

For Immediate Release
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United Therapeutics Corporation Reports Second Quarter 2020 Financial Results

- Second quarter Orenitram[®] revenue growth of 40% year-over-year
- INCREASE sNDA submitted to FDA

Silver Spring, Md. and Research Triangle Park, N.C., July 29, 2020: United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the quarter ended June 30, 2020.

“I am pleased with our performance during the second quarter, and feel that we are well positioned for a return to revenue growth in the near term as our prescriptions and new patient starts have been approaching pre-pandemic levels,” said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. “Orenitram continues to grow following our *FREEDOM-EV* label update, and we believe the *INCREASE* study results will lead to significant Tyvaso growth. In addition, our new subcutaneous Remunity Pump and intravenous Implantable System for Remodulin products, while delayed, are nevertheless forthcoming in the near term as manufacturing and regulatory requests get resolved.”

SECOND QUARTER 2020 FINANCIAL RESULTS

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

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2020	2019		
Revenues	\$ 362.0	\$ 373.6	\$ (11.6)	(3)%
Net income	\$ 107.1	\$ 205.1	\$ (98.0)	(48)%
Non-GAAP earnings ⁽¹⁾	\$ 163.2	\$ 159.7	\$ 3.5	2 %
Net income, per basic share	\$ 2.43	\$ 4.68	\$ (2.25)	(48)%
Net income, per diluted share	\$ 2.41	\$ 4.66	\$ (2.25)	(48)%
Non-GAAP earnings, per diluted share ⁽¹⁾	\$ 3.68	\$ 3.63	\$ 0.05	1 %

(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
	2020	2019		
Net product sales:				
Remodulin®	\$ 119.0	\$ 155.8	\$ (36.8)	(24)%
Tyvaso®	119.2	109.6	9.6	9 %
Orenitram®	75.4	54.0	21.4	40 %
Unituxin®	29.0	25.1	3.9	16 %
Adcirca®	19.4	29.1	(9.7)	(33)%
Total revenues	\$ 362.0	\$ 373.6	\$ (11.6)	(3)%

The reduction in Remodulin revenue was driven primarily by a reduction in quantities sold in Europe, which we believe resulted from generic competition and the impact of COVID-19, and to a lesser extent, by a reduction in quantities sold in the United States, which we believe resulted from COVID-19 related reductions in new patient prescriptions and new patient starts due to access restrictions at physician offices. The growth in Orenitram revenue resulted primarily from an increase in quantities sold, as the number of patients being treated with Orenitram has grown following the update to Orenitram's labeling to reflect the *FREEDOM-EV* clinical trial results. The decrease in Adcirca revenues was driven by continued erosion of market share due to generic competition.

Expenses

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

Category:	Three Months Ended June 30,		Dollar Change	Percentage Change
	2020	2019		
Cost of product sales	\$ 23.9	\$ 28.9	\$ (5.0)	(17)%
Share-based compensation expense (benefit) ⁽¹⁾	2.0	(2.2)	4.2	211 %
Total cost of product sales	\$ 25.9	\$ 26.7	\$ (0.8)	(3)%

(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 June 30,		Dollar Change	Percentage Change
	2020	2019		
Research and development projects	\$ 78.3	\$ 95.8	\$ (17.5)	(18)%
Share-based compensation expense (benefit) ⁽¹⁾	11.4	(9.9)	21.3	215 %
Total research and development expense	\$ 89.7	\$ 85.9	\$ 3.8	4 %

(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):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2020	2019		
Category:				
General and administrative	\$ 54.8	\$ 51.0	\$ 3.8	7 %
Sales and marketing	12.7	13.7	(1.0)	(7)%
Share-based compensation expense (benefit) ⁽¹⁾	38.4	(25.1)	63.5	253 %
Total selling, general, and administrative expense	\$ 105.9	\$ 39.6	\$ 66.3	167 %

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

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

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2020	2019		
Category:				
Stock options	\$ 9.2	\$ 18.1	\$ (8.9)	(49)%
Restricted stock units	5.5	3.8	1.7	45 %
Share tracking awards plan (STAP)	36.7	(59.4)	96.1	162 %
Employee stock purchase plan	0.4	0.3	0.1	33 %
Total share-based compensation expense (benefit)	\$ 51.8	\$ (37.2)	\$ 89.0	239 %

The increase in share-based compensation expense for the three months ended June 30, 2020, as compared to the same period in 2019, was primarily due to an increase in STAP expense driven by a 28 percent increase in our stock price for the three months ended June 30, 2020, as compared to a 33 percent decrease in our stock price for the same period in 2019.

Other (Expense) Income, Net. The change in other (expense) income, net for the three months ended June 30, 2020, as compared to the same period in 2019, was primarily due to net unrealized and realized gains and losses on equity securities.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income, adjusted for: (i) share-based compensation expense (including expenses relating to stock options, restricted stock units, share tracking awards, and our employee stock purchase plan); (ii) net unrealized and realized losses (gains) on equity securities; (iii) impairment charges; (iv) license-related fees; and (v) 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,	
	2020	2019
Net income, as reported	\$ 107.1	\$ 205.1
Adjusted for the following items:		
Share-based compensation expense (benefit) ⁽¹⁾	51.8	(37.2)
Net unrealized and realized losses (gains) on equity securities ⁽²⁾	8.9	(29.5)
Impairment charges ⁽³⁾	—	8.8
License-related fees ⁽³⁾	12.5	—
Tax (benefit) expense	(17.1)	12.5
Non-GAAP earnings	\$ 163.2	\$ 159.7
Non-GAAP earnings per share:		
Basic	\$ 3.70	\$ 3.65
Diluted	\$ 3.68	\$ 3.63
Weighted average number of common shares outstanding:		
Basic	44.1	43.8
Diluted	44.4	44.0

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

(2) Recorded within “other (expense) income, net” on our consolidated statements of operations.

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

NEW PRODUCT COMMERCIALIZATION UPDATE

In our near-term time horizon, we plan to launch Tyvaso for a new indication, and to launch three new products for pulmonary arterial hypertension (PAH): the Remunity™ Pump, the Trevyent® system, and the Implantable System for Remodulin.

Tyvaso in pulmonary hypertension due to interstitial lung disease (PH-ILD) — INCREASE. On February 24, 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.

We presented these and other highlights of the *INCREASE* data at a recent virtual session of the American Thoracic Society entitled “Inhaled Treprostinil in Interstitial Lung Disease-Associated Pulmonary Hypertension: The *INCREASE* Study.” We expect to make the full results of the study available through upcoming journal publications. In addition, we recently submitted the *INCREASE* study results to the U.S. Food and Drug Administration (FDA) in

support of an efficacy supplement to the Tyvaso new drug application (sNDA), which we expect to result in revised labeling reflecting the outcome of the *INCREASE* study.

Remunity Pump for Remodulin. We commenced launch activities for the Remunity Pump for Remodulin, including shipping training devices to specialty pharmacies and certain health care practitioners, and entering into agreements with specialty pharmacies to purchase Remunity Pumps and accessories and to pre-fill the Remunity cartridges exclusively with Remodulin. We also confirmed with the relevant Centers for Medicare & Medicaid Services Pricing, Data Analysis, and Coding Contractor that the Remunity Pump will be treated as durable medical equipment under the Medicare Part B Durable Medical Equipment program, and will share the same billing codes and billing guidance as existing subcutaneous pumps currently used with Remodulin. We started working with large PAH medical centers to identify patient candidates for the Remunity Pump, and have been training staff at these centers on how to use the product. However, the timing of our ability to commence commercial sales has been delayed due to pandemic-related issues impacting the ability of our partner, DEKA Research & Development Corp. (DEKA), to secure certain components and raw materials necessary to manufacture a continuous supply of pumps, pump disposables, and pump controllers. We are working closely with DEKA to build safety stock of these components and raw materials to a level that would allow us to withstand a significant supplier disruption without adverse impact to our patient base. We implemented this strategy due to the increasing COVID-19 infection rates observed in the United States during the second quarter of 2020, as many of the Remunity Pump component suppliers are located domestically. We are working to commence commercial sales of the Remunity Pump in the near-term, but we cannot predict the precise timing due to the factors described above, as well as the potential for additional pandemic-related constraints that physicians and patients may experience.

Trevyent. We submitted a 505(b)(1) new drug application (NDA) to the FDA for our Trevyent disposable treprostinil pump system in June 2019. In April 2020, the FDA issued a complete response letter (CRL) related to our NDA indicating that some of the deficiencies previously raised by the FDA had not yet been addressed to its satisfaction. We have one year from the date of the CRL to resubmit our NDA to the FDA, which is expected to trigger a six-month review period by the FDA. We are preparing our NDA resubmission, which we expect to file in 2021.

Implantable System for Remodulin (ISR). Developed in collaboration with Medtronic, Inc. (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. Medtronic continues to work toward satisfying these conditions, but in December 2019, due to FDA communications, Medtronic informed us that these conditions will not be satisfied in 2020. As such we expect a delay in the ISR launch until 2021.

RESEARCH AND DEVELOPMENT UPDATE

Our clinical studies remain open, and enrollment of new patients has resumed at select study sites for certain studies.

Most of our ongoing clinical studies paused enrollment during the first quarter of 2020 due to the pandemic, but patients already enrolled in studies continue to receive the study drug and complete necessary clinical evaluations as appropriate.

The following studies have since re-opened enrollment at select sites:

- the *BREEZE* and pivotal pharmacokinetics studies of Treprostinil Technosphere®;
- the *ADVANCE OUTCOMES* study of ralinepag;
- the *SAPPHIRE* study of Aurora-GT™;
- our phase I study of Unexisome™ for bronchopulmonary dysplasia; and
- our phase I study of OreniPro™.

We have also recommenced startup activities for the *ADVANCE CAPACITY* study of ralinepag. While enrollment of the *PERFECT* study of Tyvaso in pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD) remains paused, we are continuing new clinical site startup activities for this study.

Although we re-opened enrollment of certain studies at a limited number of clinical trial sites, it is difficult to predict when we will be able to reopen enrollment at additional sites for these studies, and whether we will experience further disruptions as the pandemic unfolds. In addition, it is unclear what impact the pandemic may have on the timing of future studies, such as *TETON*. As such, we expect that completion and data readouts for several of our ongoing and planned studies will be delayed, but we do not currently expect delays of our near-, medium-, and long-term windows for product launch plans. To mitigate potential delays, we are expanding our efforts to enter into contracts with additional clinical study sites and complete other site activation activities for certain studies where practicable so that we may rapidly resume enrollment of our clinical studies at the appropriate time.

Treprostinil Technosphere dry powder inhaler — *BREEZE*. The *BREEZE* study (NCT03950739) seeks to evaluate 45 patients on a stable dose of Tyvaso after switching to our new dry powder inhaler (DPI) form of treprostinil, which we licensed from MannKind. The primary endpoint of the study is the number of subjects with treatment-emergent adverse events after three weeks of treatment with the DPI. In March 2020, we commenced a second clinical study in healthy volunteers to compare the pharmacokinetics of Treprostinil Technosphere to Tyvaso. We expect results of these two studies, combined with long-term stability studies of the DPI product, will form the basis of a 505(b)(1) NDA to the FDA.

Unituxin in relapsed/refractory neuroblastoma — *ANBL1221*. We are pursuing an indication expansion for Unituxin for the treatment of pediatric patients with relapsed or refractory neuroblastoma based on the results of the Children’s Oncology Group’s *ANBL1221* study (NCT01767194). We met with the FDA in April of this year to discuss the content needed to support a supplemental biologics license application (BLA). We are working with Children’s Oncology Group to secure additional information ahead of a potential supplemental BLA.

Tyvaso in PH-COPD — *PERFECT*. The *PERFECT* study (NCT03496623) seeks to evaluate Tyvaso in patients with 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 on active treatment compared to placebo. A contingent design for the study allows for the evaluation of 314 patients in two parallel groups.

Tyvaso in patients with chronic fibrosing interstitial lung disease (CFILD) — *TETON*. We are commencing a new phase III registration study called *TETON*, which is a randomized, double-blind, placebo-controlled, 24-week, phase III study of Tyvaso in subjects with CFILD (which includes patients with idiopathic interstitial pneumonias, chronic hypersensitivity pneumonitis, and environmental/occupational lung disease). Subjects will be randomized in a 1:1 ratio to receive inhaled treprostinil or placebo. The primary endpoint of this study is planned to be the change from baseline to week 24 in absolute forced vital capacity (FVC). This study was prompted by data from the *INCREASE* study, which demonstrated improvements in parameters of lung function in pulmonary hypertension patients with fibrotic lung disease (FVC and reduced exacerbations of underlying lung disease).

Ralinepag phase III development program — *ADVANCE CAPACITY* and *ADVANCE OUTCOMES*. We have two ongoing phase III clinical studies to support the potential registration of oral ralinepag for PAH.

- *ADVANCE CAPACITY*. The phase III *ADVANCE CAPACITY* study (NCT04084678) seeks to evaluate 193 subjects with PAH, randomized between oral ralinepag and placebo at a 2:1 ratio, along with PAH background therapy, for 28 weeks. The primary endpoint of the study is the change from baseline to week 28 in peak oxygen consumption assessed by cardiopulmonary exercise testing.
- *ADVANCE OUTCOMES*. The phase III *ADVANCE OUTCOMES* study (NCT03626688) seeks to evaluate approximately 700 PAH patients, randomized 1:1 between oral ralinepag and placebo along with background therapy. The primary endpoint is the time from randomization to the first adjudicated protocol-defined clinical worsening event.

Autologous cell therapy for PAH — *SAPPHIRE*. Conducted by our Canadian affiliate Northern Therapeutics, Inc., the phase II *SAPPHIRE* study seeks to evaluate the use of autologous endothelial progenitor cells (EPCs) genetically engineered to express endothelial nitric oxide synthase in patients with PAH taking conventional PAH treatments. The

study seeks to enroll 45 PAH patients in one of three arms: (i) placebo for six months followed by autologous EPCs for six months; (ii) autologous EPCs for six months followed by placebo for six months; and (iii) autologous EPCs for 12 months. The primary endpoint is the change in 6MWD from baseline to month six.

INDUCEMENT RESTRICTED STOCK UNITS

On July 24, 2020, we granted a total of 916 restricted stock units under our 2019 Inducement Stock Incentive Plan to three newly hired employees. These restricted stock units vest in three equal installments on July 31, 2021, 2022, and 2023, 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 provide this information in accordance with Nasdaq Listing Rule 5635(c)(4).

CONFERENCE CALL

We will host a teleconference on Wednesday, July 29, 2020, 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: 2886748.

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

ABOUT UNITED THERAPEUTICS

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.

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 launch plans for the Remunity Pump, Trevyent and the ISR, our planned expansion of the Tyvaso label to include the results of the *INCREASE* study and to increase the addressable U.S. patient population for Tyvaso, our research and development plans and regulatory filings related to Treprostinil Technosphere, Unituxin, the *TETON*, *PERFECT* and *SAPPHIRE* studies, ralinepag, our organ transplantation programs, our efforts to re-open enrollment of our clinical trials in light of COVID-19, our expectation that we will sustain our success in the long-term, and similar statements concerning anticipated future events and expectations that are not historical facts. These forward-looking statements are subject to certain risks and uncertainties, including the effects of and uncertainty surrounding the COVID-19 pandemic, as well 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. 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 July 29, 2020, 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, Trevyent, Tyvaso, and Unituxin are registered trademarks of United Therapeutics Corporation and its subsidiaries. Aurora-GT, OreniPro, Remunity, and Unexisome are trademarks of United Therapeutics Corporation.

Technosphere is a registered trademark of MannKind 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,	
	2020	2019
	(Unaudited)	
Revenues:		
Net product sales	\$ 362.0	\$ 373.6
Total revenues	362.0	373.6
Operating expenses:		
Cost of product sales	25.9	26.7
Research and development	89.7	85.9
Selling, general, and administrative	105.9	39.6
Total operating expenses	221.5	152.2
Operating income	140.5	221.4
Interest income	7.2	10.8
Interest expense	(5.6)	(12.2)
Other (expense) income, net	(8.2)	30.4
Total other (expense) income, net	(6.6)	29.0
Income before income taxes	133.9	250.4
Income tax expense	(26.8)	(45.3)
Net income	\$ 107.1	\$ 205.1
Net income per common share:		
Basic	\$ 2.43	\$ 4.68
Diluted	\$ 2.41	\$ 4.66
Weighted average number of common shares outstanding:		
Basic	44.1	43.8
Diluted	44.4	44.0

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	June 30, 2020
Cash, cash equivalents, and marketable investments	\$ 2,570.1
Total assets	4,219.4
Total liabilities	1,125.7
Total stockholders' equity	3,093.7