## **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 Re	port (Date of earliest event Reported): May 6,	2020
		VANCE BIOPHARMA, Name of Registrant as Specified in its Charter	
	Cayman Islands (State or Other Jurisdiction of Incorporation)	<b>001-36033</b> (Commission File Number)	98-1226628 (I.R.S. Employer Identification Number)
	(Addresses, including zip code, a	Ugland House, South Church Street own, Grand Cayman, Cayman Islands KY1- (650) 808-6000 and telephone number, including area code, of  intended to simultaneously satisfy the filing of	principal executive offices)
prov	isions (see General Instruction A.2. below):  Written communications pursuant to Rule 425 und	er the Securities Act (17 CFR 230.425)	
	Soliciting material pursuant to Rule 14a-12 under		
	Pre-commencement communications pursuant to F	Rule 14d-2(b) under the Exchange Act (17 CFF	R 240.14d-2(b))
	Pre-commencement communications pursuant to F	Rule 13e-4(c) under the Exchange Act (17 CFR	240.13e-4(c))
	rate by check mark whether the registrant is an emergi ter) or Rule 12b-2 of the Securities Exchange Act of 1		the Securities Act of 1933 (§ 230.405 of this
			Emerging growth company $\Box$
	emerging growth company, indicate by check mark if ed financial accounting standards provided pursuant t		ded transition period for complying with any new or
Secu	rities 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	ТВРН	NASDAQ Global Market

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

On May 6, 2020, Theravance Biopharma, Inc. issued a press release and is holding a conference call regarding its financial results for the quarter ended March 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 May 6, 2020
- 99.2 Slide deck entitled First Quarter 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: May 6, 2020 By: /s/ Andrew Hindman Andrew Hindman

Senior Vice President and Chief Financial Officer



#### Theravance Biopharma, Inc. Reports First Quarter 2020 Financial Results and Provides Business Update

- TD-0903, an investigational lung-selective nebulized Janus kinase inhibitor (JAKi) with the potential to treat Acute Lung Injury in hospitalized patients with COVID-19, has progressed to Phase 1 clinical testing
- Pipeline momentum impacted by COVID-19 disruption, studies continue to enroll; ampreloxetine and TD-1473 study readouts expected to move into 2021
- YUPELRI® (revefenacin) growth continued in first quarter 2020, in partnership with Mylan; trajectory could be affected by COVID-19 in second quarter
- · Maintains 2020 financial guidance

**DUBLIN, IRELAND – MAY 6, 2020 –** Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the first quarter ended March 31, 2020. Revenue for the first quarter 2020 was \$19.9 million. Operating loss was \$72.5 million, or \$57.2 million excluding share-based compensation expense. Cash, cash equivalents and marketable securities totaled \$492.1 million as of March 31, 2020.

"As we are each challenged by COVID-19 – personally and professionally, I want to thank our employees who have supported the communities we serve: the most vulnerable with respiratory illness and immune deficiencies, healthcare professionals across the globe and each other in extremely troublesome times. I could not be prouder, "said Rick E Winningham, Chief Executive Officer: "Theravance Biopharma moved to remote working conditions in early March 2020 for the vast majority of our workforce. Our past investment in technology infrastructure is enabling us to rapidly shift and service our business. Our geographic diversification of clinical trial sites as well as supply chain is minimizing impact on our clinical trial programs. The commitment of our lab-based personnel to work in our laboratories during this time has been crucial to continued progress of our pipeline programs."

"Our commercial team remains focused on delivering YUPELRI to the COPD community – always a vulnerable community and especially during this pandemic – to both the people with COPD and the healthcare professionals that treat them; our team has been continuously available to support them with YUPELRI. As the only once-daily nebulized maintenance therapy for COPD, we believe YUPELRI has made a difference for the community during these challenging times."

"We are well-capitalized to continue our pipeline momentum. We have significantly accelerated internal research and development efforts on TD-0903, a lung-selective nebulized JAKi with the potential to treat hospitalized patients with Acute Lung Injury (ALI) caused by COVID-19 to prevent progression to Acute Respiratory Distress Syndrome (ARDS) and the need for assisted ventilation. The learnings from the early clinical experience of TD-0903 will not only benefit the program in its potential for the treatment of COVID-19 lung hyperinflammation but will inform the broader clinical program in other severe inflammatory conditions of the lung. We are working in close collaboration with our partner, Janssen, on TD-1473, a gut-selective oral JAKi in development for inflammatory intestinal disease and TD-5202, gut-selective irreversible JAK3 inhibitor in development for inflammatory intestinal diseases. TD-8236, our lung-selective dry powder inhaler pan-JAK inhibitor in development for inflammatory lung disease, continues to progress. Ampreloxetine, a norepinephrine reuptake inhibitor (NRI) is under evaluation for treatment of symptomatic neurogenic orthostatic hypotension (nOH), a rare disease, in a Phase 3 clinical program. We continue to move these programs forward despite the significant hurdles imposed by social distancing and government lockdowns around the world."

"As we look ahead, as a company with a legacy in developing respiratory medicines, we hope our inhaled JAK inhibitor program can help make a meaningful contribution to the COVID-19 story as we continue to progress our other high priority programs of TD-1473 and ampreloxetine."



#### **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), reimbursed by Part B Medicare program
- Data as of January 2020 show that YUPELRI achieved an 87% share of the nebulized LAMA market and a 13.7% share of the long-acting nebulized market (including Durable Medical Equipment)
- · YUPELRI is manufactured in the United States and supply chains are monitored regularly; no disruption of supply is currently anticipated
- In-person field calls on YUPELRI ceased as of mid-March 2020; as with most pharmaceuticals, sales momentum has been affected by COVID-19; the team is leveraging established relationships, digital technology, and non-personal promotion to continue the dialogue with stakeholders to continue sales growth; an "Insight and Innovation Think Tank" has been established to evolve "next practices" during the peri- and post-COVID-19 period

#### **Key Pipeline Progress**

The COVID-19 pandemic is a significant threat to public health throughout the world and the Company has been diligently monitoring and adapting to the threat. Theravance Biopharma has been evaluating each of its clinical trial programs to determine necessary modifications and working closely with regulators, ethics committees, sites, CROs and data safety monitoring boards. The Company appreciates the pragmatism, collaboration and the ongoing prioritization of the clinical trial participants and all of those caring for them. Given the significant strains on the healthcare system across the globe, Theravance Biopharma took the decision in mid-March to temporarily suspend adding new patients to the screening phase for its TD-1473 and ampreloxetine trials for 4 weeks, in order to prioritize ongoing support for patients who were already in screening and those patients who were already randomized. As a result, the studies were able to continue randomizing existing screened patients into the studies and the randomized patients were able to continue to receive study medication per the protocol requirements. Screening of new patients is now resuming in some countries in a controlled and measured fashion as individual sites confirm their ability to support the study requirements and new patients are able to be assessed for their eligibility to participate in the studies. The global nature of the TD-1473 and ampreloxetine clinical programs will allow for flexibility as COVID-19 control measures evolve in different countries. The situation is expected to continue to change at different rates in different countries around the world in response to COVID-19 interventions, and as a result it is not possible to provide an accurate re-estimation of expected completion dates for these programs at this time outside of our guidance of shifting data delivery to 2021.

In light of the COVID-19 pandemic, the Company is implementing mitigation plans to ensure patients in the clinical trials have continued access to drug supply and regular visits with their physicians for study visits per trial protocols. The Company continues to develop strategies to reduce patient needs to travel to sites in hopes of avoiding unnecessary exposure while balancing safety monitoring of investigational products. The Company is working closely with regulators and Ethics Committees and taking steps to ensure protection of patients, site personnel and clinical trial integrity.

#### Partnered with Janssen Biotech, Inc.:

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 originally planned for late-2020 and now expected in 2021 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

Ampreloxetine (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 originally planned for late-2020 and now expected in 2021
  - · 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 2H 2020
- · Phase 2 lung allergen challenge initiated in 4Q 2019; data expected 2H 2020

TD-0903 (lung-selective nebulized pan-JAK inhibitor for treatment of Acute Lung Injury caused by COVID-19)

- · Initiated Phase 1 study to assess the safety, tolerability and pharmacokinetics of single- and multiple-ascending doses (SAD/MAD) in healthy volunteers
- The program will then initially move to a nested Phase 2 study in hospitalized patients with COVID-19 with the first part (an ascending dose study) being conducted in the same clinical setting in the UK as the Phase 1 study; the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom approved the Phase 2 study today
- The second part of the Phase 2 study will be a larger, multi-center study conducted at hospital-based clinical sites in the UK, and potentially other clinical sites in the European Union and United States; both of the latter territories would join the Phase 2 study program subject to review and approval of the relevant regulatory approvals required by the relevant EU National Competent Authorities and Food and Drug Administration (FDA)



#### **Economic Interest**

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

- · 1Q 2020 net sales of \$249 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- GSK sNDA for asthma expected 2H 2020; The European Medicines Agency accepted the regulatory submission for the treatment of asthma in adults supported by the Phase III CAPTAIN study; FDA postponed Advisory Committee Meeting originally scheduled for April 21, 2020 regarding mortality sNDA and no additional public information available at this time

#### 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 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 retained by Company.

#### **First Quarter Financial Results**

- Revenue: Revenue for the first quarter of 2020 was \$19.9 million, comprised of collaboration revenue of \$6.6 million primarily attributed to the Janssen collaboration agreement for TD-1473 and \$11.7 million in Mylan collaboration revenue related to YUPELRI. Revenue for the first quarter represents a \$14.5 million increase over the same period in 2019. The increase was primarily due to an increase in Mylan collaboration revenue related to YUPELRI and a larger portion of recognized revenue related to the \$100.0 million upfront payment from the Janssen collaboration agreement that was entered into in February 2018.
- Research and Development Expenses: Research and Development (R&D) expenses for the first quarter of 2020 were \$66.0 million, compared to \$53.8 million in the same period in 2019. The \$12.2 million increase was primarily due to a \$12.4 million increase in external-related expenses related to the advancement of our priority programs, notable TD-1473, ampreloxetine, and TD-8236, a \$1.7 million increase in share-based compensation expense, and a \$2.2 million decrease in employee-related expenses. First quarter R&D expenses included non-cash share-based compensation of \$7.9 million.
- Selling, General and Administrative (SG&A) Expenses: SG&A expenses for the first quarter of 2020 were \$26.3 million, compared to \$25.2 million in the same period in 2019. The \$1.1 million increase was primarily attributed to a \$1.4 million increase in share-based compensation expense, a \$0.8 million increase in employee-related expenses, and a \$0.6 million increase in external-related expenses. These increases were partially offset by a \$1.4 million decrease related to collaboration expenses payable to Mylan in connection with the commercialization of YUPELRI which was formally launched in the first quarter of 2019. First quarter SG&A expenses included non-cash share-based compensation of \$7.4 million.
- Cash, Cash Equivalents and Marketable Securities Cash, cash equivalents and marketable securities totaled \$492.1 million as of March 31, 2020.



#### 2020 Financial Guidance

- **Operating Loss** (excluding share-based compensation): The Company is not changing financial guidance and 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

Additionally, as previously announced, the Company closed its public offering of 5,500,000 ordinary shares at a price to the public of \$27.00 per share on February 14, 2020. The gross proceeds to Theravance Biopharma from the offering are approximately \$148.5 million, before deducting underwriting discounts and commissions and estimated offering expenses.

On March 2, 2020 Theravance Biopharma announced the closing of a private placement of \$400 million in aggregate principal amount of non-recourse 9.5% fixed rate term notes. The notes are secured by a portion of the future payments the Company expects to receive related to royalties due on net sales of TRELEGY ELLIPTA, with 75% of such payments to be used to satisfy the debt obligations until the notes are repaid and the remaining 25% of such payments being directed to benefit the Company on an ongoing basis. The Company used a portion of the net proceeds from this transaction to repay in full the remaining outstanding balance of the \$250 million Triple PhaRMA<sup>SM</sup> 9.0% fixed rate term notes due 2033 and intends to use the remainder of the net proceeds to support continued execution of its key development programs.

#### 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 2 pm PT / 9 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 8371418. Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at <a href="https://www.theravance.com">www.theravance.com</a>, 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 June 5, 2020. An audio replay will also be available through 8:00 pm ET on May 13, 2020 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 8371418.

#### **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<sup>®</sup> and the Cross/Star logo are registered trademarks of the Theravance Biopharma group of companies. YUPELRI<sup>®</sup> 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 2020 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 forwardlooking 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. In addition, while we expect the COVID-19 pandemic to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI, our clinical development programs (in particular our later stage clinical programs for TD-1473 and Ampreloxetine) and the value of and market for our common 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 pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. Other risks affecting Theravance Biopharma are in the company's Form 10-K filed with the SEC on February 27, 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 and Investor Relations 917-214-6603



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

	N	1arch 31, 2020	De	ecember 31, 2019
Assets	(1	U <b>naudited)</b>		(1)
Current assets:				
Cash and cash equivalents and short-term marketable securities	\$	487,031	\$	280,831
Receivables from collaborative arrangements		14,214		11,996
Receivables from licensing arrangements		1,200		10,000
Amounts due from TRC, LLC		26,282		28,574
Other prepaid and current assets		5,491		7,087
Total current assets		534,218		338,488
Property and equipment, net		13,905		12,644
Long-term marketable securities		5,067		4,985
Operating lease assets		46,106		46,604
Restricted cash		833		833
Other assets		5,280		5,272
Total assets	\$	605,409	\$	408,826
	-			
Liabilities and Shareholders' Deficit				
Current liabilities	\$	98,040	\$	111,703
Convertible senior notes due 2023, net		226,158		225,890
Non-recourse notes due 2035, net		373,854		-
Non-recourse notes due 2033, net		-		219,300
Long-term operating lease liabilities		47,199		47,725
Other long-term liabilities		18,094		28,048
Shareholders' deficit		(157,936)		(223,840)
Total liabilities and shareholders' deficit	\$	605,409	\$	408,826

<sup>(1)</sup> 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.

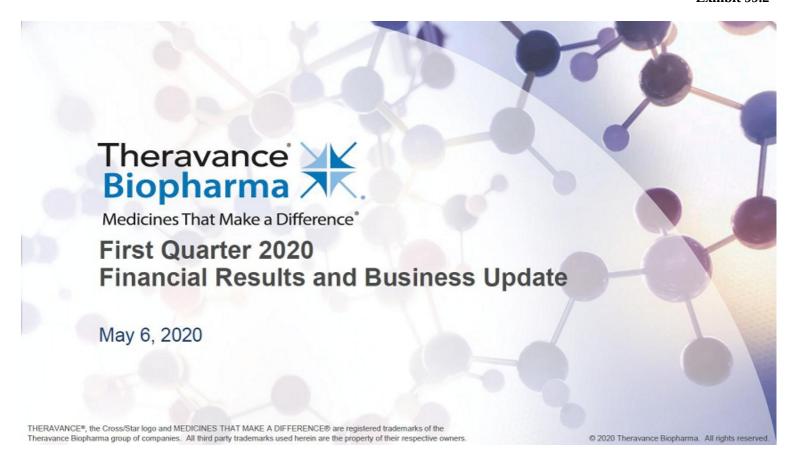


# THERAVANCE BIOPHARMA, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS 3(In thousands, except per share data)

	Three Mont	ıs Ende	led March 31,	
	2020		2019	
	(U	naudite	d)	
Revenue:				
Collaboration revenue	\$ 6,6	32 \$	5,338	
Licensing revenue	1,5	)0	-	
Mylan collaboration agreement	11,7	30	-	
Total revenue	19,8	52	5,338	
Costs and expenses:				
Research and development (1)	66,0	13	53,818	
Selling, general and administrative (1)	26,3		25,186	
Total costs and expenses	92,3		79,004	
Loss from operations	(72,4	76)	(73,666)	
Income from investment in TRC, LLC	13,5	15	6,229	
Interest expense	(9,9	41)	(7,858)	
Loss on extinguishment of debt	(15,4	54)	-	
Interest and other income, net	1,4	50	2,795	
Loss before income taxes	(82,9	06)	(72,500)	
Provision for income tax expense	(1	47)	(80)	
Net loss	\$ (83,0	53) \$	(72,580)	
Net loss per share:				
Basic and diluted net loss per share	\$ (1.	40) \$	(1.32)	
Shares used to compute basic and diluted net loss per share	59,4	53	54,938	

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

	Tl	nree Months E	nded	March 31,	
(In thousands)	·	2020		2019	
Research and development	\$	7,865	\$	6,159	
Selling, general and administrative		7,411		6,061	
Total share-based compensation expense	\$	15,276	\$	12,220	



## 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 2020 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 the impacts on 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, 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-K filed with the SEC on February 27, 2020, and other periodic reports filed with the SEC.



# Q1 Financial results and business update agenda

Introduction	Gail B. Cohen Vice President, Corporate Communications & Investor Relations
Overview	Rick E Winningham Chief Executive Officer
Commercial and	Brett Haumann, M.D. Senior Vice President, Chief Medical Officer
Development Update	Frank Pasqualone Senior Vice President, Chief Commercial Operations Officer
Financial Update	Andrew Hindman Senior Vice President, Chief Financial Officer
Closing Remarks	Rick E Winningham Chief Executive Officer



## Theravance Biopharma response to COVID-19

### SAFEGUARD EMPLOYEES/ COMMUNITIES

- Travel restrictions and remote work since early March
- Lab-based employees, with appropriate safety precautions, contributing in the labs
- Suspended in-person customer visits
- COVID-19 Task Force established

# CLINICAL

- Screening of new patients was temporarily suspended for 4 weeks in mid-March
- Driving to maintain the integrity of our clinical data
- Delays in clinical trial activity; working to minimize impact whilst ensuring safety of patients/study staff

#### YUPELRI®

- Continued need for COPD medications
- ▶ Digital technology playing important role in continuing Field Force dialogue
- Manufactured in the US, no disruption of supply currently anticipated

### WELL CAPITALIZED

Cash, cash equivalents and marketable securities totaled \$492.1M as of March 31, 2020

#### TD-0903

- Lung-selective nebulized pan-JAK inhibitor accelerated into clinical development
- Potential to treat the cytokine storm associated with Acute Lung Injury (ALI) in hospitalized COVID-19 patients



## Pan-JAK inhibitor designed specifically for lung diseases

Leveraging >20 years of experience in design of novel respiratory drugs

#### Respiratory experience

- Historical involvement in development of beta-agonists in collaboration with GSK to support combination therapies (ANORO ELLIPTA, BREO ELLIPTA, TRELEGY ELLIPTA)\*
- Discovered and developed YUPELRI® (revefenacin) inhalation solution, the first and only once-daily, nebulized bronchodilator approved for maintenance treatment for COPD

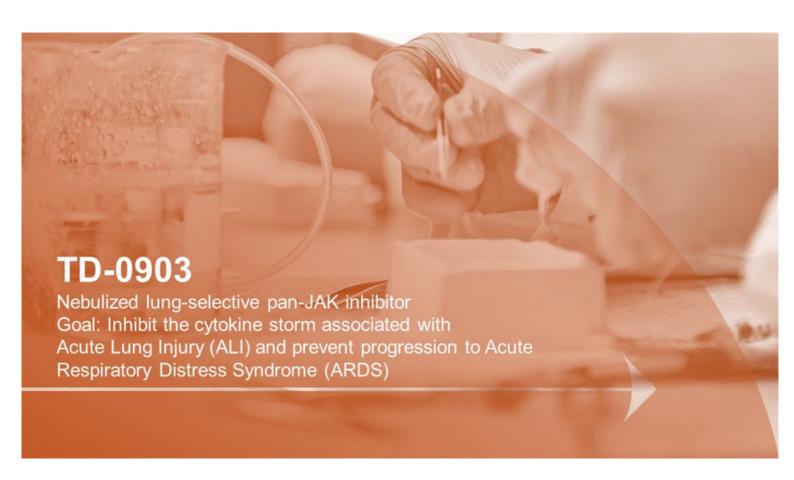
#### Organ-selective therapeutic targets

Driving discovery, development and commercialization of organ-selective small-molecule medicines

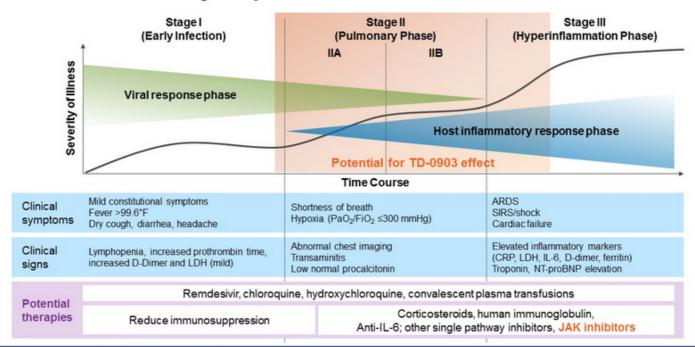




\* Prior to Theravance Biopharma's spin-off from Innoviva, Inc. in June 2014.
COPD, chronic obstructive pulmonary disease, STAT, signal transducer and activator of transcription.



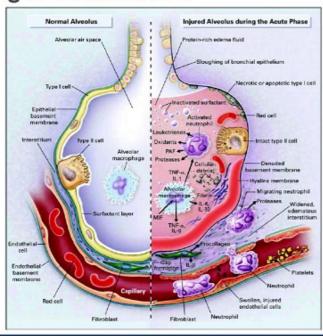
## Host inflammatory response to COVID-19 drives ALI and ARDS



Theravance Biopharma

Adapted from Siddiqi HK, et al. J Heart Lung Transplant 2020 Mar 20.

# Multiple pathogenic processes contribute to alveolar injury during ALI and ARDS<sup>1</sup>



- Host factors driving the initiation and progression of exuberant inflammatory response<sup>2</sup>
  - Rapid viral replication
  - Infection of alveolar epithelial cells
  - Delayed IFN response
  - Macrophage and neutrophil accumulation



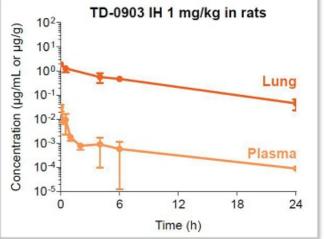
Liu KD, Matthay MA, Clin J Am Soc Nephrol 2008; 3:578-86; 2. Channappanavar R, Perlman S, Semin Immunopathol 2017; 39:529-39.
 IEM. Interferon.

## TD-0903: Potent, lung-selective inhaled pan-JAKi

Design: maximal anti-inflammatory activity in pulmonary tissue while minimizing systemic exposure

- High affinity for JAK1, JAK2, JAK3, and Tyk2 kinase domains
- High potency for inhibition of cytokine-induced activation of JAK-STAT signaling pathways
  - In vitro: human epithelial and immune cells
  - In vivo: murine inhalation cytokine-challenge models
- Lung-selective design
  - High lung-to-plasma ratios in pre-clinical species
  - Rapid systemic clearance with no evidence of systemic immunosuppression
  - PK/PD modeling supports extended duration of action
- Well tolerated in 28-day GLP studies







Bronchoalveolar lavage mulo lymphocytes and relevant mediators inhibited by QA tool JAK inhibitor 1 H06692.

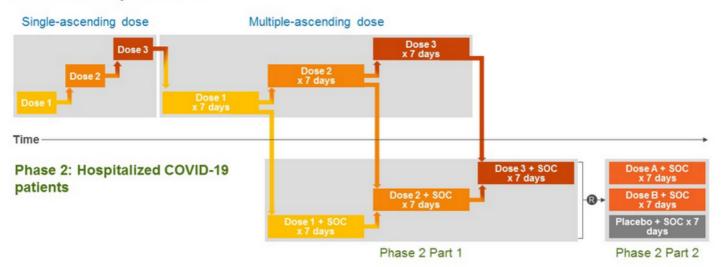
Based on internal data on file.

Tak Tymphine kinese.

# TD-0903: Development plan designed to progress rapidly

Program is subject to ongoing regulatory and IRB review and approval

### Phase 1: Healthy volunteers

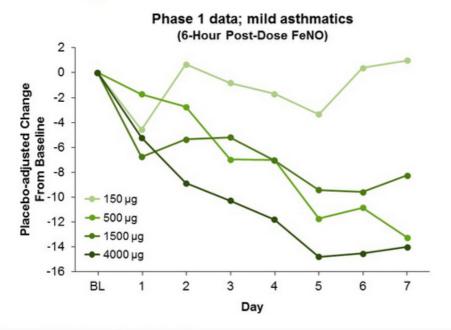


SOC, standard of care.



# 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 2H 2020



FeNO, fractional exhaled nitric exi

## 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









# 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 COPD<sup>1</sup>

9% of COPD patients (~800,000) use nebulizers for ongoing maintenance therapy; 41% use nebulizers at least occasionally for bronchodilator therapy<sup>2</sup>

Nebulized therapy associated with reduced hospital readmissions in low PIFR patients<sup>3</sup>









TBPH and MYL worldwide strategic collaboration to develop and commercialize nebulized YUPELRI® (revefenacin)¹



Companies copromote under US profit/loss share



1. Global Strategy for Diagnosis, Management, and Prevention of COPD, 2018; 2. TBPH market research (N = 160 physicians); refers to US COPD patients 3. Loh CH, et al. Ann Am Thorac Soc. 2017 Aug;14:1305-11.

## YUPELRI® launch metrics

Strong customer acceptance and market uptake

### 

176 wins (equates to 312 accounts)

~90 reviews scheduled (>475 potential accounts)

100% medical support requests fulfilled <30 days

### PATIENT

Field force productivity goals exceeded

~40,000 patients2 prescribed (through Q1 2020)

### ACCESS

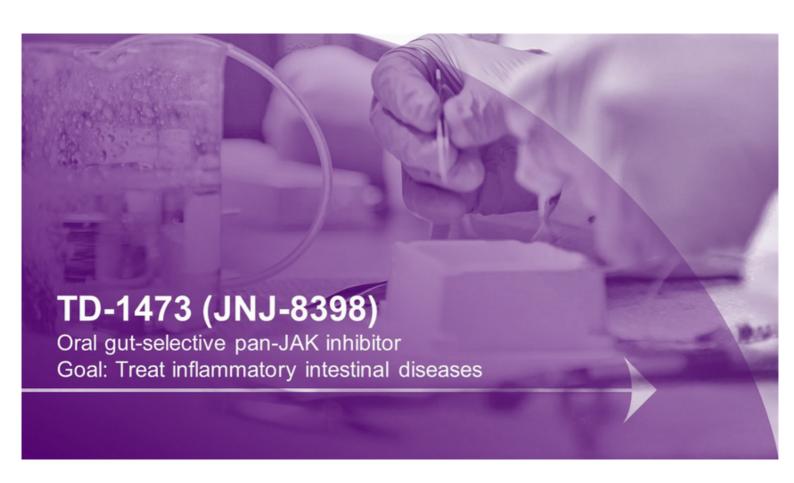
100% Medicare Part B3

61% of commercial payer coverage YUPELRI® (comprises ~8% of the YUPELRI® business)

Permanent J-CODE (J-7677) issued4

Majority of YUPELRI® volume flows through durable medical equipment channel (approximately 3-month lag in data capture); remaining volume flows through hospitals, retail and long-term care pharmacies. Wholesale acquisition cost (WAC): \$1,066 per month (or ~\$35 per day).

1. As of April 30, 2020. 2. TBPH estimate derived from integrating multiple data sources. 3. For patients with supplemental insurance. 4. Effective July 1, 2019.



Journal of Crohn's and Colitis, 2020, 1–12 doi:10.1093/ecco-jcc/jjaa049 Advance Access publication March 11, 2020 Original Article



### Original Article

## Development of Gut-Selective Pan-Janus Kinase Inhibitor TD-1473 for Ulcerative Colitis: A Translational Medicine Programme

William J. Sandborn, a,\* Deanna D. Nguyen, b,\* David T. Beattie, b,† Patrick Brassil, b Whitney Krey, b,† Jacky Woo, b Eva Situ, b,† Reuben Sana, b Erik Sandvik, b M. Teresa Pulido-Rios, b Raj Bhandari, c Jonathan A. Leighton, d Ravi Ganeshappa, b David L. Boyle, f Brihad Abhyankar, Melanie A. Kleinschek, b Richard A. Graham, b Julian Panesh



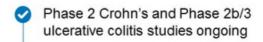


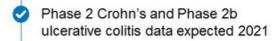
## TD-1473: Gut-selective pan-JAK inhibitor

Late-stage studies in Crohn's disease and ulcerative colitis





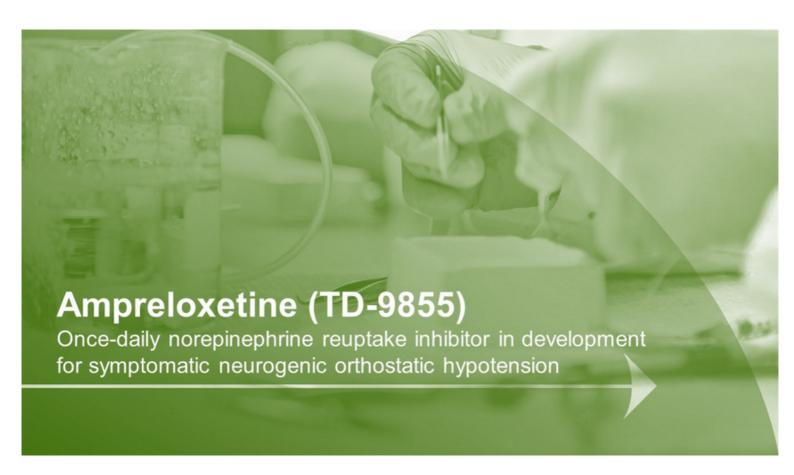




Global collaboration with Janssen leverages joint development expertise and provides significant economics to TBPH<sup>2</sup>



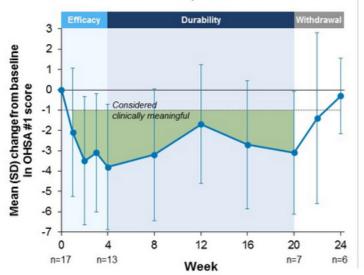
Maintenance phase of the study will have induction responder patients re-randomized to active doses compared to placebo at 44 weeks.
 Deal value up to \$18 in payments to TBPH, including \$100M upfront; proft-share in US (33% TBPH, 67% Janssen); double-digit royaties to TBPH ex-US



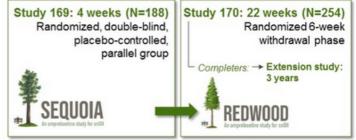
# Ampreloxetine: Potential to provide meaningful and durable symptom improvement to underserved patients

## Ampreloxetine

Phase 2 data in nOH; 20 weeks of treatment



### Phase 3 Registrational Program



Phase 3 registrational program ongoing; 4-week efficacy data expected 2021

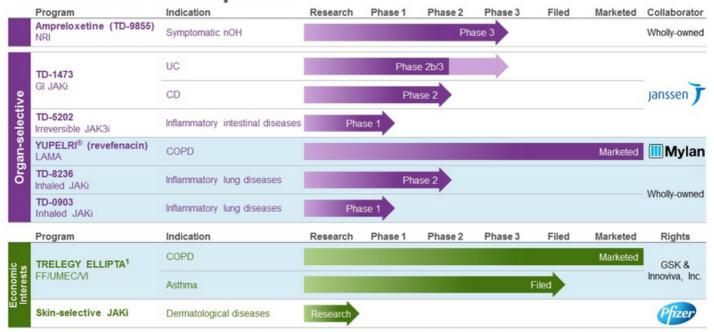


Baseline OHSA #1 (Orthostatic Hypotension Symptom Assessment Question 1) >4 points.

Negative change indicates improvement in symptoms, improvement of 1 point is defined as the MCD (minimal clinically important difference).

ITT. intention-te-treat nOH neuroenic orthostatic hypotension: SD. standard deviation.

# Key programs supported by proven development and commercial expertise



Theravance Biopharma M. MedidnesThat Make a Difference

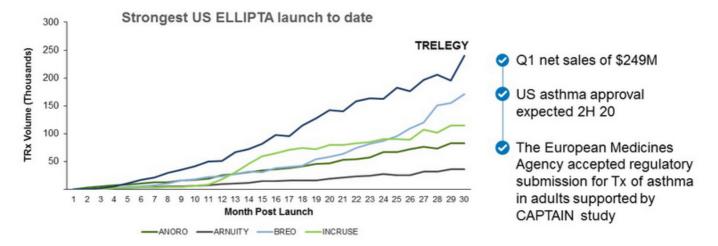
1. IBM1 holds 85% economic interest in upward-terming royarty stream of 6.5% = 10% payable by GSK (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC greement over the next four fiscaliquaters). 75% of royalizes received retained by TBPH. All statements concerning TRELEGY ELLPTA based or subtley available information.

3. quartonized in corepination.



## **Economic interest in GSK's TRELEGY ELLIPTA**

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



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



1. TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC Agreement over the next four fiscal quarters) 75% of royalties piedged to service outstanding notes, 25% of royalties retained by TBPH. Our non-recourse Triple II 9.5% Fixed Rate Term Notes due on or before 2035 All statements concerning TRELEGY ELLIPTA based on publicly available information. TRELEGY ELLIPTA is FF/UNEC/VI or fluticasone furoate/umecidinium/vilanterol; comprised of ICS, LAMA, and LABA, active components of Anoro (UNEC/VI).

# First quarter 2020 financial highlights Well capitalized with \$492.1M<sup>1</sup> as of March 31, 2020

1 WILL \$492. TW as OF Walter 51, 2020	Three Months Ended March 31		
\$, in thousands	2020	2019	
	(Unaudited)		
Collaboration revenue	6,632	5,338	
Licensing revenue	1,500	_	
Mylan collaboration agreement	11,730	_	
Total revenue	19,862	5,338	
Research and development <sup>2</sup>	66,013	53,818	
Selling, general and administrative <sup>2</sup>	26,325	25,186	
Total costs and expenses	92,338	79,004	
Loss from operations	(72,476)	(73,666)	
Share-based compensation expense:			
Research and development	7,865	6,159	
Selling, general and administrative	7,411	6,061	
Total share-based compensation expense	15,276	12,220	
Operating loss excluding share-based compensation	(57,200)	(61,446)	





# Multiple potential milestones and value-driving catalysts expected in 2020, 2021 and beyond

## TD-5202 Phase 1 topline data TD-0903 Phase 1 study in healthy volunteers in the UK Phase 2 study in hospitalized patients with COVID-19 in the UK - Part 2: multi-center study conducted at hospital-based clinical sites in the UK, and potentially other clinical sites in the European Union and United State TD-8236 Phase 1 Part C data in severe asthmatics Phase 2 allergen challenge data GSK's TRELEGY ELLIPTA<sup>1</sup> FDA decision for asthma and separately for mortality benefit vs. ANORO in COPD 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 GSK's TRELEGY ELLIPTA



TBPH holds 85% economic interest in upward-tiering royally stream of 6.5% — 10% payable by GSK (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC Agreement over the next four fiscal quarters). 75% of royalties received pledged to service outstanding notes, 25% of royalties received retained by TBPH. All statements concerning TRELEGY ELLIPTA based on publicly available information.

## In conclusion



- Staying focused in respiratory and advancing our innovative lungselective pipeline with TD-0903 and TD-8236
- Continuing to drive YUPELRI® sales growth



 Continuing our strong collaboration with Janssen on our gut-selective compounds TD-1473 and TD-5202



Committed to the patients who need treatment alternatives for nOH, a rare disease, and progressing advancement of ampreloxetine

Theravance Biopharma's commitment to our mission, to 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... has never been stronger.



# 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.



1. TBPH market research (N=160 physicians); refers to US COPD patients

## 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.



OATP, organic anion transporting polypeptide