# 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): April 16, 2014 (April 14, 2014)

## **ENDO INTERNATIONAL PLC**

(Exact Name of Registrant as Specified in Its Charter)

Ireland
(State or other jurisdiction of incorporation)

001-36326 (Commission File Number) Not Applicable (I.R.S. Employer Identification No.)

Glandore Business Centres
No. 33 Fitzwilliam Square
Dublin 2, Ireland
(011)-353-1-669-6634
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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))

#### Item 8.01. Other Events.

As previously reported in Endo Health Solutions Inc.'s Form 10-K filed with the SEC on March 3, 2014, in February 2014, the United States Food and Drug Administration (the "FDA") conducted an inspection of the Minnetonka, Minnesota facility of American Medical Systems, Inc. ("AMS"), a subsidiary of Endo International plc. Following such inspection, the FDA issued three observations on a Form 483 Notice of Inspectional Observations dated February 24, 2014 (the "Form 483 Notice"). These observations, previously self-identified by AMS, were being addressed through a corrective action plan which AMS originally expected to complete beyond 2015.

AMS provided the FDA an accelerated action plan to address its internal findings in a letter dated February 24, 2014. Subsequently, in a Form 483 response letter dated March 10, 2014, AMS provided the FDA with a comprehensive response to the Form 483 Notice to further expand on the action plan, explain the corrective actions being undertaken by AMS and reaffirm its commitment to achieving full sustainable compliance with applicable laws and regulations. On March 20, 2014 AMS management met with the FDA, expanded further on the action plan and agreed on the approach.

On April 14, 2014, AMS received a Warning Letter from the FDA, dated April 10, 2014. The Warning Letter relates to the same matters as identified in the Form 483 Notice. Specifically, the Warning Letter discusses observations related to process validation, risk analysis and corrective and preventive action procedures.

The letter states that the corrective actions which AMS reviewed with the FDA on March 20, 2014 appear to be adequate, but it goes on to state that many of the actions have not yet been completed and will need to be validated in a follow-up inspection. AMS has 15 days to respond to the Warning Letter.

AMS is currently drafting a response to the April 10, 2014 Warning Letter, in addition to continuing to implement its corrective action plan as agreed with the FDA. AMS is committed and expects to continue to make significant progress during the remainder of 2014, with completion of the proposed corrective actions expected to occur by the end of 2015.

AMS expects only limited related impact to its business at this time. The Minnetonka, Minnesota facility will continue to manufacture and ship products while AMS works with the FDA.

However, failure to promptly correct the violations addressed in the April 10, 2014 Warning Letter or to comply with the U.S. medical device regulatory requirements in general could result in, among other things, fines, injunctions, consent decrees, civil money penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket approvals, withdrawals or suspensions of current product applications and criminal prosecution.

### **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.

ENDO INTERNATIONAL PLC (Registrant)

By: /s/ CAROLINE B. MANOGUE

Name: Caroline B. Manogue

Title: Executive Vice President, Chief Legal Officer &

Secretary

Dated: April 16, 2014