

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2022**

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM TO
Commission File Number: 001-36326**

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

Ireland
(State or other jurisdiction of incorporation or organization)

68-0683755
(I.R.S. Employer Identification No.)

**First Floor, Minerva House, Simmonscourt Road
Ballsbridge, Dublin 4, Ireland**
(Address of principal executive offices)

Not Applicable
(Zip Code)

011-353-1-268-2000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Ordinary shares, nominal value \$0.0001 per share	ENDP	The NASDAQ Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of ordinary shares, nominal value \$0.0001 per share outstanding as of April 28, 2022 was 235,113,574.

ENDO INTERNATIONAL PLC
INDEX

	Page
<u>Forward-Looking Statements</u>	<u>i</u>
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	<u>1</u>
<u>Condensed Consolidated Balance Sheets (Unaudited)</u>	<u>1</u>
<u>Condensed Consolidated Statements of Operations (Unaudited)</u>	<u>2</u>
<u>Condensed Consolidated Statements of Comprehensive (Loss) Income (Unaudited)</u>	<u>3</u>
<u>Condensed Consolidated Statements of Cash Flows (Unaudited)</u>	<u>4</u>
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	<u>6</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>31</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>43</u>
<u>Item 4. Controls and Procedures</u>	<u>44</u>
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	<u>45</u>
<u>Item 1A. Risk Factors</u>	<u>45</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>48</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>48</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>48</u>
<u>Item 5. Other Information</u>	<u>48</u>
<u>Item 6. Exhibits</u>	<u>48</u>
<u>Signatures</u>	<u>49</u>

FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this document contain information that includes or is based on “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Forward-looking statements include, without limitation, any statements relating to the status and outcome of litigation, any future financial results, cost savings, revenues, expenses, net income and income per share, as well as future financing activities, the impact of the novel strain of coronavirus referred to as COVID-19 on the health and welfare of our employees and on our business (including any economic impact, anticipated return to historical purchasing decisions by customers, changes in consumer spending, decisions to engage in certain medical procedures, future governmental orders that could impact our operations and the ability of our manufacturing facilities and suppliers to fulfill their obligations to us), the expansion of our product pipeline and any development, approval, launch or commercialization activities, the outcome or progress of our contingency planning, including any potential bankruptcy filing, and any other statements that refer to Endo’s expected, estimated or anticipated future results. We have tried, whenever possible, to identify such statements with words such as “believe,” “expect,” “anticipate,” “intend,” “estimate,” “plan,” “project,” “forecast,” “will,” “may” or similar expressions. We have based these forward-looking statements on our current expectations, assumptions 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 including, without limitation, the risks related to the impact of COVID-19 (such as, without limitation, the scope and duration of the pandemic, governmental actions and restrictive measures, delays and cancellations of medical procedures, manufacturing and supply chain disruptions and other impacts to our business); the timing or results of any pending or future litigation, investigations or claims or actual or contingent liabilities, settlement discussions, negotiations or other adverse proceedings, including proceedings involving opioid-related matters, antitrust matters and tax matters with the United States (U.S.) Internal Revenue Service (IRS); unfavorable publicity regarding the misuse of opioids; changing competitive, market and regulatory conditions; changes in legislation; our ability to obtain and maintain adequate protection for our intellectual property rights; the impacts of competition such as those related to the loss of VASOSTRICT® exclusivity; the timing and uncertainty of the results of both the research and development and regulatory processes, including regulatory decisions, product recalls, withdrawals and other unusual items; domestic and foreign health care and cost containment reforms, including government pricing, tax and reimbursement policies; technological advances and patents obtained by competitors; the performance, including the approval, introduction and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; our ability to develop or expand our product pipeline and to continue to develop the market for QWO®, XIAFLEX® and other branded or unbranded products; the impact that known and unknown side effects may have on market perception and consumer preference; the success of any acquisition, licensing or commercialization; the effectiveness of advertising and other promotional campaigns; the timely and successful implementation of any strategic and/or optimization initiatives; the uncertainty associated with the identification of and successful consummation and execution of external corporate development initiatives and strategic partnering transactions; our ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner; the timing and uncertainty of the results of our strategic review and any related potential bankruptcy; and the other risks and uncertainties more fully described under the caption “Risk Factors” in Part I, Item 1A of the Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on March 1, 2022 (the Annual Report), in Part II, Item 1A of this report and in other reports that we file with the SEC. These risks and uncertainties, many of which are outside of our control, and any other risks and uncertainties that we are not currently able to predict or identify, individually or in the aggregate, could have a material adverse effect on our business, financial condition, results of operations and cash flows and could cause our actual results to differ materially and adversely from those expressed in forward-looking statements contained or referenced in this document, including with respect to opioid, tax or antitrust related proceedings or any other litigation; our ability to adjust to changing market conditions; our ability to attract and retain key personnel; our ability to maintain compliance with our financial obligations under certain of our outstanding debt obligations and avoid related downgrades of our debt and long-term corporate credit ratings (which could increase our cost of capital) and/or potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries’ outstanding indebtedness; our ability to incur additional borrowings in compliance with the covenants in our then-existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness; and/or the potential for a significant reduction in our short-term and long-term revenues and/or any other factor that could cause us to be unable to fund our operations and liquidity needs, such as future capital expenditures and payment of our indebtedness. As a result of the possibility or occurrence of any such result, we have engaged in and, at any given time, may further engage in strategic reviews of all or a portion of our business. Any such review or contingency planning could ultimately result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. Those remedial measures could include a potential bankruptcy filing which, if it were to occur, would subject us to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, as further described herein. We would, in that event, also be subject to risks and uncertainties caused by the actions of creditors and other third parties with interests that may be inconsistent with our plans.

We do not undertake any obligation to update our forward-looking statements after the date of this document for any reason, even if new information becomes available or other events occur in the future, except as may be required under applicable securities laws. 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, in Part I, Item 1A of the Annual Report and in Part II, Item 1A of this report, we provide a cautionary discussion of 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.

PART I. FINANCIAL INFORMATION**Item 1. Financial Statements**

ENDO INTERNATIONAL PLC
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(Dollars in thousands, except share and per share data)

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,413,150	\$ 1,507,196
Restricted cash and cash equivalents	181,768	124,114
Accounts receivable, net	473,295	592,019
Inventories, net	283,826	283,552
Prepaid expenses and other current assets	131,391	200,484
Income taxes receivable	9,362	7,221
Total current assets	<u>\$ 2,492,792</u>	<u>\$ 2,714,586</u>
PROPERTY, PLANT AND EQUIPMENT, NET	407,225	396,712
OPERATING LEASE ASSETS	33,203	34,832
GOODWILL	3,197,011	3,197,011
OTHER INTANGIBLES, NET	2,253,271	2,362,823
DEFERRED INCOME TAXES	1,126	1,138
OTHER ASSETS	62,583	60,313
TOTAL ASSETS	<u>\$ 8,447,211</u>	<u>\$ 8,767,415</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 808,278	\$ 836,898
Current portion of legal settlement accrual	528,541	580,994
Current portion of operating lease liabilities	11,024	10,992
Current portion of long-term debt	26,116	200,342
Income taxes payable	2,183	736
Total current liabilities	<u>\$ 1,376,142</u>	<u>\$ 1,629,962</u>
DEFERRED INCOME TAXES	15,961	21,628
LONG-TERM DEBT, LESS CURRENT PORTION, NET	8,040,992	8,048,980
LONG-TERM LEGAL SETTLEMENT ACCRUAL, LESS CURRENT PORTION	5,000	—
OPERATING LEASE LIABILITIES, LESS CURRENT PORTION	31,688	33,727
OTHER LIABILITIES	288,426	277,104
COMMITMENTS AND CONTINGENCIES (NOTE 13)		
SHAREHOLDERS' DEFICIT:		
Euro deferred shares, \$0.01 par value; 4,000,000 shares authorized and issued at both March 31, 2022 and December 31, 2021	44	45
Ordinary shares, \$0.0001 par value; 1,000,000,000 shares authorized; 235,109,154 and 233,690,816 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	24	23
Additional paid-in capital	8,956,973	8,953,906
Accumulated deficit	(10,053,489)	(9,981,515)
Accumulated other comprehensive loss	(214,550)	(216,445)
Total shareholders' deficit	<u>\$ (1,310,998)</u>	<u>\$ (1,243,986)</u>
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	<u>\$ 8,447,211</u>	<u>\$ 8,767,415</u>

See accompanying Notes to Condensed Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(Dollars and shares in thousands, except per share data)

	Three Months Ended March 31,	
	2022	2021
TOTAL REVENUES, NET	\$ 652,259	\$ 717,919
COSTS AND EXPENSES:		
Cost of revenues	273,215	305,293
Selling, general and administrative	227,161	187,174
Research and development	36,130	29,739
Acquired in-process research and development	2,900	—
Litigation-related and other contingencies, net	25,154	637
Asset impairment charges	19,953	3,309
Acquisition-related and integration items, net	(1,377)	(5,022)
Interest expense, net	134,949	134,341
Loss on extinguishment of debt	—	13,753
Other expense, net	1,289	912
(LOSS) INCOME FROM CONTINUING OPERATIONS BEFORE INCOME TAX	\$ (67,115)	\$ 47,783
INCOME TAX (BENEFIT) EXPENSE	(1,815)	724
(LOSS) INCOME FROM CONTINUING OPERATIONS	\$ (65,300)	\$ 47,059
DISCONTINUED OPERATIONS, NET OF TAX (NOTE 3)	(6,674)	(5,535)
NET (LOSS) INCOME	\$ (71,974)	\$ 41,524
NET (LOSS) INCOME PER SHARE—BASIC:		
Continuing operations	\$ (0.28)	\$ 0.20
Discontinued operations	(0.03)	(0.02)
Basic	\$ (0.31)	\$ 0.18
NET (LOSS) INCOME PER SHARE—DILUTED:		
Continuing operations	\$ (0.28)	\$ 0.20
Discontinued operations	(0.03)	(0.03)
Diluted	\$ (0.31)	\$ 0.17
WEIGHTED AVERAGE SHARES:		
Basic	233,879	230,551
Diluted	233,879	238,671

See accompanying Notes to Condensed Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME (UNAUDITED)
(Dollars in thousands)

	Three Months Ended March 31,	
	2022	2021
NET (LOSS) INCOME	\$ (71,974)	\$ 41,524
OTHER COMPREHENSIVE INCOME:		
Net unrealized gain on foreign currency	\$ 1,895	\$ 1,692
Total other comprehensive income	\$ 1,895	\$ 1,692
COMPREHENSIVE (LOSS) INCOME	<u>\$ (70,079)</u>	<u>\$ 43,216</u>

See accompanying Notes to Condensed Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(Dollars in thousands)

	Three Months Ended March 31,	
	2022	2021
OPERATING ACTIVITIES:		
Net (loss) income	\$ (71,974)	\$ 41,524
Adjustments to reconcile Net (loss) income to Net cash provided by operating activities:		
Depreciation and amortization	106,315	118,485
Share-based compensation	4,929	9,993
Amortization of debt issuance costs and discount	3,705	3,551
Deferred income taxes	(5,731)	(1,719)
Change in fair value of contingent consideration	(1,377)	(5,453)
Loss on extinguishment of debt	—	13,753
Acquired in-process research and development charges	2,900	—
Asset impairment charges	19,953	3,309
Loss on sale of business and other assets	135	355
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	118,844	37,182
Inventories	(12,030)	(3,802)
Prepaid and other assets	83,904	16,606
Accounts payable, accrued expenses and other liabilities	(47,597)	(44,868)
Income taxes payable/receivable, net	(657)	54,924
Net cash provided by operating activities	<u>\$ 201,319</u>	<u>\$ 243,840</u>
INVESTING ACTIVITIES:		
Capital expenditures, excluding capitalized interest	(23,025)	(16,733)
Capitalized interest payments	(1,840)	(1,133)
Acquisitions, including in-process research and development, net of cash and restricted cash acquired	(24,520)	—
Proceeds from sale of business and other assets, net	541	818
Net cash used in investing activities	<u>\$ (48,844)</u>	<u>\$ (17,048)</u>

ENDO INTERNATIONAL PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(Dollars in thousands)

	Three Months Ended March 31,	
	2022	2021
FINANCING ACTIVITIES:		
Proceeds from issuance of notes, net	—	1,279,978
Proceeds from issuance of term loans, net	—	1,980,000
Repayments of notes	(180,342)	—
Repayments of term loans	(5,000)	(3,295,475)
Repayments of other indebtedness	(1,470)	(1,321)
Payments for debt issuance and extinguishment costs	—	(5,904)
Payments for contingent consideration	(523)	(387)
Payments of tax withholding for restricted shares	(1,863)	(4,863)
Proceeds from exercise of options	—	622
Net cash used in financing activities	\$ (189,198)	\$ (47,350)
Effect of foreign exchange rate	331	399
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS	\$ (36,392)	\$ 179,841
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, BEGINNING OF PERIOD	1,631,310	1,385,000
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, END OF PERIOD	\$ 1,594,918	\$ 1,564,841

See accompanying Notes to Condensed Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
FOR THE THREE MONTHS ENDED MARCH 31, 2022

NOTE 1. BASIS OF PRESENTATION

Endo International plc is an Ireland-domiciled specialty pharmaceutical company that conducts business through its operating subsidiaries. Unless otherwise indicated or required by the context, references throughout to “Endo,” the “Company,” “we,” “our” or “us” refer to Endo International plc and its subsidiaries.

The accompanying unaudited Condensed Consolidated Financial Statements of Endo International plc and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X of the SEC for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying Condensed Consolidated Financial Statements of Endo International plc and its subsidiaries, which are unaudited, include all normal and recurring adjustments necessary for a fair statement of the Company’s financial position as of March 31, 2022 and the results of its operations and its cash flows for the periods presented. Operating results for the three months ended March 31, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. The year-end Condensed Consolidated Balance Sheet data as of December 31, 2021 was derived from audited financial statements but does not include all disclosures required by U.S. GAAP.

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our Consolidated Financial Statements and accompanying Notes included in the Annual Report.

Certain prior period amounts have been reclassified to conform to the current period presentation. The reclassification adjustments primarily relate to changes to the presentation of certain costs and expenses in our Condensed Consolidated Statements of Operations. Specifically, effective with the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022, the Company has added a new financial statement line item labeled Acquired in-process research and development. Any prior period amounts of acquired in-process research and development charges presented in this report have been reclassified to this line item from the existing financial statement line item labeled Research and development.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of our Condensed Consolidated Financial Statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts and disclosures in our Condensed Consolidated Financial Statements, including the Notes thereto, and elsewhere in this report. For example, we are required to make significant estimates and assumptions related to revenue recognition, including sales deductions, long-lived assets, goodwill, other intangible assets, income taxes, contingencies, financial instruments and share-based compensation, among others. Some of these estimates can be subjective and complex. Uncertainties related to the continued magnitude and duration of the COVID-19 pandemic, the extent to which it will impact our estimated future financial results, worldwide macroeconomic conditions including interest rates, employment rates, consumer spending, health insurance coverage, the speed of the anticipated recovery and governmental and business reactions to the pandemic, including any possible re-initiation of shutdowns or renewed restrictions, have increased the complexity of developing these estimates, including the allowance for expected credit losses and the carrying amounts of long-lived assets, goodwill and other intangible assets. Furthermore, as a result of the possibility or occurrence of an unfavorable outcome with respect to any legal proceeding, we have engaged in and, at any given time, may further engage in strategic reviews of all or a portion of our business. Any such review or contingency planning could ultimately result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. These actions could include a bankruptcy filing which could ultimately result in, among other things, asset impairment charges that may be material. Although we believe that our estimates and assumptions are reasonable, there may be other reasonable estimates or assumptions that differ significantly from ours. Further, our estimates and assumptions are based upon information available at the time they were made. Actual results may differ significantly from our estimates, including as a result of the uncertainties described in this report, those described in our other reports filed with the SEC or other uncertainties.

Significant Accounting Policies Added or Updated since December 31, 2021

There have been no significant changes to our significant accounting policies since December 31, 2021. For additional discussion of the Company’s significant accounting policies, see Note 2. Summary of Significant Accounting Policies in the Consolidated Financial Statements included in Part IV, Item 15 of the Annual Report.

NOTE 3. DISCONTINUED OPERATIONS**Astora**

The operating results of the Company's Astora business, which the Board of Directors (the Board) resolved to wind down in 2016, are reported as Discontinued operations, net of tax in the Condensed Consolidated Statements of Operations for all periods presented. The following table provides the operating results of Astora Discontinued operations, net of tax, for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Loss from discontinued operations before income taxes	\$ (6,674)	\$ (6,221)
Income tax benefit	\$ —	\$ (686)
Discontinued operations, net of tax	\$ (6,674)	\$ (5,535)

Loss from discontinued operations before income taxes includes mesh-related legal defense costs and certain other items.

The cash flows from discontinued operating activities related to Astora included the impact of net losses of \$6.7 million and \$5.5 million for the three months ended March 31, 2022 and 2021, respectively, and the impact of cash activity related to vaginal mesh cases. During the periods presented above, there were no material net cash flows related to Astora discontinued investing activities and there was no depreciation or amortization expense related to Astora.

NOTE 4. RESTRUCTURING**2020 Restructuring Initiative**

On November 5, 2020, the Company announced the initiation of several strategic actions to further optimize the Company's operations and increase overall efficiency (the 2020 Restructuring Initiative). These actions were initiated with the expectation of generating significant cost savings to be reinvested, among other things, to support the Company's key strategic priority to expand and enhance its product portfolio. These actions, which we have been progressing, include the following:

- Optimizing the Company's retail generics business cost structure by exiting manufacturing sites in Irvine, California and Chestnut Ridge, New York, as well as certain sites in India. Certain of the sites have already been exited and certain products historically manufactured at these sites have been transferred to other internal and external sites within the Company's manufacturing network.
- Improving operating flexibility and reducing general and administrative costs by transferring certain transaction processing activities to third-party global business process service providers.
- Increasing organizational effectiveness by further integrating the Company's commercial, operations and research and development functions, respectively, to support the Company's key strategic priorities.

As a result of the 2020 Restructuring Initiative, the Company's global workforce is ultimately expected to be reduced by up to approximately 500 net full-time positions. The Company expects to realize annualized pre-tax cash savings (without giving effect to the costs described below) of approximately \$85 million to \$95 million by the first half of 2023, primarily related to reductions in Cost of revenues of approximately \$65 million to \$70 million and other expenses, including Selling, general and administrative and Research and development expenses, of approximately \$20 million to \$25 million.

As a result of the 2020 Restructuring Initiative, the Company expects to incur total pre-tax restructuring-related expenses of approximately \$165 million to \$185 million, of which approximately \$140 million to \$155 million relates to the Generic Pharmaceuticals segment, with the remaining amounts relating to our other segments and certain corporate unallocated costs. These estimates consist of accelerated depreciation charges of approximately \$45 million to \$55 million, asset impairment charges of approximately \$50 million, employee separation, continuity and other benefit-related costs of approximately \$55 million to \$60 million and certain other restructuring costs of approximately \$15 million to \$20 million. Cash outlays associated with the 2020 Restructuring Initiative are expected to be approximately \$75 million and consist primarily of employee separation, continuity and other benefit-related costs and certain other restructuring costs. By the end of 2022, the Company expects that substantially all of these costs will have been incurred and substantially all related cash payments will have been made.

The following pre-tax net amounts related to the 2020 Restructuring Initiative are included in the Company's Condensed Consolidated Statements of Operations during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net restructuring charges related to:		
Accelerated depreciation	\$ 3,677	\$ 6,907
Inventory adjustments	766	5,049
Employee separation, continuity and other benefit-related costs	2,378	6,610
Certain other restructuring costs	574	858
Total	<u>\$ 7,395</u>	<u>\$ 19,424</u>

These pre-tax net amounts were primarily attributable to our Generic Pharmaceuticals segment, which incurred \$5.0 million and \$14.9 million of pre-tax net charges during the three months ended March 31, 2022 and 2021, respectively. The remaining amounts related to our other segments and certain corporate unallocated costs.

As of March 31, 2022, cumulative amounts incurred to date include charges related to accelerated depreciation of approximately \$50.9 million, asset impairments related to certain identifiable intangible assets, operating lease assets and disposal groups totaling approximately \$49.5 million, inventory adjustments of approximately \$10.8 million, employee separation, continuity and other benefit-related costs, net of approximately \$55.0 million and certain other restructuring costs of approximately \$3.3 million. Of these amounts, approximately \$133.9 million was attributable to the Generic Pharmaceuticals segment, with the remaining amounts relating to our other segments and certain corporate unallocated costs.

The following pre-tax net amounts related to the 2020 Restructuring Initiative are included in the Company's Condensed Consolidated Statements of Operations during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net restructuring charges included in:		
Cost of revenues	\$ 3,259	\$ 15,296
Selling, general and administrative	1,156	3,542
Research and development	2,980	586
Total	<u>\$ 7,395</u>	<u>\$ 19,424</u>

Changes to the liability for the 2020 Restructuring Initiative during the three months ended March 31, 2022 were as follows (in thousands):

	Employee Separation, Continuity and Other Benefit- Related Costs	Certain Other Restructuring Costs	Total
Liability balance as of December 31, 2021	\$ 10,979	\$ 205	\$ 11,184
Net charges	2,378	574	2,952
Cash payments	(7,785)	(779)	(8,564)
Liability balance as of March 31, 2022	<u>\$ 5,572</u>	<u>\$ —</u>	<u>\$ 5,572</u>

Of the liability at March 31, 2022, approximately \$5.1 million is classified as current and is included in Accounts payable and accrued expenses in the Condensed Consolidated Balance Sheets, with the remaining amount classified as noncurrent and included in Other liabilities.

2022 Restructuring Initiative

On April 28, 2022, the Company communicated the initiation of actions to streamline and simplify certain functions, including its commercial organization, to increase its overall organizational effectiveness and better align with current and future needs (the 2022 Restructuring Initiative). These actions were initiated with the expectation of generating cost savings, a portion of which will be reinvested in 2022 to support the Company's key strategic priority to expand and enhance its product portfolio.

As a result of the 2022 Restructuring Initiative, the Company's global workforce is ultimately expected to be reduced by up to approximately 125 net full-time positions. The Company expects to realize annualized pre-tax cash savings (without giving effect to the costs described below) of approximately \$55 million to \$65 million by the second quarter of 2023, primarily related to reductions in Selling, general and administrative expenses.

As a result of the 2022 Restructuring Initiative, the Company expects to incur total pre-tax restructuring-related expenses of approximately \$40 million to \$55 million, the majority of which relates to the Branded Pharmaceuticals segment, with the remaining amounts relating to our other segments and certain corporate unallocated costs. These estimates consist of employee separation, continuity and other benefit-related costs of approximately \$25 million to \$35 million and certain other restructuring costs of approximately \$15 million to \$20 million. Cash outlays associated with the 2022 Restructuring Initiative are expected to be approximately \$30 million and consist primarily of employee separation, continuity and other benefit-related costs. The Company anticipates these actions will be substantially completed by the second quarter of 2023, with substantially all cash payments made by then.

The following pre-tax net amounts related to the 2022 Restructuring Initiative are included in the Company's Condensed Consolidated Statements of Operations during the three months ended March 31, 2022 (in thousands):

	Three Months Ended March 31, 2022
Net restructuring charges related to:	
Inventory adjustments	\$ 1,557
Employee separation, continuity and other benefit-related costs	20,320
Certain other restructuring costs	7,555
Total	\$ 29,432

These pre-tax net amounts were primarily attributable to our Branded Pharmaceuticals segment, which incurred \$16.3 million of pre-tax net charges during the three months ended March 31, 2022. The remaining amounts related to our Generic Pharmaceuticals segment and certain corporate unallocated costs.

The following pre-tax net amounts related to the 2022 Restructuring Initiative are included in the Company's Condensed Consolidated Statements of Operations during the three months ended March 31, 2022 (in thousands):

	Three Months Ended March 31, 2022
Net restructuring charges included in:	
Cost of revenues	\$ 12,115
Selling, general and administrative	13,626
Research and development	3,691
Total	\$ 29,432

Changes to the liability for the 2022 Restructuring Initiative during the three months ended March 31, 2022 were as follows (in thousands):

	Employee Separation, Continuity and Other Benefit- Related Costs	Total
Liability balance as of December 31, 2021	\$ —	\$ —
Net charges	20,320	20,320
Cash payments	—	—
Liability balance as of March 31, 2022	\$ 20,320	\$ 20,320

Of the liability at March 31, 2022, approximately \$16.0 million is classified as current and is included in Accounts payable and accrued expenses in the Condensed Consolidated Balance Sheets, with the remaining amount classified as noncurrent and included in Other liabilities.

NOTE 5. SEGMENT RESULTS

The Company's four reportable business segments are Branded Pharmaceuticals, Sterile Injectables, Generic Pharmaceuticals and International Pharmaceuticals. These segments reflect the level at which the chief operating decision maker regularly reviews financial information to assess performance and to make decisions about resources to be allocated. Each segment derives revenue from the sales or licensing of its respective products and is discussed in more detail below.

We evaluate segment performance based on Segment adjusted income from continuing operations before income tax, which we define as (Loss) income from continuing operations before income tax and before acquired in-process research and development charges; acquisition-related and integration items, including transaction costs and changes in the fair value of contingent consideration; cost reduction and integration-related initiatives such as separation benefits, continuity payments, other exit costs and certain costs associated with integrating an acquired company's operations; certain amounts related to strategic review initiatives; asset impairment charges; amortization of intangible assets; inventory step-up recorded as part of our acquisitions; litigation-related and other contingent matters; certain legal costs; gains or losses from early termination of debt; debt modification costs; gains or losses from the sales of businesses and other assets; foreign currency gains or losses on intercompany financing arrangements; and certain other items.

Certain of the corporate expenses incurred by the Company are not directly attributable to any specific segment. Accordingly, these costs are not allocated to any of the Company's segments and are included in the results below as "Corporate unallocated costs." Interest income and expense are also considered corporate items and not allocated to any of the Company's segments. The Company's Total segment adjusted income from continuing operations before income tax is equal to the combined results of each of its segments.

Branded Pharmaceuticals

Our Branded Pharmaceuticals segment includes a variety of branded products in the areas of urology, orthopedics, endocrinology, medical aesthetics and bariatrics, among others. The products in this segment include XIAFLEX[®], SUPPRELIN[®] LA, NASCOBAL[®] Nasal Spray, AVEED[®], QWO[®], PERCOCET[®], TESTOPEL[®], EDEX[®] and LIDODERM[®], among others.

Sterile Injectables

Our Sterile Injectables segment consists primarily of branded sterile injectable products such as VASOSTRICT[®], ADRENALIN[®] and APLISOL[®], among others, and certain generic sterile injectable products, including ertapenem for injection (the authorized generic of Merck Sharp & Dohme Corp.'s (Merck) Invanz[®]) and ephedrine sulfate injection, among others.

Generic Pharmaceuticals

Our Generic Pharmaceuticals segment consists of a product portfolio including solid oral extended-release, solid oral immediate-release, liquids, semi-solids, patches, powders, ophthalmics and sprays and includes products that treat and manage a wide variety of medical conditions.

International Pharmaceuticals

Our International Pharmaceuticals segment includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin Labs Inc. (Paladin). The key products of this segment serve various therapeutic areas, including attention deficit hyperactivity disorder, pain, women's health, oncology and transplantation.

The following represents selected information for the Company's reportable segments for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net revenues from external customers:		
Branded Pharmaceuticals	\$ 204,861	\$ 206,635
Sterile Injectables	240,028	308,745
Generic Pharmaceuticals	185,944	180,873
International Pharmaceuticals (1)	21,426	21,666
Total net revenues from external customers	\$ 652,259	\$ 717,919
Segment adjusted income from continuing operations before income tax:		
Branded Pharmaceuticals	\$ 77,666	\$ 93,769
Sterile Injectables	191,254	242,639
Generic Pharmaceuticals	66,382	34,104
International Pharmaceuticals	4,381	7,471
Total segment adjusted income from continuing operations before income tax	\$ 339,683	\$ 377,983

(1) Revenues generated by our International Pharmaceuticals segment are primarily attributable to external customers located in Canada.

There were no material revenues from external customers attributed to an individual country outside of the U.S. during any of the periods presented.

The table below provides reconciliations of our Total consolidated (loss) income from continuing operations before income tax, which is determined in accordance with U.S. GAAP, to our Total segment adjusted income from continuing operations before income tax for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Total consolidated (loss) income from continuing operations before income tax	\$ (67,115)	\$ 47,783
Interest expense, net	134,949	134,341
Corporate unallocated costs (1)	43,281	39,474
Amortization of intangible assets	90,234	95,130
Acquired in-process research and development charges	2,900	—
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (2)	57,649	23,720
Certain litigation-related and other contingencies, net (3)	25,154	637
Certain legal costs (4)	32,732	19,276
Asset impairment charges (5)	19,953	3,309
Acquisition-related and integration items, net (6)	(1,377)	(5,022)
Loss on extinguishment of debt	—	13,753
Foreign currency impact related to the remeasurement of intercompany debt instruments	1,198	1,147
Other, net (7)	125	4,435
Total segment adjusted income from continuing operations before income tax	<u>\$ 339,683</u>	<u>\$ 377,983</u>

- (1) Amounts include certain corporate overhead costs, such as headcount, facility and corporate litigation expenses and certain other income and expenses.
- (2) Amounts for the three months ended March 31, 2022 include net employee separation, continuity and other benefit-related charges of \$32.3 million, accelerated depreciation charges of \$3.7 million and other net charges, including those related to strategic review initiatives, of \$21.6 million. Amounts for the three months ended March 31, 2021 include net employee separation, continuity and other benefit-related charges of \$8.5 million, accelerated depreciation charges of \$6.9 million and other net charges, including those related to strategic review initiatives, of \$8.3 million. These amounts relate primarily to our restructuring activities as further described in Note 4. Restructuring, certain continuity and transitional compensation arrangements, certain other cost reduction initiatives and certain strategic review initiatives.
- (3) Amounts include adjustments to our accruals for litigation-related settlement charges and certain settlement proceeds related to suits filed by our subsidiaries. Our material legal proceedings and other contingent matters are described in more detail in Note 13. Commitments and Contingencies.
- (4) Amounts relate to opioid-related legal expenses.
- (5) Amounts primarily relate to charges to impair intangible assets. For additional information, refer to Note 9. Goodwill and Other Intangibles.
- (6) Amounts primarily relate to changes in the fair value of contingent consideration.
- (7) Amounts for the three months ended March 31, 2021 primarily relate to \$3.9 million of third-party fees incurred in connection with the March 2021 Refinancing Transactions, which were accounted for as debt modification costs. Refer to Note 12. Debt for additional information. Other amounts in this row relate to gains and losses on sales of businesses and other assets and certain other items.

Asset information is not reviewed or included within our internal management reporting. Therefore, the Company has not disclosed asset information for each reportable segment.

During the three months ended March 31, 2022 and 2021, the Company disaggregated its revenue from contracts with customers into the categories included in the table below (in thousands). The Company believes these categories depict how the nature, timing and uncertainty of revenue and cash flows are affected by economic factors.

	Three Months Ended March 31,	
	2022	2021
Branded Pharmaceuticals:		
<i>Specialty Products:</i>		
XIAFLEX®	\$ 99,484	\$ 95,270
SUPPRELIN® LA	28,830	28,028
Other Specialty (1)	20,744	20,032
Total Specialty Products	\$ 149,058	\$ 143,330
<i>Established Products:</i>		
PERCOCET®	\$ 26,175	\$ 25,625
TESTOPEL®	8,880	11,189
Other Established (2)	20,748	26,491
Total Established Products	\$ 55,803	\$ 63,305
Total Branded Pharmaceuticals (3)	\$ 204,861	\$ 206,635
<i>Sterile Injectables:</i>		
VASOSTRICT®	\$ 155,890	\$ 223,946
ADRENALIN®	33,823	29,437
Other Sterile Injectables (4)	50,315	55,362
Total Sterile Injectables (3)	\$ 240,028	\$ 308,745
Total Generic Pharmaceuticals (5)	\$ 185,944	\$ 180,873
Total International Pharmaceuticals (6)	\$ 21,426	\$ 21,666
Total revenues, net	\$ 652,259	\$ 717,919

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, AVEED® and QWO®.

(2) Products included within Other Established include, but are not limited to, EDEX® and LIDODERM®.

(3) Individual products presented above represent the top two performing products in each product category for the three months ended March 31, 2022 and/or any product having revenues in excess of \$25 million during any quarterly period in 2022 or 2021.

(4) Products included within Other Sterile Injectables include ertapenem for injection, APLISOL® and others.

(5) The Generic Pharmaceuticals segment is comprised of a portfolio of products that are generic versions of branded products, are distributed primarily through the same wholesalers, generally have no intellectual property protection and are sold within the U.S. During the three months ended March 31, 2022, varenicline tablets (our generic version of Pfizer Inc.'s Chantix®), which launched in September 2021, made up 10% of consolidated total revenues. No other individual product within this segment has exceeded 5% of consolidated total revenues for the periods presented.

(6) The International Pharmaceuticals segment, which accounted for less than 5% of consolidated total revenues for each of the periods presented, includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through our operating company Paladin.

NOTE 6. FAIR VALUE MEASUREMENTS

Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Financial Instruments

The financial instruments recorded in our Condensed Consolidated Balance Sheets include cash and cash equivalents, restricted cash and cash equivalents, accounts receivable, accounts payable and accrued expenses, acquisition-related contingent consideration and debt obligations. Included in cash and cash equivalents and restricted cash and cash equivalents are money market funds representing a type of mutual fund required by law to invest in low-risk securities (for example, U.S. government bonds, U.S. Treasury Bills and commercial paper). Money market funds pay dividends that generally reflect short-term interest rates. Due to their initial maturities, the carrying amounts of non-restricted and restricted cash and cash equivalents (including money market funds), accounts receivable, accounts payable and accrued expenses approximate their fair values.

Restricted Cash and Cash Equivalents

Amounts reported as Restricted cash and cash equivalents in our Condensed Consolidated Balance Sheets at March 31, 2022 and December 31, 2021 include restricted cash and cash equivalents associated with litigation-related matters, including \$136.4 million and \$78.4 million, respectively, held in Qualified Settlement Funds (QSFs) for mesh- and opioid-related matters. See Note 13. Commitments and Contingencies for further information about litigation-related matters. Additionally, at both March 31, 2022 and December 31, 2021, approximately \$45.0 million of restricted cash and cash equivalents related to certain insurance-related matters.

Acquisition-Related Contingent Consideration

The fair value of contingent consideration liabilities is determined using unobservable inputs; hence, these instruments represent Level 3 measurements within the above-defined fair value hierarchy. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes recorded in earnings. The estimates of fair value are uncertain and changes in any of the estimated inputs used as of the date of this report could have resulted in significant adjustments to fair value. See the “Recurring Fair Value Measurements” section below for additional information on acquisition-related contingent consideration.

Recurring Fair Value Measurements

The Company’s financial assets and liabilities measured at fair value on a recurring basis at March 31, 2022 and December 31, 2021 were as follows (in thousands):

	Fair Value Measurements at March 31, 2022 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
Assets:				
Money market funds	\$ 15,079	\$ —	\$ —	\$ 15,079
Liabilities:				
Acquisition-related contingent consideration—current	\$ —	\$ —	\$ 4,674	\$ 4,674
Acquisition-related contingent consideration—noncurrent	\$ —	\$ —	\$ 13,302	\$ 13,302
	Fair Value Measurements at December 31, 2021 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
Assets:				
Money market funds	\$ 134,847	\$ —	\$ —	\$ 134,847
Liabilities:				
Acquisition-related contingent consideration—current	\$ —	\$ —	\$ 5,748	\$ 5,748
Acquisition-related contingent consideration—noncurrent	\$ —	\$ —	\$ 14,328	\$ 14,328

At March 31, 2022 and December 31, 2021, money market funds include \$15.1 million and \$16.2 million, respectively, in QSFs to be disbursed to litigation claimants. Amounts in QSFs are considered restricted cash equivalents. See Note 13. Commitments and Contingencies for further discussion of our litigation. At March 31, 2022 and December 31, 2021, the differences between the amortized cost and the fair value of our money market funds were not material, individually or in the aggregate.

Fair Value Measurements Using Significant Unobservable Inputs

The following table presents changes to the Company’s liability for acquisition-related contingent consideration, which is measured at fair value on a recurring basis using significant unobservable inputs (Level 3), for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Beginning of period	\$ 20,076	\$ 36,249
Amounts settled	(802)	(1,151)
Changes in fair value recorded in earnings	(1,377)	(5,453)
Effect of currency translation	79	118
End of period	\$ 17,976	\$ 29,763

At March 31, 2022, the fair value measurements of the contingent consideration obligations were determined using risk-adjusted discount rates ranging from 10.0% to 15.0% (weighted average rate of approximately 10.6%, weighted based on relative fair value). Changes in fair value recorded in earnings related to acquisition-related contingent consideration are included in our Condensed Consolidated Statements of Operations as Acquisition-related and integration items, net. Amounts recorded for the current and noncurrent portions of acquisition-related contingent consideration are included in Accounts payable and accrued expenses and Other liabilities, respectively, in our Condensed Consolidated Balance Sheets.

The following table presents changes to the Company's liability for acquisition-related contingent consideration during the three months ended March 31, 2022 by acquisition (in thousands):

	Balance as of December 31, 2021	Changes in Fair Value Recorded in Earnings	Amounts Settled and Other	Balance as of March 31, 2022
Auxilium acquisition	\$ 9,038	\$ (235)	\$ —	\$ 8,803
Lehigh Valley Technologies, Inc. acquisitions	3,600	(1,221)	(279)	2,100
Other	7,438	79	(444)	7,073
Total	<u>\$ 20,076</u>	<u>\$ (1,377)</u>	<u>\$ (723)</u>	<u>\$ 17,976</u>

Nonrecurring Fair Value Measurements

The Company's financial assets and liabilities measured at fair value on a nonrecurring basis during the three months ended March 31, 2022 were as follows (in thousands):

	Fair Value Measurements during the Three Months Ended March 31, 2022 (1) using:			Total Expense for the Three Months Ended March 31, 2022
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	
Intangible assets, excluding goodwill (2)	\$ —	\$ —	\$ 14,207	\$ (19,953)
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 14,207</u>	<u>\$ (19,953)</u>

(1) The fair value amounts are presented as of the date of the fair value measurement as these assets are not measured at fair value on a recurring basis. Such measurements generally occur in connection with our quarter-end financial reporting close procedures.

(2) These fair value measurements were determined using risk-adjusted discount rates ranging from 9.5% to 11.0% (weighted average rate of approximately 10.8%, weighted based on relative fair value).

NOTE 7. INVENTORIES

Inventories consist of the following at March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Raw materials (1)	\$ 96,832	\$ 90,453
Work-in-process (1)	73,520	82,728
Finished goods (1)	113,474	110,371
Total	<u>\$ 283,826</u>	<u>\$ 283,552</u>

(1) The components of inventory shown in the table above are net of allowance for obsolescence.

Inventory that is in excess of the amount expected to be sold within one year is classified as noncurrent inventory and is not included in the table above. At March 31, 2022 and December 31, 2021, \$22.7 million and \$10.7 million, respectively, of noncurrent inventory was included in Other assets in the Condensed Consolidated Balance Sheets. As of March 31, 2022 and December 31, 2021, the Company's Condensed Consolidated Balance Sheets included approximately \$11.3 million and \$12.2 million, respectively, of capitalized pre-launch inventories related to products that were not yet available to be sold.

NOTE 8. LEASES

The following table presents information about the Company's right-of-use assets and lease liabilities at March 31, 2022 and December 31, 2021 (in thousands):

	Balance Sheet Line Items	March 31, 2022	December 31, 2021
Right-of-use assets:			
Operating lease right-of-use assets	Operating lease assets	\$ 33,203	\$ 34,832
Finance lease right-of-use assets	Property, plant and equipment, net	36,054	38,365
Total right-of-use assets		<u>\$ 69,257</u>	<u>\$ 73,197</u>
Operating lease liabilities:			
Current operating lease liabilities	Current portion of operating lease liabilities	\$ 11,024	\$ 10,992
Noncurrent operating lease liabilities	Operating lease liabilities, less current portion	31,688	33,727
Total operating lease liabilities		<u>\$ 42,712</u>	<u>\$ 44,719</u>
Finance lease liabilities:			
Current finance lease liabilities	Accounts payable and accrued expenses	\$ 7,004	\$ 6,841
Noncurrent finance lease liabilities	Other liabilities	16,510	18,374
Total finance lease liabilities		<u>\$ 23,514</u>	<u>\$ 25,215</u>

The following table presents information about lease costs and expenses and sublease income for the three months ended March 31, 2022 and 2021 (in thousands):

	Statement of Operations Line Items	Three Months Ended March 31,	
		2022	2021
Operating lease cost	Various (1)	\$ 2,726	\$ 3,736
Finance lease cost:			
Amortization of right-of-use assets	Various (1)	\$ 2,311	\$ 2,311
Interest on lease liabilities	Interest expense, net	\$ 253	\$ 367
Other lease costs and income:			
Variable lease costs (2)	Various (1)	\$ 2,507	\$ 3,022
Sublease income	Various (1)	\$ (1,840)	\$ (933)

(1) Amounts are included in the Condensed Consolidated Statements of Operations based on the function that the underlying leased asset supports. The following table presents the components of such aggregate amounts for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cost of revenues	\$ 1,606	\$ 3,058
Selling, general and administrative	\$ 4,044	\$ 5,024
Research and development	\$ 54	\$ 54

(2) Amounts represent variable lease costs incurred that were not included in the initial measurement of the lease liability such as common area maintenance and utilities costs associated with leased real estate and certain costs associated with our automobile leases.

The following table provides certain cash flow and supplemental noncash information related to our lease liabilities for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash payments for operating leases	\$ 2,943	\$ 2,883
Operating cash payments for finance leases	\$ 437	\$ 548
Financing cash payments for finance leases	\$ 1,470	\$ 1,321

NOTE 9. GOODWILL AND OTHER INTANGIBLES

Goodwill

The following table presents information about our goodwill at March 31, 2022 and December 31, 2021 (in thousands):

	Branded Pharmaceuticals	Sterile Injectables	Generic Pharmaceuticals	International Pharmaceuticals	Total
Goodwill as of December 31, 2021	\$ 828,818	\$ 2,368,193	\$ —	\$ —	\$ 3,197,011
Goodwill as of March 31, 2022	\$ 828,818	\$ 2,368,193	\$ —	\$ —	\$ 3,197,011

The carrying amounts of goodwill at March 31, 2022 and December 31, 2021 are net of the following accumulated impairments (in thousands):

	Branded Pharmaceuticals	Sterile Injectables	Generic Pharmaceuticals	International Pharmaceuticals	Total
Accumulated impairment losses as of December 31, 2021	\$ 855,810	\$ 363,000	\$ 3,142,657	\$ 550,355	\$ 4,911,822
Accumulated impairment losses as of March 31, 2022	\$ 855,810	\$ 363,000	\$ 3,142,657	\$ 556,129	\$ 4,917,596

Other Intangible Assets

Changes in the amounts of other intangible assets for the three months ended March 31, 2022 are set forth in the table below (in thousands).

Cost basis:	Balance as of December 31, 2021	Acquisitions	Impairments	Effect of Currency Translation	Balance as of March 31, 2022
Licenses (weighted average life of 14 years)	\$ 442,107	\$ —	\$ —	\$ —	\$ 442,107
Tradenames	6,409	—	—	—	6,409
Developed technology (weighted average life of 12 years)	6,226,139	—	(19,953)	2,701	6,208,887
Total other intangibles (weighted average life of 12 years years)	\$ 6,674,655	\$ —	\$ (19,953)	\$ 2,701	\$ 6,657,403
Accumulated amortization:	Balance as of December 31, 2021	Amortization	Impairments	Effect of Currency Translation	Balance as of March 31, 2022
Licenses	\$ (419,932)	\$ (1,144)	\$ —	\$ —	\$ (421,076)
Tradenames	(6,409)	—	—	—	(6,409)
Developed technology	(3,885,491)	(89,090)	—	(2,066)	(3,976,647)
Total other intangibles	\$ (4,311,832)	\$ (90,234)	\$ —	\$ (2,066)	\$ (4,404,132)
Net other intangibles	\$ 2,362,823				\$ 2,253,271

Amortization expense for the three months ended March 31, 2022 and 2021 totaled \$90.2 million and \$95.1 million, respectively. Amortization expense is included in Cost of revenues in the Condensed Consolidated Statements of Operations.

Impairments

Goodwill and, if applicable, indefinite-lived intangible assets are tested for impairment annually and when events or changes in circumstances indicate that the asset might be impaired. Our annual assessment is performed as of October 1.

As part of our goodwill and intangible asset impairment assessments, we estimate the fair values of our reporting units and our intangible assets using an income approach that utilizes a discounted cash flow model or, where appropriate, a market approach.

The discounted cash flow models are dependent upon our estimates of future cash flows and other factors including estimates of (i) future operating performance, including future sales, long-term growth rates, gross margins, operating expenses, discount rate and the probability of achieving the estimated cash flows and (ii) future economic conditions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rates applied to the estimated cash flows are determined depending on the overall risk associated with the particular assets and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. Any impairment charges resulting from annual or interim goodwill and intangible asset impairment assessments are recorded to Asset impairment charges in our Condensed Consolidated Statements of Operations.

During the three months ended March 31, 2022 and 2021, we incurred asset impairment charges of \$20.0 million and \$2.9 million, respectively, associated with other intangible assets and we did not record any goodwill impairment charges. These pre-tax non-cash asset impairment charges related primarily to certain developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability.

NOTE 10. CONTRACT ASSETS AND LIABILITIES

Our revenue consists almost entirely of sales of our products to customers, whereby we ship products to a customer pursuant to a purchase order. Revenue contracts such as these do not generally give rise to contract assets or contract liabilities because: (i) the underlying contracts generally have only a single performance obligation and (ii) we do not generally receive consideration until the performance obligation is fully satisfied. At March 31, 2022, the unfulfilled performance obligations for these types of contracts relate to ordered but undelivered products. We generally expect to fulfill the performance obligations and recognize revenue within one week of entering into the underlying contract. Based on the short-term initial contract duration, additional disclosure about the remaining performance obligations is not required.

Certain of our other revenue-generating contracts, including license and collaboration agreements, may result in contract assets and/or contract liabilities. For example, we may recognize contract liabilities upon receipt of certain upfront and milestone payments from customers when there are remaining performance obligations.

The following table shows the opening and closing balances of contract assets and contract liabilities from contracts with customers (dollars in thousands):

	March 31, 2022	December 31, 2021	\$ Change	% Change
Contract assets, net (1)	\$ 12,925	\$ 13,005	\$ (80)	(1)%
Contract liabilities, net (2)	\$ 4,522	\$ 4,663	\$ (141)	(3)%

- (1) At March 31, 2022 and December 31, 2021, approximately \$3.0 million and \$2.8 million, respectively, of these contract asset amounts are classified as current and are included in Prepaid expenses and other current assets in the Company's Condensed Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other assets.
- (2) At March 31, 2022 and December 31, 2021, approximately \$0.6 million and \$0.6 million, respectively, of these contract liability amounts are classified as current and are included in Accounts payable and accrued expenses in the Company's Condensed Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other liabilities. During the three months ended March 31, 2022, approximately \$0.1 million of revenue was recognized that was included in the contract liability balance at December 31, 2021.

During the three months ended March 31, 2022, we recognized revenue of \$1.3 million relating to performance obligations satisfied, or partially satisfied, in prior periods. Such revenue generally relates to changes in estimates with respect to our variable consideration.

NOTE 11. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Trade accounts payable	\$ 101,007	\$ 123,129
Returns and allowances	179,649	183,116
Rebates	135,115	150,039
Chargebacks	2,516	2,617
Other sales deductions	2,358	2,500
Accrued interest	159,363	106,735
Accrued payroll and related benefits	81,252	90,029
Accrued royalties and other distribution partner payables	34,176	58,422
Acquisition-related contingent consideration—current	4,674	5,748
Other	108,168	114,563
Total	<u>\$ 808,278</u>	<u>\$ 836,898</u>

NOTE 12. DEBT

The following table presents information about the Company's total indebtedness at March 31, 2022 and December 31, 2021 (dollars in thousands):

	March 31, 2022			December 31, 2021		
	Effective Interest Rate	Principal Amount	Carrying Amount	Effective Interest Rate	Principal Amount	Carrying Amount
7.25% Senior Notes due 2022		\$ —	\$ —	7.25 %	\$ 8,294	\$ 8,294
5.75% Senior Notes due 2022		—	—	5.75 %	172,048	172,048
5.375% Senior Notes due 2023	5.62 %	6,127	6,116	5.62 %	6,127	6,111
6.00% Senior Notes due 2023	6.28 %	56,436	56,239	6.28 %	56,436	56,203
5.875% Senior Secured Notes due 2024	6.14 %	300,000	298,099	6.14 %	300,000	297,928
6.00% Senior Notes due 2025	6.27 %	21,578	21,425	6.27 %	21,578	21,413
7.50% Senior Secured Notes due 2027	7.70 %	2,015,479	1,998,469	7.70 %	2,015,479	1,997,777
9.50% Senior Secured Second Lien Notes due 2027	9.68 %	940,590	933,579	9.68 %	940,590	933,330
6.00% Senior Notes due 2028	6.11 %	1,260,416	1,252,911	6.11 %	1,260,416	1,252,667
6.125% Senior Secured Notes due 2029	6.34 %	1,295,000	1,279,165	6.34 %	1,295,000	1,278,718
Term Loan Facility	6.12 %	1,980,000	1,943,905	6.12 %	1,985,000	1,947,633
Revolving Credit Facility	2.75 %	277,200	277,200	2.63 %	277,200	277,200
Total long-term debt, net		\$ 8,152,826	\$ 8,067,108		\$ 8,338,168	\$ 8,249,322
Less: current portion, net		26,127	26,116		200,342	200,342
Total long-term debt, less current portion, net		\$ 8,126,699	\$ 8,040,992		\$ 8,137,826	\$ 8,048,980

The Company and its subsidiaries, with certain customary exceptions, guarantee or serve as issuers or borrowers of the debt instruments representing substantially all of the Company's indebtedness at March 31, 2022. The obligations under (i) the 5.875% Senior Secured Notes due 2024, (ii) the 7.50% Senior Secured Notes due 2027, (iii) the 6.125% Senior Secured Notes due 2029 and (iv) the Credit Agreement (as defined below) and related loan documents are secured on a *pari passu* basis by a first priority lien (subject to certain permitted liens) on the collateral securing such instruments, which collateral represents substantially all of the assets of the issuers or borrowers and the guarantors party thereto (subject to customary exceptions). The obligations under the 9.50% Senior Secured Second Lien Notes due 2027 are secured by a second priority lien (subject to certain permitted liens) on, and on a junior basis with respect to, the collateral securing the obligations under the Credit Agreement, the 5.875% Senior Secured Notes due 2024, the 7.50% Senior Secured Notes due 2027 and the 6.125% Senior Secured Notes due 2029 and the related guarantees. Our senior unsecured notes are unsecured and effectively subordinated in right of priority to the obligations under the Credit Agreement, the 5.875% Senior Secured Notes due 2024, the 7.50% Senior Secured Notes due 2027, the 9.50% Senior Secured Second Lien Notes due 2027 and the 6.125% Senior Secured Notes due 2029, in each case to the extent of the value of the collateral securing such instruments.

The aggregate estimated fair value of the Company's long-term debt, which was estimated using inputs based on quoted market prices for the same or similar debt issuances, was \$7.1 billion and \$8.0 billion at March 31, 2022 and December 31, 2021, respectively. Based on this valuation methodology, we determined these debt instruments represent Level 2 measurements within the fair value hierarchy.

Credit Facilities

The Company and certain of its subsidiaries are party to the Credit Agreement, which, immediately following the March 2021 Refinancing Transactions (as defined and further described below) provided for (i) a \$1,000.0 million senior secured revolving credit facility (the Revolving Credit Facility) and (ii) a \$2,000.0 million senior secured term loan facility (the Term Loan Facility and, together with the Revolving Credit Facility, the Credit Facilities). Current amounts outstanding as of March 31, 2022 under the Credit Facilities are set forth in the table above. As of March 31, 2022, \$76.0 million of commitments under the Revolving Credit Facility have matured and \$924.0 million of commitments remain outstanding under the Revolving Credit Facility. After giving effect to net borrowings under the Revolving Credit Facility and issued and outstanding letters of credit, approximately \$639.9 million of remaining credit is available under the Revolving Credit Facility as of March 31, 2022. Additionally, the Company's outstanding debt agreements contain a number of restrictive covenants, including certain limitations on the Company's ability to incur additional indebtedness.

As of March 31, 2022 and December 31, 2021, we were in compliance with all covenants contained in the Credit Agreement.

Senior Notes and Senior Secured Notes

As of March 31, 2022 and December 31, 2021, we were in compliance with all covenants contained in the indentures governing our various senior notes and senior secured notes.

Debt Financing Transactions

Set forth below are certain disclosures relating to debt financing transactions that occurred during the three months ended March 31, 2022 or the year ended December 31, 2021. For additional disclosures relating to debt financing transactions that occurred during the year ended December 31, 2021, refer to Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of the Annual Report.

March 2021 Refinancing

In March 2021, the Company executed certain transactions (the March 2021 Refinancing Transactions) that included:

- refinancing in full its previously-existing term loans, which had approximately \$3,295.5 million of principal outstanding immediately before refinancing (the Existing Term Loans), with the proceeds from: (i) a new \$2,000.0 million term loan (the Term Loan Facility) and (ii) \$1,295.0 million of newly issued 6.125% Senior Secured Notes due 2029 (collectively, the Term Loan Refinancing);
- extending the maturity of approximately \$675.3 million of existing revolving commitments under the Revolving Credit Facility to March 2026; and
- making certain other modifications to the credit agreement that was in effect immediately prior to the March 2021 Refinancing Transactions (the Prior Credit Agreement).

The changes to the Credit Facilities and the Prior Credit Agreement were effected pursuant to an amendment and restatement agreement entered into by the Company in March 2021 (the Restatement Agreement), which amended and restated the Prior Credit Agreement (as amended and restated by the Restatement Agreement, the Credit Agreement), among Endo International plc, certain of its subsidiaries, the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent, issuing bank and swingline lender.

The \$2,000.0 million portion of the Term Loan Refinancing associated with the new term loan was accounted for as a debt modification, while the \$1,295.0 million portion associated with the new notes issued was accounted for as an extinguishment. During the first quarter of 2021, in connection with the Term Loan Refinancing, \$7.8 million of deferred and unamortized costs associated with the Existing Term Loans, representing the portion associated with the extinguishment, was charged to expense and is included in the Loss on extinguishment of debt line item in the Condensed Consolidated Statements of Operations. The Company also incurred an additional \$56.7 million of new costs and fees, of which: (i) \$29.2 million and \$17.6 million have been deferred to be amortized as interest expense over the terms of the Term Loan Facility and the newly issued 6.125% Senior Secured Notes due 2029, respectively; (ii) \$6.0 million was considered debt extinguishment costs and was charged to expense in the first quarter of 2021 and is included in the Loss on extinguishment of debt line item in the Condensed Consolidated Statements of Operations; and (iii) \$3.9 million was considered debt modification costs and was charged to expense in the first quarter of 2021 and is included in the Selling, general and administrative expense line item in the Condensed Consolidated Statements of Operations.

During the first quarter of 2021, the Company also incurred \$2.1 million of new costs and fees associated with the extension of the Revolving Credit Facility, which have been deferred and are being amortized as interest expense over the new term of the Revolving Credit Facility.

October 2021 Revolving Credit Facility Repayment and January 2022 Senior Notes Repayments

In October 2021, commitments under the Revolving Credit Facility of approximately \$76.0 million matured, thereby reducing the remaining commitments outstanding under the Revolving Credit Facility. This maturity, which reduced the remaining credit available under the Revolving Credit Facility, occurred because the 7.25% Senior Notes due 2022 and the 5.75% Senior Notes due 2022 were not refinanced or repaid in full prior to the date that was 91 days prior to their January 15, 2022 maturity dates. As a result of this maturity, the Company repaid approximately \$22.8 million of borrowings in October 2021, representing the amount that had been borrowed pursuant to these matured commitments. The 7.25% Senior Notes due 2022 and the 5.75% Senior Notes due 2022 were repaid in January 2022.

NOTE 13. COMMITMENTS AND CONTINGENCIES

Legal Proceedings and Investigations

We and certain of our subsidiaries are involved in various claims, legal proceedings and internal and governmental investigations (collectively, proceedings) arising from time to time, including, among others, those relating to product liability, intellectual property, regulatory compliance, consumer protection, tax and commercial matters. While we cannot predict the outcome of these proceedings and we intend to vigorously prosecute or defend our position as appropriate, there can be no assurance that we will be successful or obtain any requested relief. An adverse outcome in any of these proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows. We are subject to a number of matters that are not being disclosed herein because, in the opinion of our management, these matters are immaterial both individually and in the aggregate with respect to our financial position, results of operations and cash flows.

We believe that certain settlements and judgments, as well as legal defense costs, relating to certain product liability or other matters are or may be covered in whole or in part under our 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 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 realization of the potential claim for recovery is considered probable.

Notwithstanding the foregoing, amounts recovered under our insurance policies could be materially less than stated coverage limits and may not be adequate to cover damages, other relief and/or costs relating to claims. In addition, there is no guarantee that insurers will pay claims in the amounts we expect or that coverage will otherwise be available. We may not have and may be unable to obtain or maintain insurance on acceptable terms or with adequate coverage against potential liabilities or other losses, including costs, judgments, settlements and other liabilities incurred in connection with current or future legal proceedings, regardless of the success or failure of the claim. For example, we do not have insurance sufficient to satisfy all of the opioid claims that have been made against us and, should we suffer an adverse judgment, appeal and similar bonds may not be available in such amounts as may be necessary to further challenge all or part of such judgment. We also generally no longer have product liability insurance to cover claims in connection with the mesh-related litigation described herein. Additionally, we may be limited by the surviving insurance policies of acquired entities, which may not be adequate to cover potential liabilities or other losses. Even where claims are submitted to insurance carriers for defense and indemnity, there can be no assurance that the claims will be covered by insurance or that the indemnitors or insurers will remain financially viable or will not challenge our right to reimbursement in whole or in part. The failure to generate sufficient cash flow or to obtain other financing could affect our ability to pay the amounts due under those liabilities not covered by insurance. Additionally, the nature of our business, the legal proceedings to which we are exposed and any losses we suffer may increase the cost of insurance, which could impact our decisions regarding our insurance programs.

As a result of the possibility or occurrence of an unfavorable outcome with respect to any legal proceeding, we have engaged in and, at any given time, may further engage in strategic reviews of all or a portion of our business. Any such review or contingency planning could ultimately result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. Actions that may be evaluated or pursued could include reorganization or restructuring activities of all or a portion of our business, asset sales or other divestitures, cost-saving initiatives or other corporate realignments, seeking strategic partnerships and exiting certain product or geographic markets. Some of these actions could take significant time to implement and others may require judicial or other third-party approval. As further described below, thousands of governmental persons and entities and private plaintiffs have filed suit against us and/or certain of our subsidiaries alleging opioid-related claims. We have not been able to settle most of the opioid claims made against us and, as a result, we are exploring a wide array of potential actions as part of our contingency planning. These actions could include a bankruptcy filing which, if it were to occur, would subject us to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, including, but not limited to, by causing increased difficulty obtaining and maintaining commercial relationships on competitive terms with customers, suppliers and other counterparts; increased difficulty retaining and motivating key employees, as well as attracting new employees; diversion of management's time and attention to dealing with bankruptcy and restructuring activities rather than focusing exclusively on business operations; incurrence of substantial costs, fees and other expenses associated with bankruptcy proceedings; and loss of ability to maintain or obtain sufficient financing sources for operations or to fund any reorganization plan and meet future obligations. We would, in that event, also be subject to risks and uncertainties caused by the actions of creditors and other third parties with interests that may be inconsistent with our plans. Certain of these risks and uncertainties could also occur if our suppliers or other third parties believe that we may pursue one or more significant corporate transactions or other remedial measures.

As of March 31, 2022, our accrual for loss contingencies totaled \$533.5 million, the most significant components of which relate to: (i) product liability and related matters associated with transvaginal surgical mesh products, which we have not sold since March 2016 and (ii) various opioid-related matters as further described herein. Although we believe there is a 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. As of March 31, 2022, \$528.5 million of our accrual for loss contingencies is classified in the Current portion of legal settlement accrual in the Condensed Consolidated Balance Sheets, with the remainder classified as Long-term legal settlement accrual, less current portion. The timing of the resolution of certain of these matters remains uncertain.

Vaginal Mesh Matters

Since 2008, we and certain of our subsidiaries, including American Medical Systems Holdings, Inc. (AMS) (subsequently converted to Astora Women's Health Holding LLC and merged into Astora Women's Health LLC and referred to herein as AMS and/or Astora), have been named as defendants in multiple lawsuits in various state and federal courts in the U.S., Canada, Australia and other countries, alleging personal injury resulting from the use of transvaginal surgical mesh products designed to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). We have not sold such products since March 2016. Plaintiffs claim a variety of personal injuries, including chronic pain, incontinence, inability to control bowel function and permanent deformities, and seek compensatory and punitive damages, where available.

Various Master Settlement Agreements (MSAs) and other agreements have resolved approximately 71,000 filed and unfiled U.S. mesh claims as of March 31, 2022. These MSAs and other agreements were entered into at various times between June 2013 and the present, were solely by way of compromise and settlement and were not 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 the settlement funds will be deposited, establish participation requirements and allow for a reduction of the total settlement payment in the event participation thresholds are not met. Funds deposited in QSFs are considered restricted cash and/or restricted cash equivalents. Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating product use, the dismissal of any lawsuit and the release of the claim as to us and all affiliates. Prior to receiving funds, an individual claimant must 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 settlement funds, amounts allocated to individual claimants and other terms of the agreements.

The following table presents the changes in the mesh-related QSFs and liability accrual balances during the three months ended March 31, 2022 (in thousands):

	Mesh Qualified Settlement Funds	Mesh Liability Accrual
Balance as of December 31, 2021	\$ 78,402	\$ 258,137
Additional charges	—	—
Cash contributions to Qualified Settlement Funds, net	—	—
Cash distributions to settle disputes from Qualified Settlement Funds	(4,978)	(4,978)
Other cash distributions to settle disputes	—	(2,674)
Other (1)	1	590
Balance as of March 31, 2022	<u>\$ 73,425</u>	<u>\$ 251,075</u>

(1) Amounts deposited in the QSFs may earn interest, which is generally used to pay administrative costs of the funds and is reflected in the table above as an increase to the QSF and Mesh Liability Accrual balances. Any interest remaining after all claims have been paid will generally be distributed to the claimants who participated in that settlement. Also included within this line are foreign currency adjustments for settlements not denominated in U.S. dollars.

Charges related to vaginal mesh liability and associated legal fees and other expenses for all periods presented are reported in Discontinued operations, net of tax in our Condensed Consolidated Statements of Operations.

As of March 31, 2022, the Company has made total cumulative mesh liability payments of approximately \$3.6 billion, \$73.4 million of which remains in the QSFs as of March 31, 2022. We currently expect to fund all of the remaining payments under all previously executed mesh settlement agreements within the next 12 months. As funds are disbursed out of the QSFs from time to time, the 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 liability accrual and decrease cash and cash equivalents.

We were contacted in October 2012 regarding a civil investigation initiated by various U.S. 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 subsequently received additional subpoenas from California and other states. We are cooperating with the investigations.

We will continue to vigorously defend any unresolved claims and to explore other options as appropriate in our best interests. The next trial is currently scheduled to begin in September 2022. Trials may occur earlier or later than currently scheduled, as timing remains uncertain due to the impact of COVID-19 and other factors.

Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any additional losses that could be incurred.

Although the Company believes it has appropriately estimated the probable total amount of loss associated with all mesh-related matters as of the date of this report, litigation is ongoing in certain cases that have not settled, and it is reasonably possible that further claims may be filed or asserted and that adjustments to our overall liability accrual may be required. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Opioid-Related Matters

Since 2014, multiple U.S. states as well as other governmental persons or entities and private plaintiffs in the U.S. and Canada have filed suit against us and/or certain of our subsidiaries, including Endo Health Solutions Inc. (EHSI), Endo Pharmaceuticals Inc. (EPI), Par Pharmaceutical, Inc. (PPI), Par Pharmaceutical Companies, Inc. (PPCI), Endo Generics Holdings, Inc. (EGHI), Vintage Pharmaceuticals, LLC, Generics Bidco I, LLC, DAVA Pharmaceuticals, LLC, Par Sterile Products, LLC (PSP LLC) and in Canada, Paladin and Endo Ventures Limited, as well as various other manufacturers, distributors, pharmacies and/or others, asserting claims relating to the defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications, including certain of our products. As of April 28, 2022, filed cases in the U.S. of which we were aware include, but are not limited to, approximately 20 cases filed by or on behalf of states; approximately 2,925 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 310 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers and approximately 215 cases filed by individuals, including but not limited to legal guardians of children born with neonatal abstinence syndrome. Certain of the U.S. cases have been filed as putative class actions; to date, however, no court has certified a litigation class. The Canadian cases include an action filed by British Columbia on behalf of a proposed class of all federal, provincial and territorial governments and agencies in Canada that paid healthcare, pharmaceutical and treatment costs related to opioids; an action filed in Alberta by the City of Grand Prairie, Alberta, and The Corporation of the City of Brantford, Ontario, on behalf of a proposed class of all local or municipal governments in Canada; an action filed in Saskatchewan by the Peter Ballantyne Cree Nation and the Lac La Ronge Indian Band, on behalf of a proposed class of all First Nations communities and local or municipal governments in Canada; and five additional putative class actions, filed in British Columbia, Manitoba, Ontario and Quebec, seeking relief on behalf of Canadian residents who were prescribed and/or consumed opioid medications.

The complaints in the cases assert a variety of claims, including but not limited to statutory claims asserting violations of public nuisance, consumer protection, unfair trade practices, racketeering, Medicaid fraud and/or drug dealer liability laws and/or common law claims for public nuisance, fraud/misrepresentation, strict liability, negligence and/or unjust enrichment. The claims are generally based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or alleged failures to take adequate steps to identify and report suspicious orders and to prevent abuse and diversion. Plaintiffs have sought various remedies including, without limitation, declaratory and/or injunctive relief; compensatory, punitive and/or treble damages; restitution, disgorgement, civil penalties, abatement, attorneys' fees, costs and/or other relief. The damages sought exceed our applicable insurance.

Many of the U.S. cases have been coordinated in a federal multidistrict litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio; however, in April 2022, the Judicial Panel on Multidistrict Litigation issued an order suggesting that, based on the progress of the MDL, it would no longer transfer new cases filed in or removed to federal court to the MDL. Other cases are pending in various federal or state courts. A case in Superior Court in Orange County, California, *People of the State of California v. Purdue Pharma L.P., et al.*, has been tried to verdict. The plaintiffs in the case, Orange, Santa Clara and Los Angeles Counties and the City of Oakland, asserted claims against EPI and EHESI, among others, for public nuisance, alleged violations of California's Unfair Competition Law and alleged violations of California's False Advertising Law. Following a bench trial on liability, the court issued a final decision in defendants' favor on all counts in December 2021. The plaintiffs filed a notice of appeal in February 2022. Other opioid-related cases are at various stages in the litigation process. Some cases are at the pleading or discovery stage; others are approaching the trial stage. Certain cases have been stayed pending settlement discussions; excluding such cases the next trial is currently set to begin in early 2023. Trials may occur earlier or later than currently scheduled, as timing remains uncertain due to the impact of COVID-19 and other factors.

In September 2019, EPI, EHESI, PPI and PPCI received subpoenas from the New York State Department of Financial Services (DFS) seeking documents and information regarding the marketing, sale and distribution of opioid medications in New York. In June 2020, DFS commenced an administrative action against the Company, EPI, EHESI, PPI and PPCI alleging violations of the New York Insurance Law and New York Financial Services Law. In July 2021, DFS filed an amended statement of charges. The amended statement of charges alleges that fraudulent or otherwise wrongful conduct in the marketing, sale and/or distribution of opioid medications caused false claims to be submitted to insurers and seeks civil penalties for each allegedly fraudulent prescription as well as injunctive relief. In July 2021, EPI, EHESI, PPI and PPCI, among others, filed a petition for judgment in New York state court seeking to prohibit DFS from proceeding with its administrative enforcement action. In December 2021, DFS filed a motion to dismiss that proceeding, which remains pending.

In February 2022, the court in *Dunaway, et al. v. Purdue Pharma, L.P., et al.* (now known as *Bedford County, et al. v. AmerisourceBergen Drug Corp., et al.*), a case pending in the Circuit Court for Cumberland County, Tennessee, entered an order imposing certain sanctions, including a default judgment on liability, against EPI and EHSI based on alleged discovery improprieties in a different case which EPI and EHSI had settled in August 2021. Because discovery in the earlier case had also been provided to the *Dunaway* plaintiffs, the *Dunaway* court deemed the alleged discovery improprieties to have occurred in *Dunaway* as well. The sanctions order also severed EPI and EHSI from the remaining defendants and set a damages trial to begin in April 2023. In a separate order, the *Dunaway* court denied a motion by EPI and EHSI to disqualify the judge based on, among other things, statements he made about the lawsuit to the press and on Facebook. In March 2022, EPI and EHSI appealed both orders. In April 2022, the Tennessee Court of Appeals, ruling on the appeal of the disqualification order, reversed the trial court's order denying disqualification, vacated the sanctions order and remanded the case for reassignment to a different judge. It also denied the separate appeal of the sanctions order as moot.

Since 2019, the Company and/or certain of its subsidiaries have executed a number of settlement agreements to resolve governmental opioid claims brought by certain states, counties, cities and/or other governmental entities. Certain related developments include but are not limited to the following:

- In September 2019, EPI, EHSI, PPI and PPCI executed a settlement agreement with two Ohio counties providing for payments totaling \$10 million and up to \$1 million of VASOSTRICT® and/or ADRENALIN®.
- In January 2020, EPI and PPI executed a settlement agreement with the state of Oklahoma providing for a payment of \$8.75 million.
- In August 2021, EPI, EHSI, nine counties in eastern Tennessee, eighteen municipalities within those counties and a minor individual executed a settlement agreement providing for a payment of \$35 million.
- In September 2021, Endo International plc, EPI, EHSI, PPI and PPCI executed a settlement agreement with the state of New York and two of its counties providing for a payment of \$50 million.
- In October 2021, EPI and EHSI executed a settlement agreement with the Alabama Attorney General's office intended to resolve opioid-related cases and claims of the state and other Alabama governmental persons and entities in exchange for a total payment of \$25 million.
- In December 2021, Endo International plc, EPI, EHSI, PPI and PPCI executed a settlement agreement with the Texas Attorney General's office and four Texas counties intended to resolve opioid-related cases and claims of the state and other Texas governmental persons and entities in exchange for a total payment of \$63 million.
- In January 2022, EPI and EHSI executed a settlement agreement with the Florida Attorney General's office intended to resolve opioid-related cases and claims of the state and other Florida governmental persons and entities in exchange for a total payment of up to \$65 million.
- In February 2022, EPI and EHSI executed a settlement agreement with the Louisiana Attorney General's office intended to resolve opioid-related cases and claims of the state and other Louisiana governmental persons and entities in exchange for a total payment of \$7.5 million.
- In March 2022, EPI, EHSI and PPI executed a settlement agreement with the West Virginia Attorney General's office intended to resolve opioid-related cases and claims of the state and other West Virginia governmental persons and entities in exchange for a total payment of \$26 million.

Each agreement was solely by way of compromise and settlement and was not in any way an admission of wrongdoing, fault or liability of any kind by us or any of our subsidiaries.

While the specific terms of the agreements vary, the Alabama, Florida, Louisiana, Texas and West Virginia settlements are each subject to participation by the state's political subdivisions. Certain agreements also provide for injunctive relief. Some agreements provide for additional payments in the event certain conditions, such as a comprehensive resolution of government-related opioid claims, are met; Florida may also be entitled to additional payments in the event we enter into a settlement with the attorney general of a state with a smaller population than Florida for an amount greater than \$65 million prior to November 15, 2022.

To date, Florida and Texas have met the required participation thresholds. In some states, certain governmental entities have declined to participate in the settlements and/or actively taken steps to try to challenge the release of their claims. For example:

- The plaintiffs in *Mobile County Board of Health, et al. v. Richard Sackler, et al.*, a case pending in the Circuit Court of Mobile County, Alabama, have to date refused to dismiss their claims against our subsidiaries. In April 2022, EPI and EHSI filed a motion in *State of Alabama v. Endo Health Solutions Inc., et al.*, which is pending in the Circuit Court of Montgomery County, Alabama, seeking an order enjoining the *Mobile County Board of Health* plaintiffs from continuing their case and directing their compliance with the Alabama settlement. The Alabama Attorney General filed a brief supporting this motion, which remains pending. Meanwhile, the *Mobile County Board of Health* plaintiffs filed a separate motion in their own lawsuit, seeking a declaration that they are not bound by the Alabama settlement; the Mobile County court denied that motion in April 2022.
- In March 2022, two public hospitals in Florida filed an emergency motion to intervene in *State of Florida v. Walgreen Co.* to stay court approval of our subsidiaries' settlement in Florida. In April 2022, the court denied the motion to intervene and entered a final consent judgment dismissing the state's claims against EPI and EHSI with prejudice. Meanwhile, the Florida Attorney General commenced a separate declaratory judgment action against those same public hospitals, as well as additional public hospitals and a school board, in a different Florida state court, seeking a judicial declaration that their claims were released by the Florida Attorney General's settlements with EPI, EHSI and other companies. The declaratory judgment action remains pending.

It is reasonably possible that other governmental persons or entities in states where we have reached settlements will bring similar challenges or otherwise continue to bring and/or litigate claims against us and our subsidiaries notwithstanding the settlements. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Certain settlement agreements provide for the creation of QSFs into which settlement funds will be deposited and/or provide for the repayment of some or all of the settlement amount under certain conditions. Depending on the terms of the respective agreements, funds deposited in QSFs have been and may continue to be considered restricted cash and/or restricted cash equivalents for a period of time subsequent to the initial funding. Distribution of funds from the QSF is conditioned upon certain criteria that vary by agreement.

We recorded total charges for opioid-related matters of \$10.0 million during the three months ended March 31, 2022 and, as of March 31, 2022, our corresponding accrual totaled \$268.7 million. In addition to the developments described above, our accrual for opioid-related matters as of March 31, 2022 includes amounts relating to certain unresolved matters for which, based on the progress of ongoing settlement negotiations and/or certain other factors, the Company believes a loss is probable and can reasonably be estimated. As further described below, the Company may be exposed to additional losses in excess of the amounts currently accrued, which could be material.

To the extent unresolved, we will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests, including entering into settlement negotiations and settlements even in circumstances where we believe we have meritorious defenses. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition to the lawsuits and administrative matters described above, the Company and/or its subsidiaries have received certain subpoenas, civil investigative demands (CIDs) and informal requests for information concerning the sale, marketing and/or distribution of prescription opioid medications, including but not limited to the following:

Various state attorneys general have served subpoenas and/or CIDs on EHSI and/or EPI. We are cooperating with the investigations.

In January 2018, EPI received a federal grand jury subpoena from the U.S. District Court for the Southern District of Florida seeking documents and information related to OPANA[®] ER, other oxycodone products and marketing of opioid medications. We are cooperating with the investigation.

In December 2020, the Company received an administrative subpoena issued by the U.S. Attorney's Office for the Western District of Virginia seeking documents related to McKinsey & Company. The Company received a related subpoena in May 2021, also issued by the U.S. Attorney's Office for the Western District of Virginia. We are cooperating with the investigation.

Similar investigations may be brought by others or the foregoing matters may be expanded or result in litigation. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Ranitidine Matters

In June 2020, an MDL pending in the U.S. District Court for the Southern District of Florida, *In re Zantac (Ranitidine) Products Liability Litigation*, was expanded to add PPI and numerous other manufacturers and distributors of generic ranitidine as defendants. The claims are generally based on allegations that under certain conditions the active ingredient in Zantac[®] and generic ranitidine medications can break down to form an alleged carcinogen known as N-Nitrosodimethylamine (NDMA). The complaints assert a variety of claims, including but not limited to various product liability, breach of warranty, fraud, negligence, statutory and unjust enrichment claims. Plaintiffs generally seek various remedies including, without limitation, compensatory, punitive and/or treble damages; restitution, disgorgement, civil penalties, abatement, attorneys' fees and costs as well as injunctive and/or other relief. Similar complaints against various defendants, in some instances including PPI, have also been filed in certain state courts, including California, Pennsylvania and Illinois. PPI and its subsidiaries have not manufactured or sold ranitidine since 2016.

The MDL court has issued various case management orders, including orders directing the filing of "master" and short-form complaints, establishing a census registry process for potential claimants and addressing various discovery issues. In December 2020, the court dismissed the master complaints as to PPI and other defendants with leave to amend certain claims. Certain plaintiffs, including third-party payers pursuing class action claims, have appealed the dismissal orders to the U.S. Court of Appeals for the Eleventh Circuit. In February 2021, various other plaintiffs filed an amended master personal injury complaint, a consolidated amended consumer economic loss class action complaint and a consolidated medical monitoring class action complaint. PPI was not named as a defendant in the consumer economic loss complaint or the medical monitoring complaint. In July 2021, the MDL court dismissed all claims in the master complaints as to PPI and other generic defendants with prejudice on federal preemption grounds. In November 2021, the MDL court issued a final judgment as to PPI and other generic defendants. Certain MDL plaintiffs have appealed the July 2021 dismissal order and/or the November 2021 judgment.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Generic Drug Pricing Matters

Since March 2016, various private plaintiffs, state attorneys general and other governmental entities have filed cases against our subsidiary PPI and/or, in some instances, the Company, Generics Bidco I, LLC, DAVA Pharmaceuticals, LLC, DAVA International, LLC, EPI, EHSI and/or PPCI, as well as other pharmaceutical manufacturers and, in some instances, other corporate and/or individual defendants, alleging price-fixing and other anticompetitive conduct with respect to generic pharmaceutical products. These cases, which include proposed class actions filed on behalf of direct purchasers, end-payers and indirect purchaser resellers, as well as non-class action suits, have generally been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Eastern District of Pennsylvania. There is also a proposed class action filed in the Federal Court of Canada on behalf of a proposed class of Canadian purchasers.

The various complaints and amended complaints generally assert claims under federal and/or state antitrust law, state consumer protection statutes and/or state common law, and seek damages, treble damages, civil penalties, disgorgement, declaratory and injunctive relief, costs and attorneys' fees. Some claims are based on alleged product-specific conspiracies and other claims allege broader, multiple-product conspiracies. Under these overarching conspiracy theories, plaintiffs generally seek to hold all alleged participants in a particular conspiracy jointly and severally liable for all harms caused by the alleged conspiracy, not just harms related to the products manufactured and/or sold by a particular defendant.

The MDL court has issued various case management and substantive orders, including orders denying certain motions to dismiss, and discovery is ongoing.

We will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In December 2014, our subsidiary PPI received from the Antitrust Division of the U.S. Department of Justice (DOJ) a federal grand jury subpoena issued by the U.S. District Court for the Eastern District of Pennsylvania addressed to "Par Pharmaceuticals." The subpoena requested documents and information focused primarily on product and pricing information relating to the authorized generic version of Lanoxin[®] (digoxin) oral tablets and generic doxycycline products, and on communications with competitors and others regarding those products. We are cooperating with the investigation.

In May 2018, we and our subsidiary PPCI each received a CID from the DOJ in relation to a False Claims Act investigation concerning whether generic pharmaceutical manufacturers engaged in price-fixing and market allocation agreements, paid illegal remuneration and caused the submission of false claims. We are cooperating with the investigation.

Similar investigations may be brought by others or the foregoing matters may be expanded or result in litigation. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Other Antitrust Matters

Beginning in June 2014, multiple alleged purchasers of OPANA[®] ER sued our subsidiaries EHSI and EPI and other pharmaceutical companies, including Impax Laboratories, LLC (formerly Impax Laboratories, Inc. and referred to herein as Impax) and Penwest Pharmaceuticals Co., which our subsidiary EPI had acquired, alleging violations of antitrust law arising out of an agreement between EPI and Impax to settle certain patent infringement litigation and EPI's introduction of reformulated OPANA[®] ER. Some cases were filed on behalf of putative classes of direct and indirect purchasers, while others were filed on behalf of individual retailers or health care benefit plans. The cases have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of Illinois. The various complaints assert claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally seek damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. In June 2021, the court denied defendants' motions for summary judgment, granted in part and denied in part certain evidentiary motions filed by defendants and granted direct and indirect purchaser plaintiffs' motions for class certification. In August 2021, following an appeal and remand from the U.S. Court of Appeals for the Seventh Circuit, the district court amended its class certification order to certify a narrower end-payer class. A bifurcated liability and damages trial is currently scheduled to begin in June 2022; however, the timing of trials is uncertain due to the impact of COVID-19 and other factors.

Beginning in February 2009, the U.S. Federal Trade Commission (FTC) and certain private plaintiffs sued our subsidiaries PPCI (since June 2016, EGHI) and/or PPI as well as other pharmaceutical companies alleging violations of antitrust law arising out of the settlement of certain patent litigation concerning the generic version of AndroGel[®] and seeking damages, treble damages, equitable relief and attorneys' fees and costs. The cases were consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of Georgia. In May 2016, plaintiffs representing a putative class of indirect purchasers voluntarily dismissed their claims with prejudice. In February 2017, the FTC voluntarily dismissed its claims against EGHI with prejudice. In June 2018, the MDL court granted in part and denied in part various summary judgment and evidentiary motions filed by defendants. In particular, among other things, the court rejected two of the remaining plaintiffs' causation theories and rejected damages claims related to AndroGel[®] 1.62%. In July 2018, the court denied certain plaintiffs' motion for certification of a direct purchaser class. In November 2019, PPI and PPCI entered into settlement agreements with all but one of the plaintiffs remaining in the MDL; a settlement with the remaining plaintiff was reached in April 2021. The settlement agreements were solely by way of compromise and settlement and were not in any way an admission of wrongdoing, fault or liability of any kind. Separately, in August 2019, several alleged direct purchasers filed suit in the U.S. District Court for the Eastern District of Pennsylvania asserting claims substantially similar to those asserted in the MDL, as well as additional claims against other defendants relating to other alleged conduct. In January 2020, the U.S. District Court for the Eastern District of Pennsylvania denied defendants' motion to transfer venue to the Northern District of Georgia. The case is currently in discovery.

Beginning in May 2018, multiple complaints were filed in the U.S. District Court for the Southern District of New York against PPI, EPI and/or us, as well as other pharmaceutical companies, alleging violations of antitrust law arising out of the settlement of certain patent litigation concerning the generic version of Exforge[®] (amlodipine/valsartan). Some cases were filed on behalf of putative classes of direct and indirect purchasers; others are non-class action suits. The various complaints assert claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally seek damages, treble damages, equitable relief and attorneys' fees and costs. In September 2018, the putative class plaintiffs stipulated to the dismissal without prejudice of their claims against EPI and us, and the retailer plaintiffs later did the same. PPI filed a partial motion to dismiss certain claims in September 2018, which was granted in August 2019. In March 2022, the putative class plaintiffs filed motions for class certification. The court has ordered that the cases be trial-ready by January 2023; however, the timing of trials is uncertain due to the impact of COVID-19 and other factors.

Beginning in August 2019, multiple complaints were filed in the U.S. District Court for the Southern District of New York against PPI and other pharmaceutical companies alleging violations of antitrust law arising out the settlement of certain patent litigation concerning generic versions of Seroquel XR[®] (extended-release quetiapine fumarate). The claims against PPI are based on allegations that PPI entered into an exclusive acquisition and license agreement with Handa Pharmaceuticals, LLC (Handa) in 2012 pursuant to which Handa assigned to PPI certain rights under a prior settlement agreement between Handa and AstraZeneca resolving certain patent litigation. Some cases were filed on behalf of putative classes of direct and indirect purchasers; others are non-class action suits. The various complaints assert claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally seek damages, treble damages, equitable relief and attorneys' fees and costs. In October 2019, the defendants filed various motions to dismiss and, in the alternative, moved to transfer the litigation to the U.S. District Court for the District of Delaware. In August 2020, the Southern District of New York granted the motion to transfer without ruling on the motions to dismiss. In January 2021, the defendants filed motions to dismiss in the District of Delaware, which remain pending.

Beginning in June 2020, multiple complaints were filed against Jazz Pharmaceuticals and other pharmaceutical companies, including PPI, alleging violations of state and federal antitrust laws in connection with the settlement of certain patent litigation concerning generic versions of Xyrem[®] (sodium oxybate). Some cases were filed on behalf of putative classes of indirect purchasers; others are non-class action suits. The cases have been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Northern District of California. The various complaints allege that Jazz entered into a series of “reverse-payment” settlements, including with PPI, to delay generic competition for Xyrem[®] and assert claims under Sections 1 and 2 of the Sherman Act, Section 16 of the Clayton Act, state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally seek damages, treble damages, equitable relief and attorneys’ fees and costs. In April 2021, the defendants moved to dismiss the complaints that had been filed as of that time. In August 2021, the court issued an order dismissing certain aspects of the plaintiffs’ claims but otherwise denying the motions to dismiss. The cases are currently in discovery.

Beginning in June 2021, multiple complaints were filed on behalf of a putative class of direct purchasers in the U.S. District Court for the District of Massachusetts against Takeda Pharmaceuticals, PPI and us, alleging violations of federal antitrust law in connection with the settlement of certain patent litigation related to generic versions of Amitiza[®] (lubiprostone). The complaints allege that Takeda and PPI entered into a settlement agreement that delayed the entry of generic Amitiza[®] and assert claims under Section 1 and Section 2 of the Sherman Act. Plaintiffs seek damages, treble damages and attorneys’ fees and costs. In September 2021, the plaintiffs voluntarily dismissed all claims against Endo International plc. In December 2021, PPI filed a motion to dismiss, which remains pending.

In August 2021, a putative class action complaint was filed in the U.S. District Court for the Eastern District of Pennsylvania against Takeda Pharmaceuticals, EPI, PPI and others, alleging violations of federal antitrust law in connection with the settlement of certain patent litigation related to generic versions of Colcrys[®] (colchicine). The complaint alleged, among other things, that a distribution agreement between Takeda and PPI with respect to an authorized generic was in effect an output restriction conspiracy. The plaintiff asserts claims under Section 1 and Section 2 of the Sherman Act and seeks damages, treble damages and attorneys’ fees and costs. In December 2021, the court dismissed the complaint for failure to state a claim (the plaintiff had already voluntarily dismissed all claims against EPI in November 2021). In January 2022, the plaintiff filed an amended complaint. In February 2022, the defendants filed a motion to dismiss the amended complaint, which the court granted in part and denied in part in March 2022. The case is currently in discovery.

In January 2021, the FTC filed a lawsuit in the U.S. District Court for the District of Columbia against us, EPI, Impax Laboratories, LLC and Amneal Pharmaceuticals, Inc., generally alleging that the 2017 settlement of a contract dispute between EPI and Impax (now Amneal) constituted unfair competition in violation of Section 5(a) of the FTC Act. The complaint generally sought injunctive and equitable monetary relief. In April 2021, the defendants filed motions to dismiss, which the court granted in March 2022.

To the extent unresolved, we will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matters may be expanded. We are unable to predict the outcome of these matters or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Securities Litigation

In June 2020, a putative class action entitled *Benoit Albiges v. Endo International plc, Paul V. Campanelli, Blaise Coleman, and Mark T. Bradley* was filed in the U.S. District Court for the District of New Jersey by an individual shareholder on behalf of himself and all similarly situated shareholders. The lawsuit alleges violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder relating to the marketing and sale of opioid medications and the New York Department of Financial Services’ administrative action against the Company, EPI, EHSI, PPI and PPCI. In September 2020, the court appointed Curtis Laakso lead plaintiff in the action. The plaintiffs filed an amended complaint in November 2020. In January 2021, the defendants filed a motion to dismiss, which the court granted in August 2021. In November 2021, the plaintiffs filed a second amended complaint, which among other things added allegations about discovery issues in certain opioid-related lawsuits. In January 2022, the defendants moved to dismiss the second amended complaint.

To the extent unresolved, we will continue to vigorously defend the foregoing matter and to explore other options as appropriate in our best interests. Similar matters may be brought by others or the foregoing matter may be expanded. We are unable to predict the outcome of this matter or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Other Government Investigations

In March 2022, EPI received a CID from the Texas Attorney General's office seeking documents and information related to hormone blocker products. This followed the Texas Attorney General's December 2021 announcement of an investigation into whether EPI and AbbVie Inc. had advertised or promoted such products, including SUPPRELIN[®] LA and VANTAS[®], for unapproved uses. We are cooperating with the investigation.

Similar investigations may be brought by others or the foregoing matter may be expanded or result in litigation. We are unable to predict the outcome of this matter or to estimate the possible range of any losses that could be incurred. Adjustments to our overall liability accrual may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

VASOSTRICT[®] Related Matters

Beginning in April 2018, PSP LLC and PPI received notice letters from Eagle Pharmaceuticals, Inc. (Eagle), Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent, Fresenius Kabi USA, LLC (Fresenius), Dr. Reddy's Laboratories, Inc., Aurobindo Pharma Limited and Gland Pharma Limited advising of the filing by such companies of Abbreviated New Drug Applications (ANDAs)/New Drug Applications (NDAs) for generic versions of VASOSTRICT[®] (vasopressin IV solution (infusion)) 20 units/ml and/or 200 units/10 ml. Beginning in May 2018, PSP LLC, PPI and Endo Par Innovation Company, LLC filed lawsuits against Eagle, Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent and Fresenius in the U.S. District Court for the District of Delaware or New Jersey within the 45-day deadline to invoke a 30-month stay of U.S. Food and Drug Administration (FDA) approval pursuant to the Hatch-Waxman legislative scheme. In December 2020, we separately filed suit against Eagle, Amneal Pharmaceuticals LLC, Dr. Reddy's Laboratories, Inc. and Aurobindo Pharma Limited in the U.S. District Court for the District of New Jersey in connection with a newly issued VASOSTRICT[®] genotyping patent. Beginning in May 2020 through January 2021, we reached settlements with American Regent, Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Fresenius, Aurobindo Pharma Limited and Dr. Reddy's Laboratories, Inc. We have voluntarily dismissed all cases pending against those defendants. The remaining Delaware cases against Eagle and Amneal Pharmaceuticals LLC have been consolidated and a trial was held in July 2021. In August 2021, the court issued an opinion holding that Eagle's proposed generic product will not infringe PPI's asserted patent claims. We have appealed the ruling. The court made no finding regarding the validity of the patents. During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT[®] were launched, beginning with Eagle's generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives have entered the market, including an authorized generic. These launches began to significantly impact both Endo's market share and product price toward the middle of the first quarter of 2022, and the effects of competition have since increased and are likely to continue to increase throughout 2022 and beyond. This competition could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Other Proceedings and Investigations

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.

NOTE 14. OTHER COMPREHENSIVE INCOME

During the three months ended March 31, 2022 and 2021, there were no tax effects allocated to any component of Other comprehensive income and there were no reclassifications out of Accumulated other comprehensive loss. Substantially all of the Company's Accumulated other comprehensive loss balances at March 31, 2022 and December 31, 2021 consist of Foreign currency translation loss.

NOTE 15. SHAREHOLDERS' DEFICIT

The following table presents a reconciliation of the beginning and ending balances in Total shareholders' deficit for the three months ended March 31, 2022 (in thousands):

	Euro Deferred Shares	Ordinary Shares	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Deficit
BALANCE, DECEMBER 31, 2021	\$ 45	\$ 23	\$ 8,953,906	\$ (9,981,515)	\$ (216,445)	\$ (1,243,986)
Net loss	—	—	—	(71,974)	—	(71,974)
Other comprehensive income	—	—	—	—	1,895	1,895
Compensation related to share-based awards	—	—	4,929	—	—	4,929
Tax withholding for restricted shares	—	—	(1,863)	—	—	(1,863)
Other	(1)	1	1	—	—	1
BALANCE, MARCH 31, 2022	\$ 44	\$ 24	\$ 8,956,973	\$ (10,053,489)	\$ (214,550)	\$ (1,310,998)

The following table presents a reconciliation of the beginning and ending balances in Total shareholders' deficit for the three months ended March 31, 2021 (in thousands):

	Euro Deferred Shares	Ordinary Shares	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Deficit
BALANCE, DECEMBER 31, 2020	\$ 49	\$ 23	\$ 8,938,012	\$ (9,368,270)	\$ (217,753)	\$ (647,939)
Net income	—	—	—	41,524	—	41,524
Other comprehensive income	—	—	—	—	1,692	1,692
Compensation related to share-based awards	—	—	9,993	—	—	9,993
Exercise of options	—	—	622	—	—	622
Tax withholding for restricted shares	—	—	(4,863)	—	—	(4,863)
Other	(2)	—	—	—	—	(2)
BALANCE, MARCH 31, 2021	\$ 47	\$ 23	\$ 8,943,764	\$ (9,326,746)	\$ (216,061)	\$ (598,973)

Share-Based Compensation

The Company recognized share-based compensation expense of \$4.9 million and \$10.0 million during the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, the total remaining unrecognized compensation cost related to non-vested share-based compensation awards amounted to \$20.2 million.

As of March 31, 2022, the weighted average remaining requisite service period for non-vested restricted stock units and performance share units was 1.6 years.

NOTE 16. OTHER EXPENSE, NET

The components of Other expense, net for the three months ended March 31, 2022 and 2021 are as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net loss on sale of business and other assets (1)	\$ 135	\$ 355
Foreign currency loss, net (2)	1,712	1,385
Net loss from our investments in the equity of other companies (3)	86	151
Other miscellaneous, net	(644)	(979)
Other expense, net	<u>\$ 1,289</u>	<u>\$ 912</u>

(1) Amounts primarily relate to the sales of certain intellectual property rights and certain other assets.

(2) Amounts relate to the remeasurement of the Company's foreign currency denominated assets and liabilities.

(3) Amounts relate to the income statement impacts of our investments in the equity of other companies, including investments accounted for under the equity method.

NOTE 17. INCOME TAXES

The following table displays our (Loss) income from continuing operations before income tax, Income tax (benefit) expense and Effective tax rate for the three months ended March 31, 2022 and 2021 (dollars in thousands):

	Three Months Ended March 31,	
	2022	2021
(Loss) income from continuing operations before income tax	\$ (67,115)	\$ 47,783
Income tax (benefit) expense	\$ (1,815)	\$ 724
Effective tax rate	2.7 %	1.5 %

The change in Income tax (benefit) expense for the three months ended March 31, 2022 compared to the prior year period primarily relates to the decrease in pre-tax earnings.

The Company maintains a full valuation allowance against the net deferred tax assets in the U.S., Luxembourg and certain other foreign tax jurisdictions as of March 31, 2022. It is possible that within the next 12 months there may be sufficient positive evidence to release a portion or all of the valuation allowance. Release of these valuation allowances would result in a benefit to income tax expense for the period the release is recorded, which could have a material impact on net earnings. The timing and amount of the potential valuation allowance release are subject to significant management judgment and prospective earnings.

On June 3, 2020, in connection with the IRS's examination of our U.S. income tax return for the fiscal year ended December 31, 2015 (2015 Return), we received an acknowledgement of facts (AoF) from the IRS related to transfer pricing positions taken by Endo U.S., Inc. and its subsidiaries (Endo U.S.). The AoF asserted that Endo U.S. overpaid for certain pharmaceutical products that it purchased from certain non-U.S. related parties and proposed a specific adjustment to our 2015 U.S. income tax return position. On September 4, 2020, we received a Form 5701 Notice of Proposed Adjustment (NOPA) that is consistent with the previously disclosed AoF. We believe that the terms of the subject transactions are consistent with comparable transactions for similarly situated unrelated parties, and we intend to contest the proposed adjustment. While the NOPA is not material to our business, financial condition, results of operations or cash flows, the IRS could seek to apply its position to subsequent tax periods and propose similar adjustments. The aggregate impact of these adjustments, if sustained, could have a material adverse effect on our business, financial condition, results of operations and cash flows. Although the timing of the outcome of this matter is uncertain, it is possible any final resolution of the matter could take a number of years.

In connection with the IRS's examination of our 2015 Return, on December 31, 2020, the IRS issued a Technical Advice Memorandum (TAM) that we previously disclosed regarding the portion of our 2015 NOL that we believe qualifies as a specified product liability loss (SLL). The TAM concurred in part with our positions on the 2015 Return but disagreed with our position that the AMS worthless stock loss qualifies as an SLL. On April 23, 2021, we received draft NOPAs from the IRS consistent with the TAM. We continue to disagree with the IRS's position and the draft NOPAs received and, if necessary, intend to contest any additional tax determined to be owed with respect to the NOPAs. However, if we were unsuccessful in contesting the IRS's position, we have preliminarily estimated that we would have additional cash taxes payable to the IRS of between \$70 million and \$250 million excluding interest. We continue to discuss this position with the IRS and the actual amount that may be owed to the IRS if we are unsuccessful may be different than our preliminary estimate. Although the timing of the outcome of this matter is uncertain, it is possible any final resolution of the matter could take a number of years.

NOTE 18. NET (LOSS) INCOME PER SHARE

The following is a reconciliation of the numerator and denominator of basic and diluted net (loss) income per share for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Numerator:		
(Loss) income from continuing operations	\$ (65,300)	\$ 47,059
Loss from discontinued operations, net of tax	(6,674)	(5,535)
Net (loss) income	<u>\$ (71,974)</u>	<u>\$ 41,524</u>
Denominator:		
For basic per share data—weighted average shares	233,879	230,551
Dilutive effect of ordinary share equivalents	—	8,120
For diluted per share data—weighted average shares	<u>233,879</u>	<u>238,671</u>

Basic per share amounts are computed based on the weighted average number of ordinary shares outstanding during the period. Diluted per share amounts are computed based on the weighted average number of ordinary shares outstanding and, if there is net income from continuing operations during the period, the dilutive effect of ordinary share equivalents outstanding during the period.

The dilutive effect of ordinary share equivalents is measured using the treasury stock method. Any stock options and/or awards that have been issued but for which a grant date has not yet been established are not considered in the calculation of basic or diluted weighted average shares.

The following table presents, for the three months ended March 31, 2022 and 2021, outstanding stock options and stock awards that could potentially dilute per share amounts in the future that were not included in the computation of diluted per share amounts for the periods presented because to do so would have been antidilutive (in thousands):

	Three Months Ended March 31,	
	2022	2021
Stock options	6,005	3,734
Stock awards	7,553	103

NOTE 19. SUBSEQUENT EVENT

In May 2022, we announced that our Endo Ventures Limited subsidiary had acquired six development-stage ready-to-use injectable product candidates from Nevakar Injectables, Inc., a subsidiary of Nevakar, Inc., for an upfront cash payment of \$35 million. This transaction meaningfully expands our Sterile Injectables segment’s ready-to-use product pipeline. The product candidates are in various stages of development, with the first launch expected in 2025. With this acquisition, the Company will control all remaining development, regulatory, manufacturing and commercialization activities for the acquired product candidates.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations describes the principal factors affecting the results of operations, liquidity and capital resources and critical accounting estimates of Endo International plc. This discussion should be read in conjunction with the accompanying quarterly unaudited Condensed Consolidated Financial Statements and the related Notes thereto and the Annual Report. The Annual Report includes additional information about our significant accounting policies, practices and the transactions that underlie our financial results, as well as a detailed discussion of the most significant risks and uncertainties associated with our financial and operating results. Except for the historical information contained in this report, including the following discussion, this report contains forward-looking statements that involve risks and uncertainties. See “Forward-Looking Statements” beginning on page i of this report.

Unless otherwise indicated or required by the context, references throughout to “Endo,” the “Company,” “we,” “our” or “us” refer to Endo International plc and its subsidiaries.

RESULTS OF OPERATIONS

Our quarterly results have fluctuated in the past and may continue to fluctuate. These fluctuations may be due to the business and financial statement effects of, among other things, new product launches by us or our competitors; market acceptance of our products; purchasing patterns of our customers; changes in pricing; changes in the availability of our products; litigation-related and other contingencies; mergers, acquisitions, divestitures and other related activity; restructurings and other cost-reduction initiatives; financing transactions; COVID-19; acquired in-process research and development charges; asset impairment charges; share-based and other long-term incentive compensation; and changes in the fair value of financial instruments. The following summary highlights certain recent developments that have resulted in and/or could in the future result in fluctuations in our results of operations and/or changes in our liquidity and capital resources:

- Since 2019, developments related to COVID-19 have continued to evolve rapidly and are likely to continue to do so. The duration and severity of the direct and indirect effects of COVID-19 on our results remain difficult to anticipate and, in many instances, outside of our control. As such, the impacts from COVID-19 on our consolidated results and the results of our business segments to date may not be directly comparable to any historical period and are not necessarily indicative of its impact on our results for any future periods, and the evolving nature of the COVID-19 pandemic could increase the degree to which our results, including the results of our business segments, fluctuate in the future. Additionally, the numerous uncertainties related to COVID-19 have impacted our ability to forecast our future operations; however, any future impact could be material.
- In November 2020, we announced the initiation of several strategic actions, collectively referred to as the 2020 Restructuring Initiative, to further optimize operations and increase overall efficiency. We have been progressing these actions. For example, during the second half of 2021, we entered into definitive agreements to sell certain assets related to our retail generics business, as well as certain associated liabilities. These sales closed in the fourth quarter of 2021. We have recorded and expect to record certain charges to complete these activities in anticipation of realizing annualized cost savings. For further discussion of this initiative, including a discussion of amounts recognized and expected future charges, refer to Note 4. Restructuring of the Condensed Consolidated Financial Statements included in Part I, Item 1.
- In March 2021, we completed a series of financing transactions, collectively referred to herein as the March 2021 Refinancing Transactions, which are further discussed in Note 12. Debt of the Condensed Consolidated Financial Statements included in Part I, Item 1.
- In March 2021, we launched QWO[®] (collagenase clostridium histolyticum-aes) for the treatment of moderate to severe cellulite in the buttocks of adult women. We have been progressing and expect to continue to progress our cellulite treatment development programs for QWO[®]. For example, in May 2022, we announced the planned upcoming launch of a new multi-cohort, open-label study relevant to the use of QWO[®] for the treatment of moderate to severe cellulite in the buttocks of adult women. This study, which will test different interventions to assess their potential impact on reduction of bruising, has been created with the flexibility to add cohorts in order to test additional interventions over time if desired.
- In November 2021, our PSP LLC subsidiary entered into a cooperative agreement with the U.S. government to expand our Sterile Injectables segment's fill-finish manufacturing production capacity and capabilities at our Rochester, Michigan plant to support the U.S. government's national defense efforts regarding production of critical medicines advancing pandemic preparation. Refer to Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of the Annual Report for additional discussion of the terms of this agreement.
- During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT[®] were launched, beginning with a generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives have entered the market, including an authorized generic. These launches began to significantly impact both Endo's market share and product price toward the middle of the first quarter of 2022, and the effects of competition have since increased and are likely to continue to increase throughout 2022 and beyond. Additionally, beginning late in the first quarter of 2022, COVID-19-related hospital utilization levels began to decline, resulting in significantly decreased market volumes for both branded and competing generic alternatives to VASOSTRICT[®]. As a result of these factors, we anticipate experiencing a period of significant VASOSTRICT[®] vial destocking during the second quarter of 2022, which is expected to result in significant reductions to VASOSTRICT[®] revenues in this period.
- In February 2022, we launched VASOSTRICT[®] in a ready-to-use bottle, representing the first and only ready-to-use formulation of the drug. While we have seen some market conversion to the bottle since its launch, the factors described in the preceding bullet point have had and could continue to have a material adverse effect on our business, financial condition, results of operations and cash flows.
- In April 2022, we communicated the initiation of certain actions, collectively referred to as the 2022 Restructuring Initiative, to streamline and simplify certain functions, including our commercial organization, to increase our overall organizational effectiveness and better align with current and future needs. We have recorded and expect to record certain charges to complete these actions in anticipation of realizing annualized cost savings. For further discussion of this initiative, including a discussion of amounts recognized and expected future charges, refer to Note 4. Restructuring of the Condensed Consolidated Financial Statements included in Part I, Item 1.

- In May 2022, we announced that our Endo Ventures Limited subsidiary had acquired six development-stage ready-to-use injectable product candidates from Nevakar Injectables, Inc., a subsidiary of Nevakar, Inc., for an upfront cash payment of \$35 million. This transaction is expected to result in increased expenses beginning in the second quarter of 2022, which could include a \$35 million acquired in-process research and development charge and other research and development costs. For further discussion, see Note 19. Subsequent Event of the Condensed Consolidated Financial Statements included in Part I, Item 1.
- In addition to our other legal proceedings, we, along with others, are the subject of various legal proceedings regarding the sale, marketing and/or distribution of prescription opioid medications. We have not been able to settle most of the opioid claims made against us and, as a result, there are opioid-related claims pending against us at various stages in the litigation process. Some cases are at the pleading or discovery stage; others are approaching the trial stage. Other cases have also been set for trial in various courts around the country. The timing of any scheduled trial or other legal proceeding is subject to change. It is possible that our legal proceedings, including those relating to opioid claims, could have a material adverse effect on our business, financial condition, results of operations and cash flows, including in the short term. The implications of these legal proceedings could result in a possible restructuring of our or our subsidiaries' obligations through a bankruptcy filing which, if it were to occur, would subject us to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, as further described in Part I, Item 1A. "Risk Factors" in the Annual Report. For further discussion, see Note 13. Commitments and Contingencies of the Condensed Consolidated Financial Statements included in Part I, Item 1.

COVID-19 Update and Other Key Trends

We are closely monitoring the ongoing impact of COVID-19 on all aspects of our business, the pharmaceutical industry and the economy as a whole, including how it has and will continue to impact our workforce, our customers and the patients they serve, our manufacturing and supply chain operations, our research and development (R&D) programs and regulatory approval processes and our liquidity and access to capital. For example, we have continued to experience changes in customer demand as the COVID-19 pandemic continues to evolve, which are difficult to predict.

When compared to pre-COVID-19 levels, VASOSTRIC[®] has generally experienced increased sales volumes as a result of the COVID-19 pandemic based primarily on increased utilization levels associated with treating patients infected with COVID-19, including those with vasodilatory shock. However, COVID-19 has also contributed to significant fluctuations in VASOSTRIC[®] revenues from period to period based on both: (i) increases and decreases in utilization levels based on variability in the COVID-19 pandemic and (ii) channel inventory stocking and destocking patterns over time. Most recently, VASOSTRIC[®] has begun to experience significant revenue declines as a result of generic competition, which began in late January 2022, as well as changes in the COVID-19 pandemic. Specifically, beginning late in the first quarter of 2022, COVID-19-related hospital utilization levels began to decline, resulting in significantly decreased market volumes for both branded and competing generic alternatives to VASOSTRIC[®]. As a result of these factors, we anticipate experiencing a period of significant VASOSTRIC[®] vial destocking during the second quarter of 2022, which is expected to result in significant reductions to VASOSTRIC[®] revenues in this period.

On the other hand, certain of our products that are physician administered, including XIAFLEX[®], have generally experienced decreased sales volumes during the COVID-19 pandemic due to reduced physician office activity and patient office visits because of the COVID-19 pandemic. While these products have generally been recovering since early 2020, they have continued to be impacted by COVID-19-related market conditions for specialty product office-based procedures, including medical and administrative staff shortages in physicians' offices, reduced physician office activity and lower numbers of in-person patient office visits. While we saw improving market conditions and a recovery in demand beginning in March 2022, these conditions have continued to contribute to variability in these products' recoveries, as well as uncertainty about future revenues.

Future changes in the COVID-19 pandemic could further impact future revenues for these and/or other products.

We continue to closely monitor the evolving situation and implement plans intended to limit the impact of COVID-19 on our business so that we can continue to produce the critical care medicines that hospitals and healthcare providers need to treat patients, including those with COVID-19. For additional information about the impact of COVID-19 on our business, related risks and uncertainties and actions we have taken to date, refer to the discussion below, together with the discussion contained in the Annual Report.

Due to uncertainties in certain key assumptions, the Company is only providing information about estimated revenue trends for the second quarter ending June 30, 2022 (as compared to the first quarter ended March 31, 2022) at this time. These estimated revenue trends reflect the expectations of our management team based on information available to them at the time such estimates were made. Our estimates are subject to significant risks and uncertainties that could cause our actual results to differ materially from those indicated below. Additionally, these estimates are not necessarily indicative of future period results.

- For the second quarter of 2022, we expect XIAFLEX[®] revenues to increase compared to the first quarter of 2022 based on expectations of slightly improving market conditions and a modest recovery in demand. We expect overall revenues from our Branded Pharmaceuticals segment to be generally in line with or increase slightly compared to the first quarter of 2022.
- For the second quarter of 2022, we expect revenues from our Sterile Injectables segment to decline significantly as compared to the first quarter of 2022, primarily driven by reductions to both price and volumes for VASOSTRICT[®] based on the effects of generic competition, lower overall market volumes for both branded and competing generic alternatives to VASOSTRICT[®] and expected destocking based on reduced hospital utilization levels.
- For the second quarter of 2022, we expect our Generic Pharmaceuticals segment revenues to continue to be impacted by competitive pressures for certain products in this portfolio, resulting in an overall decline in this segment's revenues as compared to the first quarter of 2022.

Consolidated Results Review

The following table displays our revenue, gross margin, gross margin percentage and other pre-tax expense or income for the three months ended March 31, 2022 and 2021 (dollars in thousands):

	Three Months Ended March 31,		% Change
	2022	2021	2022 vs. 2021
Total revenues, net	\$ 652,259	\$ 717,919	(9)%
Cost of revenues	273,215	305,293	(11)%
Gross margin	\$ 379,044	\$ 412,626	(8)%
<i>Gross margin percentage</i>	<i>58.1 %</i>	<i>57.5 %</i>	
Selling, general and administrative	\$ 227,161	\$ 187,174	21 %
Research and development	36,130	29,739	21 %
Acquired in-process research and development	2,900	—	NM
Litigation-related and other contingencies, net	25,154	637	NM
Asset impairment charges	19,953	3,309	NM
Acquisition-related and integration items, net	(1,377)	(5,022)	(73)%
Interest expense, net	134,949	134,341	— %
Loss on extinguishment of debt	—	13,753	(100)%
Other expense, net	1,289	912	41 %
(Loss) income from continuing operations before income tax	\$ (67,115)	\$ 47,783	NM

NM indicates that the percentage change is not meaningful or is greater than 100%.

Total revenues, net. The decrease in revenues for the three months ended March 31, 2022 was primarily due to revenue decreases related to VASOSTRICT[®] and the Established Products portfolio of our Branded Pharmaceuticals segment, partially offset by increased revenues from the Specialty Products portfolio of our Branded Pharmaceuticals segment and our Generic Pharmaceuticals segment. Our revenues are further disaggregated and described below under the heading "Business Segment Results Review."

Cost of revenues and gross margin percentage. During the three months ended March 31, 2022 and 2021, Cost of revenues includes certain amounts that impact its comparability, as well as the comparability of gross margin percentage, including amortization expense and amounts related to continuity and separation benefits, cost reductions and strategic review initiatives. The following table summarizes such amounts (in thousands):

	Three Months Ended March 31,	
	2022	2021
Amortization of intangible assets (1)	\$ 90,234	\$ 95,130
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (2)	\$ 15,737	\$ 15,296

- (1) Amortization expense fluctuates based on changes in the total amount of amortizable intangible assets and the rate of amortization in effect for each intangible asset, both of which can vary based on factors such as the amount and timing of acquisitions, dispositions, asset impairment charges, transfers between indefinite- and finite-lived intangibles assets, changes in foreign currency rates and changes in the composition of our intangible assets impacting the weighted average useful lives and amortization methodologies being utilized. The decrease during the three months ended March 31, 2022 was primarily driven by prior asset impairment charges and decreases in the rate of amortization expense for certain assets, partially offset by the impact of certain in-process research and development assets previously put into service.
- (2) Amounts include, among other things, certain accelerated depreciation charges, inventory adjustments and employee separation, continuity and other benefit-related costs, including amounts related to restructurings. For further discussion of our restructuring initiatives, including a discussion of amounts recognized and expected future charges, refer to Note 4. Restructuring of the Condensed Consolidated Financial Statements included in Part I, Item 1.

The decrease in Cost of revenues for the three months ended March 31, 2022 was primarily due to decreased revenues and decreased amortization expense.

Selling, general and administrative. The increase for the three months ended March 31, 2022 was primarily due to increased costs associated with certain legal matters, strategic review initiatives and restructuring and other cost reduction initiatives. Refer to Note 4. Restructuring of the Condensed Consolidated Financial Statements included in Part I, Item 1 for further discussion of certain restructuring initiatives, including a discussion of amounts recognized and expected future charges.

Research and development. The amount of R&D expense we record in any period varies depending on the nature and stage of development of our R&D programs.

Our R&D efforts are focused on the development of a diversified portfolio of innovative and clinically differentiated product candidates. In early 2020, we announced that we had initiated our XIAFLEX[®] development programs for the treatment of plantar fibromatosis and adhesive capsulitis, which are continuing to progress. For example, we recently progressed our plantar fibromatosis development program with the initiation of a Phase 2 study in the fourth quarter of 2021.

We have been progressing and expect to continue to progress our cellulite treatment development programs for QWO[®], which was launched in March 2021 for the treatment of moderate to severe cellulite in the buttocks of adult women. For example, in May 2022, we announced the planned upcoming launch of a new multi-cohort, open-label study relevant to the use of QWO[®] for the treatment of moderate to severe cellulite in the buttocks of adult women. This study, which will test different interventions to assess their potential impact on reduction of bruising, has been created with the flexibility to add cohorts in order to test additional interventions over time if desired.

We also expect to continue to focus investments in ready-to-use and other product candidates in our Sterile Injectables segment, potentially including acquisitions and/or license and commercialization agreements such as the second-quarter 2022 Nevakar Injectables, Inc. transaction that is further described in Note 19. Subsequent Event of the Condensed Consolidated Financial Statements included in Part I, Item 1. As our development programs progress, it is possible that our R&D expenses could increase.

The increase in R&D expense for the three months ended March 31, 2022 was primarily driven by increased costs associated with our XIAFLEX[®] development programs, as well as increased costs associated with certain restructuring and other cost reduction initiatives. Refer to Note 4. Restructuring of the Condensed Consolidated Financial Statements included in Part I, Item 1 for further discussion of certain restructuring initiatives, including a discussion of amounts recognized and expected future charges.

Acquired in-process research and development. We recognize Acquired in-process research and development charges in periods in which we acquire in-process research and development from third parties or incur (up to the point of regulatory approval) related upfront or milestone payments to third parties. To the extent we enter into agreements to acquire in-process research and development in the future and/or incur upfront or milestone payments to third parties related to in-process research and development, Acquired in-process research and development charges could increase in the future, and the amounts of any increases could be material. For example, as a result of the second-quarter 2022 Nevakar Injectables, Inc. transaction that is further described in Note 19. Subsequent Event of the Condensed Consolidated Financial Statements included in Part I, Item 1, we expect to record a charge of \$35 million in the second quarter of 2022.

Litigation-related and other contingencies, net. Included within Litigation-related and other contingencies, net are changes to our accruals for litigation-related settlement charges and certain settlement proceeds related to suits filed by our subsidiaries. Our material legal proceedings and other contingent matters are described in more detail in Note 13. Commitments and Contingencies of the Condensed Consolidated Financial Statements included in Part I, Item 1. As further described therein, adjustments to the corresponding liability accruals may be required in the future, including in the short term. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Asset impairment charges. The following table presents the components of our total Asset impairment charges for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Other intangible asset impairment charges	\$ 19,953	\$ 2,882
Property, plant and equipment impairment charges	—	427
Total asset impairment charges	<u>\$ 19,953</u>	<u>\$ 3,309</u>

For additional discussion, refer to Note 9. Goodwill and Other Intangibles of the Condensed Consolidated Financial Statements included in Part I, Item 1, as well as the “CRITICAL ACCOUNTING ESTIMATES” section herein.

Acquisition-related and integration items, net. Acquisition-related and integration items, net primarily consist of the net benefit from changes in the fair value of acquisition-related contingent consideration liabilities resulting from changes to our estimates regarding the timing and amount of the future revenues of the underlying products and changes in other assumptions impacting the probability of incurring, and extent to which we could incur, related contingent obligations. See Note 6. Fair Value Measurements of the Condensed Consolidated Financial Statements included in Part I, Item 1 for further discussion of our acquisition-related contingent consideration.

Interest expense, net. The components of Interest expense, net for the three months ended March 31, 2022 and 2021 are as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Interest expense	\$ 135,075	\$ 134,697
Interest income	(126)	(356)
Interest expense, net	<u>\$ 134,949</u>	<u>\$ 134,341</u>

The increase in interest expense for the three months ended March 31, 2022 was primarily attributable to an increase to the weighted average interest rate applicable to our total indebtedness following the March 2021 Refinancing Transactions, partially offset by decreases to the principal amount of our indebtedness, which were primarily attributable to the partial repayment of the Revolving Credit Facility in October 2021 and the January 2022 Senior Notes Repayments. Refer to Note 12. Debt of the Condensed Consolidated Financial Statements included in Part I, Item 1 for further discussion of these transactions. Changes in interest rates could increase our interest expense in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Interest income varies primarily based on the amounts of our interest-bearing investments, such as money market funds, as well as changes in the corresponding interest rates.

Loss on extinguishment of debt. The amount during the three months ended March 31, 2021 relates to the March 2021 Refinancing Transactions. Refer to Note 12. Debt of the Condensed Consolidated Financial Statements included in Part I, Item 1 for further discussion.

Other expense, net. The components of Other expense, net for the three months ended March 31, 2022 and 2021 are as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net loss on sale of business and other assets	\$ 135	\$ 355
Foreign currency loss, net	1,712	1,385
Net loss from our investments in the equity of other companies	86	151
Other miscellaneous, net	(644)	(979)
Other expense, net	<u>\$ 1,289</u>	<u>\$ 912</u>

For additional information on the components of Other expense, net, refer to Note 16. Other Expense, Net of the Condensed Consolidated Financial Statements included in Part I, Item 1.

Income tax (benefit) expense. The following table displays our (Loss) income from continuing operations before income tax, Income tax (benefit) expense and Effective tax rate for the three months ended March 31, 2022 and 2021 (dollars in thousands):

	Three Months Ended March 31,	
	2022	2021
(Loss) income from continuing operations before income tax	\$ (67,115)	\$ 47,783
Income tax (benefit) expense	\$ (1,815)	\$ 724
<i>Effective tax rate</i>	<i>2.7 %</i>	<i>1.5 %</i>

Our tax rate is affected by recurring items, such as tax rates in non-U.S. jurisdictions as compared to the notional U.S. federal statutory tax rate, and the relative amount of income or loss in those various jurisdictions. It is also impacted by certain items that may occur in any given period, but are not consistent from period to period.

The change in Income tax (benefit) expense for the three months ended March 31, 2022 compared to the prior year period primarily relates to the decrease in pre-tax earnings.

The Company maintains a full valuation allowance against the net deferred tax assets in the U.S., Luxembourg and certain other foreign tax jurisdictions as of March 31, 2022. It is possible that within the next 12 months there may be sufficient positive evidence to release a portion or all of the valuation allowance. Release of these valuation allowances would result in a benefit to income tax expense for the period the release is recorded, which could have a material impact on net earnings. The timing and amount of the potential valuation allowance release are subject to significant management judgment and prospective earnings.

We are incorporated in Ireland and also maintain subsidiaries in, among other jurisdictions, the U.S., Canada, India, the United Kingdom and Luxembourg. The IRS and other taxing authorities may continue to challenge our tax positions. The IRS presently is examining certain of our subsidiaries' U.S. income tax returns for fiscal years ended between December 31, 2011 and December 31, 2015 and, in connection with those examinations, is reviewing our tax positions related to, among other things, certain intercompany arrangements, including the level of profit earned by our U.S. subsidiaries pursuant to such arrangements, and a product liability loss carryback claim. For additional information, including a discussion of related recent developments and their potential impact on us, refer to Note 17. Income Taxes of the Condensed Consolidated Financial Statements included in Part I, Item 1.

During the third quarter of 2020, the IRS opened an examination into certain of our subsidiaries' U.S. income tax returns for fiscal years ended between December 31, 2016 and December 31, 2018. The IRS will likely examine our tax returns for other fiscal years and/or for other tax positions. Similarly, other tax authorities are currently examining our non-U.S. tax returns. Additionally, other jurisdictions where we are not currently under audit remain subject to potential future examinations. Such examinations may lead to proposed or actual adjustments to our taxes that may be material, individually or in the aggregate. See the risk factor "The IRS and other taxing authorities may continue to challenge our tax positions and we may not be able to successfully maintain such positions" in Part I, Item 1A. "Risk Factors" in the Annual Report for more information.

Discontinued operations, net of tax. The operating results of the Company's Astora business, which the Board resolved to wind down in 2016, are reported as Discontinued operations, net of tax in the Condensed Consolidated Statements of Operations for all periods presented. The following table provides the operating results of Astora Discontinued operations, net of tax, for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Loss from discontinued operations before income taxes	\$ (6,674)	\$ (6,221)
Income tax benefit	\$ —	\$ (686)
Discontinued operations, net of tax	\$ (6,674)	\$ (5,535)

The pre-tax amounts during the three months ended March 31, 2022 and 2021 were primarily related to mesh-related legal defense costs and certain other items. For additional discussion of mesh-related matters, refer to Note 13. Commitments and Contingencies of the Condensed Consolidated Financial Statements included in Part I, Item 1.

Business Segment Results Review

Revenues, net. The following table displays our revenue by reportable segment for the three months ended March 31, 2022 and 2021 (dollars in thousands):

	Three Months Ended March 31,		% Change
	2022	2021	2022 vs. 2021
Branded Pharmaceuticals	\$ 204,861	\$ 206,635	(1)%
Sterile Injectables	240,028	308,745	(22)%
Generic Pharmaceuticals	185,944	180,873	3 %
International Pharmaceuticals (1)	21,426	21,666	(1)%
Total net revenues from external customers	\$ 652,259	\$ 717,919	(9)%

(1) Revenues generated by our International Pharmaceuticals segment are primarily attributable to external customers located in Canada.

Branded Pharmaceuticals. The following table displays the significant components of our Branded Pharmaceuticals revenues from external customers for the three months ended March 31, 2022 and 2021 (dollars in thousands):

	Three Months Ended March 31,		% Change
	2022	2021	2022 vs. 2021
<i>Specialty Products:</i>			
XIAFLEX®	\$ 99,484	\$ 95,270	4 %
SUPPRELIN® LA	28,830	28,028	3 %
Other Specialty (1)	20,744	20,032	4 %
Total Specialty Products	\$ 149,058	\$ 143,330	4 %
<i>Established Products:</i>			
PERCOCET®	\$ 26,175	\$ 25,625	2 %
TESTOPEL®	8,880	11,189	(21)%
Other Established (2)	20,748	26,491	(22)%
Total Established Products	\$ 55,803	\$ 63,305	(12)%
Total Branded Pharmaceuticals (3)	\$ 204,861	\$ 206,635	(1)%

(1) Products included within Other Specialty include NASCOBAL® Nasal Spray, AVEED® and QWO®.

(2) Products included within Other Established include, but are not limited to, EDEX® and LIDODERM®.

(3) Individual products presented above represent the top two performing products in each product category for the three months ended March 31, 2022 and/or any product having revenues in excess of \$25 million during any quarterly period in 2022 or 2021.

Specialty Products

As noted above, certain of our products that are physician administered, including XIAFLEX®, have generally experienced decreased sales volumes during the COVID-19 pandemic due to reduced physician office activity and patient office visits because of the COVID-19 pandemic. While these products have generally been recovering since early 2020, they have continued to be impacted by COVID-19-related market conditions for specialty product office-based procedures, including medical and administrative staff shortages in physicians' offices, reduced physician office activity and lower numbers of in-person patient office visits. While we saw improving market conditions and a recovery in demand beginning in March 2022, these conditions have continued to contribute to variability in these products' recoveries, as well as uncertainty about future revenues. Further changes as a result the COVID-19 pandemic could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The increase in XIAFLEX® revenues for the three months ended March 31, 2022 was primarily attributable to increased net price, partially offset by slightly lower volumes resulting primarily from COVID-19-related market conditions as noted above.

The increase in SUPPRELIN® LA revenues for the three months ended March 31, 2022 was primarily attributable to increased net price.

Established Products

The increase in PERCOCET® revenues for the three months ended March 31, 2022 was primarily attributable to increased net price, partially offset by decreased volumes.

The decrease in TESTOPEL® revenues for the three months ended March 31, 2022 was primarily attributable to decreased net price.

The decrease in Other Established Products revenues for the three months ended March 31, 2022 was primarily attributable to ongoing competitive pressures impacting this product portfolio and certain other factors.

Sterile Injectables. The following table displays the significant components of our Sterile Injectables revenues from external customers for the three months ended March 31, 2022 and 2021 (dollars in thousands):

	Three Months Ended March 31,		% Change
	2022	2021	2022 vs. 2021
VASOSTRICT®	\$ 155,890	\$ 223,946	(30)%
ADRENALIN®	33,823	29,437	15 %
Other Sterile Injectables (1)	50,315	55,362	(9)%
Total Sterile Injectables (2)	\$ 240,028	\$ 308,745	(22)%

(1) Products included within Other Sterile Injectables include ertapenem for injection, APLISOL® and others.

(2) Individual products presented above represent the top two performing products within the Sterile Injectables segment for the three months ended March 31, 2022 and/or any product having revenues in excess of \$25 million during any quarterly period in 2022 or 2021.

The decrease in VASOSTRICT® revenues for the three months ended March 31, 2022 was primarily driven by decreases to both net price and volume, which were primarily attributable to the impact of generic competition as well as lower overall market demand as COVID-19-related hospital utilization levels decline. During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® were launched, beginning with a generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives have entered the market, including an authorized generic. These launches began to significantly impact both Endo's market share and product price toward the middle of the first quarter of 2022, and the effects of competition have since increased and are likely to continue to increase throughout 2022 and beyond. Additionally, beginning late in the first quarter of 2022, COVID-19-related hospital utilization levels began to decline, resulting in significantly decreased market volumes for both branded and competing generic alternatives to VASOSTRICT®. As a result of these factors, we anticipate experiencing a period of significant VASOSTRICT® vial destocking during the second quarter of 2022, which is expected to result in significant reductions to VASOSTRICT® revenues in this period. In February 2022, we launched VASOSTRICT® in a ready-to-use bottle, representing the first and only ready-to-use formulation of the drug. While we have seen some market conversion to the bottle since its launch, the factors described above have had and could continue to have a material adverse effect on our business, financial condition, results of operations and cash flows. For additional information, refer to Note 13. Commitments and Contingencies of the Condensed Consolidated Financial Statements included in Part I, Item 1 under the heading "VASOSTRICT® Related Matters."

The increase in ADRENALIN® revenues for the three months ended March 31, 2022 was primarily attributable to increased net price.

The decrease in Other Sterile Injectables revenues for the three months ended March 31, 2022 was primarily attributable to competitive pressures across multiple products within the product portfolio.

Generic Pharmaceuticals. The increase in Generic Pharmaceuticals revenues for the three months ended March 31, 2022 was primarily attributable to revenues from varenicline tablets (our generic version of Pfizer Inc.'s Chantix®), which launched in September 2021, partially offset by competitive pressures on certain generic products.

Segment adjusted income from continuing operations before income tax. The following table displays our Segment adjusted income from continuing operations before income tax (the measure we use to evaluate segment performance) by reportable segment for the three months ended March 31, 2022 and 2021 (dollars in thousands):

	Three Months Ended March 31,		% Change
	2022	2021	2022 vs. 2021
Branded Pharmaceuticals	\$ 77,666	\$ 93,769	(17)%
Sterile Injectables	\$ 191,254	\$ 242,639	(21)%
Generic Pharmaceuticals	\$ 66,382	\$ 34,104	95 %
International Pharmaceuticals	\$ 4,381	\$ 7,471	(41)%

Branded Pharmaceuticals. The decrease in Segment adjusted income from continuing operations before income tax for the three months ended March 31, 2022 was primarily attributable to increased costs associated with our investment in consumer marketing efforts supporting XIAFLEX®, as well as decreased gross margins, including as a result of decreased revenues, as further described above.

Sterile Injectables. The decrease in Segment adjusted income from continuing operations before income tax for the three months ended March 31, 2022 was primarily attributable to the gross margin effect of the decreased revenues further described above.

Generic Pharmaceuticals. The increase in Segment adjusted income from continuing operations before income tax for the three months ended March 31, 2022 was primarily attributable to the gross margin effects of the increased revenues further described above and favorable changes in product mix.

International Pharmaceuticals. The decrease in Segment adjusted income from continuing operations before income tax for the three months ended March 31, 2022 was primarily attributable to changes in product mix.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are primarily for working capital for operations, licenses, capital expenditures, mergers and acquisitions (including upfront and milestone payments to third parties), contingent liabilities, debt service payments, income taxes and litigation-related matters. The Company's working capital was \$1,116.7 million at March 31, 2022 compared to working capital of \$1,084.6 million at December 31, 2021. The amounts at March 31, 2022 and December 31, 2021 include restricted cash and cash equivalents associated with litigation-related matters, including \$136.4 million and \$78.4 million, respectively, held in QSFs for mesh- and opioid-related matters. Although these amounts in QSFs are included in working capital, they are required to be used for legal settlements.

Cash and cash equivalents, which primarily consisted of bank deposits and money market accounts, totaled \$1,413.2 million at March 31, 2022 compared to \$1,507.2 million at December 31, 2021. While we currently expect our operating cash flows, together with our cash, cash equivalents, restricted cash and restricted cash equivalents, to be sufficient to cover our principal liquidity requirements over the next year, this cannot be predicted with certainty due to a number of risks and uncertainties as further described herein. For example, we may face decreased revenues as a result of COVID-19 and, to the extent COVID-19 has resulted in any increase to our Cash and cash equivalents, including as a result of any increase in revenues, such increase could be temporary. We may face unexpected costs in connection with our business operations, our ongoing and future legal proceedings, governmental investigations and other contingent liabilities, including potential costs related to settlements and judgments, as well as legal defense costs, and the implementation of our COVID-19 related policies and procedures. As a result of the possibility or occurrence of an unfavorable outcome with respect to any legal proceeding, we have engaged in and, at any given time, may further engage in strategic reviews of all or a portion of our business. Any such review or contingency planning could ultimately result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. Those remedial measures could include a potential bankruptcy filing which, if it were to occur, would subject us to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, as further described in Part I, Item 1A. "Risk Factors" in the Annual Report. Additionally, on a longer-term basis, we may not be able to accurately predict the effect of certain developments on our sales and gross margins, such as the degree of market acceptance, patent protection and exclusivity of our products, pricing pressures (including those due to the impact of competition), the effectiveness of our sales and marketing efforts and the outcome of our current efforts to develop, receive approval for and successfully launch our product candidates. Furthermore, we may not be successful in implementing, or may face unexpected changes or expenses in connection with, our strategic direction, including the potential for opportunistic corporate development transactions. Any of the above could have a material adverse effect on our business, financial condition, results of operations and cash flows and require us to seek additional sources of liquidity and capital resources as described below.

To the extent our operating cash flows, together with our cash, cash equivalents, restricted cash and restricted cash equivalents, become insufficient to cover our liquidity and capital requirements, including funds for any future acquisitions and other corporate transactions, we may be required to seek third-party financing, including additional draws on our Revolving Credit Facility or additional credit facilities, and/or engage in one or more capital market transactions. There can be no assurance that we would be able to obtain any required financing on a timely basis or at all. Further, lenders and other financial institutions could require us to agree to more restrictive covenants, grant liens on our assets as collateral (resulting in an increase in our total outstanding secured indebtedness) and/or accept other terms that are not commercially beneficial to us in order to obtain financing. Such terms could further restrict our operations and exacerbate any impact on our results of operations and liquidity that may result from any of the factors described above or other factors.

We may also, from time to time, seek to enter into certain transactions to reduce our leverage and/or interest expense and/or to extend the maturities of our outstanding indebtedness or obtain greater covenant flexibility. Such transactions could include, for example, transactions to exchange existing indebtedness for our ordinary shares or other debt (including exchanges of unsecured debt for secured debt), to issue equity (including convertible securities) or to repurchase, redeem, exchange or refinance our existing indebtedness (including the Credit Agreement) as well as our outstanding senior notes. Any of these transactions could impact our liquidity or results of operations, including requiring us to take charges. Further, the terms of any such transactions, including the amount of any exchange consideration and terms of any refinanced debt, could also be less favorable than we have been able to obtain in the past.

We may also require additional financing to fund our future operational needs or for future corporate transactions, including acquisitions. We have historically had broad access to financial markets that provide liquidity; however, we cannot be certain that funding will be available to us in the future on terms acceptable to us, or at all. Any issuances of equity securities or convertible securities, in connection with an acquisition or otherwise, could have a dilutive effect on the ownership interest of our current shareholders and may adversely impact net income per share in future periods. An acquisition may be accretive or dilutive and, by its nature, involves numerous risks and uncertainties. As a result of acquisition efforts, if any, we are likely to experience significant charges to earnings for merger and related expenses (whether or not the acquisitions are consummated) that may include transaction costs, closure costs or costs of restructuring activities.

Indebtedness. The Company and certain of its subsidiaries are party to the Credit Agreement governing the Credit Facilities and the indentures governing our various senior secured and senior unsecured notes. As of March 31, 2022, approximately \$2.0 billion was outstanding under the Term Loan Facility, approximately \$0.3 billion was outstanding under the Revolving Credit Facility and approximately \$5.9 billion was outstanding under the senior secured and senior unsecured notes.

After giving effect to net borrowings under the Revolving Credit Facility and issued and outstanding letters of credit, approximately \$0.6 billion of remaining credit was available under the Revolving Credit Facility at March 31, 2022. Additionally, the Company's outstanding debt agreements contain a number of restrictive covenants, including certain limitations on the Company's ability to incur additional indebtedness.

The Credit Agreement and the indentures governing our various senior secured notes and the 6.00% Senior Notes due 2028 contain certain covenants and events of default. As of March 31, 2022 and December 31, 2021, the Company was in compliance with all such covenants. We have eliminated substantially all of the restrictive covenants and certain events of default in the indentures governing our senior unsecured notes, except for those in the indenture governing the 6.00% Senior Notes due 2028.

Refer to Note 12. Debt of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this report and Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of the Annual Report for additional information about our indebtedness, including our debt financing transactions and information about covenants, maturities, interest rates, security and priority.

Credit ratings. The Company's corporate credit ratings assigned by Moody's Investors Service and Standard & Poor's are Caa1 with a negative outlook and CCC+ with a negative outlook, respectively. No report of any rating agency is being incorporated by reference herein.

Working capital. The components of our working capital and our liquidity at March 31, 2022 and December 31, 2021 are below (dollars in thousands):

	March 31, 2022	December 31, 2021
Total current assets	\$ 2,492,792	\$ 2,714,586
Less: total current liabilities	1,376,142	1,629,962
Working capital	<u>\$ 1,116,650</u>	<u>\$ 1,084,624</u>
Current ratio (total current assets divided by total current liabilities)	1.8:1	1.7:1

Net working capital increased by \$32.0 million from December 31, 2021 to March 31, 2022. During this period, working capital benefited from the favorable impacts to net current assets resulting from revenues and gross margins, which are further described above. This benefit was partially offset by the following current period activity: (i) Capital expenditures, excluding capitalized interest, of \$23.0 million; (ii) a \$20.2 million decrease to working capital resulting from certain net charges related to litigation-related and other contingencies, which are further described in Note 13. Commitments and Contingencies of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this report; and (iii) decreases to working capital related to expenses incurred for certain restructuring and other cost reduction initiatives.

The following table summarizes our Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash flow provided by (used in):		
Operating activities	\$ 201,319	\$ 243,840
Investing activities	(48,844)	(17,048)
Financing activities	(189,198)	(47,350)
Effect of foreign exchange rate	331	399
Net (decrease) increase in cash, cash equivalents, restricted cash and restricted cash equivalents	<u>\$ (36,392)</u>	<u>\$ 179,841</u>

Operating activities. Net cash provided by operating activities represents the cash receipts and cash disbursements from all of our activities other than investing activities and financing activities. Changes in cash from operating activities reflect, among other things, the timing of cash collections from customers, payments to suppliers, managed care organizations, government agencies, collaborative partners and employees in the ordinary course of business, as well as the timing and amount of cash payments and/or receipts related to interest, litigation-related matters, restructurings, income taxes and certain other items.

The \$42.5 million decrease in Net cash provided by operating activities during the three months ended March 31, 2022 compared to the prior year period was primarily due to our results of operations as described above, including reductions to VASOSTRICT® revenues. It is possible that operating cash flows could decline in the future as a result of, among other things, cash outflows for litigation-related matters and further reductions in VASOSTRICT® revenues.

Investing activities. The \$31.8 million increase in Net cash used in investing activities during the three months ended March 31, 2022 compared to the prior year period was primarily attributable to: (i) an increase in Acquisitions, including in-process research and development, net of cash and restricted cash acquired of \$24.5 million and (ii) an increase in Capital expenditures, excluding capitalized interest of \$6.3 million.

Financing activities. During the three months ended March 31, 2022, Net cash used in financing activities primarily related to: (i) Repayments of notes of \$180.3 million and (ii) Repayments of term loans of \$5.0 million.

During the three months ended March 31, 2021, Net cash used in financing activities primarily related to: (i) the March 2021 Refinancing Transactions, including the payment of approximately \$40.9 million of associated costs and fees, and (ii) Payments of tax withholding for restricted shares of \$4.9 million.

Cash Requirements for Contractual and Other Obligations. As of March 31, 2022, there were no material changes in our cash requirements for contractual and other obligations from those disclosed in the Annual Report except for those related to our indebtedness as further described in Note 12. Debt of the Condensed Consolidated Financial Statements included in Part I, Item 1.

Fluctuations. As further discussed above, our quarterly results have fluctuated in the past and may continue to fluctuate. Additionally, a substantial portion of our total revenues are through three wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

Inflation. We do not believe that inflation had a material adverse effect on our financial statements for the periods presented. However, materials, equipment and labor shortages, shipping, logistics and other delays and other supply chain and manufacturing disruptions, whether due to the evolving effects of the COVID-19 pandemic or otherwise, continue to make it more difficult and costly for us to obtain raw materials, supplies or services from third parties, to manufacture our own products and to pursue clinical development activities. Economic or political instability or disruptions, such as the conflict in Ukraine, could negatively affect our supply chain or increase our costs. If these types of events or disruptions continue to occur, they could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Off-balance sheet arrangements. We have no off-balance sheet arrangements.

CRITICAL ACCOUNTING ESTIMATES

Updates to our critical accounting estimates since December 31, 2021 are detailed below. For additional discussion of the Company's critical accounting estimates, see "Critical Accounting Estimates" in Item 7 of the Annual Report.

We have not made any substantial changes to our methodology used in our impairment tests since our previous assessment. Determination of the fair value of a reporting unit is a matter of judgment and involves the use of estimates and assumptions, which are based on management's best estimates at the time. The use of different assumptions would increase or decrease our estimated discounted future cash flows and the resulting estimated fair value of our reporting units, which could result in the fair value of a reporting unit being less than its carrying amount in an impairment test.

As further discussed under the heading “RESULTS OF OPERATIONS,” our Generic Pharmaceuticals segment and certain of the products in our Sterile Injectables segment are subject to risks and uncertainties related to future competition, including the effects of the competitive generic alternatives to VASOSTRICT[®] that were introduced beginning in late January 2022 and may continue to be introduced. If actual results for these segments differ from our expectations, as a result of competition or otherwise, and/or if we make changes to our assumptions for these segments relating to competition or any other risks or uncertainties, the estimated future revenues and cash flows could be significantly reduced, which could ultimately result in asset impairment charges that may be material. For example, in the fourth quarter of 2021, we recorded an impairment charge of \$363.0 million related to our Sterile Injectables segment’s goodwill. The discounted cash flows used in this fourth-quarter 2021 impairment test reflected assumptions related to: (i) the overall market size for both branded and generic versions of VASOSTRICT[®], including anticipated changes in demand driven in part by changes in COVID-19-related hospital utilization; (ii) the timing and extent of potential competitive impacts on VASOSTRICT[®] revenues; (iii) the extent and speed of any conversion of the market for VASOSTRICT[®] to the RTU pre-mix VASOSTRICT[®] bottle we launched in February 2022; and (iv) various assumptions regarding the Company’s pipeline Sterile Injectables products, including probability of success, launch timing and the competitive landscape at the time of planned launch, among other factors. While the Company’s actual results for the Sterile Injectables segment were broadly in line with expectations in the first quarter of 2022, future performance is subject to many factors that are outside the Company’s control and subject to significant uncertainty and are therefore inherently difficult to predict. Actual results going forward could differ significantly from the Company’s expectations and, if unfavorable, could result in interim impairment tests and additional impairment charges which could be material. Similarly, market-based factors such as rising interest rates could impact the Company’s determination of fair value in the future, which could also result in or increase future impairment charges.

Additionally, we are continuing to closely monitor the impact of COVID-19 on our business. It is possible that COVID-19 could result in reductions to the estimated fair values of our goodwill and other intangible assets, which could ultimately result in asset impairment charges that may be material.

Furthermore, as a result of the possibility or occurrence of an unfavorable outcome with respect to any legal proceeding, we have engaged in and, at any given time, may further engage in strategic reviews of all or a portion of our business. Any such review or contingency planning could ultimately result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. These actions could include a bankruptcy filing which could ultimately result in, among other things, asset impairment charges that may be material.

RECENT ACCOUNTING PRONOUNCEMENTS

Refer to Note 2. Summary of Significant Accounting Policies of the Condensed Consolidated Financial Statements included in Part I, Item 1, as applicable.

Item 3. *Quantitative and Qualitative Disclosures About Market Risk*

Market risk is the potential loss arising from adverse changes in the financial markets, including interest rates and foreign currency exchange rates.

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate indebtedness associated with our Credit Facilities. At March 31, 2022 and December 31, 2021, the aggregate principal amounts of such variable-rate indebtedness were \$2,257.2 million and \$2,262.2 million, respectively. Borrowings under the Credit Facilities may from time to time bear interest at variable rates, in certain cases subject to a floor. At both March 31, 2022 and December 31, 2021, a hypothetical 1% increase in the applicable rate over the floor would have resulted in \$22.6 million of incremental interest expense (representing the annual rate of expense) related to our variable-rate debt borrowings.

To the extent that we utilize additional amounts under the Revolving Credit Facility or otherwise increase the amount of our variable-rate indebtedness, we will be exposed to additional interest rate risk.

As of March 31, 2022 and December 31, 2021, we had no other assets or liabilities with significant interest rate sensitivity.

Foreign Currency Exchange Rate Risk

We operate and transact business in various foreign countries and are therefore subject to risks associated with foreign currency exchange rate fluctuations. The Company manages this foreign currency risk, in part, through operational means including managing foreign currency revenues in relation to same-currency costs and foreign currency assets in relation to same-currency liabilities. The Company is also exposed to potential earnings effects from intercompany foreign currency assets and liabilities that arise from normal trade receivables and payables and other intercompany loans. Additionally, certain of the Company’s subsidiaries maintain their books of record in currencies other than their respective functional currencies. These subsidiaries’ financial statements are remeasured into their respective functional currencies. Such remeasurement adjustments could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The assets and liabilities of certain of our international subsidiaries are also translated to U.S. dollars at period-end exchange rates. Translation adjustments arising from the use of differing exchange rates are included in Accumulated other comprehensive loss. Gains and losses on foreign currency transactions and short-term intercompany receivables from foreign subsidiaries are included in Other expense, net in the Condensed Consolidated Statements of Operations. Refer to Note 16. Other Expense, Net of the Condensed Consolidated Financial Statements included in Part I, Item 1 for the amounts of Foreign currency loss, net.

Based on the Company's significant foreign currency denominated intercompany loans, we separately considered the hypothetical impact of a 10% change in the underlying currencies of our foreign currency denominated intercompany loans, relative to the U.S. dollar, at March 31, 2022 and December 31, 2021. A 10% change at March 31, 2022 would have resulted in approximately \$10 million in incremental foreign currency losses on such date. A 10% change at December 31, 2021 would have resulted in approximately \$11 million in incremental foreign currency losses on such date.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Principal Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of March 31, 2022. Based on that evaluation, the Company's Chief Executive Officer and Principal Financial Officer concluded that the Company's disclosure controls and procedures were effective as of March 31, 2022.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the fiscal quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The disclosures under Note 13. Commitments and Contingencies of the Condensed Consolidated Financial Statements included in Part I, Item 1 are incorporated into this Part II, Item 1 by reference.

Item 1A. Risk Factors

For a discussion of our risk factors, see the information in Part I, Item 1A. “Risk Factors” in the Annual Report. There have been no material changes to our risk factors from those described therein except as set forth below.

The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business, including withdrawal or suspension of existing products.

Governmental authorities, including without limitation the FDA, impose substantial requirements on the development, manufacture, holding, labeling, marketing, advertising, promotion, distribution and sale of therapeutic pharmaceutical products. See “Governmental Regulation” in Part I, Item 1 of the Annual Report.

Regulatory approvals for the sale of any new product candidate may require preclinical studies and clinical trials that such product candidate is safe and effective for its intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product candidate. Likewise, we may not be able to demonstrate through clinical trials that a product candidate’s therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large-scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

Clinical trials can be delayed for reasons outside of our control, which can lead to increased development costs and delays in regulatory approval. It is possible that regulators, independent data monitoring committees, institutional review boards, safety committees, ethics committees and/or other third parties may request or require that we suspend or terminate our clinical trials for various reasons, including, among others, noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects or failure to demonstrate a benefit from using our product candidates. There is substantial competition to enroll patients in clinical trials, and such competition has delayed clinical development of our products in the past. For example, patients could enroll in clinical trials more slowly than expected or could drop out before or during clinical trials. In addition, we may rely on collaboration partners that may control or make changes in trial protocol and design enhancements, or encounter clinical trial compliance-related issues, which may also delay clinical trials. Product supplies may be delayed or insufficient to treat the patients participating in the clinical trials, and manufacturers or suppliers may not meet the requirements of the FDA or foreign regulatory authorities, such as those relating to current Good Manufacturing Practice (cGMP).

Compliance with clinical trial requirements and cGMP regulations requires significant expenditures and the dedication of substantial resources. The FDA may place a hold on a clinical trial and may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, or a third-party contract manufacturing facility faces manufacturing problems, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Additional delays may result if an FDA advisory committee or other regulatory authority recommends non-approval or restrictions on approval. Although the FDA is not required to follow the recommendations of its advisory committees, it usually does. A negative advisory committee meeting could signal a lower likelihood of approval, although the FDA may still end up approving our application. Regardless of an advisory committee meeting outcome or the FDA’s final approval decision, public presentation of our data may shed positive or negative light on our application.

We may seek FDA approval for certain unapproved marketed products through the 505(b)(2) regulatory pathway. See “Governmental Regulation” in Part I, Item 1 of the Annual Report. Even if we receive approval for an NDA under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA may not take timely enforcement action against companies marketing unapproved versions of the product; therefore, we cannot be sure that that we will receive the benefit of any de facto exclusive marketing period or that we will fully recoup the expenses incurred to obtain an approval. In addition, certain competitors and others have objected to the FDA’s interpretation of Section 505(b)(2). If the FDA’s interpretation of Section 505(b)(2) is successfully challenged, this could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

The ANDA approval process for a new product varies in time, generally requiring a minimum of 10 months following submission of the ANDA to FDA, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly. ANDA approvals, if granted, may not include all uses (known as indications) for which a company may seek to market a product.

The submission of an NDA, Supplemental New Drug Application (sNDA), ANDA, Biologics License Application (BLA) or Supplemental Biologics License Application (sBLA) to the FDA with supporting clinical safety and efficacy data does not guarantee that the FDA will grant approval to market the product. Meeting the FDA's regulatory requirements to obtain approval to market a drug product, which vary substantially based on the type, complexity and novelty of the product candidate, typically takes years, if approved at all, and is subject to uncertainty. The FDA or foreign regulatory authorities may not agree with our assessment of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Any approval by regulatory agencies may subject the marketing of our products to certain limits on indicated use. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we may request, may grant approval contingent on conditions such as the performance and results of costly post-marketing clinical trials or Risk Evaluation and Mitigation Strategy (REMS) or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Additionally, reimbursement by government payers or other payers may not be approved at the price we intend to charge for our products. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals or clearances of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue. We could also be at risk for the value of any capitalized pre-launch inventories related to products under development. The factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Once a product is approved or cleared for marketing, failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances; seizures or recalls of products; injunctions against the manufacture, holding, distribution, marketing and sale of a product; and civil and criminal sanctions. For example, any failure to effectively identify, analyze, report and protect adverse event data and/or to fully comply with relevant laws, rules and regulations around adverse event reporting could expose the Company to legal proceedings, penalties, fines and reputational damage. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. Meeting regulatory requirements and evolving government standards may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to other companies that compete against us.

In addition, after a product is approved or cleared for marketing, new data and information, including information about product misuse or abuse at the user level, may lead government agencies, professional societies, practice management groups or patient or trade organizations to recommend or publish guidance or guidelines related to the use of our products, which may lead to reduced sales of our products. For example, in May 2016, an FDA advisory panel recommended mandatory training of all physicians who prescribe opioids on the risks of prescription opioids. In 2016, the U.S. Centers for Disease Control and Prevention also issued a guideline for prescribing opioids for chronic pain that provides recommendations for primary care clinicians prescribing opioids for chronic pain outside of active cancer treatment, palliative care and end-of-life care. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription opioid medications in an attempt to curb abuse. These or any new regulations or requirements could be difficult and expensive for us to comply with and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The FDA scheduled a Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee in March 2017 to discuss pre- and post-marketing data about the abuse of OPANA® ER and the overall risk-benefit of this product. The advisory committees were also scheduled to discuss abuse of generic oxycodone ER and oxycodone immediate-release products. In March 2017, the advisory committees voted 18 to eight, with one abstention, that the benefits of reformulated OPANA® ER no longer outweigh its risks. While several of the advisory committee members acknowledged the role of OPANA® ER in clinical practice, others believed its benefits were overshadowed by the continuing public health concerns around the product's misuse, abuse and diversion. In June 2017, the FDA requested that we voluntarily withdraw OPANA® ER from the market and, in July 2017, after careful consideration and consultation with the FDA, we decided to voluntarily remove OPANA® ER from the market to the Company's financial detriment. During the second quarter of 2017, we began to work with the FDA to coordinate an orderly withdrawal of the product from the market. By September 1, 2017, we ceased shipments of OPANA® ER to customers and the FDA withdrew the NDA in December 2020. These actions had an adverse effect on our revenues and, as a result of these actions, we incurred certain charges. Actions similar to these, such as recalls or withdrawals, could divert management time and attention, reduce market acceptance of all of our products, harm our reputation, reduce our revenues, lead to additional charges or expenses or result in product liability claims, any of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Based on scientific developments, post-market experience, legislative or regulatory changes or other factors, the current FDA standards of review for approving new pharmaceutical products, or new indications or uses for approved or cleared products, are sometimes more stringent than those that were applied in the past.

Some new or evolving FDA review standards or conditions for approval or clearance were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have safety databases on these products that are as extensive as some products developed more recently. Accordingly, we believe the FDA may develop such databases for certain of these products, including many opioids. In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which, based on certain structural characteristics and laboratory tests, may indicate the potential for having mutagenic effects. The FDA has required, and may continue to require, more stringent controls of the levels of these or other impurities in products.

Also, the FDA may require labeling revisions, formulation or manufacturing changes and/or product modifications for new or existing products containing impurities. More stringent requirements, together with any additional testing or remedial measures that may be necessary, could result in increased costs for, or delays in, obtaining approvals. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless the effects of alleged impurities are believed to indicate a significant risk to patient health, we cannot make any such assurance.

The FDA's exercise of its authority under the FFDCA could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. For example, in 2015, the FDA sent letters to a number of manufacturers, including Endo, requiring that a randomized, double-blind, placebo-controlled clinical trial be conducted to evaluate the effect of testosterone replacement therapies on the incidence of major adverse cardiovascular events in men. The letter received by Endo required that we include new safety information in the labeling and Medication Guide for certain prescription medications containing testosterone, such as TESTIM®.

Post-marketing studies and other emerging data about marketed products, such as adverse event reports, may adversely affect sales of our products. Furthermore, the discovery of significant safety or efficacy concerns or problems with a product in the same therapeutic class as one of our products that implicate or appear to implicate the entire class of products could have an adverse effect on sales of our product or, in some cases, result in product withdrawals. The FDA has continuing authority over the approval of an NDA, ANDA or BLA and may withdraw approval if, among other reasons, post-marketing clinical or other experience, tests or data show that a product is unsafe for use under the conditions upon which it was approved or licensed, or if FDA determines that there is a lack of substantial evidence of the product's efficacy under the conditions described in its labeling.

In addition to the FDA and other U.S. regulatory agencies, non-U.S. regulatory agencies may have authority over various aspects of our business and may impose additional requirements and costs. Similar to other healthcare companies, our facilities in multiple countries across the full range of our business units are subject to routine and new-product related inspections by regulatory authorities including the FDA, the Medicines and Healthcare products Regulatory Agency, the Health Products Regulatory Authority and Health Canada. In the past, some of these inspections have resulted in inspection observations (including FDA Form 483 observations). Future inspections may result in additional inspection observations or other corrective actions, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Certain of our products contain controlled substances. Stringent Drug Enforcement Administration (DEA) and other governmental regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. In addition, failure to comply with applicable legal requirements could subject the manufacturing facilities of our subsidiaries and manufacturing partners to possible legal or regulatory action, including shutdown. Any such shutdown may adversely affect their ability to manufacture or supply product and thus, our ability to market affected products. This could have a material adverse effect on our business, financial condition, results of operations and cash flows. See also the risk described under the caption "The DEA limits the availability of the active ingredients used in many of our products as well as the production of these products, and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or complete clinical trials" in the Annual Report.

In addition, we are subject to the Federal Drug Supply Chain Security Act (DSCSA) enacted by the U.S. government, which requires development of an electronic pedigree to track and trace each prescription product at the salable unit level through the distribution system. The DSCSA will be effective incrementally over a 10-year period from its enactment on November 27, 2013. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements could require significant capital expenditures, increase our operating costs and impose significant administrative burdens.

We cannot determine what effect changes in laws, regulations or legal interpretations or requirements by the FDA, the courts or others, when and if promulgated or issued, or advisory committee meetings may have on our business in the future. Changes could, among other things, require expanded or different labeling, additional testing, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, limitations on product distribution, the recall or discontinuance of certain products and additional recordkeeping. Any such changes could result in additional litigation and may have a material adverse effect on our business, financial condition, results of operations and cash flows. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that, from time to time, we will be adversely affected by regulatory actions despite our ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Certain of these risks could be exacerbated by the impact of COVID-19.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There were no purchases or sales of equity securities by the Company during the three months ended March 31, 2022.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Number	Description	Incorporated by Reference from:		Filing Date
		File Number	Filing Type	
31.1	Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Not applicable;	filed herewith	
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Not applicable;	filed herewith	
32.1	Certification of the President and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Not applicable;	furnished herewith	
32.2	Certification of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Not applicable;	furnished herewith	
101.INS	iXBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.	Not applicable;	submitted herewith	
101.SCH	iXBRL Taxonomy Extension Schema Document	Not applicable;	submitted herewith	
101.CAL	iXBRL Taxonomy Extension Calculation Linkbase Document	Not applicable;	submitted herewith	
101.DEF	iXBRL Taxonomy Extension Definition Linkbase Document	Not applicable;	submitted herewith	
101.LAB	iXBRL Taxonomy Extension Label Linkbase Document	Not applicable;	submitted herewith	
101.PRE	iXBRL Taxonomy Extension Presentation Linkbase Document	Not applicable;	submitted herewith	
104	Cover Page Interactive Data File, formatted in iXBRL and contained in Exhibit 101	Not applicable;	submitted herewith	

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENDO INTERNATIONAL PLC

(Registrant)

/S/ BLAISE COLEMAN

Name: **Blaise Coleman**
Title: **President and Chief Executive Officer**
(Principal Executive Officer)

/S/ MARK T. BRADLEY

Name: **Mark T. Bradley**
Title: **Executive Vice President, Chief Financial Officer**
(Principal Financial Officer)

Date: May 6, 2022

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Blaise Coleman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endo International plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ BLAISE COLEMAN

Blaise Coleman

President and Chief Executive Officer
(Principal Executive Officer)

Date: May 6, 2022

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Mark T. Bradley, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endo International plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ MARK T. BRADLEY

Mark T. Bradley
Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: May 6, 2022

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Blaise Coleman, as President and Chief Executive Officer of Endo International plc (the Company), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2022 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ BLAISE COLEMAN

Name: Blaise Coleman
Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: May 6, 2022

A signed original of this written statement required by Section 906 has been provided to, and will be retained by, Endo International plc and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark T. Bradley, as Chief Financial Officer of Endo International plc (the Company), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2022 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ MARK T. BRADLEY

Name: Mark T. Bradley
Title: Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: May 6, 2022

A signed original of this written statement required by Section 906 has been provided to, and will be retained by, Endo International plc and furnished to the Securities and Exchange Commission or its staff upon request.