UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report: February 12, 2013 (Date of earliest event reported)

Theravance, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction

000-30319 (Commission File Number) **94-3265960** (IRS Employer Identification Number)

901 Gateway Boulevard, South San Francisco, C^{Λ}

of incorporation)

94080 (Zip Code)

(Address of principal executive offices)

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:

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

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 February 12, 2013 Theravance, Inc. issued a press release regarding its financial results for the quarter ended December 31, 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 <u>Theravance</u>, <u>Inc. dated February 12, 2013</u>

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: February 12, 2013

THERAVANCE, INC.

By: <u>/s/ Michael W. Aguiar</u>
Michael W. Aguiar
Chief Financial Officer

Exhibit Index

Exhibit No.

<u>Description</u>

99.1

Press Release of Theravance, Inc. dated February 12, 2013

Theravance Reports Fourth Quarter and Full Year 2012 Financial Results

SOUTH SAN FRANCISCO, CA -- (Marketwire - February 12, 2013) - Theravance, Inc. (NASDAQ: THRX) (the "Company") reported today its financial results for the fourth quarter and full year ended December 31, 2012. Revenue for the full year was \$135.8 million. Net loss for the fourth quarter and full year of 2012 was \$31.3 million and \$18.5 million, respectively, compared with \$37.0 million and \$115.3 million for the same periods of 2011. Net loss per share was \$0.33 and \$0.20 for the fourth quarter and full year of 2012, respectively, compared with a net loss per share of \$0.45 and \$1.41 for the same periods of 2011. Cash, cash equivalents, and marketable securities totaled \$343.7 million as of December 31, 2012, an increase of \$102.8 million from December 31, 2011.

"Theravance made significant progress in 2012, particularly in our lead respiratory programs partnered with GSK," said Rick E Winningham, Chief Executive Officer. "Looking forward, 2013 will be more significant for Theravance with potential regulatory events for RELVARTM/BREOTM, ANOROTM, and VIBATIV®. In addition, we continue to progress our internal programs, including Phase 2 studies in fibromyalgia and ADHD with TD-9855, a Phase 2b study in COPD with TD-4208, and a Phase 2 study in gastroparesis with velusetrag. Overall, we are well positioned both strategically and financially."

Program Highlights

Respiratory Programs with GlaxoSmithKline plc (GSK)

RELVARTM or BREOTM (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 (FF) and vilanterol (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 ELLIPTATM. RELVARTM (FF/VI for the European Union (EU) and Japan), BREOTM (FF/VI for the United States (U.S.)), and ELLIPTATM (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.

In September 2012, GSK and Theravance announced that the New Drug Application (NDA) for FF/VI for patients with COPD was accepted by the U.S. Food and Drug Administration (FDA), indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act goal date was confirmed as May 12, 2013 and the FDA's Pulmonary-Allergy Drugs Advisory Committee is scheduled to discuss the NDA for BREO™ for COPD at a meeting on March 7, 2013. GSK and Theravance also reported that the Marketing Authorization Application for FF/VI for COPD and asthma was validated by the European Medicines Agency (EMA) and GSK also submitted a Japanese New Drug Application for FF/VI for patients with COPD and asthma in September 2012.

ANORO™ (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 ELLIPTATM dry powder inhaler.

In December 2012, GSK and Theravance announced the submission to the FDA of a NDA for UMEC/VI for patients with COPD. In January 2013, GSK and Theravance announced the submission of a regulatory application to the EMA for UMEC/VI for patients with COPD, which has now been validated by the EMA. Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013.

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. Based on the results from the Phase 2b study, GSK and Theravance plan to advance '081 monotherapy into Phase 3 in 2013 and the '081/FF combination into Phase 3-enabling studies shortly.

Bacterial Infections Program

VIBATIV® (telavancin)

In November, 2012, Theravance announced a favorable outcome of the FDA's Anti-Infective Drugs Advisory Committee meeting on VIBATIV® (telavancin) 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.

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

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.

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 safety and efficacy study in adults with ADHD. In addition, we initiated a Phase 2 study with TD-9855 in patients with fibromyalgia in December 2012.

Theravance Respiratory Program

Long-Acting Muscarinic Antagonist - TD-4208

In November 2011, we announced positive topline results from a Phase 2a single-dose COPD study of TD-4208, an investigational inhaled LAMA discovered by Theravance. In this study, TD-4208 met the primary endpoint by demonstrating a statistically significant mean change from baseline in peak forced expiratory volume in one second (FEV1) compared to placebo, and was generally well tolerated. In December 2012, we initiated a Phase 2b study to evaluate the safety and pharmacokinetics of multiple doses of TD-4208.

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.

Financial Results

Revenue

Revenue was \$5.8 million for the fourth quarter of 2012 compared with \$5.4 million for the same period in 2011, an increase of \$0.4 million. For the full year of 2012, revenue was \$135.8 million, compared with \$24.5 million for the full year of 2011. The increase for the fourth quarter of 2012 was primarily due to the recognition of a portion of the upfront licensing fee from our collaboration arrangement with Merck, partially offset by a decrease of royalty revenue from sales of VIBATIV®. The increase for the full year of 2012 reflected the accelerated recognition of deferred revenue of \$125.8 million from the global collaboration arrangement with Astellas Pharma Inc. (Astellas) for the development and commercialization of VIBATIV® in the first quarter of 2012. This accelerated recognition was the result of the termination of the Astellas agreement on January 6, 2012.

Research and Development

Research and development expense for the fourth quarter of 2012 decreased to \$28.1 million compared with \$32.5 million for the same period in 2011. For the full year of 2012, research and development expense was \$117.9 million compared with \$103.6 million for the full year 2011. The decrease in the fourth quarter over the same period last year was primarily due to the completion of Phase 2 clinical activities related to TD-1211, a reduction of research and development costs due to funding the Company's research programs by collaboration partners, partially offset by higher costs related to clinical activities for TD-9855. The full year of 2012 increase was primarily due to increases in outside services related the Phase 2 clinical activities for TD-1211, TD-9855, higher employee related costs and costs related to VIBATIV® Advisory Committee activities. Total external research and development expense for the fourth quarter and full year of 2012 was \$10.3 million and \$43.1 million, respectively, compared with \$12.9 million and \$30.8 million, respectively, for the fourth quarter and the full year of 2011. Total research and development stock-based compensation expense for the fourth quarter and full year of 2012 was \$3.3 million and \$13.7 million, respectively, compared with \$3.4 million and \$13.4 million, respectively, for the fourth quarter and full year of 2011.

General and Administrative

General and administrative expense for the fourth quarter of 2012 decreased to \$7.7 million from \$8.5 million for the same period in 2011. For the full year of 2012, general and administrative expense was \$30.9 million compared with \$30.7 million for the full year of 2011. Total general and administrative stock-based compensation expense for the fourth quarter and the full year of 2012 was \$2.4 million and \$10.1 million, respectively, compared with \$2.8 million and \$11.5 million, respectively, for the fourth quarter and full year of 2011.

Cash and Cash Equivalents

Cash, cash equivalents and marketable securities totaled \$343.7 million as of December 31, 2012, an increase of \$102.8 million from December 31, 2011. This increase was primarily due to net proceeds of \$229.3 million received from the Company's private placements of common stock to an affiliate of GSK, partially offset by cash used in operations of \$128.0 million. On January 24,

2013, we announced the closing of a convertible subordinated notes offering with net proceeds of approximately \$244.4 million which are not reflected in the December 31, 2012 cash, cash equivalents, and marketable securities balance.

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 Standard 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 March 14, 2013. An audio replay will also be available through 11:59 p.m. Eastern Standard Time on February 19, 2013 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 85984300.

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: RELVARTM or BREOTM (FF/VI), ANOROTM (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.

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

RELVARTM or BREOTM (FF/VI) and ANOROTM (UMEC/VI) are investigational medicines and are not currently approved anywhere in the world. RELVARTM, BREOTM, ANOROTM and ELLIPTATM 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.

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 $\text{CrCl} \leq 50 \text{ mL/min}$ 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 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 that we will be able to respond fully or adequately to FDA's requests using currently existing clinical data and any expectation that the FDA will approve the VIBATIV® nosocomial pneumonia NDA on the basis of existing preclinical and clinical data or at all), 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 our 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 nonclinical 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 October 31, 2012 and in Theravance's prospectus supplement filed with the SEC on January 18, 2013 pursuant to Rule 424(b)(5). 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
December 31,

	(unaudited)			(unaudited)		(2)		
Revenue	\$	5,799	\$	5,361	\$	135,758	\$	24,512
Operating expenses: Research and development (1) General and		28,120		32,468		117,898		103,568
administrative (1)		7,658		8,469		30,859		30,681
Total operating expenses		35,778		40,937		148,757		134,249
Loss from operations		(29,979)		(35,576)		(12,999)		(109,737)
Interest and other income Interest expense						460 (6,003)		
Net loss	\$ ==	(31,323) ======	\$	(37,007) ======	\$	(18,542) ======	\$	(115,344)
Net loss per share: Basic and Diluted	\$ ==	(0.33)	\$	(0.45)	\$	(0.20)	\$	(1.41)
Weighted average shares: Basic and Diluted	==	95,787 ======	==	82,862 ======	===	90,909	==	82,051 ======

(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,			
	 2012		2011	-	2012		2011
	 (unaud	dit	ed)		(unaud	dit	ed)
Research and development General and administrative	\$ 3,338 2,401	\$	3,401 2,809	\$	13,667 10,116	-	13,422 11,494
Total stock-based compensation expense	\$ 5,739 ======	\$	6,210	\$	23,783	\$	24,916

(2) The condensed consolidated statement of operations amounts for the year ended December 31, 2011 are derived from audited financial statements.

THERAVANCE, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)			
,	December 30, 2012 (unaudited)		mber 31, 2011
			 (1)
Assets Cash, cash equivalents and marketable securities Other current assets Inventory Property and equipment, net Other assets	\$,	,
Total assets	\$ =====	368,582 ======	258,782 ======
Liabilities and stockholders' equity (net capital deficiency) Current liabilities (2) Deferred revenue, non-current Convertible subordinated notes Other long-term liabilities Stockholders' equity (net capital deficiency)	\$,	122,017
Total liabilities and stockholders' equity			

Total liabilities and stockholders' equity

(net capital deficiency)

\$ 368,582 \$ 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 \$4.6 million and \$18.7 million as of December 31, 2012 and December 31, 2011, respectively.

Contact Information:

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