Theravance Reports Second Quarter 2011 Financial Results

SOUTH SAN FRANCISCO, CA/July 28, 2011 — Theravance, Inc. (NASDAQ: THRX) reported today its financial results for the quarter ended June 30, 2011. Revenue for the second quarter of 2011 was $6.4 million. Net loss for the second quarter of 2011 was $25.0 million or $0.31 per share. Cash, cash equivalents and marketable securities totaled $283.9 million as of June 30, 2011.

"This is a very exciting time at Theravance as we have completed enrollment of the COPD and asthma registrational studies with RELOVAIR®" said Rick E Winningham, Chief Executive Officer. "We made significant progress during the second quarter, with GSK and Theravance reporting results from two RELOVAIR® 6-month efficacy and safety studies in COPD that support the progression of the program. Theravance also reported that telavancin, a treatment for resistant Gram-positive infections, received a positive opinion for approval in nosocomial pneumonia from the Committee for Medicinal Products for Human Use. We are pleased with our recent progress and look forward to the upcoming data from our respiratory programs with GSK."

Program Highlights

Respiratory Programs

Registrational Programs with RELOVAIR®

The registrational programs with RELOVAIR® in chronic obstructive pulmonary disease (COPD) and asthma have fully enrolled approximately 11,000 patients. RELOVAIR® is an investigational once-daily medicine that combines fluticasone furoate (FF, an inhaled corticosteroid or ICS) and vilanterol (VI, a long-acting beta$_2$ agonist or LABA) for the treatment of patients with COPD or asthma.

In COPD

The registrational 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.

In June 2011, GlaxoSmithKline (GSK) and Theravance announced the results of two 6-month efficacy and safety Phase 3 studies of RELOVAIR® for patients with COPD. Results of both studies support the continuation of the RELOVAIR® development program in the COPD patient population. These data form part of the overall evaluation of the efficacy and safety of the RELOVAIR® combination in COPD which, together with data from ongoing 12-month exacerbation studies, will be included in regulatory submissions around the world.

The two 6-month studies were placebo-controlled, double-blind, parallel-group studies that enrolled approximately 2,200 patients with moderate to severe COPD. Patients (approximately 200 per arm per study) were randomized to receive FF alone (100mcg, 200mcg), VI alone (25mcg), a combination of FF and VI (50mcg, 100mcg, or 200mcg FF plus VI 25mcg) or placebo. The studies evaluated improvement in lung function at two timepoints: over the first four hours after dosing on day 168 and 24 hours after the last dose of study drug.

These two 6-month FEV1 studies provided an initial insight into the pivotal program for RELOVAIR®

which is evaluating over 6,000 patients with COPD. The two larger 12-month exacerbation studies, which enrolled over 3,000 patients, will provide additional evaluation of the efficacy of RELOVAIR® compared with VI. The full results of all the studies will be presented at future scientific meetings.

In Asthma

The asthma registrational program is designed 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

The RELOVAIR® Phase 3b COPD program is progressing with the large Phase 3b outcomes study of 16,000 patients, which will assess the potential for RELOVAIR® to improve survival in patients with moderate COPD and a history of, or at risk for, cardiovascular disease. The results of this study are not required for the regulatory submission and will not form part of the initial New Drug Application (NDA)/Marketing Authorization Application (MAA).

In addition to the outcomes study, there are five ongoing Phase 3b COPD 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 two other studies will evaluate the effect of RELOVAIR® once-daily on arterial wall stiffness 1) compared with placebo and vilanterol for a treatment period of 24 weeks and 2) compared with tiotropium for a treatment period of 12 weeks in patients with COPD. The estimated enrollments for these studies are 410 patients and 248 patients, respectively.

LAMA/LABA Combination (GSK573719/Vilanterol or '719/VI) in COPD

Enrollment is in line with expectations for the seven studies in the Phase 3 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 molecules act through two mechanisms: antagonism of acetylcholine muscarinic receptors and agonism of $beta_2$ adrenoreceptors.

The LAMA/LABA Phase 3 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 pivotal studies that will compare improvements in lung function between '719/VI, its components and placebo, two 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 '719/VI (125/25mcg and 62.5/25mcg).

In September 2011, GlaxoSmithKline will present data from a Phase 2b clinical study and from clinical pharmacology and preclinical studies on the LAMA monotherapy, '719, at the European Respiratory Society Annual Congress in Amsterdam, Netherlands.

Inhaled Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist (MABA) in COPD

Enrollment is in line with expectations for the Phase 2b study with GSK961081 ('081) in patients with moderate to severe COPD. '081 is a single molecule bifunctional bronchodilator with both muscarinic antagonist and beta$_2$ receptor agonist activity. 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 an appropriate dose and dosing interval.

In September 2011, GlaxoSmithKline will present data from the Phase 2a proof-of-concept clinical study on MABA at the European Respiratory Society Annual Congress in Amsterdam, Netherlands.

Central Nervous System (CNS)/Pain Program

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

Recently, the first patient with opioid-induced constipation (OIC) was dosed in the Phase 2b program to assess the safety, tolerability and clinical activity of TD−1211 in patients with OIC. This study will evaluate doses and dose 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.

Financial Results

Revenue

Revenue was $6.4 million for the second quarter of 2011 compared with $6.3 million for the same period in 2010. During the second quarter of 2011, $0.7 million of royalty revenue was earned from VIBATIV® net sales of $3.9 million.

Research and Development

Research and development expense for the second quarter of 2011 increased to $22.8 million compared with $18.7 million for the same period in 2010. The increase in the second quarter of 2011 was primarily due to higher external costs related to preclinical and clinical activities and higher employee related expenses. Total external research and development expense was $5.2 million during the second quarter of 2011 compared with $3.3 million for the same period in 2010. Total research and development stock-based compensation expense for the second quarter of 2011 was $3.4 million compared with $2.6 million for the same period in 2010.

General and Administrative

General and administrative expense for the second quarter of 2011 increased to $7.2 million from $7.0 million for the same period in 2010. The increase in the second quarter of 2011 was primarily due to higher employee related expenses. Total general and administrative stock-based compensation expense for the second quarter of 2011 was $2.9 million compared with $2.7 million for the same period in 2010.

Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled $283.9 million as of June 30, 2011, a decrease of $9.9 million during the second quarter. This decrease was primarily due to cash used in operations partially offset by GSK's purchase of $6.7 million of common stock in May 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 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. 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 August 27, 2011. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on August 4, 2011 by dialing (800) 642-1687 from the U.S., or (706) 645-9291 for international callers, and entering confirmation code 72791251.

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$_2$ 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.

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 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 May 4, 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.

Contact Information:

Michael W. Aguiar
Senior Vice President and Chief Financial Officer
650-808-4100
investor.relations@theravance.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
Revenue	$ 6,389	$ 6,264	$ 12,719	$ 11,979
Operating expenses:				
Research and development (1)	22,798	18,705	43,262	39,057
General and administrative (1)	7,248	6,991	14,417	13,467
Total operating expenses	30,046	25,696	57,679	52,524
Loss from operations	(23,657)	(19,432)	(44,960)	(40,545)
Interest and other income	118	134	263	229
Interest expense	(1,506)	(1,508)	(3,015)	(3,025)
Net loss	$ (25,045)	$ (20,806)	$ (47,712)	$ (43,341)
Basic and diluted net loss per share	$ (0.31)	$ (0.28)	$ (0.59)	$ (0.63)
Shares used in computing basic and diluted net loss per share	81,811	73,282	81,415	69,124

(1) Amounts include stock-based compensation expense for the three months and six months ended June 30 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
Research and development	$ 3,379	$ 2,618	$ 6,511	$ 5,145
General and administrative	2,896	2,704	5,305	4,675
Total stock-based compensation expense	$ 6,275	$ 5,322	$ 11,816	$ 9,820

Theravance
Medicines That Make A Difference

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

	June 30, 2011	December 31, 2010
	(unaudited)	(2)
Assets		
Cash, cash equivalents and marketable securities	$ 283,887	$ 309,634
Other current assets	4,738	6,720
Property and equipment, net	10,334	10,215
Other assets	4,161	4,633
Total assets	**$ 303,120**	**$ 331,202**
Liabilities and stockholders' net capital deficiency		
Current liabilities (1)	$ 35,191	$ 40,054
Deferred revenue	127,393	137,425
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	5,518	3,643
Stockholders' net capital deficiency	(37,482)	(22,420)
Total liabilities and stockholders' net capital deficiency	**$ 303,120**	**$ 331,202**

(1) Amounts include current portion of deferred revenue of $20.6 million and $21.9 million as of June 30, 2011 and December 31, 2010, respectively.

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