Section 1: 8-K (FORM 8K)

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): **April 29, 2020**

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 April 29, 2020, United Therapeutics Corporation issued a press release setting forth its earnings for the quarter ended March 31, 2020.

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 April 29, 2020
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: April 29, 2020

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

United Therapeutics Corporation Reports
First Quarter 2020 Financial Results

- First quarter Orenitram® net revenue growth of 18% year-over-year

- Major milestones such as the INCREASE filing and Remunity™ Pump launch remain on track despite the COVID-19 pandemic

- United Therapeutics is engaged in the fight against COVID-19

Silver Spring, MD and Research Triangle Park, NC, April 29, 2020: United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the quarter ended March 31, 2020. First quarter net revenue decreased 2% to $356.3 million year-over-year while first quarter net revenue excluding Adcirca increased 0.4%, compared to the first quarter of 2019. First quarter diluted earnings per share (EPS) was $3.12 compared to an $11.32 per share loss in the first quarter of 2019. Non-GAAP diluted EPS of $3.61 was up 1% from the first quarter of 2019.

“I’m proud of the efforts of the entire United Therapeutics team to ensure continued access to our life-sustaining therapies during this unprecedented time,” said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. “We’re excited that our supplemental new drug application to expand the potential Tyvaso® patient population with the *INCREASE* study results remains on track for a mid-year filing and, along with our partner DEKA, we’re preparing for a July 2020 launch of our Remunity Pump.”

Michael Benkowitz, President and Chief Operating Officer of United Therapeutics, commented, “We’re pleased with Remodulin®’s continued resilience in the face of generic competition and Orenitram’s 18% year-over-year revenue growth, which we attribute to physician reception of the *FREEDOM-EV* data showing that Orenitram, when used in combination with an approved oral background therapy, delays disease progression *and* leads to improvement across key clinical parameters. We see these data, plus the recently announced publications demonstrating Orenitram’s positive effect on hemodynamics, risk status, and PAH-related healthcare costs, as enhancing Orenitram’s value proposition.”

FIRST QUARTER 2020 FINANCIAL RESULTS

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

	Three Months Ended March 31,			
	2020	2019	Dollar Change	Percentage Change
Revenues	$ 356.3	$ 362.6	$ (6.3)	(2)%
Net income (loss)	$ 137.7	$ (494.6)	$ 632.3	128%

Non-GAAP earnings[(1)]	$	159.2	$	157.9	$	1.3	1%
Net income (loss), per basic share	$	3.14	$	(11.32)	$	14.46	128%
Net income (loss), per diluted share	$	3.12	$	(11.32)	$	14.44	128%
Non-GAAP earnings, per diluted share[(1)]	$	3.61	$	3.58	$	0.03	1%

(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 March 31,			
	2020	2019	Dollar Change	Percentage Change
Net product sales:				
Remodulin®	$ 145.3	$ 155.5	$ (10.2)	(7)%
Tyvaso®	102.9	103.8	(0.9)	(1)%
Orenitram®	69.0	58.4	10.6	18%
Unituxin®	26.6	24.9	1.7	7%
Adcirca®	12.5	20.0	(7.5)	(38)%
Total revenues	$ 356.3	$ 362.6	$ (6.3)	(2)%

Revenues for the three months ended March 31, 2020 decreased by $6.3 million, as compared to the same period in 2019.

As of March 31, 2020, new patient starts from our treprostinil-based products (Remodulin, Tyvaso, and Orenitram) were not impacted as a result of the COVID-19 pandemic, but most of the prescriptions submitted by physicians for new patients as of this date pre-dated the outbreak in the United States. However, we have observed a decline in new prescriptions from our treprostinil-based products during the month of April 2020 that we believe is primarily due to the inability of patients to visit their physicians' offices to determine whether our medicines may be appropriate, which could lead to a reduction in new patient starts and negatively impact our revenues. Refer to *COVID-19 Impact and Our Efforts to Combat the Pandemic* below for additional discussion.

Remodulin net product sales decreased by $10.2 million for the three months ended March 31, 2020, as compared to the same period in 2019. U.S. Remodulin net product sales decreased by $6.0 million and international Remodulin net product sales decreased by $4.2 million. The total decrease of $10.2 million primarily resulted from: (1) a decrease in quantities sold of $5.7 million; and (2) the $5.4 million impact of price reductions. U.S. patient demand for Remodulin during the three months ended March 31, 2020, remained consistent with the strong demand in 2019, following the initial transition of Remodulin patients to generic treprostinil in the first half of 2019.

Tyvaso net product sales for the three months ended March 31, 2020 decreased by $0.9 million, as compared to the same period in 2019, resulting from: (1) higher gross-to-net revenue deductions of $3.5 million; and (2) a decrease in quantities sold of $2.9 million; partially offset by a $5.5 million increase in revenue due to a January 2020 price increase.

Orenitram net product sales for the three months ended March 31, 2020 increased by $10.6 million, as compared to the same period in 2019, primarily resulting from: (1) an increase in quantities sold of $7.5 million; and (2) $3.7 million due to a January 2020 price increase.

Unituxin net product sales for the three months ended March 31, 2020 increased by $1.7 million, as compared to the same period in 2019, primarily resulting from $3.8 million due to April 2019 and January 2020 price increases, partially offset by a $2.0 million decrease due to a reduction in the number of vials sold.

Adcirca net product sales for the three months ended March 31, 2020 decreased by $7.5 million, as compared to the same period in 2019. This decrease was primarily due to a continuing decrease in bottles sold as a result of generic competition for Adcirca.

Expenses

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

	Three Months Ended March 31,			
	2020	2019	Dollar Change	Percentage Change
Category:				
Cost of product sales	$ 22.2	$ 28.0	$ (5.8)	(21)%
Share-based compensation expense[(1)]	1.2	1.1	0.1	9%
Total cost of product sales	$ 23.4	$ 29.1	$ (5.7)	(20)%

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

Cost of product sales, excluding share-based compensation. The decrease in cost of product sales of $5.8 million for the three months ended March 31, 2020, as compared to the same period in 2019, was primarily attributable to a $3.3 million decrease in royalty expense for Adcirca as fewer bottles were sold as a result of generic competition for Adcirca.

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

	Three Months Ended March 31,			
	2020	2019	Dollar Change	Percentage Change
Category:				
Research and development projects	$ 68.6	$ 893.8	$ (825.2)	(92)%
Share-based compensation expense[(1)]	4.6	3.6	1.0	28%
Total research and development expense	$ 73.2	$ 897.4	$ (824.2)	(92)%

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

Research and development expense, excluding share-based compensation. Research and development expense decreased by $825.2 million for the three months ended March 31, 2020, as compared to the same period in 2019. Research and development expense for the treatment of cardiopulmonary diseases decreased by $830.4 million for the three months ended March 31, 2020, as compared to the same period in 2019, due to an $800.0 million upfront payment to Arena Pharmaceuticals, Inc. under our license agreement related to ralinepag and a $12.5 million payment under our license and collaboration agreement with MannKind Corporation, both of which occurred during the three months ended March 31, 2019.

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

	Three Months Ended March 31,			
	2020	2019	Dollar Change	Percentage Change
Category:				
General and administrative	$ 55.0	$ 53.9	$ 1.1	2%
Sales and marketing	13.0	13.6	(0.6)	(4)%
Share-based compensation expense[(1)]	25.0	24.5	0.5	2%
Total selling, general, and administrative expense	$ 93.0	$ 92.0	$ 1.0	1%

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

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

	Three Months Ended March 31,			
	2020	2019	Dollar Change	Percentage Change
Category:				
Stock options	$ 16.4	$ 15.7	$ 0.7	4%
Restricted stock units	4.0	2.2	1.8	82%
Share tracking awards plan	10.1	11.0	(0.9)	(8)%
Employee stock purchase plan	0.3	0.3	—	—%
Total share-based compensation expense	$ 30.8	$ 29.2	$ 1.6	5%

Other Income, Net. The increase in "other income, net" of $2.9 million for the three months ended March 31, 2020, as compared to the same period in 2019, was primarily due to an increase in net unrealized and realized gains on equity securities of $13.4 million, partially offset by: (1) a $4.2 million increase of net unrealized and realized foreign currency losses; and (2) a $1.5 million impairment charge on a note receivable during the first quarter of 2020. During the three months ended March 31, 2020, we recognized a $22.5 million unrealized gain on an investment in a privately-held company and $6.1 million of net unrealized and realized losses on equity securities with readily determinable fair values. During the three months ended March 31, 2019, we recognized $3.0 million of unrealized gains on equity securities with readily determinable fair values.

Impairments of Investments in Privately-Held Companies. During the quarter ended March 31, 2020, we observed indicators of impairment of the value of two of the privately-held companies in which we hold an investment. We determined each of these investments in privately-held companies was impaired and recognized total impairment charges of $5.6 million. We did not recognize any impairment charges related to our investments in privately-held companies during the three months ended March 31, 2019.

Income Tax Expense. Income tax expense was $33.9 million for the three months ended March 31, 2020, as compared to income tax benefit of $156.0 million for the same period in 2019. The effective income tax rate (ETR) for the three months ended March 31, 2020 and 2019 was 20 percent and 24 percent, respectively. For the three months ended March 31, 2020, anticipated tax credits, state audit adjustments, and the foreign sales deduction, partially offset by non-deductible compensation and state tax expense, decreased our ETR. For the three months ended March 31, 2019, anticipated tax credits and the foreign sales deduction, partially offset by non-deductible compensation and state tax expense, increased our ETR due to the pre-tax loss that resulted primarily from the upfront $800.0 million payment under our license agreement with Arena Pharmaceuticals, Inc.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income (loss), adjusted for: (i) share-based compensation expense (including expenses relating to stock options, restricted stock units, share tracking awards and our employee stock purchase plan); (ii) impairments of investments in privately-held companies; (iii) unrealized gain on investment in privately-held company; (iv) net unrealized and realized losses on equity securities; (v) other impairment charges; (vi) license-related fees; and (vii) tax impact on non-GAAP earnings adjustments.

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

	Three Months Ended March 31,	
	2020	2019
Net income (loss), as reported	$ 137.7	$ (494.6)
Adjusted for the following items:		
Share-based compensation expense[1]	30.8	29.2
Impairments of investments in privately-held companies[2]	5.6	—
Unrealized gain on investment in privately-held company[3]	(22.5)	—
Net unrealized and realized losses on equity securities[3]	6.1	—
Other impairment charges[3]	1.5	—
License-related fees[4]	—	812.5
Tax benefit[5]	—	(189.2)
Non-GAAP earnings	$ 159.2	$ 157.9
Non-GAAP earnings per share:		
Basic	$ 3.63	$ 3.61
Diluted	$ 3.61	$ 3.58
Weighted average number of common shares outstanding:		
Basic	43.9	43.7
Diluted	44.1	44.1

(1) Recorded within operating expenses on our consolidated statements of operations.

(2) Recorded within impairments of investments in privately-held companies on our consolidated statements of operations.

(3) Recorded within “other income, net” on our consolidated statements of operations.

(4) Recorded within research and development on our consolidated statements of operations.

(5) For the three months ended March 31, 2020, the impairments of investments in privately-held companies and unrealized losses on equity securities had no impact on income tax expense to the extent that we record a valuation allowance for such items against deferred tax assets. The remaining items had an offsetting effect such that they had no net tax impact for the three months ended March 31, 2020.

COVID-19 IMPACT AND OUR EFFORTS TO COMBAT THE PANDEMIC

We are closely monitoring developments related to the COVID-19 pandemic and are making every effort to ensure we remain focused on the health and well-being of our patients and our employees while maintaining business continuity. At this time, it is too early to predict what impact this pandemic, and the associated economic downturn, will have on our business. While we remain confident in our prospects over the longer term, there is considerable uncertainty and lack of visibility regarding our near-term revenue growth prospects and product development plans due to the rapidly evolving situation. Therefore, we are no longer able to predict whether our full-year 2020 net revenues will grow compared to 2019.

We're engaged in the fight against COVID-19. As a pulmonary health company, we are committed to deploying our research teams and development partners to investigate potential therapies for COVID-19 and related pulmonary conditions. Earlier this month, we expanded our existing collaboration with Celularity, Inc. to study the use of Celularity's placental-derived natural killer cell therapy, CYNK-001, to treat patients with the novel coronavirus associated with COVID-19. The U.S. Food and Drug Administration (FDA) recently cleared Celularity's investigational new drug application to evaluate CYNK-001's safety, tolerability, and efficacy for the treatment of COVID-19 in a phase I/II study of up to 86 patients. Under our agreement with Celularity, our Lung Biotechnology subsidiary will support Celularity's study of CYNK-001 as an antiviral treatment for COVID-19. We have global rights to commercialize CYNK-001 to treat COVID-19 and acute respiratory distress syndrome (ARDS), which is a major cause of patient morbidity and mortality associated with COVID-19. We are also exploring the use of other Celularity cell-based biologic products to treat ARDS. Finally, we are working with academic institutions to investigate the potential use of Tyvaso and Unexisome to treat ARDS and are expediting our biomechanical lung program to develop a version suitable for use in the hospital for COVID-19 patients needing oxygen support.

Our financial position is strong. We believe our healthy balance sheet makes us well-positioned to endure the impact of this pandemic. With enough cash, cash equivalents, and marketable securities on hand to fund our operations as we conduct them today for at least two years regardless of our future revenues, we are able to retain and hire new employees, continue our research and development and commercial activities, subject to the limitations described below, and make new strategic investments. Consequently, we expect to be able to return to "normal" operations rapidly once we are able to do so.

We have an ample supply of our products. In order to ensure access to our treprostinil-based products, and in accordance with our long-standing inventory policy, we have sufficient inventory of finished treprostinil-based products (Remodulin, Tyvaso, and Orenitram) to supply the market for two years at current levels of demand. In addition, we manufacture our own treprostinil active pharmaceutical ingredient (API) at our Silver Spring, Maryland facility and have three years' worth of API on hand at any given time. These products and API supplies are all stored at our own warehouses in the United States. Manufacturing of our treprostinil-based products, both internally and at our contract manufacturers, continues mostly as usual, and we do not currently anticipate any supply shortages of our treprostinil-based products.

We also have approximately 14 months' inventory of our Unituxin drug supply, plus raw materials for additional production, and intend to continue manufacturing Unituxin in quantities sufficient to meet current patient demand. Unlike our treprostinil-based products, Unituxin is a biologic with a shorter shelf life, so our ability to maintain longer-term inventories is limited; however, we do not currently anticipate any supply shortages of Unituxin.

We have redundant qualified manufacturing sites for our two current best-selling products: Remodulin and Tyvaso. Should either site be impacted by an outbreak, production activities could be diverted to the other qualified site, each of which is capable of supplying the worldwide market. Our internal manufacturing and packaging operations are independently staffed and physically segregated by technical capability (*e.g.*, oral solid dose, aseptic vial filling, etc.) Should any internal operation be impacted by an outbreak, we believe that area and staff could shut down and isolate, respectively, without affecting the other manufacturing areas.

To date, we have not experienced any interruption of our supply of drug products and devices needed to support our ongoing clinical trials.

Distribution of drug product to patients continues without interruption. Our specialty pharmacy distributors, which we require to maintain at least 30 days' worth of inventory on hand at any given time, continue to ship our products to patients and hospitals. Specialty pharmacies have assured us that they have exercised their continuity plans to avoid supply disruptions. They have also assured us that their nursing support services, which are required for therapy initiation and over the course of treatment to train patients to safely administer their medicine, continue through a combination of in-person and virtual visits. Similarly, we are not aware of any disruption to the distribution of Unituxin treatment for patients with neuroblastoma. As a contingency plan, we secured alternative product transportation capability that we believe will allow us to continue delivering products to distributors if traditional freight operations are disrupted.

Our commercial efforts continue but could be disrupted as a result of the COVID-19 pandemic. Our commercial field-based teams are meeting with prescribing physicians virtually instead of in person. As of March 31, 2020, COVID-19 has not had a material impact on our treprostinil-based therapies, positively or negatively, with respect to specialty pharmacy orders, new patient prescriptions or new patient starts. Thus far in April 2020, however, we have observed several COVID-19 related impacts on U.S. demand for our treprostinil-based therapies:

- One of our specialty pharmacy distributors placed a larger than normal order during April to increase its inventory beyond typical levels (but still within contractual requirements) to: (1) account for potential increased investigational use of Tyvaso for ARDS, which is a major cause of patient morbidity and mortality associated with COVID-19; (2) prepare for an anticipated increase in patient requests for 60- or 90-day refills (as compared to their typical 30-day supply); and (3) increase inventory levels across various locations to ensure uninterrupted business continuity during the COVID-19 pandemic.

- We have seen a reduction in new patient prescriptions across all of our treprostinil-based products throughout the month, which we believe is due to the inability of patients to visit their physician's office to determine whether our medicines may be appropriate.

- While new patient starts remained steady during the first half of the month, we have experienced a decline in new patient starts in the second half of the month for the reasons noted above.

We cannot predict the impact of these events on our near-term revenues. We are uncertain as to how long the reduction in new patient prescriptions and new patient starts will last, whether there will be an increase in new prescriptions and new patient starts in later months due to pent up demand, or whether these events will materially impact orders from specialty pharmacy distributors since they place orders based on current utilization trends and contractual minimum and maximum requirements.

We remain on track to launch the Remunity Pump for Remodulin in July 2020, but recognize that the launch could be delayed or limited due to pandemic-related constraints experienced by physicians and patients, the specialty pharmacy distributors that we are engaging to prefill Remunity cartridges, or any delay in DEKA's ability to supply devices to us.

Our clinical studies remain open, but many have paused new patient enrollment. Most of our ongoing clinical studies have paused enrollment during the pandemic, but patients already enrolled in studies continue to receive the study drug and complete necessary clinical evaluations as appropriate. To date, we have paused enrollment in the following studies, among others:

- *PERFECT* study related to Tyvaso in pulmonary hypertension associated with chronic obstructive pulmonary disease
- *ADVANCE OUTCOMES* and *ADVANCE CAPACITY* studies of ralinepag
- *BREEZE* and pivotal pharmacokinetics studies of Treprostinil Technosphere®
- *SAPPHIRE* study of Aurora-GT™
- phase I study of Unexisome™ for bronchopulmonary dysplasia
- phase I study of OreniPro™

As such, we expect that completion and data readouts for several of our ongoing and planned studies will be delayed, but we do not currently expect delays of our potential product launch plans relative to the near-, medium-, and long-term windows described in our Form 10-Q under Research and Development. Despite the enrollment pause in many of our other clinical studies, we continue to enroll patients in our clinical study of our ex-vivo lung perfusion technology. In addition, while enrollment is paused we are exploring ways to continue and expand our efforts to enter into contracts with additional clinical study sites and complete other site activation activities for certain studies where practicable, in order to rapidly resume enrollment of our clinical studies at the appropriate time.

Our planned regulatory activities and interactions with the FDA continue. In March 2020, the FDA announced that it was canceling or postponing all non-essential meetings. At this time, we have not experienced any delays to our upcoming regulatory activities, such as:

- our planned new drug application (NDA) supplement for Tyvaso to incorporate the results of the *INCREASE* study
- our planned biologics license application (BLA) supplement for Unituxin to reflect recent clinical study results for relapsed/refractory neuroblastoma
- Medtronic's efforts to satisfy FDA conditions to its premarket approval application (PMA) approval for the Implantable System for Remodulin

NEW PRODUCT COMMERCIALIZATION UPDATE

In our near-term time horizon, we expect to launch three products for pulmonary arterial hypertension (PAH): the Remunity Pump, the Trevyent® system, and the Implantable System for Remodulin.

Remunity Pump for Remodulin. On February 24, 2020, we announced FDA clearance of the pharmacy-filled version of the Remunity Pump for Remodulin, developed in partnership with DEKA. We plan to make the Remunity Pump available to patients by July 2020. The Remunity Pump consists of a small, lightweight, ambulatory pump that is intended to have a service life of at least three years. The Remunity Pump uses disposable prefilled cassettes, which are connected to the pump. The pump was initially cleared by the FDA in May 2019 with instructions for patient filling. Our recent 510(k) clearance enables cassettes to be prefilled with Remodulin by contracted specialty pharmacy distributors in order to improve convenience for patients. We are also developing a version of the system that includes cassettes that are prefilled as part of the manufacturing process. Our partner DEKA and its affiliates continue manufacturing work on the Remunity Pump and our contracting work with compounding pharmacy partners continues.

Trevyent. We submitted a 505(b)(1) NDA to the FDA for our Trevyent disposable treprostinil pump system in June 2019. In April 2020, the FDA issued a complete response letter (CRL) related to our NDA indicating that some of the deficiencies previously raised by the FDA had not yet been addressed to its satisfaction. We are evaluating the letter and will provide updates on our plans to resubmit our NDA at a later date. We have one year from the date of the CRL to resubmit our NDA to the FDA, which is expected to trigger a six-month review period by the agency.

Implantable System for Remodulin (ISR). Developed in collaboration with Medtronic, the PMA for ISR was approved by the FDA in December 2017. However, our ability to launch the product is subject to our partner satisfying various conditions to its PMA approval. Medtronic continues to work toward satisfying these conditions, but in December 2019, due to recent FDA communications, Medtronic informed us that these conditions will not be satisfied in 2020. As such we expect a delay in the ISR launch until 2021.

RESEARCH AND DEVELOPMENT UPDATE

Updates on selected later-stage programs are below. As noted above, enrollment in the clinical trials mentioned below has been paused due to the COVID-19 pandemic.

Tyvaso in pulmonary hypertension due to interstitial lung disease (PH-ILD) — *INCREASE*. On February 24, 2020, we reported that the *INCREASE* study of Tyvaso in patients with PH-ILD met its primary endpoint of demonstrating improvement in six-minute walk distance (6MWD). Tyvaso also showed benefits across several key subgroups, including etiology of PH-ILD, disease severity, age, gender, baseline hemodynamics, and dose. Significant improvements were also observed in each of the study's secondary endpoints, including reduction in the cardiac biomarker NT-proBNP, time to first clinical worsening event, change in peak 6MWD at Week 12, and change in trough 6MWD at week 15. Treatment with Tyvaso of up to 12 breaths per session, four times daily, in the *INCREASE* study was well tolerated and the safety profile was consistent with previous Tyvaso studies and known prostacyclin-related adverse events.

We expect to make the full results of the study available through upcoming journal publications and presentations at medical conferences. In addition, we plan to submit the results to the FDA by mid-year 2020 in support of an efficacy supplement (sNDA) to the Tyvaso new drug application, which we expect to result in revised labeling reflecting the outcome of the *INCREASE* study. In April 2020, in response to questions we submitted to the FDA along with a pre-sNDA meeting request and briefing package, the FDA indicated that the results of the *INCREASE* study appear to support our proposed indication of treatment of patients with PH-ILD to improve exercise ability and delay clinical worsening.

Treprostinil Technosphere dry powder inhaler - *BREEZE*. The *BREEZE* study (NCT03950739) seeks to evaluate 45 patients on a stable dose of Tyvaso after switching to our new dry powder inhaler (DPI) form of treprostinil, which we licensed from MannKind. The primary endpoint of the study is the number of subjects with treatment-emergent adverse events after three weeks of treatment with the DPI. In March 2020 we also commenced a second clinical study in healthy volunteers to compare the pharmacokinetics of Treprostinil Technosphere to Tyvaso.

We anticipate results of both of these studies in 2020, assuming that we can resume enrollment in a timely manner. We expect results of these two studies, combined with long-term stability studies of the DPI product, will form the basis of a 505(b)(1) new drug application to the FDA for our treprostinil DPI delivery product.

Unituxin in relapsed/refractory neuroblastoma — ANBL1221. We are pursuing an indication expansion for Unituxin for the treatment of pediatric patients with relapsed or refractory neuroblastoma based on the results of the Children Oncology Group's ANBL1221 study (NCT01767194). We met with the FDA in April of this year to discuss the content needed to support a supplemental BLA. We're working with Children's Oncology Group (COG) to secure additional information ahead of a potential supplemental BLA filing.

Tyvaso in pulmonary hypertension due to chronic obstructive pulmonary disease (PH-COPD) — *PERFECT*. The *PERFECT* study (NCT03496623) seeks to evaluate Tyvaso in patients with 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 6MWD from baseline to week 12. A contingent design for the study allows for the evaluation of 314 patients in two parallel groups.

Ralinepag phase III development program — *ADVANCE CAPACITY* and *ADVANCE OUTCOMES*. We have two ongoing phase III clinical studies to support the potential registration of oral ralinepag for PAH.

***ADVANCE CAPACITY*.** The phase III *ADVANCE CAPACITY* study (NCT04084678) seeks to evaluate 193 subjects with PAH, randomized between oral ralinepag and placebo at a 2:1 ratio, along with PAH background therapy, for 28 weeks with an optional open label extension period. The primary endpoint of the study is the change from baseline to week 28 in peak oxygen consumption (VO_2) assessed by cardiopulmonary exercise testing.

***ADVANCE OUTCOMES*.** The phase III *ADVANCE OUTCOMES* study (NCT03626688) seeks to evaluate approximately 700 PAH patients, randomized 1:1 between oral ralinepag and placebo along with background therapy. The primary endpoint is the time from randomization to the first adjudicated protocol-defined clinical worsening event.

Autologous cell therapy for PAH — *SAPPHIRE*. Conducted by our Canadian affiliate Northern Therapeutics, Inc., the phase II/III *SAPPHIRE* study seeks to evaluate the use of autologous endothelial progenitor cells (EPCs) transfected with human endothelial NO-synthase in patients with PAH taking conventional PAH treatments. The study seeks to enroll 45 PAH patients in one of three arms: (1) placebo for six months followed by autologous EPCs for six months; (2) autologous EPCs for six months followed by placebo for six months; and (3) autologous EPCs for twelve months. The primary endpoint is the change in 6MWD from baseline to month six.

CONFERENCE CALL

We will host a teleconference on Wednesday, April 29, 2020, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing (866) 209-9943 in the United States, with international callers dialing +1 (825) 312-2282. A rebroadcast of the teleconference will be available for one week and can be accessed by dialing (800) 585-8367 in the United States, with international callers dialing +1 (416) 621-4642, and using access code: 1984097.

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 related to the impacts of COVID-19 on our business and the speed at which we will be able to return to normal operations, the efficacy of our efforts to minimize disruptions on our business caused by COVID-19, the sufficiency of our cash on hand to fund our operations for at least two years, our available liquidity to make new strategic investments, our launch plans for Remunity, Trevyent and the ISR, our planned expansion of the Tyvaso label to include the results of the *INCREASE* study and to increase the addressable U.S. patient population for Tyvaso, our research and development plans and regulatory filings related to Treprostinil Technosphere, Unituxin, the *PERFECT* and *SAPPHIRE* studies, ralinepag, CYNK-001, our organ transplantation programs, our expectation that we will sustain our success in the long-term, and similar statements concerning anticipated future events and expectations that are not historical facts. These forward-looking statements are subject to certain risks and uncertainties, including the effects of and uncertainty surrounding the COVID-19 pandemic, as well 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 April 29, 2020, 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.

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Technosphere is a registered trademark of MannKind 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 March 31,	
	2020	2019
	(Unaudited)	
Revenues:		
Net product sales	$ 356.3	$ 362.6
Total revenues	356.3	362.6
Operating expenses:		
Cost of product sales	23.4	29.1
Research and development	73.2	897.4
Selling, general, and administrative	93.0	92.0
Total operating expenses	189.6	1,018.5
Operating income (loss)	166.7	(655.9)
Interest income	10.0	9.8
Interest expense	(8.2)	(10.3)
Other income, net	8.7	5.8
Impairments of investments in privately-held companies	(5.6)	—
Total other income, net	4.9	5.3
Income (loss) before income taxes	171.6	(650.6)
Income tax (expense) benefit	(33.9)	156.0
Net income (loss)	$ 137.7	$ (494.6)
Net income (loss) per common share:		
Basic	$ 3.14	$ (11.32)
Diluted	$ 3.12	$ (11.32)
Weighted average number of common shares outstanding:		
Basic	43.9	43.7
Diluted	44.1	43.7

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	March 31, 2020
Cash, cash equivalents, and marketable investments	$ 2,412.5
Total assets	4,025.9
Total liabilities	1,077.4
Total stockholders' equity	2,948.5

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