

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report: October 30, 2012  
(Date of earliest event reported)

**Theravance, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-30319**  
(Commission File  
Number)

**94-3265960**  
(IRS Employer  
Identification Number)

**901 Gateway Boulevard, South San Francisco,  
CA**  
(Address of principal executive offices)

**94080**  
(Zip Code)

**650-808-6000**  
(Registrant's telephone number, including area code)

**Not Applicable**  
(Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 2.02. Results of Operations and Financial Condition**

The information in this Current Report (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibit 99.1) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

On October 30, 2012 Theravance, Inc. issued a press release regarding its financial results for the quarter ended September 30, 2012. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

99.1 [Press Release of Theravance, Inc. dated October 30, 2012](#)

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 30, 2012

**THERAVANCE, INC.**

By: /s/ Michael W. Aguiar

Michael W. Aguiar

*Chief Financial Officer*

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**Exhibit Index**

**Exhibit No.**

99.1

**Description**

Press Release of Theravance, Inc. dated October 30, 2012

## Theravance Reports Third Quarter 2012 Financial Results

SOUTH SAN FRANCISCO, CA -- (Marketwire - October 30, 2012) - Theravance, Inc. (NASDAQ: THRX) reported today its financial results for the quarter ended September 30, 2012. Revenue for the third quarter of 2012 was \$1.4 million. Net loss for the third quarter of 2012 was \$34.7 million or \$0.37 per share. Cash, cash equivalents, and marketable securities totaled \$362.4 million as of September 30, 2012.

"Theravance made substantial progress in our clinical programs as well as corporate development during the third quarter," said Rick E Winningham, Chief Executive Officer. "In our respiratory collaborations with GSK, presentations were made at ERS for the FF/VI Phase 3 programs, the review of the regulatory filings for FF/VI has commenced in the US and Europe, and the UMEC/VI Phase 3 COPD registration program for US and Europe was completed. For our non-respiratory programs, we announced positive results in a Phase 2b study with Theravance's peripheral mu opioid receptor antagonist, TD-1211, and we recently entered into partnerships with Merck, Alfa Wassermann, and R-Pharm."

### Program Highlights

#### Respiratory Programs with GlaxoSmithKline plc (GSK)

##### Fluticasone Furoate/Vilanterol (FF/VI)

FF/VI is an investigational once-daily inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) combination treatment, comprising fluticasone furoate and vilanterol, 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 US), and Ellipta™ (for the EU, US and Japan) are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

In September 2012, GSK and Theravance announced that the New Drug Application (NDA) for FF/VI for patients with COPD was accepted by the US Food and Drug Administration (FDA), indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date was confirmed as May 12, 2013. GSK and Theravance also reported that the Marketing Authorization Application (MAA) for FF/VI for COPD and asthma was validated by the European Medicines Agency (EMA). In addition, GSK also submitted a Japanese New Drug Application (JNDA) for FF/VI for patients with COPD and asthma on September 25, 2012.

In September 2012, at the European Respiratory Society Annual Congress (ERS) in Vienna, Austria, data from the FF/VI programs in COPD and asthma were presented, including a majority of the FF/VI Phase 3a studies.

##### Umeclidinium Bromide/Vilanterol (UMEC/VI)

UMEC/VI is a once-daily investigational medicine, combining a long-acting muscarinic antagonist (LAMA) umeclidinium bromide (UMEC), and a LABA, VI, for the maintenance treatment of patients with COPD. UMEC/VI is administered by the Ellipta™ dry powder inhaler.

In August 2012, GSK and Theravance announced the completion of the Phase 3 program involving approximately 6,000 patients with COPD. The pivotal program for UMEC/VI includes two 24-week efficacy studies that compared the combination UMEC/VI, its components and placebo, two 24-week active comparator studies that compared the combination with tiotropium, a widely prescribed maintenance bronchodilator for COPD, and a 52-week safety study. Two non-pivotal 12-week crossover exercise studies will also be included in the registrational package. These studies support GSK's plans to commence global regulatory submissions for UMEC/VI from the end of 2012.

In September 2012, at ERS in Vienna, Austria, GSK presented data from Phase 1 and Phase 2b studies of UMEC. In addition, on October 24, 2012, GSK presented analyses of the UMEC dose-response curve in patients with COPD at CHEST, the annual meeting of the American College of Chest Physicians, in Atlanta, Georgia.

##### Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activities. In September 2012, at ERS in Vienna, Austria, data from the Phase 2b study of '081 were presented.

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

##### 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 consists of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. The results support progression into Phase 3 development.

##### Monoamine Reuptake Inhibitor - TD-9855

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (NSRI) for the treatment of central nervous system (CNS) conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD) and chronic pain. TD-9855 is being evaluated in an ongoing Phase 2 safety and efficacy study in adults with ADHD. In addition, Theravance plans to initiate a Phase 2 study with TD-9855 in patients with fibromyalgia in the next few months.

## **Corporate Development**

Theravance recently entered into partnership agreements for four of its programs: velusetrag (or TD-5108), cardiovascular research, TD-1792 and telavancin.

### **Alfa Wassermann**

In October 2012, Theravance and Alfa Wassermann S.p.A. entered into a development and commercialization agreement for velusetrag, Theravance's investigational 5-HT<sub>4</sub> agonist in development for gastrointestinal motility disorders. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the EU, Russia, China, Mexico and certain other countries.

### **Merck**

In October 2012, Merck, known as MSD outside the US and Canada, and Theravance signed a collaboration agreement to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure on an exclusive worldwide basis.

### **R-Pharm**

In October 2012, Theravance entered into two separate development and commercialization agreements with R-Pharm. The first was for TD-1792, Theravance's investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of resistant Gram-positive infections, which has completed a Phase 2 proof-of-concept study. The second was for telavancin, Theravance's lipoglycopeptide antibiotic approved in the US. In both of the agreements, Theravance granted R-Pharm exclusive development and commercialization rights in the Russian Federation, Ukraine, the other member countries of the Commonwealth of Independent States, and Georgia.

## **Financial Results**

### **Revenue**

Revenue was \$1.4 million for the third quarter of 2012 compared with \$6.4 million for the same period in 2011, a decrease of \$5.0 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 third quarter of 2012 decreased to \$27.0 million compared with \$27.8 million for the same period in 2011. The decrease in the third quarter of 2012 was primarily due to the completion of Phase 2 clinical activities related to TD-1211 partially offset by higher consulting costs. Total external research and development expense was \$8.8 million during the third quarter of 2012 compared with \$9.5 million for the same period in 2011. Total research and development stock-based compensation expense for the third quarter of 2012 was \$3.3 million compared with \$3.5 million for the same period in 2011.

### **General and Administrative**

General and administrative expense for the third quarter of 2012 was \$7.8 million which is approximately the same as the third quarter of 2011. Total general and administrative stock-based compensation expense for the third quarter of 2012 was \$2.6 million compared with \$3.4 million for the same period in 2011.

### **Cash and Cash Equivalents**

Cash, cash equivalents and marketable securities totaled \$362.4 million as of September 30, 2012, a decrease of \$16.3 million during the third quarter. This decrease was primarily due to cash used in operations partially offset by \$8.9 million received from GSK for its purchase of common stock in August 2012.

## **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](http://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 November 29, 2012. An audio replay will also be available through 11:59 p.m. Eastern Standard Time on November 6, 2012 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 33043909.

## **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™ (FF/VI), umeclidinium bromide/vilanterol (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 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](http://www.theravance.com).

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

Relvar™ or Breo™ (FF/VI) is an investigational medicine and is not currently approved anywhere in the world. Relvar™, Breo™ and Ellipta™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names has not yet been approved by any regulatory authority.

VIBATIV® is a registered trademark of Theravance, Inc.

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, 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 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 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 and risks of collaborating with third parties to discover, 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 1, 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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(unaudited)		(unaudited)	
Revenue	\$ 1,430	\$ 6,431	\$ 129,960	\$ 19,150
Operating expenses:				
Research and development (1)	27,026	27,837	89,778	71,099
General and administrative (1)	7,754	7,796	23,201	22,213
Total operating expenses	34,780	35,633	112,979	93,312
Income (Loss) from operations	(33,350)	(29,202)	16,981	(74,162)
Interest and other income	158	81	304	344
Interest expense	(1,500)	(1,505)	(4,503)	(4,519)
Net income (loss)	\$ (34,692)	\$ (30,626)	\$ 12,782	\$ (78,337)
	=====	=====	=====	=====

Net income (loss) per share:				
Basic	\$ (0.37)	\$ (0.37)	\$ 0.14	\$ (0.96)
	=====	=====	=====	=====
Diluted	\$ (0.37)	\$ (0.37)	\$ 0.18	\$ (0.96)
	=====	=====	=====	=====
Weighted average shares:				
Basic	95,027	82,490	89,271	81,777
	=====	=====	=====	=====
Diluted	95,027	82,490	98,381	81,777
	=====	=====	=====	=====

(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,	
	2012	2011	2012	2011
	(unaudited)		(unaudited)	
Research and development	\$ 3,259	\$ 3,510	\$ 10,329	\$ 10,021
General and administrative	2,571	3,380	7,715	8,685
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Total stock-based compensation expense	\$ 5,830	\$ 6,890	\$ 18,044	\$ 18,706
	=====	=====	=====	=====

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

	September 30, 2012	December 31, 2011
	(unaudited)	(1)
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 362,406	\$ 240,915
Other current assets	9,091	3,848
Property and equipment, net	9,579	10,372
Other assets	2,867	3,647
	-----	-----
Total assets	\$ 383,943	\$ 258,782
	=====	=====
<b>Liabilities and stockholders' equity (net capital deficiency)</b>		
Current liabilities (2)	\$ 27,090	\$ 45,496
Deferred revenue, non-current	5,790	122,017
Convertible subordinated notes	172,500	172,500
Other long-term liabilities	5,275	5,821
Stockholders' equity (net capital deficiency)	173,288	(87,052)
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Total liabilities and stockholders' equity (net capital deficiency)	\$ 383,943	\$ 258,782
	=====	=====

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

(2) Amounts include current portion of deferred revenue of \$4.9 million and \$18.7 million as of September 30, 2012 and December 31, 2011, respectively.

**Contact Information:**

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