## 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): September 26, 2022

# **Endo International plc**

(Exact name of registrant as specified in its charter)

Ireland (State or other jurisdiction of incorporation) 001-36326 (Commission File Number) 68-0683755 (IRS Employer Identification No.)

First Floor, Minerva House, Simmonscourt Road Ballsbridge, Dublin 4, Ireland (Address of principal executive offices)

Not Applicable (Zip Code)

Registrant's telephone number, including area code 011-353-1-268-2000

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:

□ 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:

	Trading	Name of each exchange
Title of each class	Symbol(s)	on which registered
Ordinary shares, nominal value \$0.0001 per	ENDP	The NASDAQ Global Select Market *
share		

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.  $\Box$ 

\* On August 26, 2022, Nasdaq suspended trading in Endo International plc's (the "**Company**") common stock and on September 14, 2022, filed a Form 25 with the Securities and Exchange Commission to delist the Company's common stock. As a result of the suspension and expected delisting, the Company's common stock began trading exclusively on the over-the-counter market on August 26, 2022, under the symbol ENDPQ.

#### Item 8.01 Other Information.

On September 22, 2022, Endo International plc (the "**Company**") was informed by its development partner, Taiwan Liposome Company, Ltd ("**TLC**"), of the top-line results from TLC's Phase 3 clinical study to evaluate the efficacy and safety of TLC599 (dexamethasone sodium phosphate extended-release liposome injectable suspension) in patients with pain from osteoarthritis ("**OA**") of the knee. While study participants treated with TLC599 showed improvement on the primary endpoint (change from baseline to week 12 on the WOMAC pain scale) consistent with the level of improvement reported in the previously conducted TLC599 Phase 2 clinical study, the difference compared to those receiving placebo was not statistically significant. Based on this data, the Company will be evaluating further options for TLC599 with TLC.

The below table includes the estimated amounts for TLC599 included in the Company's previously disclosed five year financial outlook:

\$ million Revenue	<u>2022E</u> \$—	<u>2023E</u> \$—	<u>2024E</u> \$—	<u>2025E</u> \$ 29	2026E \$71
EBITDA [a]	(50)	(5)	(11)	(8)	16
Pre-tax unlevered FCF [b]	(50)	(5)	(61)	(37)	(30)

[a] 2022E reflects estimated one-time payments of which only \$30 million has been paid while the remaining \$20 million is associated with successful Phase 3 results and is not expected to be paid in 2022.

[b] 2024-26E includes additional estimated one-time regulatory, manufacturing, and commercial milestone payments.

#### Non-GAAP Financial Measures

This Current Report on Form 8-K contains certain forward-looking financial measures that are not prescribed by or prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"), including EBITDA and pre-tax unlevered free cash flow. EBITDA represents Net income (loss) before Interest expense, net; Income tax expense; Depreciation; and Amortization, each prepared in accordance with GAAP, further adjusted by excluding other (income) expense, net; share-based compensation; acquisition-related and integration items, including transaction costs and changes in the fair value of contingent consideration; cost reduction and integration-related initiatives such as separation benefits, continuity payments, other exit costs and certain costs associated with integrating an acquired company's operations; certain amounts related to strategic review initiatives; asset impairment charges; inventory step-up recorded as part of our acquisitions; litigation-related and other contingent matters; certain legal costs; debt modification costs; discontinued operations, net of tax; and certain other items. Pre-tax unlevered free cash flow excludes cash taxes. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP financial measures. Despite the importance of these measures to management in goal setting and performance measurement, the company stresses that these are non-GAAP financial measures that have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. Because of the non-standardized definitions, EBITDA and pre-tax unlevered free cash flow and its components may not be comparable to the calculation of similar measures of other companies. These non-GAAP financial measures are presented solely to permit investors to more fully understand how management assesses performance.

The Company does not provide reconciliations of projected non-GAAP financial measures to GAAP financial measures, nor does it provide comparable projected GAAP financial measures for such projected non-GAAP financial measures. The Company is unable to provide such reconciliations without unreasonable efforts due to the inherent difficulty in forecasting and quantifying certain amounts that are necessary for such reconciliations, including, among other potential adjustments, adjustments that could be made for asset impairments, contingent consideration adjustments, legal settlements, gain / loss on extinguishment of debt, adjustments to inventory and other charges reflected in the reconciliation of historic numbers, the amounts of which could be significant.

#### Cautionary Information Regarding Trading in the Company's Securities.

The Company continues to face certain risks and uncertainties that have been affecting its business and operations, and these risks and uncertainties may affect the Company's ability to enter into a sale transaction and could impact the outcome of the Company's voluntary petitions for relief under chapter 11 of the Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York (collectively, the "**Chapter 11 Filings**"). Holders of the Company's equity securities will likely be entitled to little or no recovery on their investment following the Chapter 11 Filings, and recoveries to other stakeholders cannot be determined at this time. The Company cautions that trading in the Company's securities given the pendency of the Chapter 11 Filings is highly speculative and poses substantial risks. Trading prices for the Company's securities may bear little or no relationship to the actual value realized, if any, by holders of the Company's securities in the Chapter 11 Filings. Accordingly, the Company urges extreme caution with respect to existing and future investments in its securities.

#### Forward-looking statements

Certain information in this Current Report on Form 8-K may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation, including, but not limited to, statements with respect to the restructuring support agreement and the sale transaction, the Chapter 11 proceedings and recognition proceedings, the Company's plans regarding TLC599, and any other statements that refer to our expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect Endo's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the following: the outcome of our contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the Company's businesses and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the

operations of the Company's businesses; the unpredictability of the Company's financial results while in Chapter 11 proceedings; the Company's ability to discharge claims in Chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in Chapter 11 proceedings; the Company's ability to conduct business as usual; the Company's ability to continue to serve customers, suppliers and other business partners at the high level of service and performance they have come to expect from the Company's ability to continue to pay employees, suppliers and vendors; the ability to control costs during Chapter 11 proceedings; adverse litigation; the risk that the Company's Chapter 11 Cases may be converted to cases under Chapter 7 of the Bankruptcy Code; the Company's ability to secure operating capital; the Company's ability to take advantage of opportunities to acquire assets with upside potential; the Company's ability to execute on its strategic plan to pursue, evaluate and close an asset sale of the Company's businesses pursuant to Section 363 of the U.S. Bankruptcy Code; the impact of competition, including the loss of exclusivity and generic competition for VASOSTRICT®; our ability to satisfy judgments or settlements or pursue appeals including bonding requirements; our ability to adjust to changing market conditions; our ability to attract and retain key personnel; our inability to maintain compliance with financial covenants and operating obligations which would expose us to potential events of default under our outstanding indebtedness; our ability to incur additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes; our ability to refinance our indebtedness; a significant reduction in our short-term or long-term revenues which could cause us to be unable to fund our operations and liquidity needs or repay indebtedness; supply chain interruptions or difficulties; changes in competitive or market conditions: changes in legislation or regulatory developments: our ability to obtain and maintain adequate protection for our intellectual property rights; the timing and uncertainty of the results of both the research and development and regulatory processes, including regulatory decisions, product recalls, withdrawals and other unusual items; domestic and foreign health care and cost containment reforms, including government pricing, tax and reimbursement policies; technological advances and patents obtained by competitors; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; our ability to integrate any newly acquired products into our portfolio and achieve any financial or commercial expectations; the impact that known and unknown side effects may have on market perception and consumer preference for our products; the effectiveness of advertising and other promotional campaigns; the timely and successful implementation of any strategic initiatives; unfavorable publicity regarding the misuse of opioids; the uncertainty associated with the identification of and successful consummation and execution of external corporate development initiatives and strategic partnering transactions; our ability to advance our strategic priorities, develop our product pipeline and continue to develop the market for QWO® and other products; and our ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. In addition, U.S. and international economic conditions, including consumer confidence and debt levels, taxation, changes in interest and currency exchange rates, international relations, capital and credit availability, the status of financial markets and institutions, the impact of and response to the ongoing COVID-19 pandemic and the impact of continued economic volatility, can materially affect our results. Therefore, the reader is cautioned not to rely on these forward-looking statements. Endo expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

Additional information concerning risk factors, including those referenced above, can be found in press releases issued by Endo, as well as Endo's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in Endo's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission. Copies of Endo's press releases and additional information about Endo are available at www.endo.com or you can contact the Endo Investor Relations Department at relations.investor@endo.com.

#### Item 9.01 Financial Statements and Exhibits.

Exhibit

(d)	No.	Description.
	104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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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.

#### ENDO INTERNATIONAL PLC

By: /s/ Matthew J. Maletta

 

 Name:
 Matthew J. Maletta

 Title:
 Executive Vice President, Chief Legal Officer and Company Secretary

Date: September 26, 2022