

**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 23, 2021**

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 numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- 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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Share \$0.00001 Par Value	TBPH	NASDAQ Global Market

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 February 23, 2021, 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, 2020 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 23, 2021](#)

[99.2 Slide deck entitled Fourth Quarter and Full Year 2020 Financial Results 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 23, 2021

By: /s/ Andrew Hindman

Andrew Hindman

Senior Vice President and Chief Financial Officer



Theravance Biopharma, Inc. Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

- *Company's implied 35% share of YUPELRI® (revefenacin) net sales¹: \$13.6M Q4 2020, \$50.0M FY 2020*
- *TD-0903: Company reports positive top-line results from Part 1 of a two-part Phase 2 study*

DUBLIN, IRELAND – FEBRUARY 23, 2021 – Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) (NASDAQ: TBPH) today reported financial results for the fourth quarter and full year ended December 31, 2020.

“2020 was a critical year of growth for YUPELRI, with our commercial team persevering during a respiratory pandemic and driving increased market share,” said Rick E Winningham, Chief Executive Officer. “This same resilience was seen across our organization, laying the foundation for this year’s clinical development milestones for ampreloxetine and izecitinib. Our focus in 2021 is to deliver on these milestones in what could be a transformational year.”

“Importantly, we are also encouraged by the initial clinical data from a TD-0903 study in patients hospitalized with acute lung injury due to COVID-19. The data we are reporting today are from Part 1 of a two-part Phase 2 clinical study. The results show that inhaled administration of nebulized TD-0903, once daily over seven days, was generally well-tolerated and showed a numerical trend towards improved clinical status, reduced hospital stay and fewer deaths compared to placebo during a 28-day observation period. We look forward to reporting data from Part 2 in Q2 2021 and continuing to progress this potential therapy for those hospitalized with COVID-19.”

Quarterly Highlights

- **YUPELRI®** (revefenacin) inhalation solution, the first and only once-daily, nebulized bronchodilator approved in the U.S. for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), continued to increase market share and achieved year-over-year sales growth of 159%; its share of the nebulized COPD market increased to 18.6% through November 2020 (up from 17.4% in September 2020).
- **TD-0903**, an investigational nebulized lung-selective pan-JAK inhibitor, is in a two-part Phase 2 study (NCT04402866) comparing treatment with TD-0903 versus placebo, on a background of standard of care treatment in hospitalized patients with COVID-19 who required oxygen at the time of enrollment. Part 1 of the study explored three once-daily doses (1 mg, 3 mg, 10 mg) and matched placebo in a double-blind, multiple-ascending dose (MAD) design. Each cohort comprised eight patients (six receiving TD-0903 and two receiving placebo), all treated up to seven days with the majority receiving background standard of care therapy, including oxygen, anticoagulation and dexamethasone.
 - **Part 1 Safety:**
 - TD-0903 was generally well-tolerated across the three dose levels
 - There were no drug-related serious adverse events
 - One patient in the 10 mg dose cohort discontinued therapy after four days because of an isolated increase in liver alanine aminotransferase (ALT) that met pre-defined stopping criteria

¹ While Viatrix, Inc. (“Viatrix”) records the total YUPELRI net sales, the Company is entitled to a 35% share of the profits and losses pursuant to a co-promotion agreement with Viatrix.

o **Part 1 Exploratory Clinical Observations:**

- TD-0903 showed numerical improvements in clinical outcome and duration of hospital stay and fewer deaths compared to placebo (n=25)

	Placebo (n=6)	1 mg (n=6)	3 mg (n=7*)	10 mg (n=6)
All-Cause Mortality by Day 28	2 (33%)	1 (17%)	0 (0%)	0 (0%)
Clinical status worsened during 7-day treatment period[#]	3 (50%)	0 (0%)	0 (0%)	0 (0%)
Alive and Respiratory Failure Free on Day 28^{###}	4 (67%)	5 (83%)	6 (86%)	6 (100%)
Mean Time to Hospital Discharge (Days)	22.5	18.8	15.3	15.2

* One patient in the 3 mg group received 2 doses of TD-0903 before repeated polymerase chain reaction (PCR) testing confirmed the patient did not have COVID-19. The patient was replaced per the protocol allowances and their data is included for safety but not for efficacy.

[#] Worsening defined as a score of 8, 7 or 6 on World Health Organization (WHO) COVID-19 Clinical Status Ordinal Scale

^{###} Respiratory Failure Free defined as a score of 1, 2, 3 or 4 on WHO COVID-19 Clinical Status Ordinal Scale

o **Part 1 Biomarkers and Pharmacokinetics (PK):**

- Evidence of improvement in several relevant inflammatory biomarkers
- Low systemic exposure at all doses of nebulized TD-0903, in keeping with the lung-selective design features of the molecule

The 3 mg dose is currently being evaluated in Part 2 of the Phase 2 study, which is a randomized, double-blind, parallel-group study evaluating efficacy and safety of a seven-day course of once-daily nebulized TD-0903 compared to placebo in 198 hospitalized COVID-19 patients. The Company expects to announce data from Part 2 in Q2 2021.

Upcoming Data Milestones

- **TD-0903 Phase 2 Part 2** expected to report results in Q2 2021
- **Amprexetine** (norepinephrine reuptake inhibitor (NRI)) **for symptomatic neurogenic orthostatic hypertension (nOH) Phase 3** study expected to report results in Q3 2021
- **Izencitinib** (gut-selective oral pan-Janus kinase (JAK) inhibitor for inflammatory intestinal diseases) **Phase 2b/3** study in **ulcerative colitis** and **Phase 2** study in **Crohn's disease** expected to report results, separately, in Q3 2021

Economic Interest

- **TRELEGY** (first once-daily single inhaler triple therapy for COPD and asthma), in which the Company holds an economic interest, posted fourth quarter 2020 net sales of \$315 million (up from \$224 million in fourth quarter of 2019) and full year 2020 net sales of \$1,058 million (up from \$663 million in 2019), achieving year-over-year sales growth of 60%; Theravance Biopharma is entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product.^{2,3}

Fourth Quarter and Full Year Financial Results

- **Revenue:** Total revenue for the fourth quarter of 2020 was \$18.7 million, comprised of non-cash collaboration revenue of \$7.1 million primarily attributed to our global collaboration with Janssen and \$11.6 million in Viatris collaboration revenue. Total revenue for the fourth quarter represents a \$10.8 million decrease over the same period in 2019. Full year 2020 revenue was \$71.9 million, comprised of non-cash collaboration revenue of \$26.5 million primarily attributed to our global collaboration with Janssen, licensing revenue of \$1.5 million related to a Viatris clinical trial application milestone and \$43.9 million in Viatris collaboration revenue.
- **YUPELRI:** The Viatris collaboration revenue of \$11.6 million for the fourth quarter represents amounts receivable from Viatris and is comprised of the Company's 35% share of net sales of YUPELRI as well as its proportionate amount of the total shared costs incurred by the two companies. The non-shared YUPELRI costs incurred by Theravance Biopharma are recorded within operating expenses. While Viatris records the total net sales of YUPELRI within its financial statements, our implied 35% share of net sales of YUPELRI for the fourth quarter of 2020 was approximately \$13.6 million.
- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter of 2020 were \$65.2 million, compared to \$67.0 million in the same period in 2019. Fourth quarter R&D expenses included total non-cash share-based compensation of \$7.6 million. Full year 2020 R&D expenses were \$261.0 million, or \$229.7 million excluding non-cash share-based compensation.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the fourth quarter of 2020 were \$30.1 million, compared to \$33.0 million in the same period in 2019. Fourth quarter SG&A expenses included total non-cash share-based compensation of \$8.0 million. Full year 2020 SG&A expenses were \$108.7 million, or \$77.0 million excluding non-cash share-based compensation.
- **Operating Loss:** Operating loss for the fourth quarter of 2020 was \$76.5 million compared to \$70.6 million in the same period of 2019. Full year 2020 operating loss was \$297.8 million, or \$234.8 million excluding share-based compensation expense compared to \$251.9 million, or \$191.5 million excluding share-based compensation expense in 2019.
- **Cash Position:** Cash, cash equivalents and marketable securities totaled \$292.9 million as of December 31, 2020.

² As reported by Glaxo Group Limited or one of its affiliates (GSK); reported sales converted to USD; economic interest related to TRELEGY (the combination of fluticasone furoate, umeclidinium, and vilanterol, (FF/UMEC/VI), jointly developed by GSK and Innoviva, Inc.) entitles the 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) 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 the Company's investment in TRC is pledged to service outstanding notes, 25% of income from the Company's investment in TRC is retained by the Company.

³ On June 10, 2020, the Company disclosed in a Form 8-K that it had formally objected to Theravance Respiratory Company, LLC ("TRC") and Innoviva, as the manager of TRC, regarding their proposed plan to use TRELEGY royalties to invest in certain privately-held companies, funds that would otherwise be available for distribution to the Company under the terms of the TRC LLC Agreement. The Company intends to continue to seek to protect its interests in this matter consistent with the dispute resolution procedures of the TRC LLC Agreement. In this regard, the Company initiated an arbitration proceeding against Innoviva and TRC in October 2020 challenging the authority of Innoviva and TRC to pursue such a business plan rather than distribute such funds to the Company in a manner consistent with the LLC Agreement and the Company's 85% economic interest in TRC. The arbitration hearing was held during the week of February 16, 2021, with post-hearing briefing and arguments to take place over the next few weeks. We currently anticipate a decision in those proceedings near the end of the current quarter or early in the second quarter of 2021.



2021 Financial Guidance

Operating Expenses (excluding share-based compensation): The Company expects full year 2021 R&D expense of \$195 million to \$225 million and SG&A expense of \$80 million to \$90 million.

Conference Call and Live Webcast Today at 5 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5 pm ET / 2 pm PT / 10 pm GMT. To participate, please dial (855) 296-9648 from the U.S. or (920) 663-6266 for international callers, using the confirmation code 9469708. Those interested in listening to the conference call live via the internet may do so by visiting Theravance.com, under the Investor Relations section, Events and Presentations.

A replay will be available on Theravance.com for 30 days through March 25, 2021. An audio replay will also be available through 8:00 pm ET on March 2, 2021 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 9469708.

About Theravance Biopharma

Theravance Biopharma, Inc. is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Its purpose is to pioneer a new generation of small molecule drugs designed to better meet patient needs. Its research is focused in the areas of inflammation and immunology.

In pursuit of its purpose, Theravance Biopharma applies insights and innovation at each stage of its business and utilize its internal capabilities and those of partners around the world. The Company applies organ-selective expertise to target disease biologically, to discover and develop medicines that may expand the therapeutic index with the goal of maximizing efficacy and limiting systemic side effects. 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). Its pipeline of internally discovered programs is targeted to address significant patient needs.

Theravance Biopharma has 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.

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 registered trademark of Mylan Specialty L.P., a Viatris Company. 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, 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 expenses, excluding share-based compensation and other financial results. 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: current and 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. In addition, while we expect the effects of COVID-19 to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI® (revefenacin), our clinical development programs (including but not limited to our later stage clinical programs for izencitinib and amprelosetine), and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. These potential future developments include, but are not limited to, the ultimate duration of the COVID-19 pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, other measures taken by us and those we work with to help protect individuals from contracting COVID-19, and the effectiveness of actions taken globally to contain and treat the disease, including vaccine availability, distribution, acceptance and effectiveness. Other risks affecting Theravance Biopharma are in the Company's Form 10-Q filed with the SEC on November 9, 2020 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
917-214-6603



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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
	(Unaudited)		(Unaudited)	
Revenue:				
Collaboration revenue	\$ 7,083	\$ 9,584	\$ 26,464	\$ 31,250
Licensing revenue	-	10,000	1,500	28,500
Viartis collaboration agreement	11,647	9,915	43,893	13,664
Total revenue	18,730	29,499	71,857	73,414
Costs and expenses:				
Research and development ⁽²⁾	65,165	67,025	260,953	219,248
Selling, general and administrative ⁽²⁾	30,055	33,046	108,661	106,081
Total costs and expenses	95,220	100,071	369,614	325,329
Loss from operations	(76,490)	(70,572)	(297,757)	(251,915)
Income from investment in TRC, LLC	20,139	11,913	68,438	33,705
Interest expense	(11,680)	(8,035)	(44,585)	(31,862)
Loss on extinguishment of debt	-	-	(15,464)	-
Interest and other income, net	798	1,137	2,831	8,395
Loss before income taxes	(67,233)	(65,557)	(286,537)	(241,677)
Provision for income tax benefit (expense)	8,799	(49)	8,520	5,222
Net loss	\$ (58,434)	\$ (65,606)	\$ (278,017)	\$ (236,455)
Net loss per share:				
Basic and diluted net loss per share	\$ (0.92)	\$ (1.17)	\$ (4.46)	\$ (4.25)
Shares used to compute basic and diluted net loss per share	63,725	56,102	62,345	55,610

(1) The condensed consolidated statement of operations for the year ended December 31, 2019 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, 2019.

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

(In thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Research and development	\$ 7,570	\$ 10,615	\$ 31,294	\$ 28,953
Selling, general and administrative	7,981	13,297	31,682	31,497
Total share-based compensation expense	\$ 15,551	\$ 23,912	\$ 62,976	\$ 60,450



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

	December 31, 2020	December 31, 2019
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 292,941	\$ 280,831
Receivables from collaborative arrangements	15,868	11,996
Receivables from licensing arrangements	-	10,000
Amounts due from TRC, LLC	53,799	28,574
Prepaid clinical and development services	20,374	2,736
Other prepaid and current assets	10,359	4,351
Total current assets	<u>393,341</u>	<u>338,488</u>
Property and equipment, net	16,422	12,644
Long-term marketable securities	-	4,985
Operating lease assets	43,260	46,604
Equity in net assets of TRC, LLC	12,750	-
Restricted cash	833	833
Other assets	2,451	5,272
Total assets	<u>\$ 469,057</u>	<u>\$ 408,826</u>
Liabilities and Shareholders' Deficit		
Current liabilities		
Convertible senior notes due 2023, net	\$ 123,571	\$ 111,703
Non-recourse notes due 2035, net	226,963	225,890
Non-recourse notes due 2033, net	372,873	-
Long-term operating lease liabilities	-	219,300
Other long-term liabilities	47,220	47,725
Shareholders' deficit	2,181	28,048
Total liabilities and shareholders' deficit	<u>(303,751)</u>	<u>(223,840)</u>
	<u>\$ 469,057</u>	<u>\$ 408,826</u>

(1) The condensed consolidated balance sheet as of December 31, 2019 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, 2019.



Medicines That Make a Difference®

Fourth Quarter and Full Year 2020 Financial Results and Business Update

February 23, 2021

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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 expenses, 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 the impacts of the COVID-19 global pandemic on our business, 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, current and 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.

Other risks affecting Theravance Biopharma are in the company's Form 10-Q filed with the SEC on November 9, 2020, and other periodic reports filed with the SEC.

Agenda

Introduction

Gail B Cohen

Vice President, Corporate Communications

Overview

Rick E Winningham

Chief Executive Officer

Commercial and Development Update

Frank Pasqualone

Senior Vice President, Chief Business Officer

Brett Haumann, M.D.

Senior Vice President, Chief Medical Officer

Financial Update

Andrew Hindman

Senior Vice President, Chief Financial Officer

Closing Remarks

Rick E Winningham

Chief Executive Officer

Key programs supported by proven development and commercial expertise

	Program	Indication	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Collaborator
Organ-Selective	Amprexetine (TD-9855) NRI	Symptomatic nOH	Phase 3						Wholly-owned
	Izencitinib (TD-1473) GI JAKi	UC	Phase 2b/3					Janssen Biotech, Inc.	
		CD	Phase 2						
	TD-5202 Irreversible JAK3i	Inflammatory intestinal diseases	Phase 1						
	YUPELRI® (revedfenacin) LAMA	COPD	Marketed					VIATRIS™	
	TD-0903 Inhaled JAKi	COVID-19	Phase 2					Wholly-owned	
	TD-8236 Inhaled JAKi	Asthma	Phase 2						
Inhaled ALK5i	Idiopathic pulmonary fibrosis	Phase 1							
	Program	Indication	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Rights
Economic Interests	TRELEGY ¹ FF/UMEC/VI	COPD	Marketed					GSK & Innoviva, Inc.	
		Asthma	Marketed						
	Skin-selective JAKi	Dermatological diseases	Research					Pfizer	

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-very severe COPD¹

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

TBPH and VTRS worldwide strategic collaboration to develop and commercialize nebulized YUPELRI® (revefenacin)



Companies co-promote under US profit/loss share

YUPELRI® hospital sales and community TRx trends

Continued growth through Q4'20 across both the hospital and retail channels



Most patients that receive YUPELRI® in the hospital are discharged with an Rx¹

TRx volume represents retail only which is typically 33% of Retail + DME

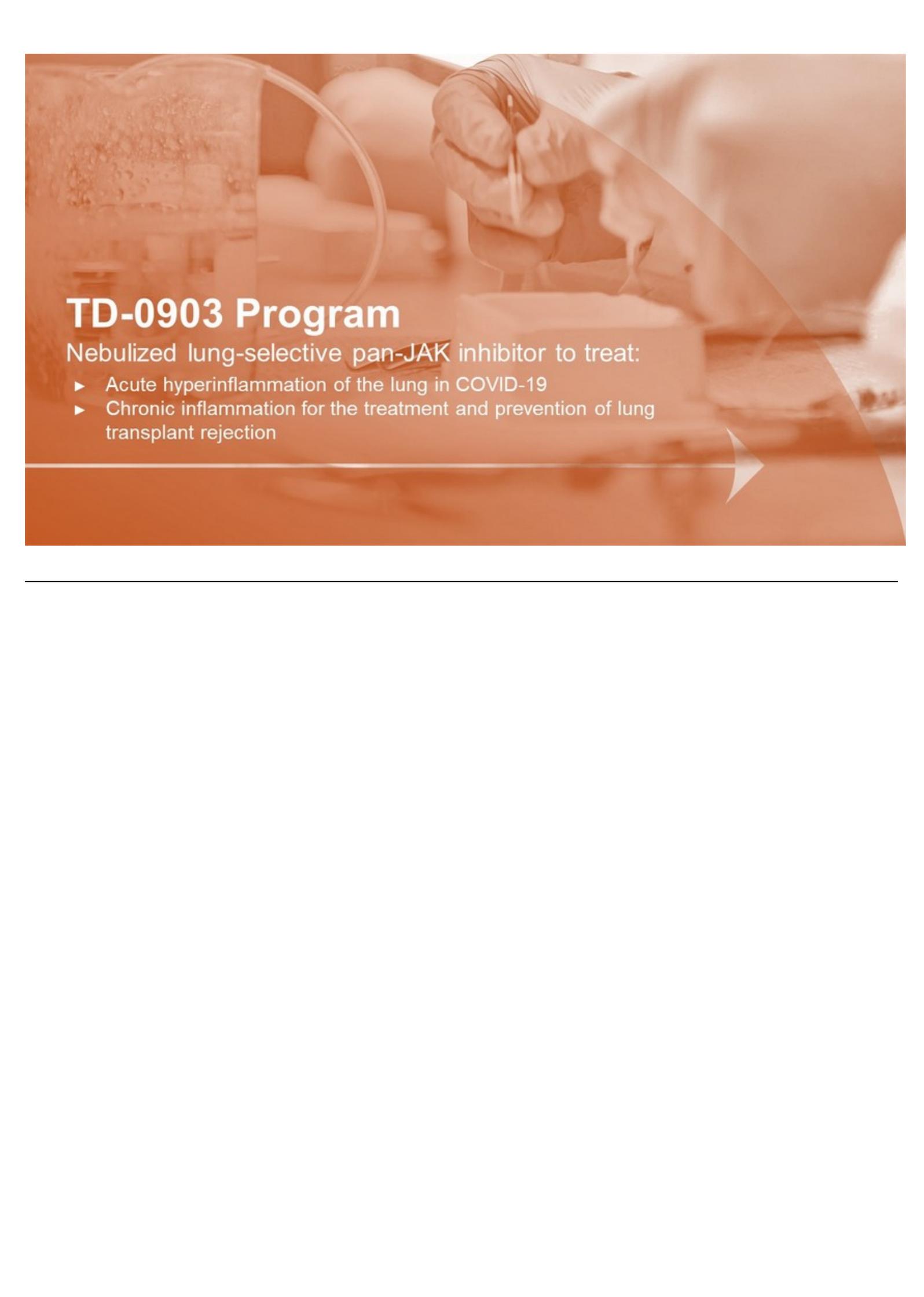
**Community LA-NEB Market Share includes Retail + DME / Med B FFS through Nov'20

TBPH implied 35% of YUPELRI® US net sales by quarter

Growth in net sales through Q1'20 and recovery in Q3'20 driven by volume



TBPH implied 35% of YUPELRI US net sales represents TBPH's split of the combined TBPH and VIATRIS net revenue



TD-0903 Program

Nebulized lung-selective pan-JAK inhibitor to treat:

- ▶ Acute hyperinflammation of the lung in COVID-19
- ▶ Chronic inflammation for the treatment and prevention of lung transplant rejection

TD-0903: a two-part placebo-controlled Phase 2 study in hospitalized patients with COVID-19 requiring oxygen support

- ▶ 7 days of once-daily nebulized treatment
- ▶ 28 days of observation in total

Part 1:

- ▶ Placebo-controlled, double-blind multiple-ascending dose (MAD)
- ▶ N= 8 per cohort (6 active, 2 placebo)
- ▶ Repeat-dose safety, tolerability, PK, clinical status, hospital stay



Part 2:

- ▶ Placebo-controlled, double-blind parallel group
- ▶ N=99 per arm
- ▶ Primary endpoint: number of Respiratory Failure-Free Days (RFD) at Day 28



Data expected Q2 2021

Executive Summary

Overall Conclusions from TD-0903 Phase 2 Part 1

Safety & Tolerability Findings

- ▶ TD-0903 was generally well-tolerated
- ▶ There were no drug-related serious adverse events
- ▶ One patient discontinued treatment on 10 mg dose because of isolated elevated liver function value

PK Data

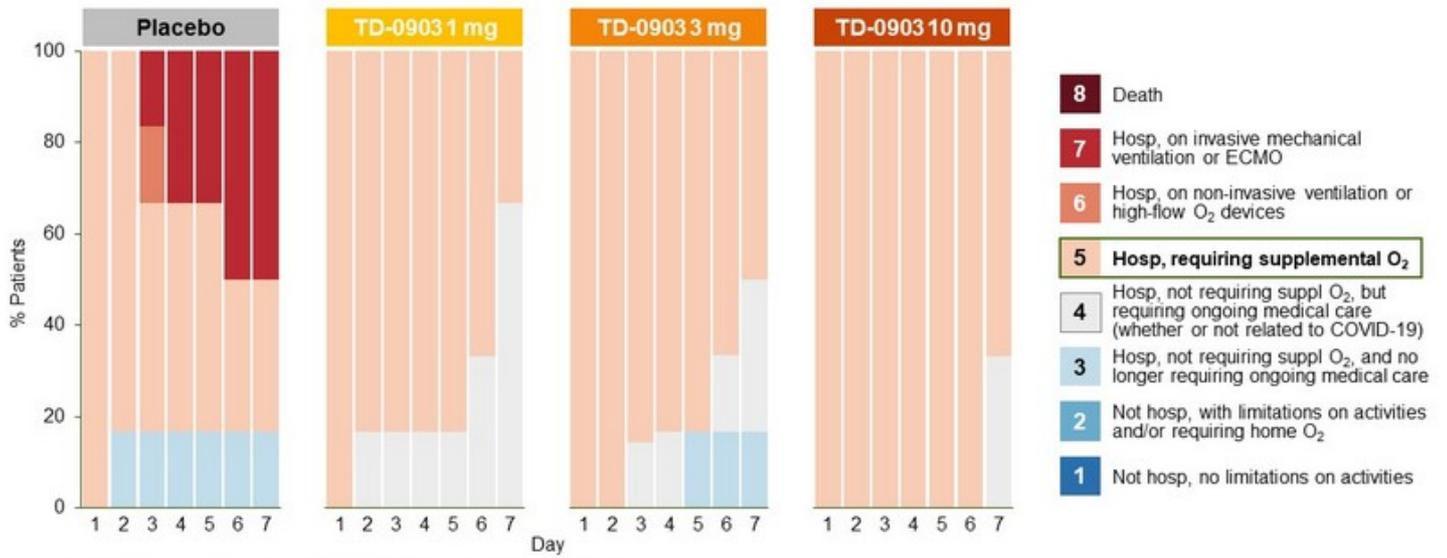
- ▶ Low, dose-dependent systemic exposure at all doses of nebulized TD-0903

Exploratory Clinical Observations

- ▶ Positive trend vs placebo in improving clinical status and reducing hospital stay
- ▶ No deaths in 3 mg and 10 mg cohorts vs 2 on placebo and 1 in 1 mg cohort
- ▶ TD-0903 improved oxygenation (S/F ratio) from baseline to Day 7
- ▶ TD-0903 reduced several relevant inflammatory biomarkers vs placebo, including CRP, IL-10 and RAGE

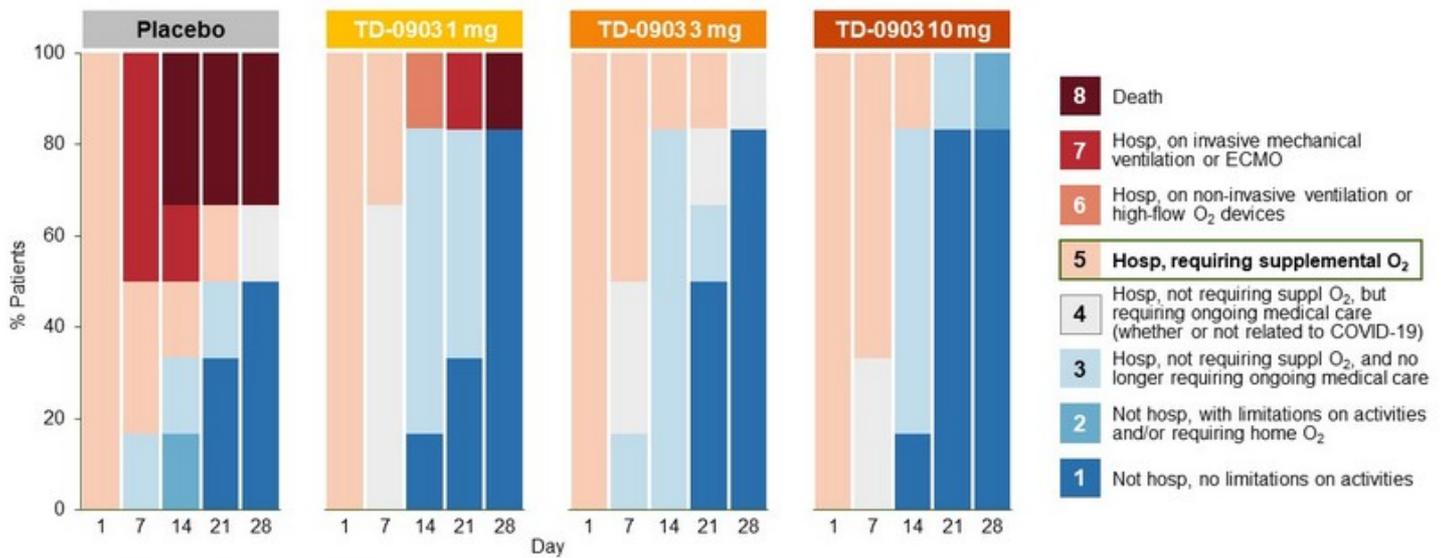
TD-0903 appears to stabilize clinical status within 7 days, compared to placebo

- ▶ TD-0903 showed a positive trend toward more clinical improvement
- ▶ 50% of placebo patients required mechanical ventilation by Day 6



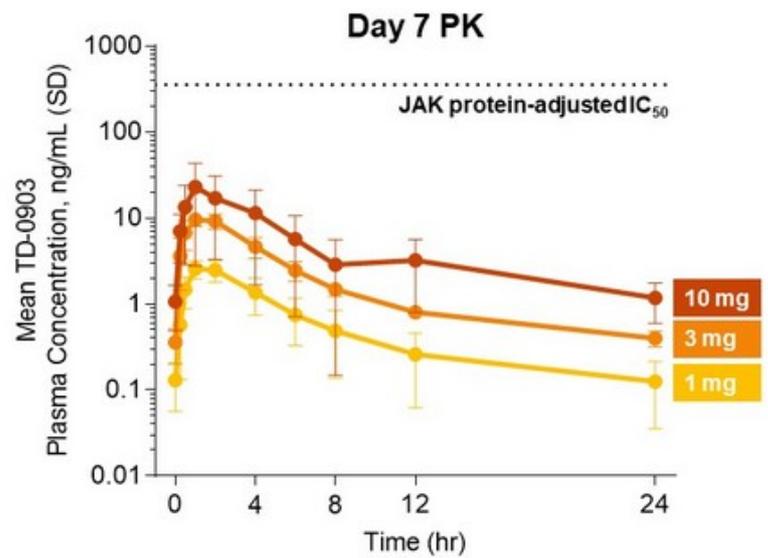
TD-0903 shows numerical improvement in clinical status compared to placebo through 28 days

- ▶ 2 deaths on placebo and 1 death on 1mg, but none on 3 and 10mg groups
- ▶ More patients out of hospital and with no limitations by Day 28 with TD-0903 than placebo

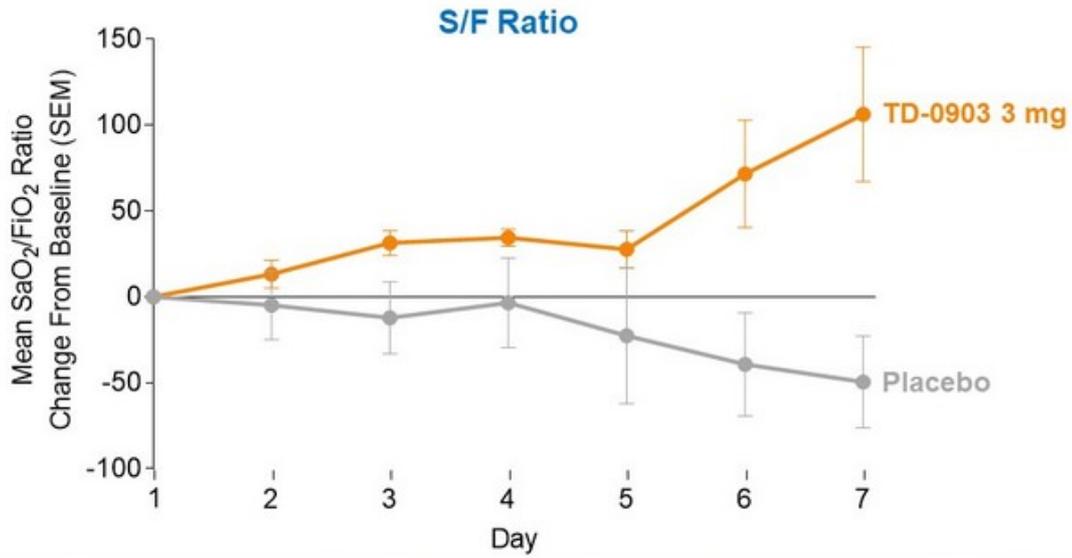


TD-0903 lung-selective profile demonstrates low plasma exposure

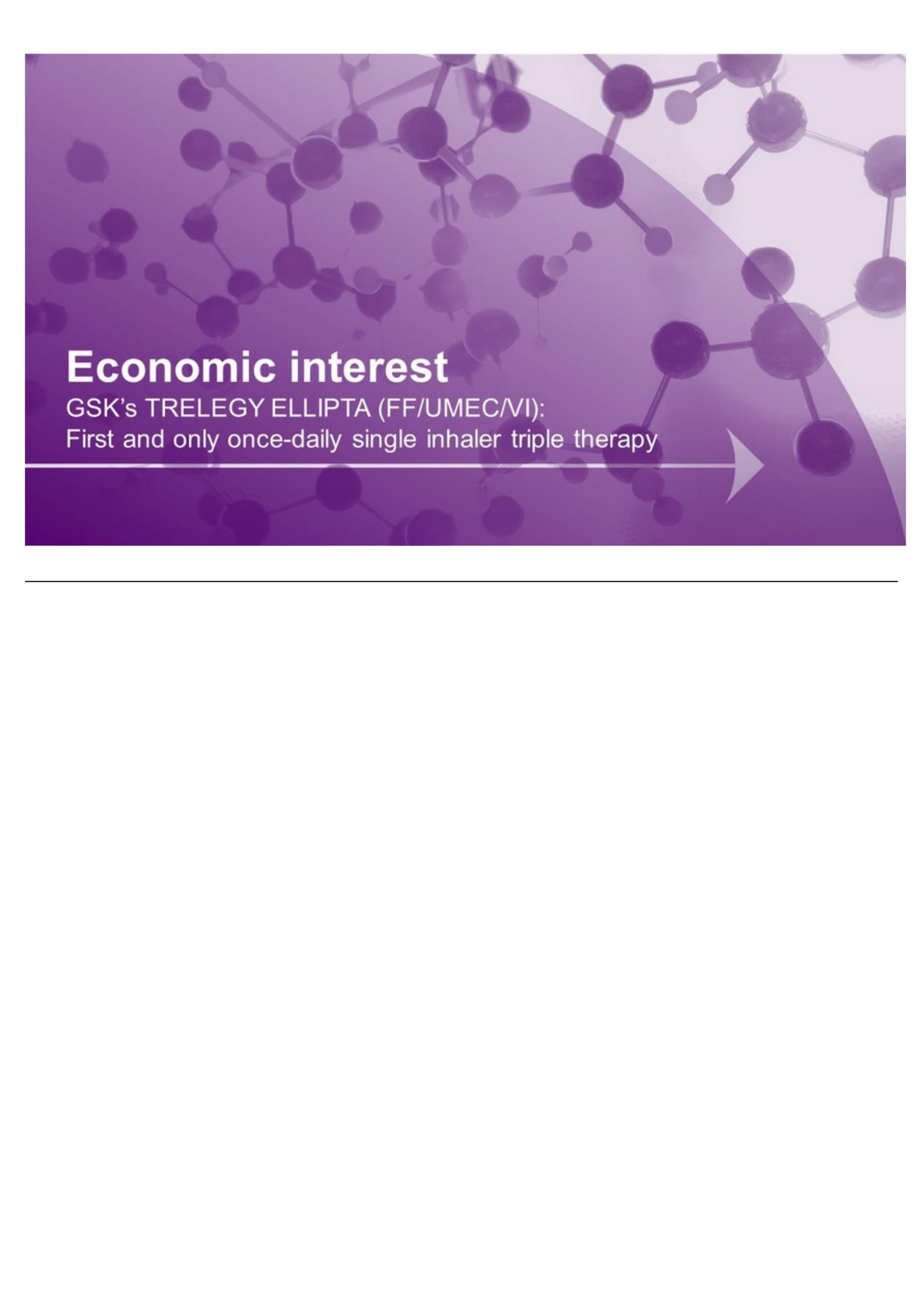
- ▶ Day 7 steady-state exposures of TD-0903 approximately dose proportional
- ▶ Initial loading dose on Day 1 for 1 mg and 3 mg doses in order to achieve near-steady-state exposures as quickly as possible
- ▶ Plasma exposures were low relative to estimated IC_{50} for systemic JAK inhibition



TD-0903 3 mg showed positive trend in improving blood oxygenation versus placebo as measured by S/F Ratio



3 mg progressed to Phase 2 Part 2 with data expected Q2 2021



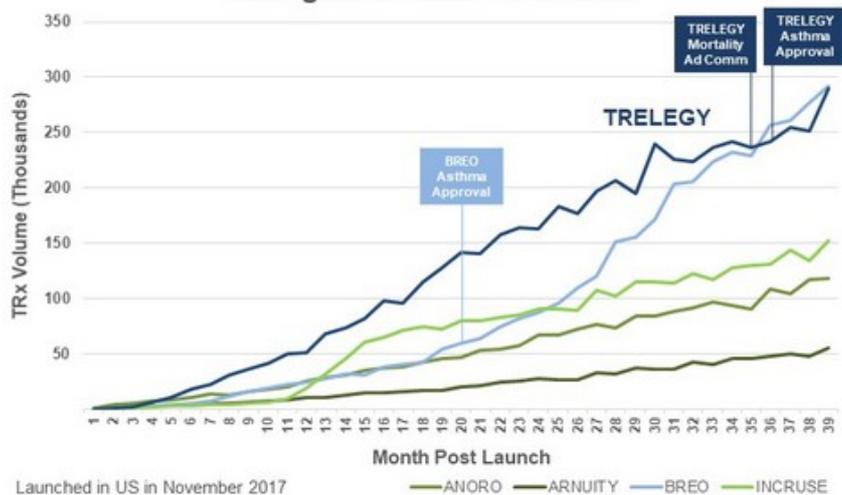
Economic interest

GSK's TRELEGY ELLIPTA (FF/UMEC/VI):
First and only once-daily single inhaler triple therapy

Economic interest in GSK's TRELEGY

Upward-tiering royalties of ~5.5–8.5% of worldwide net sales¹

Strongest US ELLIPTA Launch



TRELEGY

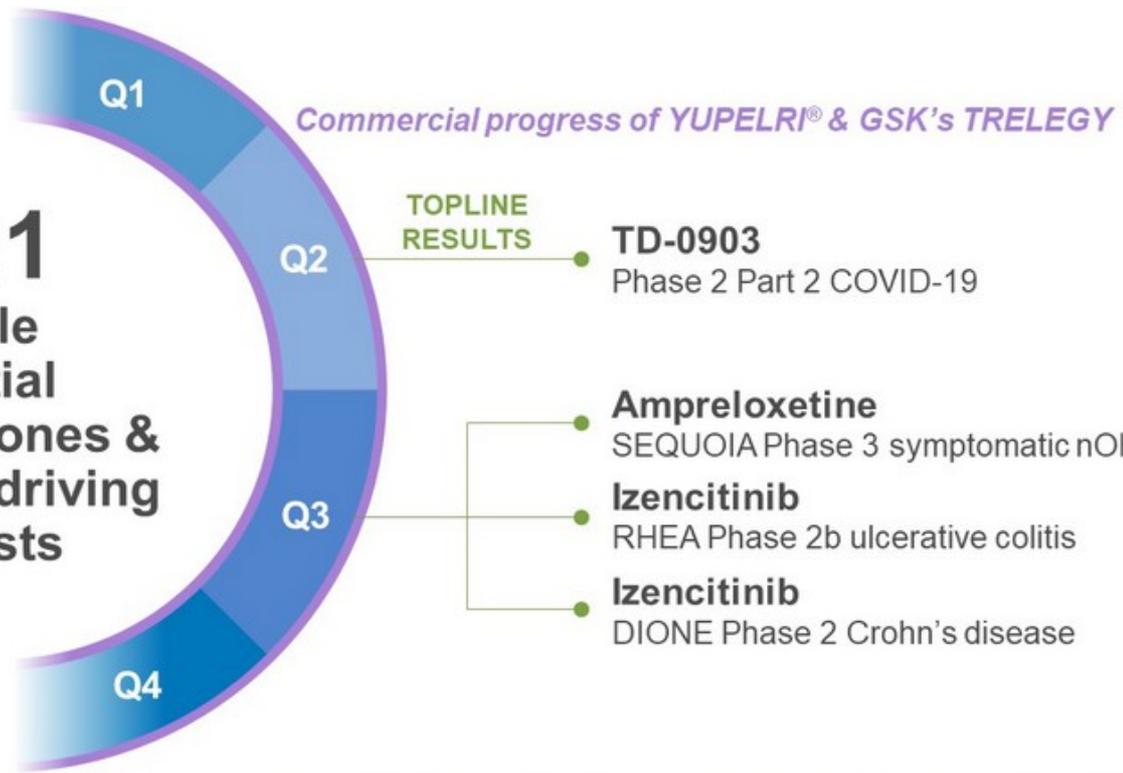
- ✓ Q4 net sales of £238MM (or \$315MM)
- ✓ Full year-over-year sales growth of 60%
- ✓ US asthma indication approved September 9, 2020, and launched Q3
 - ▶ Results from the CAPTAIN study published in *The Lancet Respiratory Medicine*

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 September 2013 through December 2020. IQVIA expressly reserves all rights, including rights of copying, distribution, & republication.

2021 Financial Guidance

	2020 Actuals		2021 Guidance
	GAAP (Including share-based comp)	Non-GAAP (Excluding share-based comp)	Non-GAAP (Excluding share-based comp)
R&D Expense	\$261M	\$230M	\$195M - \$225M
SG&A Expense	\$109M	\$77M	\$80M - \$90M
Total Operating Loss	\$298M	\$235M (used for 2020 guidance)	No Longer a Guidance Metric

2021 Multiple potential milestones & value-driving catalysts



About YUPELRI[®] (revefenacin) inhalation solution

YUPELRI[®] (revefenacin) inhalation solution is a 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.

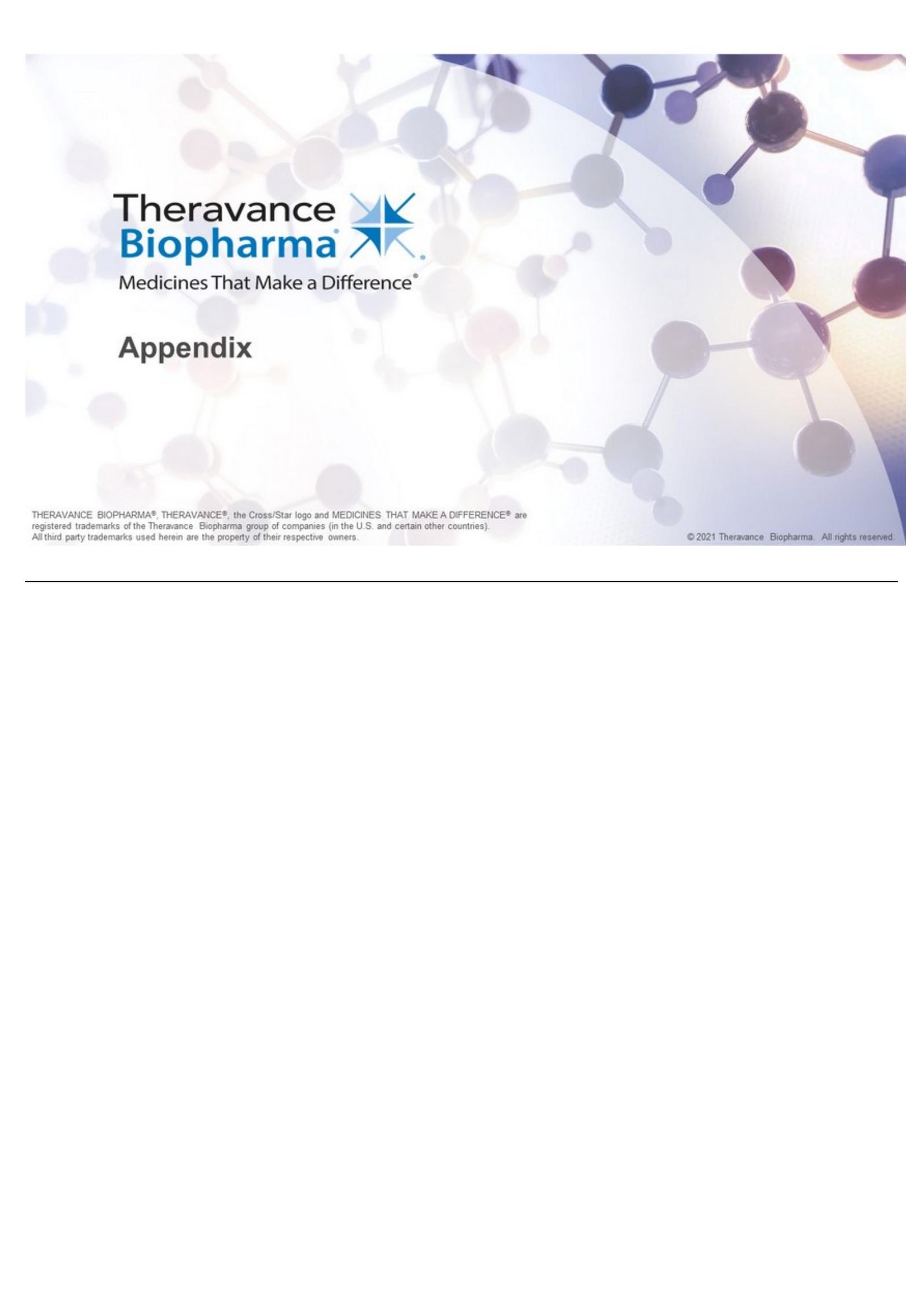
Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

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.

The background of the slide is a complex molecular structure composed of various colored spheres (blue, purple, red, yellow, grey) connected by thin lines, representing atoms and bonds. The structure is set against a light blue and white gradient background.

**Theravance
Biopharma** 
Medicines That Make a Difference®

Appendix

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TD-0903 Program

Nebulized lung-selective pan-JAK inhibitor to treat:

- ▶ Acute hyperinflammation of the lung in COVID-19
- ▶ Chronic inflammation for the treatment and prevention of lung transplant rejection

TD-0903 3 mg reduces relevant systemic biomarkers

