

**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): **November 7, 2017**

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands

(State or Other Jurisdiction of
Incorporation)

001-36033

(Commission File Number)

98-1226628

(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 number, 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))

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

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.

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2017, Theravance Biopharma, Inc. issued a press release and is holding a conference call regarding its financial results for the quarter ended September 30, 2017 and a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report and a copy of materials that will accompany the call is furnished as Exhibit 99.2 to this Current Report.

The information in Item 2.02 and in Item 9.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, 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, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

- 99.1 Press Release dated November 7, 2017
- 99.2 Materials Accompanying the Call

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 7, 2017
99.2	Materials Accompanying the Call

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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 BIOPHARMA, INC.

Date: November 7, 2017

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

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Theravance Biopharma, Inc. Reports Third Quarter 2017 Financial Results and Provides Business Update

Inflection Points for Key Development Programs Anticipated Throughout 2018

Trelegy Ellipta Launch Expected by Year-End 2017

DUBLIN, IRELAND — NOVEMBER 7, 2017 — Theravance Biopharma, Inc. (NASDAQ: TBPH) (“Theravance Biopharma” or the “Company”) today reported financial results for the third quarter ended September 30, 2017. Revenue for the third quarter of 2017 was \$4.3 million. The third quarter operating loss was \$57.0 million, or \$46.3 million excluding non-cash share-based compensation expense of \$10.7 million. Cash, cash equivalents, and marketable securities totaled \$434.4 million as of September 30, 2017.

Rick E Winningham, Chairman and Chief Executive Officer, commented: “In 2017, we continue to demonstrate the potential of our portfolio with encouraging clinical data across multiple key programs. Looking forward, we are positioned to achieve numerous clinical and regulatory milestones, with a plan to deliver on the promise of developing differentiated medicines for patients in need.”

Recent Updates¹

- Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol, previously referred to as the Closed Triple) approved in the US for the treatment of chronic obstructive pulmonary disease (COPD) in appropriate patients
- European Medicines Agency’s Committee for Medicinal Products for Human Use issued a positive opinion of Trelegy Ellipta, recommending marketing authorization for the product
- Landmark IMPACT study met primary endpoint showing reduction in exacerbations with Trelegy Ellipta compared to dual therapies in patients with COPD; safety findings were consistent with the known profile of individual medicines and their dual combinations; regulatory filings for IMPACT data expected in 2018

Expected Upcoming Milestones and Events

- Revefenacin (TD-4208, a once-daily nebulized long-acting muscarinic antagonist (LAMA) for COPD): NDA filing anticipated in 4Q 2017; potential regulatory approval in the US for COPD in 2018; Phase 3b PIFR study, designed to support commercialization, expected to complete in 1Q 2018
- Trelegy Ellipta¹: Commercial launch expected mid-November 2017; economic interest related to Trelegy Ellipta entitles Theravance Biopharma to upward tiering royalty of 5.5% to 8.5% on worldwide net sales; potential regulatory approval in the EU for COPD in late 2017; Phase 3 CAPTAIN study in asthma patients expected to complete in 2018
- TD-1473 (intestinally restricted pan-Janus kinase (JAK) inhibitor): Data from the remaining cohorts of the Phase 1b study in patients with ulcerative colitis in 2018; targeting initiation of large, multi-dose induction and maintenance study in 2018
- TD-9855 (norepinephrine serotonin reuptake inhibitor (NSRI)): Data from the Phase 2a study in patients with nOH in first half of 2018
- VIBATIV: Televancin Observational Use Registry (TOURTM) data to be published in 2018; data from the Phase 3 registrational bacteremia study in 2018 or 2019

Notes:

¹ As reported by Glaxo Group Limited or one of its affiliates (GSK)



Third Quarter Financial Results

Revenue

Revenue for the third quarter of 2017 was \$4.3 million, primarily related to US net product sales of VIBATIV[®] of \$4.1 million. In the same period in 2016, net product sales of VIBATIV[®] were \$3.9 million and revenue from collaborative arrangements was \$15.2 million, primarily driven by non-recurring revenue of \$15.1 million associated with the Takeda collaboration.

Research and Development (R&D) Expenses

R&D expenses for the third quarter of 2017 were \$39.3 million representing an increase of \$7.4 million compared to the same period in 2016. The increase is driven by costs associated with the progression of our key programs as well as employee-related costs. Third quarter R&D expenses include non-cash share-based compensation expense of \$5.0 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the third quarter of 2017 were \$20.9 million, representing an increase of \$0.7 million compared to the same period in 2016. The increase is primarily due to employee-related costs and share-based compensation, partially offset by a reduction in external expenses related to commercialization activities. Third quarter SG&A expenses include non-cash share-based compensation expense of \$5.7 million.

Other-than-Temporary Impairment Loss

In the third quarter, a non-cash impairment charge of \$8.0 million was recorded to write off the full carrying value of the non-marketable equity securities of Trek Therapeutics, PBC (TREKtx). These securities were received in 2015, pursuant to a license agreement granting TREKtx rights to TD-6450, an internally discovered NS5A inhibitor.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$434.4 million as of September 30, 2017.

2017 Financial Guidance

The Company's guidance on operating loss excluding non-cash share-based compensation for the full-year of 2017 remains unchanged at \$205.0 million to \$215.0 million. The actual amount could be above or below this forecast as a result of a variety of factors impacting our business, including the timing and cost of clinical and non-clinical studies associated with our key programs and net product sales of VIBATIV®.

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Conference Call Today at 5:00 pm ET

Theravance Biopharma will hold a conference call today at 5:00 pm ET. To participate in the live call by telephone, please dial (855) 296-9648 from the US, or (920) 663-6266 for international callers, using the confirmation code 96855845. Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at www.theravance.com, under the Investor Relations section, Presentations and Events. Please go to the website 15 minutes prior to the start of the call to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through December 7, 2017. An audio replay will also be available through 8:00 pm ET on November 14, 2017 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 96855845.

About Theravance Biopharma

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that help improve the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Our neprilysin (NEP) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases, such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop intestinally restricted pan-Janus kinase (JAK) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain drug development programs, including Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA® inhaler, previously referred to as the Closed Triple), currently approved in the US for the treatment of appropriate COPD patients and in development for the treatment of COPD in several other countries. The product is also currently in development for the treatment of asthma.

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For more information, please visit 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, expectations and future events. Theravance Biopharma 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: the Company’s strategies, plans and objectives, the Company’s regulatory strategies and timing of clinical studies (including the data therefrom), the potential benefits and mechanisms of action of the Company’s product and product candidates, the Company’s expectations for product candidates through development, potential regulatory approval and commercialization (including their potential as components of combination therapies), product sales and the Company’s expectations for its 2017 operating loss, excluding share-based compensation. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and the conference call and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma 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: delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company’s product candidates are unsafe or ineffective (including when our product candidates are studied in combination with other compounds), the feasibility of undertaking future clinical trials for our product candidates based on FDA policies and feedback, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, and risks of developing an institutional customer mix for VIBATIV® (telavancin) that meet the Company’s plan for the product. Other risks affecting Theravance Biopharma are described under the heading “Risk Factors” contained in Theravance Biopharma’s Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 9, 2017 and Theravance Biopharma’s other filings with the SEC. In addition to the risks described above and in Theravance Biopharma’s filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma’s results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

Contact Information:

Alexander Dobbin
Head of Investor Relations
650-808-4045
investor.relations@theravance.com



THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 4,140	\$ 3,901	\$ 10,664	\$ 12,571
Revenue from collaborative arrangements	135	15,174	207	30,385
Total revenue	4,275	19,075	10,871	42,956
Costs and expenses:				
Cost of goods sold	985	332	2,914	1,748
Research and development ⁽¹⁾	39,343	31,951	122,835	99,698
Selling, general and administrative ⁽¹⁾	20,944	20,286	66,069	64,143
Total costs and expenses	61,272	52,569	191,818	165,589
Loss from operations	(56,997)	(33,494)	(180,947)	(122,633)
Interest expense	(2,136)	—	(6,410)	—
Other-than-temporary impairment loss	(8,000)	—	(8,000)	—
Interest and other income (expense), net	1,124	344	3,579	839
Loss before income taxes	(66,009)	(33,150)	(191,778)	(121,794)
Provision for income taxes	868	812	6,705	1,542
Net loss	\$ (66,877)	\$ (33,962)	\$ (198,483)	\$ (123,336)
Net loss per share:				
Basic and diluted net loss per share	\$ (1.27)	\$ (0.73)	\$ (3.80)	\$ (2.86)
Shares used to compute basic and diluted net loss per share	52,611	46,470	52,165	43,080

⁽¹⁾ Amounts include share-based compensation expense as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 5,005	\$ 4,933	\$ 15,023	\$ 15,052

Selling, general and administrative	5,680	4,962	16,329	16,077
Total share-based compensation expense	<u>\$ 10,685</u>	<u>\$ 9,895</u>	<u>\$ 31,352</u>	<u>\$ 31,129</u>



THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2017 (Unaudited)	December 31, 2016 (1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 335,001	\$ 501,096
Receivables from collaborative arrangements	11,547	9,076
Prepaid taxes	289	3,060
Inventories	15,258	12,220
Other prepaid and current assets	5,038	3,051
Property and equipment, net	8,618	8,460
Long-term marketable securities	99,399	91,565
Tax receivable	8,070	—
Restricted cash	833	833
Other assets	2,106	9,893
Total assets	<u>\$ 486,159</u>	<u>\$ 639,254</u>
Liabilities and Shareholders' Equity		
Current liabilities	48,786	49,268
Long-term liabilities	253,256	239,755
Shareholders' equity	184,117	350,231
Total liabilities and shareholders' equity	<u>\$ 486,159</u>	<u>\$ 639,254</u>

(1) The condensed consolidated balance sheet at December 31, 2016 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.



Theravance Biopharma, Inc. (NASDAQ: TBPH)

3Q 2017 Financial Results and Business Update
November 7, 2017

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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.

Upcoming Milestones

Multiple Opportunities for Value Creation

Program	Milestone	Target
TD-1439 (NEP inhibitor)	Phase 1a SAD/MAD results in healthy volunteers	✓
Revefenacin (TD-4208)	Phase 3 long-term safety results in COPD patients	✓
Velusetrag (TD-5108)	Phase 2b results in Gastroparesis patients	✓
TD-1473 (JAK inhibitor)	Phase 1b results in UC patients, Cohort 1	✓
Trelegy Ellipta (FF/UMEC/VI) ¹	Phase 3 IMPACT study completion	✓
Trelegy Ellipta (FF/UMEC/VI) ¹	Regulatory approval in US for COPD ²	✓
Revefenacin (TD-4208)	NDA submission in US ³	2017
Trelegy Ellipta (FF/UMEC/VI) ¹	Potential regulatory approval in EU for COPD ³	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 ⁴	2018
Revefenacin (TD-4208)	Potential regulatory approval in US for COPD ³	2018
VIBATIV® (telavancin)	Patient registry study data (TOUR™)	2018
VIBATIV® (telavancin)	Phase 3 study data in Bacteremia patients	2018 / 2019
Trelegy Ellipta (FF/UMEC/VI) ¹	Phase 3 study completion in Asthma patients	2018

¹ Economic interests. Regulatory and clinical milestones as reported by GlaxoSmithKline. Trelegy Ellipta previously referred to as the Closed Triple. FF/UMEC/VI= Fluticasone Furoate/Umecclidinium/Vilanterol. ² For the treatment of appropriate patients with COPD. ³ Submissions, filings, and approvals are subject to preclinical and clinical data and regulatory interactions. ⁴ Peak inspiratory flow rate.

TD-1473: Phase 1b First Cohort Demonstrated Localized Target Engagement and Minimal Systemic Exposure

Objectives	Results from First Cohort of Patients at 80 mg	
Evaluate safety	✓	<ul style="list-style-type: none"> No moderate or severe AEs deemed possibly related to study drug No signal of systemic immunosuppression or changes in lipids
Confirm PK in UC patients	✓	<ul style="list-style-type: none"> Plasma levels consistent with healthy volunteer SAD/MAD data, minimal systemic exposure in patients
Confirm drug at site of action	✓	<ul style="list-style-type: none"> Relevant drug concentrations in distal colonic tissue
Evidence of target engagement by biomarkers	✓	<ul style="list-style-type: none"> Reduction on pSTAT1 in colonic tissue Reductions in serum CRP and fecal calprotectin
Signals of biologic activity at 4 weeks ¹	✓	<ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Mucosal healing achieved in two patients 2 of 10 patients on TD-1473 achieved clinical response by total Mayo Score, compared to zero patients on placebo 4 of 10 patients receiving TD-1473 achieved clinical response by partial Mayo score, compared to 1 of 3 patients on placebo

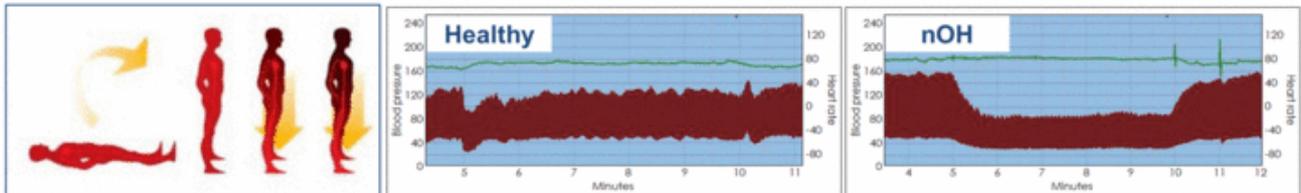
TD-1473 to advance into multi-dose induction and maintenance study in 2018

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](http://www.gastrojournal.org/article/S0016-5085(14)00999-8/pdf)
 Published online August 12, 2014. Total 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 39-42). 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. PROC2-e = rectal bleeding, stool frequency and endoscopy components of total MCB (excludes PGA). CRP = C-Reactive Protein; pSTAT1 = phosphorylated signal transducer and activator of transcription1



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 dosing

- Only droxidopa (Northera) and midodrine are FDA-approved for nOH
- Both are synthetic exogenous NE analogues that 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 may become refractory over time or discontinue due to AEs¹
 - Effectiveness of droxidopa beyond two weeks has not been established²

Opportunity exists for effective, well tolerated nOH therapies

- TD-9855, a dual norepinephrine and serotonin reuptake inhibitor (NSRI), may lead to significant benefits for patients over existing therapy

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

6 ¹ Associated with one or both therapies noted above
² Northera prescribing information

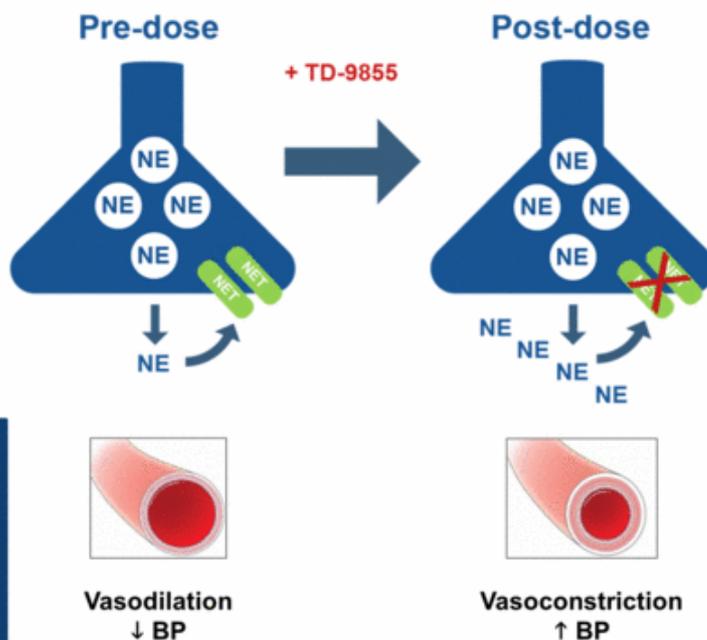
NET Inhibition with TD-9855 Has Potential to Normalize Vascular Sympathetic Tone in nOH

A path to treating nOH without introducing exogenous NE

- Blockade of NET in nOH patients inhibits endogenous neuronal NE uptake
- Increased levels of NE in the synapse cause vasoconstriction and a corresponding increase in blood pressure
- Increase in blood pressure improves nOH symptoms

Rationale for 9855 in nOH

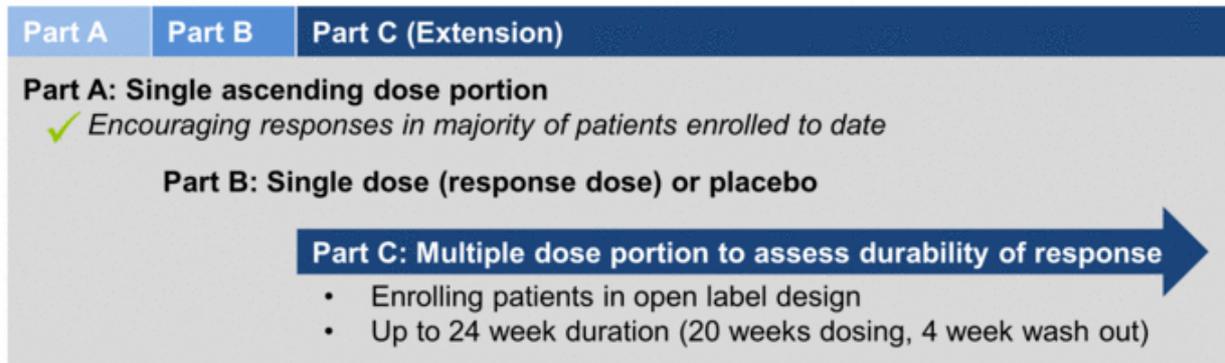
- NE dominance confirmed in humans
- QD dosing, long half-life, and metabolic profile may offer improved patient outcomes
- Favorable safety and tolerability profile established in > 500 subjects¹



7 NE = Norepinephrine; NET = Norepinephrine transporter
¹ Includes Phase 1 SAD/MAD, elderly, and PET studies in healthy subjects and Phase 2a studies in fibromyalgia and ADHD patients

TD-9855: Phase 2a Study in nOH In Progress, Results Expected 1H 2018

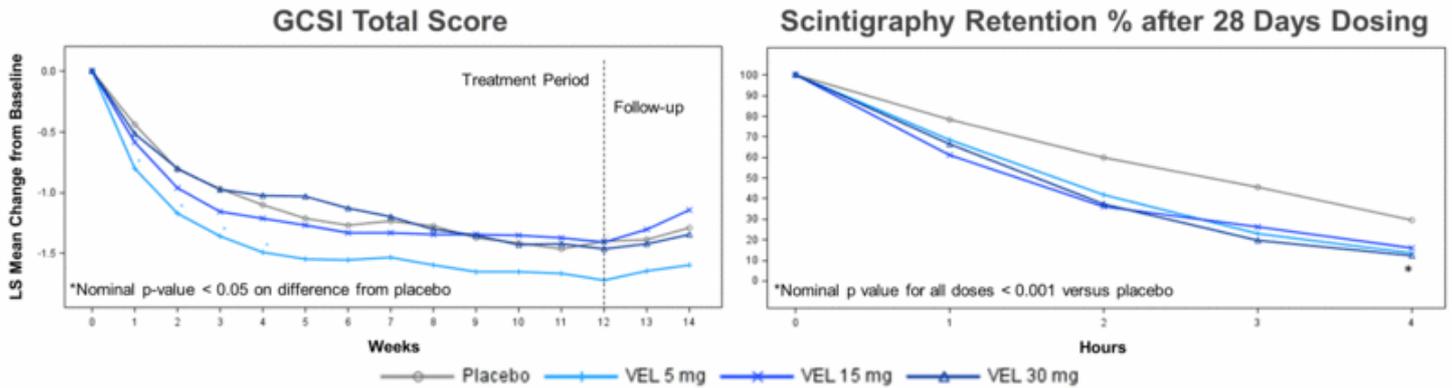
- **Purpose:** Proof of concept study to evaluate the effect of TD-9855 in improving symptoms of orthostatic intolerance
- **Key endpoints:** Change from placebo in sitting and standing blood pressure, symptom reduction, and safety/tolerability



Intention to seek expedited development path

Velusetrag: Phase 2b Study Provides First Clinical Evaluation of Effect on Gastroparesis Symptoms

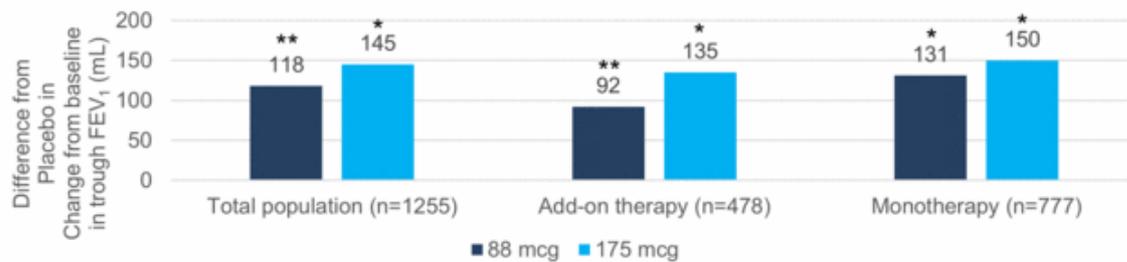
- 5 mg demonstrated statistically significant improvements in gastroparesis symptoms compared to placebo
 - 15 and 30mg doses did not improve symptoms, likely due to side effects at high doses
- All doses significantly improve gastric emptying at 4 hours



Preparing to meet with US and EU regulators to discuss validation of the GRS PRO and next phase of development

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 FEV₁
 - ✓ 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

Financial Summary

Select Financial Metrics as of September 30, 2017

	Three Months Ended September 30, 2017 <small>(in thousands)</small>
Product Sales	\$ 4,140
Revenue from Collaborative Arrangements	<u>135</u>
Total Revenue	4,275
Cost of Goods Sold	985
Research and Development ¹	39,343
Selling, General and Administrative ¹	<u>20,944</u>
Total Costs and Expenses	61,272
Operating Loss	\$ (56,997)
<i>¹ Amounts include share-based compensation expense below</i>	
Research and Development	5,005
Selling, General and Administrative	<u>5,680</u>
Total Share-based Compensation Expense	\$ 10,685
Operating Loss excluding Share-based Compensation	\$ (46,312)
Cash, Cash Equivalents and Marketable Securities as of September 30, 2017	\$ 434,400

GSK's Trelegy Ellipta Offers Significant Potential

FDA Approval for COPD in September 2017¹

Economic interest serves as an important strategic asset

- Upward-tiering royalty 5.5% - 8.5% of worldwide net sales²
- Expected to launch in US in mid-November
- Passive economic interest with no cost obligations to TBPH



Program Summary

- First and only FDA-approved once-daily single inhaler triple therapy comprising an ICS, LAMA and LABA³
- FF/UMEC/VI, active components of BREO[®] and ANORO^{®4}
- Approved for use in certain COPD patients
- Jointly managed by GSK and Innoviva⁵
- Potential regulatory approval in EU in 2017
- Phase 3 CAPTAIN asthma study underway

Landmark 10,000-patient IMPACT study in COPD

- ✓ 15% reduction in annual rate of exacerbations compared with Relvar/Breo Ellipta (FF/VI)
- ✓ 25% reduction compared with Anoro Ellipta (UMEC/VI)
- ✓ Significant improvements in lung function at week 52 compared to same dual therapies
- ✓ Improvements also observed in St. George's Respiratory Questionnaire (SGRQ) change from baseline
- ✓ Will support additional regulatory filings planned in 2018

All statements based on publically available information. ¹ For the treatment of appropriate patients with COPD. ² TBPH holds 85% economic interest in upward tiering royalty stream of 6.5% – 10% payable by GSK. ³ ICS = Inhaled corticosteroids, LAMA = long-acting muscarinic antagonist, LABA = long-acting beta2-adrenergic agonist. ⁴ FF/UMEC/VI= Fluticasone Furoate/Umeclidinium/Vilanterol. ⁵ Formerly Theravance, Inc.

Upcoming Milestones

Multiple Opportunities for Value Creation

Program	Milestone	Target
TD-1439 (NEP inhibitor)	Phase 1a SAD/MAD results in healthy volunteers	✓
Revefenacin (TD-4208)	Phase 3 long-term safety results in COPD patients	✓
Velusetrag (TD-5108)	Phase 2b results in Gastroparesis patients	✓
TD-1473 (JAK inhibitor)	Phase 1b results in UC patients, Cohort 1	✓
Trelegly Ellipta (FF/UMEC/VI) ¹	Phase 3 IMPACT study completion	✓
Trelegly Ellipta (FF/UMEC/VI) ¹	Regulatory approval in US for COPD ²	✓
Revefenacin (TD-4208)	NDA submission in US ³	2017
Trelegly Ellipta (FF/UMEC/VI) ¹	Potential regulatory approval in EU for COPD ³	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 ⁴	2018
Revefenacin (TD-4208)	Potential regulatory approval in US for COPD ³	2018
VIBATIV® (telavancin)	Patient registry study data (TOUR™)	2018
VIBATIV® (telavancin)	Phase 3 study data in Bacteremia patients	2018 / 2019
Trelegly Ellipta (FF/UMEC/VI) ¹	Phase 3 study completion in Asthma patients	2018

¹ Economic interests. Regulatory and clinical milestones as reported by GlaxoSmithKline. Trelegly Ellipta previously referred to as the Closed Triple. FF/UMEC/VI= Fluticasone Furoate/Umeclidinium/Vilanterol. ² For the treatment of appropriate patients with COPD. ³ Submissions, filings, and approvals are subject to preclinical and clinical data and regulatory interactions. ⁴ Peak inspiratory flow rate.

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 \leq 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 \leq 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.