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 11, 2017

ENDO INTERNATIONAL PLC
(Exact Name of Registrant as Specified in 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))

Item 7.01. Regulation FD Disclosure.

In connection with a proposed private financing transaction, we anticipate disclosing to prospective investors certain information. This information is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

This report is neither an offer to purchase nor a solicitation of an offer to sell any securities.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Certain information with respect to Endo.

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.

Dated: April 11, 2017

ENDO INTERNATIONAL PLC

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

Index of Exhibits

Exhibit Number	Description
99.1	Certain information with respect to Endo.

Exhibit 99.1

NON-GAAP FINANCIAL MEASURES

Adjusted earnings before interest, taxes, depreciation and amortization ("EBITDA") and Covenant Adjusted EBITDA are supplemental measures of performance and liquidity, respectively, that are not required by or determined in accordance with accounting principles generally accepted in the United States ("GAAP"). Endo International plc ("Endo International," "we," "our," "us" or similar terms) utilizes these financial measures, commonly referred to as "non-GAAP financial measures," because (i) they are used by us, along with financial measures in accordance with GAAP, to evaluate our operating performance and liquidity, (ii) we believe that they will be used by certain investors to measure our operating results and liquidity and (iii) our leverage and interest coverage ratios as defined by the Credit Facilities (as defined herein) and the indenture governing our notes are calculated based on these non-GAAP financial measures, or others that are derived from these non-GAAP financial measures. We believe that presenting these non-GAAP financial measures provides useful information about our performance across reporting periods on a consistent basis by excluding items, which may be favorable or unfavorable.

The initial identification and review of the non-GAAP adjustments necessary to arrive at these non-GAAP financial measures is performed by a team of finance professionals that include our Chief Accounting Officer and segment finance leaders, and are identified in accordance with our Adjusted Income Statement Policy, which is reviewed and approved by our audit committee. Proposed adjustments, along with any items considered but excluded, are presented to our Chief Accounting Officer, Chief Executive Officer and/or the Chief Financial Officer for their consideration. In turn, the non-GAAP adjustments are presented to the Audit Committee on a quarterly basis as part of our standard procedures for preparation and reviewing earnings releases and other quarterly materials.

There are limitations to using non-GAAP financial measures such as the measures described above. Other companies in our industry may define these measures differently than we do. As a result, it may be difficult to use these or similarly named adjusted financial measures that other companies may use to compare the performance of those companies to our performance. Because of these limitations, these non-GAAP financial measures should not be considered in isolation as measures of our liquidity, the income generated by our business, discretionary cash available to us to invest in the growth of our business or reduce indebtedness, or as substitutes for analysis of results as reported under GAAP. We compensate for these limitations by providing reconciliations of these non-GAAP financial measures to the most directly comparable GAAP measures. See the footnotes included in "Summary—Summary Consolidated Financial Data of Endo International" below for the definitions of such non-GAAP financial measures and reconciliations to the most directly comparable GAAP measures. We rely primarily on our GAAP results and are using such non-GAAP financial measures only supplementally.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Statements herein contain information that includes or is based on "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements, including estimates of future revenues, future expenses and future net income, contained in this current report and the information incorporated by reference herein are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. We have tried, whenever possible, to identify such statements by words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "projected," "forecast," "will," "may" or similar expressions. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Many factors, as more fully described under the caption "Risk Factors" contained in Item 1A of Endo International's Annual Report on Form 10-K for the year ended December 31, 2016 (the "Endo International 2016 Form 10-K"), could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained or incorporated by reference herein.

We do not undertake any obligation to update our forward-looking statements after the date of this current report for any reason, even if new information becomes available or other events occur in the future, except as required under applicable securities law. You are advised to consult any further disclosures we make on related subjects in our reports filed with the SEC and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR"). Also note that, as described under the caption "Risk Factors" contained in Item 1A of the Endo International 2016 Form 10-K, we provide a cautionary discussion of the risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by Section 27A of the Securities Act and Section 21E of the Exchange Act. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this to be a complete discussion of all potential risks or uncertainties.

SUMMARY

Unless otherwise indicated or the context otherwise requires, all references herein to (a) "Endo," "the Company," "we," "our," "us" or similar terms mean EHSI prior to February 28, 2014 and Endo International and its subsidiaries thereafter, (b) "Endo DAC" means Endo Designated Activity Company and its subsidiaries (including the Endo Finance Issuers), (c) "EHSI" means Endo Health Solutions Inc. and its subsidiaries and (d) "$" and "Dollars" mean U.S. Dollars. Endo International, the direct parent of Endo DAC, does not conduct any operations other than in support of its ownership of Endo DAC and payment of related corporate costs.

Recent Developments

FDA Advisory Committees' Vote Related to OPANA® ER

On March 14, 2017, we announced that the U.S. Food and Drug Administration's Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees (the "Committees") voted that the benefits of reformulated OPANA® ER (oxymorphone hydrochloride extended release) no longer outweigh its risks. OPANA® ER is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. While several of the Committee members acknowledged the role of OPANA® ER in clinical practice, others believed its benefits are now outweighed by the continuing public health concerns around the product's misuse, abuse and diversion. During the Committee discussion following the vote, a number of Committee members recommended that OPANA® ER remain on the market with additional regulatory restrictions to mitigate the risks.

The FDA convened these Committees to discuss pre- and post-marketing data about the abuse of OPANA® ER, the product's overall risk-benefit profile, as well as the abuse of generic oxymorphone ER and oxymorphone immediate-release ("IR") products. While the FDA will consider the Committees' vote, any decision regarding whether to take regulatory action rests solely with the FDA. We believe that OPANA® ER remains an important clinical choice for appropriate patients and will evaluate the range of available options for maintaining access for legitimate use.

New Credit Agreement

Endo International intends to enter into a new credit agreement (the "New Credit Agreement"), as guarantor, with Endo Designated Activity Company, a company duly incorporated under the laws of Ireland, Endo Luxembourg Finance Company I S.à r.l., a private limited liability company (*société à responsabilité limitée*) duly incorporated under the laws of the Grand Duchy of Luxembourg, with registered office at 2a, rue Nicolas Bové, L-1253 Luxembourg, Grand Duchy of Luxembourg and registered with the Luxembourg register of commerce and companies (*R.C.S. Luxembourg*) under number B 182645, and Endo LLC, a Delaware limited liability company, as borrowers, the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent, issuing bank and swingline lender, providing for (i) a revolving credit facility in a principal amount of approximately $1,000 million (the "New Revolving Credit Facility") and (ii) a term loan facility in a principal amount of approximately $2,965 million (the "New Term Loan Facility" and together with the New Revolving Credit Facility, the "New Credit Facilities"). The obligations under the New Credit Agreement are expected to be guaranteed by Endo International and its material subsidiaries and certain other subsidiaries from time to time (with certain exceptions) and secured by a lien on substantially all the assets (with certain exceptions) of the borrowers and the guarantors. We intend to use the net proceeds under the New Term Loan Facility, together with the net proceeds of an offering of notes and cash on hand, to repay all of our outstanding loans under our existing 2014 Term Loan A Facility (as defined herein) and all other obligations outstanding under our Existing

Credit Agreement and to pay related fees and expenses. We intend to use the proceeds of the New Revolving Credit Facility from time to time for general corporate purposes. There can be no assurance that we will enter into the New Credit Agreement on terms acceptable to us, or at all. We use the term "Credit Facilities" to refer to (i) the Existing Credit Facilities prior to effectiveness of the New Credit Agreement and (ii) the New Credit Facilities thereafter.

Summary Consolidated Financial Data of Endo International

(in thousands)	For the Year Ended December 31 2014	2015	2016
Adjusted EBITDA(1)	$ 989,095	$ 1,449,428	$ 1,669,428
Covenant Adjusted EBITDA(1)			1,747,004

(1) Adjusted EBITDA and Covenant Adjusted EBITDA are non-GAAP financial measures. We define adjusted EBITDA as net (loss) income, prepared in accordance with GAAP, before interest expense, net; income tax; depreciation and amortization; and further adjusted by excluding:

- inventory step-up amortization recorded as part of our acquisitions;
- other (income) expense, net;
- share-based compensation;
- certain upfront and milestone payments to partners;
- acquisition-related and integration items, including transaction costs, earn-out payments or adjustments, changes in the fair value of contingent consideration and bridge financing costs;
- cost reduction and integration-related initiatives such as separation benefits, retention payments, excess inventory reserves, other exit costs and certain costs associated with integrating an acquired company's operations;
- excess costs that will be eliminated pursuant to integration plans;
- asset impairment charges;
- litigation-related and other contingent matters;
- gains or losses from early termination of debt;
- discontinued operations, net of tax; and
- certain other items.

Covenant Adjusted EBITDA further adjusts adjusted EBITDA for the items described in the definition of "Consolidated Adjusted EBITDA" in the Credit Facilities including the following:

- including adjusted EBITDA from previous acquisitions as if they occurred at the beginning of the period, a component of which is the anticipated cost savings and synergies related to these acquisitions expected to be achieved on a run-rate basis within twelve months of each respective acquisition;
- excluding the impact of Litha Healthcare Group Limited ("Litha") and its subsidiaries, given that they are unrestricted subsidiaries under the indenture governing the notes; and
- including the amount of "run-rate" cost savings, synergies and operating expense reductions related to restructurings, cost savings initiatives or other initiatives from actions that are either taken or expected to be taken within 24 months, calculated as if the savings had been realized at the beginning of the period; provided that any such pro form adjustments in respect of our cost savings, synergies and operating expense reductions shall not exceed 15% of Consolidated EBITDA (prior to giving effect to such pro forma adjustments) for the period of four (4) consecutive fiscal quarters ending as of the last day of the most recent fiscal quarter for which internal financial statements are available.

We believe that adjusted EBITDA and Covenant Adjusted EBITDA are useful tools for investors and other users of our financial statements in assessing our ability to service and/or incur indebtedness, maintain current operating levels of capital assets and acquire additional operations and businesses. In addition, we

will use Covenant Adjusted EBITDA or substantially similar measures in calculating our financial ratios under our debt agreements. We believe that the most directly comparable GAAP measure to adjusted EBITDA is net loss attributable to Endo International and the most directly comparable GAAP measure to Covenant Adjusted EBITDA is net cash provided by operating activities.

Adjusted EBITDA and Covenant Adjusted EBITDA have limitations as analytical tools, and you should not consider these measures in isolation from, or as a substitute for analysis of, our financial information reported under GAAP. Some of the limitations of adjusted EBITDA and Covenant Adjusted EBITDA are:

- they do not reflect cash outlays for capital expenditures or future contractual commitments;
- they do not reflect changes in, or cash requirements for, working capital;
- they do not reflect interest expense, or the cash requirements necessary to service interest, or principal payments, on indebtedness;
- they do not reflect income tax expense, the cash necessary to pay income taxes or income tax refunds received;
- although depreciation and amortization are non-cash charges, the assets being depreciated and amortized will often have to be replaced in the future, and adjusted EBITDA and Covenant Adjusted EBITDA do not reflect cash requirements for such replacements; and
- other companies, including other companies in our industry, may not use adjusted EBITDA and Covenant Adjusted EBITDA or may calculate adjusted EBITDA and Covenant Adjusted EBITDA differently than we do, limiting their usefulness as comparative measures.

Adjusted EBITDA and Covenant Adjusted EBITDA are not measures of financial condition or profitability under GAAP and should not be considered as alternatives to cash flow from operating activities, as measures of liquidity, as alternatives to net (loss) income attributable to Endo International or operating (loss) income from continuing operations or as an indicator of operating performance.

The reconciliation between adjusted EBITDA and net loss attributable to Endo International is as follows for the periods indicated:

(in thousands)	Year Ended December 31 2014	2015	2016
Net loss attributable to Endo International	$ (721,319)	$ (1,495,042)	$ (3,347,066)
Income tax expense (benefit)[a]	38,267	(1,137,465)	(700,084)
Interest expense, net[a]	227,114	373,214	452,679
Depreciation and amortization, excluding portions classified as acquisition-related and integration items or Separation benefits and other cost reduction initiatives[a]	261,376	621,200	955,802
Acquisition-related and integration items[a][b]	77,384	105,250	87,601
Inventory step-up[a][c]	65,582	249,464	125,699
Loss on extinguishment of debt[a]	31,817	67,484	—
Other (income) expense, net[a]	(32,324)	63,691	(338)
Share-based compensation[a]	26,839	84,557	58,655
Asset impairment charges[a]	22,542	1,140,709	3,781,165
Certain litigation-related charges, net[a][d]	42,084	37,082	23,950
Upfront and milestone payments to partners[a][e]	51,774	16,155	8,330
Separation benefits and other cost reduction initiatives[a][f]	25,760	125,407	107,491
Other charges[a][g]	34,972	3,079	—
Other gains[a][h]	—	—	(7,750)
Discontinued operations, net of tax[i]	779,792	1,194,926	123,278
Net income attributable to non-controlling interests[j]	3,135	(283)	16
Excise tax adjustment[a][k]	54,300	—	—
Adjusted EBITDA	$ 989,095	$ 1,449,428	$ 1,669,428

(a) Adjusted EBITDA is calculated excluding net amounts related to discontinued operations. These reconciling adjustments represent amounts attributable to continuing operations. Discontinued operations, net of tax is reflected as a single line in the table above.

(b) Primarily consists of costs directly associated with previous acquisitions, including depreciation of $13,147,000 in 2016, and changes in the fair value of contingent consideration.

(c) Represents aggregate charges resulting from recording acquired inventory at its estimated fair value in connection with our various acquisitions and from certain manufacturing costs that will be eliminated pursuant to integration plans.

(d) Includes charges for litigation-related and other contingencies, which are further described in the Endo International 2016 Form 10-K.

(e) Represents actual payments made by us with respect to the development and commercialization of certain assets we acquired.

(f) Represents certain costs and separation benefits incurred in connection with continued efforts to enhance our cost structure and operations. Included in these amounts are separation costs, charges to write off inventory and excess inventory reserves, depreciation of $14,360,000 in 2016 and other restructuring and related costs.

(g) Represents charges related to non-recovery of certain non-trade receivables and for an additional year of the branded prescription drug fee in accordance with Internal Revenue Service ("IRS") regulations issued in the third quarter of 2014.

(h) Represents a gain related to the impact of Voltaren® Gel generic competition.

(i) Includes amounts related to our American Medical Systems, Inc. and HealthTronics, Inc. ("HealthTronics") businesses, which are classified as discontinued operations.

(j) Represents the portion of net income or loss attributable to non-controlling interests from consolidated entities in which Endo International's ownership interest is less than 100%.

(k) Adjustment for excise taxes related to the reimbursement of directors' and certain employees' tax liabilities pursuant to Section 4985 of the Internal Revenue Code, substantially all of which was advanced in December, 2014.

The reconciliation between Covenant Adjusted EBITDA and net cash provided by operating activities is as follows for the periods indicated:

(in thousands)	Year Ended December 31, 2016
Net cash provided by operating activities	$ 524,439
Changes in assets and liabilities which used cash	529,168
Other adjustments to reconcile net cash provided by operating activities and Net loss attributable to Endo International:	
Depreciation and amortization	(983,309)
Inventory step-up	(108,768)
Share-based compensation, excluding amounts settled in cash	(59,769)
Amortization of debt issuance costs and discount	(28,514)
Provision for bad debts	(6,885)
Provision for inventory reserve	(129,245)
Deferred income taxes	745,341
Net loss on disposal of property, plant and equipment	(7,302)
Change in fair value of contingent consideration	(23,823)
Asset impairment charges, including amounts classified as Other (income) expense, net	(3,802,493)
Gain on sale of business and other assets	4,110
Net income attributable to non-controlling interests(j)	(16)
Net loss attributable to Endo International	(3,347,066)
Income tax benefit(a)	(700,084)
Interest expense, net(a)	452,679
Depreciation and amortization, excluding portions classified as Acquisition-related and integration items or Separation benefits and other cost reduction initiatives(a)	955,802
Acquisition-related and integration items(a)(b)	87,601
Inventory step-up(a)(c)	125,699
Other income, net(a)	(338)
Share-based compensation(a)	58,655
Asset impairment charges(a)	3,781,165
Certain litigation-related charges, net(a)(d)	23,950
Upfront and milestone payments to partners(a)(e)	8,330
Separation benefits and other cost reduction initiatives(a)(f)	107,491
Other gains(a)(h)	(7,750)
Discontinued operations, net of tax(i)	123,278
Net income attributable to non-controlling interests(j)	16
Adjusted EBITDA	1,669,428
Run-rate cost saving and operating expenses reductions(1)	96,000
Unrestricted subsidiaries adjustments to adjusted EBITDA(m)	(18,424)
Covenant Adjusted EBITDA	$ 1,747,004

(a)-(k) Refer to footnote explanations above under the reconciliation of adjusted EBITDA and net loss attributable to Endo International.

(l) Adjustment to include run-rate synergies for 2016 generic pharmaceuticals restructuring net of benefits received in 2016 and run-rate synergies anticipated as a result of the January 2017 corporate and branded pharmaceuticals R&D restructuring program.

(m) Adjustment for removal of adjusted EBITDA of Litha and its subsidiaries, given that they are unrestricted subsidiaries under our indentures.

LEGAL PROCEEDINGS AND INVESTIGATIONS

The following information updates the information contained in Item 3 — Legal Proceedings of the Endo International 2016 Form 10-K and should be read in conjunction therewith.

We and certain of our subsidiaries are involved in various claims, legal proceedings, internal and governmental investigations (collectively, proceedings) that arise from time to time in the ordinary course of our business, including, among others, those relating to product liability, intellectual property, regulatory compliance and commercial matters. While we cannot predict the outcome of these proceedings and we intend to defend vigorously our 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. Matters that are not being disclosed herein are, in the opinion of our management, immaterial both individually and in the aggregate with respect to our financial position, results of operations and cash flows. If and when such matters, in the opinion of our management, become material either individually or in the aggregate, we will disclose such matters.

As of December 31, 2016, our reserve for loss contingencies totaled $1,015.9 million, of which $963.1 million relates to our product liability accrual for vaginal mesh cases. Although we believe 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.

Product Liability

We and certain of our subsidiaries have been named as defendants in numerous lawsuits in various U.S. federal and state courts, as well as in Canada and other countries, alleging personal injury resulting from the use of certain products of our subsidiaries. These matters are described below in more detail.

We believe that certain settlements and judgments, as well as legal defense costs, relating to certain product liability matters are or may be covered in whole or in part under our product liability insurance policies with a number of insurance carriers. In certain circumstances, insurance carriers reserve their rights to contest or deny coverage. We intend to contest vigorously any and all such disputes with our insurance carriers and to enforce our rights under the terms of our insurance policies. Accordingly, we 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 our product liability insurance policies will likely 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. In October 2008, the FDA issued a Public Health Notification (October 2008 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 provided recommendations and encouraged 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 the July 2011 update, the FDA stated that adverse events are not rare. Furthermore, the FDA 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. In January 2016, the FDA issued a statement reclassifying surgical mesh for transvaginal POP repair from Class II to Class III. Surgical mesh for SUI repair remains a Class II device.

In January 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 American Medical Systems Holdings, Inc. ("AMS"), to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. The FDA agreed to place 16 AMS study orders on hold for a variety of reasons. AMS commenced three of these post-market study orders. However, due to the wind-down of the Astora business in 2016, AMS notified the FDA of its termination of these studies and the FDA has confirmed closure of those studies.

Since 2008, we and certain of our subsidiaries, including AMS and/or Astora, have been named as defendants in multiple lawsuits in the U.S. in various state and federal courts, including a multidistrict litigation (MDL) in the U.S. District Court for the Southern District of West Virginia (MDL No. 2325), in Canada, where various class action and individual complaints are pending, and in other countries 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, and seek compensatory and punitive damages, where available.

We and certain plaintiffs' counsel representing mesh-related product liability claimants have entered into various Master Settlement Agreements ("MSAs") and other settlement agreements regarding settling up to approximately 49,000 filed and unfiled mesh claims handled or controlled by the participating counsel for an aggregate total of approximately $2.8 billion. These MSAs, which were executed at various times since June 2013, were entered into solely by way of compromise and settlement and are not in any way an admission of liability or fault by us or any of our subsidiaries. All MSAs are subject to a process that includes guidelines and procedures for administering the settlements and the release of funds. In certain cases, the MSAs provide for the creation of QSFs into which funds may be deposited pursuant to certain schedules set forth in those agreements. All MSAs have participation thresholds regarding the claims represented by each law firm party to the MSA. If certain participation thresholds are not met, then we will have the right to terminate the settlement with that law firm. In addition, one agreement gives us a unilateral right of approval regarding which claims may be eligible to participate under that settlement. To the extent fewer claims than are authorized under an agreement participate, the total settlement payment under that agreement will be reduced by an agreed-upon amount for each such non-participating claim. Funds deposited in QSFs are included in restricted cash and cash equivalents in the Consolidated Balance Sheets.

Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating the validity of the claim, a full release and a dismissal of the entire action or claim as to all AMS parties and affiliates. Prior to receiving funds, an individual claimant is required to represent and warrant that liens, assignment rights or other claims identified in the claims administration process have been or will be satisfied by the individual claimant. Confidentiality provisions apply to 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 settlements.

We expect that valid claims under the MSAs will continue to be settled. However, we intend to vigorously contest pending and future claims that are invalid, for which settlement is unable to be reached or that are in excess of the maximum claim amounts under the applicable MSAs. In addition to claims covered by MSAs, we are currently aware of approximately 10,500 claims that have been filed, asserted or that we believe are likely to be asserted. These claims have not been accrued for because we lack sufficient information to determine whether any potential loss is probable. In addition, there may be other claims asserted in the future. It is currently not possible to estimate the number or validity of any such future claims.

In order to evaluate whether a claim is probable of a loss, we must obtain and evaluate certain information pertaining to each individual claim, including but not limited to the following items: the name and social security number of the plaintiff, evidence of an AMS implant, the date of implant, the date the claim was first asserted to AMS and medical records establishing the injury alleged. Without access to and review of at least this information and the opportunity to evaluate it, we are not in a position to determine a claim's validity or whether

a loss is probable. Further, the timing and extent to which we obtain this information and our evaluation thereof, is often impacted by items outside of our control, including, without limitation, the normal cadence of the litigation process and the provision of claim information to us by plaintiff's counsel.

We will continue to monitor the situation, and, if appropriate, we will make further adjustments to our product liability accrual based on new information. We intend to continue exploring all options as appropriate in our best interests, and depending on developments, there is a possibility that we will suffer adverse decisions or verdicts of substantial amounts, or that we will enter into additional monetary settlements. Any unfavorable outcomes as a result of such litigation or settlements with respect to any asserted or unasserted claims could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Since December 31, 2016, there have been no increases in the vaginal mesh related product liability accrual. This is our preliminary view because the fiscal quarter closing procedures are not yet complete. Our actual results for the period ended March 31, 2017 may differ materially from these estimates as a result of the completion of our financial closing procedures as well as final adjustments and other developments that may arise between now and the time that our financial results for this quarterly period are finalized.

The following table presents the changes in the vaginal mesh QSFs and product liability accrual balance during the year ended December 31, 2016 (in thousands):

	Qualified Settlement Funds	Product Liability Accrual
Balance as of December 31, 2015	$ 578,970	$ 2,086,176
Additional charges	—	19,505
Cash contributions to Qualified Settlement Funds	831,131	—
Cash distributions to settle disputes from Qualified Settlement Funds	(1,134,734)	(1,134,734)
Cash distributions to settle disputes	—	(7,830)
Other	620	—
Balance as of December 31, 2016	$ 275,987	$ 963,117

The entire portion of the $963.1 million product liability accrual amount shown above is classified in the current portion of the legal settlement accrual in the December 31, 2016 Consolidated Balance Sheets. Charges related to vaginal mesh product liability for all periods presented are reported in discontinued operations, net of tax in our Consolidated Statement of Operations.

We expect to fund the payments under all current settlement agreements over the course of 2017. As the funds are disbursed out of the QSFs from time to time, the product liability accrual will be reduced accordingly with a corresponding reduction to restricted cash and cash equivalents. In addition, we may pay cash distributions to settle disputes separate from the QSFs, which will also decrease the product liability accrual and decrease cash and cash equivalents.

We were contacted in October 2012 regarding a civil investigation 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 we have subsequently received additional subpoenas from California and other states. We are currently cooperating 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.

Testosterone Cases. We and certain of our subsidiaries, including Endo Pharmaceuticals Inc. ("EPI") and Auxilium Pharmaceuticals, Inc. (subsequently converted to Auxilium Pharmaceuticals, LLC and hereinafter referred to as "Auxilium"), along with other pharmaceutical manufacturers, have been named as defendants in lawsuits alleging personal injury resulting from the use of prescription medications containing testosterone,

including Fortesta® Gel, Delatestryl®, Testim®, TESTOPEL®, Aveed® and Striant®. Plaintiffs in these suits allege various personal injuries, including pulmonary embolism, stroke and other vascular and/or cardiac injuries and seek compensatory and/or punitive damages, where available. In June 2014, multidistrict litigation ("MDL") was formed to include claims involving all testosterone replacement therapies filed against EPI, Auxilium, and other manufacturers of such products, and certain transferable cases pending in federal court were coordinated in the U.S. District Court for the Northern District of Illinois as part of MDL No. 2545. In addition, litigation has also been filed against EPI in the Court of Common Pleas for Philadelphia County and in certain other state courts. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions, and we expect cases brought in federal court to be transferred to the U.S. District Court for the Northern District of Illinois as tag-along actions to MDL No. 2545. However, we cannot predict the timing or outcome of any such litigation, or whether any such additional litigation will be brought against us. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests. As of March 31, 2017, approximately 1,250 cases are currently pending against us; some of which may have been filed on behalf of multiple plaintiffs. The first MDL trial against Auxilium involving Testim® is set to begin in November 2017, the first trial against Auxilium in the Court of Common Pleas for Philadelphia County involving Testim® is set to begin in January 2018; and the first MDL trial against EPI involving Fortesta® is set to begin in September 2018.

In November 2015, the U.S. District Court for the Northern District of Illinois entered an order granting defendants' motion to dismiss claims involving certain testosterone products that were approved pursuant to ANDAs, including TESTOPEL®. Plaintiffs filed a motion for reconsideration and clarification of this order. In March 2016, the District Court granted plaintiffs' motion in part and entered an order permitting certain claims to go forward to the extent they are based on allegations of fraudulent off-label marketing.

In November 2014, a civil class action complaint was filed in the U.S. District for the Northern District of Illinois against EPI, Auxilium, and various other manufacturers of testosterone products on behalf of a proposed class of health insurance companies and other third party payors that had paid for certain testosterone products, alleging that the marketing efforts of EPI, Auxilium, and other defendant manufacturers with respect to certain testosterone products constituted racketeering activity in violation of 18 U.S.C. §1962(c), and other civil Racketeer Influenced and Corrupt Organizations Act claims. Further, the complaint alleged that EPI, Auxilium, and other defendant manufacturers violated various state consumer protection laws through their marketing of certain testosterone products and raised other state law claims. In March 2015, defendants filed a motion to dismiss the complaint and plaintiffs responded by filing amended complaints, which defendants also moved to dismiss. In February 2016, the District Court granted in part and denied in part defendants' motion to dismiss. The District Court declined to dismiss plaintiffs' claims for conspiracy to commit racketeering activity in violation of 18 U.S.C. §1962(d) and claims for negligent misrepresentation. In April 2016, plaintiffs filed a third amended complaint, which defendants moved to dismiss in June 2016. In August 2016, the court denied the motion to dismiss and we filed a response to the third amended complaint in September 2016. In October 2015, a similar civil class action complaint was filed against EPI and other defendant manufacturers in the U.S. District for the Northern District of Illinois. Similar litigation may be brought by other plaintiffs. We are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for this matter, if any, but we intend to contest this litigation vigorously and will explore all options as appropriate in our best interests.

Unapproved Drug Litigation

In September 2013, the State of Louisiana filed a petition for damages against certain of our subsidiaries, EPI and Generics Bidco I, LLC, and over 50 other pharmaceutical companies alleging the defendants or their subsidiaries marketed products that were not approved by the FDA. See *State of Louisiana v. Abbott Laboratories, Inc., et al*., C624522 (19th Jud. Dist. La.). The State of Louisiana sought damages, fines, penalties, attorneys' fees and costs under various causes of action. In October 2015, the District Court ordered judgment for defendants on their exception for no right of action. The State of Louisiana appealed that decision and in October 2016, the Louisiana Court of Appeals, First Circuit, issued a decision affirming the dismissal as to certain counts and reversing the dismissal as to others. The State filed a petition for rehearing, which was denied by the court in

December 2016. Both sides applied to Louisiana Supreme Court for a writ of certiorari to review the First Circuit's decision. Those writs were denied in March 2017.

In March 2017, the State of Mississippi filed a complaint against our subsidiary EPI, alleging that EPI marketed products that were not approved by the FDA. See *State of Mississippi v. Endo Pharmaceuticals Inc.*, No. 25CH1:17-cv-000309 (1st Jud. Dist. Ch. Miss.). The State of Mississippi seeks damages, penalties, attorneys' fees, costs, and other relief under various causes of action.

We intend to contest the above cases vigorously and to explore other options as appropriate in our best interests. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us. We are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for this matter, if any.

Opioid-Related Litigations, Subpoenas and Document Requests

In June 2014, Corporation Counsel for the City of Chicago filed suit in Illinois state court against multiple defendants, including our subsidiaries, EHSI and EPI, for alleged violations of city ordinances and other laws relating to defendants' alleged opioid sales and marketing practices. In June 2014, the case was removed to the U.S. District Court for the Northern District of Illinois. In December 2014, defendants moved to dismiss the amended complaint and in May 2015, the District Court issued an order granting that motion in part, dismissing the case as to EHSI and EPI. In August 2015, plaintiff filed its second amended complaint against multiple defendants, including EPI and EHSI. In November 2015, defendants moved to dismiss the second amended complaint. In September 2016, the District Court granted in part and denied in part defendants' motions to dismiss and provided plaintiff an opportunity to amend its complaint. Plaintiff filed the third amended complaint in October 2016. In December 2016, defendants moved to dismiss the re-pled claims in the third amended complaint, and filed their answers as to the claims not previously dismissed by the Court.

In May 2014, a lawsuit was filed in California Superior Court (Orange County) in the name of the People of the State of California, acting by and through County Counsel for Santa Clara County and the Orange County District Attorney, against multiple defendants, including our subsidiaries EHSI and EPI (with EPI being added as part of the first amended complaint in June 2014). The complaint asserts violations of California's statutory Unfair Competition and False Advertising laws, as well as asserting a claim for public nuisance, based on alleged misrepresentations in connection with sales and marketing of opioids, including OPANA®. Plaintiff seeks declaratory relief, restitution, civil penalties (including treble damages), abatement, an injunction, and attorneys' fees and costs. Defendants, which include our subsidiaries, filed various motions attacking the pleadings, including one requesting that the Superior Court refrain from proceeding under the doctrines of primary jurisdiction and equitable abstention. That motion was granted in August 2015, and the case was stayed pending further proceedings and findings by the FDA. In June 2016, plaintiffs filed a motion to lift the stay and to amend the complaint. Defendants, including EHSI and EPI, opposed that motion. Following a hearing in July 2016, the court provided plaintiffs an opportunity to seek leave to file another amended complaint. In August 2016, plaintiffs filed a renewed motion to lift the stay and amend the complaint. In October 2016, the court granted, in part, plaintiffs' renewed motion to lift the stay and the plaintiffs filed their third amended complaint. Defendants' response to the third amended complaint is not due at this time.

In December 2015, a lawsuit was filed in the Chancery Court of the First Judicial District of Hinds County, Mississippi by the State of Mississippi against multiple defendants, including our subsidiaries EHSI and EPI. The complaint alleges violations of Mississippi's Consumer Protection Act and various other claims arising out of defendants' alleged opioid sales and marketing practices. Plaintiff seeks declaratory relief, restitution, civil penalties, abatement, an injunction, and attorneys' fees and costs. In March 2016, defendants moved to dismiss the complaint and to transfer the case from Hinds County to Rankin County. The motion to transfer was denied

in February 2017. In March 2017 Defendants petitioned for an interlocutory appeal of that ruling, and that petition remains pending. The motion to dismiss also remains pending.

In August 2016, the County of Suffolk, New York filed suit in New York state court against multiple defendants, including our subsidiaries, EHSI and EPI, for alleged violations of state false and deceptive advertising and other statutes, public nuisance, common law fraud, and unjust enrichment based on opioid sales and marketing practices. The County of Suffolk is seeking compensatory damages, interest, costs, disbursements, punitive damages, treble damages, penalties and attorneys' fees. Defendants, including our subsidiaries, filed motions to dismiss and to stay in January 2017. In February 2017, Broome County, New York, and Erie County, New York, filed similar suits in New York state court.

In March 2017, the Boone County Commission filed suit in the U.S. District Court for the Southern District of West Virginia against multiple defendants, including our subsidiary Generics Bidco I, LLC, for the alleged violation of federal and state safety laws designed to monitor, detect, and prevent the diversion of controlled substances. The complaint generally seeks compensatory and punitive damages for the alleged creation of a public nuisance.

With respect to the litigations brought on behalf of the City of Chicago, the People of the State of California, the State of Mississippi, the Counties of Suffolk, Broome and Erie and the Boone County Commission, we intend to contest those matters vigorously. We are unable to predict the outcome of these matters or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for these matters but will explore all options as appropriate in our best interests.

In September 2014, our subsidiaries EHSI and EPI received a Request for Information from the State of Tennessee Office of the Attorney General and Reporter seeking documents and information regarding the sales and marketing of opioids, including OPANA® ER. We are currently cooperating with the State of Tennessee Office of the Attorney General and Reporter in this investigation.

In August 2015, our subsidiaries EHSI and EPI received a subpoena from the State of New Hampshire Office of the Attorney General seeking documents and information regarding the sales and marketing of opioids, including OPANA® ER. We were cooperating with the State of New Hampshire Office of the Attorney General in its investigation until we learned it was being assisted by outside counsel hired on a contingent fee basis. The New Hampshire Attorney General initiated an action in the Superior Court for the State of New Hampshire to enforce the subpoena despite this contingent fee arrangement, and we (along with other companies that had received similar subpoenas) responded by filing a motion for protective order to preclude the use of contingent fee counsel. In addition, we filed a separate motion seeking declaratory relief. In March 2016, the Superior Court granted the motion for protective order on the grounds that the contingent fee agreement was invalid as *ultra vires* and that the office of the Attorney General had acted outside of its statutory authority in entering into the agreement with the contingent fee counsel. In April 2016, both the New Hampshire Attorney General and the companies that received subpoenas from the New Hampshire Attorney General, including EHSI and EPI, appealed, in part, the March 2016 Superior Court order to the New Hampshire Supreme Court. Those appeals are pending. In April 2016, the New Hampshire Attorney General also entered into a new agreement with outside counsel. In response, the companies that received a subpoena from the New Hampshire Attorney General, including EHSI and EPI, moved to enforce a part of the protective order issued by the Superior Court in March 2016 that is not being appealed by EHSI and EPI. That motion was denied in August 2016.

In April 2016, EHSI and EPI received a Civil Investigative Demand ("CID") from the Department of Justice ("DOJ") for the State of Oregon seeking documents and information regarding the sales and marketing of OPANA® ER. We are currently cooperating with the State of Oregon in its investigation.

In November 2016, Endo International and EPI received an Administrative Subpoena from the Office of the Attorney General of Maryland seeking documents and information regarding the sales and marketing of opioid products. We are currently cooperating with the State of Maryland in its investigation.

In March 2017, EPI received a subpoena from the Office of the Attorney General of New Jersey seeking documents and information regarding the sales and marketing of opioid products. We are currently cooperating with the State of New Jersey in its investigation.

Antitrust Litigation and Investigations

Multiple direct and indirect purchasers of Lidoderm® have filed a number of cases against our subsidiary EPI and co-defendants Teikoku Seiyaku Co., Ltd., Teikoku Pharma USA, Inc. (collectively, "Teikoku") and Actavis plc and certain of its subsidiaries (collectively, "Actavis"), which was subsequently acquired by Teva Pharmaceuticals Industries Ltd and its subsidiaries (collectively, "Teva") from Allergan plc ("Allergan"). Certain of these actions have been asserted on behalf of classes of direct and indirect purchasers, while others are individual cases brought by one or more alleged direct or indirect purchasers. The complaints in these cases generally allege that EPI, Teikoku and Actavis entered into an anticompetitive conspiracy to restrain trade through the settlement of patent infringement litigation concerning U.S. Patent No. 5,827,529 (the "'529 patent") and other patents. Some of the complaints also allege that Teikoku wrongfully listed the '529 patent in the Orange Book as related to Lidoderm®, that EPI and Teikoku commenced sham patent litigation against Actavis and that EPI abused the FDA citizen petition process by filing a citizen petition and amendments solely to interfere with generic companies' efforts to obtain FDA approval of their versions of Lidoderm®. The cases allege violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2) and various state antitrust and consumer protection statutes as well as common law remedies in some states. These cases generally seek damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees.

The U.S. Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, issued an order in April 2014 transferring these cases as *In Re Lidoderm Antitrust Litigation*, MDL No. 2521, to the U.S. District Court for the Northern District of California. The court granted plaintiffs' motions for class certification filed on behalf of classes of direct and indirect purchasers in February 2017. Trial is currently scheduled to begin in late 2017. We cannot predict whether or not additional cases similar to those described above will be filed by other plaintiffs or the timing or outcome of any such litigation. We expect any such cases brought in federal court to be transferred to the Northern District of California as tag-along actions to *In Re Lidoderm Antitrust Litigation*.

Multiple direct and indirect purchasers of OPANA® ER have filed cases against our subsidiaries EHSI and EPI, and other pharmaceutical companies, including Penwest Pharmaceuticals Co., which we subsequently acquired, and Impax Laboratories Inc. ("Impax"), all of which have been transferred and coordinated for pretrial proceedings in the U.S. District Court for the Northern District of Illinois by the Judicial Panel on Multidistrict Litigation. Some of these cases have been filed on behalf of putative classes of direct and indirect purchasers, while others have been filed on behalf of individual retailers or health care benefit plans. These cases generally allege that the agreement reached by EPI and Impax to settle patent infringement litigation concerning multiple patents pertaining to OPANA® ER and EPI's introduction of the re-formulation of OPANA® ER violated antitrust laws. The complaints allege violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2), various state antitrust and consumer protection statutes, as well as state common law. These cases generally seek damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. In February 2016, the District Court issued orders (i) denying defendants' motion to dismiss the claims of the direct purchasers, (ii) denying in part and granting in part defendants' motion to dismiss the claims of the indirect purchasers, but giving them permission to file amended complaints and (iii) granting defendants' motion to dismiss the complaints filed by certain retailers, but giving them permission to file amended complaints. In response to the District Court's orders, the indirect purchasers filed an amended complaint to which the defendants filed a renewed motion to dismiss certain claims, and certain retailers also filed amended complaints. The defendants successfully moved to dismiss the indirect purchaser unjust enrichment claims arising under the laws of the states of California, Rhode Island and Illinois. We cannot predict whether or not additional cases similar to those described above will be filed by other plaintiffs or the timing or outcome of any such litigation.

We are unable to predict the outcome of these matters or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for these matters, if any, but will explore all options as appropriate in our best interests.

In February 2014, our subsidiary EPI received a CID (the "February 2014 CID") from the U.S. Federal Trade Commission (the FTC). The FTC issued a second CID to EPI in March 2014 (the "March 2014 CID"). The February 2014 CID requested documents and information concerning EPI's settlement agreements with Actavis and Impax settling the OPANA® ER patent litigation, EPI's Development and Co-Promotion Agreement with Impax, and its settlement agreement with Actavis settling the Lidoderm® patent litigation, as well as information concerning the marketing and sales of OPANA® ER and Lidoderm®. The March 2014 CID requested documents and information concerning EPI's acquisition of U.S. Patent No. 7,852,482 (the "'482 patent"), as well as additional information concerning certain litigation relating to, and the marketing and sales of OPANA® ER. The FTC also issued subpoenas for investigational hearings (similar to depositions) to our employees and former employees. In March 2016, the FTC filed a lawsuit in the U.S. District Court for the Eastern District of Pennsylvania against us and our subsidiary EPI, as well as against Allergan, Actavis, Impax and Teikoku, alleging generally that the Lidoderm® settlement agreements with Actavis and the OPANA® ER settlement agreement with Impax constituted, in whole or part, unfair methods of competition in violation Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). The FTC also alleged that one provision of the agreement with Actavis violated Section 7 of the Clayton Act, 15 U.S.C. § 18. Concurrently with the filing of the FTC's complaint, Teikoku entered into a consent judgment with the FTC and was dismissed from the case. The FTC's complaint sought injunctive and declaratory relief and other remedies, including restitution and disgorgement. In June 2016, we joined in the defendants' motion to sever OPANA® ER-related claims from the Lidoderm®-related claims. In July 2016, a motion to dismiss was filed on behalf of all remaining defendants. In October 2016, the District Court granted the defendants' motion to sever the claims and ordered the FTC to file a new complaint for the OPANA® ER-related claims and to amend the existing complaint to include only the Lidoderm®-related claims. The District Court also denied the defendants' motion to dismiss as moot with leave to refile in each of the two separate actions. Subsequently in October 2016, the FTC voluntarily dismissed its pending complaint against us without prejudice. Following the FTC's voluntary dismissal, in October 2016, we, along with Impax and Actavis, filed two separate lawsuits against the FTC in the Eastern District of Pennsylvania seeking declaratory judgment relating, respectively, to the FTC's OPANA® ER-related claims and Lidoderm®-related claims. The declaratory judgment actions each sought a declaration by the court that the FTC does not have the authority under the FTC Act to bring its claims in federal court or to seek disgorgement. The declaratory judgment action concerning the OPANA® ER-related claims also sought a declaration that the FTC's claims are time-barred. In December 2016, the FTC filed a motion to dismiss the declaratory judgment actions for failure to state a claim. In January 2017, we entered into a settlement with the FTC pursuant to which the FTC re-filed claims against us, our subsidiary EPI, and other defendants in the U.S. District Court for the Northern District of California and concurrently filed a joint motion for entry of a Stipulated Order dismissing the claims against us and EPI, with prejudice. The Stipulated Order involves no monetary payment to the FTC and no admission of liability. Under the Stipulated Order, we agreed to dismiss our claims in the declaratory judgment actions, and also agreed to certain covenants relating to the future settlement of patent infringement litigation for a period of 10 years. These covenants, which are consistent with Endo's current practices in settling patent infringement cases, include a prohibition on patent settlement agreements that prevent the marketing of authorized generic products or that involve certain payments to generics manufacturers. The FTC agreed that the prior dismissal of its claims against us in the Eastern District of Pennsylvania will be treated as being with prejudice, that it will bring no other claims against us arising from the Opana® ER and Lidoderm® settlements and that it would also dismiss with prejudice its claims against our subsidiary Par Pharmaceutical Companies, Inc. (subsequently renamed Endo Generics Holdings, Inc. and referred to as "Par Pharma") in the action *FTC v. Actavis, Inc., et al.* pending in the U.S. District Court for the Northern District of Georgia. The Stipulated Order also requires the FTC to consider in good faith any requested modifications proposed by us in the event of a material change in the law governing the antitrust implications of patent infringement settlements. As of February 2017, the Stipulated Order of dismissal has been entered by the Northern District of California, we have dismissed the declaratory judgment actions filed against the FTC in the

Eastern District of Pennsylvania, and the FTC has dismissed its claims against Par Pharma in the *Actavis* case in the Northern District of Georgia.

In November 2014, EPI received a CID from the State of Florida Office of the Attorney General issued pursuant to the Florida Antitrust Act of 1980, Section 542.28 seeking documents and other information concerning EPI's settlement agreement with Actavis settling the Lidoderm® patent litigation, as well as information concerning the marketing and sales of Lidoderm®.

In February 2015, EHSI and EPI received CIDs for Production of Documents and Information from the State of Alaska Office of Attorney General issued pursuant to Alaska's Antitrust and Unfair Trade Practices and Consumer Protection law seeking documents and other information concerning settlement agreements with Actavis and Impax settling the OPANA® ER patent litigation as well as information concerning EPI's settlement agreement with Actavis settling the Lidoderm patent litigation, as well as information concerning the marketing and sales of Lidoderm®.

In February 2016, EPI received a CID from the State of South Carolina Office of the Attorney General seeking documents and other information concerning EPI's settlement agreement with Actavis settling the Lidoderm® patent litigation, as well as information concerning the marketing and sales of Lidoderm®.

In January 2009, the FTC filed a lawsuit against our subsidiary, Par Pharma, in the U.S. District Court for the Central District of California, which was subsequently transferred to the U.S. District Court for the Northern District of Georgia, and which alleged violations of antitrust law arising out of Par Pharma's settlement of certain patent litigation concerning the generic version of AndroGel®. The FTC complaint sought a finding that Par Pharma's settlement agreement violates Section 5(a) of the Federal Trade Commission Act, and a permanent injunction against Par Pharma's ability to engage in certain types of patent settlements in the future. Beginning in February 2009, certain private plaintiffs, including distributors and retailers, filed similar litigation. Generally, the complaints in the remaining private plaintiff suits seek equitable relief, unspecified damages and costs.

In February 2010, the District Court granted a motion to dismiss the FTC's claims and granted in part and denied in part a motion to dismiss the claims of the private plaintiffs. In April 2012, the U.S. Court of Appeals for the 11th Circuit affirmed the District Court's decision on the motion to dismiss the FTC's claims. In September 2012, the District Court granted a motion for summary judgment against the private plaintiffs' claims of sham litigation. In July 2013, the Supreme Court of the U.S. reversed the Court of Appeals' and District Court's decisions concerning the FTC action and remanded the case to the District Court for further proceedings. In May 2016, those private plaintiffs representing the putative class of indirect purchasers voluntarily dismissed their case against Par Pharma with prejudice. In February 2017, pursuant to the Stipulated Order described above, the FTC dismissed its claims against Par Pharma with prejudice. Claims by the direct purchasers are still pending. We intend to contest this litigation vigorously and to explore all options as appropriate in our best interests.

In February 2015, Par Pharma received a CID from the Office of the Attorney General for the State of Alaska seeking production of certain documents and information regarding Par Pharma's settlement of the AndroGel® patent litigation as well as documents produced in the aforementioned litigation filed by the FTC.

We are currently cooperating with the State of Florida Office of the Attorney General, the State of Alaska Office of the Attorney General and the State of South Carolina Office of the Attorney General in their respective investigations. Investigations and lawsuits similar to these antitrust matters described above may be brought by others. We are unable to predict the outcome of these investigations or litigations or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for these investigations or litigations, if any, but will explore all options as appropriate in our best interests.

In July 2016, Fresenius Kabi USA, LLC ("Fresenius") filed a complaint against Par Pharma and its subsidiary, Par Sterile Products, LLC, in the U.S. District Court for the District of New Jersey alleging that Par

Pharma and its subsidiary engaged in an anticompetitive scheme to exclude competition from the market for vasopressin solution for intravenous injection in view of Par Pharma's Vasostrict® (vasopressin) product. The complaint alleges violations of Sections 1 and 2 of The Sherman Antitrust Act, 15 U.S.C. §§ 1, 2, as well as the antitrust law and common law of the state of New Jersey, alleging that Par Pharma and its subsidiary entered into exclusive supply agreements with one or more active pharmaceutical ingredient ("API") manufacturers and that Fresenius has been unable to obtain vasopressin API in order to file an ANDA to obtain FDA approval for its own vasopressin product. Fresenius seeks actual, treble and punitive damages in an unspecified amount, attorneys' fees and costs and injunctive relief and demands a trial by jury. In September 2016, Par Pharma and its subsidiary filed a motion to dismiss the case for Fresenius' failure to properly state a claim under the antitrust laws. In February 2017, the District Court denied Par Pharma's motion to dismiss. We are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for this matter. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests.

False Claims Act Litigation

The Attorneys General of Florida, Indiana and Virginia and the U.S. Office of Personnel Management (the "USOPM") have issued subpoenas, and the Attorneys General of Michigan, Tennessee, Texas, and Utah have issued CIDs, to our subsidiary, Par Pharma, among other companies. The demands generally request documents and information pertaining to allegations that certain of Par Pharma's sales and marketing practices caused pharmacies to substitute ranitidine capsules for ranitidine tablets, fluoxetine tablets for fluoxetine capsules, and two 7.5 mg buspirone tablets for one 15 mg buspirone tablet, under circumstances in which some state Medicaid programs at various times reimbursed the new dosage form at a higher rate than the dosage form being substituted. Par Pharma has provided documents in response to these subpoenas to the respective Attorneys General and the USOPM. The aforementioned subpoenas and CIDs culminated in the federal and state law qui tam action brought on behalf of the U.S. and several states by Bernard Lisitza. The complaint was unsealed in August 2011. Lisitza's corrected second amended complaint generally seeks (i) a finding that defendants violated and be enjoined from future violations of the federal False Claims Act and state false claims acts; (ii) treble damages and maximum civil penalties for each violation of the federal False Claims Act and state false claims acts; (iii) an applicable percentage share of the proceeds; and (iv) expenses, fees, and costs. The U.S. intervened in this action and filed a separate complaint in September 2011, alleging claims for violations of the Federal False Claims Act and common law fraud. The U.S.'s second corrected complaint generally seeks (i) treble damages and civil penalties for violations under the federal False Claims Act and (ii) compensatory and punitive damages for common law fraud. The states of Michigan and Indiana have also intervened as to claims arising under their respective state false claim acts, common law fraud, and unjust enrichment. Michigan's complaint generally seeks (i) treble damages and civil penalties and (ii) common law compensatory and punitive damages. Indiana's amended complaint generally seeks treble damages, costs, and attorney's fees. We intend to vigorously defend this lawsuit. At this time, we are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for this matter, if any.

Pricing Matters

In March 2016, EPI received a CID from the U.S. Attorney's Office for the Southern District of New York. The CID requested documents and information regarding contracts with Pharmacy Benefit Managers regarding Frova®. We are currently cooperating with this investigation.

In December 2014, our subsidiary Par Pharma received a Subpoena to Testify Before Grand Jury from the Antitrust Division of the DOJ and issued by the U.S. District Court for the Eastern District of Pennsylvania. The subpoena requested documents and information focused primarily on product and pricing information relating to Par Pharma's authorized generic version of Lanoxin (digoxin) oral tablets and Par Pharma's generic doxycycline products, and on communications with competitors and others regarding those products. Par Pharma is currently cooperating fully with the investigation.

In December 2015, EPI received Interrogatories and Subpoena Duces Tecum from the State of Connecticut Office of Attorney General requesting information regarding pricing of certain of its generic products, including Doxycycline Hyclate, Amitriptyline Hydrochloride, Doxazosin Mesylate, Methotrexate Sodium and Oxybutynin Chloride. We are currently cooperating with this investigation.

We are unable to predict the outcome of the foregoing investigations or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for these matters but will explore all options as appropriate in our best interests.

Beginning in December 2015, two complaints, including a class action complaint, were filed in the Philadelphia Court of Common Pleas against us and certain of our subsidiaries, including Par Pharmaceutical Inc. ("PPI"), along with other manufacturers of generic pharmaceutical products, seeking compensatory and punitive or treble damages, as well as injunctive relief, and alleging that certain marketing and pricing practices by the defendant companies violated state law, including consumer protection law. The class action complaint was subsequently removed to the U.S. District Court for the Eastern District of Pennsylvania, and the plaintiff filed an amended complaint. In January 2017, defendants moved to dismiss the amended class action complaint, and that motion remains pending. The case in the Philadelphia Court of Common Pleas is stayed pending resolution of the class action. Additional similar claims may be brought by other plaintiffs in various jurisdictions. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests.

Beginning in March 2016, several class action complaints were filed in the U.S. District Courts for the Eastern District of Pennsylvania and the District of Rhode Island against us and certain of our subsidiaries, including PPI, and other manufacturers seeking compensatory and punitive or treble damages, as well as injunctive relief, and alleging that certain marketing and pricing practices regarding digoxin and doxycycline violated federal and/or state antitrust laws and/or gave rise to state consumer protection and/or unjust enrichment claims. The U.S. Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. §1407, issued an order in August 2016 establishing coordinated or consolidated pretrial proceedings for these cases in the U.S. District Court for the Eastern District of Pennsylvania under the caption *In Re Generic Digoxin and Doxycycline Antitrust Litigation*, MDL No. 2724. The direct purchaser plaintiffs and indirect purchaser plaintiffs filed consolidated amended class action complaints in January 2017, and defendants moved to dismiss those complaints in March 2017. An independent pharmacy plaintiff filed a similar class action complaint in the U.S. District Court for the Eastern District of Pennsylvania in March 2017. Additional similar claims may be brought by other plaintiffs in various jurisdictions. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests.

Since November 2016, several class action complaints have been filed in the U.S. District Court for the Eastern District of Pennsylvania against certain of our subsidiaries, including PPI, and other manufacturers seeking compensatory and punitive or treble damages, as well as injunctive relief, and alleging that certain marketing and pricing practices regarding divalproex ER violated federal and/or state antitrust laws and/or gave rise to state consumer protection and/or unjust enrichment claims. Additional similar claims may be brought by other plaintiffs in various jurisdictions. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests.

Beginning in December 2016, multiple class action complaints were filed in the U.S. District Court for the Eastern District of Pennsylvania and U.S. District Court for the Southern District of New York against us and certain of our subsidiaries, including PPI, and other manufacturers seeking compensatory and punitive or treble damages, as well as injunctive relief, and alleging that certain marketing and pricing practices regarding propranolol violated federal and/or state antitrust laws and/or gave rise to state consumer protection and/or unjust enrichment claims. Defendants moved to dismiss one direct purchaser complaint pending in the Eastern District of Pennsylvania in March 2017. The remaining Eastern District of Pennsylvania actions relating to propranolol have been stayed pending a ruling from the U.S. Judicial Panel on Multidistrict Litigation on the motion to

transfer described below. In the Southern District of New York actions, the indirect purchasers filed a consolidated amended complaint in February 2017, and the direct purchasers filed a consolidated amended complaint in March 2017. Defendants moved to dismiss both consolidated amended complaints, and those motions were denied in April 2017, except as to certain state law claims brought by the indirect purchaser plaintiffs. Additional similar claims may be brought by other plaintiffs in various jurisdictions. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests.

In March 2017, two class action complaints were filed in the U.S. District Court for the Eastern District of Pennsylvania against our subsidiary PPI, and other manufacturers seeking compensatory and punitive or treble damages, as well as injunctive relief, and alleging that certain marketing and pricing practices regarding baclofen violated federal and/or state antitrust laws and/or gave rise to state consumer protection and/or unjust enrichment claims. Additional similar claims may be brought by other plaintiffs in various jurisdictions. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests.

Also in March 2017, two class action complaints were filed, one in the U.S. District Court for the Eastern District of Pennsylvania and the other in the Southern District of New York, against us and certain of our subsidiaries, including PPI, and other manufacturers seeking compensatory and punitive or treble damages, as well as injunctive relief, and alleging that certain marketing and pricing practices regarding amitriptyline hydrochloride violated federal and/or state antitrust laws and/or gave rise to state consumer protection and/or unjust enrichment claims. Additional similar claims may be brought by other plaintiffs in various jurisdictions. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interests.

In January 2017, Rochester Drug Co-Operative, Inc. filed a motion with the U.S. Judicial Panel on Multidistrict Litigation seeking to transfer certain of the foregoing antitrust complaints to the U.S. District Court for the Eastern District of Pennsylvania for inclusion in MDL No. 2724, which would then be renamed *In re Generic Pharmaceuticals Pricing Antitrust Litigation*. In April 2017, the U.S. Judicial Panel on Multidistrict Litigation issued an order renaming MDL No. 2724 as requested and expanding it to include actions in which: (a) plaintiffs assert claims for price fixing of generic drugs in violation of the Sherman Act and/or state antitrust laws on behalf of overlapping putative nationwide classes of direct or indirect purchasers of generic pharmaceuticals; (b) the average market price of the subject generic pharmaceutical is alleged to have increased between 2012 and the present; (c) defendants are alleged to have effectuated the alleged conspiracy through direct company-to-company contacts and through joint activities undertaken through trade associations, in particular meetings of the Generic Pharmaceutical Association; and (d) the allegations stem from the same government investigation into anticompetitive conduct in the generic pharmaceuticals industry. Pursuant to this order, the propranolol and amitriptyline hydrochloride cases filed in the U.S. District Court for the Southern District of New York have been or we expect will be transferred to the U.S. District Court for the Eastern District of Pennsylvania as part of MDL No. 2724. As noted above, the digoxin and doxycycline, divalproex ER, and baclofen cases are already pending in the U.S. District Court for the Eastern District of Pennsylvania.

We are unable to predict the outcome of the foregoing matters or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for these matters but will explore all options as appropriate in our best interests.

Megace ES® (megestrol acetate oral suspension) Cases

In September 2011, PPI, along with EDT Pharma Holdings Ltd. (“Elan”) (now known as Alkermes Pharma Ireland Limited), filed a complaint against TWi Pharmaceuticals, Inc. (“TWi”) in the U.S. District Court for the District of Maryland alleging infringement of U.S. Patent No. 7,101,576 because TWi filed an ANDA with a Paragraph IV certification seeking FDA approval of a generic version of Megace® ES. A bench trial was held in October 2013, and in February 2014, the District Court issued a decision in favor of TWi, finding all asserted claims of the 7,101,576 patent invalid for obviousness. PPI appealed. In August 2014, the District Court issued a preliminary injunction enjoining TWi’s launch of its generic product pending disposition of the appeal. In

December 2014, the Federal Circuit reversed the District Court's decision, remanding for further findings of fact. In March 2015, the District Court issued another preliminary injunction enjoining TWi's launch of its generic product pending disposition of the case on remand. In July 2015, the District Court issued a new decision in favor of TWi, finding all of the asserted claims invalid, and TWi launched its generic product. PPI appealed again, and in December 2015, the District Court's decision in favor of TWi was affirmed without opinion. In February 2016, TWi moved the District Court to recover its lost profits, which TWi alleged in the amount of $16 million, resulting from the previous injunctions to which the District Court subjected TWi, as well as attorneys' fees and costs. PPI opposed TWi's motion. In September 2016, the District Court denied TWi's motion for attorneys' fees and costs and granted in part and denied in part TWi's motion to recover its lost profits, ordering PPI to pay $12.7 million. On November 21, 2016, PPI paid the judgment and bill of costs to TWi in the amount of $12.8 million (including interest), and a Notice of Satisfaction was filed with the Court on November 28, 2016 terminating the case.

Securities Related Class Action Litigation

In May 2016, a putative class action entitled *Craig Friedman v. Endo International plc, Rajiv Kanishka Liyanaarchie de Silva and Suketu P. Upadhyay* was filed in the U.S. District Court for the Southern District of New York by an individual shareholder on behalf of himself and all similarly situated shareholders. In August 2016, the Steamfitters' Industry Pension Fund and Steamfitters' Industry Security Benefit Fund were appointed lead plaintiffs in the action. In October 2016, a second amended complaint was filed, which added Paul Campanelli as a defendant, and we filed a motion to dismiss the case. In response, and without resolving the motion, the Court permitted lead plaintiffs to file a third amended complaint. The lawsuit alleges violations of Sections 10(b) and 20(a) of the Exchange Act based on Endo's revision of its 2016 earnings guidance and certain disclosures about its generics business, the integration of Par and its subsidiaries, certain other alleged business issues and the receipt of a CID from the U.S. Attorney's Office for the Southern District of New York regarding contracts with Pharmacy Benefit Managers concerning Frova®. Lead plaintiffs seek class certification, damages in an unspecified amount and attorneys' fees and costs. We filed a motion to dismiss the third amended complaint in December 2016. Briefing on that motion has been completed but no ruling has been issued. We are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for this matter, but will explore all options as appropriate in our best interests and we intend to defend this lawsuit vigorously.

In November 2016, a putative class action was filed in the U.S. District Court for the Southern District of New York by an individual shareholder on behalf of herself and all similarly situated shareholders, bearing the caption *Doris Shasha v. Endo International plc Company, Rajiv Kanishka Liyanaarchchie De Silva and Suketu P. Upadhyay*. The lawsuit alleged violations of Sections 10(b) and 20(a) of the Exchange Act. It alleged that certain of Endo's public disclosures from September 28, 2015 through November 2, 2016 contained misstatements or omissions, based on news reports of an investigation by the Department of Justice into potential price collusion in the pharmaceutical industry. In November 2016, the plaintiff voluntarily dismissed the case without prejudice.

In February 2016, a putative class action entitled *Public Employees' Retirement System of Mississippi v. Endo International plc* was filed in the Court of Common Pleas of Chester County, Pennsylvania by an institutional purchaser of shares in our June 2, 2015 public offering, on behalf of itself and all similarly situated purchasers. The lawsuit alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 against Endo, certain of Endo's current and former directors and officers, and the underwriters who participated in the offering, based on certain disclosures about Endo's generics business. Defendants have removed the case to the U.S. District Court for the Eastern District of Pennsylvania. We are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for this matter, but will explore all options as appropriate in our best interests and we intend to defend this lawsuit vigorously.

Paragraph IV Certifications on OPANA® ER

In late 2012, two patents (U.S. Patent Nos. 8,309,122 and 8,329,216) were issued to EPI covering OPANA® ER (oxymorphone hydrochloride extended-release tablets CII). In December 2012, EPI filed a complaint against Actavis in U.S. District Court for the Southern District of New York for patent infringement based on its ANDA for a non-INTAC® technology version of OPANA® ER. In May 2013 and June 2013, EPI filed similar suits in the U.S. District Court for the Southern District of New York against the following applicants for non-INTAC® technology OPANA® ER: Roxane Laboratories, Inc. ("Roxane") and Ranbaxy Laboratories Limited, which was acquired by Sun Pharmaceutical Industries Ltd. ("Ranbaxy"). Those suits allege infringement of U.S. Patent Nos. 7,851,482, 8,309,122, and 8,329,216. In July 2013, Actavis and Roxane were granted FDA approval to market all strengths of their respective non-INTAC® technology formulations of OPANA® ER. A trial in this case was held from March 2015 through April 2015 in the U.S. District Court for the Southern District of New York. In August 2015, the District Court ruled that all defendants infringed the claims of U.S. Patent Nos. 8,309,122 and 8,329,216. The District Court also ruled that the defendants failed to show that U.S. Patent Nos. 8,309,122 and 8,329,216 were invalid, enjoined the defendants from launching their generic products until the expiration of those patents and directed Actavis to withdraw its generic product within 60 days. In October 2015, the District Court tolled the 60-day period until it decided two pending post-trial motions. In April 2016, the District Court issued an order upholding its August 2015 ruling in EPI's favor and confirming the prior injunction against the manufacture or sale of the generic version of the non-INTAC® technology OPANA® ER currently offered by Actavis and the additional approved but not yet marketed generic version of the product developed by Roxane. The defendants filed appeals to the Court of Appeals for the Federal Circuit. We intend to continue vigorously asserting our intellectual property rights and to oppose any such appeal.

From September 21, 2012 through October 30, 2013, EPI and its partner Grünenthal received Paragraph IV Notices from each of Teva Pharmaceuticals USA, Inc., Amneal Pharmaceuticals, LLC ("Amneal"), ThoRx Laboratories, Inc. ("ThoRx"), Actavis, Impax and Ranbaxy (now Sun Pharmaceutical Industries Ltd.), advising of the filing by each such company of an ANDA for a generic version of the formulation of OPANA® ER with INTAC® technology. These Paragraph IV Notices refer to U.S. Patent Nos. 7,851,482, 8,075,872, 8,114,383, 8,192,722, 8,309,060, 8,309,122 and 8,329,216, which variously cover the formulation of OPANA® ER, a highly pure version of the active pharmaceutical ingredient and the release profile of OPANA® ER. EPI filed lawsuits against each of these filers in the U.S. District Court for the Southern District of New York. Each lawsuit was filed within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. A trial in this case was held from March 2015 through April 2015 in the U.S. District Court for the Southern District of New York against the remaining filers. In August 2015, the District Court issued an Opinion holding that all defendants infringed the claims of U.S. Patent Nos. 8,309,060, 8,309,122 and 8,329,216. The Opinion also held that the defendants had shown that U.S. Patent No. 8,309,060 was invalid, but that the defendants had failed to show that U.S. Patent Nos. 8,309,122 and 8,329,216 were invalid. The District Court also issued an Order enjoining the defendants from launching their generic products until the expiration of U.S. Patent Nos. 8,309,122 and 8,329,216. The defendants filed appeals to the Court of Appeals for the Federal Circuit. We intend to continue to vigorously assert our intellectual property and oppose appeals by the defendants. However, there can be no assurance that we and/or Grünenthal will be successful. If we are unsuccessful and Teva, Amneal, ThoRx, Actavis or Impax is able to obtain FDA approval of its product, generic versions of OPANA® ER INTAC® technology may be launched prior to the applicable patents' expirations in 2023. Additionally, we cannot predict or determine the timing or outcome of this defense but will explore all options as appropriate in our best interests.

In August 2014 and October 2014, the U.S. Patent Office issued U.S. Patent Nos. 8,808,737 and 8,871,779 respectively, which cover a method of using OPANA® ER and a highly pure version of the active pharmaceutical ingredient of OPANA® ER. In November 2014, EPI filed lawsuits against Teva, ThoRx, Actavis, Impax, Ranbaxy, Roxane, Amneal, and Sandoz Inc. based on their ANDAs filed against both the INTAC® technology and non-INTAC® technology versions of OPANA® ER. Those lawsuits were filed in the U.S. District Court for the District of Delaware alleging infringement of these new patents, which expire in 2027 and 2029, respectively.

On November 17, 2015, the District Court held the ‘737 patent invalid for claiming unpatentable subject matter. That patent has been dismissed from all suits and the suits administratively closed as to that patent, subject to appeal at the end of the case on the ‘779 patent. Beginning July 11, 2016, a three-day trial was held in the U.S. District Court for the District of Delaware against Teva and Amneal for infringement of the ‘779 patent. In October 2016, the District Court issued an Opinion holding that the defendants infringed the claims of U.S. Patent No. 8,871,779. The Opinion also held that the defendants had failed to show that U.S. Patent No. 8,871,779 was invalid. The District Court issued an Order enjoining the defendants from launching their generic products until the expiration of U.S. Patent No. 8,871,779 in November 2029. A trial for infringement of the ‘799 patent by Actavis was held in February 2017 in the same court (U.S. District Court for the District of Delaware) in front of the same judge.

We intend to defend vigorously our intellectual property rights and to pursue all available legal and regulatory avenues in defense of both the non-INTAC® technology formulation OPANA® ER and the INTAC® technology formulation OPANA® ER, including enforcement of the product’s intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful, competitors that already have obtained, or are able to obtain, FDA approval of their products may be able to launch their generic versions of OPANA® ER prior to the applicable patents’ expirations. Additionally, we cannot predict or determine the timing or outcome of related litigation but will explore all options as appropriate in our best interests. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of OPANA® ER and challenge the applicable patents.

Paragraph IV Certification on Fortesta® Gel

In January 2013, EPI and its licensor Strakan Limited received a notice from Watson advising of the filing by Watson of an ANDA for a generic version of Fortesta® (testosterone) Gel. In February 2013, EPI filed a lawsuit against Watson in the U.S. District Court for the Eastern District of Texas, Marshall division. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. A two-day trial was held on or about February 26 and 27, 2015. In August 2015, the District Court issued an Order holding that the asserted patents are valid and are infringed by Watson’s ANDA. As a result, the District Court ordered that the effective date for the approval of Watson’s ANDA to be the date no sooner than the latest expiration date of the ’913 Patent and the ’865 Patent in November of 2018. Watson filed an appeal in October 2015. In October 2016, the Court of Appeals for the Federal Circuit issued an opinion upholding the District Court’s decision.

We intend, and have been advised by Strakan Limited that it too intends, to defend vigorously Fortesta® Gel and to pursue all available legal and regulatory avenues in defense of Fortesta® Gel, including enforcement of the product’s intellectual property rights and approved labeling. However, there can be no assurance that we and/or Strakan will be successful. We cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in our best interests. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Fortesta® Gel and challenge the applicable patents.

Other Proceedings and Investigations

In addition to the above proceedings, proceedings similar to those described above may also be brought in the future. Additionally, we are involved in, or have been involved in, arbitrations or various other proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these other proceedings. Currently, neither we nor our subsidiaries are involved in any other proceedings that we expect to have a material effect on our business, financial condition, results of operations and cash flows.