



## Theravance Reports First Quarter 2012 Financial Results

SOUTH SAN FRANCISCO, Calif., April 26, 2012 (GLOBE NEWSWIRE) -- Theravance, Inc. (Nasdaq:THRX) reported today its financial results for the quarter ended March 31, 2012. Revenue for the first quarter of 2012 was \$127.1 million. Net income for the first quarter of 2012 was \$84.6 million or \$0.93 per diluted share. Cash, cash equivalents, and marketable securities totaled \$200.2 million as of March 31, 2012.

"This was a very productive quarter for Theravance," said Rick E Winningham, Chief Executive Officer. "We reported data from the RELOVAIR™ registrational studies and GSK remains on track to submit regulatory filings for RELOVAIR™ in COPD in the U.S. and Europe and asthma in Europe from mid-2012. We anticipate reporting the data from our Phase 3 registrational LAMA/LABA program in 2012. I am very pleased with our collaboration with GSK, which has advanced an important portfolio of therapies for the treatment of serious respiratory diseases such as COPD and asthma into late-stage development. We recently announced an agreement with GSK to increase their ownership in Theravance subject to stockholder approval, reflecting confidence in the respiratory collaboration programs. We are very excited as Theravance approaches the next phase of development in the respiratory programs and across our other therapeutic areas such as CNS/Pain."

### Program Highlights

Respiratory Programs with GlaxoSmithKline plc (GSK)

#### *RELOVAIR™*

RELOVAIR™ is an investigational once-daily inhaled corticosteroid (ICS)/long-acting beta<sub>2</sub> agonist (LABA) combination treatment, comprising fluticasone furoate and vilanterol (FF/VI), currently in development for the treatment of patients with chronic obstructive pulmonary disease (COPD) and patients with asthma.

During the first quarter of 2012, Theravance and GSK announced the completion of the overall registrational program for RELOVAIR™ in COPD and asthma. In addition, results from two non-pivotal Phase 3 studies of RELOVAIR™ compared with twice-daily Advair® (fluticasone propionate (FP)/salmeterol (SAL) (FP/SAL)) in patients with COPD and results from a pivotal Phase 3 study evaluating the efficacy and safety of FF and FP compared to placebo in the treatment of persistent asthma in adults and adolescents were announced. For COPD, GSK continues with its plans to submit regulatory applications for RELOVAIR™ in the U.S. and Europe in mid-2012. For asthma, GSK plans to submit an application in Europe in mid-2012 and GSK and Theravance are reviewing the strategy for a future U.S. filing.

In March 2012, the Salford Lung Study, the first 'real-world' effectiveness study to investigate the potential effects of RELOVAIR™ versus the standards of care in Europe, was initiated in patients with COPD.

In May 2012, GSK will be presenting clinical data from the studies of RELOVAIR™ in COPD and asthma, in particular, from a Phase 3a lung function study, at the American Thoracic Society in San Francisco, California.

#### *LAMA/LABA Combination (GSK573719/Vilanterol or '719/VI)*

The Phase 3a program for the once-daily LAMA/LABA dual bronchodilator '719/VI is progressing well. We and GSK expect to report Phase 3a results from the LAMA/LABA program in 2012. '719/VI combines two bronchodilators currently under development - '719, a long-acting muscarinic antagonist (LAMA) and VI, a LABA. These molecules act through antagonism of acetylcholine muscarinic receptors and agonism of beta<sub>2</sub> adrenoreceptors.

The LAMA/LABA Phase 3a program, which has enrolled 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 among '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 3a 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 May 2012, GSK will be presenting Phase 1 and Phase 2a data for '719 and the combination '719/VI at the American Thoracic

Society Meeting in San Francisco, California.

#### *Inhaled Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist (MABA)*

GSK961081 ('081) is a single molecule bifunctional bronchodilator with both muscarinic antagonist and beta<sub>2</sub> receptor agonist activity. In February 2012, Theravance presented at Leerink Swann Healthcare Conference topline results from a Phase 2b efficacy and safety study of '081 administered once-daily (QD) or twice-daily (BID) to 436 patients with moderate to severe COPD for 28 days. The results of the Phase 2b study and a number of ongoing non-clinical enabling studies will inform the selection of the most appropriate dose and dosing interval for '081 and progression to Phase 3 will be dependent upon successful completion of these enabling studies.

#### Central Nervous System (CNS)/Pain Program

##### *Oral Peripheral Mu Opioid Receptor Antagonist (PμMA) —TD-1211*

Enrollment is complete in two of the three studies 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 dosing 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. Topline results from the Phase 2b program are expected to be reported in mid-2012.

##### *MonoAmine Reuptake INhibitor (MARIN) — TD-9855*

Enrollment is progressing in the Phase 2 proof-of-concept study with TD-9855 in patients with Attention-Deficit/Hyperactivity Disorder (ADHD), the lead compound in Theravance's MARIN program. This Phase 2 study will evaluate the safety and efficacy of two different doses of TD-9855 in adults with ADHD. TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (NSRI) discovered by Theravance for the treatment of central nervous system (CNS) conditions such as ADHD and chronic pain.

## **Financial Results**

### Revenue

Revenue was \$127.1 million for the first quarter of 2012 compared with \$6.3 million for the same period in 2011, an increase of \$120.8 million. The increase was primarily due to a non-recurring recognition of deferred revenue of \$125.7 million resulting from the January 6, 2012 termination of our global collaboration arrangement with Astellas Pharma Inc. for the development and commercialization of VIBATIV<sup>®</sup>.

### Research and Development

Research and development expense for the first quarter of 2012 increased to \$33.2 million compared with \$20.5 million for the same period in 2011. The increase in the first quarter of 2012 was primarily due to Phase 2 clinical costs related to our PμMA and MARIN programs, costs related to our preclinical and late-stage discovery programs, and higher employee-related expenses. Total external research and development expense was \$13.2 million during the first quarter of 2012 compared with \$3.2 million for the same period 2011. Total research and development stock-based compensation expense for the first quarter of 2012 was \$3.5 million compared with \$3.1 million for the same period in 2011.

### General and Administrative

General and administrative expense for the first quarter of 2012 increased to \$7.9 million from \$7.2 million for the same period in 2011. The increase in the first quarter of 2012 was primarily due to higher external and employee-related expenses offset by lower facilities-related costs. Total general and administrative stock-based compensation expense for the first quarter of 2012 was \$2.7 million compared with \$2.4 million for the same period in 2011.

### Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled \$200.2 million as of March 31, 2012, a decrease of \$40.7 million during the first quarter. This 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. 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](http://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 May 26, 2012. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on May 3, 2012 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 63453344.

## **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<sub>2</sub> 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](http://www.theravance.com).

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RELOVAIR™ is a trademark of the GlaxoSmithKline group of companies.

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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 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, statements concerning the expected timing of the proposed stock purchase by Glaxo Group Limited (GGL), statements concerning enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning 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 non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, inability to obtain stockholder approval of or satisfy other closing conditions for the proposed stock purchase by GGL, declines in the S&P 500 index that could result in termination rights regarding the proposed stock purchase by GGL, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 27, 2012 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.

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

**Three Months Ended**

	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
	(unaudited)	
Revenue	\$ 127,099	\$ 6,331
Operating expenses:		
Research and development (1)	33,202	20,464
General and administrative (1)	7,857	7,169
Total operating expenses	<u>41,059</u>	<u>27,633</u>
Income/(Loss) from operations	86,040	(21,302)
Interest and other income	56	145
Interest expense	(1,502)	(1,510)
Net income/(loss)	<u>\$ 84,594</u>	<u>\$ (22,667)</u>
Net income/(loss) per share:		
Basic	<u>\$ 1.01</u>	<u>\$ (0.28)</u>
Diluted	<u>\$ 0.93</u>	<u>\$ (0.28)</u>
Weighted average shares:		
Basic	<u>83,590</u>	<u>80,854</u>
Diluted	<u>92,080</u>	<u>80,854</u>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
	(unaudited)	
Research and development	\$ 3,529	\$ 3,132
General and administrative	<u>2,706</u>	<u>2,409</u>
Total stock-based compensation expense	<u>\$ 6,235</u>	<u>\$ 5,541</u>

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

<b>March 31,</b>	<b>December 31,</b>
<b>2012</b>	<b>2011</b>
(unaudited)	
	(2)

**Assets**

Cash, cash equivalents and marketable securities	\$ 200,164	\$ 240,915
Other current assets	4,163	3,848
Property and equipment, net	10,059	10,372
Other assets	3,341	3,647
<b>Total assets</b>	<b>\$ 217,727</b>	<b>\$ 258,782</b>

**Liabilities and stockholders' net capital deficiency**

Current liabilities (1)	\$ 25,575	\$ 45,496
Deferred revenue	7,843	122,017
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	5,678	5,821
Stockholders' net capital deficiency	6,131	(87,052)
<b>Total liabilities and stockholders' net capital deficiency</b>	<b>\$ 217,727</b>	<b>\$ 258,782</b>

(1) Amounts include current portion of deferred revenue of \$5.8 million and \$18.7 million as of March 31, 2012 and December 31, 2011, respectively.

(2) The condensed consolidated balance sheet amounts at December 31, 2011 are derived from audited financial statements.

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