

**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): January 7, 2019

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, Simonscourt 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))

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 January 7, 2019, Endo International plc (the “Company”) intends to make a presentation at the *J.P. Morgan Healthcare Conference* (the “Presentation”), a copy of which is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. The Presentation will also be available on the Company’s website at www.endo.com.

The information in this Item 7.01 and in Exhibit 99.1 attached hereto shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in this Item 7.01 and in Exhibit 99.1 attached hereto shall not be incorporated into any registration statement or other document filed by the Company with the U.S. Securities and Exchange Commission under the Securities Act of 1933, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Number</u>	<u>Description</u>
99.1	Investor Presentation of Endo International plc dated as of January 7, 2019

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

Dated: January 7, 2019

Endo International plc J.P. Morgan Healthcare Conference

Paul Campanelli, President & CEO
January 7, 2019



©2018 Endo Pharmaceuticals, Inc. All rights reserved.

Forward Looking Statements; Non-GAAP Financial Measures

This presentation contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Statements including words such as “believes,” “expects,” “anticipates,” “intends,” “estimates,” “plan,” “will,” “may,” “look forward,” “intend,” “guidance,” “future projects” or similar expressions are forward looking statements. Because these statements reflect our current projected views, expectations and beliefs concerning future events, these forward looking statements involve risks and uncertainties. Although Endo believes that these forward looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward looking statements or information in this presentation. Investors should note that many factors, as more fully described in the documents filed by Endo with securities regulators in the United States and Canada including under the caption “Risk Factors” in Endo’s Form 10-K, Form 10-Q and Form 8-K filings, as applicable, with the Securities and Exchange Commission and with securities regulators in Canada on System for Electronic Document Analysis and Retrieval (“SEDAR”) and as otherwise enumerated herein or therein, could affect Endo’s future financial results and could cause Endo’s actual results to differ materially from those expressed in any forward looking statements. The forward looking statements in this presentation are qualified by these risk factors. Endo assumes no obligation to publicly update any forward looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities law.

Strategic Priority Execution has Led to Smaller but Stronger Company. Continuing to Focus Investments on Differentiated Products to Drive Growth

1

Reshape our Organization for Success

- **Simplify** our business through centralization and unification
- **Drive** productivity improvements
- **Create** a New Endo Culture

2

Build Our Portfolio and Capabilities for the Future

- **Enhance** Generics pipeline through investment in hard-to-produce assets & technologies
- **Transform** Branded business into a highly focused Specialty business
- **Divest** non-core assets

3

Drive Margin Expansion and De-Lever

- **Focus** on differentiated/intelligent product selection
- **Drive** EBITDA margin improvements through operational execution and continuous improvements
- **De-lever** 3-4x range over time; committed to a highly disciplined capital allocation approach

Endo Focused on Expansion of Sterile Injectables, Specialty Businesses and High-Value Generics



Branded Specialty business led by Xiaflex® growth. Preparing for commercialization of CCH



**U.S. Branded
Specialty &
Established**



**U.S. Branded
Sterile
Injectables**



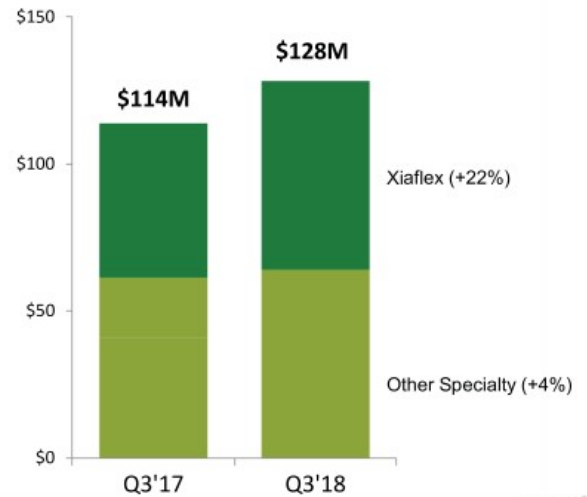
**U.S.
Generics**



International

- Strong specialty franchise focused on high margin branded products to treat conditions in urology and men's health, orthopedics and endocrinology
- Xiaflex® 22% Q3 revenue growth. Strong market penetration, with room for growth in both Peyronie's Disease and Dupuytren's Contracture
- Positioned to enter medical aesthetics with the first non-invasive injectable treatment for cellulite
- Strong commercial, marketing and distribution capabilities that will be leveraged for expansion into medical aesthetics
- U.S. Branded Specialty & Established revenue of \$234M (Q3'17) and \$220M (Q3'18), reduction driven by 2017 voluntary withdrawal of OPANA® ER

Specialty Branded Revenue (\$M)



U.S. Branded Sterile Injectable 2018 YTD Revenue Growth of >20%



U.S. Branded
Specialty &
Established



U.S. Branded
Sterile
Injectables

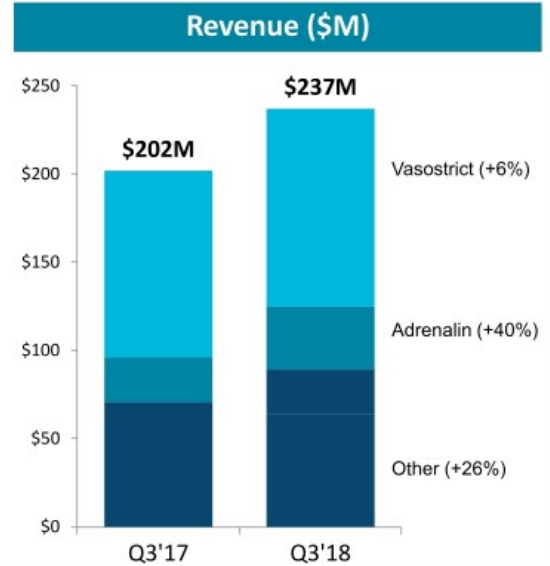


U.S.
Generics



International

- Trusted manufacturer & distributor of Sterile Injectable products to hospital/critical care setting
- Currently offer 32 products, anchored by Vasostrict®
- Plan to expand sterile footprint & capabilities through planned Q1 2019 acquisition of Somerset and the Nevakar licensing agreement
- Positioned to expand 505(b) (2) products and to grow through expanding Ready-to-Use (RTU) and other higher-value products in hospital setting



U.S Generics: Proven Expertise in First-to-File & First-to-Market Applications



U.S. Branded Specialty & Established



U.S. Branded Sterile Injectables



U.S. Generics



International

- Focused on technically challenging, high barrier generic products across multiple therapeutic areas
- Product rationalization and operational efficiencies have improved product profitability
- ~90 ANDA's filed w/ FDA; ~1/3 are FTF/FTM
- Expect 2019 to be transitional year as delayed competition is realized with key Par product launches expected in late '19

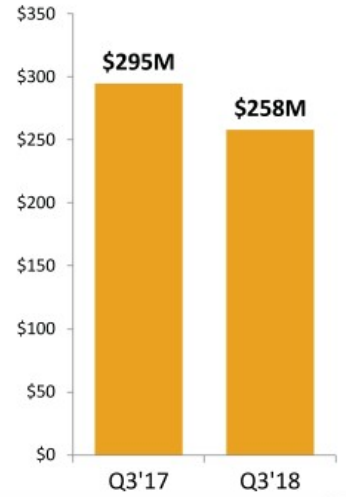
U.S. IQVIA Generics Sales (\$ in Billions)



Source: IQVIA NSP Sales Data as of 9/30/18

(a) Par excludes Branded generic products (e.g., Vasostriol) included in our U.S. Sterile Injectables business

Revenue (\$M)



Key Growth Drivers

- **Xiaflex for Peyronie’s Disease & Dupuytren’s Contracture:** continued investment in consumer activation strategies; 22% growth YTD ‘18, primarily demand driven
- **CCH for the treatment of cellulite:** expect BLA filing in 2H19, commercial launch in 2H20. Exploring Ex-US options
- **Somerset Acquisition:** expect Q1’19 close with significant expansion of sterile portfolio
- **Nevakar Licensing Agreement:** 5 differentiated 505(b)(2) products expected in late 2020 to provide potential new treatments in the hospital and critical care environment
- **Select FTF/FTM Generic settlements or agreements:**

Product	FY’17 IQVIA/Brand Sales	Settlement/Terms
DEXILANT® (dexlansoprazole)	~\$1,200m	Confidential terms
AFINITOR® (everolimus)	~\$800m	Confidential terms
AMITIZA® (lubiprostone)	~\$500m	Q1 2021
CIPRODEX® (ciprofloxacin; dexamethasone otic suspension)	~\$450m	2020
KUVAN® (sapropterin)	~\$400m	Q4 2020
GATTEX® (teduglutide)	~\$300m	Confidential terms
SABRIL® (vigabatrin tablets)	~\$200m	Confidential terms



Positive Results from Phase 3 RELEASE-1 AND RELEASE-2 Studies

No Cellulite Therapy Currently in Market Has Been Studied as Extensively as CCH for Cellulite

Largest Cellulite Trial Ever Conducted

845
Women Enrolled

18 and older
Moderate and Severe Cellulite

RELEASE-1 and RELEASE-2 are two identical multicenter, randomized, double-blind, placebo-controlled studies

Studies placed no limits on BMI, weight, and cellulite severity

Innovative Measurements Scale

Efficacy was assessed by both clinicians and patients using photonic cellulite severity scale developed by Endo and third-party experts and the scales were developed while consulting with the US Food and Drug Administration (FDA).

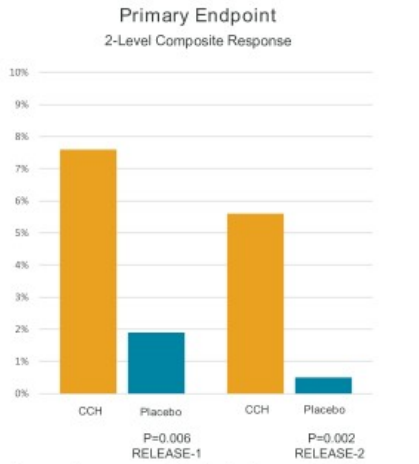
The validated Endo Cellulite Severity Scale in the Phase 3 trial was accepted by and presented at 5 prestigious, peer-reviewed congresses, including the International Society for Pharmacoeconomics and Outcomes Research

Photonic Cellulite Severity Scale (PCSS) is a 5-point scale ranging from 0 (no cellulite) to 4 (severe cellulite)

Photonic Cellulite Severity Scale (PCSS)



Phase 3: RELEASE-1 AND RELEASE-2 Studies



Assessments were measured by a two-level response in both the Clinician-Reported Photonumeric Cellulite Severity Scale (CR-PCSS) and Patient-Reported Photonumeric Cellulite Severity Scale (PR-PCSS) scores.

Key Secondary Subject Endpoints

Patient Assessment

RELEASE-1		RELEASE-2	
Subject 1-level Response Patient-Reported Photonumeric Cellulite Severity Scale in Target Buttock (PR-PCSS)			
Treatment	Placebo	Treatment	Placebo
54.3%	36.2%	57.9%	29.6%

Subject Global Aesthetic Improvement

RELEASE-1		RELEASE-2	
"Improved" or "Very Improved" or "Very Much Improved" in Target Buttock			
Treatment	Placebo	Treatment	Placebo
73.3%	43.2%	67.8%	24.1%

RELEASE-1 met 8 of 8 secondary endpoints
RELEASE-2 met 7 of 8 secondary endpoints. 1 secondary endpoint, 2-level composite response for non-target buttock, was not statistically significant (p = 0.03)

Most adverse events (AEs) were mild to moderate and primarily limited to the local injection area. The most common AEs were injection site bruising, injection site pain, injection site discoloration, injection site nodule and injection site pruritus.



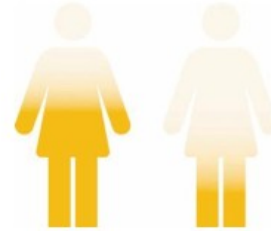
CCH for Cellulite Patients Who Saw Improvement Were Substantially Happier. Improvement Seen with 1st Injection

More Than 7 Out of 10 Subjects Saw a 1-level Improvement in PR-PCSS in a Buttock



Patients who received CCH in the trial and saw a 1-level improvement in the PR-PCSS saw a substantial increase (statistically significant against placebo, $p < 0.01$) in PR-CIS Happy scores

Improvement After First Injection



CCH for Cellulite

Placebo

Respondents in the study saw a significant separation from placebo after the 1st injection

Additional Studies in Development

Study 209 – Study focused on dosing and injection technique
Study 212 – Open-label study focused on non-obese subjects with less severe cellulite

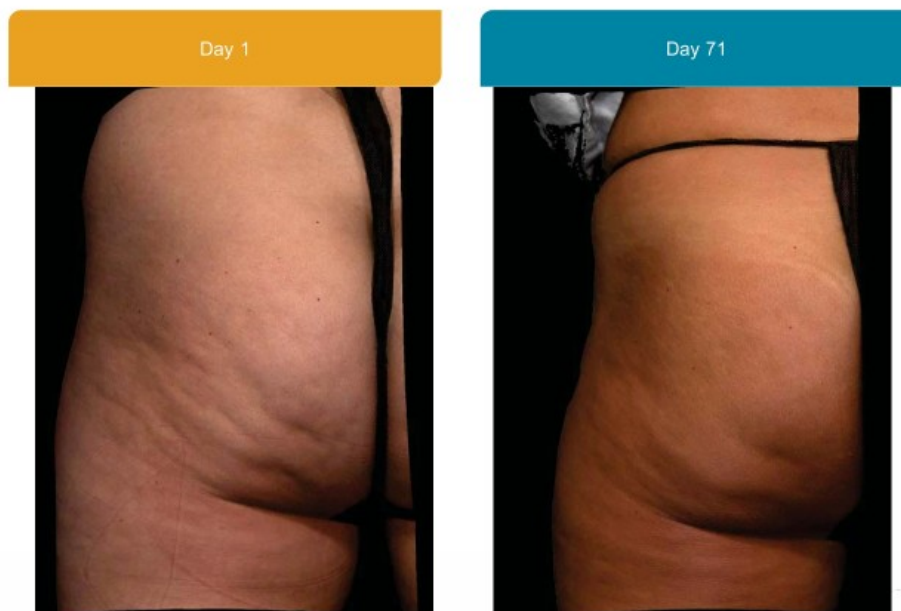
Phase 3 - 2-PT Composite Change



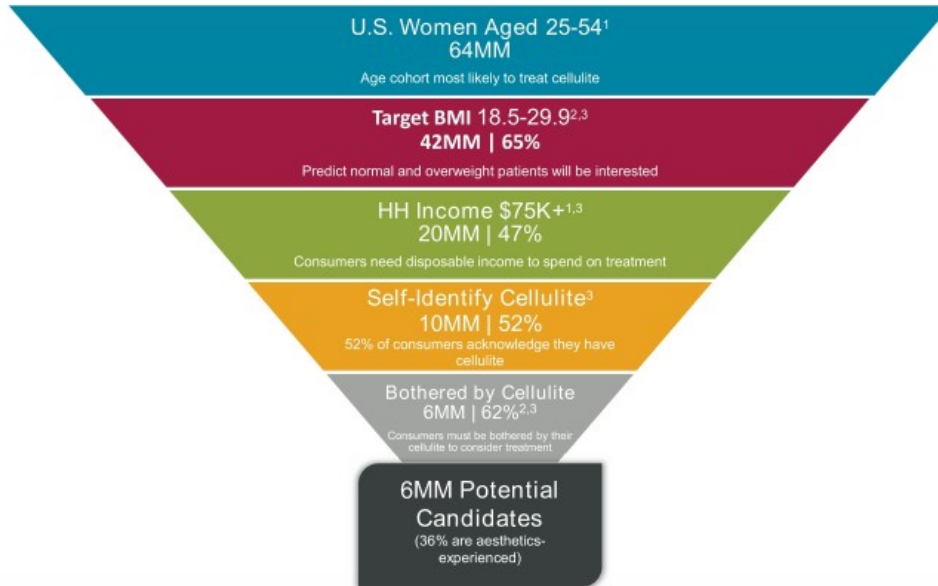
Phase 3 - 2-PT Composite Change



Phase 3 - 1-PT Composite Change



~ 6 Million U.S. Women are Potential Candidates for Cellulite Treatment



Potential market size may increase to over 11MM if the age range is increased to 21-59 as more younger women are interested in treatment

Source 1: US Census Data, Release date December 2014
Source 2 US CDC Body Mass Index Values, 2007 - 2010
Source 3 Endo Custom Quantitative Market Opportunity Consumer Market Research 2017 (Screener & Sampled Universe)
©2018 Endo Pharmaceuticals, Inc. All rights reserved 14

Successful Execution on Strategic Priorities to Date, but Journey Continues

- **Significant progress** achieved through the first phase of our multi-year turnaround plan
- **Transitioning** to the next phase of our plan with a focus on **continuing to build** our portfolio and capabilities for the future
- **Continued strong liquidity profile** and disciplined capital allocation approach; committed to de-leveraging overtime



