
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): **October 30, 2019**

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other
Jurisdiction of
Incorporation)

000-26301
(Commission
File Number)

52-1984749
(I.R.S. Employer
Identification Number)

1040 Spring Street
Silver Spring, MD
(Address of Principal Executive Offices)

20910
(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 October 30, 2019, United Therapeutics Corporation issued a press release setting forth its earnings for the quarter ended September 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 October 30, 2019 | 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: October 30, 2019

By: /s/ Paul A. Mahon

Name: Paul A. Mahon

Title: General Counsel

[\(Back To Top\)](#)

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 THIRD QUARTER 2019 FINANCIAL RESULTS

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

“We are pleased to see continued growth during the quarter in the total number of U.S. patients treated with our prostacyclin product franchise, consisting of Remodulin, Tyvaso, and Orenitram,” said Michael Benkowitz, President and Chief Operating Officer of United Therapeutics. “As we execute toward our commercial goals, we are also continuing to execute toward our clinical goals, which include the recent label update to indicate that Orenitram delays disease progression and continued progress toward near-term phase III clinical trial readouts for *DISTINCT*, the study of dinutuximab for small cell lung cancer, and *INCREASE*, the study of pulmonary hypertension associated with interstitial lung disease.”

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

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

| | Three Months Ended September 30, | | Dollar Change | Percentage Change |
|---|-------------------------------------|----------|------------------|----------------------|
| | 2019 | 2018 | | |
| Revenues | \$ 401.5 | \$ 412.7 | \$ (11.2) | (3)% |
| Net income | \$ 132.4 | \$ 106.5 | \$ 25.9 | 24% |
| Non-GAAP earnings ⁽¹⁾ | \$ 168.3 | \$ 174.9 | \$ (4.6) | (3)% |
| Net income, per basic share | \$ 3.02 | \$ 2.44 | \$ 0.58 | 24% |
| Net income, per diluted share | \$ 3.01 | \$ 2.42 | \$ 0.59 | 24% |
| Non-GAAP earnings, per diluted share ⁽¹⁾ | \$ 3.83 | \$ 3.98 | \$ (0.15) | (4)% |

(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 September 30, | | Dollar Change | Percentage Change |
|--------------------|-------------------------------------|------|------------------|----------------------|
| | 2019 | 2018 | | |
| Net product sales: | | | | |

| | | | | | | | |
|------------------------|----|--------------|----|--------------|----|---------------|-------------|
| Remodulin [®] | \$ | 168.3 | \$ | 153.6 | \$ | 14.7 | 10% |
| Tyvaso [®] | | 110.8 | | 107.8 | | 3.0 | 3% |
| Orenitram [®] | | 62.0 | | 53.8 | | 8.2 | 15% |
| Unituxin [®] | | 30.1 | | 22.9 | | 7.2 | 31% |
| Adcirca [®] | | 30.3 | | 74.6 | | (44.3) | (59)% |
| Total revenues | \$ | <u>401.5</u> | \$ | <u>412.7</u> | \$ | <u>(11.2)</u> | <u>(3)%</u> |

Revenues for the three months ended September 30, 2019 decreased by \$11.2 million as compared to the same period in 2018, driven entirely by a decrease in Adcirca revenues following the onset of generic competition in 2018. Revenues for our other four commercial products grew by \$33.1 million in the aggregate for the three months ended September 30, 2019. Additional details regarding each product are discussed below.

Remodulin net product sales increased by \$14.7 million for the three months ended September 30, 2019, as compared to the same period in 2018. \$32.7 million of the increase was due to an increase in total quantities sold, primarily to our international distributors, partially offset by a decrease of \$13.9 million due to price reductions, primarily to our international distributors, and higher gross-to-net revenue deductions of \$4.1 million. During the three months ended September 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 September 30, 2019 increased by \$3.0 million, as compared to the same period in 2018, primarily due to a price increase implemented in January 2019.

Orenitram net product sales for the three months ended September 30, 2019 increased by \$8.2 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, partially offset by higher gross-to-net revenue deductions.

Unituxin net product sales for the three months ended September 30, 2019 increased by \$7.2 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 September 30, 2019 decreased by \$44.3 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):

| Category: | Three Months Ended September 30, | | Dollar Change | Percentage Change |
|---|-------------------------------------|----------------|------------------|----------------------|
| | 2019 | 2018 | | |
| Cost of product sales | \$ 32.3 | \$ 49.5 | \$ (17.2) | (35)% |
| Share-based compensation expense ⁽¹⁾ | 0.7 | 2.4 | (1.7) | (71)% |
| Total cost of product sales | <u>\$ 33.0</u> | <u>\$ 51.9</u> | <u>\$ (18.9)</u> | <u>(36)%</u> |

(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 \$17.2 million for the three months ended September 30, 2019, as compared to the same period in 2018, was primarily attributable to a \$19.0 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):

| Category: | Three Months Ended September 30, | | Dollar Change | Percentage Change |
|---|-------------------------------------|-----------------|------------------|----------------------|
| | 2019 | 2018 | | |
| Research and development projects | \$ 83.0 | \$ 92.8 | \$ (9.8) | (11)% |
| Share-based compensation expense ⁽¹⁾ | 2.7 | 8.3 | (5.6) | (67)% |
| Total research and development expense | <u>\$ 85.7</u> | <u>\$ 101.1</u> | <u>\$ (15.4)</u> | <u>(15)%</u> |

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

Research and development expense, excluding share-based compensation. Research and development expense decreased by \$9.8 million for the three months ended September 30, 2019, as compared to the same period in 2018. Research and development expense for the treatment of cardiopulmonary diseases decreased by \$21.9 million for the three months ended September 30, 2019, as compared to the same period in 2018, due to: (1) a one-time \$10.0 million payment under a research agreement with MannKind; and (2) an up-front payment of \$10.0 million under our license agreement with Samumed, both of which occurred during the three months ended September 30, 2018. The decrease in cardiopulmonary research and development expense was partially offset by an \$11.2 million increase in research and development expense for our organ manufacturing projects due to increased preclinical and clinical work on technologies designed to increase the supply of transplantable organs and tissues.

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

| Category: | Three Months Ended September 30, | | Dollar Change | Percentage Change |
|---|-------------------------------------|-----------------|------------------|----------------------|
| | 2019 | 2018 | | |
| General and administrative | \$ 64.1 | \$ 56.1 | \$ 8.0 | 14% |
| Sales and marketing | 14.8 | 13.3 | 1.5 | 11% |
| Share-based compensation expense ⁽¹⁾ | 20.5 | 40.7 | (20.2) | (50)% |
| Total selling, general and administrative expense | <u>\$ 99.4</u> | <u>\$ 110.1</u> | <u>\$ (10.7)</u> | <u>(10)%</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 September 30, | | Dollar Change | Percentage Change |
|--|-------------------------------------|----------------|------------------|----------------------|
| | 2019 | 2018 | | |
| Stock options | \$ 18.4 | \$ 16.6 | \$ 1.8 | 11% |
| Restricted stock units | 3.8 | 2.4 | 1.4 | 58% |
| Share tracking awards plan (STAP) | 1.4 | 32.2 | (30.8) | (96)% |
| Employee stock purchase plan | 0.3 | 0.2 | 0.1 | 50% |
| Total share-based compensation expense | <u>\$ 23.9</u> | <u>\$ 51.4</u> | <u>\$ (27.5)</u> | <u>(54)%</u> |

The decrease in share-based compensation expense of \$27.5 million for the three months ended September 30, 2019, as compared to the same period in 2018, was primarily due to a \$30.8 million decrease in STAP expense driven by a 2 percent increase in our stock price for the three months ended September 30, 2019, as compared to a 13 percent increase in our stock price for the same period in 2018; partially offset by: (1) a \$1.8 million increase in stock option expense due to additional awards granted and outstanding in 2019; and (2) a \$1.4 million increase in restricted stock unit expense due to additional awards granted and outstanding in 2019.

Other Expense, Net

The increase in other expense, net of \$16.0 million for the three months ended September 30, 2019, as compared to the same period in 2018, was primarily due to the recognition of a net unrealized loss in publicly-traded equity securities. During the three months ended September 30, 2019, we recognized \$13.0 million of net unrealized losses on these securities.

Impairment of Investment in a Privately-Held Company

During the quarter ended September 30, 2018, one of the privately-held companies in which we invested experienced an event triggering an impairment analysis to evaluate the recoverability of our investment. We determined that the fair value of our investment was lower than its carrying value, resulting in an impairment charge of \$12.4 million.

Income Tax Expense

The income tax expense was \$34.5 million for the three months ended September 30, 2019, as compared to \$33.6 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 September 30, 2019 and September 30, 2018 was 33 percent and 21 percent, respectively. We recognized a loss before income taxes, and a corresponding income tax benefit, for the nine months ended September 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 nine months ended September 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 expense (including expenses relating to stock options, restricted stock units, share tracking awards and our employee stock purchase plan); (2) impairment of investment in privately-held company; (3) unrealized losses (gains) on equity securities; (4) asset impairment charges; (5) license-related fees; and (6) tax benefit on non-GAAP earnings adjustments.

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

| | Three Months Ended September 30, | |
|---|-------------------------------------|-----------------|
| | 2019 | 2018 |
| Net income, as reported | \$ 132.4 | \$ 106.5 |
| Adjusted for the following charges: | | |
| Share-based compensation expense | 23.9 | 51.4 |
| Impairment of investment in privately-held company | — | 12.4 |
| Net unrealized losses on equity securities | 13.0 | — |
| Asset impairment charges | 8.4 | — |
| License-related fees | — | 20.0 |
| Tax benefit | (9.4) | (15.4) |
| Non-GAAP earnings | <u>\$ 168.3</u> | <u>\$ 174.9</u> |
| Non-GAAP earnings per share: | | |
| Basic | <u>\$ 3.83</u> | <u>\$ 4.01</u> |
| Diluted | <u>\$ 3.83</u> | <u>\$ 3.98</u> |
| Weighted average number of common shares outstanding: | | |
| Basic | <u>43.9</u> | <u>43.6</u> |
| Diluted | <u>44.0</u> | <u>44.0</u> |

Inducement Restricted Stock Units

On October 25, 2019, we granted a total of 2,604 restricted stock units under our 2019 Inducement Stock Incentive Plan to three newly hired employees. These restricted stock units vest in three equal installments on October 31, 2020, October 31, 2021 and October 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, October 30, 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: 7462119.

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 achieving our commercial and clinical goals, including those related to the recent update to the Orenitram label, as well as upcoming readouts of our *DISTINCT* and *INCREASE* studies. 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 October 30, 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.

Orenitram, Remodulin, Tyvaso and Unituxin are registered trademarks 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 | |
|--|---------------------------|-------------|
| | September 30, | |
| | 2019 | 2018 |
| | (Unaudited) | |
| Revenues: | | |
| Net product sales | \$ 401.5 | \$ 412.7 |
| Total revenues | 401.5 | 412.7 |
| Operating expenses: | | |
| Cost of product sales | 33.0 | 51.9 |
| Research and development | 85.7 | 101.1 |
| Selling, general and administrative | 99.4 | 110.1 |
| Total operating expenses | 218.1 | 263.1 |
| Operating income | 183.4 | 149.6 |
| Interest income | 12.1 | 7.9 |
| Interest expense | (11.7) | (4.1) |
| Other expense, net | (16.9) | (0.9) |
| Impairment of investment in privately-held company | — | (12.4) |
| Total other expense, net | (16.5) | (9.5) |
| Income before income taxes | 166.9 | 140.1 |
| Income tax expense | (34.5) | (33.6) |
| Net income | \$ 132.4 | \$ 106.5 |
| Net income per common share: | | |
| Basic | \$ 3.02 | \$ 2.44 |
| Diluted | \$ 3.01 | \$ 2.42 |
| Weighted average number of common shares outstanding: | | |
| Basic | 43.9 | 43.6 |
| Diluted | 44.0 | 44.0 |

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

| | September 30, |
|---|----------------------|
| | 2019 |
| Cash, cash equivalents and marketable investments | \$ 2,300.4 |
| Total assets | 3,999.6 |
| Total liabilities | 1,283.8 |
| Total stockholders' equity | 2,715.8 |

[\(Back To Top\)](#)