

**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): **April 30, 2014**

**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 April 30, 2014, Theravance, Inc. issued a press release announcing results from a Phase 2 study of TD-9855, an investigational norepinephrine and serotonin reuptake inhibitor (NSRI), in patients with fibromyalgia (FM). Theravance management will discuss these results on a conference call today, April 30, 2014, at 5:00 p.m. Eastern Daylight Time. A copy of the press release and the slide presentation to be presented during the conference call are furnished as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Press Release dated April 30, 2014
Exhibit 99.2	Slide Presentation dated April 30, 2014

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**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: April 30, 2014

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

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated April 30, 2014
99.2	Slide Presentation dated April 30, 2014

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**Theravance**  
Medicines That Make A Difference

## Theravance Announces Positive Results From a Phase 2 Study of TD-9855 in Patients With Fibromyalgia

### *20 mg Dose Met the Primary Endpoint Showing Significant Improvement in Weekly Average Pain Score and Met Both Secondary Efficacy Endpoints*

**SOUTH SAN FRANCISCO, CA—(MARKETWIRED — APRIL 30, 2014)** Theravance, Inc. (NASDAQ: THRX) today announced positive results from a Phase 2 study of TD-9855, an investigational norepinephrine and serotonin reuptake inhibitor (NSRI), in patients with fibromyalgia (FM). The study demonstrated statistically significant and clinically meaningful improvements in the primary and secondary endpoints at the 20 mg dose of TD-9855 compared to placebo. The 5 mg dose did not meet statistical significance for the primary endpoint. Both doses were generally well tolerated.

“We are very pleased with the positive results of our Phase 2 study of TD-9855 in patients with fibromyalgia,” said Mathai Mammen, M.D., Ph.D., Senior Vice President of Research and Development. “Patients with fibromyalgia have a clear unmet medical need: a medicine that will treat their pain and address other symptoms of this disorder, including fatigue and cognitive impairment. In this Phase 2 study, TD-9855 demonstrated a beneficial impact on symptoms important to patients with fibromyalgia.”

The primary efficacy endpoint of the Phase 2 study was the average of the daily pain score during the last week of the 6-week treatment period, using an 11-point Numerical Rating Scale (Pain-NRS). Pre-specified secondary endpoints were the Fibromyalgia Impact Questionnaire (FIQ) and the Patient Global Impression of Change scale (PGIC) measured on Day 43. Three hundred ninety-two patients were randomized to one of three treatment groups: placebo, 5 mg and 20 mg TD-9855.

“There continue to be substantial unmet needs in the management of fibromyalgia,” said Dr. Lesley Arnold, Professor of Psychiatry at the University of Cincinnati College of Medicine. “Many patients with fibromyalgia do not respond to or tolerate currently available treatments. The results of this Phase 2 trial of a new norepinephrine and serotonin reuptake inhibitor provide hope that additional options might become available to patients with this common pain disorder. TD-9855 was generally well tolerated and, compared with placebo, significantly improved pain as well as other symptoms commonly associated with fibromyalgia.”

TD-9855 met the primary efficacy endpoint at 20 mg, demonstrating a statistically significant reduction of 1.4 in weekly average pain score compared to 0.9 for placebo (one-sided  $p=0.022$ ). On the FIQ, a measure of the impact of fibromyalgia symptoms, TD-9855 demonstrated a significant improvement on Day 43 compared to placebo (-16.2 vs. -10.4; one-sided  $p=0.010$ ). In an analysis of effect on a patient’s overall evaluation of treatment, as measured by the PGIC, TD-9855 had a significantly greater proportion of responders (with a rating of “very much

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improved” or “much improved” in PGIC) compared to placebo (48% vs. 32%; one-sided  $p=0.015$ ). The study included exploratory endpoints to assess fatigue; positive treatment effects were seen with the 20 mg dose on global fatigue and cognitive fatigue endpoints. Furthermore, a composite responder analysis (Pain-NRS  $\geq 30\%$  reduction, PGIC  $\leq 2$  and SF-36 Physical Component Summary  $\geq 6$  point improvement), an index of overall treatment response, revealed improvement with the 20 mg dose of TD-9855 compared to placebo.

Both doses of TD-9855 were generally well tolerated in the study. The discontinuation rate in this trial was 20.2%, and was similar across treatment groups. The five most common treatment-emergent adverse events reported were headache, nausea, dizziness, insomnia and constipation. Changes in heart rate and blood pressure with TD-9855 were within the range of those seen in approved drugs in this class. Two serious adverse events were reported in TD-9855 treatment groups, with one assessed as possibly treatment related in the 5 mg group.

### **About the Phase 2 Study of TD-9855 in Fibromyalgia**

The Phase 2 randomized, double-blind, parallel-group, placebo-controlled study evaluated the safety and efficacy of two doses of TD-9855 (5 mg and 20 mg) in 392 patients with fibromyalgia. Study medication was administered once-daily for up to 6 weeks. The primary endpoint of the study was improvement in pain. Secondary endpoints assessed improvement in core symptoms of fibromyalgia using established fibromyalgia measures, the Fibromyalgia Impact Questionnaire (FIQ) and the Patient Global Impression of Change scale (PGIC). Impact on common symptoms of fibromyalgia was also evaluated as exploratory endpoints.

### **About TD-9855**

TD-9855 is an investigational NSRI discovered by Theravance for the treatment of chronic pain and potentially other CNS disorders. TD-9855 has been administered to healthy volunteers in ascending single- and multiple-dose studies evaluating safety, tolerability and pharmacokinetics. The results of these studies showed that TD-9855 was generally well tolerated, had a predictable and linear pharmacokinetic profile and a long pharmacokinetic half-life (approximately 35 hours) supportive of once-daily dosing. Data collected from a Phase 1 positron emission tomography (PET) study confirmed CNS penetration and selectivity for norepinephrine over serotonin transporters. In preclinical studies, TD-9855 exhibited broad antinociceptive activity across a range of models of pain.

### **About Fibromyalgia**

Fibromyalgia is a chronic pain syndrome that has been estimated to affect approximately 5 million individuals in the United States. While its etiology is unknown, fibromyalgia is believed to be a disorder of pain processing which results in amplification of sensory signals within the CNS. Agents that modulate central pain processing pathways are used in the pharmacological management of fibromyalgia. In addition to widespread pain, fibromyalgia is accompanied by

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other symptoms, such as fatigue, sleep, mood and cognitive difficulties that reduce patients' overall quality of life.

## Conference Call and Webcast Information

Theravance has scheduled an analyst conference call to discuss this announcement today, April 30, 2014, at 5:00 p.m. Eastern Daylight Time. Analysts who wish to participate in the live call by telephone, please dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting Theravance's web site at [www.theravance.com](http://www.theravance.com). To listen to the live call and to download the slide presentation, please go to Theravance's web site 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance's web site for 30 days through May 30, 2014. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on May 7, 2014 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 37036014.

## About Theravance

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programs include: RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> (FF/VI), ANORO<sup>™</sup> ELLIPTA<sup>®</sup> (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist) GSK961068, each partnered with GlaxoSmithKline plc (GSK), and its Long-Acting Muscarinic Antagonist program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at [www.theravance.com](http://www.theravance.com).

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This press release contains and the conference call will contain 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. Examples of such statements include statements relating to: plans for executing the separation of Theravance into

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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, the timing, manner and amount of anticipated potential capital returns to stockholders, 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 the press release and conference call 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: difficulties in effecting the registration of Theravance Biopharma as a public company, changes in the development or operations of Theravance prior to the separation that could affect the plans for the separation of Theravance into two independent companies or the intended provision of capital returns to stockholders, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, Theravance's dependence on third parties to conduct Theravance's clinical studies, delays or failure to achieve and maintain 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 3, 2014 and the risks discussed in Theravance's 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.

(THR-X-G)

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Medicines That Make a **Difference**®

NASDAQ: THRX

## TD-9855 Phase 2 Fibromyalgia Study Results

April 30, 2014

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# 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, the timing, manner and amount of anticipated potential capital returns to stockholders, 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: difficulties in effecting the registration of Theravance Biopharma as a public company, changes in the development or operations of Theravance prior to the separation that could affect the plans for the separation of Theravance into two independent companies or the intended provision of capital returns to stockholders, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, Theravance's dependence on third parties to conduct Theravance's clinical studies, delays or failure to achieve and maintain 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 3, 2014 and the risks discussed in Theravance's 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.



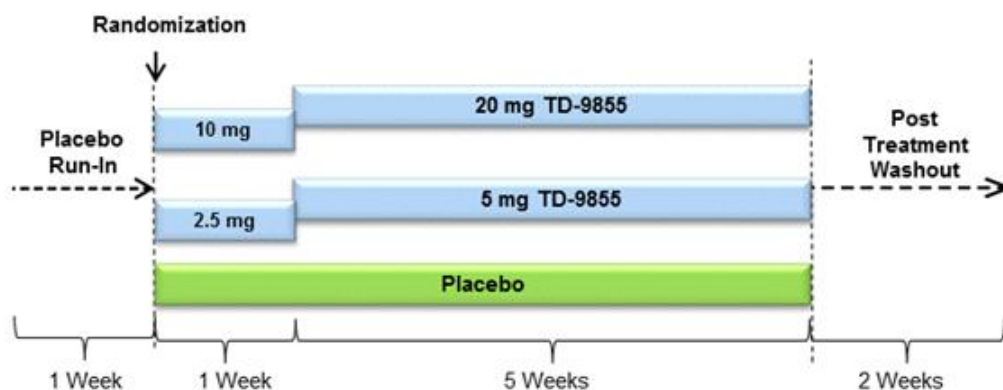
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## TD-9855 Fibromyalgia Phase 2 Design

- ▶ Randomized, double-blind, placebo-controlled, 3-arm parallel study
- ▶ 392 adult fibromyalgia patients with baseline pain scores from 4 to 9 on 11-point Pain Numerical Rating Scale (Pain-NRS)



- ▶ Primary endpoint:
  - Weekly average Pain-NRS at Week 6
- ▶ Secondary endpoints:
  - Fibromyalgia Impact Questionnaire (FIQ) on Day 43
  - Patient Global Impression of Change (PGIC) on Day 43



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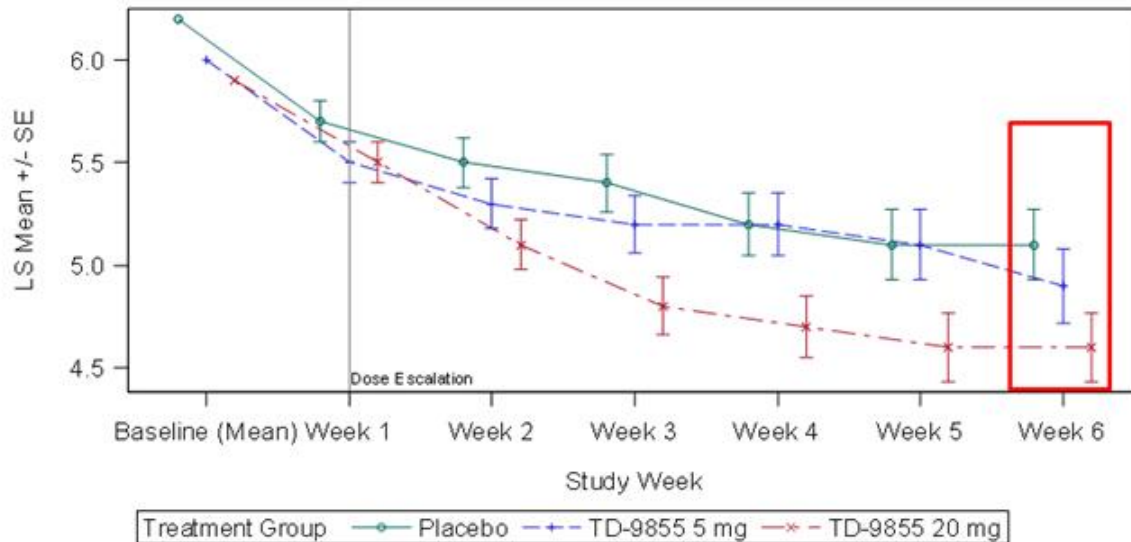
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## Primary Endpoint: Weekly Average Pain-NRS

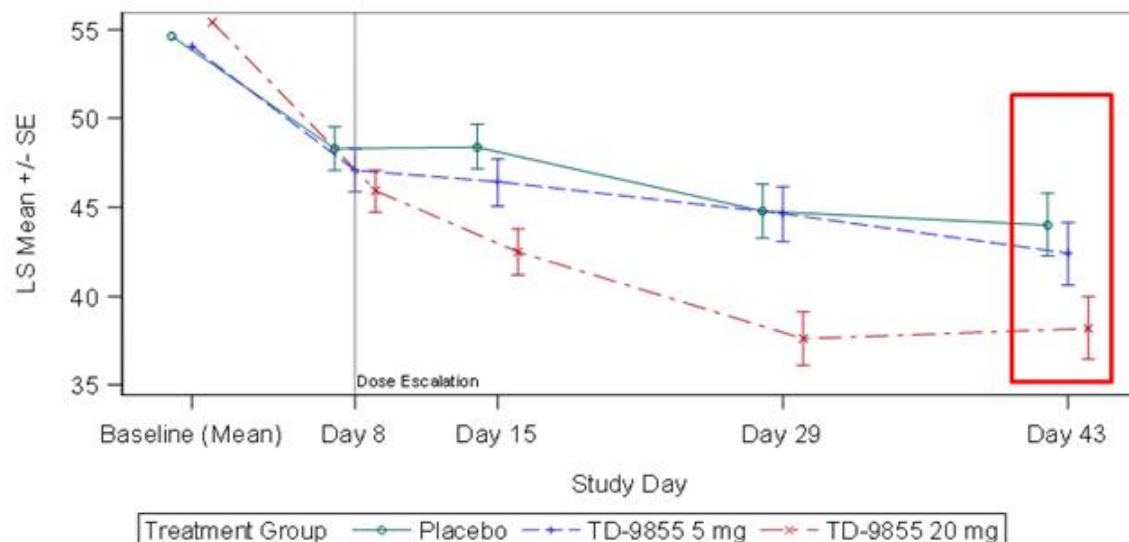
20 mg decreased weekly average pain score from baseline by 1.4 in comparison to 0.9 for placebo at Week 6  
(one-sided  $p=0.022$ )

5 mg was not significantly different from placebo



## Secondary Endpoint: Fibromyalgia Impact Questionnaire (FIQ)

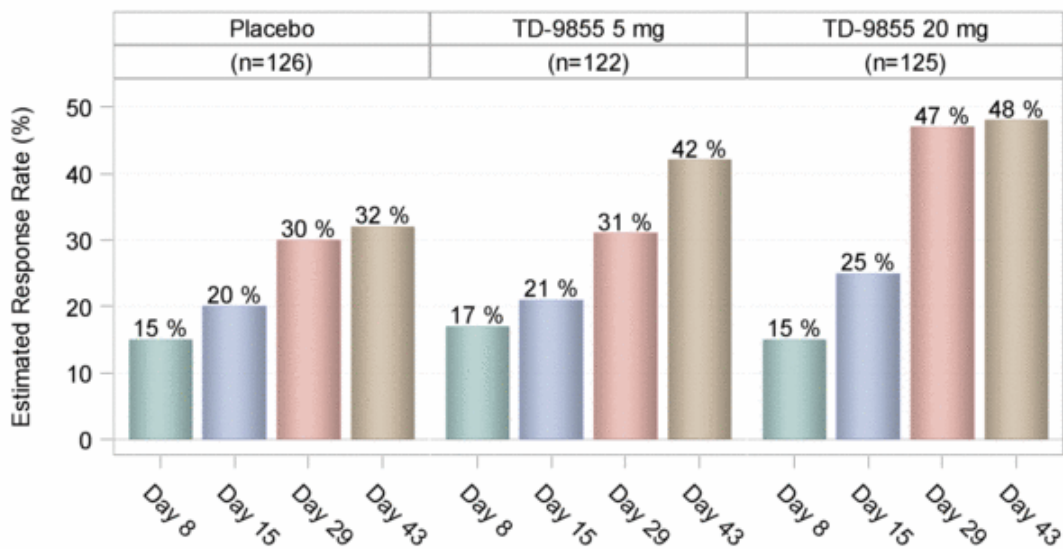
20 mg decreased FIQ from baseline by 16.2 in comparison to 10.4 for placebo on Day 43 (one-sided  $p=0.010$ )





## Secondary Endpoint: Patient Global Impression of Change (PGIC)

20 mg had greater proportion of responders in comparison to placebo on Day 43 (48% vs. 32%; one-sided p=0.015)



Response defined as: a rating of "very much improved" or "much improved" ( $\leq 2$ )



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# TD-9855 (20 mg) Demonstrated Improvements In Exploratory Endpoints

Clinically meaningful improvements in treatment response and an impact on fatigue

- ▶ A positive treatment response\* was observed on several exploratory endpoints including:
  - Composite response analysis (an index of overall treatment response)
    - $\geq 30\%$  reduction in Pain-NRS, PGIC  $\leq 2$  and SF-36 Physical Component Summary  $\geq 6$  point improvement
  - FIQ response analysis
    - $\geq 14\%$  reduction in FIQ
  - SF-36 Physical Component Summary
    - Total score and  $\geq 6$  point improvement
  - Global Fatigue Index from Multidimensional Assessment of Fatigue
  - Cognitive fatigue domain from DFS-Fibro (Daily Fatigue Scale in Fibromyalgia)

\* One-sided p-value  $\leq 0.025$



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## Safety Summary

- ▶ TD-9855 was generally well tolerated
- ▶ Two SAEs were reported in TD-9855 treatment groups, with one assessed as possibly treatment-related in the 5 mg group
- ▶ The discontinuation rate was 20.2%, and was similar across the treatment groups
- ▶ Changes in heart rate and blood pressure with TD-9855 were within the range of those seen in approved drugs in this class
- ▶ There was no significant change in mean body weight
- ▶ There were no treatment-related clinically significant abnormal laboratory findings



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# Treatment Emergent Adverse Events (TEAEs)

## Most Frequent TEAEs >5% in 20 mg

Preferred Term	Placebo (N=128)	TD-9855 5 mg (N=127)	TD-9855 20 mg (N=128)
Headache	10 (7.8%)	10 (7.9%)	17 (13.3%)
Dizziness	5 (3.9%)	7 (5.5%)	13 (10.2%)
Constipation	1 (0.8%)	6 (4.7%)	12 (9.4%)
Insomnia	4 (3.1%)	7 (5.5%)	11 (8.6%)
Nausea	9 (7.0%)	11 (8.7%)	10 (7.8%)
Fatigue	4 (3.1%)	6 (4.7%)	9 (7.0%)
Nasopharyngitis	1 (0.8%)	1 (0.8%)	8 (6.3%)
Decreased appetite	1 (0.8%)	4 (3.1%)	7 (5.5%)
Tachycardia	0	2 (1.6%)	7 (5.5%)

\* Table sorted in decreasing order of preferred term in 20 mg



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# TD-9855 Phase 2 Results Summary

- ▶ 20 mg TD-9855 met statistical significance for the primary (Pain-NRS) and secondary (FIQ, PGIC) endpoints
- ▶ 5 mg did not meet statistical significance for the primary endpoint
- ▶ TD-9855 was generally well tolerated
- ▶ Phase 2 results support further development of TD-9855



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NASDAQ: THRX

# THANK YOU

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