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 28, 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)

951 Gateway Boulevard
South San Francisco, California 94080
(650) 238-9600
(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 28, 2014 at CHEST 2014 in Austin, Texas, GlaxoSmithKline plc (GSK) presented data from two Phase 3 studies evaluating the efficacy and safety of the open triple therapy, the once-daily umeclidinium (UMEC), a long-acting muscarinic antagonist, added to fluticasone furoate/vilanterol (FF/VI), in chronic obstructive pulmonary disease. FF/VI is a once-daily combination of a long-acting $beta_2$ agonist (LABA) and inhaled corticosteroid. FF/VI has been developed under the 2002 LABA collaboration between Glaxo Group Limited and Theravance, Inc. The slide presentation is filed 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	Efficacy and Safety of Once-Daily Umeclidinium Added to Fluticasone Furoate/Vilanterol in Chronic Obstructive Pulmonary Disease: Results of Two Replicate Randomized 12-Week Studies

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 28, 2014

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Efficacy and Safety of Once-Daily Umeclidinium Added to Fluticasone Furoate/Vilanterol in Chronic Obstructive Pulmonary Disease: Results of Two Replicate Randomized 12-Week Studies

Efficacy and safety of once-daily umeclidinium added to fluticasone furoate/vilanterol in chronic obstructive pulmonary disease: results of two replicate randomized 12-week studies

Thomas M. Siler

Midwest Chest Consultants, PC, 330 First Capitol Drive, Suite 470, St Charles, Missouri, USA

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Disclosures

- *Dr Siler has:*
  - Received research support from: Boehringer-Ingelheim, Elevation, Forest Research Institute, GlaxoSmithKline, Novartis, Pearl Therapeutics and Sunovion
  - Took part in Speaker bureau for: Astra Zeneca, Boehringer-Ingelheim and UCB
  - Acted as a Consultant for: Astra Zeneca and Vapotherm
- The studies presented here were funded by GlaxoSmithKline (200109, NCT01957163; 200110, NCT02119286)

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Off-label Discussion Declaration

Thomas M. Siler

I will be discussing data of the combination use of FF/VI and UMEC at doses of 62.5 mcg and 125 mcg. UMEC 125 mcg is not an approved dose.

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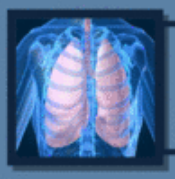
COPD and unmet medical needs



COPD is characterized by persistent airflow limitation and contributes substantially to global morbidity and mortality[1]

Central to the pharmacological management of COPD are bronchodilators (e.g. LAMAs, LABAs) and inhaled anti-inflammatories (e.g. ICS)[1]

1. Global Initiative for Chronic Obstructive Lung Disorder Report (2014) www.goldcopd.org/uploads/users/files/GOLD_Report_2014_Jan23.pdf

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Study rationale

- Combination therapies can offer improvements in pulmonary function over monotherapies, with a lower risk of side effects compared with increasing the dose of a single agent[1]

Fluticasone furoate/vilanterol (FF/VI [combined ICS/LABA]) is indicated for long-term, once-daily maintenance treatment of airflow obstruction in COPD[2]

Umeclidinium (UMEC, 62.5 mcg) is a LAMA indicated for long-term, once-daily maintenance treatment of airflow obstruction in COPD[3,4]

- These two replicate studies evaluated the efficacy and safety of UMEC added to FF/VI in patients with moderate-to-very-severe COPD

1. Global Initiative for Chronic Obstructive Lung Disorder Report (2014) www.goldcopd.org/uploads/users/files/GOLD_Report_2014_Jan23.pdf; 2. Glaxo Group Limited. RELVAR ELLIPTA® Summary of product characteristics. http://www.ema.europa.eu/docs; 3. GlaxoSmithKline. INCRUSE® Summary of product characteristics. http://www.ema.europa.eu/ema/; 4. GlaxoSmithKline. INCRUSE® Prescribing Information. https://www.gsksource.com/gskprm/

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Inclusion criteria

Key inclusion criteria

- ≥40 years of age
- established diagnosis of COPD
- current or former cigarette smoker
- had a pre- and post-albuterol FEV_1/FVC ratio of <0.7 and FEV_1 ≤70% predicted
- prior ICS treatment allowed to Visit 1
- no COPD exacerbation requirement*

Patient numbers

- **Study 1 (200109):** a total of **727** patients were enrolled, **619** included in the ITT population and **93%** completed the study
- **Study 2 (200110):** a total of **730** patients were enrolled, **619** included in the ITT population and **93%** completed the study

*patients enrolled did not need to have a history of COPD exacerbation in the 12 months prior to enrollment, and were required to withdraw if they experienced a COPD exacerbation during the run-in or study period that required additional treatment or hospitalization

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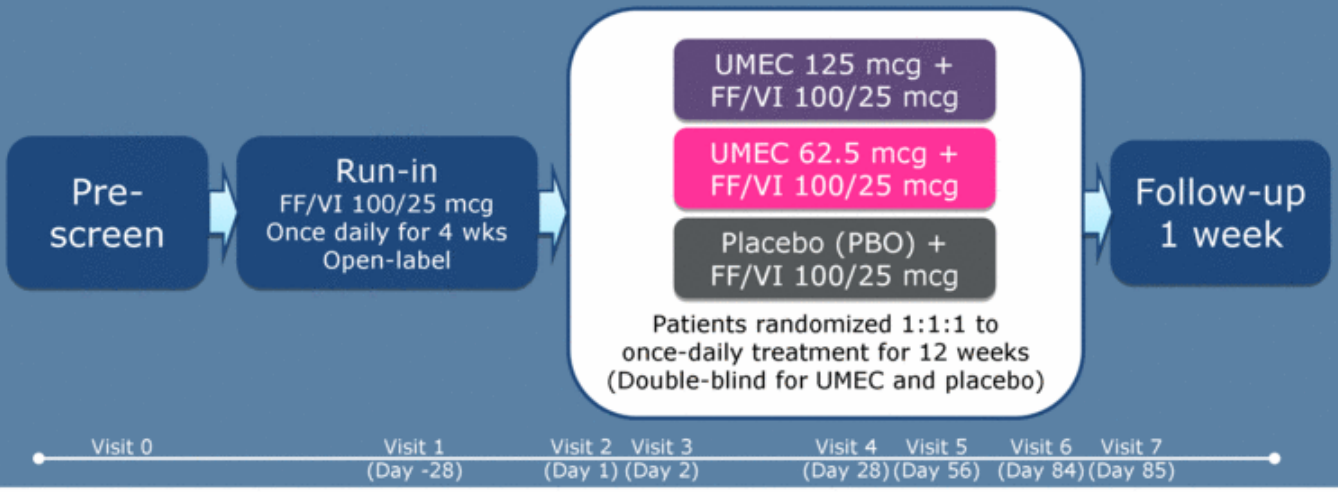
Study design

Two 12-week, randomized, double-blind, parallel-group studies



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Primary and secondary endpoints

Primary endpoint	Trough FEV_1 at Day 85
Secondary endpoint	Weighted mean FEV_1 over 0–6 h obtained post-dose on Day 84
Other key endpoints	Serial FEV_1, rescue use, SGRQ, safety (AEs, SAEs)

SGRQ, Saint George's respiratory questionnaire

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Baseline characteristics

	Study 1			Study 2		
	PBO + FF/VI 100/25 (N=206)	UMEC 62.5 + FF/VI 100/25 (N=206)	UMEC 125 + FF/VI 100/25 (N=207)	PBO + FF/VI 100/25 (N=206)	UMEC 62.5 + FF/VI 100/25 (N=206)	UMEC 125 + FF/VI 100/25 (N=207)
Age, years	64.7 (7.90)	64.9 (8.72)	63.8 (7.65)	62.6 (9.00)	62.6 (8.12)	63.4 (7.49)
Sex, male, n (%)	141 (68)	139 (67)	127 (61)	125 (61)	135 (66)	131 (63)
Current smoker at screening, n (%)	90 (44)	81 (39)	87 (42)	119 (58)	120 (58)	116 (56)
Smoking pack-years	50.6 (24.76)	50.1 (24.93)	47.9 (23.99)	46.2 (25.70)	46.8 (27.01)	45.6 (23.34)
Baseline (pre-albuterol) FEV_1, (L)	1.156 (0.453)	1.117 (0.453)	1.158 (0.445)	1.287 (0.465)	1.240 (0.442)	1.271 (0.476)
Post-albuterol FEV_1/FVC	48.0 (10.83)	47.8 (10.20)	49.2 (10.34)	49.0 (10.18)	48.1 (10.31)	48.8 (10.39)
% reversibility to albuterol	14.4 (14.36)	14.8 (11.97)	13.8 (11.62)	11.1 (12.75)	13.2 (12.88)	12.1 (11.25)
Patients with one or more COPD exacerbations, n (%)*	42 (20)	44 (21)	40 (19)	42 (20)	30 (15)	45 (22)

Values are reported as mean (standard deviation) unless otherwise stated. *within the 12 months prior to enrollment

GSK, data on file.

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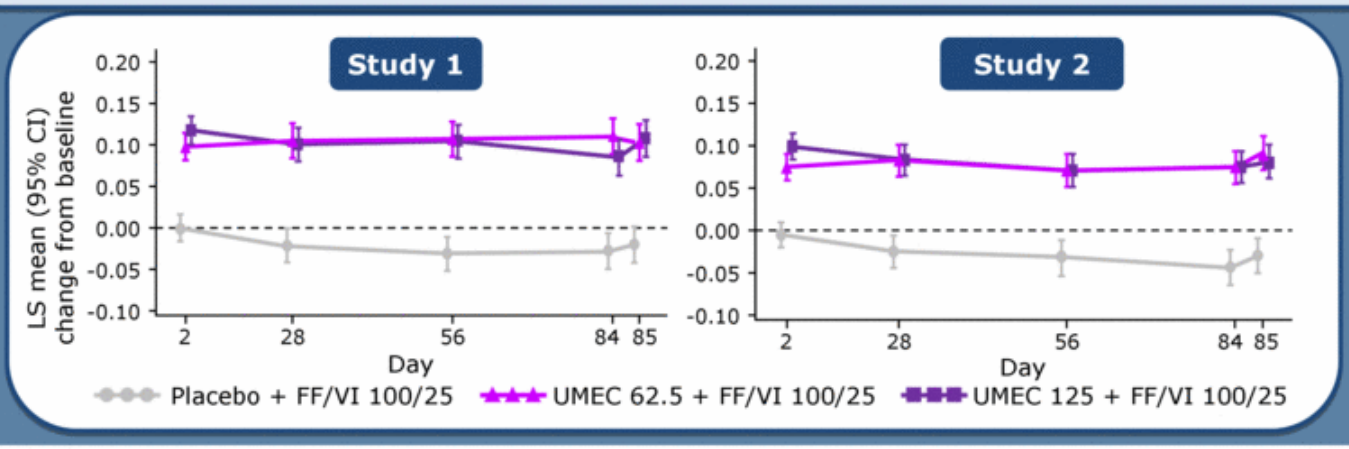
Trough FEV_1 (L) change from baseline

Both doses of UMEC+FF/VI in both studies produced statistically significant and clinically meaningful improvements in trough FEV_1 at Day 85 vs PBO + FF/VI (0.111–0.128 L, all p≤0.001).



GSK, data on file.

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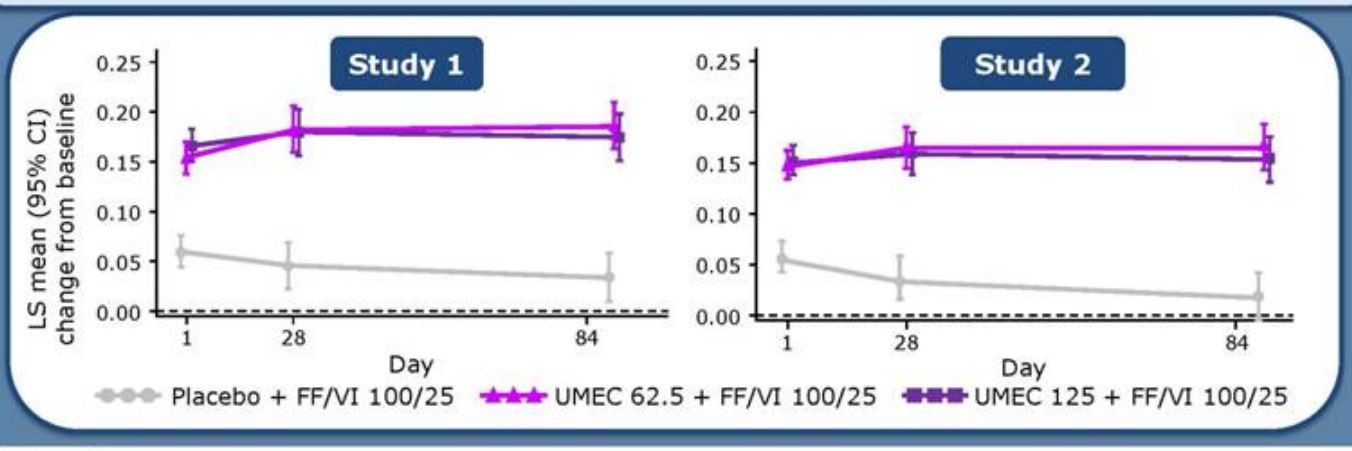
0–6 hour weighted mean FEV_1 (L)

Both doses of UMEC+FF/VI in both studies produced statistically significant and clinically meaningful improvements in 0-6 h post-dose WM FEV_1 at Day 84 vs PBO + FF/VI (0.135–0.153 L, all p≤0.001).



GSK, data on file.

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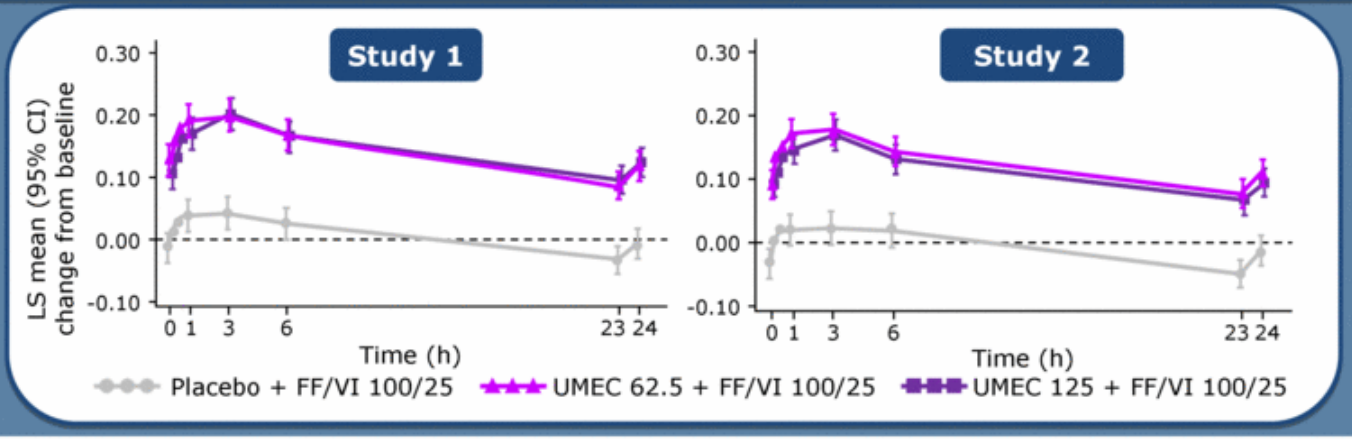
Serial FEV_1 on Day 84 (L)

Serial FEV_1 showed a rapid onset of FEV_1 improvements (statistically significant at the first measured timepoint of 15 minutes) with both doses of UMEC+FF/VI in both studies vs PBO+FF/VI, which was maintained through to Day 84 (all p≤0.001).



GSK, data on file.

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Symptomatic and HRQoL endpoints

Rescue-albuterol use over Weeks 1–12

- Both doses of UMEC + FF/VI in both studies increased the percentage of rescue-free days vs baseline (range: 5.9–14.2%) compared with PBO + FF/VI (2.3% and 3.8%)
- Significant improvements in mean rescue use in both UMEC + FF/VI groups vs PBO + FF/VI were observed in both studies (reduction of 0.2–0.4 puffs/day), with the exception of the UMEC 125 mcg + FF/VI group in Study 2

SGRQ on Day 84

- A significant 2.16-point improvement in SGRQ score was observed with UMEC 62.5 + FF/VI vs PBO + FF/VI in Study 2

Safety

	Study 1			Study 2		
	PBO + FF/VI 100/25 (N=206)	UMEC 62.5 + FF/VI 100/25 (N=206)	UMEC 125 + FF/VI 100/25 (N=207)	PBO + FF/VI 100/25 (N=206)	UMEC 62.5 + FF/VI 100/25 (N=206)	UMEC 125 + FF/VI 100/25 (N=207)
Any on-treatment AE, n (%)	72 (35)	75 (36)	80 (39)	81 (39)	67 (33)	62 (30)
Most common on-treatment AEs, n (%)						
Headache	6 (3)	9 (4)	9 (4)	5 (2)	8 (4)	4 (2)
Nasopharyngitis	7 (3)	7 (3)	10 (5)	22 (11)	11 (5)	19 (9)
Back pain	3 (1)	7 (3)	5 (2)	4 (2)	8 (4)	2 (<1)
Any on-treatment SAEs, n (%)	6 (3)	2 (<1)	8 (4)	12 (6)	8 (4)	3 (1)
Fatal AEs*, n (%)	1 (<1)	0	0	4 (2)	1 (<1)	0
COPD exacerbation	7 (3)	6 (3)	14 (7)	17 (8)	6 (3)	4 (2)
AEs of special interest, n (%)						
Cardiovascular – any event	6 (3)	5 (2)	3 (1)	6 (3)	2 (<1)	3 (1)
Pneumonia and LRTI – any event	5 (2)	2 (<1)	4 (2)	1 (<1)	2 (<1)	3 (1)

*none of the fatal AEs were considered related to the study drug

GSK, data on file.

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Conclusions

- Once-daily UMEC (62.5 or 125 mcg) added to once-daily FF/VI resulted in improvements in lung function compared with PBO + FF/VI in patients with COPD.
- Safety profiles were consistent across all treatment groups.

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Acknowledgments

- Thank you to all the investigators involved in these studies

Any questions?

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