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): **February 24, 2020**

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 each 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 8.01. Other Events.

On February 24, 2020, United Therapeutics Corporation issued press releases announcing (a) 510(k) clearance by the U.S. Food and Drug Administration of the pharmacy-filled Remunity™ delivery system for subcutaneous Remodulin® (treprostinil) Injection; and (b) positive results of the *INCREASE* clinical study of Tyvaso® (treprostinil) Inhalation System in patients with pulmonary hypertension associated with interstitial lung disease. The press releases are attached as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

REMODULIN and TYVASO are registered trademarks of United Therapeutics Corporation. REMUNITY is a trademark of United Therapeutics Corporation.

Item 9.01. Exhibits

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release dated February 24, 2020, related to the Remunity system
99.2	Press release dated February 24, 2020, related to the *INCREASE* study
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: February 24, 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

Contact: Dewey Steadman
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UNITED THERAPEUTICS AND DEKA ANNOUNCE ADDITIONAL FDA CLEARANCE RELATED TO THE UNITY SUBCUTANEOUS DELIVERY SYSTEM FOR REMODULIN®

~ Remunity™ expected to be available for patients by July 2020 ~

Research Triangle Park, NC and Manchester, NH, February 24, 2020: United Therapeutics Corporation (Nasdaq: UTHR) and DEKA Research & Development Corp. today announced receipt of an additional 510(k) clearance by the U.S. Food and Drug Administration (FDA) related to the Unity Subcutaneous Delivery System for Remodulin® (treprostinil) Injection, also referred to as the Remunity™ pump, enabling United Therapeutics to launch the system using drug reservoirs that have been prefilled by specialty pharmacies.

The Remunity system, which was jointly developed by United Therapeutics and DEKA, is indicated for continuous subcutaneous delivery of Remodulin to treat pulmonary arterial hypertension, or PAH, in adults greater than 22 years of age. The Remunity system includes a small, lightweight, ambulatory pump with an intended service life of three years, which the patient connects to a disposable prefilled cassette.

The system was initially cleared by the FDA in May 2019 with instructions for patient filling. This additional 510(k) clearance enables cassettes to be prefilled with Remodulin by contracted specialty pharmacies in order to improve convenience for patients. United Therapeutics plans to launch the Remunity system by July 2020. United Therapeutics and DEKA are also developing a future version of the system that will include disposable components that are prefilled as part of the manufacturing process.

“We’re super ‘pumped’ about launching Remunity by Independence Day,” said Dr. Martine Rothblatt, Chairman and Chief Executive Officer of United Therapeutics. “Remunity will provide a new level of freedom to our patients through improved convenience, and we believe it will provide more free time to live their beautiful lives. The system provides a wider array of notifications, alerts, and alarms than current pumps. Most amazingly, the acoustic volume sensing technology and solid-state actuator of the Remunity system enables it to control Remodulin flow rates without the use of a motor. To me, because of so few moving parts, it is like the Tesla of parenteral pumps!”

“We are excited to be launching this innovative delivery technology with United Therapeutics. We are confident that the Remunity system, particularly with the additional convenience of cassettes prefilled with Remodulin, has the potential to improve the lives of patients who depend on UT’s unique pharmaceutical advances,” said Dean Kamen, Founder and President of DEKA. “We are extremely proud of UT’s dedication to their patients and grateful to UT for their unwavering support of DEKA as we continue to develop and deliver advanced solutions to address the needs of those patients.”

About Remunity™ Pump for Remodulin® (treprostinil) Injection

Indication

The Remunity™ Pump for Remodulin® (treprostinil) Injection is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in adults (greater than 22 years of age).

Important Safety Information for Remunity

Warnings and Precautions

Do not use the system outside the conditions listed in the User Guide. Retain the User Guide for future reference. Refer to the User Guide for all warnings and cautions. Failure to comply with the following warnings and cautions may result in harm.

Limited to use with Remodulin. Only Remunity cassettes may be used with the Remunity pump. Remunity pump is for use only with FDA-cleared infusion sets: Medtronic Quick-set Infusion Set (MMT-392, MMT-393), Medtronic Silhouette Infusion Set (MMT-373), and Smiths Medical Cleo 90 Infusion Set (21-7230-24, 21-7220-24).

Prescription Information

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner. Use of this device without the training and supervision of a healthcare practitioner may lead to errors that result in harm.

See the Remunity Pump for Remodulin (treprostinil) Injection Pharmacy-Filled User Guide for further detailed important safety information including warnings, cautions, and instructions on how to properly use the system.

For further information, please call United Therapeutics Corp. at 1-877-864-8437.

The Remunity Pump for Remodulin (treprostinil) Injection is manufactured for United Therapeutics Corp.

You may report side effects to the FDA at www.fda.gov/MedWatch or call 1-800-FDA-1088.

About Remodulin® (treprostinil) Injection

Indication or What is Remodulin?

Remodulin is a prescription medication used to treat adults with pulmonary arterial hypertension (PAH; WHO Group 1), which is high blood pressure in the arteries of your lungs. Remodulin can reduce symptoms associated with exercise. Remodulin was studied mainly in patients with NYHA Functional Class II-IV symptoms. It is not known if Remodulin is safe and effective in children.

In people with PAH who need to switch from epoprostenol, Remodulin is approved to slow the worsening of symptoms.

Important Safety Information for Remodulin

Before you take Remodulin, tell your healthcare provider if you:

- Have other medical conditions or take other medicines that may affect your use of Remodulin by increasing the risk of side effects or decreasing the drug's effectiveness.
- Have liver or kidney problems. Your Remodulin dose may need to be adjusted if you have liver problems.
- Have low blood pressure or bleeding problems.
- Are taking gemfibrozil (for high cholesterol), rifampin (for infection) or other drugs that affect liver enzymes. Your doctor may need to adjust your Remodulin dosage.
- Are pregnant, breastfeeding, or planning to become pregnant. It is not known if Remodulin will harm your unborn baby or if Remodulin passes into your breast milk.

What are the serious side effects of Remodulin?

- Continuous intravenous (IV) infusions of Remodulin delivered using an external infusion pump, with a tube placed in a central vein within the chest, are associated with the risk of blood stream infections and sepsis, which may be fatal. Therefore, continuous subcutaneous (SC) infusion delivered just beneath the skin is the preferred type of delivery.
- Worsening of PAH symptoms. Do not stop taking or greatly reduce your Remodulin dose without consulting your doctor.
- Low blood pressure (symptomatic hypotension). If you have low blood pressure or are taking drugs that lower your blood pressure, the risk of low blood pressure is increased.
- Bleeding problems. Remodulin may increase the risk of bleeding in people who take blood thinners (anticoagulants).

What are the possible side effects of Remodulin?

- In clinical studies of SC infusion of Remodulin, most people experienced infusion site pain and infusion site reaction (redness, swelling, and rash). These symptoms were sometimes severe and sometimes required treatment with narcotics or discontinuation of Remodulin.
- IV infusion of Remodulin delivered through an external pump has been associated with the risk of blood stream infections, arm swelling, tingling sensations, bruising, and pain.

- The most common side effects seen with either SC or IV Remodulin were headache, diarrhea, nausea, rash, jaw pain, widening of the blood vessels (vasodilatation), and swelling from fluid retention (edema). These are not all the possible side effects of Remodulin. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at www.fda.gov/MedWatch or call 1-800-FDA-1088.

The risk information provided here is not comprehensive. To learn more about Remodulin, talk with your healthcare provider. Please see Full Prescribing Information at www.remodulin.com or call Customer Service at 1-877-UNITHER (1-877-864-8437).

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.

About DEKA

Based in Manchester, NH, DEKA is a research and development company of more than 600 employees comprised of engineering, manufacturing and quality assurance professionals focused on the development of new technologies that span a diverse set of applications. The company was founded in 1982 by Dean Kamen, an inventor who holds hundreds of U.S. and foreign patents and numerous awards, many of them for innovative medical devices that have expanded the frontiers of healthcare worldwide.

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 regarding the anticipated launch of the Remunity pump by July 4, 2020, the expected benefits to patients, our plan to develop a machine-filled version of the Remunity system, the ability of our business model to create value, our ability to sustain long-term success, and our organ transplantation research and development programs. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results. 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 February 24, 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.

REMODULIN is a registered trademark of United Therapeutics Corporation.

REMUNITY is a trademark of United Therapeutics Corporation.

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Section 3: EX-99.2 (EXHIBIT 99-2)

Exhibit 99.2

Contact: Dewey Steadman
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UNITED THERAPEUTICS ANNOUNCES *INCREASE* STUDY OF TYVASO® MEETS PRIMARY AND ALL SECONDARY ENDPOINTS

~First pivotal clinical trial to demonstrate a benefit in PH-ILD ~
~ NDA supplement to be filed by mid-year ~

Silver Spring, MD and Research Triangle Park, NC, February 24, 2020: United Therapeutics Corporation (NASDAQ: UTHR) today announced that preliminary analysis indicates that the *INCREASE* clinical study of Tyvaso® (treprostinil) Inhalation Solution in patients suffering from World Health Organization (WHO) Group 3 pulmonary hypertension associated with interstitial lung disease (PH-ILD) has met its primary efficacy endpoint of demonstrating improvement in six-minute walk distance (6MWD).

Tyvaso increased six-minute walk distance by 21 meters versus placebo (p=0.0043, Hodges-Lehmann estimate) after 16 weeks of treatment. Benefits of Tyvaso were observed 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 in PAH and known prostacyclin-related adverse events (see the discussion of adverse events below under "About Tyvaso").

"Patients with both interstitial lung disease and pulmonary hypertension have worse clinical trajectories and earlier death than patients with interstitial lung disease alone. There are currently no approved therapies for these patients and so there is a tremendous unmet need," said Aaron Waxman, M.D., Ph.D., Director of the Pulmonary Vascular Disease Program at Brigham and Women's Hospital and the chair of the *INCREASE* Study Steering Committee. "This is the largest clinical trial in this population, and the first to demonstrate a clear benefit. As a clinician, I look forward to soon having an approved treatment to offer these patients with this life-threatening disease."

"I am pleased to announce the successful outcome of the *INCREASE* phase III trial of Tyvaso in a unique kind of pulmonary hypertension, a variant that has no approved therapy," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "Some 30,000 Americans suffer from this disease, called WHO Group 3 Pulmonary Hypertension. It is a tremendous testament to our head of product development, Dr. Leigh Peterson, that her team used the unique characteristics of our inhaled medicine to achieve a highly statistically significant proof of efficacy while seeming to avoid the safety issues that have plagued systemic therapeutics."

“The results of the *INCREASE* study present a powerful message of efficacy in the interstitial lung disease patient population,” said Gil Golden, M.D., Ph.D., Chief Medical Officer of United Therapeutics. “I congratulate the patients and families who participated in this study, along with our principal investigators who produced a clear outcome that we think could change the lives of ten times the number of patients who are on Tyvaso today. This is what we mean at United Therapeutics when we say we ‘identify the corridors of indifference and run like hell down them.’”

United Therapeutics plans to submit the results to the U.S. Food and Drug Administration by mid-year in support of an efficacy supplement that is expected to result in revised labeling that reflects the outcome of the *INCREASE* study.

About *INCREASE*

INCREASE was a phase III, multicenter, randomized, double-blinded, placebo-controlled, 16-week, parallel group study of Tyvaso in patients with pulmonary hypertension associated with interstitial lung disease. Enrollment into the study was completed in August 2019 with a total of 326 patients. Patients were randomized in a 1:1 Tyvaso (n=163) or placebo (n=163).

The primary endpoint primary endpoint was to evaluate the change in 6-minute walk distance (6MWD) measured at peak exposure from Baseline to Week 16.

Secondary objectives of the study included:

- Change in plasma concentration of N-terminal pro-brain natriuretic peptide (NT-proBNP) from Baseline to Week 16
- Time to clinical worsening calculated as the time from randomization until one of the following criteria are met:
    - Hospitalization due to a cardiopulmonary indication
    - Decrease in 6MWD >15% from Baseline directly related to disease under study, at two consecutive visits, and at least 24 hours apart
    - Death (all causes)
    - Lung transplantation
- Change in peak 6MWD from Baseline to Week 12
- Change in trough 6MWD from Baseline to Week 15

Exploratory objectives of the study evaluated changes in peak 6MWD at Week 4 and Week 8, changes in quality of life as measured by the St. George’s Respiratory Questionnaire (SGRQ) and change in distance saturation product (DSP). Further exploratory analysis will also be performed on biomarkers and pharmacogenomics from this study.

Detailed study results will be made available through scientific disclosure at upcoming medical conferences and in peer-reviewed publications.

About TYVASO® (treprostinil) Inhalation Solution

What is TYVASO?

TYVASO (treprostinil) is a prescription medicine used in adults to treat pulmonary arterial hypertension (PAH; WHO Group I), which is high blood pressure in the arteries of your lungs. TYVASO can improve the ability to exercise. Your ability to exercise decreases four hours after taking TYVASO. It is not known if TYVASO is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

Before you take TYVASO, tell your healthcare provider about all of your medical conditions, including if you:

- Have lung disease, such as asthma or chronic obstructive pulmonary disease (COPD)
- Have a lung infection
- Have liver or kidney problems
- Have low blood pressure
- Have bleeding problems
- Are pregnant or plan to become pregnant. It is not known if TYVASO will harm your unborn baby
- Are breast-feeding or plan to breast-feed. It is not known if TYVASO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with TYVASO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TYVASO and other medicines may affect each other.

Especially tell your healthcare provider if you take:

- Medicines used to treat high blood pressure or heart disease
- Medicines that decrease blood clotting (anticoagulants)
- Water pills (diuretics)
- Gemfibrozil (Lopid) or rifampin (Rimactane, Rifadin, Rifamate, Rifater)

What are the possible side effects of TYVASO?

TYVASO can cause **serious side effects**, including:

- **Low blood pressure** (symptomatic hypotension)**.** If you have low blood pressure, TYVASO may lower your blood pressure more.
- **Bleeding problems.** TYVASO may increase the risk of bleeding, especially in people who take blood thinners (anticoagulants).

The **most common side effects** of TYVASO are cough, headache, throat irritation and pain, nausea, reddening of the face and neck (flushing), fainting or loss of consciousness, dizziness, and diarrhea. These are not all the possible side effects of TYVASO. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at www.fda.gov/MedWatch or call 1-800-FDA-1088.

The risk information provided here is not comprehensive. To learn more about Tyvaso, talk with your healthcare provider. Please see Full Prescribing Information, Patient Product Information, and the TD-100 and TD-300 TYVASO® Inhalation System Instructions for Use manuals at www.tyvaso.com or call 1-877-UNITHER (1-877-864-8437).

About United Therapeutics

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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.

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 regarding the timing and outcome of our supplement to the Tyvaso NDA to reflect the *INCREASE* study results, the potential benefits to patients, and the anticipated expansion of the market opportunity for Tyvaso. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results. In particular, we note that analysis of the full *INCREASE* study results is ongoing. These further analyses could have a material impact on how useful the full results will be to healthcare providers and payers, and how they will be viewed by the FDA and other regulators. All of these factors could have a material impact on how useful the final results will be to healthcare providers, and how they will be viewed by the FDA and other regulators. In addition, the forward-looking statements in this press release 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 February 24, 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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