ENDO HEALTH SOLUTIONS INC.
Form 8-K
February 19, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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FORM 8-K

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CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of Earliest Event Reported): February 19, 2014 (February 14, 2014)

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ENDO HEALTH SOLUTIONS INC.
(Exact Name of Registrant as Specified in Its Charter)

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Delaware	001-15989	13-4022871
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
1400 Atwater Drive, Malvern, PA	19355	
(Address of principal executive offices)	(Zip Code)	

Registrant's telephone number, including area code (484) 216-0000
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:
o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.06. Material Impairments.

On February 14, 2014, the Company completed its annual goodwill and in-process research and development (IPR&D) impairment analysis for 2013 as required by ASC350 "Intangibles - Goodwill and Other". As a result of the analysis, and upon the authorization from the Audit Committee of the Board of Directors, the Registrant expects to record during the fourth quarter of 2013, a pre-tax, non-cash impairment charge of approximately $495 million, representing the impairment of goodwill and certain IPR&D assets associated with our American Medical Systems, Inc. (AMS) reporting unit.

The impairment charge is the result of lower projected operating results and changes in the discount rate at AMS when compared to the assumptions used at the time of and subsequent to the acquisition. The lower projected operating results reflect changes in the assumptions related to revenue growth, market trends, business mix, cost structure including litigation expenses and other expectations about the anticipated short-term and long-term operating results of the AMS reporting unit identified as part of our fourth quarter 2013 strategic planning and budgeting processes.

Item 8.01. Other Events

We and certain of our subsidiaries are involved in various claims, legal proceedings and governmental investigations that arise from time to time in the ordinary course of our business, including relating to product liability, intellectual property, regulatory compliance and commercial matters. While we cannot predict the outcome of these ongoing legal proceedings and we and our subsidiaries intend to defend vigorously our and their position, an adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position, results of operations and cash flows.

In view of the inherent difficulty of predicting the outcome of these various claims, legal proceedings and governmental investigations, particularly where there are many claimants, each with their own unique circumstances that give rise to their alleged claims, and the claimants seek indeterminate damages and particularly given the various stages of our proceedings, unless specified otherwise below, we and our subsidiaries are unable to predict the outcome of these matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss. Accordingly, there are claims, legal proceedings and governmental investigations in which we and certain of our subsidiaries are involved where a loss is reasonably possible in future periods and for which we have not accrued a related liability. In addition, it is reasonably possible that a future loss could exceed the related accrued liability and could have a material adverse effect on our current and future financial position, results of operations and cash flows.

Product Liability

We and certain of our subsidiaries have been named as defendants in numerous lawsuits in various federal and state courts, as well as in Canada, alleging personal injury resulting from the use of certain of our products and the products of our subsidiaries.

The Company believes that certain settlements and judgments, as well as legal defense costs, relating to product liability matters are or may be covered in whole or in part under its product liability insurance policies with a limited number of insurance carriers. In certain circumstances, insurance carriers reserve their rights with respect to coverage, or contest or deny coverage. The Company and its subsidiaries intend to contest vigorously all such disputes with respect to their insurance coverage and to enforce their rights under the terms of these insurance policies, and accordingly, the Company will record receivables with respect to amounts due under these policies, only when the resolution of any dispute has been reached and realization of the potential claim for recovery is considered probable. Amounts recovered under the Company's product liability insurance policies may be less than the stated coverage

limits and may not be adequate to cover damages and/or costs relating to claims. In addition, there is no guarantee that insurers will pay claims or that coverage will otherwise be available.

Vaginal Mesh Cases. On October 20, 2008, the FDA issued a Public Health Notification regarding potential complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The notification provides recommendations and encourages physicians to seek specialized training in mesh procedures, to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

In July 2011, the FDA issued an update to the October 2008 Public Health Notification regarding mesh to further advise the public and the medical community of the potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI. In this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair. The

July 2011 notification continued to encourage physicians to seek specialized training in mesh procedures, to consider and to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications. The FDA also convened an advisory panel which met on September 8-9, 2011 to further address the safety and effectiveness of transvaginal surgical mesh used to treat POP and SUI. At the conclusion of the meetings, the advisory panel recommended reclassifying transvaginal mesh products used to treat POP to Class III devices (premarket approval) and recommended that manufacturers of these products be required to conduct additional post-market surveillance studies. The advisory panel recommended that transvaginal surgical mesh products used to treat SUI remain as Class II devices. Regarding retropubic and transobturator (TOT) slings, the advisory panel recommended that no additional post-market surveillance studies are necessary. Regarding mini-slings, the advisory panel recommended premarket studies for new devices and additional post-market surveillance studies.

On January 3, 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for POP and of single incision mini-slings for urinary incontinence, such as our subsidiary AMS, to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. AMS received a total of nineteen class-wide post-market study orders regarding its pelvic floor repair and mini-sling products; however, the FDA agreed to place sixteen of these study orders on hold for a variety of reasons. Three of these post-market study orders remain active and AMS is continuing the process of complying with these orders. In these orders, the FDA also noted that it is still considering the recommendation of the September 9, 2011 advisory committee that urogynecological surgical mesh for transvaginal repair of POP be reclassified from Class II to Class III.

Since 2008, AMS, and more recently, in certain cases the Company or certain of its subsidiaries, have been named as defendants in multiple lawsuits in various federal and state courts, as well as in Canada, alleging personal injury resulting from the use of transvaginal surgical mesh products designed to treat POP and SUI. Plaintiffs in these suits allege various personal injuries including chronic pain, incontinence and inability to control bowel function and permanent deformities. On February 7, 2012, a multidistrict litigation (MDL) was formed, and cases pending in federal courts are now consolidated in the Southern District of West Virginia as part of MDL No. 2325. Similar cases in various state courts around the country are also currently pending. As of February 14, 2014, approximately 22,000 filed mesh cases are currently pending against AMS and/or the Company or certain of its subsidiaries, some of which may have been filed on behalf of multiples plaintiffs. In addition, other cases have been served upon AMS pursuant to a tolling agreement order issued in the MDL in May 2013. Any complaint properly served on AMS from the effective date of that order on May 15, 2013 through October 1, 2013, and ultimately filed with the court at a later date, may be deemed filed as of the service date. Some of these cases served pursuant to the tolling agreement have been filed with the court, and we expect that there will be a number of additional complaints filed with the court at a later date pursuant to the tolling agreement order. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. The majority of the currently pending cases are in the MDL. The Company cannot predict the ultimate number of cases to be filed against it with certainty, and we expect that more cases may be filed in subsequent periods.

On June 14, 2013, AMS, and certain plaintiffs' counsel representing mesh-related product liability claimants entered into a definitive Master Settlement Agreement (the MSA) regarding a set inventory of filed and unfiled mesh cases handled or controlled by the participating counsel. The MSA was entered into solely by way of compromise and settlement and is not in any way an admission of liability or fault by the Company or AMS, Under the terms of the MSA, AMS paid $54.5 million in July 2013 into a settlement fund held in escrow by a mutually agreed upon escrow agent. The MSA establishes a claims administration process that includes guidelines and procedures for administering the settlement. Distribution of funds to any individual is conditioned upon a full release and a dismissal with prejudice of the entire action or claim as to all AMS parties and affiliates. Prior to receiving an award, an individual claimant shall represent and warrant that liens, assignment rights, or other claims that are identified in the claims administration process have been or will be satisfied by the individual claimant. The amount of settlement awards to participating claimants, the claims evaluation process and procedures used in conjunction with award distributions, and the

negotiations leading to the settlement shall be kept confidential by all parties and their counsel. The Company has agreed with plaintiffs' counsel involved in this settlement that a sufficient number of releases have been submitted to permit the parties to proceed with a distribution of certain funds from the escrow. Accordingly, approximately $43 million was released from the escrow fund during the fourth quarter of 2013.

During the fourth quarter of 2013, the Company recorded an incremental pre-tax charge in the amount of approximately $316 million increasing the Company's product liability accrual to approximately $520 million as of December 31, 2013. The liability is for all known pending and estimated future claims primarily related to vaginal mesh cases, which the Company believes represents the minimum anticipated loss AMS will sustain with respect to these cases, which amount includes potential liabilities and/or possible settlements. The increase in our reserve reflects management's ongoing assessment of our product liability portfolio, including the vaginal mesh cases, the status of the company's ongoing settlement discussions related to vaginal mesh litigation and the inherent uncertainty as to the ultimate costs of resolving this litigation.

AMS and the Company intend to contest vigorously all currently pending cases and any future cases that may be brought, if any, and to explore other options as appropriate in the best interests of the Company and AMS. However, it is not possible at this time to determine with certainty the ultimate outcome of these matters or the effect of potential future claims. We will continue to monitor each related legal claim and adjust the accrual for new information and further developments. Nevertheless, we believe it is possible that the outcomes of such cases could result in losses in excess of insurance reimbursement levels that could have a material adverse effect on our business, financial condition, results of operations and cash flows. As of December 31, 2013, no insurance recoveries for these matters have been recorded.

Although the Company believes there is a reasonable possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. In most product liability litigations of this nature, plaintiffs allege a wide variety of claims, ranging from allegations of serious injury caused by the products to efforts to obtain compensation notwithstanding the absence of any significant injury. Given the wide range of alleged injuries and the early stage of this litigation, as evidenced in part by the fact that AMS has not yet received or had the opportunity to review complete information regarding all plaintiffs and their medical conditions, the Company and AMS are unable to fully evaluate the claims at this time.

In addition, we have been contacted regarding a civil investigation that has been initiated by a number of state attorneys general into mesh products, including transvaginal surgical mesh products designed to treat POP and SUI. In November, 2013, we received a subpoena relating to this investigation from the state of California, and have subsequently received additional subpoenas from other states. We are cooperating fully with this investigation. At this time, we cannot predict or determine the outcome of this investigation or reasonably estimate the amount or range of amounts of fines or penalties, if any, that might result from a settlement or an adverse outcome from this investigation.

A copy of the press release announcing the goodwill and IPR&D impairment charge and increase to our product liability reserve is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of the Registrant, dated February 19, 2014

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 HEALTH SOLUTIONS INC.
(Registrant)

By:	/s/ CAROLINE B. MANOGUE
Name:	Caroline B. Manogue
Title:	Executive Vice President, Chief Legal Officer & Secretary

Dated: February 19, 2014

INDEX TO EXHIBITS

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