# 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 4, 2023**

# TEVA PHARMACEUTICAL INDUSTRIES LIMITED
**(Exact name of registrants as specified in its charter)**

| **Israel** | **001-16174** | **Not Applicable** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation))** | **(Commission File Number)** | **(IRS Employer Identification Number)** |

**124 Dvora Hanevi'a Street**
**Tel Aviv 6944020, Israel**
**(Address of Principal Executive Offices, including Zip Code)**

**+972- 3-914-8213**
**(Registrant's Telephone Number, including Area Code)**

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

**Copies of communications to:**

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 4, 2023, Teva Pharmaceutical Industries Ltd. (the "Company") issued a press release announcing its entry into an exclusive collaboration with Sanofi to co-develop and co-commercialize Teva's TEV-48574 asset, a novel anti-TL1A therapy for the treatment of ulcerative colitis and Crohn's disease, two types of inflammatory bowel disease. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

The information in this Item 7.01 and Exhibit 99.1 hereto is being furnished to the Securities and Exchange Commission (the "Commission") and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act or the Exchange Act, except as set forth by specific reference in such filing.

**Cautionary Note Regarding Forward-Looking Statements**

The foregoing description of the collaboration agreement contain "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. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression. Important factors that could cause or contribute to such differences include risks relating to: our exclusive collaboration with Sanofi, including uncertainties around the effective date of the collaboration and our ability to satisfy the closing conditions related thereto; risks related to the timing of and our ability to achieve expected results for TEV-48574 (anti-TL1A), including our ability to commercialize TEV-48574 (anti-TL1A); the extent to which we will realize the anticipated financial and other benefits of the Sanofi collaboration; our ability to satisfy the conditions to receiving milestone cash payments under the Sanofi collaboration agreement; the risk that we will incur significant costs in connection with the development of TEV-48574 (anti-TL1A), which may exceed any revenue generated by TEV-48574 (anti-TL1A); risks that regulatory approvals and other requirements may delay the development and commercialization of TEV-48574 (anti-TL1A); our ability to successfully compete in the marketplace, including our ability to develop and commercialize biopharmaceutical products, our ability to achieve expected results from investments in our product pipeline, our ability to develop and commercialize additional pharmaceutical products, our ability to successfully launch and execute our new Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, and to sustain and focus our portfolio of generics medicines, and the effectiveness of our patents and other measures to protect our intellectual property rights; our business and operations in general, including, the impact of global economic conditions and other macroeconomic developments and the governmental and societal responses thereto, and costs and delays resulting from the extensive pharmaceutical regulation to which we are subject. Investors should read the important risk factors described in the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and Current Reports on Form 8-K filed with the Commission. Forward-looking statements speak only as of the date on which they are made, and the Company assumes 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. Investors are cautioned not to put undue reliance on these forward-looking statements.

**ITEM 9.01 Financial Statements and Exhibits**

(d) Exhibits

| Exhibit No. | Description of Document |
|---|---|
| 99.1 | Press release of the Company issued on October 4, 2023. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

Date: October 4, 2023

By: /s/ Eli Kalif
Name: Eli Kalif
Title: Executive Vice President, Chief Financial Officer

**Exhibit 99.1**

**Press Release**

*Sanofi and Teva announce exclusive collaboration to deliver inflammatory bowel disease treatment*

- TEV ‘574, a novel anti-TL1A therapy, is being developed to treat ulcerative colitis and Crohn’s disease
- Collaboration supports Sanofi’s immunology strategy of exploring novel mechanisms of action for chronic inflammatory diseases
- Collaboration leverages the innovative R&D and commercial expertise of both companies

**Paris, France and Parsippany, New Jersey, October 4, 2023**. Sanofi (EURONEXT: SAN and NASDAQ: SNY) and Teva Pharmaceuticals, a U.S. subsidiary of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) announce today a collaboration to co-develop and co-commercialize asset TEV ‘574, currently in Phase 2b clinical trials for the treatment of Ulcerative Colitis and Crohn’s Disease, two types of inflammatory bowel disease.

***Paul Hudson***

Chief Executive Officer, Sanofi

*“Anti-TL1As are a promising class of therapies, and we believe that TEV ‘574 could emerge as a best-in-class option for people living with serious gastrointestinal diseases. This collaboration strengthens our commitment to advancing innovative treatment options for inflammatory conditions with a high unmet need and bolsters our goal to be an industry leader in immunology.”*

***Richard Francis***

President and Chief Executive Officer, Teva

*“This is a new era for Teva, and our robust, innovative pipeline is key to our Pivot to Growth strategy. This collaboration further validates the great science that Teva has to offer with our internally developed anti-TL1A. We are honored to partner with Sanofi to bring their proven capabilities, leadership, and success in the immunology and gastroenterology space together with our capabilities to optimize development and global launches.”*

Under the terms of the new collaboration agreement, Teva will receive an upfront payment of €469 million ($500 million) and up to €940 million ($1 billion) in development and launch milestones. Each company will equally share the development costs globally and net profits and losses in major markets, with other markets subject to a royalty arrangement and Sanofi will lead the development of the Phase 3 program. Teva will lead commercialization of the product in Europe, Israel and specified other countries, and Sanofi will lead commercialization in North America, Japan, other parts of Asia and the rest of the world. The transaction will become effective after customary closing conditions are met. Initial program results are expected to be available in 2024.

Inflammatory bowel disease (IBD) is the term for two conditions – Crohn’s disease and ulcerative colitis – characterized by chronic inflammation of the gastrointestinal (GI) tract. Prolonged inflammation results in damage to the GI tract. The common symptoms for both conditions are persistent diarrhea, rectal bleeding, abdominal pain, fatigue, and weight loss. An estimated ~10 million people worldwide live with IBD.

**Teva Investor Call**

Teva will hold an investor call and live webcast today (Wednesday, October 4, 2023) at 8:00 a.m. ET to discuss this collaboration. To participate, please register in advance **here** to obtain a local or toll-free phone number and your personal pin. A live webcast of the call will be available on Teva's website at: https://ir.tevapharm.com/Events-and-Presentations.

*About Sanofi*

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions. Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

*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 innovative 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 innovative and biopharmaceutical products. Learn more at www.tevapharm.com.

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**Sanofi Forward-Looking Statements**

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and

commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that pandemics or other global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

**Teva 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. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include: risks relating to our exclusive collaboration with Sanofi, including uncertainties around the effective date of the collaboration and our ability to satisfy the closing conditions related thereto; risks related to the timing of and our ability to achieve expected results for TEV-48574 (anti-TL1A), including our ability to commercialize TEV-48574 (anti-TL1A); the extent to which we will realize the anticipated financial and other benefits of the Sanofi collaboration; our ability to satisfy the conditions to receiving milestone cash payments under the Sanofi collaboration agreement; the risk that we will incur significant costs in connection with the development of TEV-48574 (anti-TL1A), which may exceed any revenue generated by TEV-48574 (anti-TL1A); risks that regulatory approvals and other requirements may delay the development and commercialization of TEV-48574 (anti-TL1A); our ability to successfully compete in the marketplace, including our ability to develop and commercialize biopharmaceutical products, competition for our innovative medicines, including AUSTEDO®, AJOVY® and COPAXONE®, our ability to achieve expected results from investments in our product pipeline, our ability to develop and commercialize additional pharmaceutical products, and the effectiveness of our patents and other measures to protect our intellectual property rights; our ability to successfully launch and execute our new Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, and to sustain and focus our portfolio of generics medicines; 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, the impact of global economic conditions and other macroeconomic developments and the governmental and societal responses thereto, and costs and delays resulting from the extensive pharmaceutical regulation to which we are subject; compliance, regulatory and litigation matters, including failure to comply with complex legal and regulatory environments; other financial and economic risks; and other factors discussed in our Quarterly Report on Form 10-Q for the second quarter of 2023 and in our Annual Report on Form 10-K for the year ended December 31, 2022, including in the section captioned "Risk Factors." 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.