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): **May 21, 2014**

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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):

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 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 May 21, 2014 at the American Thoracic Society (ATS) 2014 International Conference held in San Diego, California, Theravance, Inc. presented data from a Phase 2b study with TD-4208 as a nebulized aqueous solution in patients with chronic obstructive pulmonary disease (COPD). TD-4208 is an investigational, once-daily inhaled long-acting muscarinic antagonist discovered by Theravance, Inc. A copy of the poster is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
Exhibit 99.1	A Randomized, Crossover, 7-day Study of Once-daily TD-4208, a Long-Acting Muscarinic Antagonist (LAMA) in Subjects with COPD

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: May 21, 2014

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	A Randomized, Crossover, 7-day Study of Once-daily TD-4208, a Long-Acting Muscarinic Antagonist (LAMA) in Subjects with COPD

Exhibit 99.1

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A Randomized, Crossover, 7-day Study of Once-daily TD-4208, a Long-Acting Muscarinic Antagonist (LAMA) in Subjects with COPD

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(1) Theravance, Inc., South San Francisco, CA. (2) Medicines Evaluation Unit, Manchester, UK.

ABSTRACT

Background: TD-4208 is a lung-selective inhaled muscarinic antagonist shown previously to have a long duration of action in subjects with COPD after single administration.

Rationale: To investigate the dose response relationship for the bronchodilator effect and safety of nebulized TD-4208 administered once daily for 7 days in subjects with COPD.

Methods: Fifty-nine subjects (mean age 63.9 years) with moderate to severe COPD were randomized in a double-blind, incomplete block, 5-period crossover study. Inhaled corticosteroid use was permitted; long- and short-acting bronchodilators were restricted appropriately during the study in order that pharmacodynamic measurements were not confounded. Treatments (22, 44, 88, 175, 350, 700 µg TD-4208 or matching placebo) were given as an inhalation solution by PARI nebulizer in the morning of each day for 7 days, followed by a washout period (mean 14.9 range (10,36) days) after each treatment period. Spirometry (FEV_1) was collected on Day 1 and for 24 hours on Day 7/8 of each period. Adverse events, vital signs, ECGs and clinical laboratory tests were monitored throughout.

Results: All doses of TD-4208 produced statistically significant increases in FEV_1 versus placebo on trough FEV_1 and weighted mean FEV_1 over 24 h. Examination of the profiles on Day 7 showed the bronchodilator effect was sustained for 24 hours for all doses. Adverse events were generally mild and occurred with similar frequencies in all groups including placebo; discontinuations from the study (n=7) and serious adverse events (n=3) were unrelated to treatment. There was no indication of significant systemic antimuscarinic activity at any dose.

Conclusions: Following multiple doses, nebulized TD-4208, administered once-daily, was generally well tolerated and demonstrated a bronchodilator effect in COPD that was sustained over 24 hours.

Table 1: Pharmacodynamic Effect of TD-4208 on Day 7 (ITT Population)

	Placebo-adjusted LS Means change from baseline in FEV_1 (mL)					
TD-4208 dose	**22 µg**	**44 µg**	**88 µg**	**175 µg**	**350 µg**	**700 µg**
n	40	39	39	39	39	40
Trough FEV_1*	53.5	55.0	75.4	114.2	94.4	81.6
(95% CI)	(16.5, 90.5)	(15.9, 94.1)	(37.7, 113.0)	(75.7, 152.6)	(57.7, 131.1)	(42.8, 119.5)
Weighted mean FEV_1 0-24 h	83.2	90.9	101.8	147.7	130.1	112.0
(95% CI)	(52.3, 114.2)	(59.1, 122.7)	(70.2, 133.3)	(115.5, 179.9)	(99.2, 160.9)	(80.5, 143.5)

*Trough FEV_1 is the mean of the 23- and 24-h serial spirometry measurements.

INTRODUCTION

Unmet Need

- The Global Initiative for the Treatment of Obstructive Lung Disease (GOLD) recommends the use of long-acting muscarinic antagonist (LAMA) bronchodilators as first-line therapy for subjects with persistent COPD symptoms. [4]
- Currently approved LAMAs are administered via handheld devices and require dexterity, co-ordination of respiratory effort and the ability to maintain a requisite inspiratory flow rate for effective delivery.
- Nebulizer therapy is recognized as suitable for patients who prefer (or require) this method of administration because of limitations in physical or cognitive capabilities and/or disease severity.
- There are no once-daily nebulized bronchodilators currently available for those patients for whom nebulized therapy would be appropriate.
- The opportunity exists to meet the needs of these patients with a novel, nebulized, once-daily LAMA.

The TD-4208 Nebulized Development Program

- TD-4208 is a lung-selective inhaled muscarinic antagonist currently in clinical development as a once-daily inhalation solution for administration using a standard jet nebulizer.

- In recently reported results from a single-dose study, nebulized TD-4208 (350 and 700 µg) demonstrated evidence of sustained bronchodilation over 24 hours with a time to onset similar to ipratropium bromide in patients with COPD. Both doses were well tolerated and there were no serious adverse events reported. [2], [3]

OBJECTIVES

- To characterize the improvements in lung function resulting from administering nebulized TD-4208 once per day for 7 days in subjects with COPD.
- To evaluate the safety and tolerability profile of nebulized TD-4208 administered once per day for 7 days in subjects with COPD.

KEY INCLUSION AND EXCLUSION CRITERIA

- Male or female between the ages of 40 and 75 years with a current or past smoking history >10 pack years.
- FEV_1 / FVC ratio < 0.7 at screening.
- Post-ipratropium FEV_1 (30%-80%) of predicted normal value after withholding short-acting bronchodilators for at least 6 hours and long-acting bronchodilators for at least 24 hours.
- At least a 120 mL increase in FEV_1 within 1 hour of receiving 500 µg of ipratropium bromide from a PARI LC Sprint® nebulizer.
- No COPD exacerbation or other lung infection within 6 weeks prior to screening.
- Daily maintenance inhaled/systemic corticosteroids (≤1000 µg of fluticasone propionate equivalent or < 10 mg prednisone).

RESULTS

Table 2. Demographics (ITT Population)

	DOSE						
	Placebo	**22 µg**	**44 µg**	**88 µg**	**175 µg**	**350 µg**	**700 µg**
n	59	40	39	39	39	39	40
Age yrs mean (SD)	63.9 (6.85)	62.6 (6.71)	63.9 (6.62)	65.4 (7.01)	63.3 (7.46)	64.5 (6.46)	64.1 (6.62)
Sex M/F	56/44	55/45	54/46	59/41	56/44	59/41	53/47
Race: Caucasian (%)	100	100	100	100	100	100	100
BMI $m.kg^{-2}$ mean (SD)	28.8 (5.92)	29.4 (6.54)	27.9 (5.18)	29.0 (5.92)	29.0 (6.44)	28.6 (4.85)	28.7 (6.38)

Figure 1. FEV_1 Profiles over 24 hours on Day 7/8 (ITT Population)

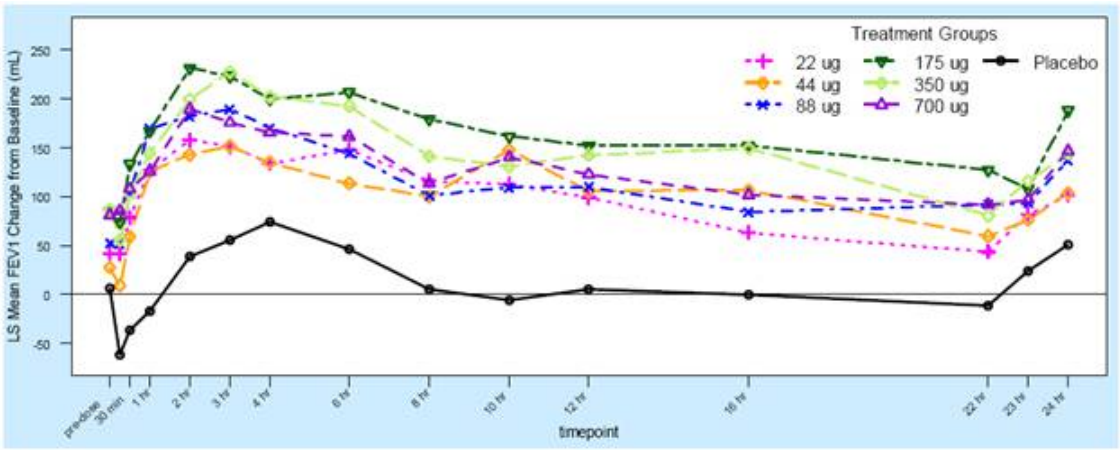
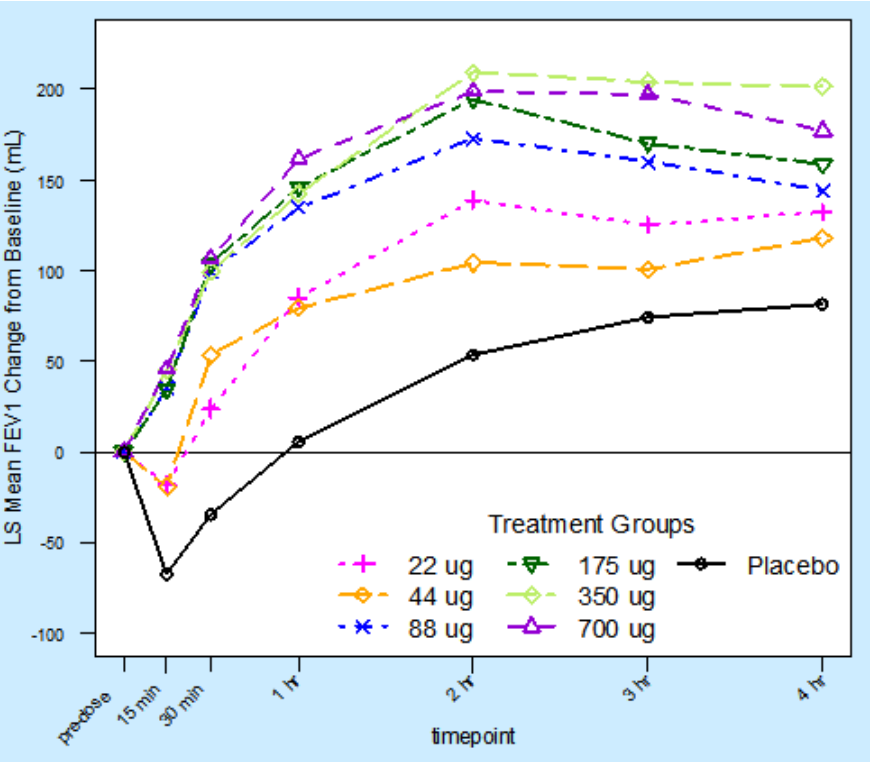


Table 3. FEV_1 Ratio of Peak to Trough and Weighted Mean (0-12 h) : Weighted mean (12-24 h) on Day 7/8 (ITT Population)

	DOSE					
	22 µg	**44 µg**	**88 µg**	**175 µg**	**350 µg**	**700 µg**
Peak (0-6h) to Trough FEV_1	1.09	1.08	1.11	1.08	1.10	1.09
WM FEV_1 (0-12 h:) : WM FEV_1 (12-24 h)	1.04	1.02	1.03	1.02	1.02	1.03

Figure 2. FEV_1 Profiles over 4 hours on Day 1 (ITT Population)



- Noting that this was an incomplete block crossover design, demographics were generally comparable between treatment groups (Table 2).
- No carry-over effect was observed between treatment periods.
- General dose ordering was observed on Day 1 (Figure 2).
- Following once-daily administration, sustained bronchodilation was evident on Day 7 (Figure 1, Table 3) across the range of doses tested (22, 44, 88, 175, 350 and 700 µg).
- The clinical effect was less marked with doses of 22, 44 and 88 µg, particularly at the onset of the Day 7 profile (marking the trough of the Day 6 dose).
- 175 µg produced the greatest numerical improvements and there was no additional benefit on change from baseline FEV_1 with the 350 µg or 700 µg dose.
- Analysis of the responder rates (Table 4) indicates that a greater proportion of patients responded to the 350 µg than to the 175 µg dose, but this effect was not observed for the 700 µg dose.

Table 4. Responder Analysis at Day 7/8 Trough (ITT Population)

	DOSE						
Response threshold	**Placebo (N=59)**	**22 µg (N=40)**	**44 µg (N=39)**	**88 µg (N=39)**	**175 µg (N=39)**	**350 µg (N=39)**	**700 µg (N=40)**
100 mL	11 (18.6%)	16 (40.0%)	13 (33.3%)	20 (51.3%)	21 (53.8%)	25 (64.1%)	16 (40.0%)
150 mL	6 (10.2%)	7 (17.5%)	11 (28.2%)	15 (38.5%)	10 (25.6%)	19 (48.7%)	12 (30.0%)

Table 5. AE Frequency (Events with frequency >1; Safety population)

Preferred Term	**Placebo (N=61)**	**22 µg (N=41)**	**44 µg (N=39)**	**88 µg (N=40)**	**175 µg (N=37)**	**350 µg (N=41)**	**700 µg (N=37)**
Headache	9 (14.8%)	3 (7.3%)	2 (5.1%)	3 (7.5%)	4 (10.8%)	3 (7.3%)	5 (13.5%)
Cough	1 (1.6%)	2 (4.9%)	1 (2.6%)	2 (5.0%)	2 (5.4%)	2 (4.9%)	2 (5.4%)
Dyspnoea	4 (6.6%)	1 (2.4%)	1 (2.6%)	1 (2.5%)	2 (5.4%)	2 (4.9%)	1 (2.7%)
Back pain		2 (4.9%)		1 (2.5%)	1 (2.7%)	1 (2.4%)	
Rash		1 (2.4%)	1 (2.6%)		2 (5.4%)		1 (2.7%)
COPD		1 (2.4%)		3 (7.5%)			
Fatigue		2 (4.9%)	2 (5.1%)				
Nasopharyngitis	2 (3.3%)	1 (2.4%)	1 (2.6%)				
Nausea	1 (1.6%)		2 (5.1%)		1 (2.7%)		
Oropharyngeal pain			1 (2.6%)	1 (2.5%)	2 (5.4%)		
Contusion		2 (4.9%)	1 (2.6%)				
Haematoma	1 (1.6%)			2 (5.0%)			
Rhinorrhoea			2 (5.1%)		1 (2.7%)		
Catheter site pain			2 (5.1%)				
Foot fracture			2 (5.1%)				
Hypotension			2 (5.1%)				

- TD-4208 was well tolerated. There were no deaths and no SAEs related to study medication.

- Cough was reported infrequently across all treatment periods, however there was no relationship with time of dosing, or dose of TD-4208.

- 3 SAEs were reported: pneumonia in one subject (placebo period; discontinued); transient ischemic attack (22 µg period; resolved); chest pain (22 µg period; no evidence of ischemia; discontinued).

CONCLUSIONS

- TD-4208 produced clinically relevant bronchodilation across a range of doses following dosing on Day 1.

- The bronchodilator effect of TD-4208 was sustained for 24 hours following dosing on Day 7.

- The study provides the first assessment of the dose response for TD-4208, to be further evaluated in longer-term studies.

- TD-4208 was generally well tolerated and did not result in systemic anticholinergic effects following repeat-dose administration.

- TD-4208 offers the potential for once-daily use in patients with COPD for whom handheld inhaler devices are either unsuitable or not preferred.

REFERENCES

[1] In Vivo Pharmacological Characterization of TD-4208, a Novel Lung-Selective Inhaled Muscarinic Antagonist with Sustained Bronchoprotective Effect in Experimental Animal Models. M. T. Pulido-Rios, et al. *J Pharmacol Exp Ther* **2013** 346:241-250.

[2] A Randomized, Crossover Study to Examine the Pharmacodynamics and Safety of a New Antimuscarinic TD-4208 in Patients with COPD. Potgieter P.D., et al., *European Respiratory Society* **2012**, Poster Abstract 2878.

[3] Single-Dose Pharmacokinetics of TD-4208, A Novel Long-Acting Muscarinic Antagonist, in Patients with COPD. Baldwin M., et al., *American Thoracic Society Meeting* **2013**, Poster Abstract A1496.

[4] http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html