



Theravance Reports Second Quarter 2010 Financial Results

SOUTH SAN FRANCISCO, CA/July 22, 2010 – Theravance, Inc. (NASDAQ: THRX) reported today its financial results for the quarter ended June 30, 2010. Revenue for the second quarter of 2010 was \$6.3 million. Net loss for the second quarter of 2010 was \$20.8 million or \$0.28 per share. Cash, cash equivalents and marketable securities totaled \$210.7 million as of June 30, 2010.

“I am pleased with the progress of our key programs in the second quarter of 2010,” said Rick E Winningham, Chief Executive Officer. “Enrollment in the RELOVAIR™ COPD and asthma programs continues to progress with ten Phase 3 studies now underway. Enrollment is also progressing in a Phase 2 proof of concept study in our peripheral mu antagonist program with the lead compound TD-1211 for the treatment of opioid-induced constipation. We recently completed a Phase 1 single-ascending dose study with TD-9855, the lead compound in our monoamine reuptake inhibitor program for the treatment of pain, and we are planning to advance this compound into a Phase 1 multiple-ascending dose study in the third quarter of 2010. The VIBATIV™ launch is progressing in the US and VIBATIV is under review by the European Medicines Agency for the treatment of nosocomial pneumonia and complicated skin and soft tissue infections in adults. This is an exciting time for the company and we look forward to a productive second half of the year with further development of our pipeline.”

Program Highlights

RELOVAIR™ (previously Horizon) – Asthma

Enrollment is progressing in the Phase 3 asthma program. In March 2010, GlaxoSmithKline (GSK) and Theravance announced that the first asthma patient commenced treatment with RELOVAIR™ (fluticasone furoate/vilanterol trifenate) in an asthma exacerbation study, marking the start of the Phase 3 asthma clinical development program with this once-daily therapy.

The Phase 3 asthma program consists of eight studies, five of which are underway, 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 chronic obstructive pulmonary disease (COPD) program), a 12-week low-dose combination and 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 fluticasone furoate versus fluticasone propionate, a 12-week study of vilanterol trifenate versus salmeterol, and a hypothalamic-pituitary-adrenal (HPA) axis study.

In the Phase 3 asthma program, four studies are currently recruiting patients:

- Exacerbation Study – ~2,000 patients
- 24-Week High Dose Combination Efficacy Study – ~1,000 patients
- 24-Week Head-to-Head Study of RELOVAIR™ versus Advair®/Seretide – ~100 patients
- Hypothalamic-Pituitary-Adrenal (HPA) Axis Study – ~200 patients



Enrollment of approximately 500 patients in the 12-month safety study has been completed and treatments are currently ongoing.

RELOVAIR™ (previously Horizon) – Chronic Obstructive Pulmonary Disease (COPD)

The Phase 3 program in COPD was initiated in October 2009 and enrollment is progressing. The overall program, which is comprised of five studies encompassing 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 vilanterol trifenate and fluticasone furoate versus other treatments for COPD.

All five Phase 3 studies in COPD are underway. Four of the five studies are currently recruiting patients; one has fully enrolled and is ongoing.

Patients across all of the RELOVAIR™ programs will be dosed using a unique single-step activation inhaler. This novel delivery device was developed utilizing GSK's expertise in device development and valuable patient input.

VIBATIV™ (telavancin)

VIBATIV was launched in the United States (US) in the fourth quarter of 2009 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. The VIBATIV launch is progressing in the US and VIBATIV is under review by the European Medicines Agency for the treatment of nosocomial pneumonia and complicated skin and soft tissue infections in adults.

Peripheral Mu Opioid Receptor Antagonist (PUMA) – TD-1211

Enrollment is progressing in the Phase 2 clinical study with TD-1211, an orally-administered peripherally selective mu opioid receptor antagonist (PUMA), for the treatment of opioid-induced constipation (OIC). TD-1211 is a potent, multivalent inhibitor of the mu opioid receptor designed to alleviate gastrointestinal side effects of opioid analgesic therapy without affecting analgesia. This "proof of concept" study is designed to assess the efficacy, tolerability and safety of TD-1211 in patients with OIC. We expect to report top-line data from this study toward the end of 2010.

Financial Results

Revenue

Revenue was \$6.3 million for the second quarter of 2010 compared with \$5.5 million for the same period in 2009. Revenue for the second quarter 2010 consisted of the amortization of deferred revenues from our collaborations with GSK and Astellas of \$5.7 million, net revenues recognized for the sale of VIBATIV inventory to Astellas of \$0.5 million, and VIBATIV royalties earned of \$0.1 million.



Research and Development

Research and development expense for the second quarter of 2010 decreased to \$18.7 million compared with \$20.0 million for the same period in 2009. The decrease was primarily due to lower external costs from our new drug discovery programs and facilities costs. Results for the second quarter of 2009 included a one-time reimbursement from Astellas that reduced expenses by \$1.0 million. Total external research and development expense excluding the reimbursement from Astellas was \$3.3 million during the second quarter of 2010 compared with \$4.0 million for the same period in 2009. Total research and development stock-based compensation expense for the second quarter of 2010 was \$2.6 million compared with \$3.1 million for the same period in 2009.

General and Administrative

General and administrative expense for the second quarter of 2010 increased to \$7.0 million from \$6.8 million for the same period in 2009. Total general and administrative stock-based compensation expense for the second quarter of 2010 was \$2.7 million compared with \$2.2 million for the same period in 2009.

Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled \$210.7 million as of June 30, 2010, a decrease of \$14.7 million during the second quarter. The decrease was primarily due to 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 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 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 21, 2010. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on July 29, 2010 by dialing (800) 642-1687 from the US, or (706) 645-9291 for international callers, and entering confirmation code 82579723.

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 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.

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VIBATIV is a trademark of Astellas Pharma Inc.

RELOVAIR is a trademark of Glaxo Group Limited. Mark is intended for U.S. and subject to FDA approval.

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 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, 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 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 May 5, 2010 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(unaudited)		(unaudited)	
Revenue	\$ 6,264	\$ 5,493	\$ 11,979	\$ 15,037
Operating expenses:				
Research and development (1)	18,705	20,020	39,057	39,577
General and administrative (1)	6,991	6,796	13,467	13,848
Restructuring charges	—	30	—	1,313
Total operating expenses	<u>25,696</u>	<u>26,846</u>	<u>52,524</u>	<u>54,738</u>
Loss from operations	(19,432)	(21,353)	(40,545)	(39,701)
Interest and other income	134	1,172	229	1,819
Interest expense	(1,508)	(1,511)	(3,025)	(3,027)
Net loss	<u>\$ (20,806)</u>	<u>\$ (21,692)</u>	<u>\$ (43,341)</u>	<u>\$ (40,909)</u>
Basic and diluted net loss per share	<u>\$ (0.28)</u>	<u>\$ (0.35)</u>	<u>\$ (0.63)</u>	<u>\$ (0.65)</u>
Shares used in computing basic and diluted net loss per share	<u>73,282</u>	<u>62,842</u>	<u>69,124</u>	<u>62,567</u>

(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,	
	2010	2009	2010	2009
	(unaudited)		(unaudited)	
Research and development	\$ 2,618	\$ 3,055	\$ 5,145	\$ 6,062
General and administrative	2,704	2,219	4,675	4,325
Total stock-based compensation expense	<u>\$ 5,322</u>	<u>\$ 5,274</u>	<u>\$ 9,820</u>	<u>\$ 10,387</u>



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

	June 30, 2010	December 31, 2009
	<u>(unaudited)</u>	<u>(2)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 210,693	\$ 155,390
Other current assets	5,530	6,652
Property and equipment, net	11,049	12,927
Other assets	5,177	6,424
Total assets	<u>\$ 232,449</u>	<u>\$ 181,393</u>
 Liabilities and stockholders' net capital deficiency		
Current liabilities (1)	\$ 36,004	\$ 38,946
Deferred revenue	147,946	157,426
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	1,957	1,515
Stockholders' net capital deficiency	(125,958)	(188,994)
Total liabilities and stockholders' net capital deficiency	<u>\$ 232,449</u>	<u>\$ 181,393</u>

(1) Amounts include current portion of deferred revenue of \$22.8 million and \$23.7 million as of June 30, 2010 and December 31, 2009, respectively.

(2) The condensed consolidated balance sheet amounts at December 31, 2009 are derived from audited financial statements.