

**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 23, 2012**

**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 contained in this Item 7.01 and in the accompanying exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.*

On October 23, 2012 at the United European Gastroenterology Week, Amsterdam, Netherlands, Theravance, Inc. presented data from the Phase 2b Study 0084 with TD-1211 in patients with opioid-induced constipation (OIC). These Phase 2b data were also presented on October 23, 2012, at the American College of Gastroenterology's 77th Annual Scientific Meeting, Las Vegas, Nevada. 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. A copy of the slide presentation 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	Slide Presentation Titled "TD-1211 Demonstrates Improvement in Bowel Movement Frequency and Bristol Stool Scores in a Phase 2b Study of Patients with Opioid-Induced Constipation (OIC)"

**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 23, 2012

By: /s/ Michael W. Aguiar

**Michael W. Aguiar**  
**Chief Financial Officer**

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**EXHIBIT INDEX**

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# **TD-1211 Demonstrates Improvement in Bowel Movement Frequency and Bristol Stool Scores in a Phase 2b Study of Patients with Opioid-Induced Constipation (OIC)**

Ross Vickery, PhD,<sup>1</sup> Yu-Ping Li, PhD,<sup>1</sup> Ullrich Schwertschlag, MD, PhD,<sup>1</sup> Neil Singla, MD,<sup>2</sup>  
Lynn Webster, MD,<sup>3</sup> Daniel Canafax, PharmD<sup>1</sup>  
<sup>1</sup> Theravance, Inc., So. San Francisco, CA; <sup>2</sup> Lotus Clinical Research, Pasadena, CA;  
<sup>3</sup> Lifetree Clinical Research, Salt Lake City, UT

**Daniel Canafax, PharmD**  
**VP, Clinical Research**  
**Theravance, Inc.**

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# Disclosures

- **Dr. Canafax is an employee of Theravance, Inc.**
- **Theravance, Inc., is investigating TD-1211 as a potential new treatment option for OIC**

## TD-1211 for Opioid-Induced Constipation

- Theravance-discovered, multivalent,  $\mu$ -opioid receptor neutral antagonist
- Peripherally selective
- Designed to normalize bowel movement frequency and quality
- Once daily oral dosing

# Phase 2b Study 0084 Design

- **Randomized, double-blind, placebo-controlled study**
- **TD-1211 doses: 5, 10, 15 mg, or placebo, once daily**
- **Study duration: 5-weeks treatment**
  - ◆ **Initiation with 5 mg TD-1211 or placebo once daily for 4 days**
- **Non-cancer pain patients with chronic OIC**
  - ◆ **≤5 SBMs during a 2-week baseline period, and**
  - ◆ **≥1 additional symptom of constipation for ≥25% of bowel movements**
- **Chronic opioid use**
  - ◆ **Total daily dose of ≥30 mg morphine equivalent units**
  - ◆ **Stable opioid regimen ≥14 days**
- **Protocol-permitted rescue laxative**

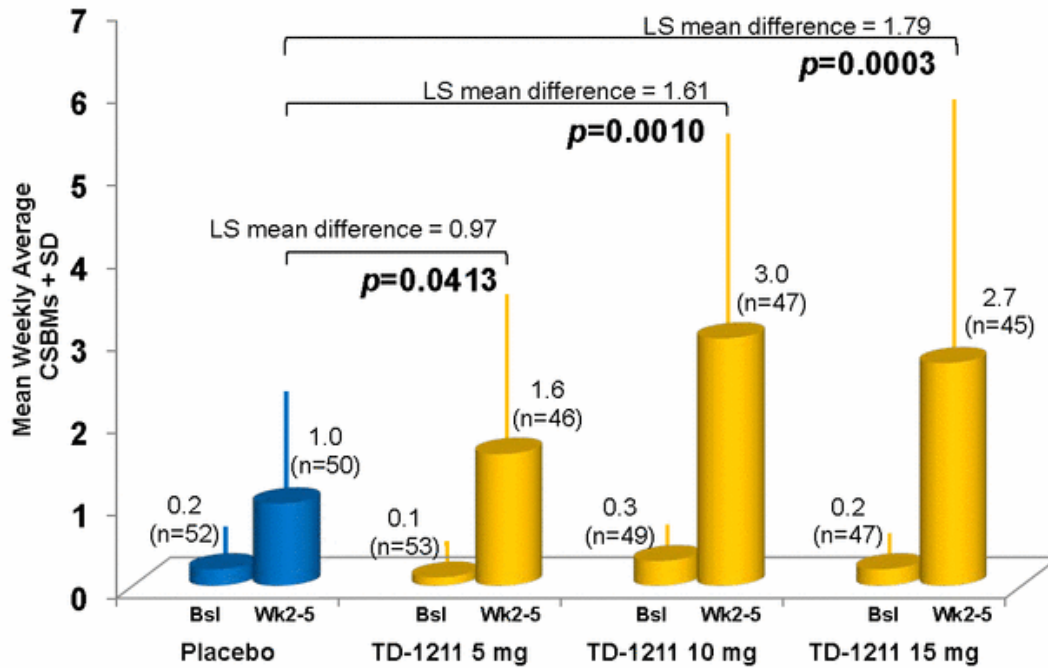
# Patient Demographics

- **Baseline characteristics similar across all treatment groups**

<b>Patients randomized</b>	<b>217</b>
<b>Mean age, yrs (range)</b>	<b>49 (21–65)</b>
<b>% female</b>	<b>59%</b>
<b>Mean duration of OIC, years <math>\pm</math> SD</b>	<b>6.0 <math>\pm</math> 5.6</b>
<b>Mean baseline SBMs/week</b>	<b>1.1–1.2</b>
<b>Mean opioid dose, MEU (range)</b>	<b>145 (30–1740)</b>
<b>Most common reason for chronic opioid use</b>	<b>Back pain, 43%</b>

# Primary Endpoint - Change From Baseline in Average Weekly CSBMs Over Weeks 2 to 5 of Treatment

## Complete Spontaneous Bowel Movements (CSBMs)

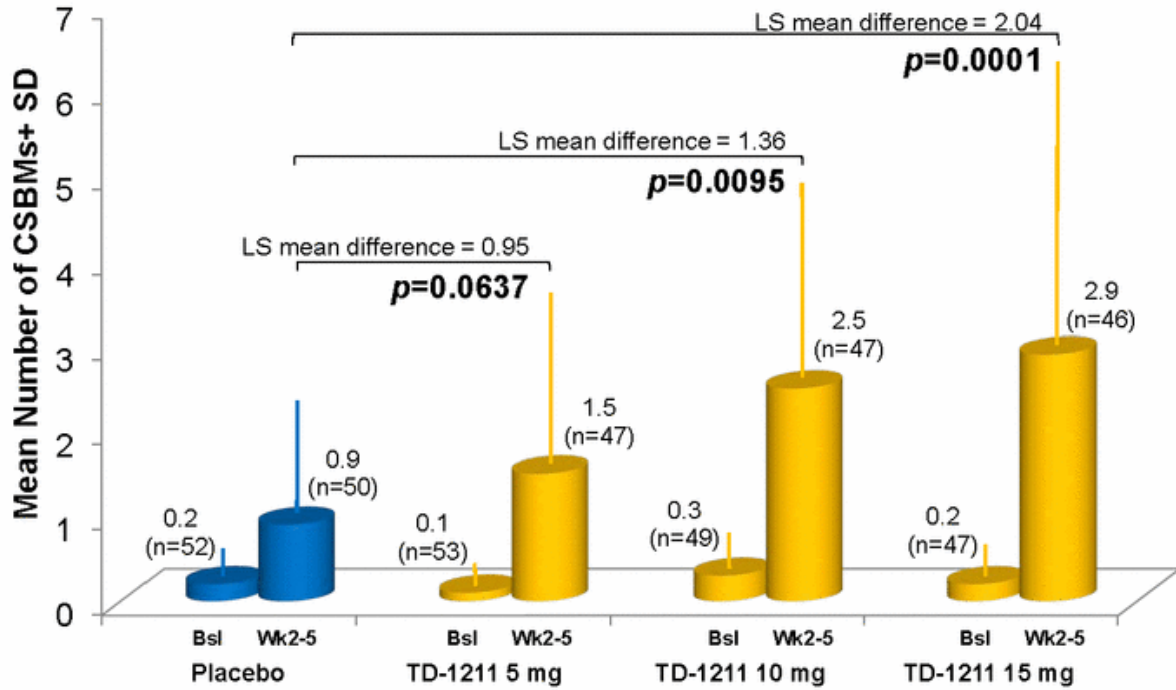


LS means difference = least squares mean difference from placebo; Efficacy Analysis (EA) population



# Change From Baseline in Weekly CSBMs During Week 5 of Treatment

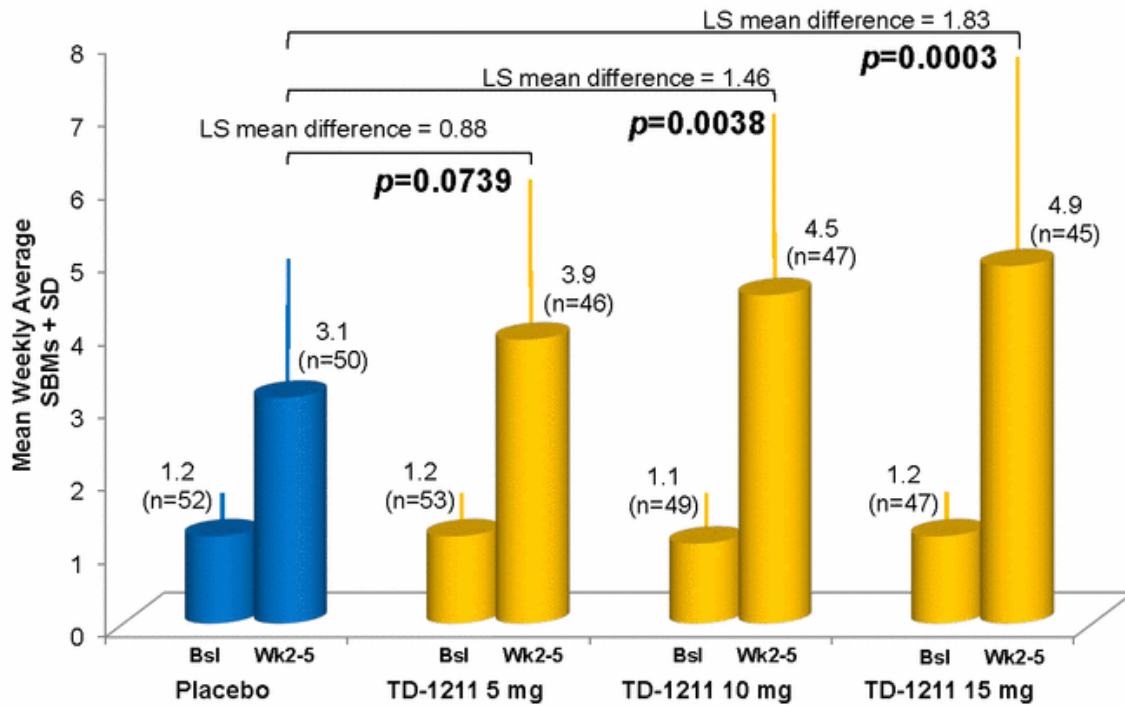
## Complete Spontaneous Bowel Movements (CSBMs)



- Durable response observed through Week 5

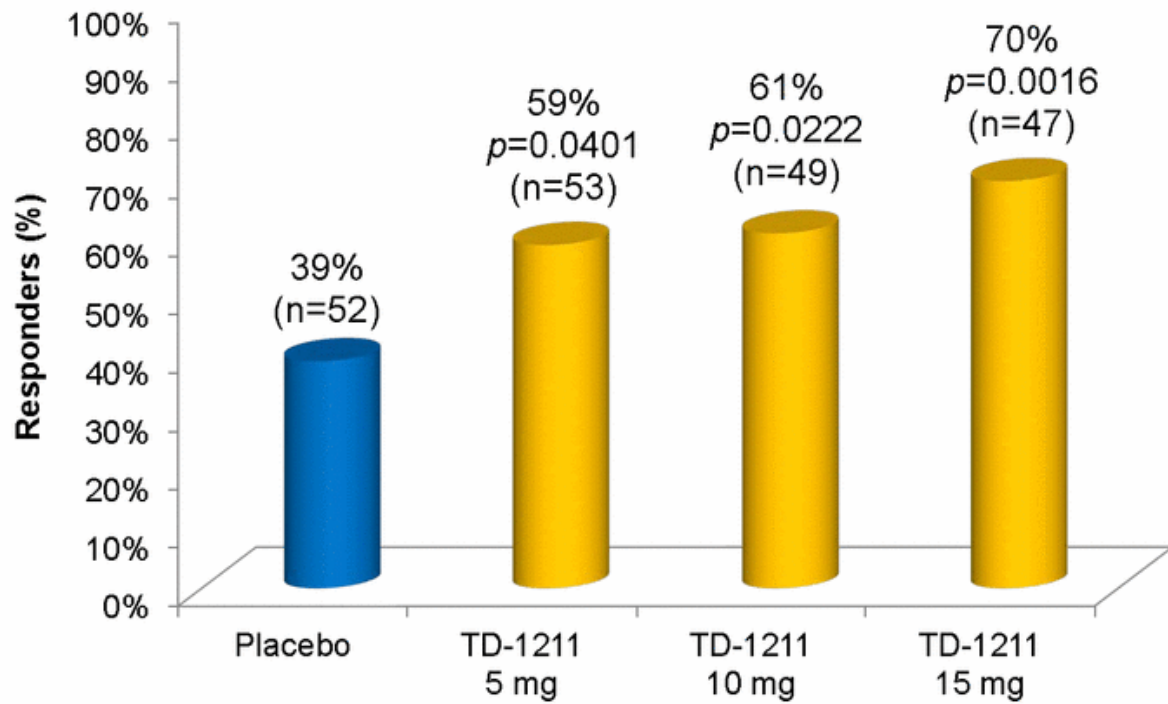
# Change From Baseline in Average Weekly SBMs Over Weeks 2 to 5 of Treatment

## Spontaneous Bowel Movements (SBMs)



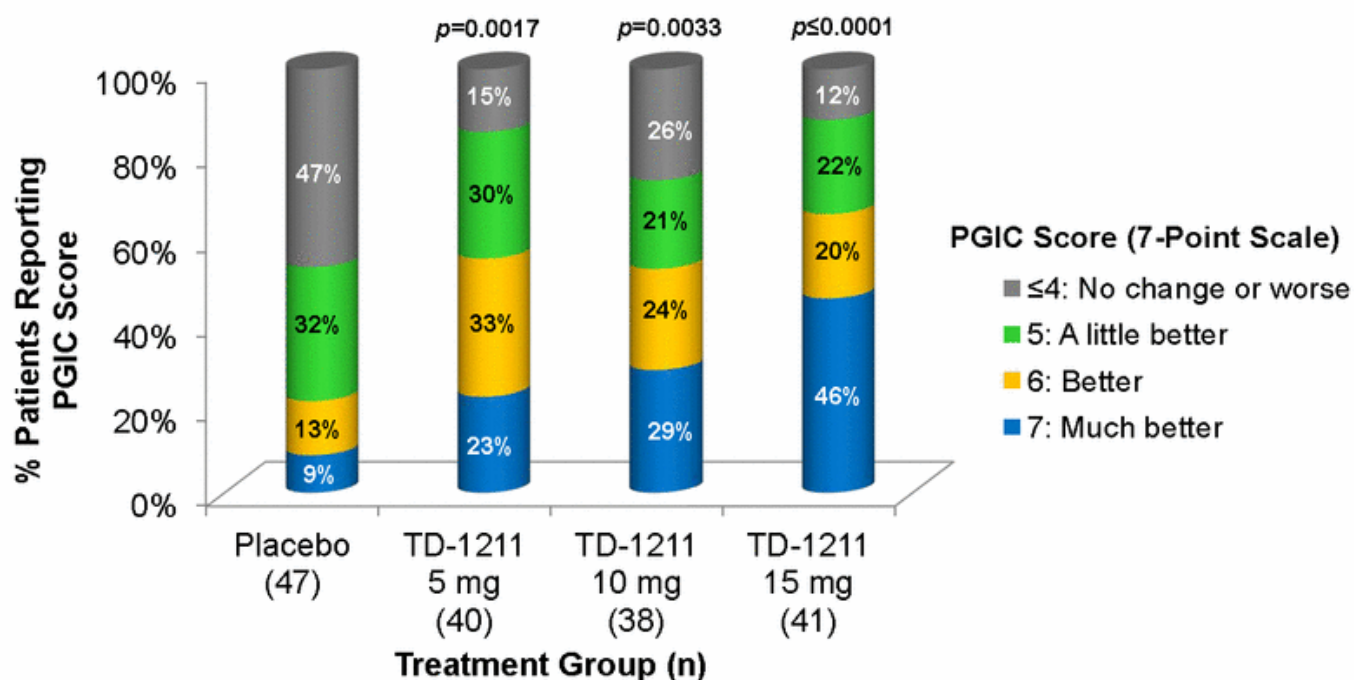
LS means difference = least squares mean difference from placebo; EA population

# Pre-Specified Responder Analysis



**Responder definition:  $\geq 3$  SBMs per week and an increase of at least 1 SBM per week from baseline for  $\geq 3$  weeks over Weeks 2 to 5**

# Patient's Global Impression of Change in Constipation



End of Treatment response to: "Since the end of the 2-week qualification period and before the first dose of study medication, how would you describe the change in your constipation?"

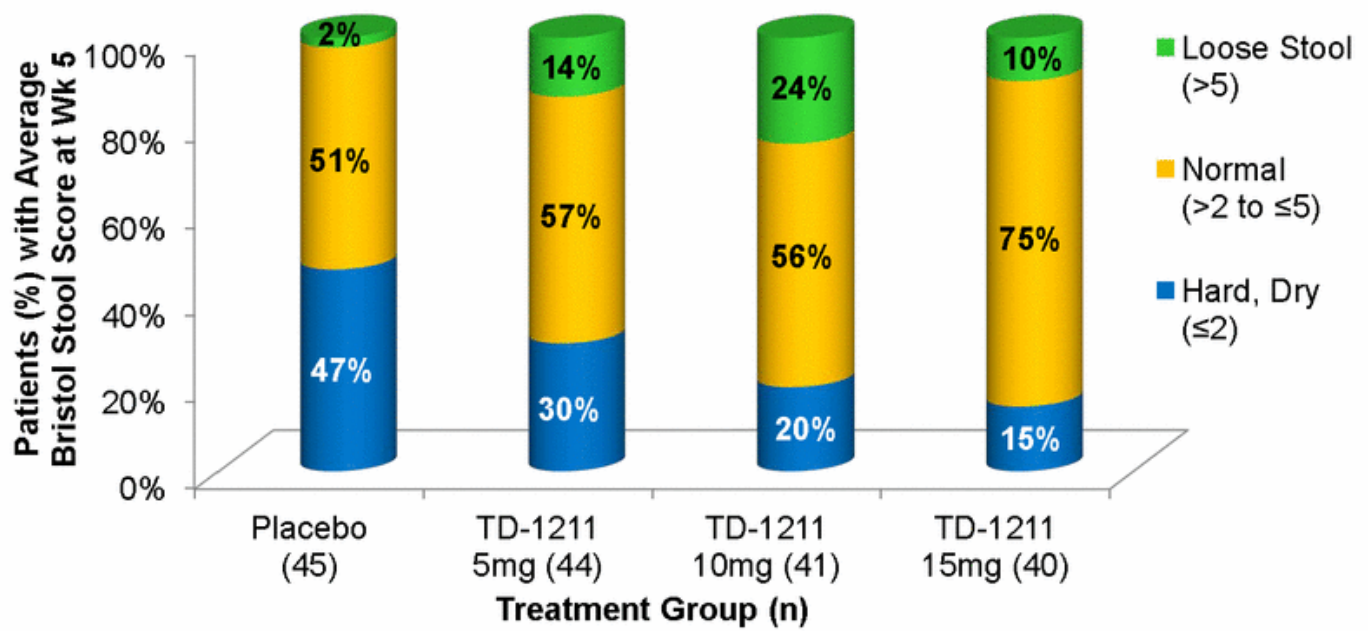
# Time to First Bowel Movement

	Patients, n (%)	
	Placebo n=52	TD-1211 Combined n=149
<b>Number of patients with at least one SBM within:</b>		
4 hours	5 (10)	56 (38)
<b>8 hours</b>	<b>9 (17)</b>	<b>77 (52)</b>
16 hours	17 (33)	87 (58)
24 hours	30 (58)	99 (66)
48 hours	39 (75)	124 (83)

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SBMs = spontaneous bowel movements. EA population

# Bristol Stool Scale Scores for SBMs at End of Treatment (Week 5)



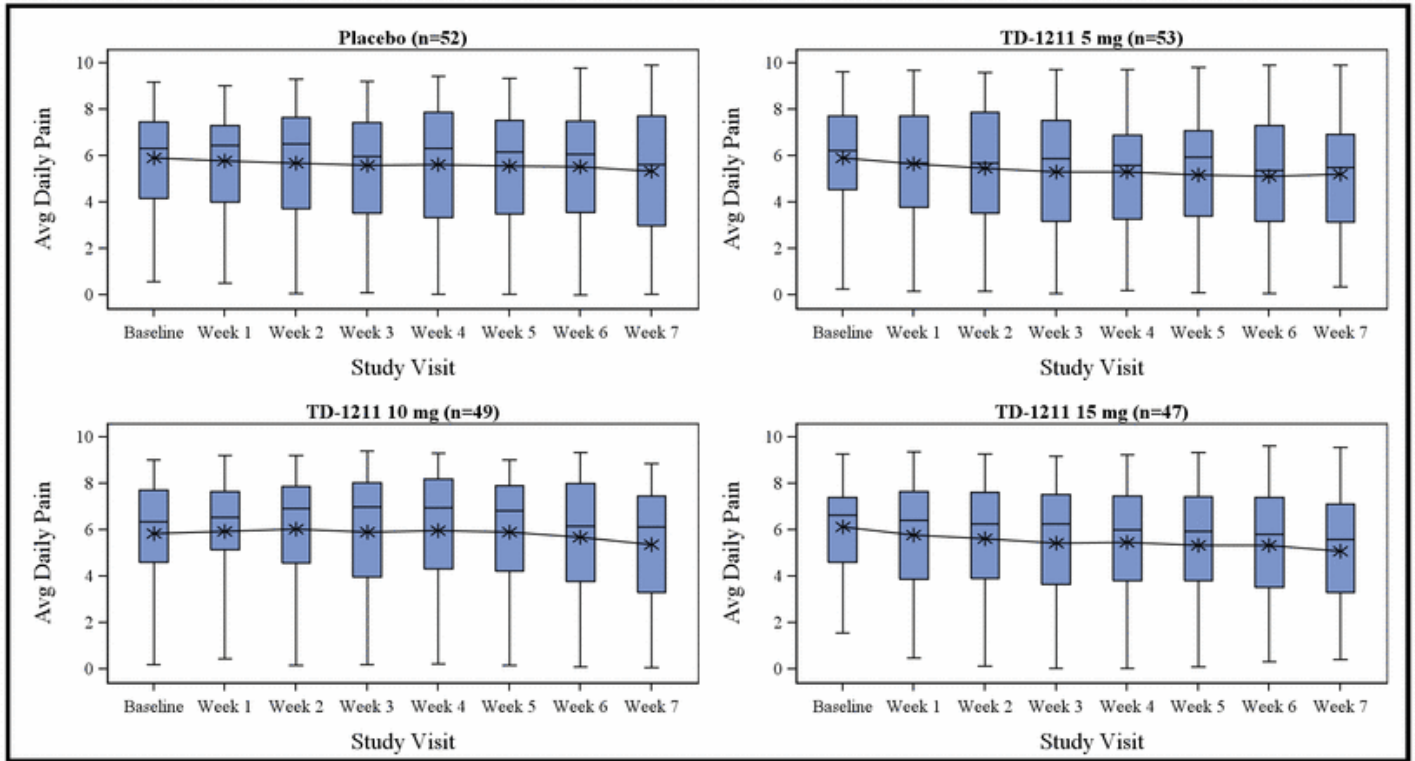
- Patients with average BSS scores at baseline among treatment groups: 54-67% hard, dry and 29-43% normal

# Overall TEAEs Similar Between TD-1211 and Placebo, with GI TEAEs Predominant

Safety Population	Patients, n (%)				
	Placebo n=54	TD-1211 Dose Group			All TD-1211 n=161
		5 mg n=56	10 mg n=53	15 mg n=52	
<b>Any TEAE</b>	<b>24 (44)</b>	<b>22 (39)</b>	<b>29 (55)</b>	<b>22 (42)</b>	<b>73 (45)</b>
<b>GI disorders (occurring in ≥2 patients)</b>	<b>11 (20)</b>	<b>13 (23)</b>	<b>15 (28)</b>	<b>14 (27)</b>	<b>42 (26)</b>
Abdominal pain	6 (11)	7 (13)	6 (11)	8 (15)	21 (13)
Abdominal pain upper	1 (2)	2 (4)	3 (6)	2 (4)	7 (4)
Diarrhea	0	4 (7)	6 (11)	4 (8)	14 (9)
Flatulence	3 (6)	1 (2)	2 (4)	1 (2)	4 (3)
Nausea	2 (4)	4 (7)	8 (15)	3 (6)	15 (9)
Vomiting	1 (2)	4 (7)	1 (2)	0	5 (3)

- **A majority of treatment-related GI adverse events were associated with initiation of treatment, resolved within a few days, and were mild or moderate**

# Average Daily Pain Scores (0-10 scale) Per Week



EA population. Weeks 6 +7 = follow-up period



## Summary of Study 0084

- **TD-1211 was generally well tolerated**
- **No clinically significant laboratory, ECG, or vital sign abnormalities**
- **No treatment-related SAEs**
- **No evidence of CNS penetration, interference with analgesia, or central withdrawal**
- **Majority of patients reported their constipation was better or much better on treatment**
- **Clinically meaningful response to treatment**