



United Therapeutics Corporation Reports Second Quarter 2018 Financial Results

August 1, 2018

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Aug. 1, 2018 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) today announced its financial results for the quarter ended June 30, 2018.

"Our second quarter net revenues totaled \$444 million and we are treating a larger number of patients, compared to the prior year, suffering from pulmonary arterial hypertension with our prostacyclin product franchise, which consists of Orenitram, Remodulin, and Tyvaso," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "We also continued to invest in our innovative product pipeline, which includes seven Phase III clinical trials in cardiopulmonary diseases and oncology as well as programs in regenerative medicine and organ manufacturing to ultimately provide a cure for PAH and other end-stage organ diseases. We believe this product pipeline uniquely positions United Therapeutics to deliver long-term revenue growth to our stakeholders."

Update on SteadyMed Acquisition

Our previously-announced acquisition of SteadyMed Ltd. (SteadyMed) has satisfied two key closing conditions. On July 20, 2018, the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 expired, and on July 30, 2018, SteadyMed's shareholders approved the transaction. Under Israeli law, closing may not occur until at least thirty days have passed since the SteadyMed shareholders approved the transaction. Assuming all remaining conditions to closing of this transaction are satisfied or waived, we expect the transaction to be completed in the third quarter of this year. SteadyMed's lead drug product candidate is Trevyent®, a development-stage drug-device combination product that combines SteadyMed's PatchPump® technology with treprostinil to treat pulmonary arterial hypertension.

Financial Results for the Three Months Ended June 30, 2018 compared to the Three Months Ended June 30, 2017

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

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2018	2017		
Revenues	\$ 444.5	\$ 444.6	\$ (0.1)	— %
Net income (loss)	\$ 172.9	\$ (56.0)	\$ 228.9	409 %
Non-GAAP earnings(1)	\$ 189.1	\$ 199.2	\$ (10.1)	(5) %
Net income (loss), per basic share	\$ 4.01	\$ (1.25)	\$ 5.26	421 %
Net income (loss), per diluted share	\$ 3.98	\$ (1.25)	\$ 5.23	418 %
Non-GAAP earnings, per diluted share(1)	\$ 4.36	\$ 4.37	\$ (0.01)	— %

(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 following table presents the components of total revenues (dollars in millions):

	Three Months Ended June 30,		Dollar Change	Percentage Change
	2018	2017		
Net product sales:				
Remodulin®	\$ 159.5	\$ 157.7	\$ 1.8	1 %
Tyvaso®	105.9	104.2	1.7	2 %
Adcirca®	109.8	120.6	(10.8)	(9) %
Orenitram®	49.5	46.0	3.5	8 %
Unituxin®	19.8	16.1	3.7	23 %
Total revenues	<u>\$ 444.5</u>	<u>\$ 444.6</u>	<u>\$ (0.1)</u>	<u>— %</u>

Revenues for the three months ended June 30, 2018 decreased by \$0.1 million as compared to the same period in 2017. Remodulin net product sales increased by \$1.8 million due to a \$16.7 million increase in U.S. net product sales partially offset by a \$14.9 million decrease in international net product sales. U.S. net product sales increased due to an increase in quantities ordered from our U.S. distributors, which do not precisely reflect

underlying patient demand, and a price increase implemented in April 2018, which was the first price increase for Remodulin since 2010. International net product sales decreased primarily due to a reduction in the price at which we sell Remodulin to an international distributor in connection with a transfer of additional regulatory and commercial responsibilities to that distributor in 2017. Tyvaso net product sales increased by \$1.7 million primarily due to a price increase. Adcirca net product sales decreased by \$10.8 million primarily due to a decrease in the number of bottles sold, partially offset by price increases that were determined by Lilly. Orenitram net product sales increased by \$3.5 million primarily due to an increase in the number of patients being treated with Orenitram. Unituxin net product sales increased by \$3.7 million primarily due to an increase in the number of vials sold and a price increase implemented in 2017.

Expenses

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

Category:	Three Months Ended June 30,		Dollar Change	Percentage Change
	2018	2017		
Cost of product sales	\$ 61.1	\$ 19.3	\$ 41.8	217 %
Share-based compensation expense (benefit)(1)	0.6	(0.4)	1.0	250 %
Total cost of product sales	<u>\$ 61.7</u>	<u>\$ 18.9</u>	<u>\$ 42.8</u>	<u>226 %</u>

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

Cost of product sales, excluding share-based compensation. The increase in cost of product sales of \$41.8 million for the three months ended June 30, 2018, as compared to the same period in 2017, was primarily due to a \$40.7 million increase in the royalty expense for Adcirca. As a result of an amendment to our license agreement with Lilly, effective December 1, 2017 our royalty rate on net product sales of Adcirca increased from five percent to an effective rate of approximately 42.5 percent.

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

Category:	Three Months Ended June 30,		Dollar Change	Percentage Change
	2018	2017		
Research and development projects	\$ 79.1	\$ 61.6	\$ 17.5	28 %
Share-based compensation expense (benefit)(1)	3.2	(1.8)	5.0	278 %
Total research and development expense	<u>\$ 82.3</u>	<u>\$ 59.8</u>	<u>\$ 22.5</u>	<u>38 %</u>

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

Research and development expense, excluding share-based compensation. The increase in research and development expense of \$17.5 million for the three months ended June 30, 2018, as compared to the same period in 2017, was driven by the continued investment in our innovative product pipeline to treat cardiopulmonary diseases and cancer.

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

Category:	Three Months Ended June 30,		Dollar Change	Percentage Change
	2018	2017		
General and administrative	\$ 50.8	\$ 51.6	\$ (0.8)	(2) %
Sales and marketing	15.6	15.5	0.1	1 %
Share-based compensation expense(1)	16.7	0.3	16.4	NM (2)
Total selling, general and administrative expense	<u>\$ 83.1</u>	<u>\$ 67.4</u>	<u>\$ 15.7</u>	<u>23 %</u>

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

(2) Calculation is not meaningful.

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

Category:	Three Months Ended June 30,		Dollar Change	Percentage Change
	2018	2017		
Stock options	\$ 15.5	\$ 12.2	\$ 3.3	27 %
Restricted stock units	2.0	0.5	1.5	300 %
Share tracking awards plan (STAP)	2.7	(14.9)	17.6	118 %
Employee stock purchase plan	0.3	0.3	—	— %
Total share-based compensation expense (benefit)	<u>\$ 20.5</u>	<u>\$ (1.9)</u>	<u>\$ 22.4</u>	<u>NM (1)</u>

(1) Calculation is not meaningful.

The increase in share-based compensation expense of \$22.4 million for the three months ended June 30, 2018, as compared to the same period in 2017, was primarily due to: (1) a \$17.6 million increase in STAP expense related to an increase in our stock price during the three months ended June 30, 2018, as compared to a decrease in our stock price during the same period in 2017; and (2) a \$3.3 million increase in stock option expense due to additional awards granted and outstanding in 2018.

Loss Contingency

In December 2017, we entered into a civil Settlement Agreement with the U.S. Government to resolve a DOJ investigation related to our support of 501(c)(3) organizations that provide financial assistance to patients. During the second quarter of 2017, we recorded a \$210.0 million accrual relating to this matter, and ultimately paid this amount, plus interest, to the U.S. Government upon settlement.

Impairment of Investment in a Privately-Held Company

During the quarter ended June 30, 2017, one of our investments in a privately-held company experienced an event triggering an impairment analysis to evaluate the recoverability of our investment. We determined that the fair value of our investment as of June 30, 2017 was lower than its carrying value, resulting in an impairment charge of \$46.5 million. As of June 30, 2017, the adjusted carrying value of our investment in this company was \$53.5 million. The carrying value of this asset has not been further adjusted since June 30, 2017.

Income Tax Expense

The provision for income taxes was \$45.0 million for the three months ended June 30, 2018, as compared to \$100.2 million for the same period in 2017. The provision for income taxes is based on an estimated effective tax rate for the entire year. The estimated annual effective tax rate is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are updated or revised. Our effective tax rate (ETR) as of June 30, 2018 and June 30, 2017 was approximately 21 percent and approximately 60 percent, respectively. Our ETR for the six months ended June 30, 2018 decreased as compared to the same period in 2017 due to the impacts of The Tax Cuts and Jobs Act as well as the \$210.0 million accrual in connection with the civil settlement described above and the \$46.5 million impairment charge described above that did not meet the criteria for tax deductibility at that time.

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) loss contingency; (3) impairment of investment in privately-held company; and (4) tax impact on non-GAAP earnings adjustments.

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

	Three Months Ended June 30,	
	2018	2017
Net income (loss), as reported	\$ 172.9	\$ (56.0)
Adjusted for the following charges:		
Share-based compensation expense (benefit)(1)	20.5	(1.9)
Loss contingency(2)	—	210.0
Impairment of investment in privately-held company(2)	—	46.5
Tax (benefit) expense(1)	<u>(4.3)</u>	<u>0.6</u>

Non-GAAP earnings	<u>\$ 189.1</u>	<u>\$ 199.2</u>
Non-GAAP earnings per share:		
Basic	<u>\$ 4.39</u>	<u>\$ 4.44</u>
Diluted	<u>\$ 4.36</u>	<u>\$ 4.37</u>
Weighted average number of common shares outstanding:		
Basic	<u>43.1</u>	<u>44.9</u>
Diluted	<u>43.4</u>	<u>45.6</u>

(1) We calculated the total tax impact of non-discrete quarterly non-GAAP earnings adjustments based on our estimated annual effective tax rates, before considering discrete items, of approximately 21 percent and approximately 33 percent for the quarters ended June 30, 2018 and June 30, 2017, respectively.

(2) As of June 30, 2017, these non-GAAP earnings adjustments did not meet the criteria for tax deductibility.

Conference Call

We will host a half-hour teleconference on Wednesday, August 1, 2018, 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: 4434188.

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

About United Therapeutics

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions.

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 excluding certain expenses that we do not consider when evaluating and comparing the performance of our core operations and making operating decisions. 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 potential revenue growth, and the potential for our programs to result in a cure for PAH and other end-stage organ diseases. 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 August 1, 2018, 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]

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	
June 30,	
<u>2018</u>	<u>2017</u>

(Unaudited)

Revenues:

Net product sales	\$ 444.5	\$ 444.6
Total revenues	444.5	444.6
Operating expenses:		
Cost of product sales	61.7	18.9
Research and development	82.3	59.8
Selling, general and administrative	83.1	67.4
Loss contingency	—	210.0
Total operating expenses	227.1	356.1
Operating income	217.4	88.5
Other (expense) income:		
Interest expense	(2.9)	(1.4)
Other, net	3.4	3.6
Impairment of investment in privately-held company	—	(46.5)
Total other income (expense), net	0.5	(44.3)
Income before income taxes	217.9	44.2
Income tax expense	(45.0)	(100.2)
Net income (loss)	\$ 172.9	\$ (56.0)
Net income (loss) per common share:		
Basic	\$ 4.01	\$ (1.25)
Diluted	\$ 3.98	\$ (1.25)
Weighted average number of common shares outstanding:		
Basic	43.1	44.9
Diluted	43.4	44.9

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	June 30, 2018
Cash, cash equivalents and marketable investments	\$ 1,791.3
Total assets	3,244.9
Total liabilities and temporary equity	679.3
Total stockholders' equity	2,565.6

View original content: <http://www.prnewswire.com/news-releases/united-therapeutics-corporation-reports-second-quarter-2018-financial-results-300689803.html>

SOURCE United Therapeutics Corporation

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