Theravance® Biopharma®

Medicines That Make a Difference®

# Theravance Biopharma, Inc. (NASDAQ: TBPH)

## 2Q 2018 Financial Results and Business Update

## August 1, 2018

# 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 May 9, 2018, and other periodic reports filed with the SEC.

# Portfolio Advancements in 2018

## TD-1473 (JAKi)

### Partnership with global leader in Immunology

Global collaboration with Janssen Biotech in inflammatory intestinal disease

## TD-9855 (NSRI)

### Positive top-line four-week results in nOH

Durable symptom improvements; clinically meaningful benefit in standing SBP

## YUPELRI™ (LAMA)

### NDA accepted by FDA and under review

Assigned PDUFA date of November 13, 2018

## Economic interest in Trelegy serves as an important strategic asset[1]

- Promising initial launch by GSK following approvals in US and EU in late 2017
- Expanded COPD indication approved by FDA, supported by data from IMPACT study
- Entitled to upward-tiering royalty of 5.5% - 8.5% of worldwide net sales



JAK = Janus kinase. NSRI = norepinephrine serotonin reuptake inhibitor. nOH = neurogenic orthostatic hypotension. SBP = systolic blood pressure. LAMA = long-acting muscarinic antagonist. PDUFA = Prescription Drug User Fee Act. [1] All statements based on publically available information. Approved in US for the treatment of COPD and for the treatment of appropriate patients with COPD in EU. TBPH holds 85% economic interest in upward tiering royalty stream of 6.5% – 10% payable by GSK

# TD-9855: Overview of Phase 2 Study in nOH

*Study in patients with neurogenic orthostatic hypotension*

Three-part design in patients with nOH:

**A**
- Single ascending dose portion of TD-9855 (up to 20 mg)
- Testing blood pressure response to TD-9855

**B**
- Double-blind
- Placebo-controlled
- Single dose (Part A response dose) or placebo

**C**
- Extension phase
- Open label design
- Up to 24 weeks (20 weeks dosing, 4 week wash out)
- Primary endpoint at 4 weeks

*Patients started on Part A, and responders moved to Part B and/or Part C (extension phase)*

**Purpose:** To evaluate the effect of TD-9855 in improving blood pressure and key nOH symptoms

**Part C:** Responders in Part A eligible for open-label TD-9855 for up to 5 months

- Designed to assess durability of effect
- Primary assessment at four weeks (Day 29)
- Efficacy evaluations: OHSA[1] #1; standing time duration; standing Systolic Blood Pressure (SBP)
- Also assessed safety and PK of TD-9855



[1] OHSA = Orthostatic Hypotension Symptom Assessment. OHSA #1 measures dizziness (cardinal symptom of nOH), lightheadedness, feeling faint, or feeling of impending black out

# TD-9855: Top-line Phase 2 Results in nOH

*Parts A and B*

## A Initial responses observed

### Responses reported in majority of patients treated

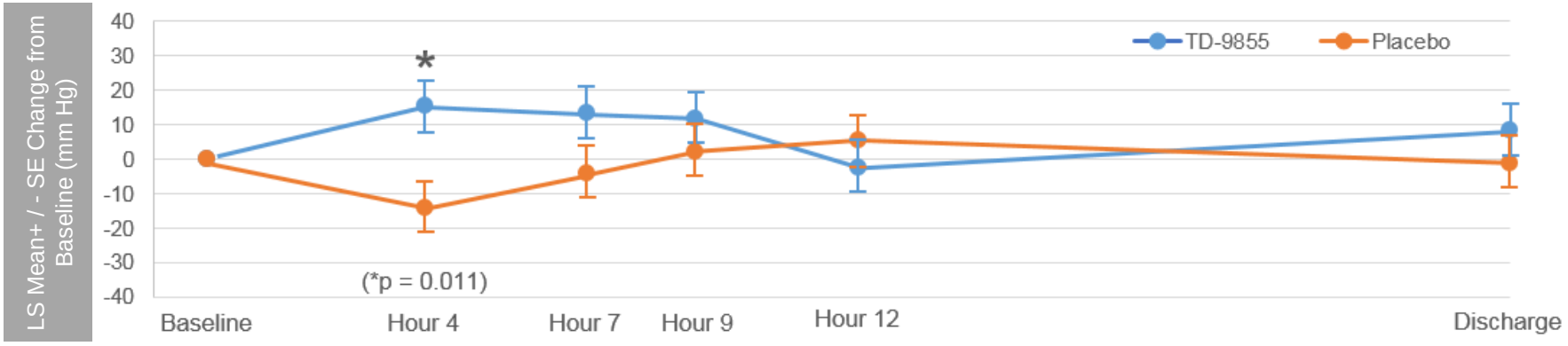
- 27 of 34 patients enrolled in Part A showed improvements in SBP and/or standing time
- Responses observed above 5 mg

## B Confirmation vs. placebo

### Statistically significant difference of 30 mm Hg at 4 hours post-dose (p = 0.011)

- TD-9855 increased SBP from a low baseline
- SBP dropped on placebo during the day as expected, in response to postural changes and eating
- No evidence of supine hypertension with TD-9855 overnight

**Part B Change from Baseline SBP**



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# TD-9855: Top-line Phase 2 Results in nOH

*Part C (extension phase)*

## C Durability of effect observed in repeat dose extension phase

16 of 21 patients (76%) completed four weeks of treatment

Reductions in symptom severity, with most pronounced benefit in patients with symptomatic nOH[1]

- Mean reduction in OHSA #1 = 2.4 at four weeks (n=16)
- 13 completers had OHSA #1 $\geq$ 4 at baseline; **mean reduction in group = 3.8 at four weeks**

Consistent increases in SBP through four weeks

- Clinically meaningful increases in standing SBP (7 mm Hg or greater) after standing for three minutes at all time points on all weekly clinic visits

Generally well tolerated; no serious adverse events assessed as drug-related

**Positive results across the three-part study, including durability of effect, provide basis to begin registrational Phase 3 program in nOH in late 2018 or early 2019**



[1] Symptomatic defined as OSHA #1 $\geq$ 4.

# TD-1473: Encouraging Findings in Phase 1b Study

*4-week treatment in 40 patients with ulcerative colitis*

## Key Findings

| | |
|---|---|
| **Favorable overall safety and tolerability** | No systemic or opportunistic infections (including herpes zoster) |
| | No evidence of reduce white cell counts |
| **Minimal systemic exposure** | Plasma levels of TD-1473 very low |
| | Consistent in all cohorts to levels observed in healthy volunteers |
| **Biologic activity in GI tract** | Rates of **clinical response** higher for all active doses compared to placebo[1] |
| | Clinical responses matched by **dose-dependent reductions in surrogate biomarkers**[2] |
| | **Endoscopic improvements and mucosal healing** reported in all active arms; none reported in placebo arm |
| | **Rectal bleeding** scores improved above placebo at highest two doses |
| | Dose-related increases in local GI tissue drug concentrations; higher two doses produced mean concentrations above the JAK IC50 |

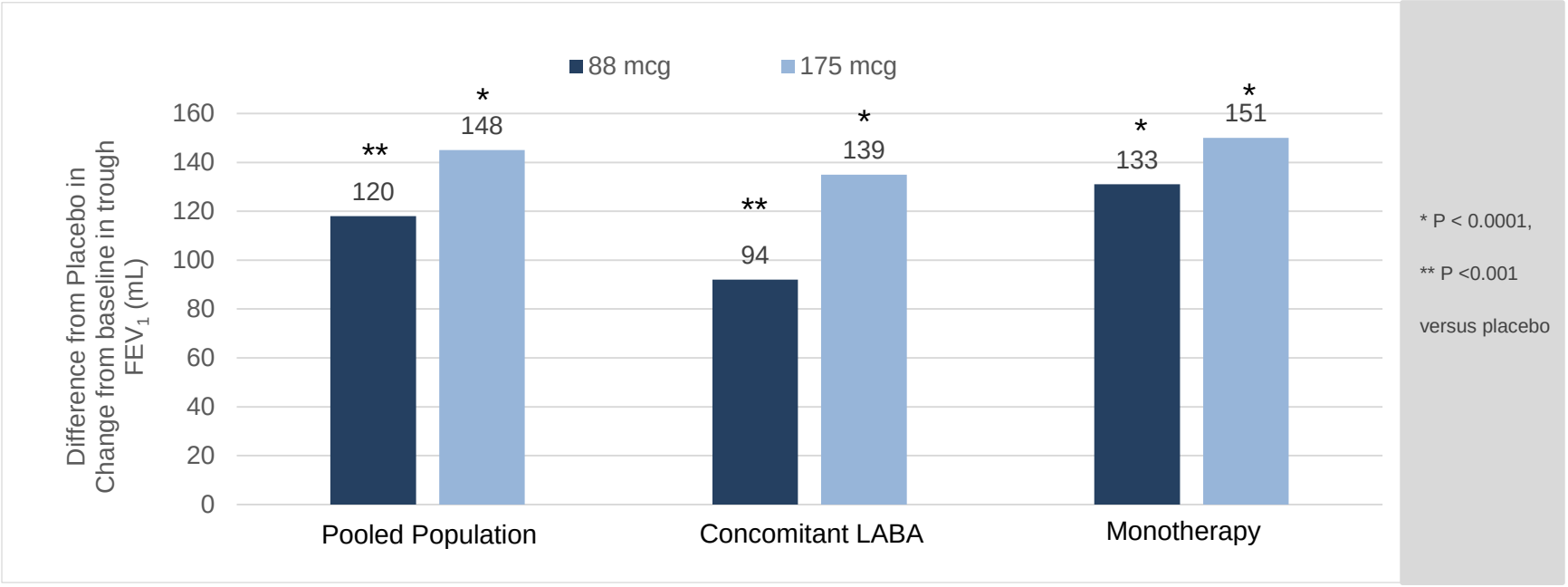
**Presentation of full results at future medical meeting;**
**progressing into Phase 2b/3 in UC and Phase 2 in Crohn's disease in 2H 2018**



[1] Clinical response as measured by both partial and full Mayo
[2] Surrogate biomarkers include C-reactive protein (CRP) and fecal calprotectin

# YUPELRI™: PDUFA Date November 13, 2018

*Potential as first once-daily nebulized LAMA for COPD*




- NDA supported by Phase 3 efficacy and safety studies
- Primary endpoint achieved for both doses in 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 in 12-month safety study



$FEV_1$ = forced expiratory volume in one second; pooled analysis

# 2Q 2018 Financial Highlights

| | Three Months Ended, June 30, | |
|---|---|---|
| | **2018** | **2017** |
| | ($, in thousands) Unaudited | |
| **Total Revenue** | **23,476** | **3,509** |
| Cost of Goods Sold | (1,448) | 1,364 |
| Research and Development[1] | 48,621 | 42,927 |
| Selling, General and Administrative[1] | 25,007 | 24,339 |
| **Total Costs and Expenses** | **72,180** | **68,630** |
| **Operating Loss** | **(48,704)** | **(65,121)** |
| *[1]Amounts include share-based compensation expense below* | | |
| Research and Development | 6,904 | 4,917 |
| Selling, General and Administrative | 6,951 | 5,481 |
| **Total Share-based Compensation Expense** | **13,855** | **10,398** |
| **Operating Loss excluding Share-based Compensation** | **(34,849)** | **(54,723)** |
| **Cash, Cash Equivalents and Marketable Securities as of June 30, 2018** | **371,155** | |

# GSK's Trelegy Ellipta Offers Significant Potential

*First and only once-daily single inhaler triple therapy*

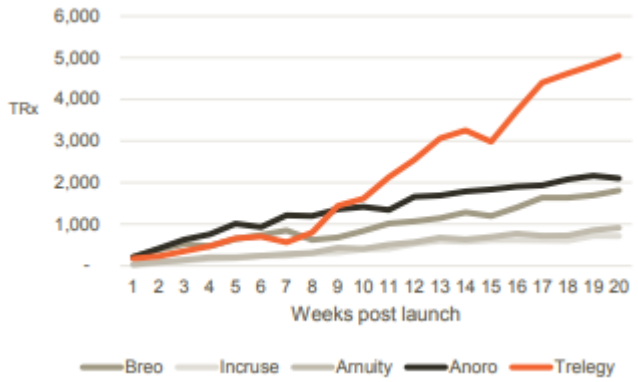
## Economic interest in Trelegy Ellipta serves as an important strategic asset

- Upward-tiering royalty 5.5% - 8.5% of worldwide net sales[1]
- Passive economic interest; no product cost obligations

## Program Summary

- Approved for COPD in US and EU[2]
- FF/UMEC/VI: Comprise of ICS, LAMA, and LABA, active components of Breo® (FF/VI) and Anoro® (UMEC/VI)
- Phase 3 CAPTAIN asthma study in progress

## Strongest US Ellipta launch to date




Launched in US in November 2017

**Source: GSK; IQVIA NPA weekly TRx data**

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All statements based on publically available information. Trelegy Ellipta jointly managed by GSK and Innoviva (formerly Theravance, Inc.) [1] TBPH holds 85% economic interest in upward tiering royalty stream of 6.5% – 10% payable by GSK. [2] Approved in EU for treatment of appropriate patients with COPD.
ICS = Inhaled corticosteroids. LABA = long-acting beta2-adrenergic agonist

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# Focus on Strategic Priorities

*Commitment to developing transformational medicines*

| | | |
|---|---|---|
| Opportunities to Create Transformational Medicines | YUPELRI™ (revefenacin) | Nebulized LAMA in COPD (PDUFA date November 13, 2018) |
| | TD-1473 | Intestinally-restricted JAK inhibitor for inflammatory intestinal diseases |
| | TD-9855 | NSRI in symptomatic neurogenic orthostatic hypotension |
| | TD-8236 | Inhaled JAK inhibitor for serious respiratory diseases |
| | Research | R&D Day to highlight new programs advancing towards clinic |
| Strategic Asset | Trelegy Ellipta | (FF/UMEC/VI) Single inhaler triple therapy in COPD |

*Managed by GSK and Innoviva[1]*



[1] Economic interest. FF/UMEC/VI= Fluticasone Furoate/Umeclidinium/Vilanterol. Innoviva formerly Theravance, Inc.

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Q&A

*Thank you*