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): **October 24, 2012**

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
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(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 8.01 Other Events.

On October 24, 2012, GlaxoSmithKline (GSK) presented a poster titled, "An analysis of the dose response of umeclidinium (GSK573719) administered once or twice daily in patients with COPD" at CHEST 2012, the annual meeting of the American College of Chest Physicians (ACCP), in Atlanta, Georgia. Umeclidinium (GSK573719 or UMEC), a long-acting muscarinic antagonist (LAMA), combined with vilanterol (VI), a long-acting beta agonist (LABA), is a once-daily investigational medicine for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). UMEC/VI is in development under the LABA collaboration agreement between GSK and the Theravance, Inc. (the "Company"). The poster is filed as Exhibits 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	An analysis of the dose response of umeclidinium (GSK573719) administered once or twice daily in patients 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: October 24, 2012

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

EXHIBIT INDEX

Exhibit	Description
Exhibit 99.1	An analysis of the dose response of umeclidinium (GSK573719) administered once or twice daily in patients with COPD

Poster No 2076

An analysis of the dose response of umeclidinium (GSK573719) administered once or twice daily in patients with COPD

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INTRODUCTION

- Treatment with long-acting muscarinic antagonists (LAMAs) has been shown to significantly improve lung function in patients with chronic obstructive pulmonary disease (COPD).(1)-(3)
- Umeclidinium bromide (UMEC) is an inhaled LAMA in development as a once-daily (OD) treatment for COPD.
- This is an integrated analysis of two Phase 2B dose-ranging studies which was conducted to further understand UMEC dose response in conjunction with other dose-ranging data.

OBJECTIVES

- To evaluate the dose response of UMEC using pooled data from two studies of OD UMEC doses 15.6, 31.25, 62.5, 125, 250, 500, and 1000mcg and twice-daily (BID) UMEC doses 15.6, 31.25, 62.5, 125, and 250mcg in patients with COPD.

METHODS

Study design and population

- Meta-analysis of two multicenter, randomized, double-blind, placebo-controlled, 3-way cross-over, incomplete block studies: AC4115321 (NCT01372410) and AC4113073 (NCT00950807)
  - similar treatment effects were observed for Days 7 and 14 in AC4113073; therefore, AC4115321 (7-day study) and AC4113073 (14-day study) were chosen for this meta-analysis.
- Eligible patients were male or female, aged 40-80 years with a history of COPD, current or former cigarette smokers of $\geq$10 pack-years, a post-salbutamol forced expiratory volume in one second (FEV_1)/forced vital capacity (FVC) ratio of $\leq$0.70, and a post-salbutamol FEV_1 of $\geq$35% and $\leq$70% predicted.

Treatment

- AC4115321 patients were randomized to a sequence of three 7-day treatment periods, separated by a 10–14 day washout period
  - four OD UMEC doses (15.6, 31.25, 62.5, 125mcg) or two BID UMEC doses (15.6, 31.25mcg) were administered via dry powder inhaler.
- AC4113073 patients were randomized to a sequence of three 14-day treatment periods, separated by a 10–14 day washout period
  - five OD UMEC doses (62.5, 125, 250, 500, 1000mcg) or three BID UMEC doses (62.5, 125, 250mcg) were administered via dry powder inhaler.
- In both studies, placebo and open-label OD tiotropium 18mcg were comparators. Patients in AC4115321 received 3 out of 8 possible treatments and patients in AC4113073 received 2 out of 9 possible active treatments plus placebo.

Endpoints

- Primary endpoint: trough FEV_1 at the end of each treatment period (Day 8, AC4115321; Day 15, AC4113073).
- Secondary endpoints
  - trough FEV_1 on Day 7
  - weighted mean 0-24h FEV_1 at last treatment day of each period
  - serial FEV_1 at each time point over 24h after morning dosing at last treatment day of each period (Day 7, AC4115321; Day 14, AC4113073).

Analyses

- A population model-based analysis using the total daily UMEC dose was used for the primary analysis and included comparison between OD versus BID dosing.
- A linear mixed effects (ANCOVA) analysis was utilized to compare UMEC dose with placebo for trough FEV_1 and weighted mean FEV_1. A repeated measures analysis was utilized to examine serial FEV_1.

RESULTS

Demographics

- 321 patients were included (145, AC4115321; 176, AC4113073).

- Demographic characteristics
  - 95% White; 48% female
  - age, mean (range): 59.9 (41–80) years
  - body mass index (range): 26.84 (14.7–35.2) kg/m^2
  - 66% were current smokers (mean smoking history 38.8 years; mean smoking pack-years 50.6)
  - patients had moderate to severe airflow obstruction with a mean post-bronchodilator % predicted FEV_1 of 51.9% (standard deviation [SD]: 9.85) and mean FEV_1/FVC ratio of 50.5% (SD: 10.16).

Final dose response model

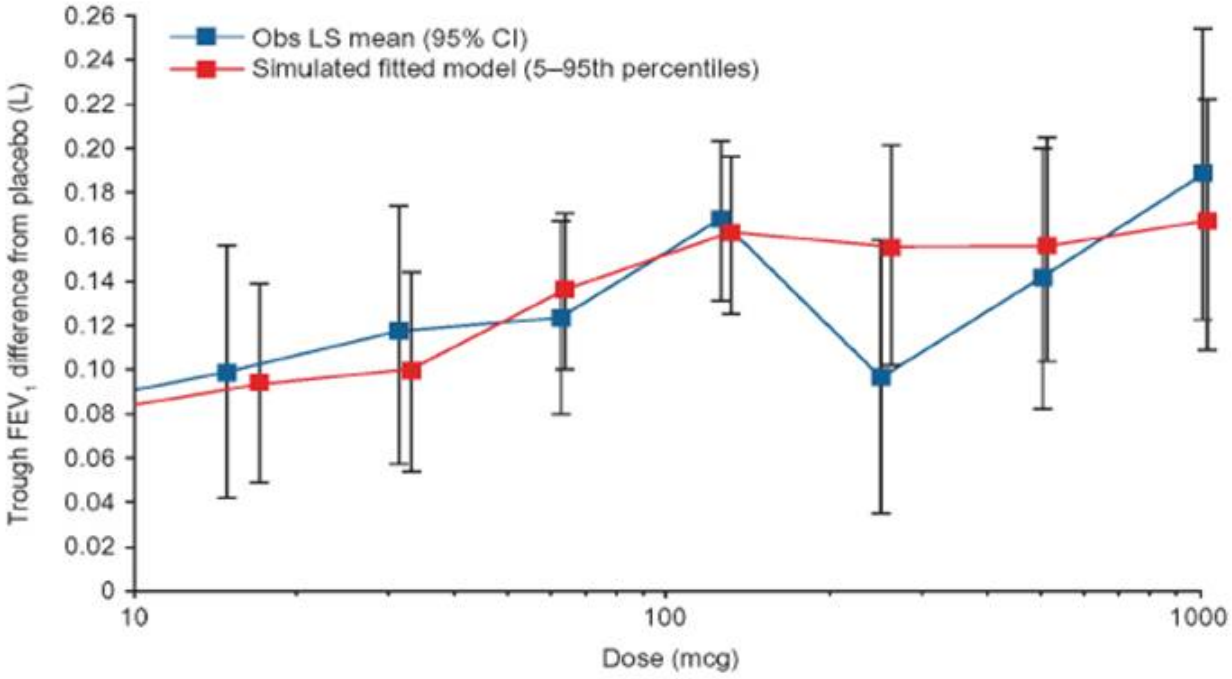
- A physiological effect (E_{max}) model was optimal in defining the relationship between UMEC dose and trough FEV_1 at the end of the treatment period
  - a clear monotonic dose response was observed over OD and BID dose regimens
  - UMEC doses ≥62.5mcg OD were strongly differentiated from lower doses
  - BID dosing did not provide benefit over OD dosing for comparisons of the same total daily dose or when a lower total daily dose was given BID.

- Potency (dose that yields 50% of E_{max} [ED_{50}]) estimate was 33mcg after OD dosing (95% confidence interval [CI]: 25–41).

- Predicted E_{max} value was 0.187L after OD dosing (CI: 0.170–0.210).

- Simulated FEV_1 responses were plotted over the curve for the observed least square (LS) mean FEV_1 (95% CI) response (**Figure 1**)
  - simulated dose response was similar to the LS mean from the mixed model analysis.

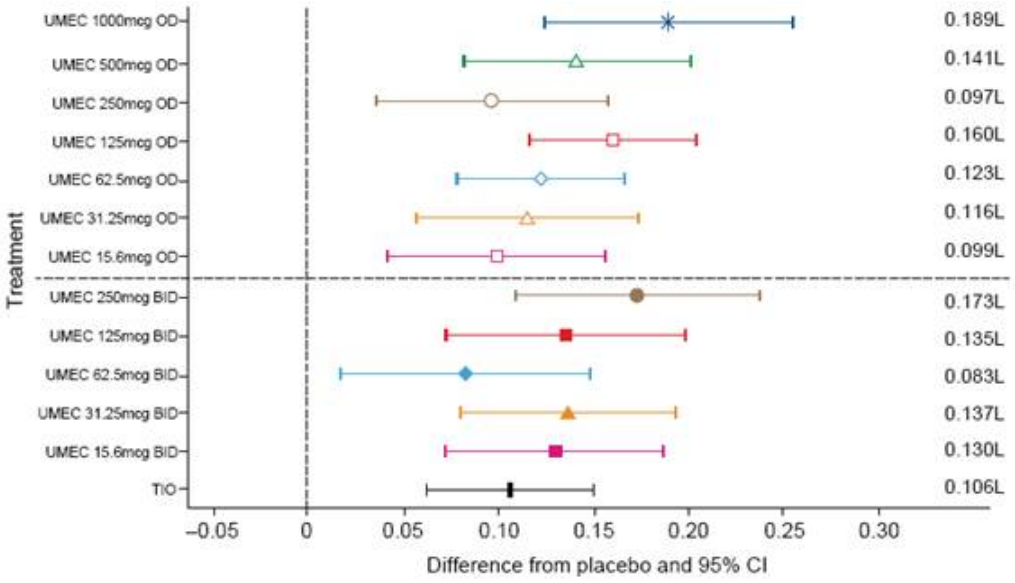
FIGURE 1. OBSERVED LS MEAN TROUGH FEV_1 AND SIMULATED MEDIAN



Trough FEV_1 at the end of the treatment period

- Adjusted mean change from baseline in trough FEV_1 demonstrated statistically significant differences compared with placebo for all UMEC OD and BID doses (**Figure 2**)
  - dose ordering was observed over OD dose regimens from 15.6 to 125mcg.

FIGURE 2. ADJUSTED MEAN DIFFERENCE FROM PLACEBO IN CHANGE FROM BASELINE TROUGH FEV_1 (L) AT THE END OF TREATMENT PERIOD



- The probability of achieving a certain response at a given dose and the expected response (5–95th percentiles) at a given dose are shown in **Table 1**
  - doses below 62.5mcg OD are likely to provide a suboptimal improvement in trough FEV_1
  - no evidence for any marked clinical benefit for the BID regimen compared with the OD regimen based on total daily dose of UMEC from the dose response model was demonstrated.

TABLE 1. CHANGE FROM BASELINE FEV_1 AT TROUGH (A) PROBABILITY % THAT A CERTAIN DOSE WILL EXCEED TARGET FEV_1 RESPONSE (B) EXPECTED RESPONSE AT A CERTAIN DOSE

UMEC dose (mcg)	(A) 80mL	100mL	130mL	150mL	(B) Expected response	90% probability of response is between
15.6 OD	72	44	11	3	96	(51—144)
31.25 OD	76	50	16	5	100	(55—149)
62.5 OD	100	96	63	27	138	(103—172)
125 OD	100	100	91	66	159	(124—198)
250 OD	99	96	77	56	155	(103—204)
500 OD	99	96	79	57	156	(104—204)
1000 OD	99	96	85	66	164	(105—223)
15.6 BID	85	65	27	10	112	(60—160)
31.25 BID	84	64	23	7	111	(61—154)
62.5 BID	98	92	70	46	146	(92—204)
125 BID	99	94	76	51	151	(95—204)
250 BID	99	97	87	75	175	(111—239)

0–24h weighted mean FEV_1

- Statistically significant ($p<0.001$) increases from baseline in weighted mean 0–24h FEV_1 at last treatment day were demonstrated for all UMEC OD (0.105–0.152L) and BID (0.123–0.145L) doses compared with placebo
  - dose ordering was observed for the OD doses, with a plateau in response at ≥125mcg.

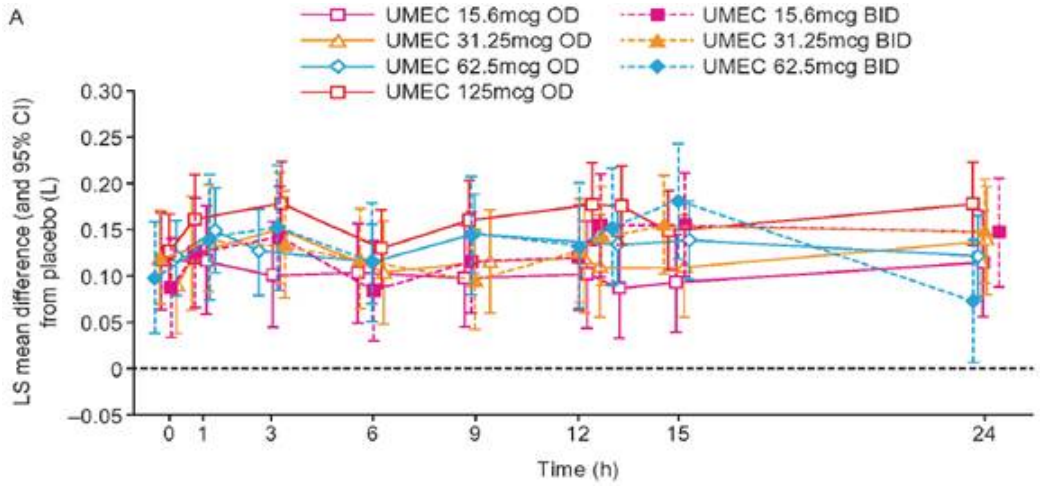
Serial FEV1 at the last day of the treatment period

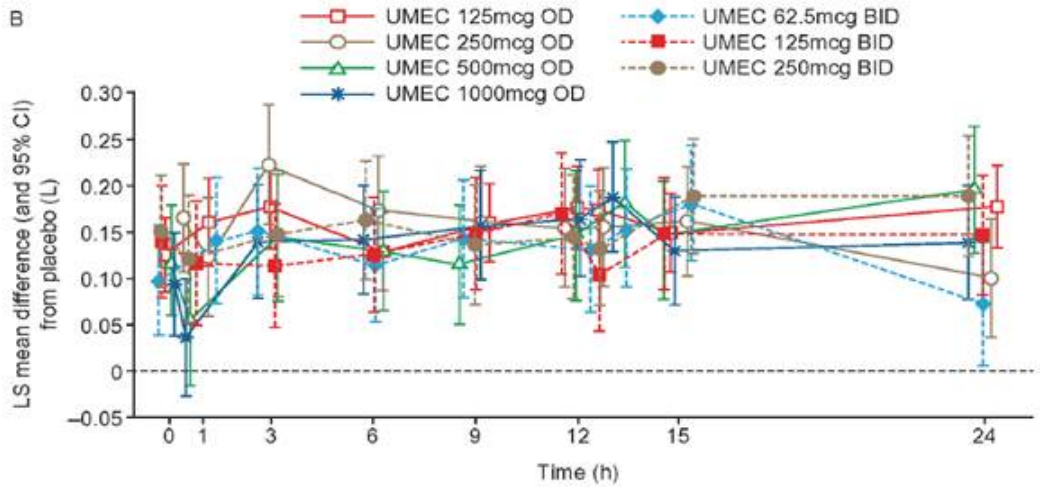
- Statistically significant improvements in FEV_1 over 24h were demonstrated for all UMEC OD and BID doses compared with placebo at each time point, except for UMEC 500mcg and 1000mcg OD doses at 1h **(Figure 3).**

- Statistically significant improvements were also observed over 24h for tiotropium compared with placebo.

- Increases in FEV_1 with all UMEC OD doses compared with placebo were consistent across all time points over the 24-h period.

FIGURE 3. ADJUSTED MEAN CHANGE FROM BASELINE IN FEV_1 (L) OVER TIME ON LAST TREATMENT DAY FOR (A) DOSES OF ≤125MCG OD AND (B) DOSES of ≥62.5MCG BID





CONCLUSIONS

- A dose-response model using data from two dose-ranging studies demonstrated a clear monotonic dose response for UMEC in patients with COPD
  - the potency estimate was 33mcg after OD dosing.
- The dose-response model and evaluation of trough and 0–24h data demonstrate that doses at or above 62.5mcg OD provide optimal bronchodilation.
- These data demonstrate that OD dosing is an appropriate dosing interval for UMEC.
- This analysis, in association with other dose-ranging studies in COPD patients and healthy volunteers, supports UMEC dose response and dosing interval.

REFERENCES

(1) O'Donnell DE, et al. Am J Respir Crit Care Med. 1998;158:1557-1565.

(2) Casaburi R, et al. Eur Respir J. 2002;19:217-224.

(3) O'Donnell DE, et al. Eur Respir J. 2004;23:832-840.

ACKNOWLEDGEMENTS

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- J Donohue, has served as consultant to Almirall, AZ, BI, Dey, Elevation Pharmaceuticals, Forest Laboratories, GlaxoSmithKline, Novartis, Pearl Pharmaceuticals, Pfizer and Sunovion; and has received research grants from BI, GlaxoSmithKline and Novartis. All other authors are employees of, and own stock in, GlaxoSmithKline.
- Chang-Qing Zhu, of GlaxoSmithKline, was the statistician for this study.
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