United Therapeutics Corporation Reports Second Quarter 2021 Financial Results

Tyvaso® (treprostinil) Inhalation Solution net revenue growth of 29% year over year; total net revenue growth of 23% year over year

Tyvaso DPI™ NDA under review with FDA action expected in October 2021

SILVER SPRING, MD. and RESEARCH TRIANGLE PARK, N.C., August 4, 2021: United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the quarter ended June 30, 2021. Total revenue in the second quarter of 2021 grew 23% year over year to $446.5 million, compared to $362.0 million in the second quarter of 2020.

"We are pleased to continue our expansion into new indications outside of WHO Group 1 PAH with strong Tyvaso financial results, and with patient enrollment continuing in our *PERFECT* and *TETON* phase 3 studies in COPD-associated pulmonary hypertension and in IPF, respectively," said Martine Rothblatt, Ph.D., Chairperson and Chief Executive Officer of United Therapeutics. "Meanwhile, we are also focused on expanding our medical armamentarium for PAH with the continued progress of our phase 3 studies of once-daily ralinepag, and with our next-generation treprostinil molecules and delivery systems."

"As we build traction with the Tyvaso PH-ILD launch, I am also tremendously excited about the uptake of all of our products during the past quarter," said Michael Benkowitz, President and Chief Operating Officer of United Therapeutics. "Indeed, we are currently seeing some of the highest levels of referrals of Tyvaso and Orenitram since their launches and we're well on our way to our goal of doubling the number of Tyvaso patients on therapy by the end of 2022."

SECOND QUARTER 2021 FINANCIAL RESULTS

Key financial highlights include (dollars in millions, except per share data):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020		
Revenues	$ 446.5	$ 362.0	$ 84.5	23 %
Net income	$ 172.6	$ 107.1	$ 65.5	61 %
Non-GAAP earnings[1]	$ 193.5	$ 163.2	$ 30.3	19 %
Net income, per basic share	$ 3.85	$ 2.43	$ 1.42	58 %
Net income, per diluted share	$ 3.65	$ 2.41	$ 1.24	51 %
Non-GAAP earnings, per diluted share[1]	$ 4.09	$ 3.68	$ 0.41	11 %

(1) See definition of non-GAAP earnings, a non-GAAP financial measure, and a reconciliation of net income to non-GAAP earnings below.

Revenues

The table below summarizes the components of total revenues (dollars in millions):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020		
Net product sales:				
Remodulin®	$ 139.8	$ 119.0	$ 20.8	17 %
Tyvaso®	153.8	119.2	34.6	29 %
Orenitram®	76.2	75.4	0.8	1 %
Unituxin®	53.1	29.0	24.1	83 %
Adcirca®	23.6	19.4	4.2	22 %
Total revenues	**$ 446.5**	**$ 362.0**	**$ 84.5**	**23 %**

Net product sales from our treprostinil-based products (Remodulin, Tyvaso, and Orenitram) grew by $56.2 million in the second quarter of 2021 compared to the second quarter of 2020. The increase in Remodulin revenues was driven by a $19.0 million increase in sales outside the United States. While generic competition continues to increase pressure on our international Remodulin revenues, this increase primarily reflects the irregular ordering patterns we typically experience with our international distributors. The growth in Tyvaso revenues resulted primarily from an increase in quantities sold, reflecting an increased number of patients following the pulmonary hypertension associated with interstitial lung disease (**PH-ILD**) label expansion. The growth in Unituxin revenues resulted primarily from an increase in quantities sold.

Expenses

Cost of product sales. The table below summarizes cost of product sales by major category (dollars in millions):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020		
Category:				
Cost of product sales	$ 35.8	$ 23.9	$ 11.9	50 %
Share-based compensation expense[(1)]	1.4	2.0	(0.6)	(30)%
Total cost of product sales	**$ 37.2**	**$ 25.9**	**$ 11.3**	**44 %**

(1) Refer to *Share-based compensation* below.

Cost of product sales, excluding share-based compensation. Cost of product sales for the three months ended June 30, 2021 increased as compared to the same period in 2020, primarily due to an increase in product costs due to an overall increase in sales.

Research and development expense. The table below summarizes research and development expense by major category (dollars in millions):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020		
Category:				
Research and development projects	$ 69.5	$ 78.3	$ (8.8)	(11)%
Share-based compensation expense[(1)]	4.8	11.4	(6.6)	(58)%
Total research and development expense	**$ 74.3**	**$ 89.7**	**$ (15.4)**	**(17)%**

(1) Refer to *Share-based compensation* below.

Research and development expense, excluding share-based compensation. Research and development expense for the three months ended June 30, 2021 decreased as compared to the same period in 2020, primarily due to: (1) a decrease in milestone payments for the Tyvaso DPI program; (2) a decrease in spending due to the completion of the phase 3 *DISTINCT* study of Unituxin in 2020; and (3) a decrease in spending following our decision to discontinue development of biomechanical lungs in March 2021.

Selling, general, and administrative expense. The table below summarizes selling, general, and administrative expense by major category (dollars in millions):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020		
Category:				
General and administrative	$ 72.8	$ 54.8	$ 18.0	33 %
Sales and marketing	17.1	12.7	4.4	35 %
Share-based compensation expense[(1)]	22.9	38.4	(15.5)	(40)%
Total selling, general, and administrative expense	**$ 112.8**	**$ 105.9**	**$ 6.9**	**7 %**

(1) Refer to *Share-based compensation* below.

General and administrative, excluding share-based compensation. The increase in general and administrative expense for the three months ended June 30, 2021, as compared to the same period in 2020, was primarily due to: (1) an increase in legal expenses related to litigation matters; (2) an increase in expenses related to disposals of property, plant, and equipment; and (3) an increase in consulting expenses.

Share-based compensation. The table below summarizes share-based compensation expense by major category (dollars in millions):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020		
Category:				
Stock options	$ 5.7	$ 9.2	$ (3.5)	(38)%
Restricted stock units	6.5	5.5	1.0	18 %
Share tracking awards plan (**STAP**)	16.4	36.7	(20.3)	(55)%
Employee stock purchase plan	0.5	0.4	0.1	25 %
Total share-based compensation expense	**$ 29.1**	**$ 51.8**	**$ (22.7)**	**(44)%**

The decrease in share-based compensation expense for the three months ended June 30, 2021, as compared to the same period in 2020, was primarily due to: (1) a decrease in STAP expense driven by a seven percent increase in our stock price for the three months ended June 30, 2021, as compared to a 28 percent increase in our stock price for the same period in 2020; and (2) a decrease in stock option expense due to fewer awards granted and outstanding in 2021.

Other expense, net. The change in other expense, net for the three months ended June 30, 2021, as compared to the same period in 2020, was primarily due to net unrealized and realized gains and losses on equity securities.

Income tax expense. Income tax expense for the three months ended June 30, 2021 and 2020, was $43.9 million and $26.8 million, respectively. The effective income tax rate was 20 percent for the three months ended June 30, 2021 and 2020.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income, adjusted for: (1) share-based compensation expense (including expenses relating to stock options, restricted stock units, share tracking awards, and our employee stock purchase plan); (2) impairment charges; (3) net changes in recurring fair value measurements; (4) license-related fees; (5) unrealized gains on investments in privately-held companies; (6) purchase of a priority review voucher; and (7) tax impact on non-GAAP earnings adjustments.

A reconciliation of net income to non-GAAP earnings is presented below (in millions, except per share data):

	Three Months Ended June 30,	
	2021	2020
Net income, as reported	$ 172.6	$ 107.1
Adjusted for the following items:		
Share-based compensation expense[1]	29.1	51.8
Impairment charges[2]	2.3	—
Net changes in recurring fair value measurements[3]	2.1	8.9
License-related fees[4]	—	12.5
Unrealized gains on investments in privately-held companies	—	—
Purchase of a priority review voucher	—	—
Tax benefit	(12.6)	(17.1)
Non-GAAP earnings	**$ 193.5**	**$ 163.2**
Non-GAAP earnings per share:		
Basic	**$ 4.32**	**$ 3.70**
Diluted	**$ 4.09**	**$ 3.68**
Weighted average number of common shares outstanding:		
Basic	**44.8**	**44.1**
Diluted	**47.3**	**44.4**

(1) Recorded within *operating expenses* on our consolidated statements of operations.

(2) For the three months ended June 30, 2021, we recognized impairment charges of $2.3 million related to investments in privately-held companies. These impairment charges were recorded within *impairments of investments in privately-held companies* on our consolidated statements of operations.

(3) For the three months ended June 30, 2021 and June 30, 2020, we recognized $1.3 million of net unrealized losses and $8.9 million of net unrealized and realized losses, respectively, on equity securities issued by public companies. For the three months ended June 30, 2021, we recognized a $0.8 million loss related to changes in the fair values of our contingent consideration assets. The net unrealized and realized losses on equity securities and changes in fair value of our contingent consideration assets were recorded within *other expense, net* on our consolidated statements of operations.

(4) Recorded within *research and development* on our consolidated statements of operations.

PRODUCT COMMERCIALIZATION UPDATE

Thus far in 2021, we launched one new product and one new product indication. In February 2021, we launched commercial sales of the Remunity Pump for Remodulin, and in April 2021, we launched a label expansion for Tyvaso to include an indication for PH-ILD following approval by the U.S. Food and Drug Administration (**FDA**) on March 31, 2021. We expect FDA action on our Tyvaso DPI new drug application (**NDA**) in October 2021.

Remunity Pump for Remodulin. In February 2021, we launched sales of the Remunity Pump for Remodulin. The Remunity Pump is a pre-filled, semi-disposable system for subcutaneous delivery of treprostinil. The system consists of a small, lightweight, durable pump and controller designed to have a service life of at least three years. The pump uses disposable cartridges filled with Remodulin, which can be connected to the pump with less patient manipulation than is typically involved in filling other currently-available subcutaneous pumps.

Tyvaso Inhalation Solution in PH-ILD. In February 2020, the *INCREASE* study of Tyvaso in patients with PH-ILD met its primary endpoint of demonstrating improvement in six-minute walk distance (**6MWD**). Tyvaso also showed benefits across several key subgroups, including etiology of PH-ILD, disease severity, age, gender, baseline hemodynamics, and dose. Significant improvements were also observed in each of the study's secondary endpoints, including reduction in the cardiac biomarker NT-proBNP, time to first clinical worsening event, change in peak 6MWD at week 12, and change in trough 6MWD at week 15. Treatment with Tyvaso of up to 12 breaths per session, four times daily, in the *INCREASE* study was well tolerated and the safety profile was consistent with previous Tyvaso studies and known prostacyclin-related adverse events. Comprehensive data from the *INCREASE* study were published in the *New England Journal of Medicine*.

The FDA approved Tyvaso for the PH-ILD indication on March 31, 2021, and we launched commercial efforts for the new indication shortly thereafter.

Tyvaso DPI. In April 2021, we submitted an NDA for Tyvaso DPI for pulmonary arterial hypertension (**PAH**) and PH-ILD indications. The FDA accepted our NDA for review, and we expect the agency's review to be complete in October 2021. This represents an expedited review timeframe as a result of our use of the priority review voucher we purchased for $105.0 million in January 2021. The FDA has indicated that approval of the NDA would be subject to an inspection of the Tyvaso DPI manufacturing facility in Danbury, Connecticut, operated by our partner MannKind Corporation, which has been commenced by the FDA and is ongoing.

Our Tyvaso DPI NDA includes the results of two clinical studies we conducted of Tyvaso DPI. One was a study in healthy volunteers, comparing the pharmacokinetics of Tyvaso DPI to Tyvaso Inhalation Solution. The study was completed in October 2020, and demonstrated comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution. In December 2020, we completed a clinical study (called *BREEZE*), which evaluated the safety and pharmacokinetics of switching PAH patients from Tyvaso Inhalation Solution to Tyvaso DPI. The *BREEZE* study demonstrated the safety and tolerability of Tyvaso DPI in subjects with PAH transitioning from Tyvaso Inhalation Solution, and comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution.

Implantable System for Remodulin. In June 2021, we and Medtronic, Inc. (**Medtronic**) agreed to discontinue further efforts to develop and commercialize the Implantable System for Remodulin (**ISR**). We are working with Medtronic on a mutually-agreed approach to wind-down the development program, and to support patients already enrolled in clinical studies of the ISR, at United Therapeutics' sole expense.

RESEARCH AND DEVELOPMENT UPDATE

Updates on select later-stage programs are below.

Tyvaso in chronic fibrosing interstitial lung diseases — *TETON*. We have launched a new phase 3 program called *TETON*, which will be comprised of one or more phase 3 studies of Tyvaso in subjects with various forms of chronic fibrosing interstitial lung diseases, including patients with idiopathic interstitial pneumonias (**IIP**), chronic hypersensitivity pneumonitis (**CHP**), and environmental/occupational lung disease. The first *TETON* study is enrolling subjects with idiopathic pulmonary fibrosis. The primary endpoint of this study is the change in absolute forced vital capacity (**FVC**) from baseline to week 52.

The *TETON* program was prompted by data from the *INCREASE* study, which demonstrated improvements in certain key parameters of lung function in pulmonary hypertension patients with fibrotic lung disease. Specifically, in the *INCREASE* study, treatment with Tyvaso resulted in significant improvements in percent predicted FVC at weeks 8 and 16, with subjects having underlying etiologies of IIP showing greater improvement. Consistent positive effects were also observed in patients with CHP and environmental/occupational lung disease. These data points, combined with substantial preclinical evidence of antifibrotic activity of treprostinil, suggest that Tyvaso may offer a treatment option for patients with fibrotic lung disease.

Tyvaso in PH-COPD — *PERFECT*. Enrollment is ongoing for the phase 3 *PERFECT* study evaluating Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with chronic obstructive pulmonary disease (**PH-COPD**). In a 30-week crossover study, 136 subjects will be randomized between inhaled treprostinil and placebo for a 26-week treatment period. The primary endpoint of the study is the change in 6MWD from baseline to week 12.

Ralinepag phase 3 clinical studies — *ADVANCE CAPACITY* and *ADVANCE OUTCOMES*. We are enrolling two phase 3 clinical studies to support the potential approval of oral ralinepag for PAH.

INDUCEMENT RESTRICTED STOCK UNITS

On July 30, 2021, we granted a total of 141 restricted stock units under our 2019 Inducement Stock Incentive Plan to one newly hired employee. These restricted stock units vest in three equal installments on July 31, 2022, 2023, and 2024, assuming continued employment on such dates, and are subject to the standard terms and conditions we filed with the SEC as Exhibit 10.2 to our Current Report on Form 8-K on March 1, 2019. We are providing this information in accordance with Nasdaq Listing Rule 5635(c)(4).

WEBCAST

We will host a webcast to discuss our second quarter 2021 financial results on Wednesday, August 4, 2021, at 9:00 a.m. Eastern Time. The webcast can be accessed live via our website at https://ir.unither.com/events-and-presentations/default.aspx. A replay of the webcast will also be available at the same location on our website.

UNITED THERAPEUTICS: ENABLING INSPIRATION

United Therapeutics Corporation focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture, and our bioinformatics leadership. We also believe that our determination to be responsible citizens — having a positive impact on patients, the environment, and society — will sustain our success in the long term.

Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are focused on addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company.

Please visit unither.com to learn more.

NON-GAAP FINANCIAL INFORMATION

This press release contains a financial measure, non-GAAP earnings, which does not comply with United States generally accepted accounting principles (**GAAP**). This measure supplements our financial results prepared in accordance with GAAP as reported below.

We use non-GAAP earnings to assist us in: (1) planning, including the preparation of our annual operating budget; (2) allocating resources in an effort to enhance the financial performance of our business; (3) evaluating the effectiveness of our operational strategies; and (4) assessing our capacity to fund capital expenditures and expand our business. We believe this non-GAAP financial measure improves investors' understanding of our financial results by providing greater transparency with respect to the information our management uses to evaluate and compare the performance of our core operations and make operating decisions. This non-GAAP financial measure enables investors to see our business through the eyes of our management. However, there are limitations in the use of this non-GAAP financial measure in that it excludes certain operating expenses that are recurring in nature. In addition, our calculation of this non-GAAP financial measure may differ from the methodology used by other companies. The presentation of this non-GAAP financial measure should not be considered in isolation or as a substitute for our financial results prepared in accordance with GAAP. A reconciliation of net income, the most directly comparable GAAP financial measure, to non-GAAP earnings can be found in the table above under the heading, *Non-GAAP Earnings*.

FORWARD-LOOKING STATEMENTS

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, our prospects following the launches of our Remunity Pump for Remodulin and Tyvaso for patients with PH-ILD, our expectations concerning the timing and success of our efforts to obtain the necessary FDA approvals to launch Tyvaso DPI, statements regarding our research and development plans related to the *PERFECT* and *TETON* studies of Tyvaso, the *ADVANCE* studies of ralinepag, and our organ transplantation programs, and our expectation that we will sustain our success in the long-term. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic reports filed with the Securities and Exchange Commission, that could cause actual results to differ materially from anticipated results. These risks include, in particular, the risk that we will not obtain the necessary FDA approvals to launch Tyvaso DPI. Consequently, such forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of August 4, 2021, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events, or any other reason.

ORENITRAM, REMODULIN, REMUNITY, TYVASO, and UNITUXIN are registered trademarks of United Therapeutics Corporation and its subsidiaries.

TYVASO DPI is a trademark of United Therapeutics Corporation.

ADCIRCA is a registered trademark of Eli Lilly and Company.

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In millions, except per share data)

	Three Months Ended June 30,	
	2021	2020
	(Unaudited)	
Revenues:		
Net product sales	$ 446.5	$ 362.0
Total revenues	446.5	362.0
Operating expenses:		
Cost of product sales	37.2	25.9
Research and development	74.3	89.7
Selling, general, and administrative	112.8	105.9
Total operating expenses	224.3	221.5
Operating income	222.2	140.5
Interest income	4.0	7.2
Interest expense	(4.7)	(5.6)
Other expense, net	(2.7)	(8.2)
Impairments of investments in privately-held companies	(2.3)	—
Total other expense, net	(5.7)	(6.6)
Income before income taxes	216.5	133.9
Income tax expense	(43.9)	(26.8)
Net income	**$ 172.6**	**$ 107.1**
Net income per common share:		
Basic	**$ 3.85**	**$ 2.43**
Diluted	**$ 3.65**	**$ 2.41**
Weighted average number of common shares outstanding:		
Basic	**44.8**	**44.1**
Diluted	**47.3**	**44.4**

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	June 30, 2021
Cash, cash equivalents, and marketable investments	$ 3,292.9
Total assets	4,844.9
Total liabilities	1,205.4
Total stockholders' equity	3,639.5

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