Theravance Reports Third Quarter 2011 Financial Results

SOUTH SAN FRANCISCO, CA/October 27, 2011 — Theravance, Inc. (NASDAQ: THRX) reported today its financial results for the quarter ended September 30, 2011. Revenue for the third quarter of 2011 was $6.4 million. Net loss for the third quarter of 2011 was $30.6 million or $0.37 per share. Cash, cash equivalents, and marketable securities totaled $265.2 million as of September 30, 2011.

"We are pleased with another quarter of significant progress with our key programs," said Rick E Winningham, Chief Executive Officer. "Our respiratory programs with GSK continue to move forward in line with our expectations. We anticipate reporting topline results from the RELOVAIR™ Phase 3 exacerbation studies in COPD in early 2012 and from the asthma program during the first half of 2012. In addition, we are excited about the recent expansion of the MABA program under the Strategic Alliance. Under the expanded MABA agreement, GSK licensed additional preclinical MABA compounds and returned full rights to our MARIN and ARNI programs. We remain confident with our lead MABA compound, '081 and we believe the expansion of the MABA agreement gives us multiple opportunities to succeed in the MABA program. In our non-respiratory programs, VIBATIV® was approved in Europe and we made progress in enrollment in the Phase 2b program in opioid-induced constipation with TD-1211."

Program Highlights

Respiratory Programs

Registrational Programs with RELOVAIR™ in COPD and Asthma

The registrational programs for RELOVAIR™ in chronic obstructive pulmonary disease (COPD) and asthma remain on track. 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.

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. GlaxoSmithKline (GSK) and Theravance anticipate reporting topline results from the registrational program in COPD in early 2012. The asthma registrational program is designed to determine the safety and efficacy of RELOVAIR™ in asthma patients who remain uncontrolled on their current treatment. The program includes 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. GSK and Theravance anticipate reporting topline results from the registrational program in asthma in the first half of 2012.

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 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).

In September 2011, GSK presented data from preclinical, clinical pharmacology studies and a Phase 2b study on the LAMA, '719, at the European Respiratory Society (ERS) Annual Congress in Amsterdam, Netherlands. On October 26, 2011, GSK also presented data from a further Phase 2b study of the LAMA, '719, at CHEST 2011, the annual meeting of the American College of Chest Physicians (ACCP), in Honolulu, Hawaii.

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

The Phase 2b program for GSK961081 ('081) continues in line with expectations. '081 is a single molecule bifunctional bronchodilator with both muscarinic antagonist and $beta_2$ receptor agonist activity. The primary objective of the Phase 2b study is to evaluate dose response, dose interval, efficacy, and safety of '081 by studying once-daily doses (100mcg, 400mcg, and 800mcg), twice-daily doses (100mcg, 200mcg, and 400mcg), the active comparator salmeterol twice-daily (50mcg) and placebo over a 28-day period. Data from this Phase 2b study will support the selection of a dose and dosing interval for further studies of '081. GSK and Theravance anticipate reporting topline results from the Phase 2b study in the first half of 2012.

In September 2011, GSK presented data from a Phase 2a proof-of-concept clinical study of the MABA '081 at the ERS Annual Congress in Amsterdam, Netherlands.

During the third quarter, GSK initiated a Phase 1 study of '081 in combination with fluticasone propionate (FP), an inhaled corticosteroid (ICS). The primary objective of this single-dose study is to evaluate the safety, pharmacokinetics and pharmacodymanics of the combination of '081 and FP versus its components. Theravance received a milestone payment of $3.0 million under the Strategic Alliance Agreement for the initiation of the study.

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 1 development, and its Angiotensin Receptor-NEP Inhibitor (ARNI) program in preclinical development.

Bacterial Infections

VIBATIV® (telavancin hydrochloride) in Nosocomial Pneumonia in Europe

In September 2011, Astellas Pharma Europe Ltd., a subsidiary of Tokyo-based Astellas Pharma Inc., and Theravance announced that the European Commission granted marketing authorization for VIBATIV® (telavancin hydrochloride), following the Committee for Human Medicinal Products' (CHMP) positive opinion in May 2011. VIBATIV®, discovered by Theravance, is a bactericidal, once-daily injectable lipoglycopeptide antibacterial agent with a dual mechanism of action against Gram-positive bacteria, including resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA).

The VIBATIV® marketing authorization from the European Commission is granted for the treatment of adults with nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. The marketing authorization for VIBATIV® is valid in all Member States of the European Community. Norway and Iceland have also authorized sale in their respective territories. Launch plans are under review.

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 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 third quarter of 2011 compared with $5.3 million for the same period in 2010. During the third quarter of 2011, $0.8 million of royalty revenue was earned from VIBATIV® net sales of $4.5 million.

Research and Development

Research and development expense for the third quarter of 2011 increased to $27.8 million compared with $18.5 million for the same period in 2010. The increase in the third quarter of 2011 was primarily due to higher external costs and facilities related costs associated with clinical activities related to our PμMA and MARIN programs and higher employee related expenses. Total external research and development expense was $9.5 million during the third quarter of 2011 compared with $3.5 million for the same period in 2010. Total research and development stock-based compensation expense for the third quarter of 2011 was $3.5 million compared with $2.6 million for the same period in 2010.

General and Administrative

General and administrative expense for the third quarter of 2011 increased to $7.8 million from $6.6 million for the same period in 2010. The increase in the third quarter of 2011 was primarily due to higher employee related expenses offset by lower facilities related costs. Total general and administrative stock-based compensation expense for the third quarter of 2011 was $3.4 million compared with $1.9 million for the same period in 2010.

Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled $265.2 million as of September 30, 2011, a decrease of $18.7 million during the third quarter. This decrease was primarily due to cash used in operations offset by the $3.0 million milestone payment received from GSK for the initiation of a Phase 1 combination study in the MABA program and $2.0 million received from GSK for the purchase of common stock in August 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 November 26, 2011. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on November 3, 2011 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 11464221.

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.

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

VIBATIV® is a registered trademark of Astellas Pharma Inc.

ADVAIR®/SERETIDE™ and RELOVAIR™ are trademarks of GlaxoSmithKline.

VIBATIV® Important Safety Information (U.S.)
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® versus discontinuing and initiating therapy with an alternative agent should be assessed. Clinical cure rates in telavancin-treated patients were lower in patients with baseline CrCl ≤50 mL/min compared to those with CrCl >50 mL/min. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate/severe renal impairment.

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 intravenous 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.

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 thromboplastin 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 3 cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy urine.

In the Phase 3 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 in the U.S., please visit www.VIBATIV.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 August 3, 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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
Revenue	$ 6,431	$ 5,302	$ 19,150	$ 17,281
Operating expenses:				
Research and development (1)	27,837	18,537	71,099	57,594
General and administrative (1)	7,796	6,610	22,213	20,077
Total operating expenses	35,633	25,147	93,312	77,671
Loss from operations	(29,202)	(19,845)	(74,162)	(60,390)
Interest and other income	81	136	344	364
Interest expense	(1,505)	(1,513)	(4,519)	(4,537)
Net loss	$ (30,626)	$ (21,222)	$ (78,337)	$ (64,563)
Basic and diluted net loss per share	$ (0.37)	$ (0.29)	$ (0.96)	$ (0.91)
Shares used in computing basic and diluted net loss per share	82,490	73,726	81,777	70,675

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
Research and development	$ 3,510	$ 2,564	$ 10,021	$ 7,709
General and administrative	3,380	1,933	8,685	6,607
Total stock-based compensation expense	$ 6,890	$ 4,497	$ 18,706	$ 14,316

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

	September 30, 2011	December 31, 2010
	(unaudited)	(2)
Assets		
Cash, cash equivalents and marketable securities	$ 265,169	$ 309,634
Other current assets	3,996	6,720
Property and equipment, net	10,206	10,215
Other assets	3,954	4,633
Total assets	**$ 283,325**	**$ 331,202**
Liabilities and stockholders' net capital deficiency		
Current liabilities (1)	$ 39,814	$ 40,054
Deferred revenue	124,435	137,425
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	5,728	3,643
Stockholders' net capital deficiency	(59,152)	(22,420)
Total liabilities and stockholders' net capital deficiency	**$ 283,325**	**$ 331,202**

(1) Amounts include current portion of deferred revenue of $20.9 million and $21.9 million as of September 30, 2011 and December 31, 2010, respectively.

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