



Theravance Reports Fourth Quarter and Full Year 2009 Financial Results

SOUTH SAN FRANCISCO, CA/February 11, 2010 – Theravance, Inc. (NASDAQ: THRX) reported today its financial results for the fourth quarter and full year ended December 31, 2009. Revenue for the full year was \$24.4 million which included \$0.8 million in royalties related to sales of VIBATIV™ (telavancin) which was launched during the fourth quarter. Net loss for the fourth quarter and full year of 2009 was \$22.2 million and \$85.3 million, respectively, compared with \$15.9 million and \$93.6 million for the same periods of 2008. Net loss per share was \$0.35 and \$1.35 for the fourth quarter and full year of 2009, respectively, compared with a net loss per share of \$0.26 and \$1.53 for the same periods of 2008.

“It was a very exciting fourth quarter for Theravance with the initiation of the large Phase 3 RELOVAIR™ program with GSK in COPD and the commercial launch of VIBATIV for complicated skin and skin structure infections in the United States with our partner, Astellas, as well as approval in Canada,” said Rick E Winningham, Chief Executive Officer. “Enrollment in the Phase 3 RELOVAIR program in COPD is progressing well. I am particularly pleased that VIBATIV is receiving positive reception from physicians in the U.S. and that Astellas generated net sales of \$4.3 million following the November launch. 2009 was a productive year for Theravance and we look forward to the progress of the RELOVAIR program and further development of our pipeline in 2010.”

Program Highlights

Respiratory Programs

RELOVAIR™ (previously Horizon)

In October 2009, GlaxoSmithKline (GSK) and Theravance announced that the first patient has commenced treatment in the Phase 3 program to develop a next-generation combination treatment for patients with chronic obstructive pulmonary disease (COPD). The Phase 3 program comprises a broad range of large scale Phase 3 studies to evaluate the investigational once-a-day long-acting beta agonist (LABA), 642444 ('444), in combination with the once-a-day inhaled corticosteroid (ICS), fluticasone furoate (FF), for the treatment of COPD. The overall program, which will study more than 6,000 patients, includes two 12-month exacerbation studies, two 6-month efficacy and safety studies, a detailed lung function profile study, and studies to assess the potential for superiority of the fixed combination of '444 and FF versus other treatments for COPD.

Enrollment is progressing well for the two 12-month exacerbation studies and two 6-month efficacy and safety studies in the Phase 3 RELOVAIR program in COPD.



Bacterial Infections Program

VIBATIV™ (telavancin)

In November 2009, Theravance and Astellas Pharma US, Inc. announced the commercial launch in the United States of VIBATIV™ (telavancin) 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. VIBATIV, also approved by Health Canada for the treatment of adult patients with cSSSI, is targeted to launch in Canada in 2010 with our partner, Astellas.

Since the commercial launch in November and through December 31, 2009 VIBATIV had net sales of \$4.3 million, a substantial portion of which was related to the initial wholesaler stocking.

Telavancin

In November 2009, the European Medicines Agency (EMA) completed the validation phase for the Marketing Authorization Application (MAA) for telavancin for the treatment of NP, including ventilator-associated pneumonia, and complicated skin and soft tissue infections (cSSTI) in adults. Astellas Pharma Europe B.V., a European affiliate of Astellas Pharma Inc. (Astellas), submitted the MAA in October 2009 under the Centralized Procedure and applied for marketing authorization for telavancin in the Member States of the European Union (EU), plus Iceland, Liechtenstein and Norway.

On January 28, 2010, we announced that we received a letter from the FDA indicating our response to the November 2009 Complete Response letter for our telavancin New Drug Application for the treatment of nosocomial pneumonia due to Gram-positive organisms was incomplete. We have not met with the FDA yet to discuss this letter. It is unclear at this point what the standard for approval is for this indication. We do not have an estimated timeline for the resolution of these issues.

Financial Results

Revenue

Revenue was \$3.8 million for the fourth quarter of 2009 compared with \$5.9 million for the same period of 2008, a decrease of \$2.1 million. Total royalty revenue during the fourth quarter from the sales of VIBATIV was \$0.8 million. For the full year of 2009, revenue was \$24.4 million, compared with \$23.1 million for the full year of 2008. All milestone payments received to date under the company's partnership agreements are being amortized over the relevant performance periods rather than being recognized when received.

Research and Development

Research and development expense for the fourth quarter of 2009 increased to \$18.4 million compared with \$15.2 million for the same period of 2008. For the full year of 2009, research and development expense was \$77.5 million compared with \$82.0 million for the full year of 2008. The increase for the fourth quarter of 2009 was primarily due to a \$4.9 million reimbursement of development expenses received from Astellas in the fourth quarter of 2008. The decrease for



the full year of 2009 was primarily due to lower external costs related to the regulatory process for telavancin and the impact of the Astellas reimbursement. Total external research and development expense for the fourth quarter and full year of 2009, excluding reimbursements, was \$3.3 million and \$17.4 million, respectively, compared with \$5.6 million and \$22.8 million, respectively, for the fourth quarter and full year of 2008. Total research and development stock-based compensation expense for the fourth quarter and full year of 2009 was \$2.6 million and \$11.5 million, respectively, compared with \$2.7 million and \$10.3 million, respectively, for the fourth quarter and full year of 2008.

General and Administrative

General and administrative expense for the fourth quarter of 2009 increased to \$6.4 million from \$5.9 million for the same period in 2008. For the full year of 2009, general and administrative expense was \$27.1 million compared with \$28.9 million for the full year of 2008. The increase in the fourth quarter of 2009 was primarily due to higher employee-related expenses. The decrease for the full year of 2009 was primarily due to lower external and facilities-related expenses. Total general and administrative stock-based compensation expense for the fourth quarter and full year of 2009 was \$2.0 million and \$8.5 million, respectively, compared with \$1.9 million and \$7.8 million, respectively, for the fourth quarter and full year of 2008.

Restructuring Charges

The company incurred restructuring charges totaling \$1.1 million for the full year of 2009. The charges resulted primarily from a loss recognized on the sublease of excess space in one of the company's South San Francisco, CA buildings as well as employee severance and benefits resulting from the reduction in force announced in April 2008.

Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled \$155.4 million as of December 31, 2009, an increase of \$1.2 million during the fourth quarter. This increase was primarily due to a \$20.0 million milestone payment received from Astellas partially offset by 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 Standard Time today. To participate in the live call by telephone, please dial 888-710-4013 from the U.S., or 913-312-0418 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 March 13, 2010. An audio replay will also be available through 11:59 p.m. Eastern Standard Time on February 18, 2010 by dialing 888-203-1112 from the U.S., or 719-457-0820 for international callers, and entering confirmation code 2324359.



About Theravance

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. 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 gastrointestinal motility dysfunction. The company's key programs include: VIBATIV™ (telavancin) with Astellas Pharma Inc. and the RELOVAIR™ program and Bifunctional Muscarinic Antagonist-Beta₂ Agonist (MABA) program with GlaxoSmithKline plc. By leveraging its proprietary insight of multivalency toward drug discovery, Theravance is pursuing a next generation 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.

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VIBATIV is a trademark of Astellas Pharma Inc.

RELOVAIR is a trademark of Glaxo Group Limited.

About VIBATIV

VIBATIV was discovered by Theravance in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including MRSA. VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby VIBATIV both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. VIBATIV is indicated for the treatment of adult patients with cSSSI caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus group* (includes *S. anginosus*, *S. intermedius* and *S. constellatus*) and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

VIBATIV Important Safety Information

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 ($\geq 10\%$ of patients treated with VIBATIV) observed in the Phase III cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy urine.

In the Phase III 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 and medication guide, 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 goals and timing of clinical studies 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, or to successfully launch, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 4, 2009 and the risks discussed in our other periodic filings with the 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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
	(unaudited)		(unaudited)	(2)
Revenue	\$ 3,822	\$ 5,947	\$ 24,374	\$ 23,096
Operating expenses:				
Research and development (1)	18,406	15,170	77,524	82,020
General and administrative (1)	6,393	5,945	27,066	28,861
Restructuring charges	(162)	306	1,145	5,419
Total operating expenses	<u>24,637</u>	<u>21,421</u>	<u>105,735</u>	<u>116,300</u>
Loss from operations	(20,815)	(15,474)	(81,361)	(93,204)
Interest and other income	115	1,066	2,111	5,242
Interest expense	(1,510)	(1,517)	(6,052)	(5,681)
Net loss	<u>\$ (22,210)</u>	<u>\$ (15,925)</u>	<u>\$ (85,302)</u>	<u>\$ (93,643)</u>
Basic and diluted net loss per share	<u>\$ (0.35)</u>	<u>\$ (0.26)</u>	<u>\$ (1.35)</u>	<u>\$ (1.53)</u>
Shares used in computing basic and diluted net loss per share	<u>63,729</u>	<u>61,810</u>	<u>63,027</u>	<u>61,390</u>

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
	(unaudited)		(unaudited)	(2)
Research and development	\$ 2,566	\$ 2,725	\$ 11,542	\$ 10,264
General and administrative	2,050	1,892	8,458	7,755
Total stock-based compensation expense	<u>\$ 4,616</u>	<u>\$ 4,617</u>	<u>\$ 20,000</u>	<u>\$ 18,019</u>

(2) The condensed consolidated statement of operations amounts for the year ended December 31, 2008 are derived from audited financial statements.



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

	December 31, 2009	December 31, 2008
	<u>(unaudited)</u>	<u>(2)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 155,390	\$ 200,605
Other current assets	6,652	9,356
Property and equipment, net	12,927	16,206
Other assets	6,424	9,989
Total assets	<u>\$ 181,393</u>	<u>\$ 236,156</u>
 Liabilities and stockholders' net capital deficiency		
Current liabilities, net of current portion of deferred revenue (1)	\$ 15,224	\$ 20,167
Deferred revenue (1)	181,148	176,559
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	1,515	1,879
Stockholders' net capital deficiency	(188,994)	(134,949)
Total liabilities and stockholders' net capital deficiency	<u>\$ 181,393</u>	<u>\$ 236,156</u>

(1) Deferred revenue includes the current portion of \$23.7 million and \$23.8 million as of December 31, 2009 and December 31, 2008, respectively. The 2009 net change in total deferred revenue is a result of additional milestones payments received offset by amortization.

(2) The condensed consolidated balance sheet amounts at December 31, 2008 are derived from audited financial statements.