

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event Reported): **September 5, 2013**

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

(I.R.S. Employer Identification Number)

**901 Gateway Boulevard
South San Francisco, California 94080
(650) 808-6000**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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 (see General Instruction A.2. below):

- 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))

Item 7.01 Regulation FD Disclosure.

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 (the "Securities Exchange Act of 1934"), 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 September 5, 2013 at 8:30 a.m. Eastern Daylight Time, management of Theravance, Inc. will hold a conference call to discuss the results announced on September 4, 2013 from Phase 2b study 0091 of TD-4208, an investigational long-acting muscarinic antagonist, administered once-a-day as a nebulized aqueous solution in patients with moderate to severe chronic obstructive pulmonary disease. A copy of the slide presentation to be presented during the conference call is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Theravance TD-4208 Phase 2b Study 0091 Results Slide Presentation dated September 5, 2013

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.

THERAVANCE, INC.

Date: September 5, 2013

By: /s/ Michael W. Aguiar
Michael W. Aguiar
Chief Financial Officer

3

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Theravance TD-4208 Phase 2b Study 0091 Results Slide Presentation dated September 5, 2013

4



Theravance®



Medicines That Make a **Difference**®

NASDAQ: THRX

TD-4208 Phase 2b Study 0091 Results

September 5, 2013



Safe Harbor

This presentation contains 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. The words "anticipate", "expect", "goal," "intend", "objective," "opportunity," "plan", "potential", "target" and similar expressions are intended to identify such forward-looking statements. Examples of such statements include statements relating to: plans for executing the separation of Theravance into two independent companies, the expected timing of the separation, expectations for the amount and estimated duration of the funding of Theravance Biopharma at the time of the separation, the strategies, plans and objectives of the two companies following the separation, expectations related to the staffing of the two companies, the timing, manner and amount of anticipated potential returns of capital to stockholders if the separation is consummated, the possible tax effects of the separation, the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, expectations for product candidates through development and commercialization, and the timing of seeking regulatory approval of product candidates. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this presentation 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 the 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 in preparing audited financial statements for Theravance Biopharma, difficulties in effecting the registration of Theravance Biopharma as a public company, failure to obtain necessary consents from third parties, changes in the development or operations of Theravance prior to the separation that could affect the plans for the separation or the cash available for the initial funding of the independent companies, delays encountered in obtaining, or the failure to obtain, the receipt of a private letter ruling from the Internal Revenue Service (should Theravance seek to effect the separation on a tax-free basis), the anticipated separation of Theravance into two independent companies or the intended return of capital to stockholders, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties to conduct our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products and risks associated with establishing distribution capabilities for telavancin with appropriate technical expertise and supporting infrastructure. Other risks affecting Theravance are described 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, 2013 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.



Theravance®

2



TD-4208 Phase 2b Study 0091 Design

- ▶ Randomized, double-blind, placebo-controlled, multicenter, incomplete block 5-period cross-over study
- ▶ 62 patients with moderate to severe COPD
- ▶ 6 doses of TD-4208 (22, 44, 88, 175, 350 and 700 mcg)
- ▶ Patients received placebo and 4 doses of TD-4208 for 7 days
- ▶ Primary Endpoint: Change from baseline in trough FEV₁
- ▶ Secondary Endpoints: AUC, weighted mean, peak (0-24 hours serial FEV₁)
- ▶ Safety, tolerability and pharmacokinetics evaluation



Theravance®

3



Efficacy Summary

- ▶ Primary endpoint was met for all doses
 - Statistically significant placebo corrected trough FEV₁ ranged from 53 mL to 114 mL on Day 7
- ▶ All secondary endpoints were met for all doses versus placebo
 - Weighted mean FEV₁ (0-24 hour) ranged from 83 mL to 148 mL
- ▶ Median time to reach 100 mL improvement in FEV₁ ranged from 0.5 to 1 hour for all TD-4208 doses

TD-4208 demonstrated significant bronchodilation over 24 hours

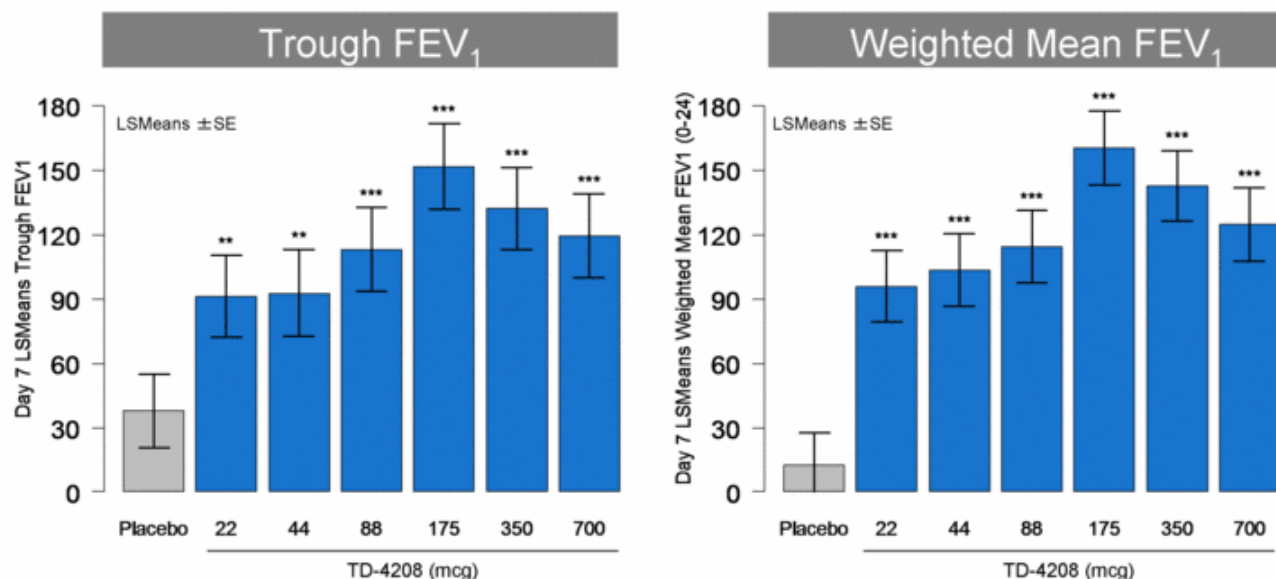


Theravance®

4



Day 7 Trough and Weighted Mean (0-24h) FEV₁



P-values versus placebo: <0.05* <0.01** <0.001***

All doses achieved statistical significance versus placebo

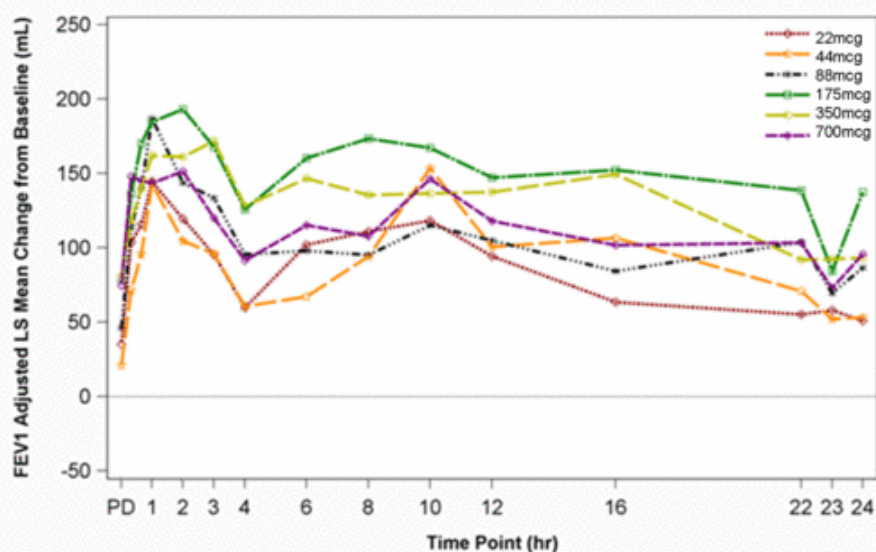


Theravance®

5



24-Hour Spirometry Profile Supports QD Dosing



Day 7	22 mcg (N=40)	44 mcg (N=39)	88 mcg (N=39)	175 mcg (N=39)	350 mcg (N=39)	700 mcg (N=40)
AUC (12-24) to (0-12)	0.96	0.98	0.97	0.98	0.98	0.97

Consistent profile over 24 hours



Theravance®



Safety Summary

- ▶ Treatment-related adverse events (AEs) are comparable to placebo
- ▶ No serious adverse events (SAEs) related to treatment
- ▶ No discontinuations due to AEs related to treatment
- ▶ Review of laboratory panels revealed no abnormal trends
- ▶ No clinically significant changes in vital signs
- ▶ No significant change in ECG heart rate, rhythm or QT interval
- ▶ Lack of systemic AEs consistent with low systemic drug levels

All doses of TD-4208 were generally well tolerated and had a safety/tolerability profile comparable to placebo



Theravance®

7



Most Frequent Treatment-Related Adverse Events

Treatment-related AEs with ≥ 2 patients

	Placebo (N=61)	TD-4208					
		22 mcg (N=41)	44 mcg (N=39)	88 mcg (N=40)	175 mcg (N=37)	350 mcg (N=41)	700 mcg (N=37)
Subjects Reporting any Treatment-related Event	11 (18.0%)	5 (12.2%)	3 (7.7%)	3 (7.5%)	5 (13.5%)	3 (7.3%)	6 (16.2%)
Dyspnoea	3 (4.9%)	0	1 (2.6%)	0	2 (5.4%)	1 (2.4%)	1 (2.7%)
Headache	4 (6.6%)	3 (7.3%)	0	0	0	0	1 (2.7%)
Cough	0	1 (2.4%)	1 (2.6%)	0	2 (5.4%)	1 (2.4%)	1 (2.7%)
Dry mouth	0	0	0	0	0	1 (2.4%)	1 (2.7%)
Nausea	1 (1.6%)	0	1 (2.6%)	0	0	0	0
Rash	0	0	0	0	1 (2.7%)	0	1 (2.7%)



Theravance®

8



TD-4208 Phase 2b Study 0091 Results Summary

- ▶ All doses met primary and secondary efficacy endpoints
- ▶ TD-4208 demonstrated significant bronchodilation over 24 hours
- ▶ All doses of TD-4208 were generally well tolerated and had a safety/tolerability profile comparable to placebo
- ▶ Phase 2b results support further development of TD-4208 as once-a day nebulized treatment for COPD

Theravance®

9



Theravance®

Medicines That Make a **Difference**®

NASDAQ: THRX

THANK YOU

