

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 4, 2020**

United Therapeutics Corporation

(Exact Name of Registrant as Specified in its 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 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 4, 2020, United Therapeutics Corporation issued a press release announcing the United States District Court for the District of New Jersey issued a decision in favor of United Therapeutics and Smiths Medical ASD, Inc. denying the request for preliminary injunction sought by Sandoz Inc. and RareGen, LLC in pending antitrust litigation. The press release is attached as Exhibit 99.1 is are incorporated herein by reference.

Item 9.01. Exhibits

(d) Exhibits

Exhibit No.	Description of Exhibit
<u>99.1</u>	<u>Press Release dated February 4, 2020.</u>
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 4, 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
Phone: (202) 919-4097
E-mail: ir@unither.com

UNITED THERAPEUTICS DEFEATS PRELIMINARY INJUNCTION MOTION IN LITIGATION WITH SANDOZ AND RAREGEN

Silver Spring, MD and Research Triangle Park, NC, February 4, 2020: United Therapeutics Corporation (Nasdaq: UTHR) announced that on January 29, 2020, the United States District Court for the District of New Jersey issued a decision in favor of United Therapeutics and Smiths Medical ASD, Inc. denying the request for preliminary injunction sought by Sandoz Inc. and RareGen, LLC in pending antitrust litigation. According to the Court, “[Sandoz and RareGen] have not met their burden of demonstrating a reasonable probability of eventual success in the litigation.” The unsealed opinion was just released by the Court.

By way of background, United Therapeutics and Smiths Medical ASD, Inc. were named as defendants in a lawsuit filed in federal court by Sandoz and RareGen on April 16, 2019. The lawsuit alleges that United Therapeutics engaged in anticompetitive conduct in connection with efforts by Sandoz and RareGen to launch their generic version of Remodulin[®] (treprostini) Injection. The claims center around access to both Smiths Medical’s CADD-MS[®]3 pump, which is used for the subcutaneous delivery of Remodulin, and to the cartridges used with the pump. Smiths Medical decided in 2014 to discontinue the pump and related cartridges, and in response, United Therapeutics invested millions of dollars to fund production of additional pumps and cartridges for its patients. Sandoz and RareGen allege that United Therapeutics’ purchase of these additional cartridges for Remodulin patients constitutes a violation of antitrust law. Following expedited discovery in the litigation, Sandoz and RareGen filed a motion seeking a preliminary injunction to obtain the cartridges that were produced by Smiths Medical under the supply agreement with United Therapeutics.

In finding that Sandoz and RareGen failed to demonstrate they were likely to prevail in the litigation, the Court noted that Sandoz and RareGen “produced no evidence UTC’s purchase of [the cartridges for the CADD-MS3 system] was motivated by or intended to forestall Sandoz’s entry into the subcutaneous market.” Rather, United Therapeutics made a significant investment under an agreement with Smiths Medical that ensured the CADD-MS3 pump would continue to be available to deliver Remodulin for a period of time after Smiths Medical announced discontinuation of the pump.

The Court noted that the agreements between Smiths Medical and United Therapeutics, which made more cartridges available than would otherwise exist, were in fact procompetitive. The Court’s opinion noted: “The Court is persuaded from the wording of the original 2016 Pump Supply Agreement that UTC’s concern was not keeping Sandoz out of the market for treprostini, but rather with ensuring continuity of supplies of pumps and cartridges for its customers at a time when there were no other treprostini competitor, and that the exclusive nature of this production agreement was contemplated from inception.”

The Court also found that Sandoz “was aware or should have been aware of CADD-MS® 3 problems as early as May 2016.” Yet Sandoz failed to take action to ensure delivery means for its own patients.

In addition to United Therapeutics’ investment in additional cartridges, United Therapeutics continues to innovate and develop new and improved systems to deliver this therapy. If Sandoz and RareGen had taken the same care, they could have been able to serve their patients rather than resorting to litigation in an effort to remedy their own poor planning.

The Court also denied United Therapeutics’ and Smiths Medical’s motion to dismiss the entire action, so the case may continue to be litigated. Nonetheless, this decision is an important milestone in vindicating United Therapeutics’ belief that the claims against it are meritless.

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.

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 our efforts to defend a lawsuit filed by Sandoz and RareGen, the likelihood that we will prevail in the litigation, 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. 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 4, 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.

CADD-MS is a registered trademark of Smiths Medical ASD, Inc.

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