



For Immediate Release

UNITED THERAPEUTICS CORPORATION REPORTS THIRD QUARTER 2021 FINANCIAL RESULTS

SILVER SPRING, MD. and RESEARCH TRIANGLE PARK, N.C., November 3, 2021: United Therapeutics Corporation (Nasdaq: UTHR), a public benefit corporation with a purpose to provide a brighter future for patients, today announced its financial results for the quarter ended September 30, 2021. Total revenue in the third quarter of 2021 grew 17% year over year to \$444.7 million, compared to \$380.1 million in the third quarter of 2020.

“Our momentum continues with growing patient use of our medicines, which are delivered by infusion, inhalation, and tablets,” said Martine Rothblatt, Ph.D., Chairperson and Chief Executive Officer of United Therapeutics. “I’m also very excited about the progress of our six phase 3 clinical trials across various forms of pulmonary hypertension and pulmonary fibrosis.”

“We continue to add new Tyvaso® patients following the approval in PH-ILD earlier this year, with approximately 4,000 U.S. patients on Tyvaso therapy at the end of the third quarter,” said Michael Benkowitz, President and Chief Operating Officer of United Therapeutics. “Referrals for Tyvaso remain strong, and we’re well on our way toward our goal of reaching 6,000 U.S. patients on Tyvaso by the end of 2022.”

THIRD QUARTER 2021 FINANCIAL RESULTS

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

	Three Months Ended September 30,		Dollar Change	Percentage Change
	2021	2020		
Revenues	\$ 444.7	\$ 380.1	\$ 64.6	17 %
Net income	\$ 162.7	\$ 171.2	\$ (8.5)	(5)%
Non-GAAP earnings ⁽¹⁾	\$ 198.0	\$ 173.0	\$ 25.0	14 %
Net income, per basic share	\$ 3.62	\$ 3.86	\$ (0.24)	(6)%
Net income, per diluted share	\$ 3.42	\$ 3.84	\$ (0.42)	(11)%
Non-GAAP earnings, per diluted share ⁽¹⁾	\$ 4.16	\$ 3.88	\$ 0.28	7 %

(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 September 30,		Dollar Change	Percentage Change
	2021	2020		
Net product sales:				
Tyvaso®	\$ 164.2	\$ 129.5	\$ 34.7	27 %
Remodulin®	125.4	124.5	0.9	1 %
Orenitram®	85.2	74.7	10.5	14 %
Unituxin®	55.3	37.6	17.7	47 %
Adcirca®	14.6	13.8	0.8	6 %
Total revenues	\$ 444.7	\$ 380.1	\$ 64.6	17 %

Net product sales from our treprostinil-based products (Tyvaso, Remodulin, and Orenitram) grew by \$46.1 million in the third quarter of 2021 compared to the third quarter of 2020. 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 Orenitram revenues resulted from an increase in quantities sold, reflecting an increased number of patients and, to a lesser extent, a price increase. The growth in Unituxin revenues resulted from an increase in quantities sold and, to a lesser extent, price increases. Unituxin revenues in the third quarter of 2021 included \$9.0 million related to the launch of Unituxin in Japan.

Expenses

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

Category:	Three Months Ended September 30,		Dollar Change	Percentage Change
	2021	2020		
Cost of product sales	\$ 26.8	\$ 24.5	\$ 2.3	9 %
Share-based compensation expense (benefit) ⁽¹⁾	0.9	(0.5)	1.4	280 %
Total cost of product sales	\$ 27.7	\$ 24.0	\$ 3.7	15 %

(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):

Category:	Three Months Ended September 30,		Dollar Change	Percentage Change
	2021	2020		
Research and development projects	\$ 73.5	\$ 71.8	\$ 1.7	2 %
Share-based compensation expense (benefit) ⁽¹⁾	5.7	(3.1)	8.8	284 %
Total research and development expense	\$ 79.2	\$ 68.7	\$ 10.5	15 %

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

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

Category:	Three Months Ended September 30,		Dollar Change	Percentage Change
	2021	2020		
General and administrative	\$ 73.9	\$ 62.8	\$ 11.1	18 %
Sales and marketing	17.2	12.4	4.8	39 %
Share-based compensation expense (benefit) ⁽¹⁾	18.0	(8.9)	26.9	302 %
Total selling, general, and administrative expense	\$ 109.1	\$ 66.3	\$ 42.8	65 %

(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 September 30, 2021, as compared to the same period in 2020, was primarily due to: (1) an increase in legal expenses related to litigation matters; and (2) an increase in consulting expenses.

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

Category:	Three Months Ended September 30,		Dollar Change	Percentage Change
	2021	2020		
Stock options	\$ 5.8	\$ 9.2	\$ (3.4)	(37)%
Restricted stock units	6.2	5.5	0.7	13 %
Share tracking awards plan (STAP)	12.2	(27.5)	39.7	144 %
Employee stock purchase plan	0.4	0.3	0.1	33 %
Total share-based compensation expense (benefit)	\$ 24.6	\$ (12.5)	\$ 37.1	297 %

The increase in share-based compensation expense for the three months ended September 30, 2021, as compared to the same period in 2020, was primarily due to an increase in STAP expense driven by a three percent increase in our stock price for the three months ended September 30, 2021, as compared to a 17 percent decrease in our stock price for the same period in 2020, partially offset by 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 September 30, 2021, as compared to the same period in 2020, was primarily due to an increase in net unrealized losses on equity securities.

Income tax expense. *Income tax expense* for the three months ended September 30, 2021 and 2020, was \$41.7 million and \$47.8 million, respectively. The effective income tax rate (ETR) for the three months ended September 30, 2021 and 2020 was 20 percent and 22 percent, respectively. The ETR for the three months ended September 30, 2021 decreased compared to the ETR for the three months ended September 30, 2020 primarily due to a decrease in valuation allowance, partially offset by increases in blended state income tax rates.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income, adjusted for: (1) share-based compensation expense (benefit); (2) impairment charges; (3) unrealized gain on an investment in a privately-held company; (4) net changes in recurring fair value measurements; (5) license-related fees; (6) certain other costs incurred outside our normal course of business; 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 September 30,	
	2021	2020
Net income, as reported	\$ 162.7	\$ 171.2
Adjusted for the following items:		
Share-based compensation expense (benefit) ⁽¹⁾	24.6	(12.5)
Impairment charges ⁽²⁾	1.2	8.9
Unrealized gain on an investment in a privately-held company ⁽³⁾	—	(2.3)
Net changes in recurring fair value measurements ⁽⁴⁾	25.8	3.0
License-related fees ⁽⁵⁾	1.0	3.6
Other	—	—
Tax (benefit) expense	(17.3)	1.1
Non-GAAP earnings	\$ 198.0	\$ 173.0
Non-GAAP earnings per share:		
Basic	\$ 4.41	\$ 3.90
Diluted	\$ 4.16	\$ 3.88
Weighted average number of common shares outstanding:		
Basic	44.9	44.4
Diluted	47.6	44.6

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

(2) For the three months ended September 30, 2021, we recognized impairment charges of \$1.2 million related to property, plant, and equipment. These impairment charges were recorded within *research and development* on our consolidated statements of operations. For the three months ended September 30, 2020, we recognized impairment charges of \$5.4 million related to property, plant, and equipment and recorded these charges within *selling, general, and administrative* on our consolidated statements of operations. For the three months ended September 30, 2020, we also recognized impairment charges of \$3.5 million related to an investment in a privately-held company and recorded these charges within *impairment of investment in privately-held company* on our consolidated statements of operations.

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

(4) For the three months ended September 30, 2021 and 2020, we recognized \$18.3 million of net unrealized losses and \$3.0 million of net unrealized and realized losses, respectively, on publicly-traded equity securities. For the three months ended September 30, 2021, we recognized a \$2.7 million loss related to changes in the fair values of our contingent consideration assets and a \$4.8 million loss related to changes in fair values of our contingent consideration liabilities. The net unrealized and realized losses on equity securities issued by public companies and changes in fair values of our contingent consideration assets were recorded within *other expense, net*, on our consolidated statements of operations, and the changes in fair values of our contingent consideration liabilities were recorded within *research and development* on our consolidated statements of operations.

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

PRODUCT COMMERCIALIZATION UPDATE

In 2021, we have 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.

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 separate controller. 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. 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 a new drug application (NDA) for Tyvaso DPI for pulmonary arterial hypertension (PAH) and PH-ILD indications. In October 2021 we received a complete response from the FDA noting a single deficiency preventing approval of Tyvaso DPI, related to an open inspection issue at a third-party facility that performs analytical testing of treprostinil drug substance. The FDA did not cite any deficiencies or issues related to operations performed at any United Therapeutics or MannKind Corporation facility for manufacturing, testing, and packaging of treprostinil drug substance, finished Tyvaso DPI drug product, or its associated device. All other requests from the agency have been addressed. We believe that the single deficiency identified in the complete response will be resolved quickly and that Tyvaso DPI can be approved by the summer of 2022, if not earlier.

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.

RESEARCH AND DEVELOPMENT UPDATE

Updates on select later-stage programs are below.

Tyvaso in chronic fibrosing interstitial lung diseases — *TETON*. We are enrolling a phase 3 study called *TETON*, which is a U.S. study of Tyvaso in patients with idiopathic pulmonary fibrosis (IPF). The primary endpoint of this study is the change in absolute forced vital capacity (FVC) from baseline to week 52. We are planning an additional phase 3 study of Tyvaso in IPF patients that will be similar to *TETON*, but will be conducted outside the United States.

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 idiopathic interstitial

pneumonias showing greater improvement. Consistent positive effects were also observed in patients with chronic hypersensitivity pneumonitis 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 October 29, 2021, we granted a total of 1,040 restricted stock units under our 2019 Inducement Stock Incentive Plan to five newly hired employees. These restricted stock units vest in three equal installments on October 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 third quarter 2021 financial results on Wednesday, November 3, 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

We build on the strength of our research and development expertise and a distinctive, entrepreneurial culture that encourages diversity, innovation, creativity, sustainability, and, simply, fun. Since inception, our mission has been to find a cure for pulmonary arterial hypertension and other life-threatening diseases. Toward this goal we have successfully gained FDA approval for five medicines, we are always conducting new clinical trials, and we are working to create an unlimited supply of manufactured organs for transplantation.

We are the first publicly-traded biotech or pharmaceutical company to take the form of a public benefit corporation (PBC). Our public benefit purpose is to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs. At the same time, we seek to provide our shareholders with superior financial performance and our communities with earth-sensitive energy utilization.

You can learn more about what it means to be a PBC here: unither.com/PBC.

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, statements related to our revenue growth prospects, our goal of reaching 6,000 U.S. patients on Tyvaso by the end of 2022, 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, and the *ADVANCE* studies of ralinepag, statements relating to our mission to find a cure for pulmonary hypertension and other life-threatening diseases, our ongoing and future clinical trials and other research and development efforts, and our goals of furthering our public benefit purpose, providing superior financial performance for shareholders, and providing our communities with earth-sensitive energy utilization. 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 November 3, 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.

Contact: Dewey Steadman

Phone: (202) 919-4097

Email: ir@unither.com

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

	Three Months Ended September 30,	
	2021	2020
	(Unaudited)	
Revenues:		
Net product sales	\$ 444.7	\$ 380.1
Total revenues	444.7	380.1
Operating expenses:		
Cost of product sales	27.7	24.0
Research and development	79.2	68.7
Selling, general, and administrative	109.1	66.3
Total operating expenses	216.0	159.0
Operating income	228.7	221.1
Interest income	3.8	6.4
Interest expense	(4.6)	(4.9)
Other expense, net	(23.5)	(0.1)
Impairment of investment in privately-held company	—	(3.5)
Total other expense, net	(24.3)	(2.1)
Income before income taxes	204.4	219.0
Income tax expense	(41.7)	(47.8)
Net income	\$ 162.7	\$ 171.2
Net income per common share:		
Basic	\$ 3.62	\$ 3.86
Diluted	\$ 3.42	\$ 3.84
Weighted average number of common shares outstanding:		
Basic	44.9	44.4
Diluted	47.6	44.6

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	September 30, 2021
Cash, cash equivalents, and marketable investments	\$ 3,509.1
Total assets	5,048.9
Total liabilities	1,219.2
Total stockholders' equity	3,829.7