UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15 (d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 2, 2022**

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-26301**	**52-1984749**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

1040 Spring Street Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code:
(301) 608-9292

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.01 per share	UTHR	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 2, 2022, United Therapeutics Corporation issued a press release setting forth its earnings for the quarter ended September 30, 2022.

A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01. Exhibits

This information shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press Release dated November 2, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

UNITED THERAPEUTICS CORPORATION

Dated: November 2, 2022

By: /s/ Paul A. Mahon
Name: Paul A. Mahon
Title: General Counsel

Exhibit 99.1

For Immediate Release
Contact: Dewey Steadman
Phone: (202) 919-4097
Email: ir@unither.com

United Therapeutics Corporation Reports Third Quarter 2022 Financial Results

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., November 2, 2022: United Therapeutics Corporation (Nasdaq: UTHR), a public benefit corporation, today announced its financial results for the quarter ended September 30, 2022. Total revenues in the third quarter of 2022 grew 16% year-over-year to $516.0 million, compared to $444.7 million in the third quarter of 2021.

“We are thrilled to report the highest quarterly revenue in our history,” said **Martine Rothblatt, Ph.D.**, Chairperson and CEO of United Therapeutics. “On top of our historic performance, we continue to innovate with the recent launch of the pivotal *TETON 2* study of Tyvaso in idiopathic pulmonary fibrosis, which adds to the four other registration studies we have underway.”

“We are extremely pleased to have achieved several commercial milestones in the third quarter, highlighted by Tyvaso becoming our first $1 billion annual run rate product,” said **Michael Benkowitz**, President and Chief Operating Officer of United Therapeutics. “Tyvaso DPI has provided a catalyst to our growth trajectory and has us well positioned to achieve our goal of 6,000 patients on Tyvaso by the end of the year.”

THIRD QUARTER 2022 FINANCIAL RESULTS

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

	Three Months Ended September 30,			
	2022	2021	Dollar Change	Percentage Change
Revenues	$ 516.0	$ 444.7	$ 71.3	16 %
Net income	$ 239.3	$ 162.7	$ 76.6	47 %
Net income, per basic share	$ 5.26	$ 3.62	$ 1.64	45 %
Net income, per diluted share	$ 4.91	$ 3.42	$ 1.49	44 %

Revenues

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

	Three Months Ended September 30,			
	2022	2021	Dollar Change	Percentage Change
Net product sales:				
Tyvaso®(1)	$ 257.7	$ 164.2	$ 93.5	57 %
Remodulin®(2)	114.0	125.4	(11.4)	(9)%
Orenitram®	87.5	85.2	2.3	3 %
Unituxin®	46.1	55.3	(9.2)	(17)%
Adcirca®	10.7	14.6	(3.9)	(27)%
Total revenues	$ 516.0	$ 444.7	$ 71.3	16 %

(1) Net product sales include both the drug product and the respective inhalation devices for both Tyvaso and Tyvaso DPI®.

(2) Net product sales include sales of infusion devices, such as the Remunity® Pump.

Net product sales from our treprostinil-based products (Tyvaso, Remodulin, and Orenitram) grew by $84.4 million for the third quarter of 2022, as compared to the same period in 2021. The growth in Tyvaso revenues resulted primarily from an increase in quantities sold and, to a lesser extent, the impact of a price increase and lower gross-to-net deductions. The increase in quantities sold was driven by our launch of sales of Tyvaso DPI in June 2022 and continued growth in the number of patients following the Tyvaso label expansion in March 2021 to include the treatment of pulmonary hypertension associated with interstitial lung disease (**PH-ILD**). The decrease in Remodulin revenues was due to a $6.8 million decrease in international Remodulin net product sales and a $4.6 million decrease in U.S. Remodulin net product sales.

Expenses

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

	Three Months Ended September 30,			
	2022	2021	Dollar Change	Percentage Change
Category:				
Cost of product sales	$ 37.1	$ 26.8	$ 10.3	38 %
Share-based compensation expense[1]	0.1	0.9	(0.8)	(89)%
Total cost of product sales	$ 37.2	$ 27.7	$ 9.5	34 %

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

Cost of product sales, excluding share-based compensation. Cost of product sales for the three months ended September 30, 2022 increased as compared to the same period in 2021, primarily due to an increase in royalty expense and product costs due to an overall increase in sales.

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

	Three Months Ended September 30,			
	2022	2021	Dollar Change	Percentage Change
Category:				
External research and development[1]	$ 37.6	$ 35.7	$ 1.9	5 %
Internal research and development[2]	29.1	30.8	(1.7)	(6)%
Share-based compensation expense[3]	2.0	5.7	(3.7)	(65)%
Impairments[4]	—	1.2	(1.2)	(100)%
Other[5]	(2.6)	5.8	(8.4)	(145)%
Total research and development expense	$ 66.1	$ 79.2	$ (13.1)	(17)%

(1) *External research and development* primarily includes fees paid to third parties (such as clinical trial sites, contract research organizations, and contract laboratories) for preclinical and clinical studies and payments to third-party contract manufacturers before FDA approval of the relevant product.

(2) *Internal research and development* primarily includes salary-related expenses for research and development functions, internal costs to manufacture product candidates before FDA approval, and internal facilities-related expenses, including depreciation, related to research and development activities.

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

(4) *Impairments* primarily includes impairment charges to write-down the carrying value of in-process research and development and of certain property, plant, and equipment as a result of research and development activities.

(5) *Other* primarily includes upfront fees and milestone payments to third parties under license agreements related to development-stage products, and adjustments to the fair value of our contingent consideration obligations.

Research and development expense, excluding share-based compensation. Research and development expense for the three months ended September 30, 2022 decreased as compared to the same period in 2021, primarily due to adjustments to the fair value of our contingent consideration obligations.

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

	Three Months Ended September 30,			
	2022	2021	Dollar Change	Percentage Change
Category:				
General and administrative	$ 85.7	$ 73.9	$ 11.8	16 %
Sales and marketing	17.2	17.2	—	— %
Share-based compensation (benefit) expense[(1)]	(4.5)	18.0	(22.5)	(125)%
Total selling, general, and administrative expense	$ 98.4	$ 109.1	$ (10.7)	(10)%

(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, 2022, as compared to the same period in 2021, was primarily due to: (1) an increase in branded prescription drug fee expense associated with sales of Tyvaso; and (2) an impairment expense related to property, plant, and equipment.

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

	Three Months Ended September 30,			
	2022	2021	Dollar Change	Percentage Change
Category:				
Stock options	$ 5.7	$ 5.8	$ (0.1)	(2)%
Restricted stock units	9.9	6.2	3.7	60 %
Share tracking awards plan (**STAP**)	(18.5)	12.2	(30.7)	(252)%
Employee stock purchase plan	0.5	0.4	0.1	25 %
Total share-based compensation (benefit) expense	$ (2.4)	$ 24.6	$ (27.0)	(110)%

The increase in share-based compensation benefit for the three months ended September 30, 2022, as compared to the same period in 2021, was primarily due to an increase in STAP benefit driven by an 11 percent decrease in our stock price for the three months ended September 30, 2022, as compared to a three percent increase in our stock price for the same period in 2021.

Other expense, net. The decrease in *other expense, net* of $17.6 million for the three months ended September 30, 2022, as compared to the same period in 2021, was primarily due to net unrealized and realized gains and losses on equity securities.

Income tax expense. *Income tax expense* for the three months ended September 30, 2022 and 2021 was $73.2 million and $41.7 million, respectively. The effective income tax rate (**ETR**) for the three months ended September 30, 2022 and 2021 was 23 percent and 20 percent, respectively. The ETR for the three months ended September 30, 2022 increased compared to the ETR for the three months ended September 30, 2021 primarily due to an increase in the valuation allowance in the current period compared to a decrease in the prior period.

PRODUCT COMMERCIALIZATION UPDATE

Tyvaso DPI. The FDA approved Tyvaso DPI in May 2022 for pulmonary arterial hypertension (**PAH**) and PH-ILD. Our first commercial shipments to specialty pharmacies occurred in June 2022 and the first patients started Tyvaso DPI therapy shortly thereafter.

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. In April 2022, the Centers for Medicare and Medicaid Services updated its Local Coverage Determination (**LCD**) for Tyvaso to include an indication for PH-ILD. This LCD became effective on June 5, 2022.

Remunity Pump for Remodulin. In February 2021, we launched U.S. commercial sales of the Remunity Pump for Remodulin, which is a pre-filled, semi-disposable system for subcutaneous delivery of treprostinil. The Remunity Pump consists of a small, lightweight, durable pump and separate controller. The Remunity Pump uses disposable cassettes 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. The Remunity Pump was initially made available to patients in the United States primarily by contracted specialty pharmacies, with weekly shipments of disposable cassettes pre-filled with Remodulin. In September 2022, we launched a patient-filled version, which enables patients to receive monthly shipments of Remunity cassettes and Remodulin instead of weekly shipments of pre-filled cassettes.

RESEARCH AND DEVELOPMENT UPDATE

Updates on select later-stage programs are below.

Tyvaso in IPF — *TETON 1* and *TETON 2*. We are enrolling two phase 3 studies, called *TETON 1* and *TETON 2*, of Tyvaso for the treatment of idiopathic pulmonary fibrosis (**IPF**). *TETON 1* is being conducted in the United States and Canada, and *TETON 2* is being conducted outside the United States and Canada. The primary endpoint of both studies is the change in absolute forced vital capacity (**FVC**) from baseline to week 52. The *TETON 1* study enrolled its first patient in June 2021, and the *TETON 2* study enrolled its first patient in October 2022.

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 an underlying etiology of IPF showing the greatest improvement. Consistent positive effects were also observed in patients with chronic hypersensitivity pneumonitis and environmental/occupational lung disease. In May 2022, data from the *INCREASE* open-label, long-term extension trial were presented at a medical conference, indicating that improvements in FVC were sustained for at least 64 weeks for IPF patients. For those patients who received placebo during the *INCREASE* study, marked improvements in FVC were observed following transition to active Tyvaso during the open-label extension study. 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.

Ralinepag phase 3 studies — *ADVANCE CAPACITY* and *ADVANCE OUTCOMES*. We are enrolling two phase 3 studies to support the potential approval of oral ralinepag for PAH.

Centralized Lung Evaluation System (CLES) for *ex-vivo* lung perfusion (EVLP). We are evaluating the use of the CLES technology for EVLP through a registration study of 186 lung transplant participants. Enrollment for this study is nearly complete.

Tyvaso in PH-COPD — *PERFECT*. In September 2022, we discontinued the *PERFECT* clinical study of Tyvaso for the treatment of WHO Group 3 pulmonary hypertension associated with chronic obstructive pulmonary disease. We terminated the study in accordance with a recommendation of the study's independent Data Safety Monitoring Committee (**DSMC**), following a routine safety and efficacy analysis conducted by the DSMC.

WEBCAST

We will host a webcast to discuss our third quarter 2022 financial results on Wednesday, November 2, 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

At United Therapeutics, our vision and mission are one. We use our enthusiasm, creativity, and persistence to innovate for the unmet medical needs of our patients and to benefit our other stakeholders. We are bold and unconventional. We have fun, we do good. 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*.

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 goal of achieving 6,000 patients on Tyvaso by the end of 2022, our clinical trials and other research and development plans, including the *TETON* studies of Tyvaso*,* the *ADVANCE* studies of ralinepag, our clinical study of the CLES technology for EVLP, and our goals of innovating for the unmet medical needs of our patients and to benefit our other stakeholders, furthering our public benefit purpose of developing novel pharmaceutical therapies and technologies that expand the availability of transplantable organs, 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. 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 2, 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 September 30,	
	2022	2021
	(Unaudited)	
Revenues:		
Net product sales	$ 516.0	$ 444.7
Total revenues	516.0	444.7
Operating expenses:		
Cost of product sales	37.2	27.7
Research and development	66.1	79.2
Selling, general, and administrative	98.4	109.1
Total operating expenses	201.7	216.0
Operating income	314.3	228.7
Interest income	13.3	3.8
Interest expense	(9.2)	(4.6)
Other expense, net	(5.9)	(23.5)
Total other expense, net	(1.8)	(24.3)
Income before income taxes	312.5	204.4
Income tax expense	(73.2)	(41.7)
Net income	$ 239.3	$ 162.7
Net income per common share:		
Basic	$ 5.26	$ 3.62
Diluted	$ 4.91	$ 3.42
Weighted average number of common shares outstanding:		
Basic	45.5	44.9
Diluted	48.7	47.6

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	September 30, 2022
Cash, cash equivalents, and marketable investments	$ 4,059.4
Total assets	5,781.6
Total liabilities	1,219.4
Total stockholders' equity	4,562.2