For immediate release

UNITED THERAPEUTICS CORPORATION REPORTS FIRST QUARTER 2021 FINANCIAL RESULTS

*Tyvaso® (treprostinil) Inhalation Solution approved for pulmonary hypertension associated with interstitial lung disease (**PH-ILD**)*

*Tyvaso DPI™ New Drug Application (**NDA**) submitted to U.S. Food and Drug Administration*

*TETON study of Tyvaso in idiopathic pulmonary fibrosis (**IPF**) expected to enroll its first patients in the second quarter of 2021*

SILVER SPRING, MD. AND RESEARCH TRIANGLE PARK, N.C., May 5, 2021: United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the quarter ended March 31, 2021. Total revenue in the first quarter of 2021 grew 6% year over year to $379.1 million, compared to $356.3 million in the first quarter of 2020.

"2021 is already a historic year for United Therapeutics, with the recent FDA approval and launch of Tyvaso for treatment of PH-ILD, submission of the Tyvaso DPI NDA, and the launch of our Remunity® Pump for Remodulin®," said Martine Rothblatt, Ph.D., Chairperson and Chief Executive Officer of United Therapeutics. "In addition to these product launches and the potential Tyvaso DPI approval in December, we are progressing our late-stage pipeline with the commencement of the pivotal *TETON* study of Tyvaso in IPF, continued enrollment of the pivotal *PERFECT* study of Tyvaso in PH-COPD, and the ongoing pivotal *ADVANCE* studies of ralinepag."

"Following approval in late March, we're already gaining traction with physicians for Tyvaso in PH-ILD, with patient referrals and starts beginning in April," said Michael Benkowitz, President and Chief Operating Officer of United Therapeutics. "The commercial launch of Tyvaso in PH-ILD builds on the momentum we're already seeing for the Remunity Pump for Remodulin, which provides significant improvements over legacy subcutaneous delivery options."

FIRST QUARTER 2021 FINANCIAL RESULTS

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

	Three Months Ended March 31,		Dollar Change	Percentage Change
	2021	2020		
Revenues	$ 379.1	$ 356.3	$ 22.8	6 %
Net income	$ 28.3	$ 137.7	$ (109.4)	(79)%
Non-GAAP earnings[1]	$ 162.1	$ 159.2	$ 2.9	2 %
Net income, per basic share	$ 0.63	$ 3.14	$ (2.51)	(80)%
Net income, per diluted share	$ 0.61	$ 3.12	$ (2.51)	(80)%
Non-GAAP earnings, per diluted share[1]	$ 3.49	$ 3.61	$ (0.12)	(3)%

(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 March 31,		Dollar Change	Percentage Change
	2021	2020		
Net product sales:				
Remodulin®	$ 130.2	$ 145.3	$ (15.1)	(10)%
Tyvaso®	123.0	102.9	20.1	20 %
Orenitram®	72.4	69.0	3.4	5 %
Unituxin®	43.9	26.6	17.3	65 %
Adcirca®	9.6	12.5	(2.9)	(23)%
Total revenues	**$ 379.1**	**$ 356.3**	**$ 22.8**	**6 %**

Net product sales from our treprostinil-based products (Remodulin, Tyvaso, and Orenitram) grew by $8.4 million in the first quarter of 2021 compared to the first quarter of 2020. The reduction in Remodulin revenues was due to decreases of $10.2 million and $4.9 million in U.S. Remodulin net product sales and international Remodulin net product sales, respectively. The growth in Tyvaso revenues resulted primarily from an increase in quantities sold, reflecting an increased number of patients. 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 March 31,		Dollar Change	Percentage Change
	2021	2020		
Category:				
Cost of product sales	$ 21.3	$ 22.2	$ (0.9)	(4)%
Share-based compensation expense[1]	1.7	1.2	0.5	42 %
Total cost of product sales	**$ 23.0**	**$ 23.4**	**$ (0.4)**	**(2)%**

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

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

	Three Months Ended March 31,		Dollar Change	Percentage Change
	2021	2020		
Category:				
Research and development projects	$ 297.2	$ 68.6	$ 228.6	333 %
Share-based compensation expense[1]	6.5	4.6	1.9	41 %
Total research and development expense	**$ 303.7**	**$ 73.2**	**$ 230.5**	**315 %**

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

Research and development expense, excluding share-based compensation. Research and development expense for the three months ended March 31, 2021 increased as compared to the same period in 2020, due to: (1) a $107.3 million in-process research and development (**IPR&D**) impairment charge related to our March 2021 decision to discontinue the U.S. development of Trevyent®; (2) a $105.0 million purchase of a pediatric disease priority review voucher, which we redeemed upon submission of the Tyvaso DPI new drug application; (3) a $11.6 million impairment charge related to repurposing one of our facilities; and (4) a $6.1 million IPR&D impairment charge related to our decision to discontinue development of biomechanical lungs.

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

	Three Months Ended March 31,		Dollar Change	Percentage Change
	2021	2020		
Category:				
General and administrative	$ 71.6	$ 55.0	$ 16.6	30 %
Sales and marketing	13.7	13.0	0.7	5 %
Share-based compensation expense[(1)]	31.9	25.0	6.9	28 %
Total selling, general, and administrative expense	**$ 117.2**	**$ 93.0**	**$ 24.2**	**26 %**

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

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

	Three Months Ended March 31,		Dollar Change	Percentage Change
	2021	2020		
Category:				
Stock options	$ 8.3	$ 16.4	$ (8.1)	(49)%
Restricted stock units	5.7	4.0	1.7	43 %
Share tracking awards plan	25.7	10.1	15.6	154 %
Employee stock purchase plan	0.4	0.3	0.1	33 %
Total share-based compensation expense	**$ 40.1**	**$ 30.8**	**$ 9.3**	**30 %**

Other income, net. The changes in other income, net for the three months ended March 31, 2021, as compared to the same period in 2020, were primarily due to net unrealized and realized gains and losses on equity securities. During the three months ended March 31, 2021, we sold an investment that we held in a publicly-traded company. We received $108.9 million in cash from the sale of the investment and realized a gain of $91.9 million.

Income tax expense. Income tax expense for the three months ended March 31, 2021 and 2020 was $4.2 million and $33.9 million, respectively. The effective income tax rate (**ETR**) for the three months ended March 31, 2021 and 2020 was 13 percent and 20 percent, respectively. The ETR for the three months ended March 31, 2021 decreased compared to the ETR for the three months ended March 31, 2020 primarily due to excess tax benefits from share-based compensation recognized as a discrete item, relative to the amount of pretax income, and a decrease in valuation allowance, partially offset by an increase in state tax expense.

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) impairments of investments in privately-held companies; (3) unrealized gain on an investment in a privately-held company; (4) net changes in recurring fair value measurements; (5) the purchase of a priority review voucher; (6) IPR&D impairment charges; (7) other impairment charges; and (8) 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 March 31,	
	2021	2020
Net income, as reported	$ 28.3	$ 137.7
Adjusted for the following items:		
Share-based compensation expense[1]	40.1	30.8
Impairments of investments in privately-held companies[2]	—	5.6
Unrealized gain on an investment in a privately-held company[3]	—	(22.5)
Net changes in recurring fair value measurements[4]	(100.7)	6.1
Purchase of a priority review voucher[5]	105.0	—
IPR&D impairment charges[5]	113.4	—
Other impairment charges[6]	17.0	1.5
Tax benefit	(41.0)	—
Non-GAAP earnings	**$ 162.1**	**$ 159.2**
Non-GAAP earnings per share:		
Basic	**$ 3.63**	**$ 3.63**
Diluted	**$ 3.49**	**$ 3.61**
Weighted average number of common shares outstanding:		
Basic	**44.6**	**43.9**
Diluted	**46.4**	**44.1**

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

(2) Recorded within *impairments of investments in privately-held companies* on our consolidated statements of operations.

(3) Recorded within *other income, net* on our consolidated statements of operations.

(4) For the three months ended March 31, 2021 and March 31, 2020, we recognized $96.8 million of net unrealized and realized gains and $6.1 million of net unrealized and realized losses, respectively, on equity securities issued by public companies. For the three months ended March 31, 2021, we recognized a $1.9 million gain related to changes in the fair values of our contingent consideration assets and a $2.0 million gain related to changes in the fair values of our contingent consideration liabilities. The net unrealized and realized gains and losses on equity securities is recorded within *other income, net* on our consolidated statements of operations. The change in fair value of our contingent consideration assets is recorded within *other income, net* on our consolidated statements of operations, and the change in fair value of our contingent consideration liabilities is recorded within *research and development* on our consolidated statements of operations.

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

(6) For the three months ended March 31, 2021, we recognized $17.0 million of impairment charges related to property, plant, and equipment, of which $15.5 million was recorded within *research and development* on our consolidated statements of operations and $1.5 million was recorded within *selling, general, and administrative* on our consolidated statements of operations. For the three months ended March 31, 2020, we recognized a $1.5 million impairment charge on a note receivable, which was recorded within *other income, net* on our consolidated statements of operations.

PRODUCT COMMERCIALIZATION UPDATE

Thus far in 2021, we have already 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 FDA approval on March 31, 2021. We are targeting FDA approval of Tyvaso DPI in late 2021.

Remunity Pump for Remodulin. In February 2021, we announced the commercial launch of the Remunity Pump for Remodulin. The Remunity Pump is a pre-filled, semi-disposable system for subcutaneous delivery of treprostinil, developed in collaboration with DEKA Research & Development Corp. under an exclusive development and license agreement. 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, we reported that 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 recently 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. If the FDA accepts our NDA, we expect the agency's review to be complete in December 2021. This represents an expedited review timeframe based on the use of a priority review voucher we purchased for $105.0 million in January 2021.

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. We completed the study in October 2020, and announced in January 2021 that the study 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. In January 2021, we announced that the study demonstrated safety and tolerability of Tyvaso DPI in subjects with PAH transitioning from Tyvaso Inhalation Solution.

Implantable System for Remodulin (ISR). Developed in collaboration with Medtronic, the premarket approval application (**PMA**) for the ISR was approved by the FDA in December 2017. However, our ability to launch the product is subject to Medtronic satisfying various conditions to its PMA approval. We are working with Medtronic to meet these conditions to the FDA's satisfaction. Based on feedback the FDA recently provided to Medtronic, we do not believe these conditions will be satisfied in time for a 2021 launch. We are working with Medtronic to determine the timing required to address this new feedback. Our ability to launch the ISR on a timely basis, or at all, depends on our ability to work with Medtronic to satisfy the FDA's conditions and other factors, many of which are entirely outside our control.

RESEARCH AND DEVELOPMENT UPDATE

Updates on selected later-stage programs are below.

Tyvaso in chronic fibrosing interstitial lung diseases — *TETON*. We are launching 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 designed to enroll subjects with IPF. The primary endpoint of this study is the change in absolute forced vital capacity (**FVC**) from baseline to week 52. We expect to start patient enrollment in this study in the second quarter of 2021.

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 (NCT03496623) 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.

Unituxin in relapsed/refractory neuroblastoma — ANBL1221. Following comments from the FDA ahead of our planned supplemental biologics license application submission, we elected to discontinue development of Unituxin in relapsed/refractory neuroblastoma.

INDUCEMENT RESTRICTED STOCK UNITS

On April 30, 2021, we granted a total of 454 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 April 30, 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).

CONFERENCE CALL

We will host a teleconference on Wednesday, May 5, 2021, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing (866) 209-9943 in the United States, with international callers dialing +1 (825) 312-2282. A rebroadcast of the teleconference will be available for one week and can be accessed by dialing (800) 585-8367 in the United States, with international callers dialing +1 (416) 621-4642, and using access code: 3044748.

This teleconference will also be webcast and can be accessed via our website at https://ir.unither.com/events-and-presentations/default.aspx.

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 recent 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 approvals to launch Tyvaso DPI and the Implantable System for Remodulin, 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 the products we expect to launch in 2021. 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 May 5, 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.

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

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Revenues:		
Net product sales	$ 379.1	$ 356.3
Total revenues	379.1	356.3
Operating expenses:		
Cost of product sales	23.0	23.4
Research and development	303.7	73.2
Selling, general, and administrative	117.2	93.0
Total operating expenses	443.9	189.6
Operating (loss) income	(64.8)	166.7
Interest income	4.7	10.0
Interest expense	(4.6)	(8.2)
Other income, net	97.2	8.7
Impairments of investments in privately-held companies	—	(5.6)
Total other income, net	97.3	4.9
Income before income taxes	32.5	171.6
Income tax expense	(4.2)	(33.9)
Net income	**$ 28.3**	**$ 137.7**
Net income per common share:		
Basic	**$ 0.63**	**$ 3.14**
Diluted	**$ 0.61**	**$ 3.12**
Weighted average number of common shares outstanding:		
Basic	**44.6**	**43.9**
Diluted	**46.4**	**44.1**

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	March 31, 2021
Cash, cash equivalents, and marketable investments	$ 3,164.8
Total assets	4,641.0
Total liabilities	1,195.6
Total stockholders' equity	3,445.4

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