



## UNITED THERAPEUTICS CORPORATION REPORTS FOURTH QUARTER AND FULL YEAR 2020 FINANCIAL RESULTS

Silver Spring, MD and Research Triangle Park, NC, February 24, 2021: United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the fourth quarter and year ended December 31, 2020. Full year net revenue rose to \$1,483 million, as U.S. patients being treated with the company’s treprostinil-based therapies reached an all-time high during the fourth quarter.

“We’re entering 2021 better positioned than at any time in our history,” said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. “We are working toward four product launches this year, led by the recent launch of the Remunity® Pump and followed by the upcoming Tyvaso® label expansion into pulmonary hypertension associated with interstitial lung disease (PH-ILD), the Implantable System for Remodulin® (ISR), and the innovative Tyvaso DPI™ device, assuming we receive the relevant FDA approvals. At the same time, our development teams continue to drive innovation in the pulmonary hypertension space as detailed in the recent *New England Journal of Medicine* publication of our INCREASE data in PH-ILD and our recent announcement of Tyvaso DPI clinical data, which suggest a comparable systemic treprostinil exposure to our approved Tyvaso Inhalation System.”

“We are pleased that our treprostinil-based products achieved another record year of annual net revenues and total U.S. patients on therapy, trends we expect to continue, fueled by our four planned product launches this year,” said Michael Benkowitz, President and Chief Operating Officer of United Therapeutics. “We are deep into commercial launch preparations for Tyvaso in PH-ILD and expect that this indication could expand the use of Tyvaso to more than double the current number of patients on therapy in the near term. Additionally, we’re focused on the ISR and the Tyvaso DPI launches targeted for later this year.”

### FOURTH QUARTER AND FULL YEAR 2020 FINANCIAL RESULTS

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

|   | Three Months Ended<br>December 31, |          | Year Ended<br>December 31, |            |
|---|------------------------------------|----------|----------------------------|------------|
|   | 2020                               | 2019     | 2020                       | 2019       |
| Revenues  | \$ 384.9                           | \$ 311.1 | \$ 1,483.3                 | \$ 1,448.8 |
| Net income (loss)                                   | \$ 98.8                            | \$ 52.6  | \$ 514.8                   | \$ (104.5) |
| Non-GAAP earnings <sup>(1)</sup>                    | \$ 149.3                           | \$ 86.3  | \$ 644.7                   | \$ 569.2   |
| Net income (loss), per basic share                  | \$ 2.22                            | \$ 1.20  | \$ 11.65                   | \$ (2.39)  |
| Net income (loss), per diluted share                | \$ 2.19                            | \$ 1.20  | \$ 11.54                   | \$ (2.39)  |
| Non-GAAP earnings, per diluted share <sup>(1)</sup> | \$ 3.31                            | \$ 1.96  | \$ 14.46                   | \$ 12.94   |

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

## Revenues

|                    | Three Months Ended<br>December 31, |          | Dollar<br>Change | Percentage<br>Change | Year Ended<br>December 31, |            | Dollar<br>Change | Percentage<br>Change |
|--------------------|------------------------------------|----------|------------------|----------------------|----------------------------|------------|------------------|----------------------|
|                    | 2020                               | 2019     |                  |                      | 2020                       | 2019       |                  |                      |
| Net product sales: |                                    |          |                  |                      |                            |            |                  |                      |
| Remodulin®         | \$ 127.9                           | \$ 107.4 | \$ 20.5          | 19 %                 | \$ 516.7                   | \$ 587.0   | \$ (70.3)        | (12)%                |
| Tyvaso®            | 131.7                              | 91.4     | 40.3             | 44 %                 | 483.3                      | 415.6      | 67.7             | 16 %                 |
| Orenitram®         | 74.0                               | 50.9     | 23.1             | 45 %                 | 293.1                      | 225.3      | 67.8             | 30 %                 |
| Unituxin®          | 29.7                               | 33.6     | (3.9)            | (12)%                | 122.9                      | 113.7      | 9.2              | 8 %                  |
| Adcirca®           | 21.6                               | 27.8     | (6.2)            | (22)%                | 67.3                       | 107.2      | (39.9)           | (37)%                |
| Total revenues     | \$ 384.9                           | \$ 311.1 | \$ 73.8          | 24 %                 | \$ 1,483.3                 | \$ 1,448.8 | \$ 34.5          | 2 %                  |

Net product sales of our treprostiniil-based products (Remodulin, Tyvaso, and Orenitram) grew by \$65.2 million for the year ended December 31, 2020, as compared to 2019. This increase was driven by growth in U.S. net product sales of our treprostiniil-based products of \$122.6 million in 2020, as compared to 2019, partially offset by a \$57.4 million decline in net product sales of our treprostiniil-based products outside the United States.

In addition, as previously disclosed, our 2019 quarterly results were impacted by a mistake by one of our U.S. distributors in its utilization data, which resulted in the distributor ordering more product than normal, primarily in the third quarter of 2019. Upon the distributor's correction of its utilization data in the fourth quarter of 2019, the distributor reduced its purchases of our products in the fourth quarter of 2019 in order to normalize its inventory levels (collectively, the **Corrected Order**). We estimate that the Corrected Order reduced net product sales for Remodulin, Tyvaso, and Orenitram by approximately \$18.3 million, \$12.7 million, and \$6.1 million, respectively, or \$37.1 million in total, during the fourth quarter of 2019. Absent the Corrected Order, there would have been no change in U.S. net product sales for Remodulin and our net product sales for Tyvaso and Orenitram would have grown by 27 percent and 30 percent, respectively, in the fourth quarter of 2020, as compared to the fourth quarter of 2019. We are providing these non-GAAP financial measures to show the period-to-period revenue change for these products in the absence of the Corrected Order to improve investors' understanding of our financial results. In addition, while this inventory fluctuation had a significant impact on our U.S. revenues during the third and fourth quarters of 2019, the effect on full-year U.S. revenues was negligible.

The year-over-year increase in quarterly revenues for Remodulin, Tyvaso, and Orenitram were all impacted by the Corrected Order, as discussed above. In addition, the increases in year-over-year quarterly revenues for Tyvaso and Orenitram resulted from: (1) an increase in quantities sold, reflecting a growing number of patients; and (2) to a lesser extent, price increases for Tyvaso.

The reduction in annual Remodulin revenues for 2020 compared to 2019 was primarily driven by: (1) a reduction in quantities sold in Europe, which we believe resulted from generic competition and the impact of COVID-19; and (2) to a lesser extent, a reduction in U.S. Remodulin revenues, which we believe resulted from the impact of COVID-19. The growth in annual Tyvaso revenues for 2020 compared to 2019 was due to an increase in quantities sold, reflecting a growing number of patients, and price increases. The growth in annual Orenitram revenues for 2020 compared to 2019 was due to an increase in quantities sold, as the number of patients being treated with Orenitram grew following the update to Orenitram's labeling to reflect the *FREEDOM-EV* clinical trial results. The decrease in annual Adcirca revenues for 2020 compared to 2019 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<br>December 31, |                | Dollar<br>Change | Percentage<br>Change | Year Ended<br>December 31, |                 | Dollar<br>Change | Percentage<br>Change |
|--------------------------------|------------------------------------|----------------|------------------|----------------------|----------------------------|-----------------|------------------|----------------------|
|                                | 2020                               | 2019           |                  |                      | 2020                       | 2019            |                  |                      |
| Cost of product sales          | \$ 30.4                            | \$ 28.2        | \$ 2.2           | 8 %                  | \$ 101.0                   | \$ 117.4        | \$ (16.4)        | (14)%                |
| Share-based<br>compensation    | 4.4                                | 0.6            | 3.8              | 633 %                | 7.1                        | 0.2             | 6.9              | NM <sup>(2)</sup>    |
| Total cost of product<br>sales | <u>\$ 34.8</u>                     | <u>\$ 28.8</u> | <u>\$ 6.0</u>    | <u>21 %</u>          | <u>\$ 108.1</u>            | <u>\$ 117.6</u> | <u>\$ (9.5)</u>  | <u>(8)%</u>          |

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

(2) Calculation is not meaningful.

*Cost of product sales, excluding share-based compensation.* The decrease in cost of product sales for the year ended December 31, 2020, as compared to the same period in 2019, was primarily attributable to decreases in royalty expense for Adcirca, as fewer bottles were sold following the onset of generic competition for Adcirca beginning in August 2018.

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

| Category:                                 | Three Months Ended<br>December 31, |                 | Dollar<br>Change | Percentage<br>Change | Year Ended<br>December 31, |                   | Dollar<br>Change  | Percentage<br>Change |
|---|------------------------------------|-----------------|------------------|----------------------|----------------------------|-------------------|-------------------|----------------------|
|   | 2020                               | 2019            |                  |                      | 2020                       | 2019              |                   |                      |
| Research and<br>development projects      | \$ 109.5                           | \$ 109.6        | \$ (0.1)         | — %                  | \$ 328.2                   | \$ 1,182.2        | \$ (854.0)        | (72)%                |
| Share-based<br>compensation               | 16.6                               | 4.0             | 12.6             | 315 %                | 29.5                       | 0.4               | 29.1              | NM <sup>(2)</sup>    |
| Total research and<br>development expense | <u>\$ 126.1</u>                    | <u>\$ 113.6</u> | <u>\$ 12.5</u>   | <u>11 %</u>          | <u>\$ 357.7</u>            | <u>\$ 1,182.6</u> | <u>\$ (824.9)</u> | <u>(70)%</u>         |

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

(2) Calculation is not meaningful.

*Research and development expense, excluding share-based compensation.* The decrease in research and development expense for the year ended December 31, 2020, as compared to the same period in 2019, was due to a one-time, \$800.0 million up-front payment to Arena Pharmaceuticals, Inc. (**Arena**) under our license agreement related to ralinepag during the year ended December 31, 2019. The remainder of the decrease resulted primarily from: (1) the completion of the phase 3 *BEAT* study of esuberaprost in April 2019, the completion of the phase 3 *DISTINCT* study of Unituxin in February 2020, and the discontinuation of the phase 3 *SOUTHPAW* study of Orenitram in October 2019; (2) a decrease in spending due to terminated drug delivery device projects; and (3) an impairment charge related to the termination of a license agreement during the year ended December 31, 2019.

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

| Category:  | Three Months Ended<br>December 31, |                 | Dollar<br>Change | Percentage<br>Change | Year Ended<br>December 31, |                 | Dollar<br>Change | Percentage<br>Change |
|--|------------------------------------|-----------------|------------------|----------------------|----------------------------|-----------------|------------------|----------------------|
|  | 2020                               | 2019            |                  |                      | 2020                       | 2019            |                  |                      |
| General and administrative                         | \$ 69.2                            | \$ 61.7         | \$ 7.5           | 12 %                 | \$ 241.8                   | \$ 230.7        | \$ 11.1          | 5 %                  |
| Sales and marketing                                | 16.8                               | 18.6            | (1.8)            | (10)%                | 54.9                       | 60.7            | (5.8)            | (10)%                |
| Share-based compensation                           | 72.7                               | 24.9            | 47.8             | 192 %                | 127.2                      | 44.8            | 82.4             | 184 %                |
| Total selling, general, and administrative expense | <u>\$ 158.7</u>                    | <u>\$ 105.2</u> | <u>\$ 53.5</u>   | <u>51 %</u>          | <u>\$ 423.9</u>            | <u>\$ 336.2</u> | <u>\$ 87.7</u>   | <u>26 %</u>          |

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

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

| Category:                              | Three Months Ended<br>December 31, |                | Dollar<br>Change | Percentage<br>Change | Year Ended<br>December 31, |                | Dollar<br>Change | Percentage<br>Change |
|--|------------------------------------|----------------|------------------|----------------------|----------------------------|----------------|------------------|----------------------|
|  | 2020                               | 2019           |                  |                      | 2020                       | 2019           |                  |                      |
| Stock options                          | \$ 9.2                             | \$ 18.3        | \$ (9.1)         | (50)%                | \$ 44.0                    | \$ 70.5        | \$ (26.5)        | (38)%                |
| Restricted stock units                 | 5.5                                | 3.5            | 2.0              | 57 %                 | 20.5                       | 13.3           | 7.2              | 54 %                 |
| Share tracking awards plan (STAP)      | 78.5                               | 7.3            | 71.2             | 975 %                | 97.8                       | (39.7)         | 137.5            | 346 %                |
| Employee stock purchase plan           | 0.5                                | 0.4            | 0.1              | 25 %                 | 1.5                        | 1.3            | 0.2              | 15 %                 |
| Total share-based compensation expense | <u>\$ 93.7</u>                     | <u>\$ 29.5</u> | <u>\$ 64.2</u>   | <u>218 %</u>         | <u>\$ 163.8</u>            | <u>\$ 45.4</u> | <u>\$ 118.4</u>  | <u>261 %</u>         |

The increase in share-based compensation expense for the quarter and year ended December 31, 2020, as compared to the same periods in 2019, was primarily due to an increase in STAP expense driven by a 50 percent and a 72 percent increase in our stock price during the quarter and year ended December 31, 2020, respectively, as compared to a 10 percent increase and 19 percent decrease in our stock price for the quarter and year ended December 31, 2019, respectively. The increase in share-based compensation expense for the year ended December 31, 2020 was partially offset by a decrease in stock option expense due to fewer awards granted and outstanding in 2020 as compared to the same period in 2019.

**Other income, net.** The increase in other income, net for the quarter and year ended December 31, 2020, as compared to the same periods in 2019, was primarily due to net unrealized and realized gains on our investments in privately-held companies and our investments in publicly-traded equity securities.

**Income taxes.** Income tax expense was \$124.1 million for the year ended December 31, 2020, as compared to income tax benefit of \$60.5 million for the same period in 2019. For the year ended December 31, 2019, the income tax benefit resulted primarily from the \$800.0 million payment under our license agreement with Arena which caused us to incur a net loss before taxes. For the years ended December 31, 2020 and 2019, our effective income

tax rates (ETR) were approximately 19 percent and 37 percent, respectively. Changes to the ETR for the years ended December 31, 2020 and 2019 were primarily due to tax credits, partially offset by non-deductible compensation, which decreased our tax expense for 2020 and increased our tax benefit for 2019.

## Non-GAAP Earnings

Non-GAAP earnings is defined as net income (loss), 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) unrealized gains on investments in privately-held companies; (3) impairments of investments in privately-held companies; (4) asset impairment charges; (5) license-related fees; (6) net changes in recurring fair value measurements; and (7) tax impact on non-GAAP earnings adjustments.

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

|  | Three Months Ended<br>December 31, |                | Year Ended<br>December 31, |                 |
|--|------------------------------------|----------------|----------------------------|-----------------|
|  | 2020                               | 2019           | 2020                       | 2019            |
| Net income (loss), as reported   | \$ 98.8                            | \$ 52.6        | \$ 514.8                   | \$ (104.5)      |
| Adjusted for the following charges:  |                                    |                |                            |                 |
| Share-based compensation expense <sup>(1)</sup>                            | 93.7                               | 29.5           | 163.8                      | 45.4            |
| Unrealized gains on investments in privately-held companies <sup>(2)</sup> | (0.7)                              | —              | (25.5)                     | —               |
| Impairments of investments in privately-held companies <sup>(3)</sup>      | —                                  | —              | 9.1                        | —               |
| Asset impairment charges <sup>(4)</sup>                                    | —                                  | —              | 6.9                        | 17.2            |
| License-related fees <sup>(5)</sup>  | 17.5                               | 12.5           | 33.6                       | 825.0           |
| Net changes in recurring fair value measurements <sup>(6)</sup>            | (43.7)                             | (1.9)          | (25.7)                     | (21.4)          |
| Tax benefit  | (16.3)                             | (6.4)          | (32.3)                     | (192.5)         |
| Non-GAAP earnings  | <u>\$ 149.3</u>                    | <u>\$ 86.3</u> | <u>\$ 644.7</u>            | <u>\$ 569.2</u> |
| Non-GAAP earnings per share:   |                                    |                |                            |                 |
| Basic  | <u>\$ 3.36</u>                     | <u>\$ 1.97</u> | <u>\$ 14.59</u>            | <u>\$ 13.00</u> |
| Diluted  | <u>\$ 3.31</u>                     | <u>\$ 1.96</u> | <u>\$ 14.46</u>            | <u>\$ 12.94</u> |
| Weighted average number of common shares outstanding:                      |                                    |                |                            |                 |
| Basic  | <u>44.5</u>                        | <u>43.9</u>    | <u>44.2</u>                | <u>43.8</u>     |
| Diluted  | <u>45.1</u>                        | <u>44.0</u>    | <u>44.6</u>                | <u>44.0</u>     |

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

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

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

(4) For the year ended December 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, and we recognized a \$5.4 million impairment charge related to property, plant, and equipment, which was recorded within selling, general, and administrative expense on our consolidated statements of operations.

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

(6) For the quarter and year ended December 31, 2020, we recognized \$43.1 million and \$25.1 million of net unrealized and realized gains, respectively, on equity securities issued by public companies. For the quarter and year ended December 31, 2020, we recognized a \$4.1 million gain related to changes in the fair values of our contingent consideration assets, partially offset by a \$3.5 million expense related to changes in the fair values of our contingent consideration liabilities. The net unrealized and realized gains 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 expense on our consolidated statements of operations.

## PRODUCT COMMERCIALIZATION UPDATE

In 2021, we plan to launch four new products and indications. In February 2021, we launched commercial sales of the Remunity Pump for Remodulin. In April 2021, we plan to launch a label expansion for Tyvaso, to include an indication for PH-ILD, assuming FDA approval. We also plan to launch the Implantable System for Remodulin and Tyvaso DPI, assuming the FDA grants the necessary clearances.

**Remunity Pump for Remodulin.** In February 2020, we announced FDA clearance of the pharmacy-filled version of the Remunity Pump for Remodulin, developed in collaboration with DEKA Research & Development Corp (**DEKA**). In February 2021, we announced the first commercial shipments of the Remunity Pump to specialty pharmacies. The Remunity Pump is a pre-filled, semi-disposable system for subcutaneous delivery of treprostinil, developed in collaboration with DEKA 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*.

In April 2020, the FDA indicated that the results of the *INCREASE* study appear to support our proposed indication of treatment of patients with PH-ILD to improve exercise ability and delay clinical worsening. In June 2020, we submitted an efficacy supplement (**sNDA**) to the Tyvaso new drug application (**NDA**), which we expect to result in revised labeling reflecting the outcome of the *INCREASE* study. In August 2020, the FDA accepted the sNDA for review, which we expect will be completed in April 2021.

**Implantable System for Remodulin.** 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 by the fourth quarter of 2021, with a goal of commencing launch activities during late 2021. Our ability to launch the ISR in 2021, 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.

**Tyvaso DPI.** We have completed two clinical studies 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 pulmonary arterial hypertension (**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. We are awaiting the final pharmacokinetics data from the *BREEZE* study. The FDA has indicated that these two studies will be the only additional clinical studies necessary to support FDA approval. If our pending sNDA for Tyvaso Inhalation Solution to treat PH-ILD is approved by the FDA in April 2021, we plan to submit an NDA later in April 2021 seeking an indication for Tyvaso DPI that includes both PAH and PH-ILD. In January 2021, we purchased a pediatric disease priority review voucher for \$105.0 million, which we plan to redeem upon submission of the Tyvaso DPI NDA. The voucher is expected to reduce the typical 12-month timeframe for FDA to review the Tyvaso DPI NDA to eight months.

## RESEARCH AND DEVELOPMENT UPDATE

Updates on selected later-stage programs are below.

**Tyvaso in chronic fibrosing interstitial lung diseases — *TETON*.** We are planning 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 idiopathic pulmonary fibrosis (**IPF**). The primary endpoint of this study is planned to be 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.

In December 2020, the FDA granted orphan designation for treprostinil to treat IPF.

**Tyvaso in pulmonary hypertension due to chronic obstructive pulmonary disease — *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. 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.

**Trevyent.** We are developing Trevyent, a drug-device combination product that combines our two-day, single use, disposable PatchPump® technology with treprostinil, for the subcutaneous treatment of PAH. We submitted a 505(b)(1) NDA for Trevyent to the FDA 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. In January 2021, we met with the FDA to discuss certain deficiencies noted in the CRL, and our plans to address them. The FDA clarified certain matters and indicated that a small clinical study of Trevyent in PAH patients may be required to evaluate further the pharmacokinetic profile and safety as correlated to the pump performance. We are assessing the FDA's comments and awaiting additional written feedback from the agency, but currently believe that

resubmission of our NDA will likely be delayed to 2022. We anticipate a six-month review period by the FDA following our resubmission.

**Unituxin in relapsed/refractory neuroblastoma — ANBL1221.** We are pursuing an indication expansion for Unituxin in 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 2020 to discuss the proposed label expansion, and plan to file a supplemental BLA in the near term.

## **INDUCEMENT RESTRICTED STOCK UNITS**

On February 19, 2021, we granted a total of 909 restricted stock units under our 2019 Inducement Stock Incentive Plan to two newly hired employees. These restricted stock units vest in three equal installments on February 28, 2022, February 28, 2023, and February 28, 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, February 24, 2021, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing +1 (866) 393-4306 in the United States, with international callers dialing +1 (763) 488-9145. A rebroadcast of the teleconference will be available for one week and can be accessed by dialing +1 (855) 859-2056 in the United States, with international callers dialing +1 (404) 537-3406, and using access code: 8999095.

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

## **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 expectation that our treprostinil-based revenues will continue to grow, that we will launch Tyvaso in PH-ILD in 2021, that we expect the launch of Tyvaso in PH-ILD will more than double the current number of patients on therapy, that we will launch the Implantable System for Remodulin and Tyvaso DPI in 2021, our research and development plans and regulatory filings related to Tyvaso DPI, Unituxin, the *PERFECT* and *TETON* studies, ralinepag, 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 February 24, 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, PatchPump, Remodulin, Remunity, Trevyent, 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<br>December 31, |                | Year Ended<br>December 31, |                   |
|--|------------------------------------|----------------|----------------------------|-------------------|
|  | 2020                               | 2019           | 2020                       | 2019              |
| Revenues:  |                                    |                |                            |                   |
| Net product sales                                      | \$ 384.9                           | \$ 311.1       | \$ 1,483.3                 | \$ 1,448.8        |
| Total revenues   | 384.9                              | 311.1          | 1,483.3                    | 1,448.8           |
| Operating expenses:                                    |                                    |                |                            |                   |
| Cost of product sales                                  | 34.8                               | 28.8           | 108.1                      | 117.6             |
| Research and development                               | 126.1                              | 113.6          | 357.7                      | 1,182.6           |
| Selling, general, and administrative                   | 158.7                              | 105.2          | 423.9                      | 336.2             |
| Total operating expenses                               | 319.6                              | 247.6          | 889.7                      | 1,636.4           |
| Operating income (loss)                                | 65.3                               | 63.5           | 593.6                      | (187.6)           |
| Interest income  | 5.0                                | 11.5           | 28.6                       | 44.2              |
| Interest expense                                       | (4.8)                              | (10.0)         | (23.5)                     | (44.2)            |
| Other income, net                                      | 48.9                               | 3.3            | 49.3                       | 22.6              |
| Impairments of investments in privately-held companies | —                                  | —              | (9.1)                      | —                 |
| Total other income, net                                | 49.1                               | 4.8            | 45.3                       | 22.6              |
| Income (loss) before income taxes                      | 114.4                              | 68.3           | 638.9                      | (165.0)           |
| Income tax (expense) benefit                           | (15.6)                             | (15.7)         | (124.1)                    | 60.5              |
| Net income (loss)                                      | <u>\$ 98.8</u>                     | <u>\$ 52.6</u> | <u>\$ 514.8</u>            | <u>\$ (104.5)</u> |
| Net income (loss) per common share:                    |                                    |                |                            |                   |
| Basic  | <u>\$ 2.22</u>                     | <u>\$ 1.20</u> | <u>\$ 11.65</u>            | <u>\$ (2.39)</u>  |
| Diluted  | <u>\$ 2.19</u>                     | <u>\$ 1.20</u> | <u>\$ 11.54</u>            | <u>\$ (2.39)</u>  |
| Weighted average number of common shares outstanding:  |                                    |                |                            |                   |
| Basic  | <u>44.5</u>                        | <u>43.9</u>    | <u>44.2</u>                | <u>43.8</u>       |
| Diluted  | <u>45.1</u>                        | <u>44.0</u>    | <u>44.6</u>                | <u>43.8</u>       |

**SELECTED CONSOLIDATED BALANCE SHEET DATA**  
(In millions)

|   | December 31, |            |
|---|--------------|------------|
|   | 2020         | 2019       |
| Cash, cash equivalents, and marketable securities | \$ 2,984.6   | \$ 2,253.4 |
| Total assets                                      | 4,615.0      | 3,913.4    |
| Total liabilities                                 | 1,219.8      | 1,133.0    |
| Total stockholders' equity                        | 3,395.2      | 2,780.4    |

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