

**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): February 24, 2020

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 February 24, 2020, Theravance Biopharma, Inc. issued a press release and is holding a conference call regarding its financial results for the quarter and full year ended December 31, 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 February 24, 2020](#)

[99.2](#) [Slide deck entitled Fourth Quarter and Full Year 2019 Financial Highlights and Business Update](#)

104 Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

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: February 24, 2020

By: /s/ Andrew Hindman

Andrew Hindman

Senior Vice President and Chief Financial Officer



Theravance Biopharma, Inc. Reports Fourth Quarter and Full-Year 2019 Financial Results and Provides Business Update

- *YUPELRI® (revefenacin) is realizing strong customer acceptance and market uptake, in partnership with Mylan*
- *Phase 1 of TD-5202 single-ascending dose and multiple-ascending dose studies evaluated the safety and tolerability of TD-5202 in healthy subjects; data showed TD-5202 was generally well tolerated, supporting advancement*
- *Full-year operating loss, excluding share-based compensation expense, was lower than the Company's previously stated financial guidance for 2019¹*
- *Multiple potential value-driving catalysts expected in 2020 and beyond*

DUBLIN, IRELAND – FEBRUARY 24, 2020 – Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) (NASDAQ: TBPH) today reported financial results for the fourth quarter and full year ended December 31, 2019. Revenue for the fourth quarter and full year 2019 was \$29.5 million and \$73.4 million, respectively. Full-year operating loss was \$251.9 million or \$191.5 million excluding share-based compensation expense. Cash, cash equivalents and marketable securities totaled \$285.8 million as of December 31, 2019.

Rick E Winningham, Chairman and Chief Executive Officer, commented: “2019 was a year of achievement for Theravance Biopharma across our business. We successfully launched YUPELRI with Mylan and advanced our development- and research-stage pipeline, further building a diversified portfolio with promising, differentiated programs in every stage of development. Our roster of partnerships continued to strengthen, with ongoing successful collaborations with Mylan for YUPELRI and Janssen for TD-1473 and TD-5202. In addition, we entered into a new agreement with Pfizer to out-license our skin-selective pan-JAK inhibitor program. Our partnerships complement and expand our capabilities and execution and underscore our potential to transform the treatment of serious diseases.”

“As we look ahead, 2020 will be an important year for our Company. We have established a strong capital position, augmented by our partnerships, as well as TRELEGY ELLIPTA royalties and YUPELRI commercialization. We are optimistic about future data readouts, especially our wholly owned programs -- ampreloxetine in nOH and TD-8236 in asthma -- which could both represent new treatment paradigms for patients with debilitating chronic diseases. The combined strengths of our research engine, pipeline, proven development expertise and commercial infrastructure have set the stage for a data- and catalyst-rich 2020 -- a year that we believe can deliver meaningful value for stakeholders.”

Corporate Highlights

Partnered with Mylan:

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

- First and only once-daily, nebulized bronchodilator approved in the U.S. for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)
- One year post-launch -- continued strong customer acceptance across key market metrics; combined Theravance Biopharma/Mylan sales infrastructures covering the hospital, hospital discharge, and home health settings



- o Data as of October 2019 show that YUPELRI achieved an 86% share of the nebulized LAMA market and a 10.7% share of the long-acting nebulized market (including Durable Medical Equipment)

Partnered with Janssen:

TD-5202 (gut-selective irreversible JAK3 inhibitor for inflammatory intestinal diseases):

- TD-5202 was generally well tolerated as a single oral dose up to 2000 milligrams and as a twice-daily oral dose up to 2000 milligrams total per day given for 10 consecutive days in healthy subjects

TD-1473 (gut-selective oral pan-Janus kinase (JAK) inhibitor for inflammatory intestinal diseases):

- 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 for late-2020

Amprelosetine (TD-9855, norepinephrine reuptake inhibitor (NRI) for symptomatic nOH):

- Ongoing registrational program in symptomatic neurogenic orthostatic hypertension (nOH) comprised of two studies:
 - Phase 3 four-week treatment study (SEQUOIA) to demonstrate efficacy, with data expected in late 2020
 - Phase 3 four-month open label study followed by a six-week randomized withdrawal phase (REDWOOD) to demonstrate durability of response

TD-8236 (lung-selective inhaled pan-JAK inhibitor for inflammatory lung diseases):

- Part C extension portion of the Phase 1 trial assessing additional biomarkers in more severe asthmatics underway with results expected in mid-2020
- Phase 2 lung allergen challenge initiated in 4Q 2019; data expected in mid-2020

TRELEGY ELLIPTA (first once-daily single inhaler triple therapy for COPD)²:

- 4Q 2019 net sales of \$221.5 million and full-year 2019 net sales of \$661.3 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Product now launched for COPD in 38 markets, including China
- GSK filed sNDA 2Q 2019 for mortality benefit compared with ANORO in COPD and sNDA for use in patients with asthma in 3Q 2019

Notes:

¹ Theravance Biopharma's full-year operating loss, excluding share-based compensation expense, was below the 2019 guidance of \$200 million to \$210 million operating loss excluding share-based compensation due to the Pfizer upfront payment of \$10 million being recognized as revenue in late December.

² 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 Theravance Respiratory Company, LLC ("TRC LLC") expenses paid and the amount of cash, if any, expected to be used in TRC over the next four fiscal quarters). 75% of the income from Company's investment in TRC is pledged to service outstanding PharmaSM notes, 25% of income from Company's investment in TRC is retained by Company.

Fourth Quarter and Full Year Financial Results

- **Revenue:** Revenue for the fourth quarter of 2019 was \$29.5 million, comprised of collaboration revenue of \$9.6 million primarily attributed to the upfront payment from Janssen for TD-1473, licensing revenue of \$10.0 million related to the upfront payment from Pfizer for rights to our skin-selective pan-JAK inhibitor program, and revenue from the Mylan collaboration agreement of \$9.9 million. Revenue for the fourth quarter represents a \$13.8 million increase over the same period in 2018. The increase was primarily due to licensing revenue associated with the upfront payment from Pfizer and an increase in revenue from the Mylan collaboration agreement, partially offset by a decrease in product sales which resulted from the sale of VIBATIV[®] to Cumberland Pharmaceuticals in late-2018. Full-year 2019 revenue was \$73.4 million, comprised of collaboration revenue of \$31.3 million primarily associated with our global collaboration with Janssen, licensing revenue of \$28.5 million related to upfronts from Pfizer and Mylan and revenue from the Mylan collaboration of \$13.7 million.
- **Research and Development Expenses:** Research and Development (R&D) expenses for the fourth quarter of 2019 were \$67.0 million, compared to \$52.3 million in the same period in 2018. The increase was primarily due to an increase in employee-related costs and share-based compensation related to long-term retention and incentive awards, plus external-related costs associated with the progression of our key programs. Full-year 2019 R&D expenses were \$219.2 million, or \$190.3 million excluding non-cash share-based compensation.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the fourth quarter of 2019 were \$33.0 million, compared to \$25.5 million in the same period in 2018. The increase was primarily due to an increase in share-based compensation related to long-term retention and incentive awards. Full-year 2019 SG&A expenses were \$106.1 million, or \$74.6 million excluding non-cash share-based compensation.
- **Cash, Cash Equivalents and Marketable Securities** Cash, cash equivalents and marketable securities totaled \$285.8 million as of December 31, 2019.

2020 Financial Guidance

- **Operating Expenses:** The Company expects full-year 2020 operating loss, excluding share-based compensation, of \$205 million to \$225 million. Operating loss guidance does not include:
 - Royalty income for TRELEGY ELLIPTA which the Company recognizes in its statement of operations as “income from investment in TRC, LLC;”
 - or
 - Potential future business development collaborations

Note: timing and cost of clinical studies associated with key programs, among other factors, could impact financial guidance.

Additionally, as announced on February 11th, 2020, we closed our public offering of 5,500,000 ordinary shares at a price to the public of \$27.00 per share. The gross proceeds to Theravance Biopharma from the offering are approximately \$148.5 million, before deducting underwriting discounts and commissions and estimated offering expenses.



Conference Call and Live Webcast Today at 5:00 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5:00 pm ET (2:00 pm PT / 10:00 pm GMT). 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 5775588. 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.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through March 25, 2020. An audio replay will also be available through 8:00 pm ET on March 2, 2020 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 5775588.

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 Limited 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.

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 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: potential future disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result 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 in the company's Prospectus Supplement filed with the Securities and Exchange Commission (SEC) on February 12, 2020, Form 10-Q filed with the SEC on November 8, 2019, and other periodic reports filed 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:
Gail B. Cohen
Corporate Communications and Investor Relations
917-214-6603



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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ -	\$ 2,415	\$ -	\$ 15,304
Collaboration revenue	9,584	10,047	31,250	41,791
Licensing revenue	10,000	-	28,500	-
Mylan collaboration agreement	9,915	3,275	13,664	3,275
Total revenue	<u>29,499</u>	<u>15,737</u>	<u>73,414</u>	<u>60,370</u>
Costs and expenses:				
Cost of goods sold	-	632	-	715
Research and development ⁽²⁾	67,025	52,269	219,248	201,348
Selling, general and administrative ⁽²⁾	33,046	25,457	106,081	97,058
Total costs and expenses	<u>100,071</u>	<u>78,358</u>	<u>325,329</u>	<u>299,121</u>
Loss from operations	(70,572)	(62,621)	(251,915)	(238,751)
Income from investment in TRC, LLC	11,913	5,428	33,705	11,182
Interest expense	(8,035)	(4,071)	(31,862)	(10,482)
Interest and other income, net	1,137	7,822	8,395	11,966
Loss before income taxes	(65,557)	(53,442)	(241,677)	(226,085)
Provision for income tax benefit (expense)	(49)	3,256	5,222	10,561
Net loss	<u>\$ (65,606)</u>	<u>\$ (50,186)</u>	<u>\$ (236,455)</u>	<u>\$ (215,524)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.17)</u>	<u>\$ (0.92)</u>	<u>\$ (4.25)</u>	<u>\$ (3.99)</u>
Shares used to compute basic and diluted net loss per share	<u>56,102</u>	<u>54,555</u>	<u>55,610</u>	<u>53,969</u>

⁽¹⁾The condensed consolidated statement of operations for the year ended 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.

⁽²⁾Amounts include share-based compensation expense as follows:

(In thousands)	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Research and development	\$ 10,615	\$ 5,806	\$ 28,953	\$ 25,563
Selling, general and administrative	13,297	5,908	31,497	25,750
Total share-based compensation expense	<u>\$ 23,912</u>	<u>\$ 11,714</u>	<u>\$ 60,450</u>	<u>\$ 51,313</u>



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

	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(Unaudited)</u>	<u>(1)</u>
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 280,831	\$ 505,276
Receivables from collaborative arrangements	11,996	10,053
Receivables from licensing arrangements	10,000	-
Amounts due from TRC, LLC	28,574	5,422
Other prepaid and current assets	7,087	12,072
Total current assets	<u>338,488</u>	<u>532,823</u>
Property and equipment, net	12,644	13,176
Long-term marketable securities	4,985	11,869
Operating lease assets	46,604	-
Restricted cash	833	833
Other assets	5,272	1,534
Total assets	<u>\$ 408,826</u>	<u>\$ 560,235</u>
Liabilities and Shareholders' Deficit		
Current liabilities	\$ 111,703	\$ 98,554
Convertible senior notes due 2023, net	225,890	224,818
Non-recourse notes due 2033, net	219,300	229,535
Long-term operating lease liabilities	47,725	-
Other long-term liabilities	28,048	58,917
Shareholders' deficit	(223,840)	(51,589)
Total liabilities and shareholders' deficit	<u>\$ 408,826</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.



Medicines That Make a Difference®

Fourth Quarter and Full Year 2019 Financial Highlights and Business Update

February 24, 2020

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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 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, the Company's expectations regarding its allocation of resources, 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 and other financial results.

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 potential future disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result 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 the company are described under the heading "Risk Factors" and elsewhere in the company's Prospectus Supplement filed with the Securities and Exchange Commission (SEC) on February 12, 2020, Form 10-Q filed with the SEC on November 8, 2019, and other periodic reports filed with the SEC.

Strategic objective

Transform the treatment of serious diseases through the discovery, development, and commercialization of ***organ-selective medicines*** designed to maximize patient benefit while minimizing patient risk

Creating transformational value for stakeholders



Innovative and productive **research engine** feeding **pipeline of organ-selective assets**



Proven **development expertise** and established **commercial infrastructure**



Strategic partnerships complement internal capabilities and balance technical, execution and financial risks



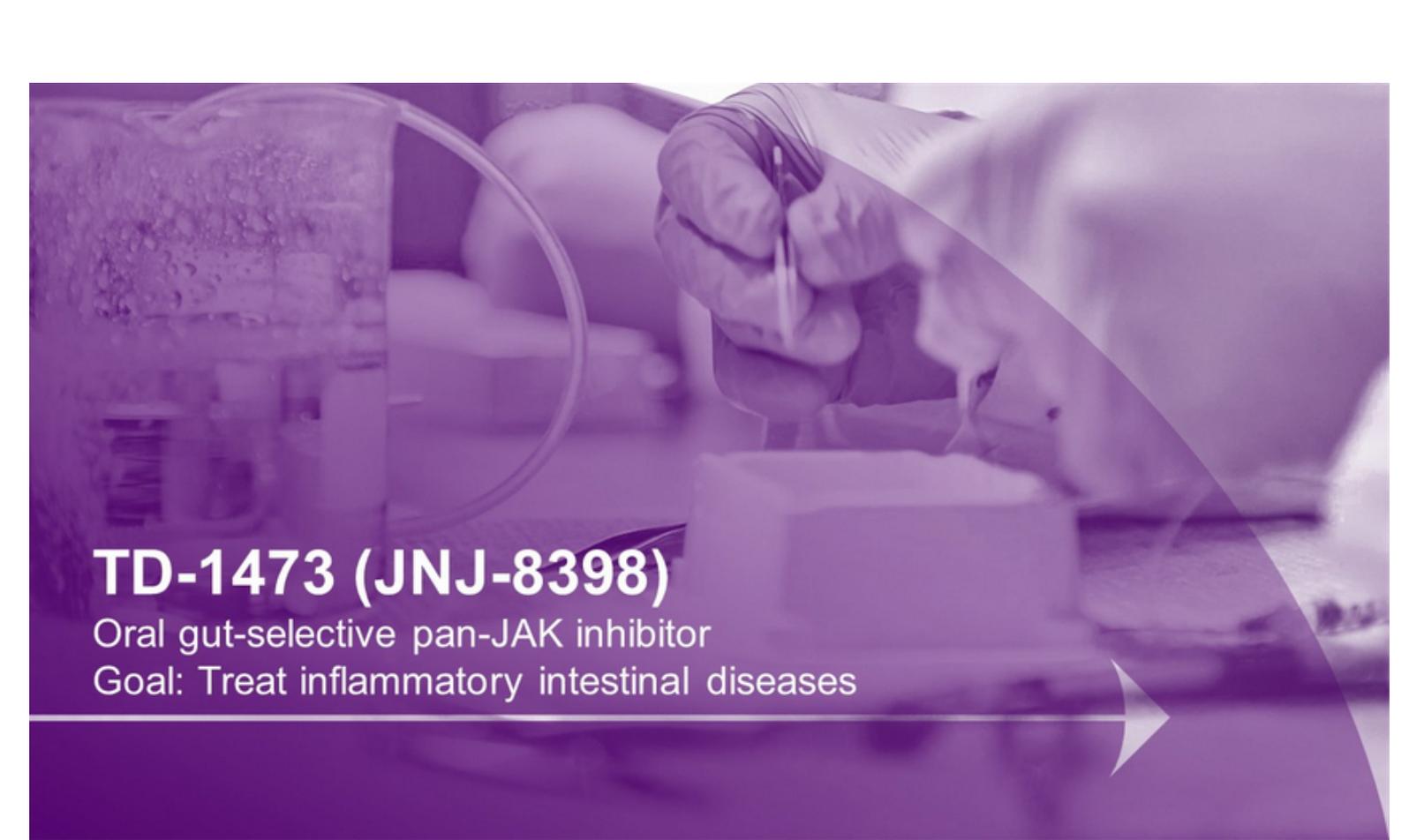
Strong capital position augmented by TRELEGY ELLIPTA¹ royalties and YUPELRI[®] launch



Multiple milestones and **value driving catalysts** in 2020 and beyond

Key programs supported by proven development and commercial expertise

	Program	Indication	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Collaborator
Organ-selective	YUPELRI® (revefenacin) LAMA	COPD	[Progress bar]					Marketed	Mylan
	TD-1473 GI JAKi	UC	[Progress bar]			Phase 2b/3			Janssen
		CD	[Progress bar]			Phase 2			
	TD-8236 Inhaled JAKi	Inflammatory lung diseases	[Progress bar]			Phase 2			Wholly-owned
	TD-5202 Irreversible JAK3i	Inflammatory intestinal diseases	[Progress bar]			Phase 1			Janssen
New programs	Multiple	[Progress bar]			Research			Wholly-owned	
	Amprelosetine (TD-9855) NRI	Symptomatic neurogenic orthostatic hypotension	[Progress bar]			Phase 3			Wholly-owned
Economic Interests	TRELEGY ELLIPTA ¹ FF/UMEC/M	COPD	[Progress bar]					Marketed	GSK & Innoviva, Inc.
		Asthma	[Progress bar]					Filed	
	Skin-selective JAKi	Dermatological diseases	[Progress bar]			Research			Pfizer



TD-1473 (JNJ-8398)

Oral gut-selective pan-JAK inhibitor

Goal: Treat inflammatory intestinal diseases

TD-1473: Gut-selective pan-JAK inhibitor

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



- ✓ Phase 2 Crohn's and Phase 2b/3 UC studies ongoing
- ✓ Phase 2 Crohn's and Phase 2b UC data expected late-2020
- ✓ Global collaboration with **JNJ** leverages joint development expertise and provides significant economics to **TBPH⁴**



TD-5202

Organ-gut selective irreversible JAK3 inhibitor

Goal: Treat inflammatory intestinal diseases



TD-5202 FIH Overall Results Summary

TD-5202: generally well-tolerated (single dose ≤ 2000 mg, multiple doses ≤ 1000 mg BID) for 10 consecutive days in healthy subjects



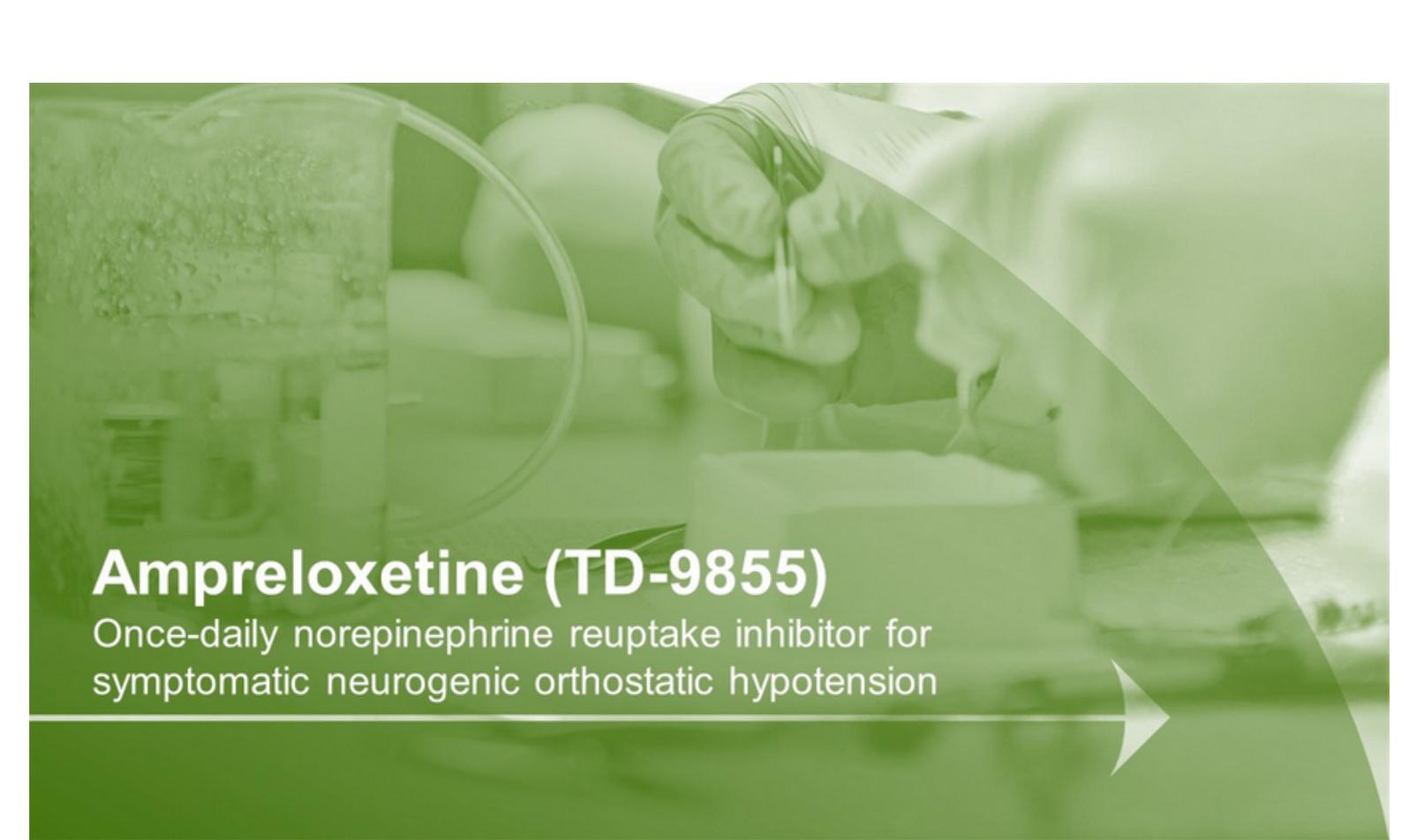
- ▶ No SAEs or severe AEs were reported
- ▶ All treatment-emergent AEs in TD-5202-treated subjects were mild in severity



- ▶ No clinically significant changes from baseline in vital signs and ECG assessments
- ▶ No clinically significant changes in chemistry or hematology parameters
 - No changes in NK cell count



- ▶ Systemic exposures were dose proportional from 100 to 1000 mg BID
- ▶ Low steady-state systemic exposures: mean $C_{max,ss}$ ~11-fold below the protein-adjusted JAK IC_{50} at the highest tested dose (1000 mg BID), consistent with a gut-selective approach



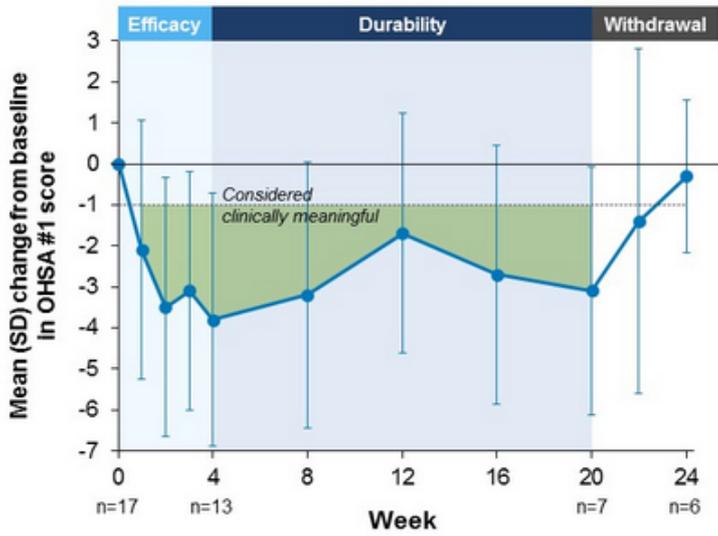
Ampreloxetine (TD-9855)

Once-daily norepinephrine reuptake inhibitor for symptomatic neurogenic orthostatic hypotension

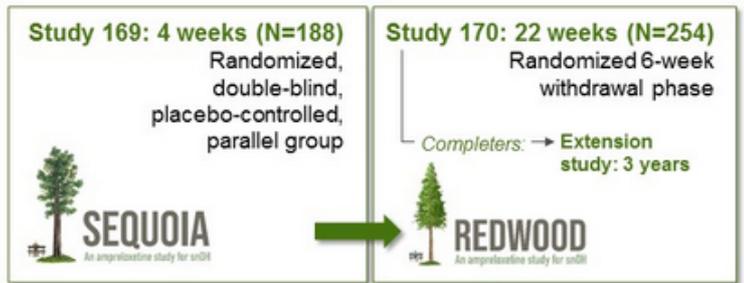
Potential to provide meaningful and durable symptom improvement to underserved patients

Amprexetine

Phase 2 data in nOH; 20 weeks of treatment



Phase 3 Registrational Program



- ✓ Phase 3 registrational program ongoing; 4-week efficacy data expected late 2020

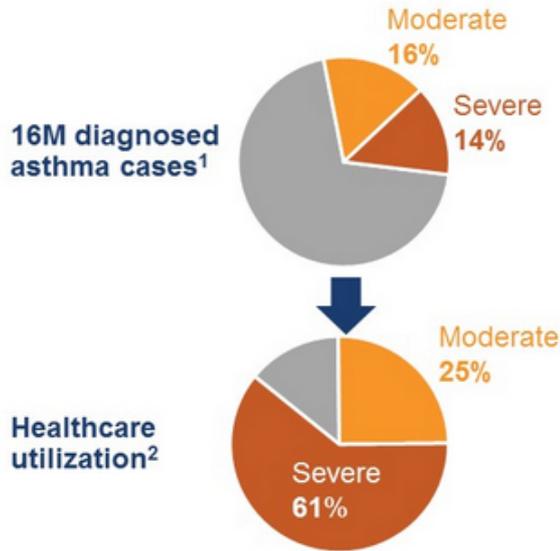


TD-8236

Inhaled lung-selective pan-JAK inhibitor
Goal: Treat moderate-to-severe asthma
regardless of T2 phenotype

High medical and economic burden in uncontrolled asthma

Small portion of US patients cause ~\$58B in medical costs



JAK/STAT cytokines implicated in moderate to severe asthma

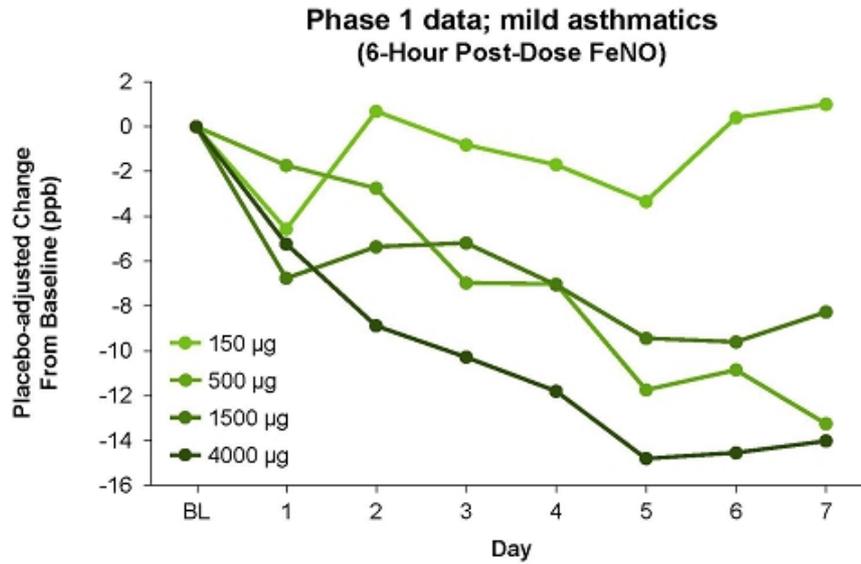
T2-high	T2-low
IL-4	IL-23/IL-12
IL-13	IL-6
IL-5	IL-27
TSLP	IFN- γ

Bold denotes biologics in development or approved

Inhaled pan-JAK inhibitor has the potential to address patient needs regardless of T2 phenotype

TD-8236: Lung-selective pan-JAK inhibitor

PRELIMINARY POSITIVE FENO DATA IN MILD ASTHMATICS



▶ Phase 1 biomarker study in moderate to severe asthmatics ongoing; data expected mid-2020

TD-8236: Lung-selective pan-JAK inhibitor

PHASE 2 ALLERGEN CHALLENGE STUDY

TD-8236 Phase 2 Lung Allergen Challenge 12 weeks (N=21)

Dose characterization
Randomized, double-blind, placebo-controlled,
crossover study

- ✓ Phase 2 allergen challenge study underway
- ✓ Data expected 2020



**Early-stage
organ-selective programs**

Opportunity to address multiple therapeutic areas with novel organ-selective approach



Inhaled nebulized
lung-selective pan-JAKi

Prevention of lung
transplant rejection

~2,500 per year
in US



Inhaled nebulized
lung-selective ALK5i

Idiopathic pulmonary
fibrosis

US prevalence:
~140,000¹



Intravitreal
eye-selective pan-JAKi

Diabetic macular
edema

US prevalence:
~2.7 million



**YUPELRI[®] (revefenacin)
inhalation solution**

First and only once-daily, nebulized
maintenance medicine for COPD

YUPELRI® (revefenacin) inhalation solution

FDA-APPROVED FOR THE MAINTENANCE TREATMENT OF COPD



First and only once-daily, nebulized maintenance medicine for COPD

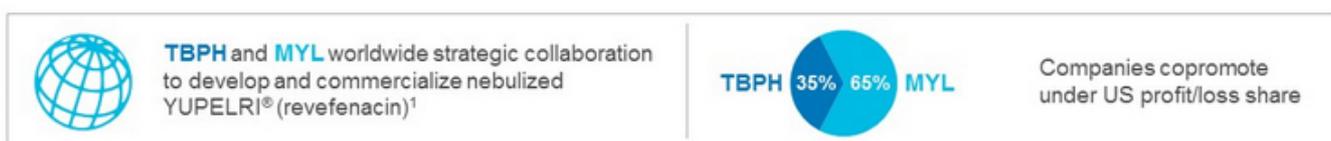
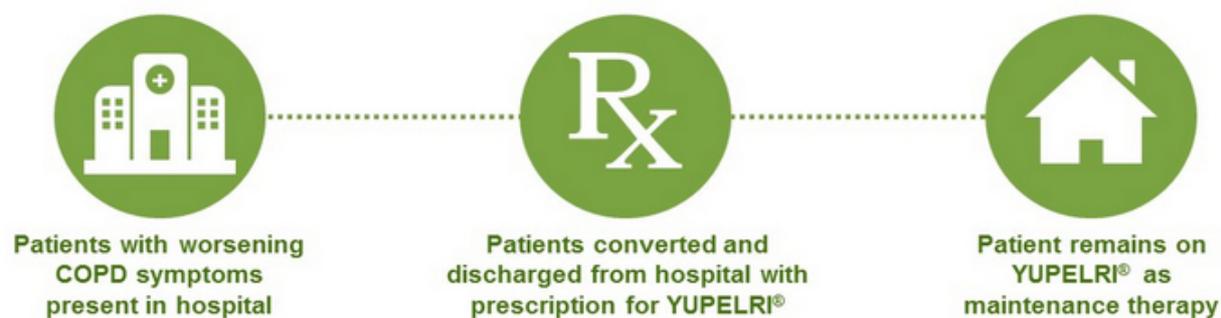
Once-daily LAMAs are first-line therapy for moderate to severe COPD¹

9% of COPD patients (~800,000) use nebulizers for ongoing maintenance therapy; 41% use nebulizers at least occasionally for bronchodilator therapy²

Nebulized therapy associated with reduced hospital readmissions in low PIFR patients³

YUPELRI® commercial strategy

COMBINED SALES INFRASTRUCTURES TARGET HCPS AT KEY INTERSECTIONS



YUPELRI® launch metrics

STRONG CUSTOMER ACCEPTANCE AND MARKET UPTAKE

✓ FORMULARY¹

85 wins
(equates to 220 accounts)

~70 reviews scheduled
(>400 potential accounts)

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

✓ PATIENT

Field force productivity goals
exceeded

~30,000 patients² prescribed
(through Q4 2019)

✓ ACCESS

100% Medicare Part B³

~50% commercial

Permanent J-CODE issued⁴

Fourth Quarter 2019 Financial Highlights

WELL CAPITALIZED WITH \$285.8M¹ AS OF DECEMBER 31, 2019

(\$, in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Product sales	\$ -	\$ 2,415	\$ -	\$ 15,304
Collaboration revenue	9,584	10,047	31,250	41,791
Licensing revenue	10,000	-	28,500	-
Mylan collaboration agreement	9,915	3,275	13,664	3,275
Total revenue	29,499	15,737	73,414	60,370
Cost of goods sold	-	632	-	715
Research and development ⁽²⁾	67,025	52,269	219,248	201,348
Selling, general and administrative ⁽²⁾	33,046	25,457	106,081	97,058
Total costs and expenses	100,071	78,358	325,329	299,121
Loss from operations	(70,572)	(62,621)	(251,915)	(238,751)
Share-based compensation expense:				
Research and development	10,615	5,806	28,953	25,563
Selling, general and administrative	13,297	5,908	31,497	25,750
Total share-based compensation expense	23,912	11,714	60,450	51,313
Operating loss excluding share-based compensation	\$ (46,660)	\$ (50,907)	\$ (191,465)	\$ (187,438)



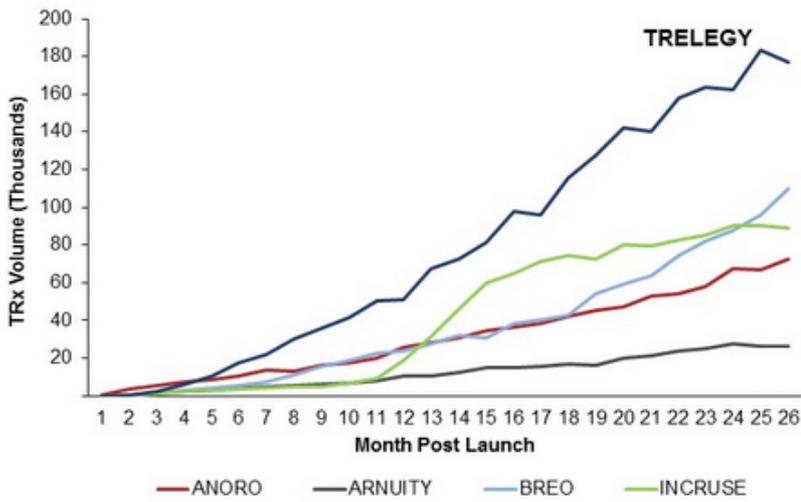
Economic interest

GSK's TRELEGY ELLIPTA (FF/UMEC/VI):

First and only once-daily single inhaler triple therapy

Economic interest in GSK's TRELEGY ELLIPTA

UPWARD-TIERING ROYALTIES OF ~5.5% TO 8.5% OF WORLDWIDE NET SALES¹



- ✓ Strongest US ELLIPTA launch to date
- ✓ ~31% share in class
- ✓ Marketed in 38 countries, including China launched in 4Q19
- ✓ sNDA filed 2Q19 for mortality benefit compared with ANORO in COPD
- ✓ sNDA filed 3Q19 for use in asthma

Launched in US in November 2017

Source: GSK, IQVIA, NPA weekly TRx data. This information is an estimate derived from the use of information under license from the following IQVIA information service: NPA for the time period Sep 2013 through Nov 2019. IQVIA expressly reserves all rights, including rights of copying, distribution, and republication.



The Theravance Biopharma Difference

Multiple potential milestones and value driving catalysts expected in 2020 and beyond

2020

TD-5202

- ▶ Phase 1 topline data

2021

TD-8236

- ▶ Phase 1 Part C data in severe asthmatics
- ▶ Phase 2 allergen challenge data

TRELEGY ELLIPTA¹

- ▶ FDA decision for asthma and separately for mortality benefit vs. ANORO in COPD
- ▶ Upsizing of note facility

Ampreloxetine

- ▶ Phase 3 4-week efficacy data

TD-1473

- ▶ Phase 2b/3 ulcerative colitis topline data
- ▶ Phase 2 Crohn's topline data

Commercial progression of YUPELRI® and TRELEGY ELLIPTA

Creating transformational value for stakeholders

Innovative research yielding organ-selective assets



Proven development and commercial expertise



Strategic partnerships



Strong capital position



Value driving catalysts



Strategic objective

Transform the treatment of serious diseases through the discovery, development, and commercialization of **organ-selective medicines** designed to maximize patient benefit while minimizing patient risk

About YUPELRI® (revefenacin) inhalation solution

YUPELRI® (revefenacin) inhalation solution is a novel once-daily nebulized LAMA approved for the maintenance treatment of COPD in the US.

Market research by Theravance Biopharma indicates approximately 9% of the treated COPD patients in the US use nebulizers for ongoing maintenance therapy.¹ LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI is positioned as the first once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI's stability in both metered dose inhaler and dry powder device formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

YUPELRI® (revefenacin) inhalation solution

YUPELRI® inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Important Safety Information (US)

YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta2-agonist.

As with other inhaled medicines, YUPELRI can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with YUPELRI, it should be treated immediately with an inhaled, short-acting bronchodilator. YUPELRI should be discontinued immediately and alternative therapy should be instituted.

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Patients should be instructed to immediately consult their healthcare provider if they develop any signs and symptoms of acute narrow-angle glaucoma, including eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema.

Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If a reaction occurs, YUPELRI should be stopped at once and alternative treatments considered.

The most common adverse reactions occurring in clinical trials at an incidence greater than or equal to 2% in the YUPELRI group, and higher than placebo, included cough, nasopharyngitis, upper respiratory infection, headache and back pain.

Coadministration of anticholinergic medicines or OATP1B1 and OATP1B3 inhibitors with YUPELRI is not recommended.

YUPELRI is not recommended in patients with any degree of hepatic impairment.