts include stock-based compensation expense for the three months ended March 31 as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
	(unaudited)	
Research and development	\$ 3,132	\$ 2,527
General and administrative	2,409	1,970
Total stock-based compensation expense	<u>\$ 5,541</u>	<u>\$ 4,497</u>



**THERAVANCE, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands)

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
	(unaudited)	(2)
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 293,819	\$ 309,634
Other current assets	6,453	6,720
Property and equipment, net	10,548	10,215
Other long-term assets	4,288	4,633
<b>Total assets</b>	<b>\$ 315,108</b>	<b>\$ 331,202</b>
<b>Liabilities and stockholders' net capital deficiency</b>		
Current liabilities (1)	\$ 33,419	\$ 40,054
Deferred revenue	132,409	137,425
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	4,599	3,643
Stockholders' net capital deficiency	(27,819)	(22,420)
<b>Total liabilities and stockholders' net capital deficiency</b>	<b>\$ 315,108</b>	<b>\$ 331,202</b>

(1) Amounts include current portion of deferred revenue of \$21.2 million and \$21.9 million as of March 31, 2011 and December 31, 2010, respectively.

(2) The condensed consolidated balance sheet amounts at December 31, 2010 are derived from audited financial statements.