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): December 6, 2022

Endo International plc
(Exact name of registrant as specified in its charter)

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

First Floor, Minerva House, Simmonscourt Road Ballsbridge, Dublin 4, Ireland	**Not Applicable**
(Address of principal executive offices)	**(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value $0.0001 per share	ENDPQ (1)	(1)

(1) On August 26, 2022, Endo International plc's ordinary shares, which previously traded on the Nasdaq Global Select Market under the symbol ENDP, began trading exclusively on the over-the-counter market under the symbol ENDPQ. On September 14, 2022, Nasdaq filed a Form 25-NSE with the United States Securities and Exchange Commission and Endo International plc's ordinary shares were subsequently delisted from the 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 2.05. Costs Associated with Exit or Disposal Activities.

On December 6, 2022, Endo International plc (together with its direct and indirect subsidiaries, "Endo" or the "Company") announced that it will cease the production and sale of Endo Aesthetics' QWO® (collagenase clostridium histolyticum-aaes) in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration.

This decision is expected to result in annualized pre-tax cash savings of approximately $50 million to $60 million and a reduction to Endo's global workforce of approximately 90 full-time positions. In connection with ceasing production and sales of QWO®, Endo expects to incur total pre-tax restructuring charges of approximately $235 million to $250 million in the fourth quarter 2022. These estimated restructuring charges primarily consist of non-cash asset impairment charges of approximately $220 million to $230 million and $15 million to $20 million of cash costs related to employee separation costs and other charges. The Company believes that it is authorized to make this decision in the ordinary course; however, out of an abundance of caution, the Company will seek entry of an order from the United States Bankruptcy Court for the Southern District of New York approving this decision as a reasonable exercise of the Company's business judgment.

Cleansing Materials

In connection with the decision, Endo delivered materials pursuant to confidentiality agreements (the "NDAs") entered into by the Company (the "Cleansing Materials"). Pursuant to the NDAs, the Company has agreed to publicly disclose certain information, including the Cleansing Materials, upon the occurrence of certain events as set forth in the NDAs. A copy of the Cleansing Materials is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K. The Cleansing Materials are based solely on information available to the Company as of December 5, 2022.

The estimated savings, reductions, charges and costs noted above are subject to a number of assumptions. Actual results may differ materially as a result of various important factors, including the risks and uncertainties described under the heading "Cautionary Note Regarding Forward-Looking Statements" in the press release included as Exhibit 99.1 to this Current Report on Form 8-K, which are incorporated by reference herein.

Item 2.06. Material Impairments.

The information required by this Item 2.06 is included under Item 2.05 of this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Number	Description
99.1	Press Release
99.2	Cleansing Materials
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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, hereunto duly authorized.

Dated: December 6, 2022

ENDO INTERNATIONAL PLC

By: /s/ Matthew J. Maletta
Name: Matthew J. Maletta
Title: Executive Vice President,
Chief Legal Officer and Company Secretary

FOR IMMEDIATE RELEASE

Endo to Cease Production and Sale of Qwo® (collagenase clostridium histolyticum-aaes)

DUBLIN, December 6, 2022 – Endo International plc (OTC: ENDPQ) announced today that it will cease the production and sale of Endo Aesthetics' Qwo® (collagenase clostridium histolyticum-aaes) in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration.

For more than a year, Endo worked to address those concerns, including launching an open-label study in June 2022, APHRODITE, to test different interventions and whether they might mitigate bruising. Although certain APHRODITE study cohorts' results reflected a modest reduction of bruising area and severity, none achieved a consistent level of reduced bruising following initial treatment to adequately alleviate the market's concerns.

"After careful consideration, we have determined that QWO does not represent a viable commercial opportunity for Endo," said Blaise Coleman, President and CEO of Endo. "This difficult decision unfortunately results in a workforce reduction. We are grateful for the dedication and hard work of all team members who supported QWO and our Endo Aesthetics business, and we are committed to providing support and assistance to our impacted team members."

This decision is expected to result in annualized pre-tax cash savings of approximately $50 million to $60 million and a reduction to Endo's global workforce of approximately 90 full-time positions. In connection with ceasing QWO production and sales, the Company expects to incur pre-tax cash restructuring charges of approximately $15 million to $20 million and record a total pre-tax restructuring charge of approximately $235 million to $250 million in the fourth quarter 2022. The Company will seek any necessary approvals from the United States Bankruptcy Court for the Southern District of New York in connection with this decision.

QWO remains an FDA-approved product with clinically proven results and an established safety profile, so practices may continue to use unexpired QWO that they have in stock, as well as order additional supply. Alternatively, practitioners can return unused QWO purchased prior to this announcement for a refund. Practices will be notified about these options.

INDICATION

Qwo® is indicated for the treatment of moderate to severe cellulite in the buttocks of adult women.

IMPORTANT SAFETY INFORMATION FOR QWO

CONTRAINDICATIONS

QWO is contraindicated in patients with a history of hypersensitivity to collagenase or to any of the excipients or the presence of infection at the injection sites.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions including anaphylaxis have been reported with the use of collagenase clostridium histolyticum. If such a reaction occurs, further injection of QWO should be discontinued and appropriate medical therapy immediately instituted. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions.

Injection Site Bruising

In clinical trials, 84% of subjects treated with QWO experienced injection site bruising. Subjects with coagulation disorders or using anticoagulant or antiplatelet medications (except those taking ≤150 mg aspirin daily) were excluded from participating in Trials 1 and 2.

QWO should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet (except those taking ≤150 mg aspirin daily) or anticoagulant therapy.

Substitution of Collagenase Products

QWO must not be substituted with other injectable collagenase products.

QWO is not intended for the treatment of Peyronie's Disease or Dupuytren's Contracture.

ADVERSE REACTIONS

In clinical trials, the most commonly reported adverse reactions in patients treated with QWO with an incidence ≥ 10% were at the injection site: bruising, pain, nodule and pruritus.

Click for Full Prescribing Information for QWO.

About Endo

Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

Certain information in this press release 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, the statements by Mr. Coleman and any statements related to the Company's efforts to expand and enhance its portfolio or the decision to cease production and sale of QWO, including any estimated expenses, charges,

costs or savings, and any other statements that refer to 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 the Company'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 outcome of the Company's 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 strategy; risks and uncertainties associated with chapter 11 proceedings; the negative impacts on the Company's businesses as a result of filing for and operating under chapter 11 protection; the time, terms 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; and 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 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 the Company, as well as the Company'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 the Company'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 the Company's press releases and additional information about the Company are available at www.endo.com or you can contact the Company's Investor Relations Department at relations.investor@endo.com.

Endo International plc:

Media:	*Investors:*
Linda Huss	Laure Park
media.relations@endo.com	relations.investor@endo.com

###

Confidential
Cleansing Material

endo.com

Disclaimer

This document has been prepared by Endo International plc ("Endo" or the "Company") and its advisors from information provided by Company management and other sources and is subject in all respects to the confidentiality agreement you have executed with the Company. All communications or inquiries relating to Endo or its affiliates should be directed to its advisors. No personnel of Endo or its affiliates should be contacted under any circumstances.

This document is "as is" and is based, in part, on information obtained from other sources. We have assumed and relied upon the accuracy and completeness of such information for purposes of this document and have not independently verified any such information. Neither we nor any of our affiliates or agents, makes any representation or warranty, express or implied, in relation to the accuracy or completeness of the information contained in this document or any oral information provided in connection herewith, or any data it generates and expressly disclaim any and all liability (whether direct or indirect, in contract, tort or otherwise) in relation to any of such information or any errors or omissions therein. Any views or terms contained herein are preliminary, and are based on financial, economic, market and other conditions prevailing as of the date of this document and are subject to change. We undertake no obligations or responsibility to update any of the information contained in this document. Past performance does not guarantee or predict future performance.

This document does not constitute an offer to sell or the solicitation of an offer to buy any security, nor does it constitute an offer or commitment to lend, syndicate or arrange a financing, underwrite or purchase or act as an agent or advisor or in any other capacity with respect to any transaction, or commit capital, or to participate in any trading strategies, and does not constitute legal, regulatory, accounting or tax advice to the recipient. This document does not constitute and should not be considered as any form of financial opinion or recommendation by us or any of our affiliates. This document is not a research report and should not be construed as such.

This document is for informational purposes only and does not purport to contain all of the information that may be required to evaluate a possible decision with respect to a transaction involving the Company or any of its indebtedness. The Company and all of its respective affiliates, directors, officers, employees and advisers do not make any representation or warranty, express or implied, as to the accuracy or completeness of the information contained in this document or any other written, oral or other communications transmitted or otherwise made publicly available. This document is not intended to be all-inclusive or to contain all the information that a person may desire in considering a transaction and is not intended to form the basis for entering into such a transaction. You should consult your own legal, regulatory, tax, business, financial and accounting advisors to the extent you deem necessary and must make your own decision and perform your own independent investigation and analysis of the information and topics covered in this document. The information contained in this document is preliminary in nature and is subject to change, and any such changes may be material. Except as otherwise expressly noted herein, this document speaks as of the date noted on the title page. The delivery of this document does not create any implication that there has been no change in the business and affairs of Endo or its affiliates since such date. Neither Endo, its advisors, nor any of their respective affiliates or representatives undertake any obligation to update any of the information contained herein or to correct any inaccuracies or omissions that may become apparent.

This document (i) has been prepared at the direction of the Company, (ii) from materials and information supplied by the Company and from other sources, (ii) contains confidential information, (iii) is being delivered for informational purposes only on a confidential basis and (iv) does not purport to contain all of the information that may be required or relevant to your evaluation of any potential transaction. You are responsible for conducting your own investigation and analysis and should consult your own professional advisors.

By accepting this document, you agree that (i) neither you nor your agents, representatives, directors or employees will copy, reproduce or distribute to others this document, in whole or in part, at any time; (ii) you will keep confidential all information contained herein; and (iii) you will not use this document for any purpose, other than deciding whether to proceed with a further investigation of the Company or any transaction involving the Company or any of its indebtedness.

Certain statements in this document may constitute "forward-looking statements" within the meaning of the federal securities laws. The Company's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Forward-looking statements include, but are not limited to, statements regarding the Company or expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "budget," "forecast," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "could," "strive," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. You should carefully consider the risks and uncertainties described in the "Risk Factors" section of the Company's annual report filed with the Securities and Exchange Commission (the "SEC") and other documents filed by the Company from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Most of these factors are outside the Company's control and are difficult to predict. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Readers are cautioned not to put undue reliance on forward-looking statements, and no person assumes any obligation and no person intends to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. No assurance is given that the Company will achieve its expectations.

Executive Summary

- The unfavorable perception of intense bruising following initial treatment and the risk of prolonged skin discoloration has created a significant and sustained hesitancy in QWO utilization in the market.
- A number of commercial and medical initiatives were launched over the last 18 months to address the issue; however, the limitations of new clinical data has been a significant constraint to making progress.
- The QWO APHRODITE open-label clinical study was launched in 2Q22 to evaluate different potentially commercially viable interventions to mitigate initial bruising and the risk of prolonged skin discoloration.
- Imaging data from 7 cohorts has been obtained and, while a modest reduction of bruising area and severity was observed in certain cohorts, the extent of bruising reduction was not consistent among all participants and is believed to be insufficient to adequately alleviate the market concerns.
- Based on the study results, our recommended course of action is to immediately cease further production and commercialization of QWO.
- This action will result in annual pre-tax cash savings of ~$50M-60M [a] starting in FY23 and result in one-time cash and non-cash restructuring charges of up to ~$20M and ~$230M, respectively, in 4Q22.

[a] Based on May 2022 long-term plan as reflected in the Management Presentation; assumes transition actions are fully implemented by January 1, 2023.

APHRODITE-1 study results

- APHRODITE study primary endpoint is severity of bruising at days 3 to 5 following initial injection as this is the most important market concern that needs to be addressed.
  - Secondary Endpoint – bruising resolution assessment at day 10 to 14
  - Efficacy assessment – day 90
  - Discoloration assessment – day 180
- Our conclusions as to the primary endpoint are based upon our review of adequate imaging data samples from all 7 cohorts.
- While a modest reduction of bruising area and severity was observed in certain cohorts, the extent of bruising reduction was not consistent among all participants and is believed to be insufficient to adequately alleviate the market concerns.
  - Consistent and demonstrable bruising reduction in the first few days (Day 3 to 5) following initial QWO treatment is required to confirm commercial viability.
  - Given the absence of a consistent benefit at the primary endpoint, we believe it is clinically unnecessary to await later endpoints such as bruising resolution and efficacy assessments prior to determining to cease further production and commercialization of QWO.

We expect to realize $50-60M in total annual run rate cost savings

$ millions

Cash Savings [a],[b]	2022	2023 and Thereafter
Cost of sales (fixed only)	$ -	$ 5-10
Operating expenses	-	45-50
Total	**$ -**	**$ 50-60**

One-time Charges [c]	2022	2023 and Thereafter
Cash restructuring charges	$ 15-20	$ -
Non-cash asset impairments	220-230	-
Total	**$ 235-250**	**$ -**

- The level of QWO utilization will be significantly constrained due to the inability to effectively address the negative perception of intense bruising following initial treatment and the associated risk of prolonged skin discoloration.
- The minimum level of commercial and medical resources required to support this scenario would result in a prolonged period of significant losses (i.e., gross profit < operating expenses) with low probability of achieving future profitability.

[a] Represents full year estimates and assumes transition actions are fully implemented by January 1, 2023.
[b] Based on May 2022 Long-Term Plan as reflected in the Management Presentation.
[c] Expected to be recorded in 4Q22.

Next Steps

Element	Key Activity	Tentative Date
Chapter 11	▪ Consultations with advisors to (i) the 1L group, (ii) the cross-holder group, (iii) the committees and (iv) the future claimants' representative	w/o November 28
	▪ 1L group consent	December 5 or 6
	▪ Bankruptcy court approval	January 19 [a]
Board Review	▪ Endo PLC Board approval (after committee consultations)	December 2
Communication	▪ 8-K filing	December 6 and 7
	▪ Internal communications to organization and impacted team members	
	▪ External communications to customers, clinical investigators, and other key stakeholders	

[a] Actual date could potentially be earlier if bankruptcy court provides alternative hearing date.