



## Theravance Reports Fourth Quarter and Full Year 2011 Financial Results

**SOUTH SAN FRANCISCO, CA/February 9, 2012** — Theravance, Inc. (NASDAQ: THRX) reported today its financial results for the fourth quarter and full year ended December 31, 2011. Revenue for the full year was \$24.5 million. Net loss for the fourth quarter and full year of 2011 was \$37.0 million and \$115.3 million, respectively, compared with \$19.3 million and \$83.9 million for the same periods of 2010. Net loss per share was \$0.45 and \$1.41 for the fourth quarter and full year of 2011, respectively, compared with a net loss per share of \$0.25 and \$1.16 for the same periods of 2010. Cash, cash equivalents, and marketable securities totaled \$240.9 million as of December 31, 2011, a decrease of \$68.7 million since December 31, 2010.

“I am very pleased with the progress Theravance has made since the beginning of 2011 and I am excited by our potential milestones in 2012,” said Rick E Winningham, Chief Executive Officer. “In our two lead respiratory programs with GSK, we expect GSK to submit regulatory filings for RELOVAIR™ in both COPD and asthma, and to complete the Phase 3 registrational program with LAMA/LABA this year. Recently, GSK announced the completion of a low-dose Phase 2b study in COPD with ‘719 and that the results of this study support the doses and dosing regimen being studied in Phase 3. Together, these programs provide the opportunity to treat a wide range of patients suffering from these serious diseases. We look forward to another productive and successful year.”

### Program Highlights

#### Respiratory Programs with GlaxoSmithKline plc (GSK)

##### *RELOVAIR™*

RELOVAIR™ is an investigational once-daily inhaled corticosteroid (ICS)/long-acting beta<sub>2</sub> agonist (LABA) combination treatment, comprising fluticasone furoate and vilanterol (FF/VI), currently in development for the treatment of patients with chronic obstructive pulmonary disease (COPD) or asthma.

In January 2012, Theravance and GSK announced that GSK intends to commence global regulatory filings in COPD and asthma beginning in mid-2012 based upon the initial outcomes from pivotal Phase 3 studies for once-daily RELOVAIR™ in COPD and asthma. For asthma, GSK will continue discussions with the U.S. Food and Drug Administration (FDA) on the regulatory requirements for a U.S. asthma indication.

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

Enrollment is complete for the seven ongoing studies in the Phase 3a program for the once-daily LAMA/LABA dual bronchodilator ‘719/VI. ‘719/VI combines two bronchodilators currently under development - ‘719, a long-acting muscarinic antagonist (LAMA) and VI, a LABA. These two molecules provide two mechanisms of bronchodilation for patients with COPD: antagonism of acetylcholine muscarinic receptors and agonism of beta<sub>2</sub> adrenoreceptors.



The LAMA/LABA Phase 3a program, which will evaluate over 5,000 patients with COPD globally, consists of 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 6-month pivotal studies that will compare improvements in lung function between '719/VI, its components and placebo, two 6-month studies to compare the combination with its components and 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 two doses of the combination '719/VI (125/25mcg and 62.5/25mcg). The LAMA/LABA Phase 3 program is expected to be completed in 2012.

In October 2011, data from a Phase 2b study of '719 was presented at CHEST, the annual meeting of the American College of Chest Physicians (ACCP), in Honolulu, Hawaii. Recently, GSK announced the completion of a Phase 2b study evaluating lower doses of '719 in COPD. The results of this study support the doses and dosing regimen being studied in Phase 3.

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

'081 is a single molecule bifunctional bronchodilator with both muscarinic antagonist and beta<sub>2</sub> receptor agonist activity. GSK recently completed a Phase 2b study with '081 and Theravance expects to report topline data during the first half of 2012. In addition, a Phase 1 study with '081 in combination with fluticasone propionate (FP), an ICS, has been completed, and a number of non-clinical studies are ongoing.

In October 2011, Theravance and GSK amended the 2004 Strategic Alliance Agreement to expand the MABA program. Theravance granted to GSK an exclusive license to develop and commercialize additional preclinical MABA compounds discovered by Theravance. Theravance received an upfront payment of \$1.0 million and has the potential to receive clinical, regulatory and commercial milestone payments as well as royalties on worldwide net sales if one of these MABA compounds is successfully commercialized. In connection with this amendment, Theravance regained full rights to its MonoAmine Reuptake Inhibitor (MARIN) program, which is currently in Phase 2 development, and its Angiotensin Receptor-NEP Inhibitor (ARNI) program in preclinical development.

#### Theravance Respiratory Program

##### *Long-Acting Muscarinic Antagonist (LAMA) – TD-4208*

In November 2011, Theravance announced positive topline results from a Phase 2a single-dose COPD study of TD-4208, an investigational inhaled LAMA discovered by Theravance. In this study, TD-4208 met the primary endpoint by demonstrating a statistically significant mean change from baseline in peak forced expiratory volume in one second (FEV<sub>1</sub>) compared to placebo, and was generally well-tolerated.

#### Bacterial Infections

##### *VIBATIV<sup>®</sup> (telavancin) for injection*

On January 6, 2012, Theravance regained full global rights to VIBATIV<sup>®</sup>, a bactericidal, once-daily injectable lipoglycopeptide antibiotic discovered by Theravance and approved for use in the U.S., Canada and the European Union. Theravance is evaluating global commercialization alternatives for VIBATIV<sup>®</sup> either alone or with partners.



## Central Nervous System (CNS)/Pain Program

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

Enrollment is progressing in the Phase 2b program, which will assess the safety, tolerability and clinical activity of TD-1211 in patients with opioid-induced constipation (OIC). This program is evaluating several doses and dosing regimens to provide information for the design of the Phase 3 program. 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.

### *MonoAmine Reuptake INhibitor (MARIN) — TD-9855*

In December 2011, Theravance announced the initiation of an Attention-Deficit/Hyperactivity Disorder (ADHD) Phase 2 proof-of-concept study with TD-9855, the lead compound in Theravance's MARIN program. This Phase 2 study will evaluate the safety and efficacy of two different doses of TD-9855 in adults with ADHD. TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (NSRI) discovered by Theravance for the treatment of central nervous system (CNS) conditions such as ADHD and chronic pain.

## **Financial Results**

### Revenue

Revenue was \$5.4 million for the fourth quarter of 2011 compared with \$6.9 million for the same period in 2010, a decrease of \$1.5 million. During the fourth quarter, \$0.3 million of royalty revenue was earned from VIBATIV<sup>®</sup> net sales of \$1.6 million. For the full year of 2011, revenue was \$24.5 million, compared with \$24.2 million for the full year of 2010.

### Research and Development

Research and development expense for the fourth quarter of 2011 increased to \$32.5 million compared with \$17.5 million for the same period in 2010. For the full year of 2011, research and development expense was \$103.5 million compared with \$75.1 million for the full year 2010. The increase in the fourth quarter and the full year of 2011 was primarily due to clinical costs related to our PμMA and MARIN programs and preclinical expenses related to our Hepatitis C virus (HCV) and cardiovascular programs in late-stage discovery. Total external research and development expense for the fourth quarter and full year of 2011 was \$12.9 million and \$30.8 million, respectively, compared with \$1.3 million and \$12.2 million, respectively, for the fourth quarter and full year 2010. Total research and development stock-based compensation expense for the fourth quarter and full year 2011 was \$3.4 million and \$13.4 million, respectively, compared with \$2.6 million and \$10.3 million, respectively, for the fourth quarter and full year 2010.

### General and Administrative

General and administrative expense for the fourth quarter of 2011 increased to \$8.5 million from \$7.4 million for the same period in 2010. For the full year of 2011, general and administrative expense was \$30.7 million compared with \$27.5 million for the full year of 2010. The increase in the fourth



quarter and the full year of 2011 was primarily due to higher employee-related and external expenses offset by lower facilities-related costs. Total general and administrative stock-based compensation expense for the fourth quarter and full year of 2011 was \$2.8 million and \$11.5 million, respectively, compared with \$2.1 million and \$8.7 million, respectively, for the fourth quarter and full year of 2010.

### Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled \$240.9 million as of December 31, 2011, a decrease of \$24.3 million during the fourth quarter. This decrease was primarily due to cash used in operations offset by the \$1.0 million upfront license fee received from GSK upon licensing the preclinical MABAs in October 2011 and \$1.3 million received from GSK for the purchase of common stock in November 2011.

### **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 Standard 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 March 10, 2012. An audio replay will also be available through 11:59 p.m. Eastern Standard Time on February 16, 2012 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 43487593.

### **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 its 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).

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of Theravance, Inc.

RELOVAIR™ is a trademark of the GlaxoSmithKline group of companies.

VIBATIV® is a registered trademark of Astellas Pharma Inc.



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 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 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 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.

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**THERAVANCE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

	<b>Three Months Ended</b>		<b>Twelve Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
	<b>(unaudited)</b>		<b>(unaudited)</b>	
				<b>(2)</b>
Revenue	\$ 5,361	\$ 6,942	\$ 24,512	\$ 24,223
Operating expenses:				
Research and development (1)	32,468	17,476	103,568	75,070
General and administrative (1)	8,469	7,400	30,681	27,476
Total operating expenses	<u>40,937</u>	<u>24,876</u>	<u>134,249</u>	<u>102,546</u>
Loss from operations	(35,576)	(17,934)	(109,737)	(78,323)
Interest and other income	71	141	415	505
Interest expense	(1,502)	(1,506)	(6,022)	(6,044)
Net loss	<u>\$ (37,007)</u>	<u>\$ (19,299)</u>	<u>\$ (115,344)</u>	<u>\$ (83,862)</u>
Basic and diluted net loss per share	<u>\$ (0.45)</u>	<u>\$ (0.25)</u>	<u>\$ (1.41)</u>	<u>\$ (1.16)</u>
Shares used in computing basic and diluted net loss per share	<u>82,862</u>	<u>76,210</u>	<u>82,051</u>	<u>72,070</u>

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

	<b>Three Months Ended</b>		<b>Twelve Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
	<b>(unaudited)</b>		<b>(unaudited)</b>	
Research and development	\$ 3,401	\$ 2,613	\$ 13,422	\$ 10,322
General and administrative	<u>2,809</u>	<u>2,080</u>	<u>11,494</u>	<u>8,687</u>
Total stock-based compensation expense	<u>\$ 6,210</u>	<u>\$ 4,693</u>	<u>\$ 24,916</u>	<u>\$ 19,009</u>

(2) The condensed consolidated statement of operations amounts for the year ended December 31, 2010 are derived from audited financial statements.



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

	<b>December 31, 2011</b>	<b>December 31, 2010</b>
	(unaudited)	(2)
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 240,915	\$ 309,634
Other current assets	3,848	6,720
Property and equipment, net	10,372	10,215
Other assets	3,647	4,633
<b>Total assets</b>	<b>\$ 258,782</b>	<b>\$ 331,202</b>
<b>Liabilities and stockholders' net capital deficiency</b>		
Current liabilities (1)	\$ 45,496	\$ 40,054
Deferred revenue	122,017	137,425
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	5,821	3,643
Stockholders' net capital deficiency	(87,052)	(22,420)
<b>Total liabilities and stockholders' net capital deficiency</b>	<b>\$ 258,782</b>	<b>\$ 331,202</b>

(1) Amounts include current portion of deferred revenue of \$18.7 million and \$21.9 million as of December 31, 2011 and December 31, 2010, respectively.

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