Section 1: 8-K (FORM 8-K)

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): **July 31, 2019**

United Therapeutics Corporation
(Exact Name of Registrant as Specified in its 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 July 31, 2019, United Therapeutics Corporation issued a press release setting forth its earnings for the quarter ended June 30, 2019.

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 July 31, 2019

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: July 31, 2019

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

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Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1

For Immediate Release
Contact: James Edgemond
(301) 608-9292
jedgemond@unither.com

UNITED THERAPEUTICS CORPORATION REPORTS SECOND QUARTER 2019 FINANCIAL RESULTS

Silver Spring, MD and Research Triangle Park, NC, July 31, 2019: United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the quarter ended June 30, 2019.

“Our prostacyclin product franchise, consisting of Remodulin, Tyvaso, and Orenitram, is being used by a larger number of pulmonary arterial hypertension (PAH) patients than ever before,” said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. “This momentum underscores our belief that our product franchise is well positioned to treat a large and growing number of PAH patients in need of a true prostacyclin analogue therapy. It also reinforces our commitment to advancing our innovative pipeline of next generation drug delivery systems and late stage clinical programs in cardiopulmonary diseases and oncology, as well as regenerative medicine and organ manufacturing programs to ultimately achieve our mission of finding a cure for PAH and other end-stage organ diseases.”

Financial Results for the Three Months Ended June 30, 2019 compared to the Three Months Ended June 30, 2018

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

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2019	2018		
Revenues	$ 373.6	$ 444.5	$ (70.9)	(16)%
Net income	$ 205.1	$ 172.9	$ 32.2	19%
Non-GAAP earnings[(1)]	$ 159.7	$ 189.1	$ (29.4)	(16)%
Net income, per basic share	$ 4.68	$ 4.01	$ 0.67	17%
Net income, per diluted share	$ 4.66	$ 3.98	$ 0.68	17%
Non-GAAP earnings, per diluted share[(1)]	$ 3.63	$ 4.36	$ (0.73)	(17)%

(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
	2019	2018		

Net product sales:				
Remodulin®	$ 155.8	$ 159.5	$ (3.7)	(2)%
Tyvaso®	109.6	105.9	3.7	3%
Orenitram®	54.0	49.5	4.5	9%
Unituxin®	25.1	19.8	5.3	27%
Adcirca®	29.1	109.8	(80.7)	(73)%
Total revenues	$ 373.6	$ 444.5	$ (70.9)	(16)%

Revenues for the three months ended June 30, 2019 decreased by $70.9 million as compared to the same period in 2018.

Remodulin net product sales decreased by $3.7 million for the three months ended June 30, 2019, as compared to the same period in 2018. $10.3 million of the decrease was due to price reductions, primarily to our international distributors, partially offset by a net increase in total quantities shipped of $9.4 million. The net increase in shipments was due to higher quantities sold to our international distributors, partially offset by lower quantities sold to domestic distributors. Changes in quarterly Remodulin sales do not precisely reflect underlying patient demand or changes in patient census as, during the three months ended June 30, 2019, there was an increase in the number of U.S. patients being treated with Remodulin, as compared to the same period in 2018.

Tyvaso net product sales for the three months ended June 30, 2019 increased by $3.7 million as compared to the same period in 2018. This increase was primarily due to a price increase implemented in January 2019 and an increase in the number of patients being treated with Tyvaso, partially offset by higher gross-to-net revenue reductions.

Orenitram net product sales for the three months ended June 30, 2019 increased by $4.5 million as compared to the same period in 2018. This increase was primarily due to an increase in the number of patients being treated with Orenitram and a price increase implemented in January 2019.

Unituxin net product sales for the three months ended June 30, 2019 increased by $5.3 million as compared to the same period in 2018. This increase was due to an increase in the number of vials sold and a price increase implemented in April 2019.

Adcirca net product sales for the three months ended June 30, 2019 decreased by $80.7 million as compared to the same period in 2018. This decrease was primarily due to a decrease in bottles sold following the onset of generic competition for Adcirca beginning in August 2018.

Expenses

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

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2019	2018		
Category:				
Cost of product sales	$ 28.9	$ 61.1	$ (32.2)	(53)%
Share-based compensation (benefit) expense[(1)]	(2.2)	0.6	(2.8)	(467)%
Total cost of product sales	$ 26.7	$ 61.7	$ (35.0)	(57)%

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

Cost of product sales, excluding share-based compensation. The decrease in cost of product sales of $32.2 million for the three months ended June 30, 2019, as compared to the same period in 2018, was primarily attributable to a $34.4 million decrease in royalty expense for Adcirca because fewer bottles were sold due to the launch of generic versions of Adcirca beginning in August 2018.

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

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2019	2018		
Category:				
Research and development projects	$ 95.8	$ 79.1	$ 16.7	21%
Share-based compensation (benefit) expense[(1)]	(9.9)	3.2	(13.1)	(409)%
Total research and development expense	$ 85.9	$ 82.3	$ 3.6	4%

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

Research and development expense, excluding share-based compensation. The increase in research and development expense of $16.7 million for the three months ended June 30, 2019, as compared to the same period in 2018, was driven by continued investment in our product pipeline. Research and development expense for the treatment of cardiopulmonary diseases increased by $19.0 million for the three months ended June 30, 2019, as compared to the same period in 2018, due to: (1) $11.7 million of expenditures associated with the phase III *ADVANCE* studies of ralinepag during the three months ended June 30, 2019; (2) increased spending of $2.2 million on the development of drug delivery devices; and (3) an $8.8 million in-process research and development impairment charge related to the termination of a license agreement during the three months ended June 30, 2019. The increase in total research and development expense was partially offset by a $5.4 million decrease in expense for cancer-related projects driven by the decrease in spending on the *DISTINCT* study, which is now fully-enrolled.

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
	2019	2018		
Category:				
General and administrative	$ 51.0	$ 50.8	$ 0.2	—%
Sales and marketing	13.7	15.6	(1.9)	(12)%
Share-based compensation (benefit) expense[(1)]	(25.1)	16.7	(41.8)	(250)%
Total selling, general and administrative expense	$ 39.6	$ 83.1	$ (43.5)	(52)%

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

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

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2019	2018		
Category:				
Stock options	$ 18.1	$ 15.5	$ 2.6	17%
Restricted stock units	3.8	2.0	1.8	90%
Share tracking awards plan (STAP)	(59.4)	2.7	(62.1)	NM[(1)]
Employee stock purchase plan	0.3	0.3	—	—%
Total share-based compensation (benefit) expense	$ (37.2)	$ 20.5	$ (57.7)	(281)%

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(1) Calculation is not meaningful.

The increase in share-based compensation benefit of $57.7 million for the three months ended June 30, 2019, as compared to the same period in 2018, was primarily due to a $62.1 million increase in STAP benefit driven by a 33 percent decrease in our stock price for the three months ended June 30, 2019, as compared to a 1 percent increase in our stock price for the same period in 2018; partially offset by: (1) a $2.6 million increase in stock option expense due to additional awards granted and outstanding in 2019; and (2) a $1.8 million increase in restricted stock unit expense due to additional awards granted and outstanding in 2019.

Other Income (Expense), Net

The increase in other income (expense), net of $33.7 million for the three months ended June 30, 2019, as compared to the same period in 2018, was primarily due to the recognition of a net unrealized gain in investments in equity securities with readily determinable fair values. During the three months ended June 30, 2019, we recognized $29.5 million of net unrealized gains on these securities.

Income Tax Expense

The income tax expense was $45.3 million for the three months ended June 30, 2019, as compared to $45.0 million for the same period in 2018. The income tax expense is based on an estimated effective tax rate (ETR) for the entire year. The estimated annual ETR is subject to adjustment in subsequent quarterly periods if components used to calculate the estimated annual ETR are updated or revised. Our actual ETR as of June 30, 2019 and June 30, 2018 was 28 percent and 21 percent, respectively. We recognized a loss before income taxes, and a corresponding income tax benefit, for the six months ended June 30, 2019, as a result of the one-time $800.0 million payment to Arena Pharmaceuticals, Inc. in January 2019. As a result of this loss, our anticipated tax credits and foreign sales deduction, partially offset by non-deductible compensation expense, increased our tax benefit and resulting ETR for the six months ended June 30, 2019, compared to the same period in 2018.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income, adjusted for: (1) share-based compensation (benefit) expense (including expenses relating to stock options, restricted stock units, share tracking awards and our employee stock purchase plan); (2) unrealized (gains) losses on equity securities; (3) impairment charges; and (4) tax expense (benefit) on non-GAAP earnings adjustments.

A reconciliation of net income to non-GAAP earnings is presented in the following table (dollars in millions, except per share data):

	Three Months Ended June 30,	
	2019	**2018**
Net income, as reported	$ 205.1	$ 172.9
Adjusted for the following charges:		
Share-based compensation (benefit) expense	(37.2)	20.5
Net unrealized gains on equity securities	(29.5)	—
Impairment charges	8.8	—
Tax expense (benefit)	12.5	(4.3)
Non-GAAP earnings	$ 159.7	$ 189.1
Non-GAAP earnings per share:		
Basic	$ 3.65	$ 4.39
Diluted	$ 3.63	$ 4.36
Weighted average number of common shares outstanding:		
Basic	43.8	43.1
Diluted	44.0	43.4

Inducement Restricted Stock Units

On July 29, 2019, we granted a total of 817 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 July 31, 2020, July 31, 2021 and July 31, 2022, 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 half-hour teleconference on Wednesday, July 31, 2019, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing 1-877-351-5881, with international callers dialing 1-970-315-0533. A rebroadcast of the teleconference will be available for one week by dialing 1-855-859-2056, with international callers dialing 1-404-537-3406, and using access code: 3066089.

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, statements relating to our research and development pipeline (including our efforts to address the shortage of transplantable organs), the ability of our product franchise to treat a large and growing number of PAH patients in need of a true prostacyclin analogue therapy and our ability to 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. 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 31, 2019, 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. [uthr-g]

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

	Three Months Ended June 30,	
	2019	**2018**
	(Unaudited)	
Revenues:		
Net product sales	$ 373.6	$ 444.5
Total revenues	373.6	444.5
Operating expenses:		
Cost of product sales	26.7	61.7
Research and development	85.9	82.3
Selling, general and administrative	39.6	83.1
Total operating expenses	152.2	227.1
Operating income	221.4	217.4
Interest income	10.8	6.7
Interest expense	(12.2)	(2.9)
Other income (expense), net	30.4	(3.3)
Total other income, net	29.0	0.5
Income before income taxes	250.4	217.9
Income tax expense	(45.3)	(45.0)
Net income	$ 205.1	$ 172.9
Net income per common share:		
Basic	$ 4.68	$ 4.01
Diluted	$ 4.66	$ 3.98
Weighted average number of common shares outstanding:		
Basic	43.8	43.1
Diluted	44.0	43.4

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	June 30, 2019
Cash, cash equivalents and marketable investments	$ 2,206.9
Total assets	3,898.9
Total liabilities and temporary equity	1,340.5
Total stockholders' equity	2,558.4

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