

**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) October 21, 2019

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
(Exact name of registrant as specified in its charter)

Israel
(State or Other Jurisdiction
of Incorporation)

001-16174
(Commission
File Number)

00-0000000
(IRS Employer
Identification No.)

5 Basel Street
P.O. Box 3190
Petach Tikva 4951033, Israel
(Address of Principal Executive Offices, including Zip Code)

+972-3-914-8171
(Registrant's Telephone Number, including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instruction A.2. below):

- ☐ 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 |
|------------------------------------------------------------------|-------------------|-------------------------------------------|
| American Depositary Shares, each representing one Ordinary Share | TEVA | New York Stock Exchange |

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 7.01. Regulation FD Disclosure.

On October 21, 2019, Teva Pharmaceutical Industries Ltd. issued a press release announcing the settlement of the track 1 opioid cases and confirming that there is an agreement in principle with a group of attorneys general from North Carolina, Pennsylvania, Tennessee and Texas, as well as certain defendants, for a global settlement framework to settle remaining opioid litigation. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 which are based on management’s current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to our ability to reach a final resolution of the remaining opioid-related litigation.

The information contained herein, including Exhibit 99.1, is being furnished pursuant to Item 7.01 of Form 8-K. This information shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

EXHIBITS

| Exhibit No. | Description |
|----------------------|-----------------------------------------------------------------------------------------------------|
| 99.1 | Press Release issued by Teva Pharmaceutical Industries Ltd. dated October 21, 2019. |

SIGNATURES

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, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LTD.

By: /s/ Michael McClellan
Name: Michael McClellan
Title: Chief Financial Officer

Date: October 23, 2019

Teva Settles Track 1 Opioid Cases and Reaches Agreement on Framework to Settle Remaining Litigation

PARSIPPANY, N.J. & JERUSALEM--(BUSINESS WIRE)--October 21, 2019--Teva Pharmaceutical Industries Ltd. and its affiliates today announced a settlement agreement with both Cuyahoga and Summit counties of Ohio. The settlement resolves the counties' claims and removes Teva from the Track 1 opioid litigation. Under the terms of the settlement, the Company will provide the two counties with the critical opioid treatment medication buprenorphine naloxone (sublingual tablets), known by the brand name Suboxone®, valued at \$25 million (at wholesale acquisition cost) and distributed over three years to help in the care and treatment of people suffering from addiction (to be allocated at each county's discretion) and a cash payment in the amount of \$20 million, to be paid over three years.

The Company also confirms that there is an agreement in principle with a group of attorneys general from North Carolina, Pennsylvania, Tennessee and Texas, as well as certain defendants, for a global settlement framework. The framework is designed to provide a mechanism by which the Company attempts to seek resolution of remaining potential and pending opioid claims by both the states and political subdivisions. Under this agreement, Teva would donate buprenorphine naloxone (sublingual tablets), in quantities of up to the amount needed to meet the majority of the currently estimated U.S. patient need over the next 10 years, with a value of approximately \$23 billion (at wholesale acquisition cost). Buprenorphine naloxone is the primary drug used to treat opioid addiction. The Teva product donation will significantly contribute to the care and treatment of people suffering from addiction and assist impacted communities. Teva would also provide a cash payment of up to \$250 million over 10 years.

The Company is pleased to positively contribute to solving the nationwide opioid epidemic. Teva has consistently committed to complying with all laws and regulations regarding its manufacture and sale of opioids. Neither settlement includes an admission of liability.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people's lives for more than a century. We are a global leader in generic and specialty medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at www.tevapharm.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to:

- our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; competition for our specialty products, especially COPAXONE®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; the uncertainty of commercial success of AJOVY® or AUSTEDO®; competition from companies with greater resources and capabilities; efforts of pharmaceutical companies to limit the use of generics, including through legislation and regulations; consolidation of our customer base and commercial alliances among our customers; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; price erosion relating to our products, both from competing products and increased regulation; delays in launches of new products and our ability to achieve expected results from investments in our product pipeline; our ability to take advantage of high-value opportunities; the difficulty and expense of obtaining licenses to proprietary technologies; and the effectiveness of our patents and other measures to protect our intellectual property rights;
- our substantial indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us;
- our business and operations in general, including: failure to effectively execute our restructuring plan announced in December 2017; uncertainties related to, and failure to achieve, the potential benefits and success of our senior management team and organizational structure; harm to our pipeline of future products due to the ongoing review of our R&D programs; our ability to develop and commercialize additional pharmaceutical products; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; compliance with sanctions and other trade control laws; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third party information technology systems or breaches of our data security; the failure to recruit or retain key personnel; variations in intellectual property laws that may adversely affect our ability to manufacture our products; challenges associated with conducting business globally, including adverse effects of political or economic instability, major hostilities or terrorism; significant sales to a limited number of customers in our U.S. market; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; implementation of a new enterprise resource planning system that, if deficient, could materially and adversely affect our operations and/or the effectiveness of our internal controls; and our prospects and opportunities for growth if we sell assets;
- compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; increased legal and regulatory action in connection with public concern over the abuse of opioid medications in the U.S.; governmental investigations into selling and marketing practices; potential liability for patent infringement; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks;
- other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our intangible assets; potential significant increases in tax liabilities; and the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business;

and other factors discussed in this press release, in our Quarterly Report on Form 10-Q for the second quarter of 2019 and in our Annual Report on Form 10-K for the year ended December 31, 2018, including in the sections captioned "Risk Factors" and "Forward Looking Statements." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

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