For Immediate Release
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# United Therapeutics Corporation Reports First Quarter 2022 Financial Results

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., May 4, 2022: United Therapeutics Corporation (Nasdaq: UTHR), a public benefit corporation, today announced its financial results for the quarter ended March 31, 2022. Total revenue in the first quarter of 2022 grew 22% year-over-year to $461.9 million, compared to $379.1 million in the first quarter of 2021.

"The hard work and dedication of our Unitherians has resulted in double-digit percentage revenue growth year-over-year for Tyvaso, Orenitram, Unituxin, and our total treprostinil portfolio, along with our second-highest revenue quarter ever," said Martine Rothblatt, Ph.D., Chairperson and Chief Executive Officer of United Therapeutics. "Likewise, our team is hard at work progressing our seven phase 3 studies that are now underway."

"We see continued traction for Tyvaso in pulmonary hypertension associated with interstitial lung disease, and we eagerly await the FDA's decision on Tyvaso DPI later this month," said Michael Benkowitz, President and Chief Operating Officer of United Therapeutics. "With this positive momentum, we continue to work toward reaching 6,000 patients on Tyvaso therapy by the end of 2022 and 25,000 patients on our therapies by the end of 2025."

## FIRST QUARTER 2022 FINANCIAL RESULTS

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

| | Three Months Ended March 31, | | Dollar Change | Percentage Change |
|---|---|---|---|---|
| | 2022 | 2021 | | |
| Revenues | $ 461.9 | $ 379.1 | $ 82.8 | 22 % |
| Net income | $ 239.9 | $ 28.3 | $ 211.6 | 748 % |
| Net income, per basic share | $ 5.31 | $ 0.63 | $ 4.68 | 743 % |
| Net income, per diluted share | $ 5.03 | $ 0.61 | $ 4.42 | 725 % |

### Revenues

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

| | Three Months Ended March 31, | | Dollar Change | Percentage Change |
|---|---|---|---|---|
| | 2022 | 2021 | | |
| Net product sales: | | | | |
| Tyvaso® | $ 172.0 | $ 123.0 | $ 49.0 | 40 % |
| Remodulin® | 131.7 | 130.2 | 1.5 | 1 % |
| Orenitram® | 82.8 | 72.4 | 10.4 | 14 % |
| Unituxin® | 55.6 | 43.9 | 11.7 | 27 % |
| Adcirca® | 9.8 | 9.6 | 0.2 | 2 % |
| Other | 10.0 | — | 10.0 | NM[1] |
| **Total revenues** | **$ 461.9** | **$ 379.1** | **$ 82.8** | **22 %** |

(1) Calculation is not meaningful.

Net product sales from our treprostinil-based products (Tyvaso, Remodulin, and Orenitram) grew by $60.9 million for the first quarter of 2022, as compared to the same period in 2021. The growth in Tyvaso revenues resulted primarily from an increase in quantities sold, reflecting an increased number of patients following the label expansion to treat pulmonary hypertension associated with interstitial lung disease (**PH-ILD**). The growth in Remodulin revenues was primarily due to a $9.5 million increase in international Remodulin revenues, partially offset by an $8.0 million decrease in U.S. Remodulin revenues. The increase in international Remodulin revenues was primarily due to the timing of orders by our international distributors and does not precisely reflect trends in underlying patient demand. The decrease in U.S. Remodulin revenues was primarily due to a decrease in quantities sold. The growth in Orenitram revenues resulted primarily from an increase in quantities sold and, to a lesser extent, a price increase. The growth in Unituxin revenues resulted primarily from the launch of Unituxin in Japan in September 2021 and, to a lesser extent, a price increase. The increase in other revenues resulted from an upfront payment of $10.0 million from an international distributor.

**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 |
|---|---|---|---|---|
| | 2022 | 2021 | | |
| **Category:** | | | | |
| Cost of product sales | $ 26.6 | $ 21.3 | $ 5.3 | 25 % |
| Share-based compensation (benefit) expense[(1)] | (0.7) | 1.7 | (2.4) | (141)% |
| **Total cost of product sales** | **$ 25.9** | **$ 23.0** | **$ 2.9** | **13 %** |

(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 |
|---|---|---|---|---|
| | 2022 | 2021 | | |
| **Category:** | | | | |
| Research and development projects | $ 72.6 | $ 297.2 | $ (224.6) | (76)% |
| Share-based compensation (benefit) expense[(1)] | (3.6) | 6.5 | (10.1) | (155)% |
| **Total research and development expense** | **$ 69.0** | **$ 303.7** | **$ (234.7)** | **(77)%** |

(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, 2022 decreased as compared to the same period in 2021, due to: (1) a $107.3 million in-process research and development 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 in January 2021, which we redeemed upon submission of our new drug application (**NDA**) for Tyvaso DPI™; and (3) an $11.6 million impairment charge related to repurposing one of our facilities during the first quarter of 2021.

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

| Category: | Three Months Ended March 31, 2022 | Three Months Ended March 31, 2021 | Dollar Change | Percentage Change |
|---|---|---|---|---|
| General and administrative | $ 81.3 | $ 71.6 | $ 9.7 | 14 % |
| Sales and marketing | 14.5 | 13.7 | 0.8 | 6 % |
| Share-based compensation (benefit) expense[(1)] | (16.8) | 31.9 | (48.7) | (153)% |
| **Total selling, general, and administrative expense** | **$ 79.0** | **$ 117.2** | **$ (38.2)** | **(33)%** |

(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 March 31, 2022, as compared to the same period in 2021, was primarily due to: (1) an increase in legal expenses related to litigation matters; and (2) an increase in branded prescription drug fee expense associated with sales of Tyvaso.

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

| Category: | Three Months Ended March 31, 2022 | Three Months Ended March 31, 2021 | Dollar Change | Percentage Change |
|---|---|---|---|---|
| Stock options | $ 5.5 | $ 8.3 | $ (2.8) | (34)% |
| Restricted stock units | 6.3 | 5.7 | 0.6 | 11 % |
| Share tracking awards plan (**STAP**) | (33.4) | 25.7 | (59.1) | (230)% |
| Employee stock purchase plan | 0.5 | 0.4 | 0.1 | 25 % |
| **Total share-based compensation (benefit) expense** | **$ (21.1)** | **$ 40.1** | **$ (61.2)** | **(153)%** |

The increase in share-based compensation benefit for the three months ended March 31, 2022, as compared to the same period in 2021, was primarily due to: (1) an increase in STAP benefit driven by a 17 percent decrease in our stock price for the three months ended March 31, 2022, as compared to a 10 percent increase in our stock price for the same period in 2021; and (2) a decrease in stock option expense due to fewer awards granted and outstanding in 2022.

**Other income, net.** The change in *other income, net* for the three months ended March 31, 2022, as compared to the same period in 2021, was primarily due to net unrealized and realized gains and losses on equity securities. During the first quarter of 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, 2022 and 2021, was $68.8 million and $4.2 million, respectively. The effective income tax rate (**ETR**) for the three months ended March 31, 2022 and 2021, was 22 percent and 13 percent, respectively. The ETR for the three months ended March 31, 2022 increased compared to the ETR for the three months ended March 31, 2021 primarily due to the impact of lower discrete excess tax benefits from share-based compensation relative to the amount of pretax income, and an increase in the valuation allowance compared to a decrease in the prior period.

## PRODUCT COMMERCIALIZATION UPDATE

**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 an NDA for Tyvaso DPI for pulmonary arterial hypertension (**PAH**) and PH-ILD indications. In October 2021, we received a complete response letter (**CRL**) 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 CRL noted, but did not cite as a deficiency, that the FDA had not yet completed its review of a Citizen Petition submitted to the FDA in July 2021 concerning the safety of an excipient in Tyvaso DPI.

We resubmitted our NDA in December 2021 and the FDA issued an action date for February 2022. In February 2022, the FDA requested additional information concerning the pulmonary safety of Tyvaso DPI related to the Citizen's Petition noted above. We responded to the FDA's request, and the FDA indicated that our response constituted a major amendment to the Tyvaso DPI NDA, which extended the FDA's anticipated deadline to review the pending NDA to May 2022.

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 1* and *TETON 2*.** We are enrolling a phase 3 study called *TETON 1*, which is a U.S. study of Tyvaso for the treatment of 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 in the process of commencing an additional phase 3 study of Tyvaso in IPF patients that will be similar to *TETON 1*, called *TETON 2*, but will be conducted outside of 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 for the treatment of 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 six-minute walk distance 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 April 29, 2022, we granted a total of 1,507 restricted stock units under our 2019 Inducement Stock Incentive Plan to six newly hired employees. These restricted stock units vest in three equal installments on April 30, 2023, 2024, and 2025, 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 first quarter 2022 financial results on Wednesday, May 4, 2022, 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.

## 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 goals of reaching 6,000 U.S. patients on Tyvaso by the end of 2022 and 25,000 patients on our therapies by the end of 2025, our expectations concerning the timing and success of our efforts to obtain the necessary FDA approval to launch Tyvaso DPI, our research and development plans related to the *PERFECT* and *TETON* studies of Tyvaso, the *ADVANCE* studies of ralinepag, our work to create an unlimited supply of manufactured organs for transplantation, 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 FDA approval of 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 May 4, 2022, 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, | |
|---|---|---|
| | 2022 | 2021 |
| | (Unaudited) | |
| Revenues: | | |
| Net product sales | $ 451.9 | $ 379.1 |
| Other | 10.0 | — |
| Total revenues | 461.9 | 379.1 |
| Operating expenses: | | |
| Cost of product sales | 25.9 | 23.0 |
| Research and development | 69.0 | 303.7 |
| Selling, general, and administrative | 79.0 | 117.2 |
| Total operating expenses | 173.9 | 443.9 |
| Operating income (loss) | 288.0 | (64.8) |
| Interest income | 4.3 | 4.7 |
| Interest expense | (4.7) | (4.6) |
| Other income, net | 22.8 | 97.2 |
| Impairment of investment in privately-held company | (1.7) | — |
| Total other income, net | 20.7 | 97.3 |
| Income before income taxes | 308.7 | 32.5 |
| Income tax expense | (68.8) | (4.2) |
| **Net income** | **$ 239.9** | **$ 28.3** |
| Net income per common share: | | |
| **Basic** | **$ 5.31** | **$ 0.63** |
| **Diluted** | **$ 5.03** | **$ 0.61** |
| Weighted average number of common shares outstanding: | | |
| **Basic** | **45.2** | **44.6** |
| **Diluted** | **47.7** | **46.4** |

**SELECTED CONSOLIDATED BALANCE SHEET DATA**
**(Unaudited, in millions)**

| | March 31, 2022 |
|---|---|
| Cash, cash equivalents, and marketable investments | $ 3,826.8 |
| Total assets | 5,359.8 |
| Total liabilities | 1,183.5 |
| Total stockholders' equity | 4,176.3 |