April 25, 2013

Theravance Reports First Quarter 2013 Financial Results

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 04/25/13 -- Theravance, Inc. (NASDAQ: THRX) (the "Company") reported today its financial results for the quarter ended March 31, 2013. Revenue for the first quarter of 2013 was $1.3 million. Net loss for the first quarter of 2013 was $37.4 million or $0.39 per share. Cash and cash equivalents, short-term investments and marketable securities totaled $558.4 million as of March 31, 2013.

"Theravance is off to a strong start in 2013 highlighted by the recent FDA Advisory Committee meeting which recommended approval of BREO™ ELLIPTA™ for the treatment of COPD," said Rick E Winningham, Chief Executive Officer. "This positive outcome marks another important milestone for Theravance in a year of transformation and potential growth. Today we issued a press release announcing our intention to separate the late-stage respiratory assets partnered with GSK from our biopharmaceutical operations to create two independent publicly traded companies. We believe this will provide investors with the opportunity to unlock potential value from two disparate sets of assets. Overall, we believe that Theravance is extremely well positioned both strategically and financially."

Respiratory Programs with GlaxoSmithKline plc (GSK)

RELVAR™ or BREO™ ELLIPTA™ (Fluticasone Furoate/Vilanterol, FF/VI)

FF/VI is an investigational once-daily inhaled corticosteroid/long-acting beta$_2$ agonist (LABA) combination treatment, comprising FF and VI, for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) and patients with asthma. FF/VI is administered by a new dry powder inhaler called ELLIPTA™. RELVAR™ (FF/VI for the European Union (EU) and Japan), BREO™ (FF/VI for the United States (U.S.)), and ELLIPTA™ (for the EU, U.S. and Japan) are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

On April 17, 2013, the Pulmonary-Allergy Drugs Advisory Committee to the U.S. Food and Drug Administration (FDA) recommended approval of BREO™ ELLIPTA™ for the treatment of COPD. The FDA Advisory Committee provides non-binding recommendations for consideration by the FDA, with the final decision on approval made by the FDA. The Prescription Drug User Fee Act (PDUFA) goal date for FF/VI is May 12, 2013.

On April 19, 2013, an article on the two replicate double-blind, parallel-group, randomized controlled trials comparing three doses of FF/VI with VI alone on the annual rate of exacerbations in patients with COPD became available in the online publication of the Lancet Respiratory Medicine.

In May 2013, GSK will be presenting data from Phase 3 studies of FF/VI at the American Thoracic Society International Conference held in Philadelphia, Pennsylvania.

ANORO™ ELLIPTA™ (Umeclidinium Bromide/Vilanterol, UMEC/VI)

UMEC/VI is a once-daily investigational medicine, combining a long-acting muscarinic antagonist (LAMA), UMEC, and a LABA, VI, for the maintenance treatment of patients with COPD. UMEC/VI is administered by the ELLIPTA™ dry powder inhaler. ANORO™ and ELLIPTA™ are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

In February 2013, GSK and Theravance announced that the New Drug Application (NDA) for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with COPD, was accepted by the FDA indicating that the application is sufficiently complete to permit a substantive review. The PDUFA goal date was confirmed as December 18, 2013. In addition, the Marketing Authorization Application (MAA) for UMEC/VI has been validated for assessment by the European Medicines Agency (EMA). On April 22, 2013, GSK and Theravance announced the submission of a regulatory application to the Japanese Ministry of Health, Labor and Welfare for UMEC/VI for patients with COPD. Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013.

In May 2013, GSK will be presenting data from Phase 1 and Phase 3 studies of UMEC/VI at the American Thoracic Society International Conference held in Philadelphia, Pennsylvania.

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

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta$_2$ receptor agonist activities. Based on the results from the Phase 2b study, GSK and Theravance plan to advance '081 monotherapy into Phase 3 and the '081/FF combination into Phase 3-enabling studies, later in 2013.

Bacterial Infections Programs

VIBATIV® (telavancin)

VIBATIV® is a bactericidal, once-daily injectable lipoglycopeptide antibiotic approved in the U.S. and Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) strains. In November 2012, Theravance announced a favorable outcome of the FDA's Anti-Infective Drugs Advisory Committee meeting on VIBATIV® for the treatment of nosocomial pneumonia (NP) due to susceptible isolates of Gram-positive microorganisms. Theravance remains in dialogue with the FDA on the NP indication and is working toward re-establishing consistent product supply.

Glycopeptide-Cephalosporin Heterodimer - TD-1607

In April 2013, Theravance initiated a Phase 1 randomized, double-blind, placebo-controlled single-ascending dose study designed to evaluate the safety, tolerability and pharmacokinetics of TD-1607, administered intravenously. Discovered by Theravance, TD-1607 is an investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of serious, difficult-to-treat Gram-positive infections due to resistant strains of *Staphylococcus aureus*. TD-1607 has demonstrated potent activity *in vitro* and in preclinical *in vivo* models of infection.

Central Nervous System (CNS)/Pain Programs

Oral Peripheral Mu Opioid Receptor Antagonist - TD-1211

TD-1211 is an investigational once-daily, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with a goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia. In July 2012, Theravance announced positive topline results from the Phase 2b Study 0084, the key study in the Phase 2b program evaluating TD-1211 as potential treatment for chronic, non-cancer pain patients with opioid-induced constipation. The Phase 2b program consisted of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. We are currently evaluating our Phase 3 strategy due to potentially evolving FDA requirements for this class of drug.

In May 2013, Theravance will be presenting data from Phase 2 and Phase 2b studies of TD-1211 at the American Pain Society 32nd Annual Scientific Meeting in New Orleans, Louisiana and from a Phase 2b study of TD-1211 at the Digestive Disease Week 2013 in Orlando, Florida.

Monoamine Reuptake Inhibitor - TD-9855

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor for the treatment of central nervous system conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD) and chronic pain. TD-9855 is being evaluated in an ongoing Phase 2 study in adult patients with ADHD and in an ongoing Phase 2 study in patients with fibromyalgia. Both studies are progressing and results from the Phase 2 study in ADHD are anticipated to be reported late this year or in early 2014.

Theravance Respiratory Program

Long-Acting Muscarinic Antagonist (LAMA) - TD-4208

TD-4208, an investigational LAMA for the treatment of COPD, is being evaluated in an ongoing randomized, double-blind, multiple-dose Phase 2b study to examine pharmacodynamics, safety and tolerability, and pharmacokinetics. Enrollment is on track and results from the Phase 2b study are anticipated to be reported late this year.

GI Motility Dysfunction Program

Velusetrag

Velusetrag, an oral, investigational medicine dosed once daily, is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT4 program, covering the EU, Russia, China, Mexico and certain other countries. In January 2013, Theravance and Alfa Wassermann announced the initiation of a Phase 2 proof-of-concept study to evaluate the efficacy and safety of velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis.

Corporate Development

Clinigen Group plc

In March 2013, Clinigen Group plc (Clinigen) and Theravance announced that they have entered into an exclusive commercialization agreement in the EU and certain other European countries for VIBATIV® (telavancin) for the treatment of nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. Under the terms of the agreement, Theravance has granted Clinigen exclusive commercialization rights to VIBATIV® in the EU and certain other European countries (including Switzerland and Norway). In exchange, Theravance received a $5.0 million upfront payment from Clinigen and is entitled to receive tiered royalties on net sales of VIBATIV®, ranging from 20% to 30%.

Financial Results

Revenue

Revenue was $1.3 million for the first quarter of 2013 compared with $127.1 million for the same period in 2012, a decrease of $125.8 million primarily due to the January 6, 2012 termination of our global collaboration arrangement with Astellas Pharma Inc. for the development and commercialization of VIBATIV®.

Research and Development

Research and development expense for the first quarter of 2013 decreased to $26.4 million compared with $33.2 million for the same period in 2012. The decrease in the first quarter over the same period last year was primarily due to a decrease in outside services costs related to the completion of our Phase 2 studies in our program for opioid-induced constipation with TD-1211 and, to a lesser extent, from an increase in collaborative partner R&D reimbursements. Total external research and development expense for the first quarter of 2013 was $7.1 million compared with $13.2 million for the same period in 2012. Total research and development stock-based compensation expense for the first quarter of 2013 was $3.8 million compared with $3.5 million for the same period in 2012.

General and Administrative

General and administrative expense for the first quarter of 2012 increased to $8.3 million from $7.9 million for the same period in 2012. The increase in the first quarter over the same period last year was primary due to higher external legal costs in connection with strategic initiatives and higher facilities-related costs partially offset by a decrease in employee related costs driven by a decrease in stock-based compensation expense. Total general and administrative stock-based compensation expense for the first quarter of 2013 was $2.3 million compared with $2.7 million for the same period in 2012.

Cash and Cash Equivalents, Short-Term Investments and Marketable Securities

Cash and cash equivalents, short-term investments and marketable securities totaled $558.4 million as of March 31, 2013, an increase of $214.7 million during the first quarter. The increase was primarily due to the closing of a convertible subordinated note offering with net proceeds of approximately $244.4 million on January 24, 2013 and net proceeds of $2.6 million received from the Company's private placements of common stock to an affiliate of GSK, partially offset by cash used in operations.

Conference Call and Webcast Information

As previously announced, Theravance has scheduled a conference call to discuss this announcement beginning at 5:00 p.m. Eastern Daylight Time today. 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 Theravance's web site at www.theravance.com. To listen to the live call via the internet, 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 Theravance's web site for 30 days through May 25, 2013. An audio replay

will also be available through 11:59 p.m. Eastern Daylight Time on May 2, 2013 by dialing *(855) 859-2056* from the U.S., or *(404) 537-3406* for international callers, and entering confirmation code 21878794.

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. Theravance's key programs include: RELVAR™ or BREO™ ELLIPTA™ (FF/VI), ANORO™ ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist 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 Theravance's web site at www.theravance.com.

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 US, 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 Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates (including, with respect to VIBATIV®, statements regarding any expectation (a) that we will be able to respond fully or adequately to FDA's requests using currently existing clinical data, (b) that the FDA will approve the VIBATIV® nosocomial pneumonia NDA on the basis of existing preclinical and clinical data or at all or (c) regarding the timing of the European Commission releasing the suspended marketing authorization for VIBATIV®), statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning expectations for the discovery, development and commercialization of product candidates, projections of revenue, expenses and other financial items, and plans for effecting a separation of the late-stage respiratory assets partnered with GSK from our biopharmaceutical operations to create two separately traded public companies. 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 and non-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, risks of collaborating with third parties to discover, develop and commercialize products, difficulties or delays in effecting the registration as a public company of the company to be separated, failure to obtain

necessary consents from third parties for the separation, changes in our development or operations prior to the separation that could affect the plans for the separation or the cash available for the initial funding of the independent companies, and the possibility that alternative transactions or opportunities could arise or be pursued which would alter the timing, or advisability of, or the ability to consummate, the anticipated separation transaction. 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 26, 2013 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.

(THRX-F)

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended March 31,	
	2013	***2012***
	(unaudited)	
Revenue from collaborative arrangements	$ 1,344	$ 127,099
Operating expenses:		
Research and development (1)	26,416	33,202
General and administrative (1)	8,315	7,857
Total operating expenses	34,731	41,059
Income (loss) from operations	(33,387)	86,040
Interest and other income (expense), net (2)	(1,237)	56
Interest expense	(2,736)	(1,502)
Net income (loss)	$ (37,360)	$ 84,594
Net income (loss) per share:		
Basic	$ (0.39)	$ 1.01
Diluted	$ (0.39)	$ (0.93)
Weighted-average shares:		
Basic	96,379	83,590
Diluted	96,379	92,080

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

	Three Months Ended March 31,	
	2013	***2012***
	(unaudited)	
Research and development	$ 3,797	$ 3,529
General and administrative	2,298	2,706
Total stock-based compensation expense	$ 6,095	$ 6,235

(2) Amount includes a noncash charge of $1.4 million resulting from a decrease in the fair market value of the capped call instruments related to our convertible subordinated notes issued in January 2013.

THERAVANCE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	March 31, 2013	***December 31, 2012***
	(unaudited)	(1)
Assets		

Cash, cash equivalents, short-term investments, and marketable securities	$ 558,398	$ 343,683
Other current assets	7,407	5,130
Inventory	8,049	7,514
Property and equipment, net	9,010	9,154
Other assets	8,655	3,101
Total assets	***$ 591,519***	***$ 368,582***
Liabilities and stockholders' equity (net capital deficiency)		
Current liabilities (2)	$ 29,464	$ 29,966
Deferred revenue, non-current	5,672	6,014
Convertible subordinated notes	460,000	172,500
Other long-term liabilities	4,872	5,074
Stockholders' equity (net capital deficiency)	91,511	155,028
Total liabilities and stockholders' equity (net capital deficiency)	***$ 591,519***	***$ 368,582***

(1) The condensed consolidated balance sheet amounts at December 31, 2012 are derived from audited financial statements.

(2) Amounts include current portion of deferred revenue of $9.9 million and $4.6 million as of March 31, 2013 and December 31, 2012, respectively.

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Source: Theravance, Inc.