UNITED THERAPEUTICS CORP

FORM 8-K
(Current report filing)

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Address	1040 SPRING ST
	SILVER SPRING, MD 20910
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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): **May 17, 2017**

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))

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 1.01. Entry into a Material Definitive Agreement.

On May 17, 2017, United Therapeutics Corporation (the " ***Company*** ") entered into the First Amendment (the " ***Amendment*** ") to the License Agreement, dated November 14, 2008 (the " ***Agreement*** "), with Eli Lilly and Company (" ***Lilly*** "). Under the Agreement, Lilly granted the Company an exclusive license for the right to develop, market, promote and commercialize Adcirca ® (tadalafil) for the treatment of pulmonary hypertension in the United States. Under the Agreement, the Company is obligated to pay Lilly royalties equal to five percent of the Company's net product sales of Adcirca. The purpose of the Amendment is to clarify and extend the term of the Agreement and to amend the economic terms of the Agreement following a patent expiry in November 2017.

The Agreement originally provided that it would terminate upon the later of: (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly patent covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States; or (2) expiration of any government-conferred exclusivity rights to use Adcirca for the treatment of pulmonary hypertension in the United States.

A U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017. Lilly has two additional patents expiring in April and November 2020, respectively, covering Adcirca and claiming pharmaceutical compositions and free drug particulate forms (the " ***2020 Patents*** "). The Patent Trial and Appeal Board (" ***PTAB*** ") of the U.S. Patent and Trademark Office issued a final written decision finding these patents invalid as the result of an *inter partes* review proceeding initiated by Actelion Pharmaceuticals Ltd. Lilly's appeal of the PTAB's decision is pending before the United States Court of Appeals for the Federal Circuit.

The Company has previously disclosed that it is likely to face generic competition for Adcirca following the expiration of the November 2017 patent. FDA has already tentatively approved ANDAs filed by at least two generic companies to market generic versions of Adcirca.

Under the Amendment, the term of the agreement has been amended and extended so that the Agreement will now expire on the latest to occur of (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly patent covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States; (2) expiration of any government-conferred exclusivity rights to use Adcirca for the treatment of pulmonary hypertension in the United States; or (3) December 31, 2020. As a result, even if generic competition begins in November 2017, the Company will continue to market and sell branded Adcirca. As amended, the Agreement may be terminated by either party upon six months' written notice to the other party.

Under the terms of the Amendment, beginning on December 1, 2017, the Company will pay Lilly (a) a ten percent royalty on net product sales of Adcirca; and (b) milestone payments equal to $325,000 for each $1,000,000 in net product sales. In the event that Lilly prevails in one or both of the appeals noted above: (a) the previous five percent royalty rate will apply and the effective date of the new payment structure will be deferred until the expiration, lapse, abandonment or invalidation of the last claim of the 2020 Patents covering commercialization of Adcirca for pulmonary hypertension; and (b) to the extent the Company had previously paid amounts in excess of five percent, those amounts will be refunded by Lilly.

This summary is qualified in its entirety by reference to the copy of the Amendment filed herewith as Exhibit 10.1.

Forward-Looking Statements

Statements included in this Current Report on Form 8-K 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 outlook of the Company's Adcirca business and its agreements with Lilly. These forward-looking statements are subject to certain risks and uncertainties, such as those described in the Company's periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results, and are qualified by the cautionary statements, cautionary language and risk factors set forth in the Company's periodic reports and documents filed with the Securities and Exchange Commission, including the Company's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The Company claims claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The Company is

providing this information as of May 18, 2017, and assumes no obligation to update or revise the information contained in this Current Report on Form 8-K whether as a result of new information, future events or any other reason.

Item 9.01. Exhibits

(d) Exhibits

Exhibit No.	Description of Exhibit
10.1	First Amendment to License Agreement, dated as of May 17, 2017, by and between United Therapeutics Corporation and Eli Lilly and Company

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: May 18, 2017

By: /s/ Paul A. Mahon
Name: Paul A. Mahon
Title: General Counsel

FIRST AMENDMENT TO LICENSE AGREEMENT

THIS FIRST AMENDMENT TO LICENSE AGREEMENT (the " **Amendment** ") is entered into as of May 17, 2017 (the " **Amendment Effective Date** "), by and between Eli Lilly and Company, an Indiana corporation, having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285, (" **Lilly** ") and United Therapeutics Corporation, a Delaware corporation, having its principal place of business at 1040 Spring Street, Silver Spring, Maryland 20910 (" **United Therapeutics** "). Lilly and United Therapeutics are referred to individually as a " **Party** " and collectively as the " **Parties** ."

RECITALS

WHEREAS , Lilly and United Therapeutics are parties to that certain License Agreement dated as of November 14, 2008 (the " **License Agreement** ");

WHEREAS, United Therapeutics desires to amend the License Agreement to extend its exclusive license to market, promote and commercialize tadalafil, solely under the brand name Adcirca®, for the treatment of pulmonary hypertension; and

WHEREAS , the Parties desire to amend the License Agreement to reflect the Parties' agreement with respect to certain terms and conditions as set forth herein;

NOW , **THEREFORE** , in consideration of the mutual covenants and agreements contained herein and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

AGREEMENT

1. Article 1 Definitions. Article 1 is amended to amend or add the following definition:

1.3 "Applicable Law" is amended by adding to the end of the current definition, the following: "In addition, Applicable Laws shall include Privacy Laws."

1.63 "Increased Royalty Effective Date" shall mean:

(a) initially, December 1, 2017; and

(b) in the event that Lilly prevails in Appeal #17-1017 and/or #17-1018 in the United States Court of Appeals for the Federal Circuit between ICOS Corporation — Appellant and Actelion Pharmaceuticals Ltd. - Appellee regarding the validity of U.S. Patent Nos. 6,821,975 (expiring November 19, 2020) ("975") and 7,182,958 (expiring April 26, 2020) ("958"), then the Increased Royalty Effective Date shall automatically be delayed and extended until the later to occur of (i) the expiration, lapse, abandonment or invalidation of the last claim of 975 and/or 958 covering the Commercialization of the Product in the Field in the Territory; and (ii) expiration of any government-conferred exclusivity respecting the use of the Product in the Field in the Territory. Lilly will not have any obligation to appeal any decision in Appeal #17-1017 and/or #17-1018 to the

United States Court of Appeals for the Federal Circuit en banc or to the United States Supreme Court.

1.64 " **Privacy Laws** " shall include, but not be limited to, a) the Health Insurance Portability and Accountability Act of 1996, as amended, and the implementing rules and regulations thereof, including the Privacy Rule, Security Rule, and Breach Notification Rule and all amendments to and further regulations thereof (collectively, " **HIPAA** "); b) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as amended, updated or repealed from time to time, and any implementing, derivative or related national legislation, rule, or regulation enacted thereunder by any EU Member State subject to its jurisdiction as well as the European General Data Protection Regulation (Regulation (EU) 2016/679), when it becomes applicable; and c) Section 5 of the United States Federal Trade Commission Act, including the regulation of deception and unfairness in consumer practices.

2. Section 3.4(b) Operating Principles. Meetings. Section 3.4(b) is hereby deleted in its entirety and replaced with the following:

The JSC shall hold meetings at such times and at such locations, including telephonically, as requested by either of the Parties. Other employees of each Party (including the Alliance Managers, as defined in Section 3.5(a)) involved in the Development, manufacture, or Commercialization of the Product in the Field in the Territory may attend the meetings of the JSC as nonvoting participants, and, with the consent of each Party, consultants, representatives, or advisors involved in the Development, manufacture, or Commercialization of the Product may attend meetings of the JSC as nonvoting observers; provided that such Third Party representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of each Party and that there are at least as stringent as those set forth in ARTICLE 11; and provided that the term of such obligations may be reduced by mutual agreement of the Parties so as to be commercially reasonable based on the circumstances. Each Party shall be responsible for all of its own expenses associated with participating in the JSC.

3. Section 7.2 Royalty Payments. Effective upon the Increased Royalty Effective Date, Section 7.2 shall be deleted in its entirety, renamed " **Royalty Payments and Milestones"** and replaced with the following:

(a) In consideration for the rights granted to United Therapeutics under this Agreement to continue to market, promote and commercialize the Product in the Field and the Territory and the rights with respect to use of the Lilly Product Marks and Corporate Marks of Lilly and the supply of the Product under the Manufacturing and Supply Agreement, United Therapeutics shall pay Lilly a ten percent (10%) royalty on Net Sales (" **Royalty** ") and the corresponding non-refundable (except pursuant to Section 7.2(b)) milestone payments on Net Sales (" **Milestones** ") during the Term:

Sales Milestones for Product	Milestone Payment (U.S.)
For each One Million Dollars ($1,000,000) in Net Sales during the Calendar Year	$ 325,000

Milestones per quarter will be calculated based upon year to date Calendar Year Net Sales minus Milestones paid in prior Calendar Quarters. Milestones shall be paid quarterly as set forth in Section 7.3.

For purposes of illustration, if Net Sales in the first quarter of 2018 were $45,999,444, in the second quarter were $60,265,456 in the third quarter were $35,756,899 and in the fourth quarter were $41,236,899, the royalty and milestones would be computed as follows:

Sales	A 10%	YTD Sales	# of Millions YTD	Payment/Million	Cum Payment	Previous Paid	B Net Milestones	Net Payments = A + B
$ 45,999,444	$ 4,599,944	45,999,444	**45**	$ 325,000	14,625,000		14,625,000	$ 19,224,944
$ 60,265,456	$ 6,026,546	106,264,900	**106**	$ 325,000	34,450,000	(14,625,000)	19,825,000	$ 25,851,546
$ 35,756,899	$ 3,575,690	142,021,799	**142**	$ 325,000	46,150,000	(34,450,000)	11,700,000	$ 15,275,690
$ 41,236,899	$ 4,123,690	183,258,698	**183**	$ 325,000	59,475,000	(46,150,000)	13,325,000	$ 17,448,690
$ 183,258,698							**$ 59,475,000**	**$ 77,800,870**

In the event United Therapeutics receives any non-monetary consideration in connection with the sale of the Product, United Therapeutics' payment obligation under this Section 7.2 shall be based on the fair market value of such other consideration. In such case, United Therapeutics shall disclose to Lilly the terms of any such arrangement, and the Parties shall endeavor in good faith to agree on the fair market value of the consideration received by United Therapeutics under such arrangement.

(b) In the event the initial Increased Royalty Effective Date is extended in accordance with Section 1.63(b), then any royalties and milestone payments already paid by United Therapeutics to Lilly under Section 7.2(a) in excess of the royalties that would have been payable prior to the extended Increased Royalty Effective Date (i.e., 5% of Net Sales) shall be refunded to United Therapeutics within thirty (30) days, and the original Section 7.2 of the Agreement shall be restored until the extended Increased Royalty Effective Date occurs.

4. Section 7.3 Payments and Reports. Effective upon the Increased Royalty Effective Date, Section 7.3(b) shall be deleted and replaced with the following:

United Therapeutics shall provide a report to Lilly within thirty (30) days after the end of each Calendar Quarter that summarizes Net Sales (year to date and Calendar Quarter), including, if applicable, the fair market value of all non-monetary consideration received

by United Therapeutics in exchange for the Product, and contains detailed information regarding the calculation amounts due to Lilly pursuant to Section 7.2, including the allowable deductions in the calculation of Net Sales, in a manner sufficient to enable Lilly to determine amounts due to Lilly under Section 7.2 (" **Net Sales Report** "). United Therapeutics will mail the Net Sales Report to the attention of: Eli Lilly and Company, Lilly Royalty Administration in Finance, Drop Code 1064, Lilly Corporate Center, Indianapolis, Indiana 46285. Contemporaneously with the delivery of each Net Sales Report, United Therapeutics shall make all payments due to Lilly pursuant to Section 7.2 with respect to the Calendar Quarter by wire transfer in immediately available funds in accordance with the terms of Section 7.5.

5. Section 8.4 OTC, Generic and Competitive Rights. Section 8.4 is hereby deleted in its entirety and replaced with the following.

During the Term, United Therapeutics will have no right under the terms of this Agreement with respect to (i) over-the-counter Commercialization of Product, or (ii) sell any non-branded generic version of the Product or Compound in the Field in the Territory. Any development of a Competitive Product using the Product, Lilly Know-How, Lilly Patents and/or Lilly Product Marks in the Field in the Territory requires Lilly's approval and the Parties would discuss in good faith modifications, if any, to the Royalty and/or Milestones.

6. Section 11.7 Patient Information. Section 11.7 is hereby deleted in its entirety and replaced with the following:

The Parties shall abide by Applicable Laws when undertaking all activities and obligations set forth in this Agreement, including undertaking all Commercialization and Development activities in compliance with Privacy Laws, and protecting patients' protected health information, as defined by HIPAA. The Parties shall also obtain all necessary authorizations and consents from data subjects in compliance with Applicable Laws and to enable the use and disclosure of personal information of the data subjects as contemplated by this Agreement, including exchange and sharing of personal information among the Parties.

7. Section 13.1 Term. Section 13.1 is hereby deleted in its entirety and replaced with the following:

Unless earlier terminated in accordance with the terms of this ARTICLE 13, the term of this Agreement shall begin on the Effective Date and will continue until the latest of: (a) the expiration, lapse, cancellation, abandonment or invalidation of the last Valid Claim covering the Commercialization of the Product in the Field in the Territory; (b) expiration of any government-conferred exclusivity respecting the use of the Product in the Field in the Territory; or (c) December 31, 2020 (the " **Term** ").

8. Section 13.2 Unilateral Termination by United Therapeutics. Subsection 13.2 is hereby deleted in its entirety, renamed "Mutual Termination" and replaced with the following:

Either Party shall have the right to terminate this Agreement at any time during the Term upon six (6) months prior written notice to the other Party.

8. Section 13.5 Consequences of Expiration or Termination. Subsection (a) of Section 13.5 is hereby deleted in its entirety and replaced with the following:

(a) Upon Expiry of the Term Pursuant to Section 13.1. All United Therapeutics Confidential Information shall be subject to Section 13.5(e).

9. Section 13.6 Survival. Subsection (b) of Section 13.6 is hereby deleted in its entirety.

10. Full Force and Effect. Except as specifically modified or amended by the terms of this Amendment, the License Agreement and all provisions contained therein are, and shall continue, to be in full force and effect and are hereby ratified and confirmed.

11. Counterparts. This Amendment may be executed in counterparts, each of which shall be deemed an original and both of which together shall constitute one and the same instrument.

[*Signature Page Follows*]

IN WITNESS WHEREOF , the Parties, intending to be bound hereby, have executed this Amendment by their duly authorized representatives as of the Amendment Effective Date.

ELI LILLY AND COMPANY		**UNITED THERAPEUTICS CORPORATION**	
By:	/s/ David A. Ricks	By:	/s/ Michael Benkowitz
Name:	David A. Ricks	Name:	Michael Benkowitz
Title:	President & Chief Executive Officer	Title:	President & Chief Operating Officer