

**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): **July 31, 2019**

**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.

Securities registered pursuant to Section 12(b) of the Act:

**Title of each class:**

Ordinary Share \$0.00001 Par Value

**Trading Symbol(s)**

TBPH

**Name of each exchange on which registered:**

NASDAQ Global Market

**Item 2.02. Results of Operations and Financial Condition.**

On July 31, 2019, Theravance Biopharma, Inc. issued a press release and is holding a conference call regarding its financial results for the quarter ended June 30, 2019 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 July 31, 2019](#)
- 99.2 [Slide deck entitled Second Quarter 2019 Financial Results and Business Update](#)

**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: July 31, 2019

By: /s/ Andrew Hindman

Andrew Hindman

Senior Vice President and Chief Financial Officer



## Theravance Biopharma, Inc. Reports Second Quarter 2019 Financial Results and Provides Business Update

- *Late-stage clinical studies of TD-1473 and amprelosetine progressing*
- *Phase 1 results including biomarker data in asthmatics for lung-selective inhaled pan-JAK inhibitor TD-8236 expected in September 2019*
- *Strong customer acceptance and brand performance of YUPELRI® (revefenacin) inhalation solution advancing in partnership with Mylan*
- *Arbitration against Innoviva ongoing; resolution expected in Q3 2019*

**DUBLIN, IRELAND — JULY 31, 2019** — Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) (NASDAQ: TBPH) today reported financial results for the second quarter ended June 30, 2019. Revenue for the second quarter of 2019 was \$26.2 million. Second quarter operating loss was \$42.5 million or \$31.2 million excluding share-based compensation expense. Cash, cash equivalents, and marketable securities totaled \$396.1 million as of June 30, 2019.

Rick E Winningham, Chief Executive Officer, commented: “2019 is a critical year of progress that sets the stage for what we believe will be an extraordinary year of data-driven, value-creating milestones in 2020.

“TD-1473, our gut-selective pan-JAK inhibitor, is moving forward in a Phase 2b/3 study in ulcerative colitis and a Phase 2 study in Crohn’s disease. Amprelosetine, our norepinephrine reuptake inhibitor, is advancing in a Phase 3 registrational program in symptomatic nOH. New data from the Phase 2 study of amprelosetine presented at recent scientific meetings demonstrated consistent and durable improvements in both symptom severity and daily activity performance in patients with nOH treated with amprelosetine for 20 weeks. These data further support the potential of this therapy to provide patients with greater durability of effect. The Phase 1 study of TD-8236, our lung-selective inhaled pan-JAK inhibitor, in healthy volunteers and asthmatics is ongoing, and we anticipate results in September 2019.

“The YUPELRI U.S. launch is progressing well in partnership with Mylan and we are pleased by our progress against key performance metrics. Additionally, we were excited to announce the expansion of our development and commercialization agreement with Mylan for nebulized revefenacin to include China. Lastly, sales of GSK’s TRELEGY ELLIPTA for COPD continue to grow, supported by product approvals and launches in additional geographies. We expect GSK to submit regulatory submissions in support of an asthma indication in the second half of this year, following the completion of the Phase 3 CAPTAIN study of TRELEGY ELLIPTA in patients with asthma.

“We are well capitalized and enter the second half of the year in a strong position to continue to drive our key programs toward meaningful inflection points. We are proud of our ability to advance a rich pipeline of differentiated assets that can yield a broad line-up of important milestones and catalysts over the next 12 to 18 months as our later-stage trials mature, earlier-stage programs advance to the clinic, and our commercial efforts gain traction. We look forward to the near-term resolution of the dispute with Innoviva to ensure we retain our economics related to TRELEGY ELLIPTA,” concluded Mr. Winningham.

## Program Updates

### TD-1473 (gut-selective pan-Janus kinase (JAK) inhibitor):

- Supplemental data from the four-week exploratory Phase 1b study of TD-1473 in patients with ulcerative colitis shared in an oral presentation at Digestive Disease Week (DDW) in May 2019
  - Study designed to measure signals of localized biologic activity, and with little to no systemic exposure or immunosuppression
  - Data were positive across a variety of measures, including disease activity, including rectal bleeding and endoscopic improvement, as well as biomarker changes confirming target engagement
- Registrational Phase 2b/3 induction and maintenance study in ulcerative colitis (RHEA) and Phase 2 induction study in Crohn's disease (DIONE) progressing
- Data from the Phase 2b portion of the ulcerative colitis and Phase 2 Crohn's disease studies planned late-2020

### Ampreloxetine (TD-9855, norepinephrine reuptake inhibitor (NRI)):

- New 20-week data from the Phase 2 study in patients with neurogenic orthostatic hypotension (nOH) presented at the International Association of Parkinsonism and Related Disorders (IAPRD) in June 2019 and in an oral presentation at the 32<sup>nd</sup> European Neurology Congress (ENC) in July 2019
  - Consistent and durable improvements in both symptom severity and daily activity performance in patients with nOH were sustained through 20 weeks of ampreloxetine therapy
  - Following withdrawal of ampreloxetine treatment, patients' symptom severity and daily activity scores returned to pre-treatment baseline levels
- Ongoing registrational program in symptomatic nOH comprised of two studies:
  - Phase 3 4-week treatment study (SEQUOIA) is ongoing, with data expected in 2H 2020
  - Phase 3 4-month open label study followed by a 6-week randomized withdrawal phase (REDWOOD) to demonstrate durability of response

### TD-8236 (novel, lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases):

- Phase 1 data expected in September 2019; study designed to evaluate safety and provide biomarker data of TD-8236 in healthy volunteers and asthmatic patients
  - Program goal in asthma is the prevention of exacerbations and the improvement of symptoms in patients uncontrolled by steroids despite compliance
  - TD-8236 shown to potently inhibit targeted mediators of Th2-high and Th2-low asthma in human cells in preclinical studies

### YUPELRI® (revedfenacin) inhalation solution (lung-selective nebulized long-acting muscarinic antagonist (LAMA)):

- First and only once-daily, nebulized bronchodilator approved in the US for the maintenance treatment of patients with COPD

- Launch underway with partner Mylan; continued strong customer acceptance and brand performance across key market metrics; combined sales infrastructures covering the hospital, hospital discharge, and home health settings
- Development and commercialization agreement with Mylan for nebulized revefenacin expanded to include China and certain adjacent geographies

TRELEGY ELLIPTA (first once-daily single inhaler triple therapy for COPD)<sup>1</sup>:

- Q2 2019 net sales of \$151.4 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Supplemental NDA submitted to FDA supporting revised labelling for TRELEGY ELLIPTA on reduction in risk of all-cause mortality compared with ANORO ELLIPTA in patients with COPD
- Phase 3 CAPTAIN study in asthma met primary endpoint demonstrating statistically significant improvement in lung function compared with RELVAR/BREO; regulatory submissions planned for 2H 2019
- Product now launched in 36 countries, including Japan; approval in China expected in Q4 2019

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**Notes:**

<sup>1</sup> As reported by Glaxo Group Limited or one of its affiliates (GSK); reported sales converted to USD; economic interest related to TRELEGY ELLIPTA (the combination of fluticasone furoate, aclidinium, and vilanterol, (FF/UMEC/VI), jointly developed by GSK and Innoviva, Inc.) entitles Company to upward tiering payments equal to approximately 5.5% to 8.5% on worldwide net sales of the product (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used in TRC over the next four fiscal quarters). RELVAR/BREO ELLIPTA (FF/VI). ANORO ELLIPTA (UMEC/VI).

## **Second Quarter Financial Results**

### Revenue

Total revenue for the second quarter of 2019 was \$26.2 million compared to \$23.5 million in the same period in 2018. The increase was primarily due to licensing revenue of \$18.5 million recognized in the second quarter of 2019 related to the upfront from Mylan for rights to nebulized revefenacin in China and adjacent geographies. The increase was partially offset by a decrease in product sales which resulted from the sale of VIBATIV<sup>®</sup> to Cumberland Pharmaceuticals in late-2018 and a one-time opt-in received from Alfasigma for velusetrag (TD-5108) in the second quarter of 2018.

### Research and Development (R&D) Expenses

R&D expenses for the second quarter of 2019 were \$46.4 million, compared to \$48.6 million in the same period in 2018. The decrease was primarily due to lower employee-related costs associated with the reduction in force announced in the first quarter of 2019 as well as a decrease in share-based compensation which was partially offset by an increase in external expenses related to the progression of our key programs. Second quarter R&D expenses included non-cash share-based compensation of \$5.7 million.

### Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the second quarter of 2019 were \$22.2 million, compared to \$25.0 million in the

same period in 2018. The decrease was primarily due to lower VIBATIV-related external expenses due to the sale of VIBATIV to Cumberland in late-2018 as well as a decrease in share-based compensation which was partially offset by higher collaboration expenses associated with the commercial launch of YUPELRI. Second quarter SG&A expenses included non-cash share-based compensation of \$5.6 million.

#### Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$396.1 million as of June 30, 2019. The quarter ending cash balance include proceeds from the upfront payment received from Mylan for rights to nebulized revefenacin in China and adjacent territories.

#### 2019 Financial Guidance

The Company's guidance on operating loss excluding non-cash share-based compensation for the full year of 2019 remains unchanged at \$210.0 million to \$230.0 million. Operating loss guidance does not include royalty income for TRELEGY ELLIPTA which the Company recognizes as non-operating income. The Company's share of U.S. profits and losses related to the commercialization of YUPELRI, potential future business development collaborations as well as the timing and cost of clinical studies associated with its key programs, among other factors, could impact the Company's financial guidance.

#### **Arbitration Against Innoviva**

In May 2019, the Company announced that it had initiated arbitration against Innoviva, Inc. ("Innoviva") in connection with Innoviva's failure to disburse certain royalties to Theravance Biopharma. Innoviva had caused Theravance Respiratory Company, LLC ("TRC LLC") to not make any distributions to Theravance Biopharma with respect to Theravance Biopharma's 85% economic interest in TRC LLC for the quarter ended December 31, 2018. Those distributions were due March 31, 2019. Additionally, Innoviva stated that it intended to cause TRC LLC to withhold making further cash distributions through calendar year 2019. The arbitration hearing commenced on July 23, 2019. Resolution of the arbitration should occur in the third quarter of 2019.

#### Conference Call and Live Webcast Today at 8:00 am ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 8:00 am ET. To participate in the live call by telephone, please dial (855) 296-9648 from the US, or (920) 663-6266 for international callers, and use the confirmation code 2445969. 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](http://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 August 30, 2019. An audio replay will also be available through 11:00 am ET on August 7, 2019 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 2445969.

## About Theravance Biopharma

Theravance Biopharma, Inc. (“Theravance Biopharma”) is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including TRELEGY ELLIPTA.

For more information, please visit [www.theravance.com](http://www.theravance.com).

THERAVANCE® and the Cross/Star logo are registered trademarks of the Theravance Biopharma group of companies. YUPELRI® is a United States registered trademark of Mylan Specialty L.P. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

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 current dispute with Innoviva and TRC LLC, the Company’s strategies, plans and objectives, the Company’s regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company’s product and product candidates, the potential that the Company’s research programs will progress product candidates into the clinic, the Company’s expectations for product candidates through development, potential regulatory approval and commercialization (including their differentiation from other products or potential products), product sales or profit share revenue and the Company’s expectations for its 2019 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: the nature of the current dispute with Innoviva and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result involving the current dispute could be adverse to the Company,

delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe or ineffective, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, 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, and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. 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 May 10, 2019 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:**

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investor.relations@theravance.com

For Innoviva dispute:

Profile  
Greg Marose / Charlotte Kiaie, 347-343-2999  
gmarose@profileadvisors.com / ckiaie@profileadvisors.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
<b>Revenue:</b>				
Product sales	\$ —	\$ 5,361	\$ —	\$ 9,040
Collaboration revenue	7,650	18,115	12,988	22,755
Licensing revenue	18,500	—	18,500	—
Total revenue	26,150	23,476	31,488	31,795
<b>Costs and expenses:</b>				
Cost of goods sold	—	(1,448)	—	(622)
Research and development <sup>(1)</sup>	46,399	48,621	100,217	96,386
Selling, general and administrative <sup>(1)</sup>	22,227	25,007	47,413	49,711
Total costs and expenses	68,626	72,180	147,630	145,475
Loss from operations	(42,476)	(48,704)	(116,142)	(113,680)
Income from investment in TRC, LLC	8,366	1,949	14,595	2,635
Interest expense	(7,901)	(2,137)	(15,759)	(4,274)
Interest and other income, net	2,374	1,284	5,169	2,768
Loss before income taxes	(39,637)	(47,608)	(112,137)	(112,551)
Provision for income tax (expense) benefit	(201)	6,790	(281)	6,646
<b>Net loss</b>	<b>\$ (39,838)</b>	<b>\$ (40,818)</b>	<b>\$ (112,418)</b>	<b>\$ (105,905)</b>
Net loss per share:				
Basic and diluted net loss per share	\$ (0.72)	\$ (0.76)	\$ (2.04)	\$ (1.98)
Shares used to compute basic and diluted net loss per share	55,529	53,799	55,235	53,529

<sup>(1)</sup> Amounts include share-based compensation expense as follows:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	\$ 5,720	\$ 6,904	\$ 11,880	\$ 13,463
Selling, general and administrative	5,578	6,951	11,639	14,390
Total share-based compensation expense	\$ 11,298	\$ 13,855	\$ 23,519	\$ 27,853

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

	June 30, 2019 (Unaudited)	December 31, 2018 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 396,072	\$ 505,276
Receivables from collaborative arrangements	979	10,053
Other prepaid and current assets	28,987	17,494
Total current assets	426,038	532,823
Property and equipment, net	12,662	13,176
Long-term marketable securities	—	11,869
Operating lease assets	47,831	—
Restricted cash	833	833
Other assets	5,083	1,534
Total assets	<u>\$ 492,447</u>	<u>\$ 560,235</u>
<b>Liabilities and Shareholders' Deficit</b>		
Current liabilities		
Convertible senior notes due 2023, net	\$ 110,136	\$ 98,554
Non-recourse notes due 2033, net	225,354	224,818
Long-term operating lease liabilities	217,715	229,535
Other long-term liabilities	48,565	—
Shareholders' deficit	27,901	58,917
Total liabilities and shareholders' deficit	<u>(137,224)</u>	<u>(51,589)</u>
	<u>\$ 492,447</u>	<u>\$ 560,235</u>

(1) The condensed consolidated balance sheet as of December 31, 2018 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

# Theravance Biopharma, Inc.

(NASDAQ: TBPH)

## Second Quarter 2019 Financial Results & Business Update

July 31, 2019



Medicines That Make a Difference<sup>®</sup>

THERAVANCE<sup>®</sup>, the Cross/Star logo, and MEDICINES THAT MAKE A DIFFERENCE<sup>®</sup> are registered trademarks of the Theravance Biopharma group of companies. All third party trademarks used herein are the property of their respective owners.

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## 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 may include the current dispute with Innoviva, Inc. and TRC LLC, 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 characteristics, benefits and mechanisms of action of the company's product and product candidates, the potential that the company's research programs will progress product candidates into the clinic, the company's expectations for product candidates through development, potential regulatory approval and commercialization (including their differentiation from other products or potential products), product sales or profit share revenue and the company's expectations for its 2019 operating loss, excluding share-based compensation.

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 the nature of the current dispute with Innoviva and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result involving the current dispute could be adverse to the company, 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 10, 2019, and other periodic reports filed with the SEC.

# Focus on Strategic Priorities

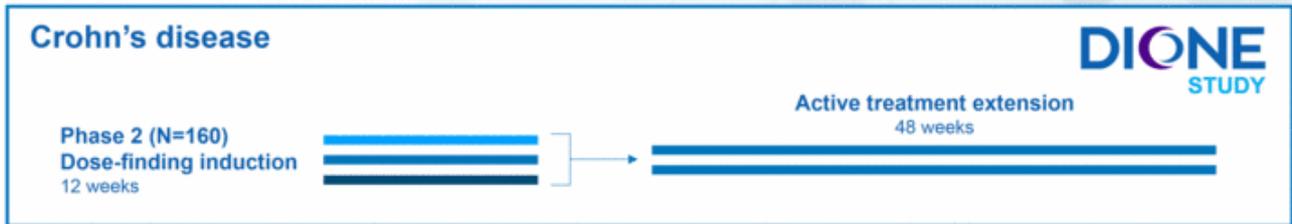
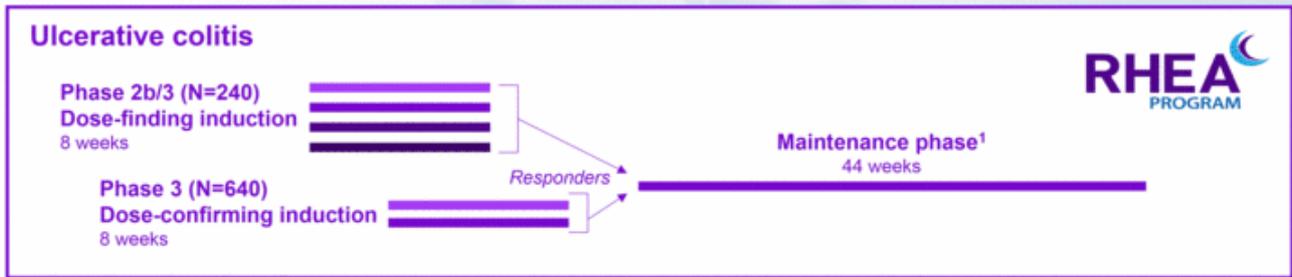
## COMMITMENT TO CREATING TRANSFORMATIONAL MEDICINES

Opportunities to Create Transformational Medicines	YUPELRI®	Nebulized LAMA in COPD <ul style="list-style-type: none"> <li>U.S. commercial launch underway</li> </ul>
	TD-1473	Gut-selective oral JAK inhibitor for inflammatory intestinal diseases <ul style="list-style-type: none"> <li>Phase 2b/3 RHEA study in ulcerative colitis ongoing; Phase 2b data planned late-2020</li> <li>Phase 2 DIONE study in Crohn's disease ongoing; data planned late-2020</li> </ul>
	Amprexetine	NRI in symptomatic neurogenic orthostatic hypotension (nOH) <ul style="list-style-type: none"> <li>Registrational Phase 3 program progressing; 4-week efficacy data expected 2H 2020</li> </ul>
	TD-8236	Lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases <ul style="list-style-type: none"> <li>Safety and biomarker data from Phase 1 study in healthy volunteers and asthmatics expected September 2019</li> </ul>
	Research	Organ-selective research platform designed to expand therapeutic index compared to conventional systemic therapies
Economic Interest	TRELEGY ELLIPTA <sup>1</sup>	Single inhaler triple therapy in COPD <ul style="list-style-type: none"> <li>Product launched in 36 countries, including Japan; China approval expected 4Q19</li> <li>sNDA submitted to FDA supporting revised labelling on reduction in risk of all-cause mortality compared with ANORO ELLIPTA in patients with COPD</li> <li>Potential sNDA for asthma indication in 2H 2019</li> </ul>

Significant existing cash resources to fund strategic priorities<sup>2</sup>

# TD-1473: Gut-selective oral JAK inhibitor

## LATE STAGE STUDIES IN ULCERATIVE COLITIS AND CROHN'S DISEASE

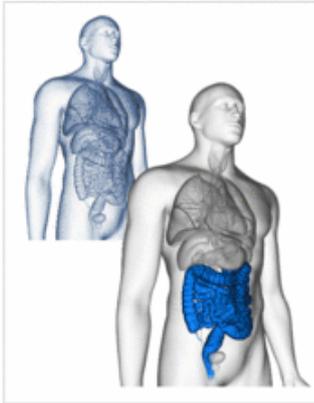


Phase 2b/3 study in UC and Phase 2 study in CD progressing; data planned late-2020

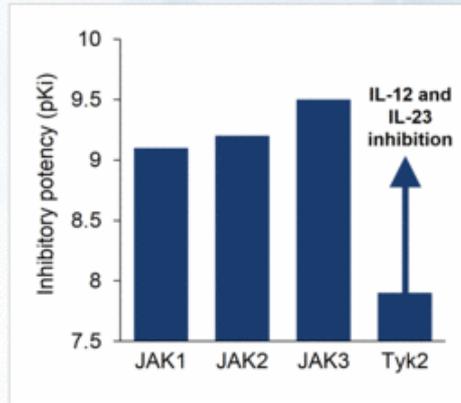
<sup>1</sup> Maintenance phase of the study will have induction responder subjects re-randomized to active doses compared to placebo at 44 weeks

# TD-1473 Research Vision

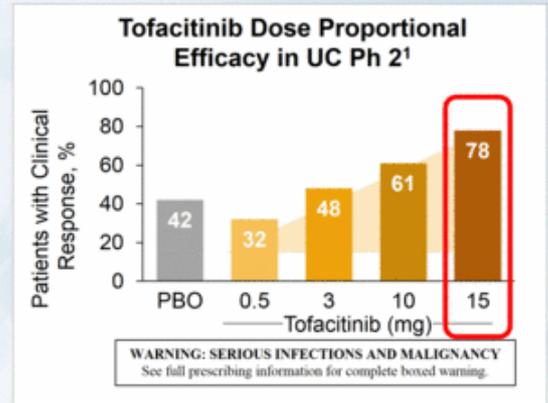
ORGAN-SELECTIVE APPROACH DESIGNED TO EXPAND THERAPEUTIC INDEX



Treat disease at site to maximize efficacy



Optimize pharmacology to include potent inhibition of Tyk2



Improve upon the efficacy of a clinically validated target

Encouraging Phase 1b data and preclinical package (including daily dose administration for 6 & 9 months)

# Amprelosetine: Phase 2 Study in nOH

## DESIGNED TO EVALUATE INITIAL AND DURABLE RESPONSE TO THERAPY

Three-part design in patients with nOH:

**A**

- Single ascending dose portion of amprelosetine (up to 20 mg)
- Testing blood pressure response to amprelosetine

**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)*

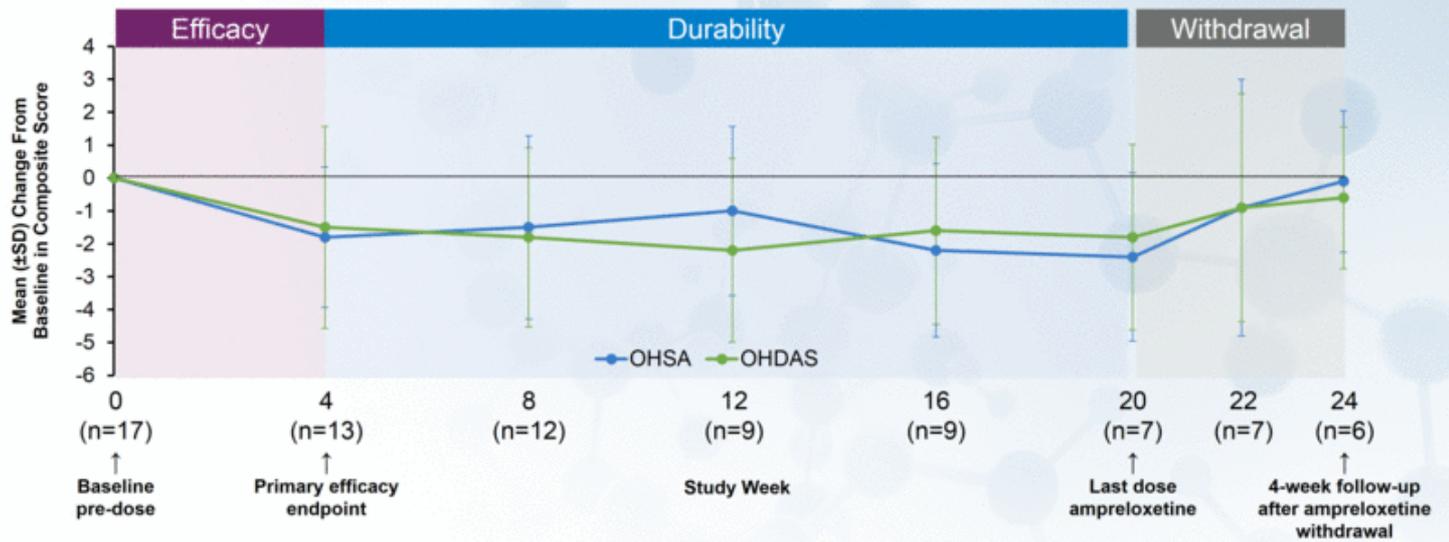
**Purpose:** To evaluate the effect of amprelosetine in improving blood pressure and key nOH symptoms

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

- Designed to assess durability of effect
- Primary assessment at four weeks (Day 29)
- Efficacy evaluations: OHSA<sup>1</sup> #1, standing time duration, standing systolic blood pressure
- Also assessed safety and pharmacokinetics of amprelosetine

# Amprexetine: Phase 2 Results in nOH

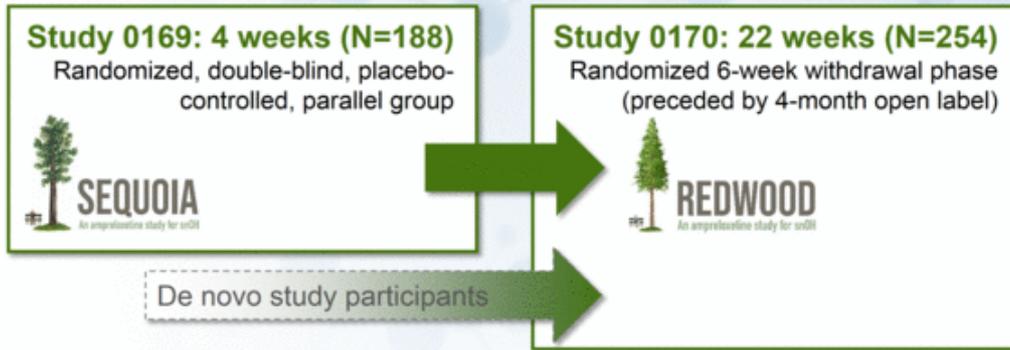
## MEAN CHANGE FROM BASELINE IN OHSA AND OHDAS COMPOSITE SCORES (SYMPTOMATIC SUBJECTS<sup>1</sup>)



Durable improvements in symptom severity and daily activity sustained out to 20 weeks

# Amprexetine Clinical Program

## PHASE 3 REGISTRATIONAL PROGRAM IN SYMPTOMATIC NOH

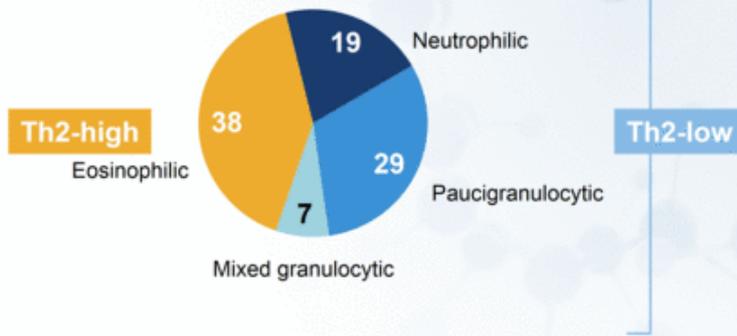


Phase 2 data supportive of ongoing Phase 3 program; Phase 3 4-week efficacy data expected 2H 2020

# TD-8236: Lung-selective Inhaled pan-JAK Inhibitor

## POTENTIAL TO ADDRESS PATIENTS NEEDS REGARDLESS OF TH2 PHENOTYPE

### Patient heterogeneity in severe asthma



### JAK/STAT cytokines implicated in severe asthma

Th2-high	Th2-low
<b>IL-4</b>	<b>IL-23/IL-12</b>
<b>IL-13</b>	<b>IL-6</b>
<b>IL-5</b>	<b>IL-27</b>
<b>TSLP</b>	<b>IFN-<math>\gamma</math></b>

*Bold denotes biologics in development or approved*

**TD-8236 shown to potently inhibit targeted mediators of Th2-high and Th2-low asthma in human cells in preclinical studies**

- ▶ Novel approved biologics address only Th2-high asthma
- ▶ Key treatment needs: Prevention of exacerbations and symptom control for patients regardless of Th2 phenotype

Phase 1 data in healthy volunteers and asthmatics (including biomarker measures) expected September 2019

# YUPELRI®: Formal Commercial Launch Underway

## FDA-APPROVED FOR THE MAINTENANCE TREATMENT OF COPD

- ▶ *First and only once-daily bronchodilator delivered in a nebulizer*
- ▶ *Higher of two doses approved: 175 mcg once daily, for use with any standard jet nebulizer*

### Unmet need for nebulized LAMA therapy

- ▶ Once-daily LAMAs are first-line therapy for moderate to severe COPD <sup>1</sup>
- ▶ No once-daily nebulized LAMAs available previously; only available in handheld devices
- ▶ Nebulized therapy associated with reduced hospital readmissions in low PIFR patients <sup>2</sup>



# Compelling Need for Once-Daily Nebulized LAMA

## ENDURING PATIENT NICHE AND SIGNIFICANT MARKET OPPORTUNITY

### Enduring patient niche

- ▶ 9% of COPD patients currently use nebulizers for ongoing maintenance therapy <sup>1</sup>
- ▶ >100M patient treatment days in nebulized COPD segment <sup>2</sup>
- ▶ 41% of COPD patients use nebulizers at least occasionally for bronchodilator therapy <sup>1</sup>
- ▶ Pricing in branded LA nebulized segment ~ 2x handheld Spiriva <sup>2</sup>

### Significant market opportunity

- ▶ YUPELRI® may be complementary to existing nebulized LABA treatments
- ▶ Mylan partnership brings commercial strength in nebulized segment

# Partnership with Mylan Brings Commercial Strength in Nebulized Opportunity

Combined sales infrastructures cover  
Hospital, Hospital Discharge and Home Health settings



## Targeting HCPs at key intersections in the patient's disease management process

- ▶ Hospital is an important site of care for patients with worsening of COPD symptoms
- ▶ Theravance Biopharma's established hospital-focused sales force is targeting the inpatient setting
- ▶ Theravance Biopharma partners with institutions to transition appropriate patients from hospital to home on YUPELRI®
- ▶ Mylan's role is to ensure patients remain on YUPELRI® for maintenance therapy in the outpatient setting

# YUPELRI® Launch Update

## ENCOURAGING INITIAL MARKET RESPONSE

### FORMULARY

**42 Wins**  
(equates to 136 accounts)

**~93 Reviews Scheduled**  
(~405 potential accounts)

**100% medical support requests fulfilled** <30 days

### PATIENT

Field force productivity goals exceeded

**~7,000 patients** prescribed  
(*thru 2Q19*)

### ACCESS

**100% Medicare Part B** <sup>1</sup>

**~46% Commercial**

**Permanent J-CODE issued**  
(*effective July 1, 2019*)

- ▶ Majority of YUPELRI® volume flows through durable medical equipment (DME) channel <sup>2</sup>; remaining volume flows through hospitals, retail and long-term care pharmacies
- ▶ WAC: \$1,030 per month (or ~\$34 per day)

# Opportunity for YUPELRI® (revefenacin) in China

## POTENTIAL TO ADDRESS LARGE AND UNDERSERVED COPD PATIENT POPULATION

### Expansion of development and commercialization agreement

- ▶ Mylan granted exclusive development and commercialization rights to revefenacin in China and adjacent territories
- ▶ Theravance Biopharma eligible to receive:
  - \$18.5 million upfront payment
  - Up to \$54 million in additional potential development and sales milestones
  - Tiered royalties on net sales, if approved
- ▶ Mylan responsible for all aspects of development and commercialization in partnered regions

### Significant market opportunity

- ▶ COPD affects ~100 million individuals in China<sup>1</sup>
- ▶ ~43% of COPD patients suffer from moderate to very severe forms of disease<sup>2</sup>
- ▶ COPD is one of the top three causes of death in China<sup>3</sup> and presents significant financial burden to healthcare system<sup>2</sup>

### Theravance Biopharma and Mylan strategic collaboration

- ▶ In 2015, the companies established a strategic collaboration to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases
  - Theravance Biopharma eligible to receive up to \$259 million in potential development and sales milestone payments, as well as profit-sharing arrangement with Mylan on US sales and tiered royalties on ex-US sales
  - Theravance Biopharma retains worldwide rights delivered through other dosage forms, including metered dose inhaler and dry powder inhaler (MDI/PDI)

# Second Quarter 2019 Financial Highlights

(\$, in thousands)	Three Months Ended, June 30,	
	2019	2018
	(Unaudited)	
Product sales	-	5,361
Collaboration revenue	7,650	18,115
License revenue	18,500	-
<b>Total revenue</b>	<b>26,150</b>	<b>23,476</b>
Cost of goods sold	-	(1,448)
Research and development <sup>2</sup>	46,399	48,621
Selling, general and administrative <sup>2</sup>	22,227	25,007
<b>Total costs and expenses</b>	<b>68,626</b>	<b>72,180</b>
<b>Loss from operations</b>	<b>(42,476)</b>	<b>(48,704)</b>
<i>Share-based compensation expense</i>		
Research and development	5,720	6,904
Selling, general and administrative	5,578	6,951
<b>Total share-based compensation expense</b>	<b>11,298</b>	<b>13,855</b>
<b>Operating loss excluding share-based compensation</b>	<b>(31,178)</b>	<b>(34,849)</b>

Well capitalized with  
\$396M as of quarter  
end<sup>1</sup>

# GSK's TRELEGY ELLIPTA

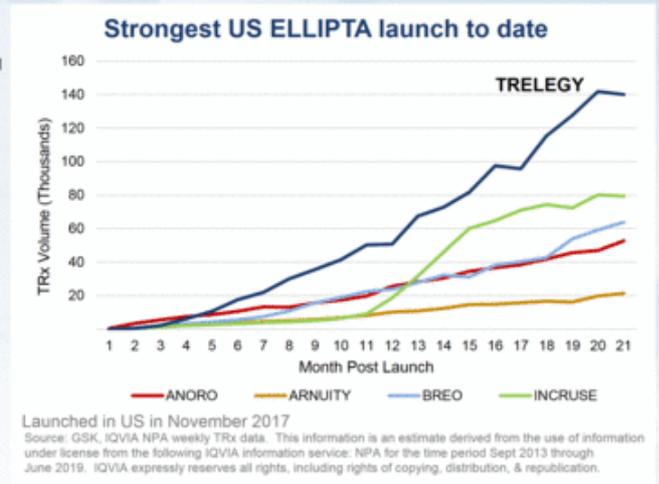
## FIRST AND ONLY ONCE-DAILY SINGLE INHALER TRIPLE THERAPY

### Economic interest in TRELEGY ELLIPTA

- ▶ Upward-tiering royalty of ~5.5% - 8.5% of worldwide net sales<sup>1</sup>
- ▶ Passive economic interest; no product cost obligations

### Growth continues after first full year on market

- ✓ Available in 36 countries, including Japan
- ✓ Additional geographies expected 2H19; potential for China approval and launch 4Q19
- ✓ sNDA submitted to FDA supporting revised labelling on reduction in risk of all-cause mortality compared with ANORO in patients with COPD
- ✓ Phase 3 CAPTAIN study in asthma met primary endpoint; regulatory submissions expected 2H 2019



# Focus on Strategic Priorities

## COMMITMENT TO CREATING TRANSFORMATIONAL MEDICINES

Opportunities to Create Transformational Medicines	YUPELRI®	Nebulized LAMA in COPD <ul style="list-style-type: none"> <li>U.S. commercial launch underway</li> </ul>
	TD-1473	Gut-selective oral JAK inhibitor for inflammatory intestinal diseases <ul style="list-style-type: none"> <li>Phase 2b/3 RHEA study in ulcerative colitis ongoing; Phase 2b data planned late-2020</li> <li>Phase 2 DIONE study in Crohn's disease ongoing; data planned late-2020</li> </ul>
	Amprexetine	NRI in symptomatic neurogenic orthostatic hypotension (nOH) <ul style="list-style-type: none"> <li>Registrational Phase 3 program progressing; 4-week efficacy data expected 2H 2020</li> </ul>
	TD-8236	Lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases <ul style="list-style-type: none"> <li>Safety and biomarker data from Phase 1 study in healthy volunteers and asthmatics expected September 2019</li> </ul>
	Research	Organ-selective research platform designed to expand therapeutic index compared to conventional systemic therapies
Economic Interest	TRELEGY ELLIPTA <sup>1</sup>	Single inhaler triple therapy in COPD <ul style="list-style-type: none"> <li>Product launched in 36 countries, including Japan; China approval expected 4Q19</li> <li>sNDA submitted to FDA supporting revised labelling on reduction in risk of all-cause mortality compared with ANORO ELLIPTA in patients with COPD</li> <li>Potential sNDA for asthma indication in 2H 2019</li> </ul>

Key programs drive near- and long-term value-creating events