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): **August 9, 2017**

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**001-36033**	**98-1226628**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

PO Box 309
Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands KY1-1104
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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 August 9, 2017, members of the Theravance Biopharma management team will be conducting meetings with analysts and investors in South San Francisco. A copy of the slide presentation is being furnished pursuant to Regulation FD as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Investor Presentation Dated August 2017

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 BIOPHARMA, INC.

Date: August 9, 2017

By: /s/ Renee D. Gala
Renee D. Gala
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Investor Presentation Dated August 2017

Theravance Biopharma

Medicines That Make a Difference®

Theravance Biopharma, Inc. (NASDAQ: TBPH)

Investor Presentation
August 2017

Cautionary Statement Regarding Forward-Looking Statements

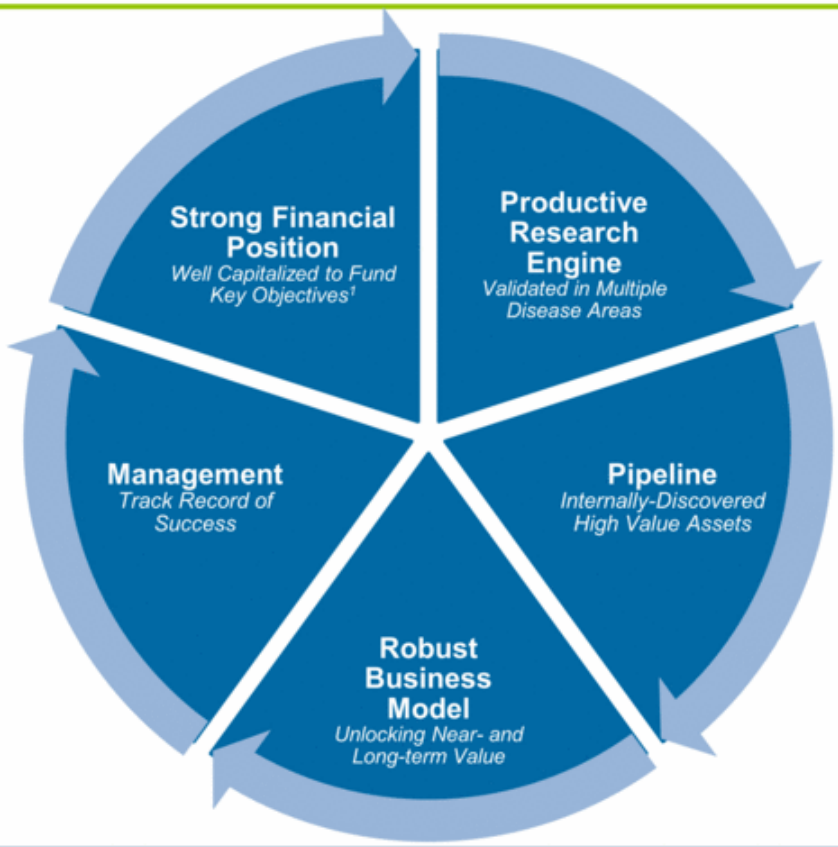
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company are subject to risks and uncertainties that may cause actual results to differ materially from the forward-looking statements or projections.

Examples of forward-looking statements in this presentation include statements relating to the company's business plans and objectives, including financial and operating results, potential partnering transactions and sales targets, the company's regulatory strategies and timing and results of clinical studies, the potential benefits and mechanisms of action of the company's product and product candidates (including their potential as components of combination therapies).

The company's forward-looking statements are based on the estimates and assumptions of management as of the date of this presentation and are subject to risks and uncertainties that may cause the actual results to be materially different than those projected, such as risks related to 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 (including when our product candidates are studied in combination with other compounds), delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities.

Other risks affecting the company are described under the heading "Risk Factors" and elsewhere in the company's Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 9, 2017, and other periodic reports filed with the SEC.

Theravance Biopharma Investment Highlights



[1] $498.3M in cash, cash equivalents, and marketable securities as of 6/30/17.

Theravance Biopharma

Upcoming Milestones

Multiple Opportunities for Value Creation

Program	Milestone	Target
TD-1439 (NEP inhibitor)	Phase 1a SAD/MAD results in healthy volunteers	*Completed*
Revefenacin (TD-4208)	Phase 3 long-term safety results in COPD patients	*Completed*
Velusetrag (TD-5108)	Phase 2b results in Gastroparesis patients	*Completed*
TD-1473 (JAK inhibitor)	Phase 1b results in UC patients, Cohort 1	*Completed*
Revefenacin (TD-4208)	NDA submission in US*	2017
VIBATIV® (telavancin)	Patient registry study data (TOUR™)	2017
Closed Triple (FF/UMEC/VI)[1]	Phase 3 IMPACT study completion	2017
Closed Triple (FF/UMEC/VI)[1]	Potential regulatory approval in US and EU for COPD*	2017
TD-1473 (JAK inhibitor)	Phase 1b results in UC patients, Cohorts 2 and 3	2018
TD-9855 (NSRI)	Phase 2a results in nOH patients	2018
Revefenacin (TD-4208)	Phase 3b study results in COPD patients with low PIFR[2]	2018
Revefenacin (TD-4208)	Potential regulatory approval in US for COPD*	2018
VIBATIV® (telavancin)	Phase 3 study data in Bacteremia patients	2018 / 2019
Closed Triple (FF/UMEC/VI)[1]	Phase 3 study completion in Asthma patients	2018
Closed Triple (FF/UMEC/VI)[1]	Supplementary regulatory submissions for Asthma*	2018

[1] Economic interests. Regulatory and clinical milestones as reported by GlaxoSmithKline
[2] Peak inspiratory flow rate
* Submissions, filings, and approvals are subject to preclinical and clinical data and regulatory interactions

Theravance Biopharma

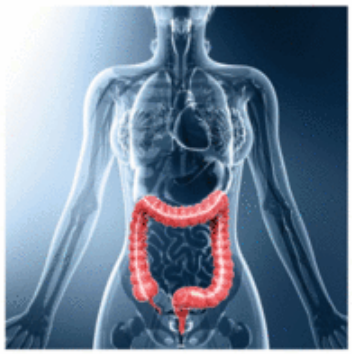
Medicines That Make a Difference®

JAK Inhibitor Program

Oral intestinally-restricted pan-Janus kinase (JAK) inhibitors for ulcerative colitis and other inflammatory intestinal diseases

Intestinally Restricted JAK Program Represents a Potential Breakthrough Approach to Treating IBD

TD-1473: An oral pan-JAK inhibitor designed to be **intestinally restricted**



- Proof of concept: MOA is validated in ulcerative colitis[1]
- SAD/MAD study complete, Phase 1b in patients underway
- Potential utility in other IBD indications: Crohn's disease, checkpoint inhibitor-induced colitis

Program objectives:

- Selective distribution to intestinal tract
- Reduction in UC disease activity score comparable to best in class therapy, but without corresponding systemic immunosuppression
- High affinity for JAK1/2/3 and TYK2

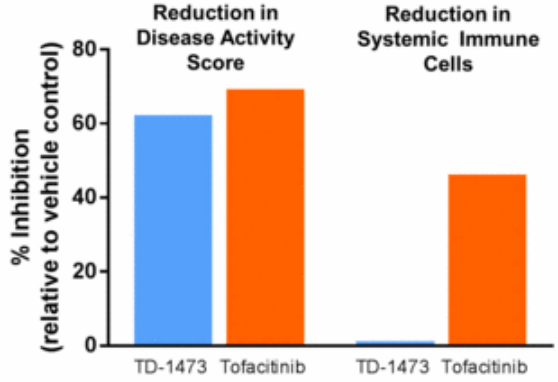
TD-3504: An innovative prodrug of tofacitinib which provides chemically distinct secondary strategy for intestinally-restricted JAK inhibition

Differentiated program designed for maximal local anti-inflammatory efficacy with minimal systemic exposure and immunosuppressive effects

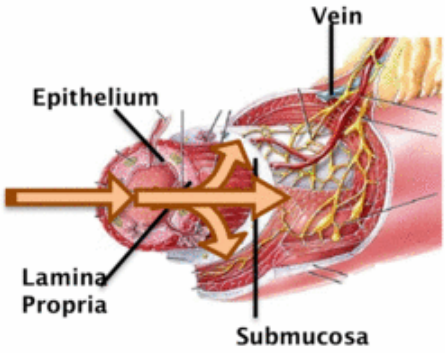
[1] Tofacitinib (Xeljanz®) - an oral, systemically available, JAK inhibitor, which has demonstrated efficacy in treating moderate to severe ulcerative colitis patients. Estimated to be 900K cases of ulcerative colitis in 2017 in the US. Source: Ulcerative Colitis Epidemiology, November 2016

TD-1473: Designed to Maximize Local Anti-Inflammatory Efficacy and Minimize Systemic Exposure

TD-1473 is Active in Rodent Colitis Model without Systemic Effects



TD-1473 Penetrates Intestinal Wall to Act Directly at the Site of Inflammation



- Preclinical findings indicate potential breakthrough approach in UC
  - ✓ Selective distribution of TD-1473 to tissues in the GI tract, with reduction in UC disease activity score comparable to systemically delivered JAK inhibitor therapy
  - ✓ No dose-related immunosuppression activity within the systemic circulation
  - ✓ Slow absorption throughout intestinal tract
  - ✓ Penetration of the GI tissue to act directly at the site of inflammation

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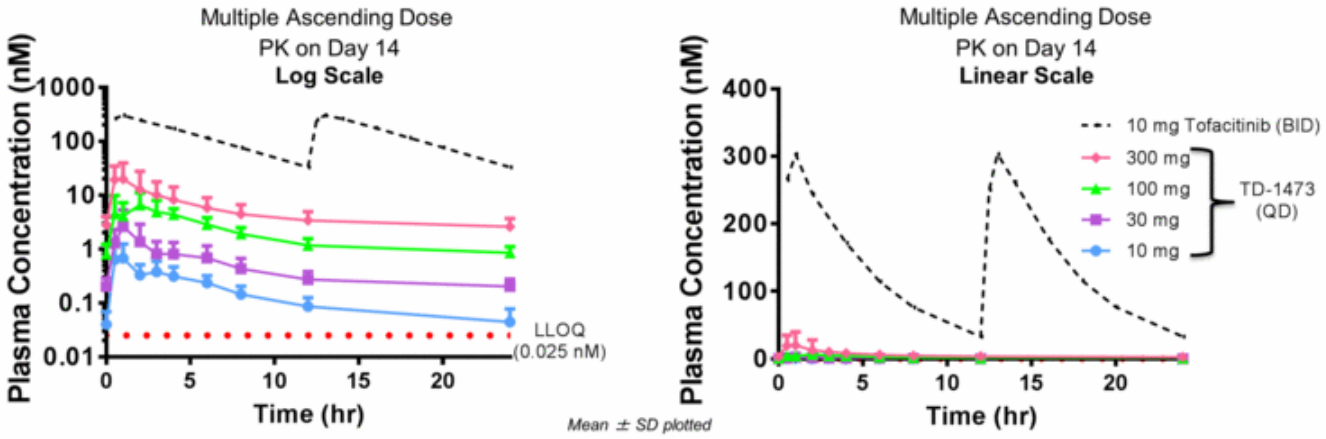
TD-1473: Phase 1 Clinical Data Support Progression into Phase 1b Trial in Ulcerative Colitis Patients

- Phase 1 study of TD-1473 in healthy subjects met target objectives:
  - ✓ Data suggest slow absorption of TD-1473 throughout intestinal tract
  - ✓ Minimal levels of TD-1473 in systemic circulation
  - ✓ High levels of TD-1473 in stool[1]
  - ✓ Well tolerated at all dose levels
- PK findings consistent with positive preclinical models



[1] Stool concentrations of TD-1473 were comparable to concentrations associated with efficacy in preclinical colitis models
Tofacitinib data: extracted from Dowty ME, et al. JPET 2014; TD-1473 data: as presented by Theravance Biopharma June 2016

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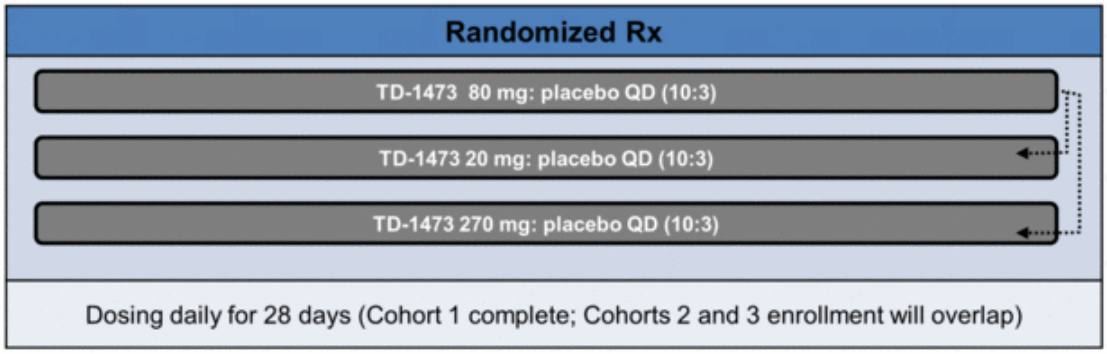
TD-1473: Phase 1b Study Progressing in Ulcerative Colitis Patients

- Phase 1b designed to evaluate safety, tolerability, PK and PD of TD-1473 in moderately-to-severely active ulcerative colitis patients over 28 days
  - Secondary/exploratory objectives to demonstrate biologic effect through biomarker analysis and clinical, endoscopic and histologic assessments



Encouraging data from first cohort support target product profile

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Evidence of Localized Target Engagement and Minimal Systemic Exposure from Cohort 1 of TD-1473 Phase 1b

Minimal Systemic Exposure; No Evidence of Systemic Immunosuppression

- Minimal levels of drug in plasma, consistent with SAD/MAD in healthy volunteers
- No evidence of infections, including no occurrences of zoster reactivation

Early Signs of Biological Target Engagement[1]

- 7 of 10 patients on TD-1473 experienced ≥ 1-point reduction in Mayo rectal bleeding subscore, compared to 1 of 3 patients on placebo
- 3 of 10 patients on TD-1473 experienced ≥ 1-point reduction in Mayo endoscopic subscore, compared to zero patients on placebo
- 2 of 10 patients on TD-1473 showed evidence of mucosal healing, compared to zero patients on placebo
- 2 of 10 patients on TD-1473 achieved clinical response by total Mayo Score[2], compared to zero patients on placebo
- 4 of 10 patients receiving TD-1473 achieved clinical response by partial Mayo score[2], compared to 1 of 3 patients on placebo
- Reductions in levels of CRP, FC and pSTAT1 in patients on TD-1473

Safety Data

- No moderate or serious adverse events (AEs) related to TD-1473
- AEs reported with TD-1473 were mild in severity; none led to discontinuation

TD-1473 to advance into induction and maintenance study in 2018

[1] Gastroenterology Vol. 148, No. 1, pages 37-51. "Converging Goals of Treatment of Inflammatory Bowel Disease From Clinical Trials and Practice." Levesque, et al. http://www.gastrojournal.org/article/S0016-5085(14)00999-8/pdf Published online August 12, 2014. Mayo Clinic Score (MCS) as referenced herein, with endoscopic subscore modified such that mild friability is scored as a 2 rather than a 1 (pages 39-40). Clinical response for partial MCS consistent with clinical response for MCS, except criteria for clinical response by partial MCS include a decrease in partial MCS of at least 2 points versus 3 points in the MCS criteria. Mucosal healing based on modified Mayo endoscopy score. CRP = C-Reactive Protein; FC = Fecal

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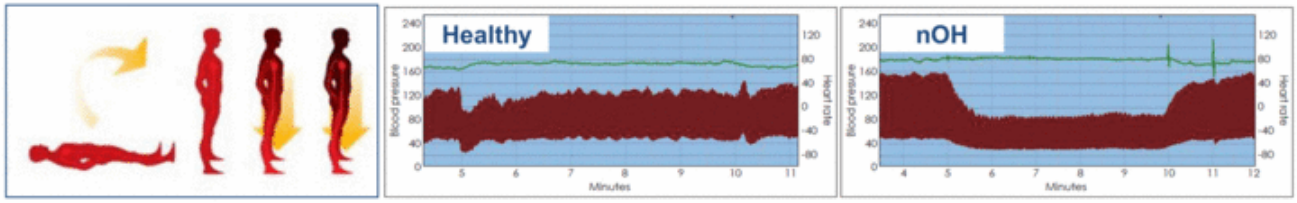
Medicines That Make a Difference®

TD-9855

Dual norepinephrine and serotonin reuptake inhibitor (NSRI) for neurogenic orthostatic hypotension (nOH)

Neurogenic Orthostatic Hypotension (nOH) Represents a Significant Unmet Need

nOH is characterized by a **sustained drop in blood pressure** that occurs **upon standing up** and is associated with the **nervous system**, specifically due to the body producing **insufficient levels of norepinephrine**



- Associated with several autonomic disorders, including Multiple System Atrophy (MSA), Parkinson's Disease (PD), and Pure Autonomic Failure (PAF)
- Orphan indication with <200k patients in US
- Symptoms include dizziness, fainting, blurred vision and weakness
- Significant impacts to QoL for both patients and family members
  - Patients limited in routine daily functions and prone to injury from falling
  - In severe cases, patients become bedridden and require caregiver support

Current Approved Therapies in Neurogenic Orthostatic Hypotension (nOH) Have Limitations

Current therapies limited in safety, efficacy, and/or dosing

- Only Northera (droxidopa) and midodrine (generic) are FDA approved for nOH
- Both impact disease by increasing vascular tone
- Significant unmet need remains due to limitations of current therapies
  - Supine hypertension (high blood pressure while lying down)
  - Require dosing three times a day
  - Patients[1] may become refractory over time or discontinue due to AEs

Opportunity exists for effective, well tolerated nOH therapies

- No evidence of other new therapeutic agents in development for nOH

Successful nOH therapy would target reduction in symptoms and offer meaningful improvements in quality of life for patients

[1] Associated with one or both therapies noted above

TD-9855: Potential Best in Class Therapy for nOH, Intention to Seek Expedited Development Path

Reasons to Pursue TD-9855 in nOH

- ✓ Designed to restore deficits in noradrenergic function
- ✓ Norepinephrine dominance confirmed in human PET study[1]
- ✓ QD dosing and long half-life may offer improved patient outcomes
- ✓ ADME studies suggest low probability of DDIs
- ✓ Favorable safety and tolerability profile established in > 500 subjects[2]

Phase 2a Study of TD-9855 in nOH
Encouraging responses in majority of patients enrolled to date in single ascending dose portion of study Phase 2a protocol amended, extending dosing for up to 20 weeks, to assess durability of response
Key endpoints include change from placebo in sitting and standing blood pressure, symptom reduction, and safety/tolerability in nOH

Phase 2a study results expected in 2018

[1] PET = Positron Emission Tomography
[2] Includes Phase 1 SAD/MAD, elderly, and PET studies in healthy subjects and Phase 2a studies in fibromyalgia and ADHD patients

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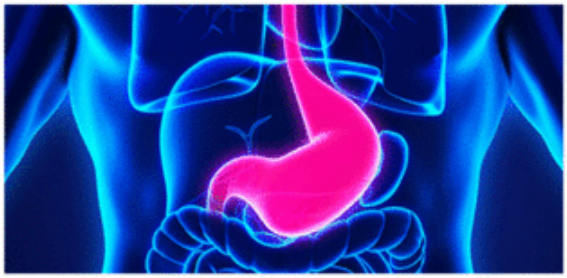
Medicines That Make a Difference®

Velusetrag (TD-5108)

Highly selective 5-HT4 agonist for gastroparesis

Velusetrag Well Positioned to Address the Unmet Patient Need in Gastroparesis



A Disease in Significant Need of Therapeutic Innovation

- Debilitating symptoms
- High prevalence[1]
  - Estimated 6M patients in US
  - Split between diabetic, idiopathic, other
- One approved therapy in 35 years
  - Safety risk limits use

Encouraging Development Progress for Velusetrag

- Highly selective 5-HT4 receptor agonist with high intrinsic activity
- Partnered ex-US with Alfasigma[2]
- FDA Fast Track designation in gastroparesis
- Long term tox and carc studies complete
- Two studies complete in gastroparesis
  - ✓ Symptom improvements at 5 mg dose
  - ✓ Reduced gastric emptying time
  - ✓ Well-tolerated in > 800 subjects exposed
  - ✓ Evaluated in idiopathic and diabetic patients

[1] Rey et al., Prevalence of Hidden Gastroparesis in the Community: The Gastroparesis "Iceberg." J. Neurogastroenterol. Motil., 2012; 18:34-42.

[2] Velusetrag is being developed by Theravance Biopharma in collaboration with Alfasigma (AS). AS holds an exclusive option to certain ex-U.S. markets. TBPH retains all U.S. rights.

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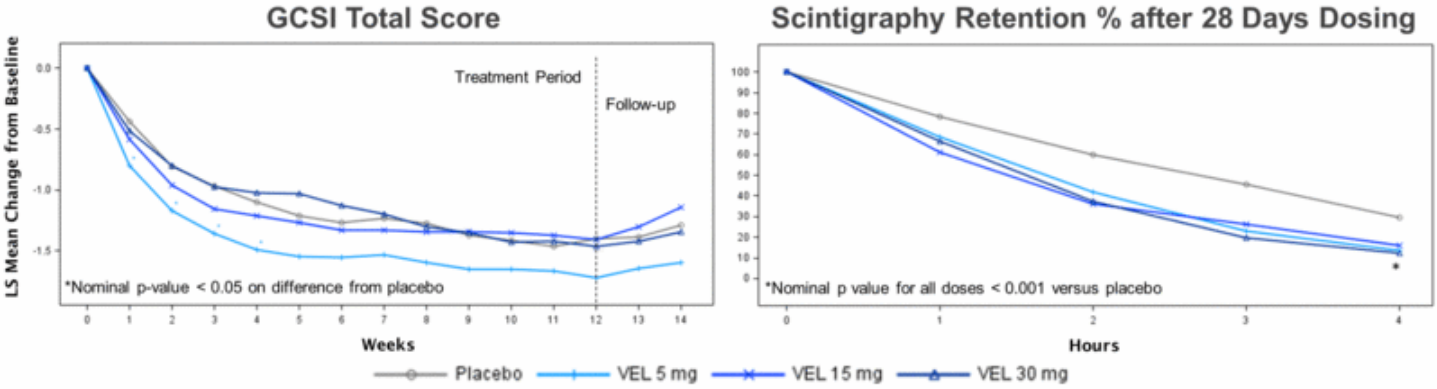
Phase 2b Results Provide POC in Symptom Effect

First Clinical Evaluation of Effect of Velusetrag on Symptoms of Gastroparesis



- 5 mg demonstrated statistically significant improvements in gastroparesis symptoms compared to placebo
  - Inverse dose response observed; 15 and 30 mg dose groups not statistically significant
- All doses significantly improve gastric emptying at 4 hours
- Generally well tolerated, AEs and SAEs comparable at 5 mg and placebo, SAEs low across all treatment groups

Statistical significance at 5 mg provides confidence in robust treatment effect

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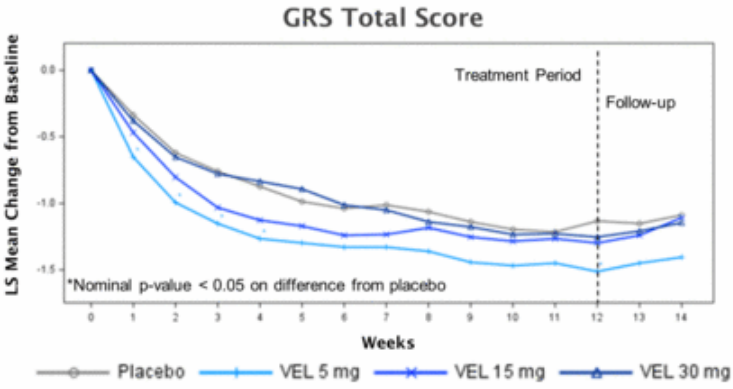
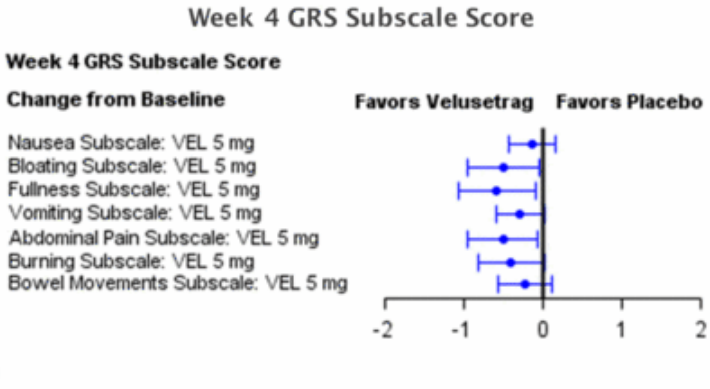
Developing Propriety PRO to Validate for Phase 3

Gastroparesis Rating Scale (GRS) Designed in Alignment with FDA Guidance





- GRS evaluates 7 symptom domains, including upper abdominal pain
- Enduring effect of 5 mg; symptom improvements at weeks 1 – 4 and week 12
- Consistent improvement across all individual GRS subscale scores

Preparing to meet with regulators to discuss validation of the GRS PRO and next phase of development for velusetrag

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Medicines That Make a Difference®

Neprilysin Inhibitor (NEPi) Program

Potential Best-in-Class Therapeutic for Cardiovascular and Renal Disease

NEPi Program: Differentiated & Versatile Platform with Multiple Development Candidates Advancing

Potential Applications for NEPi

- **IV NEPi** — AHF Monotherapy
- **ARB Combination (ARNI)** — Optimized for CHF and/or CKD
- **Non-ARB Combinations** — PDE5, PDE9, sGC, MRA…

Range of Cardiovascular and Renal Indications

Theravance NEP Inhibitor Target Product Profile

- ✓ Sustained 24-hour target engagement
- ✓ Non-renal clearance
- ✓ Favorable safety and tolerability
- ▪ Flexible administration (oral or IV)

✓ = *demonstrated in Phase 1 studies*

TD-0714 and TD-1439

- Phase 1 SAD / MAD studies complete
- Results for TD-0714 and TD-1439 met target profile and support further development

Currently evaluating next steps for compounds in NEPi clinical program, including compound and formulation selection, potential combinations, study population, and timing.

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Medicines That Make a Difference®

Late Stage & Commercial Assets, Acute Care

Revefenacin (TD-4208): *Nebulized Long-Acting Muscarinic Antagonist (LAMA)*

VIBATIV® (telavancin): *Commercial, Once-Daily, Dual Mechanism Antibiotic*

Acute Care Commercial Infrastructure Positioned to Support VIBATIV® and Revefenacin

Label Expansion Strategy for VIBATIV Growth

Potential for broadest set of indications of any branded anti-MRSA antibiotic

- ✓ Approval in cSSSI and HABP/VABP[1]
- ✓ Expanded label describes use in cSSSI and HABP/VABP with concurrent bacteremia

Phase 3 registrational study in bacteremia

- ~250 patients in ~70 sites in US & ROW
- Expected to complete in 2018/2019
- Potential sNDA submission

TOUR™ patient registry study fully enrolled

- Generating "real world" data in 1,000-patient study
- Largest enrollment seen in cSSSI, osteomyelitis, bacteremia, and pneumonia
- Results to inform additional potential indications

Complementary Products to Optimize the Acute Care Organization

Opportunity to target large, addressable patient populations

- Overlap in sales calls with pulmonologists and respiratory care physicians for VIBATIV and revefenacin
- Acute care setting provides an important inflection point in patient identification
- Revefenacin collaboration with Mylan includes co-promote and profit split in the US
  - Profit split: 65% Mylan, 35% Theravance
- Combined sales infrastructures to cover hospital, outpatient and home health treatment settings
- Phase 3b PIFR (peak inspiratory flow rate) study with revefenacin initiated, designed to support commercialization

[1] VIBATIV is approved in the US for treatment of the following infections in adult patients caused by designated susceptible bacteria: complicated skin and skin structure infections (cSSSI), hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable.

Compelling Need for Once-Daily Nebulized LAMA

Enduring Patient Niche and Significant Market Opportunity

Unmet Need for Nebulized LAMA Therapy

- Once-daily LAMAs are **first-line therapy** for moderate to severe COPD[1]
- **No nebulized LAMAs available today**; only available in handheld devices
- Nebulized therapy associated with reduced hospital readmissions in low PIFR patients[2]

Enduring Patient Niche

- **>100M patient treatment days** in nebulized COPD segment[3]
- **9%** of COPD patients currently use nebulizers for ongoing maintenance therapy[4]
- **41%** of COPD patients use nebulizers at least occasionally for bronchodilator therapy[4]
- Pricing in branded LA nebulized segment ~ 2x handheld Spiriva[3]

Significant Market Opportunity

- Revefenacin may be **complementary to existing nebulized LABA** treatments
- Mylan partnership brings commercial strength in nebulized segment

[1] Global Strategy for Diagnosis, Management, and Prevention of COPD. COPD = Chronic Obstructive Pulmonary Disease. [2] Suboptimal Inspiratory Flow Rates Are Associated with COPD and All Cause Readmissions. Loh et al., Annals of ATS 2017. [3] IMS Health information service: NSP for period MAT May, 2015. Excludes nebulized SABAs. IMS expressly reserves all rights, including rights of copying, distribution and republication. [4] TBPH market research (N = 160 physicians); Refers to US COPD patients.

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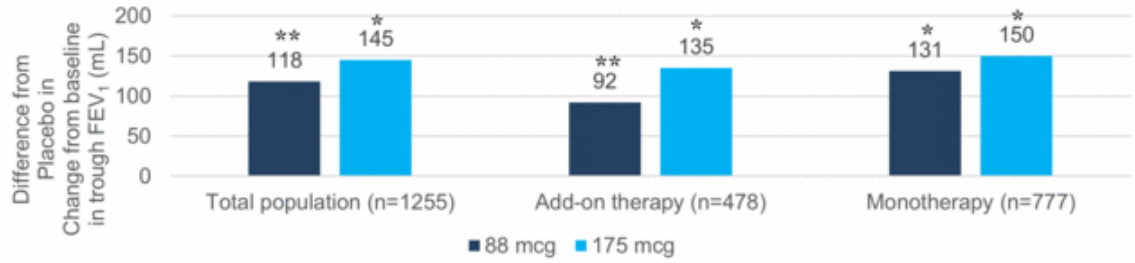
Revefenacin: Phase 3 Registrational Program Complete, with NDA Filing Planned in Late 2017

- Primary endpoint achieved for both doses in both replicate efficacy studies
  - ✓ Robust and sustained improvements in FEV_1
  - ✓ Effective as monotherapy and as add-on to LABA or LABA/ICS
  - ✓ Generally well tolerated



* P < 0.0001 versus placebo
** P <0.001 versus placebo

- Generally well tolerated in 12-month safety study
  - ✓ No new safety issues identified
  - ✓ Rates of adverse events low and comparable to standard of treatment

FEV_1 = forced expiratory volume in one second

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Medicines That Make a Difference®

Opportunities for Value Creation

Economic Interests and Upcoming Milestones

Economic Interest in GSK Respiratory Programs

Royalties from Closed Triple Expected as Early as 2018

- TBPH holds an 85% economic interest in future payments made by GSK related to the Closed Triple, MABA and MABA/ICS[1]
- Total GSK royalty rates and potential milestone obligations noted below
- Programs jointly managed by GSK and Innoviva[2]; fully funded by GSK

"Closed Triple" (FF/UMEC/VI)

- Active components of BREO® and ANORO®
- Positive top-line results reported from Phase 3 FULFIL study (~1,800 COPD patients)
- Potential for regulatory approvals of COPD in both US and EU in 2017
- Upward-tiering royalty 6.5% - 10% of annual global net sales
- Phase 3 IMPACT study ongoing in ~10,000 COPD patients; data expected 2017
- Phase 3 study in asthma initiated in 2016, with US NDA filing planned 2018

MABA, MABA/ICS (batefenterol, batefenterol/FF)

- Single molecule bifunctional bronchodilator
- Phase 2 studies of single- and combo-agent in COPD patients completed
- Upward-tiering royalty of 10% to 20% of annual global net sales up to $3.5 billion, and 7.5% above $3.5 billion for single agent and 70% of those amounts for combo
- Development and commercialization milestones up to $125 million for single agent and $250 million for both single- and combo-agent[3]

[1] TBPH holds economic interest in future payments that may be made by GSK relating to certain programs, including "Closed Triple" (FF/UMEC/VI), MABA/FF, MABA monotherapy and other future products that may be combined with VI or MABA. All statements based on publically available information. FF/UMEC/VI= Fluticasone Furoate/Umeclidinium/Vilanterol. MABA= Inhaled Bifunctional Muscarinic Antagonist -Beta2 Agonist. [2] Formerly Theravance, Inc. [3] Certain payments related to MABA program already received by Theravance, Inc.

Theravance Biopharma

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Revefenacin (TD-4208)	Potential regulatory approval in US for COPD*	2018
VIBATIV® (telavancin)	Phase 3 study data in Bacteremia patients	2018 / 2019
Closed Triple (FF/UMEC/VI)[1]	Phase 3 study completion in Asthma patients	2018
Closed Triple (FF/UMEC/VI)[1]	Supplementary regulatory submissions for Asthma*	2018

[1] Economic interests. Regulatory and clinical milestones as reported by GlaxoSmithKline
[2] Peak inspiratory flow rate
* Submissions, filings, and approvals are subject to preclinical and clinical data and regulatory interactions

About VIBATIV® (telavancin)

VIBATIV was discovered internally in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including MRSA. VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with in vitro potency and a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function.

VIBATIV for injection is approved in the U.S. for the treatment of adult patients for complicated skin & skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. In addition, VIBATIV telavancin is approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable. In addition, VIBATIV is approved in the U.S. for the treatment of adult patients with complicated skin & skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including S. aureus, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. The product labeling also describes the use of VIBATIV in treating patients with concurrent bacteremia (in addition to either skin infection or pneumonia).

VIBATIV is indicated in Canada and Russia for complicated skin & skin structure infections and HAP/VAP caused by Gram-positive bacteria, including MRSA.

VIBATIV is indicated in the European Union for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia (VAP), known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) and should be used only in situations where it is known or suspected that other alternatives are not suitable.

VIBATIV® (telavancin)

Important Safety Information (US)

Mortality
Patients with pre-existing moderate/severe renal impairment (CrCl ≤50 mL/min) who were treated with VIBATIV® for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CrCl ≤50 mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

Nephrotoxicity
New onset or worsening renal impairment occurred in patients who received VIBATIV. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV versus discontinuing and initiating therapy with an alternative agent should be assessed.

Fetal Risk
Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment.

Contraindication
Intravenous unfractionated heparin sodium is contraindicated with VIBATIV administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after VIBATIV administration.
VIBATIV is contraindicated in patients with a known hypersensitivity to the drug.

Hypersensitivity Reactions
Serious and potentially fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. VIBATIV should be used with caution in patients with known hypersensitivity to vancomycin.

Geriatric Use
Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Infusion Related Reactions
VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome" like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

QTc Prolongation
Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV prolonged the QTc interval. Use of VIBATIV should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

Most Common Adverse Reactions
The most common adverse reactions (greater than or equal to 10% of patients treated with VIBATIV) were diarrhea, taste disturbance, nausea, vomiting, and foamy urine.
Full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., is available at www.VIBATIV.com.