UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2021

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	**68-0683755**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
First Floor, Minerva House, Simmonscourt Road **Ballsbridge, Dublin 4, Ireland**	**Not Applicable**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **011-353-1-268-2000**

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

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

Securities registered pursuant to section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	Yes	☒	No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.	Yes	☐	No ☒
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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.	☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.	☒

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

The aggregate market value of the voting common equity (ordinary shares) held by non-affiliates as of June 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter) was $1,085,287,821 based on a closing sale price of $4.68 per share as reported on The NASDAQ Global Select Market on that date. Ordinary shares held by each officer and director have been excluded since such persons and beneficial owners may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no non-voting ordinary shares authorized or outstanding.

The number of ordinary shares, nominal value $0.0001 per share outstanding as of February 21, 2022 was 233,707,409.

Documents Incorporated by Reference

Portions of the registrant's proxy statement pursuant to Regulation 14A relating to its 2022 Annual General Meeting, to be filed with the Securities and Exchange Commission subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission no later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2021.

ENDO INTERNATIONAL PLC
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FOR THE YEAR ENDED DECEMBER 31, 2021

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 response to COVID-19 such as anticipated return to historical purchasing decisions by customers, the economic impact of COVID-19, 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 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 and the resulting economic crisis and levels of unemployment, governmental actions and restrictive measures implemented in response, material delays and cancellations of certain medical procedures, potential manufacturing and supply chain disruptions and other potential impacts to our business as a result of COVID-19); 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, tax matters with the United States (U.S.) Internal Revenue Service (IRS) and key products such as VASOSTRICT®; 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 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; 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 this Annual Report on Form 10-K and in other reports that we file with the Securities and Exchange Commission (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-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 in Part I, Item 1A. "Risk Factors" 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, we provide a cautionary discussion of the risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by Section 27A of the Securities Act and Section 21E of the Exchange Act. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this to be a complete discussion of all potential risks or uncertainties.

PART I

Item 1. *Business*

Overview

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.

Endo International plc is an Ireland-domiciled specialty pharmaceutical company. Endo International plc was incorporated in Ireland in 2013 as a private limited company and re-registered effective February 18, 2014 as a public limited company. Endo International plc is a holding company that conducts business through its operating subsidiaries.

Our ordinary shares are traded on the NASDAQ Global Select Market (Nasdaq) under the ticker symbol "ENDP." References throughout to "ordinary shares" refer to Endo International plc's ordinary shares (1,000,000,000 authorized, par value of $0.0001 per share). In addition, we have 4,000,000 euro deferred shares outstanding (par value of $0.01 per share).

The address of Endo International plc's headquarters is Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland (telephone number: 011-353-1-268-2000).

Our focus is on pharmaceutical products and we target areas where we believe we can build leading positions. Our operating model is based on a lean and nimble structure, the rational allocation of capital and an emphasis on high-value research and development (R&D) targets. While our primary focus is on organic growth, we evaluate and, where appropriate, execute on opportunities to expand through the licensing or acquisition of products or companies in areas that we believe serve patients and customers while offering attractive growth characteristics and margins. We believe our operating model and the execution of our corporate strategy will enable us to create shareholder value over the long-term.

The four reportable business segments in which we operate are: (1) Branded Pharmaceuticals, (2) Sterile Injectables, (3) Generic Pharmaceuticals and (4) International Pharmaceuticals. Additional information about our reportable business segments is included throughout this Part I. The results of operations of our reportable business segments are discussed in Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the heading "RESULTS OF OPERATIONS." Across all of our reportable business segments, we generated total revenues of $2.99 billion, $2.90 billion and $2.91 billion in 2021, 2020 and 2019, respectively.

For branded products, which we sell primarily through our Branded Pharmaceuticals and Sterile Injectables segments, we seek to invest in products or product candidates that have inherent scientific, regulatory, legal and technical complexities and market such products under recognizable brand names that are trademarked. For products we develop for the U.S. market, after the completion of required clinical trials and testing, we seek approvals from regulatory bodies such as through the submission of New Drug Applications (NDAs) or Biologics License Applications (BLAs) to the U.S. Food and Drug Administration (FDA). We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes, trade secrets, know-how, innovations and all of our intellectual property are important to our business and achieving a competitive position. However, there can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition. Additional information is included throughout this Part I, Item 1.

Generic products are the pharmaceutical and therapeutic equivalents of branded products and are generally sold under their generic (chemical) names rather than their brand names. For generic products, which we sell primarily through our Sterile Injectables and Generic Pharmaceuticals segments, our focus is on high-barrier-to-entry products, with an emphasis on complex sterile injectable products, such as ready-to-use (RTU) products, and first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges. In the U.S., a first-to-file product refers to a generic product for which the Abbreviated New Drug Application (ANDA) containing a patent challenge (or Paragraph IV certification) to the corresponding branded product's listed patents was the first to be filed with the FDA. In the U.S., manufacturers that launch first-to-file products, after success in litigating or otherwise resolving related patent challenges, and receive final FDA approval have the opportunity for 180 days of generic marketing exclusivity from competing generic products other than authorized generics. A first-to-market product refers to a product that is the first marketed generic equivalent of a branded product for reasons apart from statutory marketing exclusivity. This can occur, for example, when a generic product is difficult to formulate or manufacture. First-to-market products allow manufacturers to mitigate risks from competitive pressures commonly associated with commoditized generic products. Additional information is included throughout this Part I, Item 1.

Our Strategy

Endo International plc is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of high-quality, life-enhancing therapies. We are focused on driving long-term growth through a diversified and durable portfolio of businesses, continuing product development and manufacturing and commercialization excellence. Our strategic priorities include expanding and enhancing our portfolio with differentiated and durable products; reinventing how we work to better serve our customers, promote innovation and improve productivity; and being a force for good by embracing and adopting sustainable practices that benefit all of our stakeholders. Specific areas of management's focus include:

- Branded Pharmaceuticals: Accelerating performance of organic growth drivers in our Specialty Products portfolio, expanding margin in our Established Products portfolio and creating a new treatment category in the medical aesthetics market, which we entered in March 2021 with the launch of QWO® (collagenase clostridium histolyticum-aaes), which was approved by the FDA in July 2020 for the treatment of moderate to severe cellulite in the buttocks of adult women. As further described below under the heading "Select Development Projects," management is also focused on investing in key product life cycle management and other development opportunities, including in the areas of medical therapeutics and medical aesthetics.
- Sterile Injectables: Focusing on developing injectable products with inherent scientific, regulatory, legal and technical complexities, expanding the product portfolio to include other dosages and technologies and developing or acquiring high-barrier-to-entry products that are difficult to manufacture.
- Generic Pharmaceuticals: Focusing on developing or acquiring high-barrier-to-entry products, including first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges.

Additionally, as part of our Environmental, Social and Governance (ESG) strategy, we are committed to the adoption of more sustainable practices, including the promotion of Diversity, Equity and Inclusion (DE&I) in all that we do, and to operating our business in a responsible manner that seeks to minimize environmental impact, while promoting the safe, efficient and responsible use of global resources.

While our primary focus is on organic growth, we plan to continue to evaluate and, where appropriate, execute on opportunities to expand through the licensing or acquisition of products or companies. There can be no assurance that we will be successful in executing on our strategy.

Our Competitive Strengths

To successfully execute our strategy, we must continue to capitalize on our following core strengths:

Experienced and dedicated management team. We have a highly skilled and customer-focused management team in critical leadership positions across Endo. Our senior management team has extensive experience in the pharmaceutical and medical aesthetics industry, including improving business performance through organic revenue growth, operational and commercial excellence and through the identification, consummation and integration of licensing and acquisition opportunities. This experience is demonstrated through a proven track record of developing businesses and creating value. For example, in recent years, our management team has led our development and commercialization programs for QWO®, which was approved by FDA in July 2020. With our launch of QWO® in March 2021, we have built a new category in the medical aesthetics market with the first and only FDA-approved injectable for moderate to severe cellulite in the buttocks of adult women.

Operational excellence. We have efficient, high-quality manufacturing capabilities across a diversified array of dosage forms in the U.S. and India. We believe our comprehensive suite of technology, manufacturing and development competencies increases the likelihood of success in commercializing high-barrier-to-entry products and obtaining first-to-file and first-to-market status on future products, yielding more sustainable market share and profitability. For example, our expanding capabilities in the rapidly growing U.S. market for sterile products afford us with a broader and more diversified product portfolio and a greater selection of targets for potential development.

We believe that our competitive advantages include our integrated team-based approach to product development that combines our global formulation, regulatory, legal, manufacturing and commercial capabilities; our ability to introduce new generic equivalents for brand-name products; our quality and cost-effective production; our ability to meet customer and/or patient expectations and the breadth of our existing product offerings.

Growth of our branded Specialty Products portfolio while leveraging the strength of our Established Products portfolio. We have assembled a portfolio of branded products offered by our Branded Pharmaceuticals segment in the areas of urology, orthopedics, endocrinology, medical aesthetics and bariatrics, among others. Additional information on these product portfolios is included below under the heading "Products Overview."

Optimizing our portfolios to focus on differentiated products. By leveraging operational efficiency and taking actions to optimize our cost structure when appropriate, we aim to be low-cost producers of high-barrier-to-entry products, including products that meet the evolving needs of hospitals and health systems, including RTU sterile injectable products, and first-to-file and first-to-market generic opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges. We believe that focusing on products with these characteristics will result in products with longer life cycles and higher profitability than products without these characteristics.

Continuing proactive diversification of our business. Our primary focus is on organic growth. However, we plan to continue to evaluate and, where appropriate, execute on opportunities to expand through the licensing or acquisition of products or companies in areas that will serve patients and customers and that we believe will offer attractive growth characteristics and margins. In particular, we intend to continue to enhance our product lines by acquiring or licensing rights to additional products and regularly evaluating selective acquisition opportunities.

R&D expertise. Our R&D efforts are focused on the development of a diversified portfolio of innovative and clinically differentiated product candidates. For example, in recent years, our Branded Pharmaceuticals research has focused on leveraging our expertise in collagenase clostridium histolyticum (CCH) and seeking additional novel indications for this class of biologics. Our Sterile Injectables and Generic Pharmaceuticals segments seek out and develop high-barrier-to-entry products, with an emphasis on complex sterile injectable products, such as RTU products, and first-to-file or first-to-market opportunities. We periodically review our R&D pipeline in order to better direct investment toward those opportunities that we expect will deliver the greatest returns. Our current R&D pipeline consists of products in various stages of development and reflects our expanded focus on Sterile Injectables products and solutions. For additional detail, see "Select Development Projects." Our R&D and regulatory affairs staff is based primarily in India and Pennsylvania.

Targeted sales and marketing capabilities. Our sales and marketing activities are based in the U.S. and Canada and primarily focus on the promotion of our Specialty Products portfolio and Sterile Injectables segment.

We market our Specialty Products directly to specialty physicians, including those specializing in urology, orthopedics, medical aesthetics, pediatric endocrinology and bariatric surgery. Our sales force also directs its marketing efforts on retail pharmacies and other healthcare professionals. We distribute our Specialty Products through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors, independent retail and specialty pharmacies and independent specialty distributors. Our marketing policy is designed to provide physicians, pharmacies, hospitals, public and private payers and appropriate healthcare professionals with products and appropriate medical information. We work to gain access to various formularies (lists of recommended or approved medicines and other products) and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications.

In addition to advertising in professional journals, participating in medical meetings and conventions and utilizing direct mail and internet programs to provide descriptive product literature and scientific information, we have also utilized both branded and unbranded marketing and public relations campaigns across digital, social and television platforms to reach our target consumers. For example, throughout 2021, we conducted a multi-channel cellulite condition awareness campaign, Really Cellulite, and, during the fourth quarter of 2021, we launched a new multi-channel branded advertising campaign for XIAFLEX® for the treatment of Peyronie's disease (PD), including our first-ever television commercial for XIAFLEX®.

Our dedicated Sterile Injectables sales and marketing team is focused on health systems and national group purchasing organizations (GPOs). Our customers' growing complexity requires us to engage directly with key stakeholders and decision makers. Our experienced sales and marketing team is key to growing our existing portfolio and executing on new product launches.

Products Overview

Branded Pharmaceuticals

The following table displays the revenues from external customers of our Branded Pharmaceuticals segment for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Specialty Products:			
XIAFLEX®	$ 432,344	$ 316,234	$ 327,638
SUPPRELIN® LA	114,374	88,182	86,797
Other Specialty (1)	86,432	92,662	105,241
Total Specialty Products	$ 633,150	$ 497,078	$ 519,676
Established Products:			
PERCOCET®	$ 103,788	$ 110,112	$ 116,012
TESTOPEL®	43,636	35,234	55,244
Other Established (2)	113,043	139,356	164,470
Total Established Products	$ 260,467	$ 284,702	$ 335,726
Total Branded Pharmaceuticals (3)	$ 893,617	$ 781,780	$ 855,402

(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 year ended December 31, 2021 and/or any product having revenues in excess of $25 million during any quarterly period in 2021 or 2020.

Specialty Products Portfolio

Endo commercializes a number of products within the market served by specialty distributors and specialty pharmacies and in which healthcare practitioners can purchase and bill payers directly (the buy and bill market). Our current offerings primarily relate to the following areas: (i) urology treatments, which currently focus mainly on PD and testosterone replacement therapies (TRT) for hypogonadism, (ii) orthopedics treatments, which currently focus on Dupuytren's contracture (DC), (iii) pediatric endocrinology treatments, which currently focus on central precocious puberty (CPP), and (iv) medical aesthetics treatments, which currently focus on cellulite. Key product offerings in this portfolio include the following:

- XIAFLEX®, which is a non-surgical treatment for both DC (for adult patients with an abnormal buildup of collagen in the fingers that limits or disables hand function) and PD (for adult men with a collagen plaque and a penile curvature deformity of thirty degrees or greater at the start of therapy).
- SUPPRELIN® LA, which is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a gonadotropin-releasing hormone agonist, and is indicated for the treatment of CPP in children.
- NASCOBAL® Nasal Spray, which is a prescription nasal spray used as a supplement to treat vitamin B12 deficiency.
- AVEED®, which is a novel, long-acting testosterone undecanoate for injection for the treatment of hypogonadism that is dosed only five times per year after the first month of therapy.
- QWO®, which is an injectable treatment for moderate to severe cellulite in the buttocks of adult women.

Established Products Portfolio

This portfolio's current treatment offerings primarily relate to the following areas: (i) pain management, including products in the opioid analgesics segment and for the treatment of pain associated with post-herpetic neuralgia, and (ii) urology, focusing mainly on the treatment of hypogonadism. Key product offerings in this portfolio include, among others, the following:

- PERCOCET®, which is an opioid analgesic approved for the treatment of moderate to moderately-severe pain.
- TESTOPEL®, which is a unique, long-acting implantable pellet indicated for TRT in conditions associated with a deficiency or absence of endogenous testosterone.
- EDEX®, which is a penile injection used to treat erectile dysfunction caused by conditions affecting nerves, blood vessels, emotions and/or a combination of factors.
- LIDODERM®, which is a topical patch product containing lidocaine that is approved for the relief of pain associated with post-herpetic neuralgia, a condition thought to result after nerve fibers are damaged during a case of herpes zoster (commonly known as shingles).

The Company's pain products, including opioid products, are managed as mature brands and are not and have not been actively promoted for years. In December 2016, the Company announced the elimination of its entire U.S. pain product field sales force.

Sterile Injectables

The following table displays the revenues from external customers of our Sterile Injectables segment for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
VASOSTRICT®	$ 901,735	$ 785,646	$ 531,737
ADRENALIN®	124,630	152,074	179,295
Other Sterile Injectables (1)	239,732	301,127	352,099
Total Sterile Injectables (2)	$ 1,266,097	$ 1,238,847	$ 1,063,131

(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 year ended December 31, 2021 and/or any product having revenues in excess of $25 million during any quarterly period in 2021 or 2020.

The Sterile Injectables segment includes a product portfolio of approximately 35 product families, including branded sterile injectable products that are currently protected by certain patent rights and have inherent scientific, regulatory, legal and technical complexities and generic injectable products that are difficult to formulate or manufacture or face complex legal and regulatory challenges. Our sterile injectables products are manufactured in sterile facilities in various dosage forms and are administered at hospitals, clinics and long-term care facilities. Key product offerings in this segment include, among others, the following:

- VASOSTRICT®, which is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. We offer VASOSTRICT® in multiple formulations, including the RTU pre-mix bottle we launched in February 2022.
- ADRENALIN®, which is a non-selective alpha and beta adrenergic agonist indicated for emergency treatment of certain allergic reactions, including anaphylaxis.
- Ertapenem for injection (the authorized generic of Merck Sharp & Dohme Corp.'s (Merck) Invanz®), which is indicated for the treatment of certain moderate to severe infections.
- APLISOL®, which is a sterile aqueous solution of a purified protein derivative for intradermal administration as an aid in the diagnosis of tuberculosis.
- Ephedrine sulfate injection, which is an alpha and beta adrenergic agonist and a norepinephrine-releasing agent indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

Generic Pharmaceuticals

The Generic Pharmaceuticals segment includes a product portfolio of approximately 125 generic product families including solid oral extended-release, solid oral immediate-release, liquids, semi-solids, patches (which are medicated adhesive patches designed to deliver the pharmaceutical through the skin), powders, ophthalmics (which are sterile pharmaceutical preparations administered for ocular conditions) and sprays and includes products that treat and manage a wide variety of medical conditions.

Generic products are the pharmaceutical and therapeutic equivalents of branded products and are generally sold under their generic (chemical) names rather than their brand names. Generic products are substantially the same as branded products in dosage form, safety, efficacy, route of administration, quality, performance characteristics and intended use, but are generally sold at prices below those of the corresponding branded products and thus represent cost-effective alternatives for consumers.

Typically, a generic product may not be marketed until the expiration of applicable patent(s) on the corresponding branded product unless a resolution of patent litigation results in an earlier opportunity to enter the market. For additional detail, see "Governmental Regulation." However, our generics portfolio also contains certain authorized generics, which are generic versions of branded products licensed by brand drug companies under an NDA and marketed as generics. Authorized generics do not face the same regulatory barriers to introduction and are not prohibited from sale during the 180-day marketing exclusivity period granted to the first-to-file ANDA applicant. Our authorized generics include generic versions of our branded products including, for example, lidocaine patch 5% (LIDODERM®). We also aim to be a partner of choice to large companies seeking authorized generic distributors for their branded products. For example, in January 2021, we launched lubiprostone capsules (the authorized generic of Mallinckrodt plc's Amitiza®) and, in January 2020, we launched sucralfate oral suspension 1 gm/10 ml (the authorized generic of AbbVie Inc.'s Carafate®).

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.

Select Development Projects

XIAFLEX®

XIAFLEX® is currently approved by the FDA and marketed in the U.S. for the treatment of both DC and PD (two separate medical therapeutic indications). 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 may in the future develop our XIAFLEX® product for potential additional medical therapeutics indications, advancing our strategy of developing non-surgical orthopedic care solutions.

QWO®

QWO® was approved by the FDA in July 2020 for the treatment of moderate to severe cellulite in the buttocks of adult women (a medical aesthetics indication). During 2020, we put in place a U.S. aesthetics commercial team and the capabilities that enabled us to launch QWO® in March 2021. We have been progressing and expect to continue to progress our cellulite treatment development programs for QWO®. We may in the future initiate QWO® development programs for potential additional medical aesthetics indications.

As further described in Note 5. Acquisitions and Note 12. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this report, we completed our acquisition of BioSpecifics Technologies Corp., a Delaware corporation and a commercial-stage biopharmaceutical company (BioSpecifics) in December 2020. Prior to this acquisition, we had a strategic relationship with BioSpecifics since 2004 pursuant to which BioSpecifics was, among other things, entitled to a royalty stream from us related to our collagenase-based therapies, including XIAFLEX® and QWO®. Subsequent to the acquisition, BioSpecifics became our wholly-owned consolidated subsidiary.

Other

Our remaining pipeline consists mainly of a variety of product candidates in our Sterile Injectables and Generic Pharmaceuticals segments. As of December 31, 2021, these two segments were actively pursuing approximately 80 product candidates, including: (i) approximately 40 ANDAs pending with the FDA, approximately half of which represent first-to-file or first-to-market opportunities, and (ii) approximately 40 additional projects in development, more than 85% of which are associated with our Sterile Injectables segment, including RTU and other more differentiated product candidates.

Our primary approach to developing generic products for these two segments is to target high-barrier-to-entry product opportunities, including first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges as well as products that meet the evolving needs of hospitals and health systems. We expect such product opportunities to result in products that are either the exclusive generic or have two or fewer generic competitors when launched, which we believe tends to lead to more sustainable market share and profitability for our product portfolio. In our Sterile Injectables business, we also focus on developing injectable products with inherent scientific, regulatory, legal and technical complexities, as well as developing other dosage forms and technologies.

We periodically review our development projects in order to better direct investment toward those opportunities that we expect will deliver the greatest returns. This process can lead to decisions to discontinue certain R&D projects that may reduce the number of products in our previously reported pipeline.

Major Customers

We primarily sell our products to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and/or government agencies. Our wholesalers and/or distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies, hospitals, long-term care facilities, clinics, home infusion pharmacies, government facilities and managed care organizations (MCOs). Our current customer group reflects significant consolidation in recent years, marked by mergers and acquisitions and other alliances. Net revenues from direct customers that accounted for 10% or more of our total consolidated net revenues during the years ended December 31, 2021, 2020 and 2019 are as follows:

	2021	2020	2019
AmerisourceBergen Corporation	36 %	33 %	34 %
McKesson Corporation	32 %	27 %	26 %
Cardinal Health, Inc.	22 %	24 %	25 %

Revenues from these customers are included within each of our segments.

Some wholesalers and distributors have required pharmaceutical manufacturers, including us, to enter into distribution service agreements (DSAs) pursuant to which the wholesalers and distributors provide pharmaceutical manufacturers with certain services as well as certain information including, without limitation, periodic retail demand information, current inventory levels and other information. We have entered into certain of these agreements.

Competition

Branded Products

Our branded products compete with products manufactured by many other companies in highly competitive markets.

We compete principally through targeted product development and through our acquisition and in-licensing strategies, where we face intense competition as a result of the limited number of assets available and the number of competitors bidding on such assets. In addition to product development and acquisitions, other competitive factors with respect to branded products include product efficacy, safety, ease of use, price, demonstrated cost-effectiveness, marketing effectiveness, service, reputation and access to technical information.

Branded products often must compete with therapeutically similar branded or generic products or with generic equivalents. Such competition frequently increases over time. For example, if competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products could be subject to progressive price reductions and/or decreased volume of sales. To successfully compete for business, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Accordingly, we face pressure to continually seek out technological innovations and to market our products effectively.

Manufacturers of generic products typically invest far less in R&D than research-based companies and can therefore price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. Due to lower prices, generic versions, where available, may be substituted by pharmacies or required in preference to branded versions under third-party reimbursement programs.

Branded Pharmaceuticals

This segment's major competitors, including Viatris Inc. (Viatris), AbbVie Inc., Jazz Pharmaceuticals plc, Takeda Pharmaceutical Company Limited, Horizon Therapeutics Public Limited Company, AbbVie Inc. and Revance Therapeutics, Inc., among others, vary depending on therapeutic and product category, dosage strength and drug-delivery systems, among other factors.

Several of this segment's products, such as PERCOCET®, TESTOPEL®, LIDODERM® and SUPPRELIN® LA, face generic and/or other forms of competition. The degree of generic and/or other competition facing this segment could increase in the future.

Sterile Injectables

This segment's major competitors, including Hospira, Inc. (a subsidiary of Pfizer Inc.), Fresenius Kabi USA, LLC (Fresenius), Viatris, Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals, Inc. (Amneal), Hikma Pharmaceuticals PLC, Sandoz (a division of Novartis AG) and Eagle Pharmaceuticals, Inc. (Eagle), among others, vary by product. A significant portion of our sales, including sales to hospitals, clinics and long-term care facilities in the U.S., are controlled by a relatively small number of GPOs, including HealthTrust Purchasing Group, L.P., Premier Inc. and Vizient, Inc. Accordingly, it is important for us to have strong relationships with these GPOs and achieve on-time product launches in order to secure new bid opportunities.

This segment's products, including VASOSTRICT® and ADRENALIN®, face generic and/or other forms of competition. During the first quarter of 2022, multiple competing generic alternatives to VASOSTRICT® were launched, beginning with Eagle's generic, which it launched at risk and began shipping toward the end of January 2022. Since then, additional competing alternatives have entered the market, including an authorized generic. The degree of generic and/or other competition facing this segment is expected to increase in the future.

Generic Products

Generic products generally face intense competition from branded equivalents, other generic equivalents (including authorized generics) and therapeutically similar branded or generic products. Our major competitors, including Teva Pharmaceutical Industries Limited, Viatris, Sandoz, Aurobindo Pharma Limited and Amneal, among others, vary by product.

Consolidations of our customer base described above under the heading "Major Customers" have resulted in increased pricing and other competitive pressures on pharmaceutical companies, including us. Additionally, the emergence of large buying groups representing independent retail pharmacies and other distributors and the prevalence and influence of MCOs and similar institutions have increased the negotiating power of these groups, enabling them to attempt to extract various demands, including without limitation price discounts, rebates and other restrictive pricing terms. These competitive trends could continue in the future and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Newly introduced generic products with limited or no other generic competition typically garner higher prices relative to commoditized generic products. As such, our primary strategy is to compete with a focus on high-value, first-to-file or first-to-market opportunities, regardless of therapeutic category, and products that present significant barriers to entry for reasons such as complex formulation or regulatory or legal challenges. For additional detail, see "Our Competitive Strengths - Optimizing our portfolios to focus on differentiated products."

Even if we are successful in launching generic products with statutory generic exclusivity, competitors may enter the market when such exclusivity periods expire, resulting in significant price declines. Consequently, the success of our generics efforts depends on our continuing ability to select, develop, procure regulatory approvals of, overcome legal challenges to, launch and commercialize new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing capabilities. For additional detail, see "Our Competitive Strengths - Operational excellence."

Seasonality

Although our business is affected by the purchasing patterns and concentration of our customers, our business is not materially impacted by seasonality.

Patents, Trademarks, Licenses and Proprietary Property

We regard the protection of patents and other enforceable intellectual property rights that we own or license as critical to our business and competitive position. Accordingly, we rely on patent, trade secret and copyright law, as well as nondisclosure and other contractual arrangements, to protect our intellectual property. We have a portfolio of patents and patent applications owned or licensed by us that cover aspects of our products. These patents and applications generally include claims directed to the compounds and/or methods of using the compounds, formulations of the compounds, pharmaceutical salt forms of the compounds or methods of manufacturing the compounds. Our policy is to pursue patent applications on inventions that we believe are commercially important to the development and growth of our business. Certain patents relating to products that are the subject of approved NDAs are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book). The table below contains a list from the Orange Book of patent expiration dates for certain products we market.

The Orange Book does not include a listing of patents related to biological products. Included below is information about certain products for which we own or license a BLA along with the date of expiration of certain relevant patents or regulatory exclusivity. In addition, we may have other relevant regulatory protection or patents that may extend beyond the expiration dates provided below. We may also obtain further patents or additional regulatory or patent exclusivity for one or more indications for a product in the future.

As of February 21, 2022, we held approximately: 154 U.S. issued patents, 30 U.S. patent applications pending, 440 foreign issued patents and 115 foreign patent applications pending. In addition, as of February 21, 2022, we had licenses for approximately 57 U.S. issued patents, 18 U.S. patent applications pending, 166 foreign issued patents and 89 foreign patent applications pending.

Our products are subject to different patent expiration dates. For example, our patents related to NASCOBAL® Nasal Spray expire in 2024, our patents related to AVEED® expire in 2027 and our patents related to ADRENALIN® expire in 2035. We have obtained and are seeking additional patent protection for several other products that will expire into the late 2030s/early 2040s, including XIAFLEX® and QWO®.

Our patents provide protection by allowing us to exclude others from making, using, selling, offering for sale or importing that which is covered by the patent claims. When patent protection is not feasible, we may rely on trade secrets, non-patented proprietary know-how or continuing technological innovation. Many of our products are sold under trademarks. We also rely on confidentiality agreements with our employees, consultants and other parties to protect, among other things, trade secrets and other proprietary information.

There can be no assurance that our patents, licenses or other intellectual property rights will afford us protection from competition. For example, in August 2021, the U.S. District Court for the District of Delaware held that Eagle's proposed vasopressin product did not infringe our asserted patent claims related to VASOSTRICT®. The expiration of a basic product patent or loss of patent protection resulting from a legal challenge typically results in significant competition from generic products or biosimilars against the originally patented product and can result in a significant reduction in revenues for that product in a very short period of time that may never be reversed. In some cases, however, it is possible to obtain commercial benefits from product manufacturing trade secrets, patents on uses for products, patents on processes and intermediates for the economical manufacture of the active ingredients or patents for special formulations of the product or delivery mechanisms. There can also be no assurance that our confidentiality agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property.

Additionally, any pending or future patent applications made by us or our subsidiaries, our license partners or entities we may acquire in the future are subject to risks and uncertainties. The coverage claimed in any such patent applications could be significantly reduced before the patent is issued and there can be no assurance that any such applications will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of eighteen months and certain U.S. patent applications are not disclosed until the patents are issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference and other inter-parties proceedings declared by the U.S. Patent and Trademark Office (PTO) to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that any patents, if issued, will be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology. See Item 1A. Risk Factors - "Our ability to protect and maintain our proprietary and licensed third party technology, which is vital to our business, is uncertain."

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property or trade secrets or to determine the scope and validity of the proprietary rights of others. However, litigation is costly and time-consuming and there can be no assurance that we will prevail. Any successful challenges to our intellectual property rights may result in a significant loss of revenue. See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Governmental Regulation

FDA and U.S. Drug Enforcement Administration (DEA)

The pharmaceutical industry in the U.S. is subject to extensive and rigorous government regulation. The Federal Food, Drug, and Cosmetic Act (FFDCA), the Controlled Substances Act (CSA) and other federal and state statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storage, recordkeeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in criminal prosecution, fines, civil penalties, recall or seizure of products, total or partial suspension of production and/or distribution, injunctions and refusal of the government to enter into supply contracts or to approve NDAs, ANDAs, BLAs and/or other similar applications.

FDA approval is typically required before any new pharmaceutical or biologic product can be marketed. An NDA or BLA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The process generally involves, among other things:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an Investigational New Drug application (IND) for human clinical testing, which must become effective before human clinical trials may begin in the U.S.;
- approval by an independent institutional review board before each trial may be initiated and continuing review during the trial;
- performance of human clinical trials, including adequate and well-controlled clinical trials in accordance with good clinical practice, the protocol and the IND to establish the safety and efficacy of the proposed product for each intended use;
- submission to the FDA of an NDA or BLA for marketing approval, which must include data from preclinical testing and clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the product's manufacturing processes and facility or facilities to assess compliance with the FDA's current Good Manufacturing Practice (cGMP) regulations and/or review of the Chemistry, Manufacturing and Controls section of the NDA or BLA to assess whether the facilities, methods and controls are adequate to preserve the proposed product's identity, strength, quality, purity and potency;
- payment of user fees for FDA review of an NDA or BLA unless a fee waiver applies;
- agreement with the FDA on the final labeling for the product and the design and implementation of any required Risk Evaluation and Mitigation Strategy (REMS);
- satisfactory completion of an FDA advisory committee review, if applicable; and
- approval by the FDA of the NDA or BLA.

Clinical trials are typically conducted in three sequential phases, although the phases may overlap or be combined. Those phases include:

- Phase 1 trials generally involve testing the product for safety, adverse effects, dosage, tolerance, absorption, distribution, metabolism, excretion and other elements of clinical pharmacology.

- Phase 2 trials typically involve a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential adverse effects.
- Phase 3 trials are undertaken in an expanded patient population, typically at dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials, clinical investigators and the trial sponsor are also subject to regulatory inspections by the FDA and other regulatory authorities to confirm compliance with applicable regulatory standards. The process of completing clinical trials for a new product may take many years and require the expenditures of substantial resources. See Item 1A. Risk Factors - "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."

As a condition of approval of an NDA or BLA, the FDA may require further studies, including Phase 4 post-marketing studies or post-marketing data reporting, such as evaluating known or signaled safety risks. Results of post-marketing programs may limit or expand the future marketing of the products and result in the FDA requiring labeling changes, including the addition of risk information.

For some products, the FDA may require a REMS to confirm that a drug's benefits outweigh its risks. REMS could include medication guides, physician communication plans or other elements. See Item 1A. Risk Factors - "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."

In most instances, FDA approval of an ANDA is required before a generic equivalent of an existing or reference-listed drug can be marketed. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and generally instead relies principally on bioequivalence studies. Bioequivalence generally involves a comparison of the rate of absorption and levels of concentration of a generic product in the body with those of the previously approved product. When the rate and extent of absorption of systemically acting test and reference drugs are considered the same under the bioequivalence requirement, the two products are considered bioequivalent and are generally regarded as therapeutically equivalent (so long as the products also have the same active ingredient(s), strength/concentration, dosage form and route of administration), meaning that a pharmacist can substitute the generic product for the reference-listed drug. Under certain circumstances, an ANDA may also be submitted for a product authorized by approval of an ANDA suitability petition. Such petitions may be submitted to secure authorization to file an ANDA for a product that differs from a previously approved product in active ingredient, route of administration, dosage form or strength. In September 2007 and July 2012, the U.S. Congress re-authorized pediatric testing legislation, which now requires ANDAs approved via the suitability petition route to conduct pediatric testing. The timing of final FDA approval of an ANDA application depends on a variety of factors, including whether the applicant challenges any listed patents for the reference-listed drug and whether the manufacturer of the reference-listed drug is entitled to one or more statutory exclusivity periods during which the FDA is prohibited from finally approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, thus blocking ANDAs from being approved even after the patent expiration date.

Certain of our products are or could become regulated and marketed as biologic products pursuant to BLAs. Our BLA-licensed products were licensed based on a determination by the FDA of safety, purity and potency as required under the Public Health Service Act (PHSA). Although the ANDA framework referenced above does not apply to generics of BLA-licensed biologics, there is an abbreviated licensure pathway for products deemed to be biosimilar to, or interchangeable with, FDA-licensed reference biological products pursuant to the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The BPCIA framework was enacted as part of the Patient Protection and Affordable Care Act (PPACA) and could be impacted by ongoing litigation regarding the legality of the PPACA. Under the BPCIA, following the expiration of a 12-year reference exclusivity period, the FDA may license, under section 351(k) of the PHSA, a biological product that it determines is biosimilar to, or interchangeable with, a reference product licensed under section 351(a) of the PHSA. Although licensure of biosimilar or interchangeable products is generally expected to require less than the full complement of product-specific preclinical and clinical data required for innovator products, the FDA has considerable discretion over the kind and amount of scientific evidence required to demonstrate biosimilarity and interchangeability.

Some pharmaceutical products are available in the U.S. that are not the subject of an FDA-approved NDA. In 2011, the FDA's Center for Drug Evaluation and Research (CDER) Office of Compliance modified its enforcement policy with regard to the marketing of such "unapproved" marketed products (the Unapproved Drug Initiative). Under CDER's revised guidance, the FDA encourages manufacturers to obtain NDA approvals for such products by requiring unapproved versions to be removed from the market after an approved version has been introduced, subject to a grace period at the FDA's discretion. This grace period is intended to allow an orderly transition of supply to the market and to mitigate any potential related product shortage. Depending on the length of the grace period and the time it takes for subsequent applications to be approved, this may result in a period of de facto market exclusivity to the first manufacturer that has obtained an approved NDA for the previously unapproved marketed product. In November 2020, the U.S. Department of Health and Human Services (HHS) announced that it was withdrawing its Unapproved Drugs Compliance Policy Guidance and terminating the Unapproved Drug Initiative described above. However, in May 2021, HHS withdrew the November 2020 termination notice and stated that the FDA would issue new guidance on its enforcement priorities for unapproved marketed products.

Over-the-counter (OTC) products may, depending on ingredients and proposed label claims, be marketed pursuant to the OTC monograph process or could require NDA or ANDA approval. The OTC monograph process allows for OTC products to be marketed without pre-market approval and generally does not require clinical studies. The Over-the-Counter Monograph Safety, Innovation, and Reform Act, enacted on March 27, 2020, modified this process by introducing administrative orders as a replacement to rulemaking for the development of OTC monographs.

Laws and regulations impacting the pharmaceutical industry are constantly evolving. For example, the 21st Century Cures Act (Cures Act), which was signed into law on December 13, 2016, includes various provisions to accelerate the development and delivery of new treatments, such as those intended to expand the types of evidence manufacturers may submit to support FDA approval, to encourage patient-centered product development, to liberalize the communication of healthcare economic information to payers and to create greater transparency with regard to manufacturer expanded access programs. Central to the Cures Act are provisions that enhance and accelerate the FDA's processes for reviewing and approving new products and supplements to approved NDAs. The Cures Act also included $1 billion in new funding to states to supplement opioid abuse prevention and treatment activities.

More recently, in December 2019, the Further Consolidated Appropriations Act, 2020 (FCAA 2020) became law. Section 610 of Division N Title I, titled "*Actions for Delays of Generic Drugs and Biological Products*," provides generic (ANDA and 505(b)(2)) and biosimilar developers with a private right of action to obtain sufficient quantities of reference product from the brand manufacturer, or a generic or biosimilar manufacturer, necessary for approval of the developers' generic or biosimilar product. If a generic or biosimilar developer is successful in its suit, the defendant manufacturer would be required to provide sufficient quantities of product on commercially-reasonable, market-based terms and may be required to pay the developer's reasonable attorney's fees and costs as well as financial compensation under certain circumstances. The purpose of section 610 is to promote competition by facilitating the timely entry of lower-cost generic and biosimilar products. In addition, on March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in response to the COVID-19 pandemic. Among other provisions, the CARES Act made a number of changes to the FFDCA aimed at preventing drug shortages. Similarly, the FDA has issued a number of guidance documents describing the agency's expectations for how drug manufacturers should comply with various FDA requirements during the pandemic, including with respect to conducting clinical trials, distributing drug samples and reporting post-marketing adverse events. Moreover, as a result of the COVID-19 pandemic, there has been increasing political and regulatory scrutiny of foreign-sourced drugs and foreign drug supply chains, resulting in proposed legislative and executive actions, including executive orders, to incentivize or compel drug manufacturing operations to relocate to the U.S.

A sponsor of an NDA is required to identify, in its application, any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files an ANDA or NDA under Section 505(b)(2) of the FFDCA referencing the approved drug must make a certification in respect to any listed patents for the reference drug. The FDA may not approve such an ANDA or 505(b)(2) application until expiration of the reference drug's listed patents unless (i) the applicant certifies that the listed patents are invalid, unenforceable and/or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the listed drug of the basis upon which the patents are challenged and (ii) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application until the earliest of: (i) 30 months after submission; (ii) entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; (iii) such time as a court may order; or (iv) expiration of the patent.

One of the key motivators for challenging patents is the 180-day marketing exclusivity period granted to the developer of a generic version of a product that is the first to have a substantially complete ANDA received for review by the FDA and whose filing includes a certification that a reference product's listed patent(s) are invalid, unenforceable and/or not infringed (a Paragraph IV certification) and that otherwise does not forfeit eligibility for the exclusivity. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with accompanying amendments to the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act), this marketing exclusivity would begin to run upon the earlier of the commercial launch of the generic product or upon an appellate court decision in the generic company's favor or in favor of another ANDA applicant who had filed with a Paragraph IV certification and has tentative approval. In addition, the holder of the NDA for the listed drug may be entitled to certain non-patent exclusivity during which, depending on the type of exclusivity, the FDA either cannot accept or approve an application for a competing ANDA generic product or 505(b)(2) NDA product with the same active moiety. Depending on the exclusivity, the protection may apply to all of the reference drug's approved conditions of use, or may be limited to a certain condition of use or other protected label information.

The FDA also regulates pharmacies and outsourcing facilities that prepare "compounded" drugs pursuant to section 503A and 503B of the FFDCA, respectively. For instance, under section 503A of the FFDCA, pharmacies may compound drugs for an identified individual based on the receipt of a valid prescription order, or notation approved by the prescribing practitioner, that a compounded product is necessary for the identified patient. Similarly, under section 503B of the FFDCA, outsourcing facilities may compound drugs and sell them to healthcare providers, but not wholesalers or distributors. Although section 503A pharmacies and section 503B outsourcing facilities are subject to many regulatory requirements, compounded drugs are not subject to premarket review by the FDA and, therefore, may not have the same level of safety and efficacy as products subject to premarket review and approval by the FDA. Because they are not subject to premarket review, compounded drugs are frequently lower cost than either branded or generic products.

The FDA enforces regulations to require that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs conform to cGMPs. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations. Compliance with the regulations requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the products subject to NDAs and ANDAs and pre-license inspections of facilities engaged in similar activities for biologic products subject to BLAs. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients (APIs) used to formulate such products also ordinarily undergo pre-approval inspections. Failure of any facility to pass a pre-approval inspection will result in delayed approval.

Facilities that manufacture pharmaceutical or biological products must be registered with the FDA and all such products made in such facilities must be manufactured in accordance with the latest cGMP regulations. The FDA conducts periodic inspections of facilities to assess the cGMP status of marketed products. Following such inspections, the FDA could issue a Form 483 Notice of Inspectional Observations, which could require modification to certain activities identified during the inspection. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions. The FDA also may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance for a Warning Letter. FDA guidelines also provide for the issuance of Warning Letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Imported API and other components needed to manufacture our products could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or request, or in some instances require, product recalls and seek to enjoin or otherwise limit a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an unacceptable supplier, thereby disqualifying that company from selling products to federal agencies.

Certain of our subsidiaries sell products that are "controlled substances" as defined in the CSA and implementing regulations, which establish certain security and recordkeeping requirements administered by the DEA. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our products are listed by the DEA as Schedule II or III substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation.

The DEA limits the availability of the active ingredients that are subject to the CSA used in several of our products as well as the production of these products. We or our contract manufacturing organizations must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. As a result, our quotas may not be sufficient to meet commercial demand or complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. See Item 1A. Risk Factors - "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."

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. The facilities must have the security, control, accounting mechanisms and monitoring systems required by the DEA to prevent loss and diversion of controlled substances and to comply with reporting obligations. Failure to maintain compliance can result in enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke or restrict those registrations or, with the U.S. Department of Justice (DOJ), seek to impose civil penalties. In certain circumstances, violations could result in criminal proceedings.

In October 2018, the U.S. Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (H.R. 6). Intended to achieve sweeping reform to combat opioid abuse, H.R. 6, among other provisions, amends related laws administered by the FDA, DEA and the Centers for Medicare and Medicaid Services (CMS). Among other things, the law: (i) amends requirements related to the FDA's authority to include packaging requirements in REMS requirements; (ii) increases civil and criminal penalties for manufacturers and distributors for failing to maintain effective controls against diversion of opioids or for failing to report suspicious opioid orders; (iii) requires the DEA to estimate the amount of opioid diversion when establishing manufacturing and procurement quotas; (iv) implements expanded anti-kickback and financial disclosure provisions; and (v) authorizes HHS to implement a demonstration program which would award grants to hospitals and emergency departments to develop, implement, enhance or study alternative pain management protocols and treatments that limit the use and prescription of opioids in emergency departments.

Individual states also regulate controlled substances and we, as well as our third-party API suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of these products.

Government Benefit Programs

As described further in Item 1A. Risk Factors, statutory and regulatory requirements for government healthcare programs such as Medicaid, Medicare and TRICARE govern access and provider reimbursement levels, and provide for other cost-containment measures such as requiring pharmaceutical companies to pay rebates or refunds for certain sales of products reimbursed by such programs, or subjecting products to certain price ceilings. In addition to the cost-containment measures described in Item 1A. Risk Factors, sales to retail pharmacies under the TRICARE Retail Pharmacy Program are subject to certain price ceilings which require manufacturers to, among other things, pay refunds for prescriptions filled based on the applicable ceiling price limits. Beginning in the first quarter of 2017, pursuant to the Bipartisan Budget Act of 2015, manufacturers are required to pay additional rebates to state Medicaid programs if the prices of their non-innovator products rise at a rate faster than inflation (as continues to be the case for innovator products); this requirement previously existed only as to branded or innovator products and the change in law may impact our business.

The federal government may continue to pursue legislation aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. State governments also may continue to enact similar cost containment or transparency legislation. These efforts could have material consequences for the pharmaceutical industry and the Company. From time to time, legislative changes are made to government healthcare programs that impact our business. The U.S. Congress continues to examine various Medicare and Medicaid policy proposals that may result in a downward pressure on the prices of prescription products in these programs, including, most recently, as part of the House-passed Build Back Better Act. See Item 1A. Risk Factors - "The availability of third party reimbursement for our products is uncertain, and we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided."

Under the PPACA, pharmaceutical manufacturers of branded prescription products must pay an annual fee to the federal government. Each individual pharmaceutical manufacturer must pay a prorated share of the total industry fee based on the dollar value of its branded prescription product sales to specified federal programs.

Uncertainty continues to exist about the future of the PPACA as the past administration and congressional leaders took steps to repeal key PPACA provisions and the PPACA has been and continues to be subject to court challenges. For example, the Tax Cuts and Jobs Act of 2017 (TCJA) repealed the requirement that individuals maintain health insurance coverage or face a penalty (known as the individual mandate). In June 2021, the U.S. Supreme Court held that state and individual plaintiffs did not have standing to challenge the minimum essential coverage provision of the PPACA; in so holding, the U.S. Supreme Court did not consider larger constitutional questions about the validity of this provision or the validity of the PPACA in its entirety. Ongoing efforts to repeal, substantially amend, eliminate or reduce funding for the PPACA may threaten the stability of the insurance marketplace and may have consequences for the coverage and accessibility of prescription drugs. The current administration intends to strengthen and build upon the PPACA. In particular, the House-passed Build Back Better Act seeks to extend certain PPACA premium tax credits and temporarily close the so-called Medicaid coverage gap in states that have not adopted PPACA provisions to expand such coverage.

Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, violations of which can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs, and they also apply to hospitals, physicians and other potential purchasers of our products.

The federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b) prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Under the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, a person or entity need not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim, including items or services resulting from a violation of 42 U.S.C. § 1320a-7b, constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute and implementing regulations provide for certain exceptions for "safe harbors" for certain discounting, rebating or personal services arrangements, among other things, which were amended in 2020. However, the lack of uniform court interpretation of the Anti-Kickback Statute, coupled with novel enforcement theories by government authorities and stayed implementation of certain regulatory changes, make compliance with the law difficult. Violations of the federal Anti-Kickback Statute can result in significant criminal fines, exclusion from participation in Medicare and Medicaid and follow-on civil litigation, among other things, for both entities and individuals.

The civil False Claims Act and similar state laws impose liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. The Federal Physician Payments Sunshine Act and similar state laws impose reporting requirements for various types of payments to physicians and teaching hospitals. Failure to comply with reporting requirements under these laws could subject manufacturers and others to substantial civil money penalties. In addition, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical and medical device products, including state investigations of the Company regarding vaginal mesh devices previously sold by certain of our operating subsidiaries and investigations and litigation by certain government entities regarding the prior promotional practices of certain of our operating subsidiaries with respect to opioid products.

International Regulations

Through our international operations, the Company is subject to laws and regulations that differ from those under which the Company operates in the U.S. In most cases, non-U.S. regulatory agencies evaluate and monitor the safety, efficacy and quality of pharmaceutical products, govern the approval of clinical trials and product registrations and regulate pricing and reimbursement. Certain international markets have differing product preferences and requirements and operate in an environment of government-mandated, cost-containment programs, including price controls, such as the Patented Medicine Prices Review Board (PMPRB) in Canada.

In Canada, the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)* (the Amendments) were originally scheduled to come into force on July 1, 2020. Due to the COVID-19 pandemic, the Amendments have been delayed and are now set to come into force on July 1, 2022. The Amendments will introduce a number of changes to the regulation of Canadian drug prices by the PMPRB. The PMPRB is an administrative board with a mandate to protect Canadians from excessive pricing of patented medicines. Pharmaceutical manufacturers that are patentees are required to report applicable patents and file sales information so the PMPRB can monitor for excessive pricing as long as the product is considered to be a patented medicine. If it is determined the average price for a patented medicine is too high based on pricing tests developed by the PMPRB, a payment must be made to the PMPRB to offset the excessive revenues that were generated and/or the price of the medicine must be reduced. The PMPRB's authority to regulate the price of a drug product is linked to patent protection, specifically when there is a patent to an invention that is intended or capable of being used for medicine or for the preparation or production of medicine.

For patented medicines approved by Health Canada after August 21, 2019 (a cutoff date tied to the date of publication of the Amendments and not impacted by the delayed coming-into-force date), the Amendments will allow the PMPRB to consider additional factors when assessing whether a price is excessive: pharmacoeconomic value of the medicine in Canada, the size of the market for the medicine in Canada and the gross domestic product (GDP) and GDP per capita of Canada. For all patented medicines (regardless of the date of marketing authorization), the Amendments change the set of countries that the PMPRB uses for international price comparisons when assessing whether the Canadian price is excessive. Under the current regulations, the price of a Canadian medicine is compared to the price of that medicine in seven other countries, including the U.S. and Switzerland. The Amendments define a new set of eleven comparator countries, and the U.S. and Switzerland are no longer part of this basket. The implementation of the new set of comparator countries is expected to cause a decrease to permissible ceiling prices in Canada. Based on the final guidelines released by the PMPRB in October 2020, the ceiling price for a medicine is set by the median international ex-factory list price of the eleven comparator countries for most patented medicines. According to the Regulatory Impact Analysis Statement that accompanied the publication of the Amendments, the Canadian government originally estimated that the Amendments would result in 10-year total savings to public, private and out of pocket-payers of 8.8 billion Canadian dollars as a result of lower patented medicine costs. Although delays to the coming-into-force date may impact some of these savings, Health Canada anticipates that most of these savings will continue to occur as originally estimated.

Certain governments have placed restrictions on physician prescription levels and patient reimbursements, emphasized greater use of generic products and enacted across-the-board price cuts as methods of cost control.

Whether or not FDA approval has been obtained for a product, approval of the product by comparable regulatory authorities of other governments must be obtained prior to marketing the product in those jurisdictions. The approval process may be more or less rigorous than the U.S. process and the time required for approval may be longer or shorter than in the U.S.

Environmental Matters

Our operations are subject to substantial federal, state and local environmental laws and regulations concerning, among other matters, the generation, handling, storage, transportation, treatment and disposal of, and exposure to, hazardous substances. Violation of these laws and regulations, which may change, can lead to substantial fines and penalties. Many of our operations require environmental permits and controls to prevent and limit pollution of the environment. We believe that our facilities and the facilities of our third party service providers are in substantial compliance with applicable environmental laws and regulations. As part of our ESG strategy, we are committed to operating our business in a responsible manner that seeks to minimize environmental impact, while promoting the safe, efficient and responsible use of global resources.

Service Agreements

We contract with various third parties to provide certain critical services including manufacturing, packaging, supply, warehousing, distribution, customer service, certain financial functions, certain R&D activities and medical affairs, among others.

Refer to Note 12. License and Collaboration Agreements and Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information.

We primarily purchase our raw materials for the production and development of our products in the open market from third party suppliers. We attempt, when possible, to mitigate our raw material supply risks through inventory management and alternative sourcing strategies. However, some raw materials are only available from one source. We are required to identify the suppliers of all raw materials for our products in the drug applications that we file with the FDA. If the raw materials from an approved supplier for a particular product become unavailable, we would be required to qualify a substitute supplier with the FDA, which would likely interrupt manufacturing of the affected product. See Item 1A. Risk Factors for further discussion on the risks associated with the sourcing of our raw materials.

License & Collaboration Agreements and Acquisitions

We continue to seek to enhance our product line and develop a diversified portfolio of products through product acquisitions and in-licensing or acquiring licenses to products, compounds and technologies from third parties. The Company enters into strategic alliances and collaborative arrangements with third parties, which give the Company rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are primarily owned by these third parties. These alliances and arrangements can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, research collaborations and joint ventures. Such alliances and arrangements enable us to share the risk of incurring all R&D expenses that do not lead to revenue-generating products; however, because profits from alliance products are shared with the counter-parties to the collaborative arrangement, the gross margins on alliance products are generally lower, sometimes substantially so, than the gross margins that could be achieved had the Company not opted for a development partner. Refer to Note 12. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information.

Human Capital Resources

As of February 21, 2022, we have 3,103 employees, of which 457 are engaged in R&D and regulatory work, 461 in sales and marketing, 1,119 in manufacturing, 622 in quality assurance and 444 in general and administrative capacities. With the exception of certain production personnel in our Rochester, Michigan manufacturing facility, our employees are generally not represented by unions. We believe that our relations with our employees are good.

Our people strategy is focused on delivering a positive employee experience and fostering a culture of inclusion and belonging where team members can: (i) thrive within a safe working environment supported with excellent benefits; (ii) grow their careers through curiosity, exploration, learning and fulfilling on-the-job experiences; and (iii) connect with each other in a workplace that celebrates diversity and plays a meaningful role in the broader community.

Wellness and Safety

We want our team members to lead healthy lives so that, together as a team, we can better support our vision of helping everyone we serve live their best life. We offer programs intended to promote team members' physical, personal and financial well-being including medical benefits, disease management programs, stress management support, smoking cessation assistance and discounts for gym memberships. We also want to support the financial well-being of our team members and offer educational sessions on how to take advantage of Endo's Savings and Investment Plan, as well as our tax-free saving and spending accounts. Additionally, we have a robust safety program designed to educate team members about best practices and to record and/or report safety issues so that we can learn from them and continuously improve.

Workforce flexibility was something Endo needed to fully embrace in 2020, and we were pleased to see how agile, resilient and effective our team was in adapting to this new work environment. In 2021, we introduced flexible work arrangements for all office-based team members, enabling team members to determine where to work. Team members appreciate the flexibility along with the focus on maintaining an engaged, collaborative, performance-driven culture.

Career Development

Endo offers a fast-paced and challenging work environment in which people are encouraged to grow, both professionally and personally. The Company provides a variety of training programs and an educational assistance program to help team members improve their job-related skills and long-term career potential.

Diversity, Equity and Inclusion

At Endo, our diversity unites us. We are committed to cultivating, valuing and embracing every person's distinct voice. This includes promoting an environment where our team members welcome the various dimensions of our workplace culture driven by differences in races, genders (including gender identity or expression), national origin, color, sexual orientation, disability status, age and all other unique characteristics. We believe these varied perspectives are valuable and can fuel our innovation and help drive our success. Our DE&I strategy is led by our Global Head of DE&I; is championed by a global and cross-functional DE&I Leadership Council, sponsored by our Chief Executive Officer; and is focused across three strategic priorities: talent, culture and community.

To build a strong pipeline of diverse talent, Endo has taken a number of steps to revamp our recruitment, hiring and interview processes as well as team member training to be intentional and identify ways to mitigate bias and promote inclusion. Endo is also focused on reinforcing a culture where each team member is respected, valued and feels a sense of belonging. This includes offering employee resource groups, such as the recently launched AWE, Alliance for Women at Endo and VET, Veterans at Endo Together. To complement the work we are doing inside Endo to support DE&I initiatives, we are also proud to support the important work of advocacy groups that are advancing diversity, equity and inclusion across our industry and beyond.

Information about our Executive Officers

The following table sets forth, as of March 1, 2022, information about our executive officers:

Name	Age	Position and Offices
Blaise Coleman	48	President and Chief Executive Officer
Patrick Barry	54	Executive Vice President and President, Global Commercial Operations
Mark T. Bradley	52	Executive Vice President and Chief Financial Officer
Matthew J. Maletta	50	Executive Vice President and Chief Legal Officer and Company Secretary
James P. Tursi, M.D.	57	Executive Vice President, Global Research & Development

Blaise Coleman was appointed President, Chief Executive Officer and a member of the Board of Directors, effective March 2020. He previously served as Executive Vice President and Chief Financial Officer since December 2016. He joined Endo in January 2015 as Vice President of Corporate Financial Planning & Analysis, and was then promoted to Senior Vice President, Global Finance Operations in November 2015. Prior to joining Endo, Mr. Coleman held a number of finance leadership roles with AstraZeneca, most recently as the Chief Financial Officer of the AstraZeneca/Bristol-Myers Squibb US Diabetes Alliance. Prior to that, he was the Head of Finance for the AstraZeneca Global Medicines Development organization based in Mölndal, Sweden. Mr. Coleman joined AstraZeneca in 2007 as Senior Director Commercial Finance for the US Cardiovascular Business. He joined AstraZeneca from Centocor, a wholly-owned subsidiary of Johnson & Johnson, where he held positions in both the Licenses & Acquisitions and Commercial Finance organizations. Mr. Coleman's move to Centocor in early 2003 followed 7 years' experience with the global public accounting firm, PricewaterhouseCoopers LLP. Mr. Coleman is a Certified Public Accountant; he holds a Bachelor of Science degree in accounting from Widener University and an M.B.A. from the Fuqua School of Business at Duke University.

Patrick Barry was appointed Executive Vice President and President, Global Commercial Operations, effective April 2020. In this role, he has responsibility for the Company's global commercial organization across each of Endo's four reportable business segments, including Branded Pharmaceuticals, Sterile Injectables, Generic Pharmaceuticals and International Pharmaceuticals. He formerly served as Executive Vice President and Chief Commercial Officer, U.S. Branded Business since February 2018, after joining Endo in December 2016 as Senior Vice President, U.S. Branded Pharmaceuticals. Prior to joining Endo, Mr. Barry worked at Sanofi S.A. from 1992 until December 2016, holding roles of increasing responsibility in areas such as Sales Leadership, Commercial Operations, Marketing, Launch Planning and Training and Leadership Development. Most recently, he served at Sanofi S.A. as its General Manager and Head of North America General Medicines starting in September 2015 and as Vice President and Head of U.S. Specialty from April 2014 until August 2015. During this time, Mr. Barry oversaw three complex and diverse businesses with responsibility for leading sales and marketing activities for branded and generic products across the U.S. and Canada. He has a diverse therapeutic experience including aesthetics and dermatology, oncology, urology, orthopedics and medical device and surgical experience. He has an M.B.A. from Cornell University, Johnson School of Management and a B.A. in Public Relations and Marketing from McKendree University.

Mark T. Bradley was appointed Executive Vice President and Chief Financial Officer, effective March 2020. He previously served as Senior Vice President, Corporate Development & Treasurer since June 2017. Mr. Bradley joined Endo in January 2007 as a Finance Director and has held various positions of increasing responsibility since joining the Company. Prior to joining Endo, he spent nearly 7 years as a management consultant, most recently with Deloitte Consulting, providing a broad range of strategic and operational advice and services to senior executives across a number of industries. In addition, Mr. Bradley served as a Finance Director for an industrial products company for approximately 2 years. He spent the first 5 years of his career in public accounting at Ernst & Young LLP. Mr. Bradley is a licensed Certified Public Accountant and holds a Bachelor of Science degree in Accounting from Saint Joseph's University and a Master of Business Administration from The University of Texas at Austin.

Matthew J. Maletta was appointed Executive Vice President and Chief Legal Officer, effective May 2015, where he has global responsibility for all legal matters affecting the Company. He was also appointed Company Secretary, effective June 2020. Prior to joining Endo in 2015, Mr. Maletta served as Vice President, Associate General Counsel and Corporate Secretary of Allergan. In this position, he served as an advisor to the Chief Executive Officer and Board of Directors and supervised several large transactions, including the $70 billion acquisition of Allergan by Actavis in 2015. Mr. Maletta also played a key role defending Allergan from an unsolicited takeover bid by Valeant Pharmaceuticals and Pershing Square Capital Management in 2014. Mr. Maletta joined Allergan in 2002 and during his tenure, held roles of increased responsibility, including serving as the lead commercial attorney for Allergan's aesthetics businesses for several years and as Head of Human Resources in 2010. Prior to joining Allergan, Mr. Maletta was in private practice, focusing on general corporate matters, finance, governance, securities and transactions. He holds a B.A. degree in political science from the University of Minnesota, summa cum laude and Phi Beta Kappa, and a J.D. degree, cum laude, from the University of Minnesota Law School.

James P. Tursi, M.D. was appointed Executive Vice President, Global Research & Development, effective January 2022. In this role, Dr. Tursi is responsible for leading global research & development, medical affairs and regulatory operations. Prior to joining Endo, he held senior leadership roles at Ferring Pharmaceuticals U.S., Antares Pharmaceuticals and Aralez Pharmaceuticals. Prior to Aralez, Dr. Tursi was Chief Medical Officer and Vice President of Clinical R&D at Auxilium Pharmaceuticals until its acquisition by Endo in 2015. Dr. Tursi practiced medicine and surgery for over 10 years and created a medical education company, I Will Pass®, which assisted physicians in the process of board certification. He performed his residency in Gynecology and Obstetrics at the Johns Hopkins Hospital, holds a Bachelor of Science degree in Chemistry and Biology from Ursinus College and a Doctor of Medicine degree from the Medical College of Pennsylvania. Dr. Tursi is a member of the Ideal Image and Agile Therapeutics Boards of Directors.

We have employment agreements with each of our executive officers.

Available Information

Our internet address is www.endo.com. The contents of our website are not part of this Annual Report on Form 10-K and our internet address is included in this document as an inactive textual reference only. We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy reports and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC.

You can access our filings through the SEC's internet site: www.sec.gov *(intended to be an inactive textual reference only).*

You may also access copies of the Company's filings with the Canadian Securities Administrators on SEDAR through their internet site: www.sedar.com *(intended to be an inactive textual reference only).*

Item 1A. *Risk Factors*

Risk Factor Summary

The following is a summary of the risk factors contained in this Annual Report on Form 10-K that could adversely affect our business, financial condition, results of operations and cash flows. In addition to this summary, we encourage you to carefully review the full risk factors in their entirety.

Business Related Risks

- We operate in a highly competitive industry.
- Other pharmaceutical companies may obtain approval for competing versions of our products.
- Pharmacies or outsourcing facilities may produce compounded versions of our products.
- We may fail to successfully identify, develop, maintain or introduce products.
- Uncertainties exist regarding our acquisition and licensing strategy.
- Asset sales could adversely affect our prospects and opportunities for growth.
- Third party reimbursement for our products is uncertain.
- Price levels may be reduced because of social or political pressures.
- Our business is highly dependent upon market perceptions of us, our brands and the safety and quality of our products.
- Our business and financial condition may be adversely affected by existing or future legislation and regulations.
- Our customer concentration may adversely affect us.
- We are currently dependent on outside manufacturers for the manufacture of a significant amount of our products.
- We are dependent on third parties to supply raw materials used in our products and to provide services.
- We have limited experience in manufacturing biologic products and may encounter difficulties in our manufacturing processes.
- The DEA could limit the availability of active ingredients and the production of products.
- We rely on our ability to retain our key personnel and to continue to attract additional professional staff.
- Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber-attacks.
- We are subject to risks related to our global operations.
- We are subject to risks regarding widespread health problems, including the recent global coronavirus.
- Supply chain and other manufacturing disruptions could negatively impact our businesses.
- We may be impacted by the effects of climate change and encounter challenges implementing sustainability-related measures.

Litigation and Liability Related Risks

- We are regularly the subject of material legal proceedings, including significant lawsuits, product liability claims, governmental investigations and product recalls.
- We may not have and may be unable to obtain or maintain insurance adequate to cover potential liabilities.
- Public concern around the abuse of opioids or other products, including law enforcement concerns over diversion or marketing practices, regulatory efforts to combat abuse and litigation could result in costs to our business and damage our reputation.

Financial and Liquidity Related Risks

- Our ability to fund our operations, maintain adequate liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties.
- Potential impairments of goodwill and other intangibles may significantly impact our profitability.
- Our substantial indebtedness could adversely affect our financial position.
- The phase-out of London Interbank Offered Rate (LIBOR) could affect interest rates under certain of our existing indebtedness as well as our ability to seek future debt financing.
- We are restricted by covenants in our debt agreements and a default may result in acceleration of certain of our indebtedness.
- We may not realize the anticipated benefits from our strategic actions.

Legal and Regulatory Related Risks

- Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny and we may be subject to additional investigations or litigation.
- We are subject to various laws and regulations pertaining to the marketing of our products and services.
- The pharmaceutical industry is heavily regulated, which creates uncertainty and substantial compliance costs.
- We are subject to complex reporting and payment obligations under Medicaid and other drug pricing programs.
- Decreases in the degree to which individuals are covered by healthcare insurance could result in decreased use of our products.
- Regulatory or other factors may cause us to be unable to manufacture products or face interruptions in our manufacturing process.
- We may fail to obtain regulatory approval or maintain compliance with requirements in non-U.S. jurisdictions.
- The use of generic products may be limited through legislative, regulatory and other efforts.
- New tariffs and evolving trade policy between the U.S. and other countries, including China, could adversely affect us.
- We are subject to information privacy and data protection laws that include penalties for noncompliance.

Intellectual Property Related Risks

- Our ability to protect and maintain our proprietary and licensed third party technology, which is vital to our business, is uncertain.
- Third party allegations of intellectual property infringement, unfavorable outcomes in litigation and "at-risk" product launches could adversely affect us.

Risks Related to our Ordinary Shares

- The trading prices of our securities have been volatile, and investments in our securities could decline in value.
- We have no plans to pay regular dividends on our ordinary shares or to conduct ordinary share repurchases.
- Shareholder activism could cause us to incur significant expenses, hinder execution of our business strategy and impact our share price.

Tax Related Risks

- Future changes to tax laws could materially adversely affect us.
- The IRS may not agree with the conclusion that we should be treated as a non-U.S. corporation.
- The effective rate of taxation upon our results of operations is dependent on multi-national tax considerations.
- The IRS and other taxing authorities may continue to challenge our tax positions and we may not be able to successfully maintain such positions.
- Our ability to use U.S. tax attributes to offset U.S. taxable income may be limited.

Structural and Organizational Risks

- Irish law differs from the laws in effect in the U.S. and may afford less protection to our shareholders.
- Takeover attempts will be subject to Irish Takeover Rules and subject to review by the Irish Takeover Panel.
- We are an Irish company and it may be difficult to enforce judgments against us or certain of our officers and directors.

Risk Factors

The following risk factors could adversely affect our business, financial condition, results of operations and cash flows. These are not the only risks facing the Company. Other risks and uncertainties, including those not currently known to us or that we currently deem to be immaterial, could also adversely affect our business, financial condition, results of operations and cash flows.

Business Related Risks

We operate in a highly competitive industry.

The pharmaceutical industry is intensely competitive and we face competition in both our U.S. and international branded and generic pharmaceutical businesses. Competitive factors include, without limitation, product development, technological innovation, safety, efficacy, commercialization, marketing, promotion, product quality, price, cost-effectiveness, reputation, service, patient convenience and access to scientific and technical information. Many of our competitors have, and future competitors may have, greater resources than we do, and we cannot predict with certainty the timing or impact of competitors' products and commercialization strategies. Furthermore, recent market consolidation in this industry may further concentrate financial, technical and market strength and increase competitive pressure in the industry. In addition, our competitors may make greater R&D investments and have more efficient or superior processes and systems and more experience in the development of new products that permit them to respond more quickly to new or emerging technologies and changes in customer demand which may make our products or technologies uncompetitive or obsolete. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products or programs. If we fail to compete successfully, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Certain of our branded products do not currently compete with on-market generic products but are likely to face generic competition in the future. During the first quarter of 2022, multiple competing generic alternatives to VASOSTRICT® were launched, beginning with Eagle's generic, which it launched at risk and began shipping toward the end of January 2022. Since then, additional competing alternatives have entered the market, including an authorized generic. The entrance of generic competitors can occur at any time and cannot be predicted with certainty. For additional information on our patent protection, refer to Part I, Item 1 of this report "Business" under the caption "Patents, Trademarks, Licenses and Proprietary Property." Generic products we currently sell with generic exclusivity could in the future be subject to competition from other generic competitors. Some of our other products, including both branded and generic products, face generic competition and the risk of additional generic competitors entering the market. Manufacturers of generic products typically invest far less in R&D than research-based companies. Additionally, generic competitors, including Asian or other overseas generic competitors, may be able to manufacture products at costs lower than us. For these reasons, competitors may price their products lower than ours, and such differences could be significant. Due to lower prices, generic versions, where available, may be substituted by pharmacies or required in preference to branded versions under third-party reimbursement programs. As a result, generic competition could have a material adverse effect on our business, financial condition, results of operations and cash flows. Legislation encouraging early and rapid approval of generic drugs could also increase the degree of generic competition we face. See the risk factor "If other pharmaceutical companies use litigation and regulatory means to obtain approval for generic, biosimilar, OTC or other competing versions of our products, our sales may suffer" for more information.

In addition, our generics business faces competition from brand-name pharmaceutical companies, which have taken and may continue to take aggressive steps to thwart or delay competition from generic equivalents of their brand-name products, including bringing litigation alleging patent infringement or other violations of intellectual property rights. The actions taken by competing brand-name pharmaceutical companies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether. For example, if a brand-name pharmaceutical company's patent were held to be valid and infringed by our generic products in a particular jurisdiction, we would be required to either obtain a license from the patent holder or delay or cease the manufacture and sale of such generic product. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our sales may also suffer as a result of changes in consumer demand for our products, including as a result of fluctuations in consumer buying patterns, changes in market conditions or actions taken by our competitors, including the introduction of new products or price reductions for existing products. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If other pharmaceutical companies use litigation and regulatory means to obtain approval for generic, biosimilar, OTC or other competing versions of our products, our sales may suffer.

Various manufacturers have filed ANDAs seeking FDA approval for generic versions of certain of our key pharmaceutical products including, but not limited to, LIDODERM®, VASOSTRICT®, ADRENALIN® and AVEED®. In connection with such filings, these manufacturers have challenged the validity and/or enforceability of one or more of the underlying patents protecting our products. In the case of LIDODERM®, we no longer have patent protection in the markets where we sell this product. Additionally, as further discussed below, in August 2021, the U.S. District Court for the District of Delaware held that Eagle's proposed vasopressin product did not infringe our asserted patent claims related to VASOSTRICT®.

Any launch of competing versions of any of our products could decrease the revenue of such products, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our practice is to vigorously defend and pursue all available legal and regulatory avenues in defense of the intellectual property rights protecting our products. Despite our efforts, litigation is inherently uncertain, and we cannot predict the timing or outcome of our efforts. If we are not successful in defending our intellectual property rights or opt to settle, or if a product's marketing or data exclusivity rights expire or become otherwise unenforceable, our competitors could ultimately launch generic, biosimilar, OTC or other competing versions of our products. Upon the loss or expiration of patent protection for one of our products, or upon the "at-risk" launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of one of our patented products, our sales and revenues of the affected products would likely decline rapidly and materially, which could require us to write off a portion or all of the intangible assets associated with the affected product and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In the case of VASOSTRICT®, beginning in April 2018, Par Sterile Products, LLC (PSP LLC) and Par Pharmaceutical, Inc. (PPI) received notice letters from Eagle, Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent, Fresenius, Dr. Reddy's Laboratories, Inc., Aurobindo Pharma Limited and Gland Pharma Limited advising of the filing by such companies of ANDAs/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 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 competing generic alternatives to VASOSTRICT® were launched, beginning with Eagle's generic, which it launched at risk and began shipping toward the end of January 2022. Since then, additional competing alternatives have entered the market, including an authorized generic. We expect these launches to significantly impact both Endo's market share and product price beginning in the first quarter of 2022, and the effects of competition are likely 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.

There are currently ongoing legal proceedings brought by us and/or our subsidiaries and, in certain cases, our third party partners, against manufacturers seeking FDA approval for generic versions of our products. For a description of the material related legal proceedings, see Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

We also believe it is likely that manufacturers may seek FDA approvals for generic, OTC or other competing versions of other of our key pharmaceutical products, either through the filing of ANDAs, through the OTC monograph process or through the use of other means.

If pharmacies or outsourcing facilities produce compounded versions of our products, our sales may suffer.

Compounded drugs do not typically require the same R&D investments as either branded or generic drugs and, therefore, can compete favorably on price with both branded and generic versions of a drug. See "Governmental Regulation" in Part I, Item 1. The introduction of compounded versions of our products by pharmacies or outsourcing facilities could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If we fail to successfully identify and develop additional branded and generic pharmaceutical products, obtain and maintain exclusive marketing rights for our branded and generic products or fail to introduce branded and generic products on a timely basis, our revenues, gross margin and operating results may decline.

Our financial results depend, to a significant extent, upon our ability, and the ability of our partners, to identify, develop, obtain regulatory approval for, launch and commercialize a pipeline of commercially successful branded and generic products, including first-to-file or first-to-market opportunities. Due to the significant competition we face and the importance of being the first (or one of the first) to market, no assurances can be given that we will be able to develop, introduce and maintain commercially successful products in the future. Competition could cause our revenues to decrease significantly, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Identifying and developing additional product candidates are prone to risks of failure inherent in product development. We conduct R&D to enable us to manufacture and market pharmaceutical products in accordance with specific government regulations. Much of our product development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, expenses related to research, development and regulatory approval of compounds for our branded products are significantly greater than those expenses associated with generic products. Should we expand our R&D efforts, our research expenses are likely to increase. Because of the inherent risk associated with R&D efforts in the healthcare industry, particularly with respect to new products, our R&D expenditures may not result in the successful regulatory approval and introduction of new products and failure in the development of any new product can occur at any point in the process, including late in the process after substantial investment. Also, after we submit a regulatory application, the relevant governmental health authority may require that we conduct additional studies, including, for example, studies to assess the product's interaction with alcohol. As a result, we may be unable to reasonably predict the total R&D costs to develop a particular product and there is a significant risk that the funds we invest in R&D will not generate financial returns. In addition, our operating results and financial condition may fluctuate as the amount we spend to research and develop, commercialize, acquire or license new products, technologies and businesses changes.

The process of developing and obtaining regulatory approvals for new products is time-consuming, costly and inherently unpredictable. Even if we are able to identify and develop additional product candidates, we may fail to obtain exclusive marketing rights, such as the 180-day ANDA first-filer marketing exclusivity period provided for in the Hatch-Waxman amendments to the FFDCA or the 180-day exclusivity for competitive generic therapies established by the FDA Reauthorization Act of 2017, for such product candidates. Even if we were to secure such exclusivities, risks associated with securing timely approval, as well as risks of unfavorable litigation dispositions, put such exclusivities at risk of being forfeited. The approval of our ANDAs may also be stayed by the FDA for up to 30 months if such ANDAs become the subject of patent litigation. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants or with authorized generics that are not prohibited from sale during the 180-day marketing exclusivity period. Our revenues have historically included sales of generic products with limited competition resulting from marketing exclusivity or other factors, and the failure to timely and effectively file any NDA, ANDA, BLA or Supplemental Biologics License Application (sBLA) with the FDA or similar filings with other regulatory agencies, or to partner with parties that have obtained marketing exclusivity, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Furthermore, the successful commercialization of a product is subject to a number of factors, including:

- the effectiveness, ease of use and safety of our products as compared to existing products;
- customer demand and the willingness of physicians and customers to adopt our products over products with which they may have more loyalty or familiarity and overcoming any biases toward competitors' products or against our products;
- the cost of our products compared to alternative products and the pricing and commercialization strategies of our competitors;
- the success of our launch and marketing efforts;
- adverse publicity about us, our products, our competitors and their products or the industry as a whole or favorable publicity about competitors or their products;
- the advent of new and innovative alternative products;
- any unforeseen issues or adverse developments in connection with our products and any resulting litigation, regulatory scrutiny and/or harm to our reputation; and
- other risks that may be out of our control, including the decision by a collaboration partner to make substantial changes to a product's formulation or design, or a collaboration partner refusing to perform its obligations under our collaboration agreement, which may cause delays and additional costs in developing and marketing a product.

In particular, the commercial success of QWO® depends upon several factors, including our success in educating aesthetic specialty physicians and clinicians, as well as consumers, about the benefits, administration and safety of QWO®; the willingness of consumers to pay for QWO® relative to other discretionary items; the results of QWO® development programs for potential additional medical aesthetics indications; and our ability to maintain compliance with regulatory requirements applicable to QWO®.

The success of our acquisition and licensing strategy is subject to uncertainty and acquisitions or licenses may reduce our earnings, be difficult to integrate, not perform as expected or require us to obtain additional financing.

We regularly evaluate selective acquisitions and look to continue to enhance our product line by acquiring rights to additional products and compounds. Such acquisitions may be carried out through corporate acquisitions, asset acquisitions, licensing or joint venture arrangements. However, we may not be able to complete acquisitions, obtain licenses or enter into arrangements that meet our target criteria on satisfactory terms, if at all. For example, we may not be able to identify suitable acquisition candidates. In addition, any acquisition of assets and rights to products and compounds may fail to accomplish our strategic objective and may not perform as expected. Further, if we are unable to maintain, on commercially reasonable terms, product, compound or other licenses that we have acquired, our ability to develop or commercialize our products may be inhibited. In order to continue to develop and broaden our product range, we must compete to acquire assets. Our competitors may have greater resources than us and therefore be better able to complete acquisitions or licenses, which could cause us to be unable to consummate acquisitions, licensing agreements or cause the ultimate price we pay to increase. If we fail to achieve our acquisition or licensing goals, our growth may be limited.

Acquisitions of companies may expose us to additional risks, which may be beyond our control and may have a material adverse effect on our business, financial condition, results of operations and cash flows. The combination of two independent businesses is a complex, costly and time-consuming process. As a result, we may be required to devote significant management attention and resources to the integration of an acquired business into our practices and operations. Any integration process may be disruptive and may not achieve realization of expected benefits. The difficulties of combining operations of companies include, among others:

- diversion of management's attention to integration matters;
- difficulties in achieving anticipated cost or tax savings, synergies, business opportunities and growth prospects from the combination of the businesses;
- difficulties in the integration of operations and systems;
- the impact of pre-existing legal and/or regulatory issues;
- difficulties in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the companies;

- difficulties in the assimilation of employees and retention of key personnel;
- difficulties in managing the expanded operations of a larger and more complex company;
- challenges in retaining existing customers and obtaining new customers;
- potential unknown liabilities or larger liabilities than projected;
- unforeseen increases to expenses or other adverse consequences; and
- difficulties in coordinating a geographically dispersed organization.

In addition, any acquisitions may result in material unanticipated problems, expenses, liabilities, competitive responses and loss or disruption of relationships with customers, suppliers, partners, regulators and others with whom we have business or other dealings.

The benefits of mergers and acquisitions are also subject to a variety of other factors, many of which are beyond our ability to control, such as changes in the rate of economic growth in jurisdictions in which the combined company will do business, the financial performance of the combined business in various jurisdictions, currency exchange rate fluctuations and significant changes in trade, monetary or fiscal policies, including changes in interest rates and tax law of the jurisdictions in which the combined company will do business. The impact of these factors, individually and in the aggregate, is difficult to predict, in part because the occurrence of the events or circumstances relating to such factors may be interrelated, and the impact to the combined company of the occurrence of any one of these events or circumstances could be compounded or, alternatively, reduced, offset or more than offset by the occurrence of one or more of the other events or circumstances relating to such factors.

In addition, based on current acquisition prices in the pharmaceutical industry, acquisitions could decrease our net income per share and add significant intangible assets and related amortization or impairment charges. Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in additional debt obligations, increased interest expense or dilution of equity ownership. We may not be able to finance acquisitions on terms satisfactory to us, or at all.

We may decide to sell assets, which could adversely affect our prospects and opportunities for growth.

We may from time to time consider selling certain assets if we determine that such assets are not critical to our strategy or we believe the opportunity to monetize the asset is attractive or for various other reasons, including for the reduction of indebtedness. For example, as further discussed in Note 3. Discontinued Operations in the Consolidated Financial Statements included in Part IV, Item 15 of this report, in 2021, we divested of certain assets related to our retail generics business, as well as certain associated liabilities. In 2017, we divested of both Litha Healthcare Group Limited and certain assets acquired from Aspen Holdings in October 2015 and Grupo Farmacéutico Somar, S.A.P.I. de C.V. We have also divested of certain intellectual property rights throughout each of the past three years. We intend to continue to explore the sale of certain non-core assets. Although our preference is to engage in asset sales only if they advance or otherwise support our overall strategy, we may decide to sell assets in response to liquidation or other claims described herein, and any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets, products or therapeutic categories. As a result, any such sale could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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.

The availability of third party reimbursement for our products is uncertain, and we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided.

Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government healthcare programs, such as Medicaid and Medicare, private health insurers and others. We cannot be certain that, over time, third party reimbursements for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government payers, private insurers and other third party payers are increasingly attempting to contain healthcare costs by: (i) limiting both coverage and the level of reimbursement (including adjusting co-pays) for products, (ii) refusing, in some cases, to provide any coverage for off-label uses for products and (iii) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products. For instance, government agencies or third-party payers could attempt to reduce reimbursement for physician administered products through their interpretation of complex government price reporting obligations and payment and reimbursement coding rules, and could attempt to reduce reimbursement for separate physician administered products that share an active ingredient by requiring the blending of sales and pricing information in the same payment and reimbursement code.

There have been several recent U.S. Congressional inquiries, hearings and proposed and enacted federal and state legislation and rules, as well as executive orders, designed to, among other things: (i) reduce or limit the prices of drugs and make them more affordable for patients, such as by tying the prices that Medicare reimburses for physician administered drugs to the prices of drugs in other countries; (ii) reform the structure and financing of Medicare Part D pharmaceutical benefits, including through increasing manufacturer contributions to offset Medicare beneficiary costs; (iii) bring more transparency to how manufacturers price their medicines; (iv) enable the government to directly negotiate prices for drugs covered under Medicare; (v) revise rules associated with the calculation of Medicaid Average Manufacturer Price and Best Price, including with regard to the manner in which pharmaceutical manufacturers may provide copayment assistance to patients and the identification of "line extension" drugs, which affect the amount of rebates that manufacturers must pay on prescription drugs under Medicaid; (vi) eliminate anti-kickback statute discount safe harbor protection for manufacturer rebate arrangements with Medicare Part D Plan Sponsors and pharmacy benefit managers on behalf of Part D Plan Sponsors; (vii) create new anti-kickback statute safe harbors applicable to certain point-of-sale discounts to patients and fixed-fee administrative fee payment arrangements with pharmacy benefit managers; and (viii) and facilitate the importation of certain lower-cost drugs from other countries. In addition, state legislatures have enacted legislation and regulations designed to control pharmaceutical and biological product pricing, including restrictions on pricing or reimbursement at the state government level, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation of drugs from other countries (subject to federal approval) and bulk purchasing, including the National Medicaid Pooling Initiative. While we cannot predict the final form of any pending legislative, regulatory and/or administrative measures, some of the pending and enacted legislative proposals or executive rulemaking, such as those incorporating International Pricing Index or Most-Favored-Nation models, could significantly reduce the coverage and levels of reimbursement for products.

The unavailability of or a reduction in the reimbursement of our products could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may experience pricing pressure on our products due to social or political pressures, which would reduce our revenue and future profitability.

We may experience downward pricing pressure on our products due to social or political pressures, which would reduce our revenue and future profitability. Price increases have resulted in increased public and governmental scrutiny of the cost of pharmaceutical products. For example, U.S. federal prosecutors have issued subpoenas to pharmaceutical companies in connection with an investigation into pricing practices conducted by the DOJ. Several state attorneys general also have commenced drug pricing investigations and filed lawsuits against pharmaceutical companies, including PPI, and the U.S. Senate has investigated a number of pharmaceutical companies relating to price increases and pricing practices. Our revenue and future profitability could be negatively affected if these or other inquiries were to result in legislative or regulatory proposals limiting our ability to increase or maintain the prices of our products.

In addition, the federal government and a number of federal legislators continue to scrutinize pharmaceutical prices and seek ways to lower prices. For example, the Biden Administration's Prescription Drug Pricing Plan as part of the House-passed Build Back Better Act seeks to reduce prescription drug costs by, among other provisions, allowing Medicare to negotiate prices for certain high-cost prescription drugs in Medicare Parts B and D, imposing an excise tax on pharmaceutical manufacturers that refuse to negotiate pricing with Medicare, requiring inflation rebates to limit annual drug price increases in Medicare and private insurance, redesigning the Medicare Part D formula and limiting cost-sharing for insulin products. We cannot know whether this or other legislation will pass, the form that any new requirements will take or the effect that these or other requirements may have on our business. Additionally, in July 2021, President Biden issued an executive order directing the FDA to work with states to import prescription drugs from Canada. The executive order follows the FDA's October 2020 final rule and final guidance that set forth procedures for the legal importation of certain pharmaceutical products in an effort to control costs. It is unclear what effect these procedures may have on our business, financial condition, results of operations and cash flows. In addition, the U.S. Congress has held a number of hearings related to pharmaceutical prices and legislation has been introduced in the U.S. Congress that would require pharmaceutical manufacturers to justify certain price increases, among other proposed measures with potential impacts on pharmaceutical prices. A large number of individual states also have introduced legislation aimed at pharmaceutical pricing regulation, transparency or both. For example, California, Oregon, Vermont and Nevada have enacted such laws. Our revenue and future profitability could be negatively affected by the passage of these laws or similar federal or state legislation. Pressure from social activist groups and future government regulations may also put downward pressure on the prices of pharmaceutical products in the future.

Our business is highly dependent upon market perceptions of us, our brands and the safety and quality of our products and similar products, and may be adversely impacted by negative publicity or findings.

We are dependent on market perceptions and consumer preferences. Negative publicity or findings associated with product quality, safety, efficacy, patient illness, side effects or other adverse effects related to, or perceived to be related to, our products, or similar products, or our or our partners' and suppliers' manufacturing facilities, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Market perceptions and consumer preferences are very important to our business, especially with respect to our brands, company name and the safety and quality of our products. Our products and similar products are subject to market withdrawal or recall and may be claimed or proven to be ineffective or harmful to consumers.

Our products may cause known or unknown adverse or other side effects. For example, the most common side effects of QWO® include injection site bruising, pain, areas of hardness, itching, redness, discoloration, swelling and warmth in the treatment area, and QWO® may also cause other serious side effects. If we or our partners, suppliers or brands are negatively impacted by publicity, media coverage, market perception or consumer preference, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The pharmaceutical supply chain has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the internet. Third parties may illegally distribute and sell counterfeit versions of our products that do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Negative posts or comments about us on any social networking website could seriously damage our reputation. The inappropriate use of certain social media vehicles could cause brand damage or information leakage or could lead to legal implications from the improper collection and/or dissemination of personally identifiable information or the improper dissemination of material non-public information.

Unfavorable media coverage about opioid abuse could negatively affect our business, financial condition and results of operations. In recent years, opioid abuse has received a high degree of media coverage. Unfavorable publicity regarding, for example, the use or misuse of oxycodone or other prescription opioid medications, the limitations of abuse-deterrent forms, public inquiries and investigations into drug abuse, including the abuse of prescription products, litigation or regulatory activity could adversely affect our reputation. Additionally, increased scrutiny of opioids generally, whether focused on our products or otherwise, could negatively impact our relationship with healthcare providers and other members of the healthcare community. Such negative publicity could have an adverse effect on the potential size of the market for new or existing products and could decrease revenues and royalties, any of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our business and financial condition may be adversely affected by existing or future legislation and regulations.

We cannot predict with any certainty how existing laws may be applied or how laws or legal standards may change in the future. Current or future legislation and regulations, whether state or federal, or in any of the non-U.S. jurisdictions with authority over our operations, may have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, the effect of H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, enacted in October 2018, is still uncertain.

In addition, in April 2018, New York enacted a statute called the Opioid Stewardship Act (the Stewardship Act), which, among other things, provided for certain manufacturers and distributors of certain opioids in the state of New York (the Contributing Parties) to make payments to a newly created Opioid Stewardship Fund (the Fund). By its terms, the Stewardship Act required Contributing Parties to pay a combined total of up to $100 million annually into the Fund, with each Contributing Party's share based on the total amount of morphine milligram equivalents (MME) of certain opioids sold or distributed by the Contributing Party in the state of New York during the preceding calendar year, subject to potential adjustments by the New York State Department of Health. Failure of a Contributing Party to make required reports or pay its ratable share, or a Contributing Party passing on the cost of its ratable share to a purchaser, could subject the Contributing Party to penalties. In December 2018, a federal district court struck down the Stewardship Act as unconstitutional. In September 2020, an appellate court reversed on procedural grounds the district court's decision and a petition for rehearing of the appellate court decision was denied in December 2020. The U.S. Supreme Court denied certiorari in October 2021. An amendment to the Stewardship Act made clear that the law applies only to New York opioid sales or distributions for calendar years 2017 and 2018. Compliance with the Stewardship Act, or similar legislation or regulations enacted by New York or other jurisdictions, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In April 2019, New York enacted an excise tax on the first sale of every opioid unit in New York at the rate of one quarter of a cent per MME where wholesale acquisition cost (WAC) is less than $0.50 and one and one half cents per MME where WAC is equal to or greater than $0.50. For purposes of this statute, "opioid" does not include buprenorphine, methadone or morphine and "sale" does not include transfers of title from a manufacturer in New York to a purchaser outside New York when the opioid unit will be used or consumed outside New York. Several other states have enacted similar legislation or regulations providing for excise taxes or fees related to opioids and additional state or national legislation or regulations may be enacted in the future.

In October 2018, the Canadian province of British Columbia enacted a statute called the Opioid Damages and Health Care Costs Recovery Act, which allows the British Columbia government to file a direct action against opioid manufacturers and wholesalers to recover the health care costs it has incurred, and will incur, resulting from an "opioid-related wrong." The statute defines "opioid-related wrong" to include any breach of a common law, equitable or statutory duty or obligation owed to persons in British Columbia who have been or might be exposed to an opioid product. The statute, among other effects, erases limitation periods for certain claims, reverses certain burdens of proof as to causation, allows the use of population-based evidence and restricts discovery of certain documents. Similar legislation has been enacted in several other Canadian provinces. It is possible that these statutes, or similar statutes enacted by other jurisdictions, and resultant litigation, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In Canada, the prices of patented pharmaceutical products are subject to regulation by the PMPRB. Under the Canadian Patent Act and Patented Medicines Regulations, patentees of inventions that pertain to pharmaceutical products sold in Canada are required to file price and sales information about their patented pharmaceutical products with the PMPRB. The PMPRB reviews this information on an ongoing basis to ensure that the prices of patented pharmaceuticals sold in Canada are not excessive, based upon price tests established by the PMPRB. There is a risk that the price of our pharmaceutical products could be found to be excessive because the price as set at launch is non-compliant with the PMPRB's guidelines, or because our average sale prices over time are not compliant with the guidelines. Furthermore, amendments expected to come into force on July 1, 2022 will introduce a number of changes to the regulation of Canadian drug prices by the PMPRB. The PMPRB guidelines will introduce new price tests to account for changes introduced by the amendments. The application of the new price tests under the guidelines could result in the current prices of our pharmaceutical products being deemed to be excessive. Failure by us to comply with the current or future guidelines could ultimately result in us reducing the prices of the pharmaceutical products we sell in Canada and/or making a payment to the Canadian government to offset revenues deemed by the PMPRB to be excessive, which could ultimately reduce the revenues and cash flows of our International Pharmaceuticals segment and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

It is possible that these or other changes in law could have a material adverse effect on our business, financial condition, results of operations and cash flows. See "Governmental Regulation" in Part I, Item 1.

Our customer concentration may adversely affect our financial condition and results of operations.

We primarily sell our products to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and/or government agencies. Our wholesalers and/or distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies, hospitals, long-term care facilities, clinics, home infusion pharmacies, government facilities and MCOs. Our current customer group reflects significant consolidation in recent years, marked by mergers and acquisitions and other alliances. Consolidations and joint purchasing arrangements have resulted in increased pricing and other competitive pressures on pharmaceutical companies, including us. Additionally, the emergence of large buying groups representing independent retail pharmacies and other distributors and the prevalence and influence of MCOs and similar institutions have increased the negotiating power of these groups, enabling them to attempt to extract various demands, including without limitation price discounts, rebates and other restrictive pricing terms. These competitive trends could continue in the future and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Net revenues from direct customers that accounted for 10% or more of our total consolidated net revenues during the years ended December 31, 2021, 2020 and 2019 are as follows:

	2021	2020	2019
AmerisourceBergen Corporation	36 %	33 %	34 %
McKesson Corporation	32 %	27 %	26 %
Cardinal Health, Inc	22 %	24 %	25 %

Revenues from these customers are included within each of our segments. Accordingly, our revenues, financial condition or results of operations may also be unduly affected by fluctuations in the buying or distribution patterns of these customers. These fluctuations may result from seasonality, pricing, wholesaler inventory objectives or other factors. In addition, if we were to lose the business of any of these customers, or if any were to fail to pay us on a timely basis, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We are currently dependent on outside manufacturers for the manufacture of a significant amount of our products; therefore, we have and expect to continue to have limited control of the manufacturing process and related costs. Certain of our manufacturers currently constitute the sole source of one or more of our products.

Third party manufacturers currently manufacture a significant amount of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of our products. For example, Teikoku Seiyaku Co., Ltd. is our sole source of LIDODERM®. As a result of the sale of our manufacturing facilities and related assets in Chestnut Ridge, New York and Irvine, California, as further discussed in Note 3. Discontinued Operations in the Consolidated Financial Statements included in Part IV, Item 15 of this report, our reliance on third party manufacturers has increased and we are working with new third party manufacturers that we have not worked with before. Because of contractual restraints and the lead-time necessary to obtain FDA approval and/or DEA registration of a new manufacturer, there are no readily accessible alternatives to these manufacturers and replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers. Our business and financial viability are dependent on these third party manufacturers for continued manufacture of our products, the continued regulatory compliance of these manufacturers and the strength, validity and terms of our various contracts with these manufacturers. Any interruption or failure by these manufacturers to meet their obligations pursuant to various agreements with us on schedule or in accordance with our expectations, or any termination by these manufacturers of our supply arrangements, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent our ability to achieve sales expectations, cause interruptions in our supply of products to customers, cause us to incur failure-to-supply penalties, disrupt our operations or cause reputational harm to our company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We are dependent on third parties to supply raw materials used in our products and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We rely on third parties to supply raw materials used in our products. In addition, we rely on third party suppliers, distributors and collaboration partners to provide services for certain core aspects of our business, including manufacturing, packaging, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. Third party suppliers and contractors are subject to FDA and very often DEA requirements. Our business and financial viability are dependent on the continued supply of goods and services by these third parties, the regulatory compliance of these third parties and on the strength, validity and terms of our various contracts with these third parties. Any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us on schedule or in accordance with our expectations, or any termination by these third parties of their arrangements with us, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent the development, approval, manufacture or commercialization of our products, result in non-compliance with applicable laws and regulations, cause us to incur failure-to-supply penalties, disrupt our operations or cause reputational harm to our company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. We may also be unsuccessful in resolving any underlying issues with such suppliers, distributors and partners or replacing them within a reasonable time and on commercially reasonable terms.

APIs imported into the European Union (EU) must be certified as complying with the good manufacturing practice standards established by the EU, as stipulated by the International Conference for Harmonization. These regulations place the certification requirement on the regulatory bodies of the exporting countries. Accordingly, the national regulatory authorities of each exporting country must: (i) ensure that all manufacturing plants within their borders that export API into the EU comply with EU manufacturing standards and (ii) for each API exported, present a written document confirming that the exporting plant conforms to EU manufacturing standards. The imposition of this responsibility on the governments of the nations exporting API may cause a shortage of API necessary to manufacture our products, as certain governments may not be willing or able to comply with the regulation in a timely fashion, or at all. A shortage in API may cause us to cease manufacturing of certain products or to incur costs and delays to qualify other suppliers to substitute for those API manufacturers unable to export. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We are dependent on third parties to provide us with various estimates as a basis for our financial reporting. While we undertake certain procedures to review the reasonableness of this information, we cannot obtain absolute assurance over the accounting methods and controls over the information provided to us by third parties. As a result, we are at risk of them providing us with erroneous data which could impact our reporting. Refer to “CRITICAL ACCOUNTING ESTIMATES” in Part II, Item 7 of this report “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for information about our most significant accounting estimates.

We have limited experience in manufacturing biologic products and may encounter difficulties in our manufacturing processes, which could materially adversely affect our results of operations or delay or disrupt the manufacture and supply of those products which are reliant upon our manufacturing operations.

The manufacture of biologic products requires significant expertise and capital investment. Although we manufacture CCH, which is included in XIAFLEX® and QWO®, in our Horsham, Pennsylvania facility, QWO® is a new product and we have limited experience in manufacturing CCH or any other biologic products. Biologics, such as CCH, require processing steps that are highly complex and generally more difficult than those required for most chemical pharmaceuticals. In addition, TESTOPEL® is manufactured using a unique, proprietary process. If the manufacturing processes are disrupted at the facilities where our biologic products are manufactured, it may be difficult to find alternate manufacturing sites. We may encounter difficulties with the manufacture of CCH and the active ingredient of TESTOPEL®, which could delay, disrupt or halt our manufacture of such products and/or product candidates, result in supply disruption or delay, product recalls or product liability claims, require write-offs or otherwise have a material adverse effect on our business, financial condition, results of operations and cash flows.

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.

The DEA limits the availability of the active ingredients used in many of our products and sets a quota on the production of these products. We, or our contract manufacturing organizations, must annually apply to the DEA for procurement and production quotas in order to obtain these substances and produce our products. In addition, H.R. 6 amended the CSA with respect to quotas by requiring the DEA to estimate the amount and impact of diversion (including overdose deaths and abuse and overall public health impact) of fentanyl, oxycodone, hydrocodone, oxymorphone or hydromorphone and to make appropriate quota reductions. As a result, our procurement and production quotas may not be sufficient to meet commercial demand or to complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year. Any delay or refusal by the DEA in establishing our quotas, or modification of our quotas, for controlled substances could delay or result in the stoppage of clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If we are unable to retain our key personnel and continue to attract additional professional staff, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business, financial condition, results of operations and cash flows. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we may be unsuccessful in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in our industry, and we may be unable to continue to attract and retain the qualified personnel necessary for the successful development of our business.

Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber-attacks.

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. As such, we continuously invest financial and other resources to maintain, enhance, further develop, replace or add to our information technology infrastructure. Such efforts carry risks such as cost overruns, project delays and business interruptions, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. Additionally, these measures are not guaranteed to protect against all cybersecurity incidents.

In the ordinary course of our business, we collect and maintain information, which includes confidential, proprietary and personal information regarding our customers and employees, in digital form. Data maintained in digital form is subject to risk of cyber-attacks, which are increasing in frequency and sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, “hackers” and others. Cyber-attacks could include the deployment of harmful malware, viruses, worms, denial-of-service attacks, ransomware, phishing, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering and theft remain. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

We also have outsourced certain elements and functions of our operations, including elements of our information technology infrastructure, to third parties, some of which operate outside the U.S. As a result, we manage many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our and our vendors' systems make such systems potentially vulnerable to service interruptions and to security breaches from inadvertent or intentional actions by our employees, our partners, our vendors or other third parties, or from attacks by malicious third parties.

The Company and its vendors' information technology operations are spread across multiple, sometimes inconsistent platforms, which pose difficulties in maintaining data integrity across systems. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional or improper dissemination or destruction of confidential information stored in the Company's systems.

Any breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, fraud, cyber-attacks, hacking, trickery or other forms of deception or any other cause, could enable others to produce competing products, use our proprietary technology or information and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential, proprietary or personal information could result in financial, legal, business and reputational harm to our company and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The risks related to our global operations may adversely impact our revenues, results of operations and financial condition.

In 2021, approximately 3% of our total revenues were from customers outside the U.S. Some of these sales were to governmental entities and other organizations with extended payment terms. Conducting business internationally, including the sourcing, manufacturing, development, sale and distribution of our products and services across international borders, subjects us to extensive U.S. and foreign governmental trade regulations, such as various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act (FCPA), export control laws, customs and import laws and anti-boycott laws. The FCPA and similar anti-corruption laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. We cannot provide assurance that our internal controls and procedures will always protect us from criminal acts committed by our employees or third parties with whom we work. If we are found liable for violations of the FCPA or other applicable laws and regulations, either due to our own acts or out of inadvertence, or due to the acts or inadvertence of others, we could suffer significant criminal, civil and administrative penalties, including, but not limited to, imprisonment of individuals, fines, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting, as well as reputational harm. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, some countries where we source, develop, manufacture or sell products are subject to political, economic and/or social instability. Our non-U.S. R&D, manufacturing and sales operations expose us and our employees, representatives, agents and distributors to risks inherent in operating in non-U.S. jurisdictions. For example, we currently perform certain R&D and manufacturing operations in India and plan to expand these operations, including through investment in a new manufacturing site we are constructing in Indore. A disruption in our Indian operations could have a material adverse effect on our business, financial condition, results of operations and cash flows. These risks include, among others:

- the imposition of additional U.S. and non-U.S. governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- economic or political instability or disruptions, including local or regional instability, civil unrest or hostilities, rioting, military activity, terror attacks or armed hostilities;
- disruptions due to natural disasters, earthquakes, cyclones, tornados, typhoons, flooding, droughts, landslides, geological events or severe weather events which may be exacerbated by the effects of climate change;
- disruptions related to COVID-19 or other pandemics;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions including foreign exchange controls;
- supply disruptions and increases in energy and transportation costs;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- changes in global tax laws and/or the imposition by tax authorities of significant fines, penalties and additional taxes;
- pricing pressure that we may experience internationally;
- fluctuations in foreign currency exchange rates;
- competition from local, regional and international competitors;
- difficulties and costs of staffing and managing foreign operations, including cultural differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate;
- difficulties and costs of obtaining and maintaining labs, R&D sites, manufacturing facilities and other locations in which we operate;

- COVID-19 or other outbreaks, epidemics or pandemics as described in the risk factor "Widespread health problems, including the recent global coronavirus, could materially and adversely affect our business" set forth in this report;
- laws and business practices favoring local companies;
- difficulties in enforcing or defending intellectual property rights; and
- exposure to different legal and political standards due to our conducting business in foreign countries.

We also face the risk that some of our competitors have more experience with operations in such countries or with international operations generally and may be able to manage unexpected crises more easily. Furthermore, whether due to language, cultural or other differences, public and other statements that we make may be misinterpreted, misconstrued or taken out of context in different jurisdictions. Moreover, the internal political stability of, or the relationship between, any country or countries where we conduct business operations may deteriorate, including relationships between the U.S. and other countries. Changes in other countries' economic conditions, product pricing, political stability or the state of relations between any such countries are difficult to predict and could adversely affect our operations, payment and credit terms and our ability to collect foreign receivables. Any such changes could lead to a decline in our profitability and/or adversely impact our ability to do business. Any meaningful deterioration of the political or social stability in and/or diplomatic relations between any countries in which we or our partners and suppliers do business could have a material adverse effect on our business, financial condition, results of operations and cash flows. A substantial slowdown of the global economy, or major national economies, could negatively affect growth in the markets in which we operate. Such a slowdown could result in national governments making significant cuts to their public spending, including national healthcare budgets, or reducing the level of reimbursement they are willing and able to provide to us for our products and, as a result, adversely affect our revenues, financial condition or results of operations. We have little influence over these factors and changes could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We cannot provide assurance that one or more of these factors will not harm our business. Risks associated with our non-U.S. R&D, manufacturing or sales could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Widespread health problems, including the recent global coronavirus, could materially and adversely affect our business.

Public health outbreaks, epidemics or pandemics, such as the coronavirus, could materially and adversely impact our business. For example, the COVID-19 pandemic has resulted in global business and economic disruption and extreme volatility in the financial markets as many jurisdictions have placed restrictions on travel and non-essential business operations and implemented social distancing, shelter-in-place, quarantine and other similar measures for their residents to contain the spread of the virus. In response to these public health directives and orders and in order to provide for the well-being of our workforce around the globe while continuing to safely produce products upon which patients and their healthcare providers rely, we implemented alternative working practices and work-from-home requirements for appropriate employees, inclusive of our Senior Executive Team. We limited international and domestic travel, increased our already-thorough cleaning protocols throughout our facilities and prohibited non-essential visitors from our sites. We also implemented temperature screenings, health questionnaires, social distancing, modified schedules, shift rotation and/or other similar policies at our manufacturing facilities. We have since begun to adjust certain of these practices, reflecting the evolved guidelines from health and other governmental authorities, including the elimination of certain social distancing requirements for fully vaccinated team members. The effects of COVID-19, including these public health directives and orders and our policies, have had an impact on our business and may in the future materially disrupt our business (including our manufacturing and supply chain operations by significantly reducing our output), negatively impact our productivity and delay our product development programs. COVID-19 has contributed to some delays in the completion of our facility in Indore, including delays related to construction and FDA inspections.

The pandemic may have significant impacts on third-party arrangements, including those with our manufacturing, supply chain and distribution partners, information technology and other service providers and business partners. For example, there may be significant disruptions in the ability of any or all of these third-party providers to meet their obligations to us on a timely basis, or at all, which may be caused by their own financial or operational difficulties, including any closures of their facilities pursuant to a governmental order or otherwise. Additionally, as the pandemic continues to impact the supply of goods and services worldwide, we face the risk of increased pressure on global logistics network infrastructure and capacity, which could result in interruptions of supply and/or increased costs based upon inability to obtain, and/or delayed deliveries of, raw materials and/or critical supplies necessary to continue our manufacturing activities and/or those of our third party suppliers. See the risk factor "Supply chain and other manufacturing disruptions could negatively impact our businesses" for more information.

Due to these disruptions and other factors, including changes in our workforce availability and increased demand for some of our critical care products during this pandemic, our ability to meet our obligations to third-party distribution partners may be negatively impacted. As a result, we have delivered, and in the future we or our third-party providers may deliver, notices of the occurrence of *force majeure* or similar events under certain of our third-party contracts, which could result in prolonged commercial disputes and ultimately legal proceedings to enforce contractual performance and/or recover losses. Any such occurrences could result in significant management distraction and use of resources and, in the event of an adverse judgment, could result in significant cash payments. Further, the publicity of any such dispute could harm our reputation and make the negotiation of any replacement contracts more difficult and costly, thereby prolonging the effects of any resulting disruption in our operations. Such disruptions could be acute with respect to certain of our raw material suppliers where we may not have readily accessible alternatives or alternatives may take longer to source than usual. While we attempt, when possible, to mitigate our raw material supply risks through stock management and alternative sourcing strategies, some raw materials are only available from one source. Any of these disruptions could harm our ability to meet consumer demand, including any increase in demand for any of our products, including our critical care products used during a pandemic.

We have experienced, and expect to continue to experience, changes in customer demand as the COVID-19 pandemic continues to evolve, which are difficult to predict. The current economic crisis and any increases in unemployment rates resulting from COVID-19 have the potential to significantly reduce individual disposable income, result in lower levels of healthcare insurance coverage and/or depress consumer confidence, any of which could limit the ability of some consumers to purchase certain pharmaceutical products and reduce consumer spend on certain medical procedures in both the short- and medium-term. Additionally, COVID-19 has, in certain cases, reduced medical procedures including those that use our products. For example, we have, from time to time, experienced decreased sales volumes for certain of our products that are physician administered, including XIAFLEX® and SUPPRELIN® LA, as a result of 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 significantly lower numbers of in-person patient office visits. Furthermore, we are unable to predict the impact that COVID-19 may have going forward on the business, results of operations or financial position of any of our major customers, which could impact each customer to varying degrees and at different times and could ultimately impact our own financial performance. Certain of our competitors may also be better equipped to weather the impact of COVID-19 both domestically and abroad and better able to address changes in customer demand.

Additionally, our product development programs have been, and may continue to be, adversely affected by the pandemic and the prioritization of production during this pandemic. Public health directives in response to COVID-19 have in certain cases caused and may continue to cause delays, increased costs and additional challenges in our product development programs, including obtaining adequate patient enrollment and successfully bringing product candidates to market. In addition, we may face additional challenges receiving regulatory approvals as previously scheduled dates or anticipated deadlines for action by the FDA on our applications and products in development could be subject to delays beyond our control as regulators, such as the FDA, focus on COVID-19. For example, as a result of COVID-19 and its impact on medical aesthetics physician office closures and consumer spending, we moved the product launch of QWO® to March 2021. In addition, we have assessed, and expect to continue to assess, the timeline for commercialization of other products.

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 (as defined below) 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 COVID-19. In addition, a recession or market correction related to COVID-19 could materially affect our business and the value of our ordinary shares.

Additionally, COVID-19 could increase the magnitude of many of the other risks described herein and have other adverse effects on our operations that we are not able to predict. For example, the global economic disruptions and volatility in the financial markets could further depress our ability to obtain or renew insurance on satisfactory terms or at all. Further, we may be required to delay or limit our internal strategies in the short- and medium-term by, for example, redirecting significant resources and management attention away from implementing our strategic priorities or executing opportunistic corporate development transactions.

The magnitude of the effect of COVID-19 on our business will depend, in part, on the length and severity of the restrictions (including the effects of any "re-opening" actions and plans) and other limitations on our ability to conduct our business in the ordinary course, as well as the availability of effective treatments or vaccines. The longer the pandemic continues, or if there is an additional resurgence of COVID-19 in any geography (which may be driven by variants of COVID-19, such as the delta and omicron variants, or other factors), the more severely the impacts described above could affect both our domestic and international business. The extent, length and consequences of the pandemic are uncertain and impossible to predict, but could be material. COVID-19 and other similar outbreaks, epidemics or pandemics could have a material adverse effect on our business, financial condition, results of operations and cash flows and could cause significant volatility in the trading prices of our securities.

Supply chain and other manufacturing disruptions could negatively impact our businesses.

We have experienced increased pressure and infrastructure capacity challenges to our global logistics network. 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.

We may be impacted by the effects of climate change and encounter challenges implementing sustainability-related measures.

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our operations, including an adverse impact on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Severe weather events, natural disasters and other disruptions, such as earthquakes, geological events, hurricanes, cyclones, tornados, typhoons, flooding, droughts, landslides and wildfires, may pose physical risks to our facilities and disrupt the operation of our supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs.

Concern over climate change may also result in new or additional legal or regulatory requirements designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with, sourcing, manufacturing and distributing our products, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. We may be unable to successfully implement sustainability-related measures pursuant to our ESG strategy or to adequately respond to increased stakeholder focus on ESG matters including climate change.

Litigation and Liability Related Risks

We are regularly the subject of material legal proceedings, including significant lawsuits, product liability claims, governmental investigations and product recalls, any of which could have a material adverse effect on our company, including causing us to pursue one or more significant corporate transactions or remedial measures.

Our business exposes us to significant potential risks from lawsuits and other material legal proceedings including, but not limited to, matters associated with the testing, manufacturing, marketing, sale and use of our products. Some plaintiffs have received substantial damage awards against or entered into significant settlements with healthcare companies based upon various legal theories including, without limitation, claims for injuries allegedly caused by the use of their products. A number of legal proceedings that we are currently subject to have the potential to result in significant monetary and other damages for which we could be liable. As further described herein, some of these cases are at advanced procedural stages and are scheduled for trial in the near future. We have been, are currently and expect to continue to be subject to various lawsuits, product liability claims, other material legal proceedings, governmental investigations and/or product recalls, any of which could have a material adverse effect on our company or cause us to take 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, 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. See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

For example, we, along with other manufacturers of prescription opioid medications, as well as distributors and other sellers of such medications, are the subject of lawsuits and have received subpoenas and other requests for information from various federal, state and local government agencies regarding the sale, marketing and/or distribution of prescription opioid medications. Numerous claims against opioid manufacturers, including us, have been and may continue to be filed by or on behalf of various plaintiffs, including states, counties, cities, Native American tribes and/or other government-related persons or entities, hospitals, health systems, unions, health and welfare funds or other third-party payers and/or individuals. In these cases, 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. See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

At any given time, we may be engaged in settlement or similar discussions regarding various legal matters; however, settlement demands and discussions often involve significant monetary and other remedies and there can be no assurance that we will receive settlement offers that are on terms that we consider reasonable under the circumstances or indicative of the merits or potential outcome of any court proceeding with respect to the underlying claims. For example, 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.

In the past, we have made the decision to settle some claims even though we believe we had meritorious defenses because of the significant legal and other costs that would have been required to defend such claims. There can be no assurance that settlement opportunities will continue to be available generally, or be consistent with our historic experience, or that we will not settle additional claims even if we believe we have meritorious defenses. Even where settlement agreements have been reached, in certain instances they are subject to conditions and contingencies, including but not limited to participation thresholds, that may be outside of our control and may not come to pass. In addition, there can be no assurance of the impact of any settlement agreement on existing or future claims.

Awards against or settlements by us or our competitors could incentivize parties to bring additional claims against us or increase settlement demands against us. In addition to the risks of direct expenditures for defense costs, settlements and/or judgments in connection with various claims, proceedings and investigations, there is a possibility of loss of revenues, injunctions and disruption of business. Additionally, we have received, and may continue to receive, claims or requests for indemnification from other persons or entities named in or subject to discovery in various lawsuits or other legal proceedings, including certain of our customers.

We and other manufacturers of prescription opioid medications have been, and will likely continue to be, subject to negative publicity and press, which could harm our brand and the demand for our products. Certain other manufacturers of prescription opioid medications have publicly commenced, or may commence, cases to seek the protections under Chapter 11 of the Bankruptcy Code to address the claims being asserted against such manufacturers in these opioid lawsuits and others may do so or take similar measures in the future. We cannot assure you how any such decisions will impact our company.

Our current and former products may cause or appear to cause serious adverse side effects or potentially dangerous drug interactions if misused or improperly prescribed or as a result of faulty surgical technique. We are subject to various risks associated with having operated a medical device manufacturing business, including potential and actual product liability claims for defective or allegedly defective goods and increased government scrutiny and/or potential claims regarding the marketing of medical devices. For example, we and certain other manufacturers have been named as defendants in multiple lawsuits in various federal and state courts alleging personal injury resulting from the use of transvaginal surgical mesh products designed to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The FDA held a public advisory committee meeting in February 2019 during which the members of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee discussed and made recommendations regarding the safety and effectiveness of surgical mesh to treat POP. In April 2019, following the meeting, the FDA ordered that the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of POP cease selling and distributing their products in the U.S. effective immediately. Although we have not sold transvaginal surgical mesh products since March 2016, it is possible that the FDA's order and any additional FDA actions based on the outcome of the advisory committee meeting could result in additional litigation against the Company or the expansion of ongoing litigation against the Company. See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

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/or reputational damage.

In addition, in the age of social media, plaintiffs' attorneys have a wide variety of tools to advertise their services and solicit new clients for litigation, including using judgments and settlements obtained in litigation against us or other pharmaceutical companies as an advertising tool. For these or other reasons, any product liability or other litigation in which we are a defendant could have a larger number of plaintiffs than such actions have seen historically and we could also see an increase in the number of cases filed against us because of the increasing use of widespread and media-varied advertising. This could also complicate any settlement discussions we may be engaged in. Furthermore, a ruling against other pharmaceutical companies in product liability or other litigation, or any related settlement, in which we are not a defendant could have a negative impact on pending litigation where we are a defendant.

In addition, in certain circumstances, such as in the case of products that do not meet approved specifications or which subsequent data demonstrate may be unsafe, ineffective or misused, it may be necessary for us to initiate voluntary or mandatory recalls or withdraw such products from the market. Any such recall or withdrawal could result in adverse publicity, costs connected to the recall and loss of revenue. Adverse publicity could also result in an increased number of additional product liability claims, whether or not these claims have a basis in scientific fact. See the risk factor "Public concern around the abuse of opioids or other products including, without limitation, law enforcement concerns over diversion or marketing practices, regulatory efforts to combat abuse and litigation could result in costs to our business and damage our reputation" for more information.

If we are found liable in any lawsuits, including the ongoing legal proceedings related to our sale, marketing and/or distribution of prescription opioid medications, product liability claims or actions related to our sales, marketing or pricing practices or if we are subject to governmental investigations or product recalls, it could result in the imposition of material damages, including punitive damages, fines, reputational harm, civil lawsuits, criminal penalties, interruptions of business, modification of business practices, equitable remedies and other sanctions against us or our personnel as well as significant legal and other costs. At any given time, we may be engaged in settlement or similar discussions, and we may voluntarily settle claims even if we believe that we have meritorious defenses because of the significant legal and other costs that may be required to defend such claims. Any judgments, claims, settlements and related costs could be well in excess of any applicable insurance or accruals. As a result, we may experience significant negative impacts on our results of operations or financial condition. To satisfy judgments or settlements or to pursue certain appeals, we may need to seek financing or bonding, which may not be available on terms acceptable to us, or at all, when required, particularly given the nature and amount of the claims against us. Judgments against us could also cause defaults under our debt agreements (which could result in cross-defaults or cross-accelerations in other agreements) and/or restrictions on product use or business practices and we could incur losses as a result. Any of the risks above could have a material adverse effect on our business, financial condition, results of operations and cash flows and could be further exacerbated by the impact of COVID-19.

In July 2021, a court in one legal action issued an order granting a default judgment on liability against Endo Pharmaceuticals Inc. (EPI) and Endo Health Solutions Inc. (EHSI) and awarding the plaintiffs fees and costs relating to certain alleged discovery issues in an opioid-related lawsuit. Although we settled that matter, another court in a similar matter recently granted a default judgment on liability and other sanctions against EPI and EHSI for the same alleged discovery issues. See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information. We cannot assure you that other plaintiffs will not seek similar relief. Any additional default judgments or other sanctions relating to discovery matters could result in the imposition of material damages or other costs.

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. Any such actions may be complex, could entail significant costs and charges or could otherwise negatively impact shareholder value, and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all, or that they will result in their intended benefits. We are exploring a wide array of such potential actions as part of our contingency planning, including the impact such actions could have on our business and operations. 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. See the risk factor "Our ability to fund our operations, maintain adequate liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties" for more information.

See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion of the foregoing and other material legal proceedings.

We may not have and may be unable to obtain or maintain insurance adequate to cover potential liabilities.

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.

Public concern around the abuse of opioids or other products including, without limitation, law enforcement concerns over diversion or marketing practices, regulatory efforts to combat abuse and litigation could result in costs to our business and damage our reputation.

Media stories regarding drug abuse and diversion, including the abuse and diversion of prescription opioid medications and other controlled substances, are commonplace and have included the Company. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of opioids, the limitations of abuse-deterrent formulations, the ability of abusers to discover previously unknown ways to abuse our products, public inquiries and investigations into drug abuse or litigation or regulatory or enforcement activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation, on the results of litigation and on our ability to attract or maintain relationships with third-party partners, including suppliers, vendors, advisors, distributors, manufacturers, collaboration partners, administrators and agents. As a result of the timing and schedule of certain legal proceedings against us, we will likely be subject to additional press for the foreseeable future.

Manufacturers of prescription opioid medications have been the subject of significant civil and criminal investigatory and enforcement actions even in cases where such medications have received approval from the FDA or similar regulatory authorities. Numerous governmental and private persons and entities are pursuing litigation against opioid manufacturers, including us, as well as distributors and others, asserting alleged violations of various laws and regulations relating to opioids and/or other prescription medicines, relying on common law theories, and seeking to hold the defendants accountable for, among other things, societal costs associated with the misuse and abuse of prescription opioid medications as well as non-prescription opioids. A number of these legal proceedings are approaching trial or other significant events, which may result in increased settlement discussions and other activity. There is a risk we will be subject to similar investigations, enforcement actions or litigations in the future, that we will suffer adverse decisions or verdicts of substantial amounts or that we will enter into monetary settlements. Any unfavorable outcomes as a result of such proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows. 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, 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. See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information. There have been proposals in certain legislatures to restrict the ability to compromise or release liability of certain parties in such cases, and we cannot assure you whether any such proposals will be made or adopted in the future or predict how any such proposals may affect the Company.

Regulatory actions at the federal, state and local level may seek to limit or restrict the manufacturing, distribution or sale of opioids, both directly and indirectly, and/or to impose novel policy or regulatory mechanisms regarding the distribution or sales of opioids. For example, in April 2019, New York enacted an excise tax on opioids. See the risk factor “Our business and financial condition may be adversely affected by existing or future legislation and regulations” for more information.

Various government entities, including the U.S. Congress, state legislatures or other policy-making bodies in the U.S. or elsewhere have held hearings, conducted investigations and/or issued reports calling attention to opioid misuse and abuse, and some have mentioned or criticized the role of manufacturers, including us, in supplying or marketing opioid medications or failing to take adequate steps to detect or report suspicious orders or to prevent abuse and diversion. Press organizations have reported and likely will continue to report on these issues, and such reporting has and may further result in adverse publicity which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Financial and Liquidity Related Risks

Our ability to fund our operations, maintain adequate liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties.

We rely on cash from operations as well as access to the financial markets to fund our operations, maintain liquidity and meet our financial obligations. Our operations are subject to many significant risks and uncertainties, including those related to generic competition and legal challenges that could impact our key products, outstanding and future legal proceedings and governmental investigations, including those related to our sale, marketing and/or distribution of prescription opioid medications, and others. Any negative development or outcome in connection with any or all of these risks and uncertainties could result in significant consequences, including one or more of the following:

- causing a substantial portion of our cash flows from operations to be dedicated to the payment of legal or related expenses and therefore unavailable for other purposes, including the payment of principal and interest on our indebtedness, our operations, capital expenditures and future business opportunities;
- limiting our ability to adjust to changing market conditions, causing us to be more vulnerable to periods of negative or slow growth in the general economy or in our business, causing us to be unable to carry out capital spending that is important to our growth and placing us at a competitive disadvantage;
- limiting our ability to attract and retain key personnel;
- causing us to be unable to maintain compliance with or making it more difficult for us to satisfy our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt and long-term corporate ratings (which could increase our cost of capital) and exposing us to potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries' outstanding indebtedness;
- limiting our ability to incur additional borrowings under 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
- causing a significant reduction in our short-term and long-term revenues and/or otherwise causing 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 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. 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. Some of these actions could take significant time to implement and others may require judicial or other third-party approval. Additionally, we may need to refinance all or part of our then-existing indebtedness, reduce or delay capital expenditures or seek to raise additional capital. Any refinancing of our substantial indebtedness could be at significantly higher interest rates, which will depend on the conditions of the markets and our financial condition at such time, and may require us to comply with more onerous covenants, which could further restrict our business operations. Any refinancing may also increase the amount of our secured indebtedness. Negative developments in legal or other proceedings could also make it more difficult to consummate any of these transactions or for us to satisfy certain conditions required to borrow under our credit facilities. In addition, the terms of existing or future debt agreements may restrict us from consummating any of these alternatives. Likewise, any reorganizations or restructuring activities, corporate realignments, asset sales or divestitures, strategic partnerships or other actions that we take may be complex, could entail significant costs and charges or could otherwise negatively impact shareholder value, and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all, or that they will result in their intended benefits.

We have significant goodwill and other intangible assets. Consequently, potential impairments of goodwill and other intangibles may significantly impact our profitability.

Goodwill and other intangibles represent a significant portion of our assets. As of December 31, 2021 and 2020, goodwill and other intangibles comprised approximately 63% and 68%, respectively, of our total assets. Goodwill and other indefinite-lived intangible assets are subject to impairment tests at least annually. Additionally, impairment tests must be performed for certain assets whenever events or changes in circumstances indicate such assets' carrying amounts may not be recoverable.

For the years ended December 31, 2021, 2020 and 2019, we recorded asset impairment charges of $0.4 billion, $0.1 billion and $0.5 billion, respectively, which related primarily to goodwill and other intangible assets. Refer to Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report for examples and a discussion of material impairment tests and impairment charges during the years ended December 31, 2021, 2020 and 2019. The procedures and assumptions used in our goodwill and other intangible assets impairment testing are discussed in Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "CRITICAL ACCOUNTING ESTIMATES" and in Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Events giving rise to asset impairments are an inherent risk in the pharmaceutical industry and often cannot be predicted. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in future periods could be negatively impacted should additional impairments of our goodwill or other intangible assets occur. For additional discussion, refer to Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "CRITICAL ACCOUNTING ESTIMATES."

We have a substantial amount of indebtedness which could adversely affect our financial position and prevent us from fulfilling our obligations under such indebtedness, which may require us to refinance all or part of our then-outstanding indebtedness. Any refinancing of this substantial indebtedness could be at significantly higher interest rates. Additionally, we have a significant amount of floating rate indebtedness and an increase in interest rates would increase the cost of servicing our indebtedness. Despite our current level of indebtedness, we may still be able to incur substantially more indebtedness and increase the associated risks.

We currently have a substantial amount of indebtedness. As of December 31, 2021, we have total debt of approximately $8.3 billion in aggregate principal amount. Our substantial indebtedness may:

- make it difficult for us to satisfy our financial obligations, including making scheduled principal and interest payments on our indebtedness;
- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to incur judgments above certain thresholds;
- expose us to the risk of rising interest rates with respect to the borrowings under our variable rate indebtedness;
- require us to use a substantial portion of our cash on hand and/or from future operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions, such as those resulting from the COVID-19 pandemic, which may further limit our ability to satisfy our financial obligations.

If we are unable to pay amounts due under our outstanding indebtedness or to fund other liquidity needs, such as future capital expenditures or contingent liabilities as a result of adverse business developments, including expenses related to our ongoing and future legal proceedings and governmental investigations, decreased revenues or increased costs and expenses related to the impact of COVID-19 on our business, as well as increased pricing pressures or otherwise, we may be required to refinance all or part of our then-existing indebtedness, sell assets, reduce or delay capital expenditures or seek to raise additional capital, any of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. There can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all. Any refinancing of this substantial indebtedness could be at significantly higher interest rates, which will depend on the conditions of the markets and our financial condition at such time. In addition, we may be able to incur substantial additional indebtedness in the future, including secured indebtedness. If new indebtedness is added to our current debt levels, the related risks that we and our subsidiaries now face could intensify. At any time and from time to time, we may also be pursuing activities to extend our debt maturities, lower principal balances, reduce interest expense or obtain covenant flexibility. Activities could include, without limitation, one or more tender offers, exchange offers, debt-for-equity exchanges or consent solicitations. The terms of any such transactions, including the amount of any exchange consideration and terms of any refinanced debt, could be negatively impacted by a downgrade of our debt ratings or a decrease in investor interest, be less favorable than we have been able to obtain in the past or result in an increase in our total outstanding secured indebtedness. We cannot predict if or when we would conduct any such activities, whether any such activities will achieve their intended results or whether any such activities could impact our financial results or be dilutive.

While interest rates have been at record low levels, this low interest rate environment likely will not continue indefinitely. At December 31, 2021, approximately $2.0 billion and $0.3 billion of principal amounts outstanding under the Term Loan Facility (as defined below) and the Revolving Credit Facility, respectively, bear interest at variable rates. Any future borrowings by the Company could also have variable interest rates. As a result, an increase in the applicable benchmark interest rates would increase our cost of servicing our indebtedness and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The phase-out of LIBOR could affect interest rates under certain of our existing indebtedness as well as our ability to seek future debt financing.

LIBOR is the basic rate of interest used in lending between banks on the London interbank market and is widely used as a reference for setting the interest rates on loans globally. A significant portion of our outstanding indebtedness, including, at December 31, 2021, $2.0 billion outstanding under the Term Loan Facility and $0.3 billion outstanding under the Revolving Credit Facility, bears interest rates in relation to LIBOR. Any future amounts borrowed under the Term Loan Facility or Revolving Credit Facility would also bear interest rates in relation to LIBOR, depending on our interest election.

The U.K. Financial Conduct Authority, which regulates LIBOR, has announced that it intends to phase out LIBOR. Banks currently reporting information used to set U.S. dollar LIBOR are expected to stop doing so during 2023, and in 2021, the U.S. Federal Reserve Board and other regulatory bodies issued guidance encouraging banks and other financial market participants to cease entering into new contracts that use U.S. dollar LIBOR as a reference rate as soon as practicable and in any event no later than December 31, 2021.

While various bodies, including governmental agencies, are seeking to identify an alternative rate to replace LIBOR, including the Secured Overnight Financing Rate, there is uncertainty regarding which alternative reference rate will replace LIBOR. We may need to amend certain agreements that use LIBOR as a benchmark, including the Credit Agreement (as defined below), and we cannot predict what alternative index or other amendments may be negotiated with our counterparties. As a result, our interest expense could increase and our available cash flow for general corporate requirements may be adversely affected. In addition, uncertainty as to the nature of the discontinuation or modification of LIBOR, alternative reference rates or other reforms could have an adverse impact on the market for or value of any LIBOR-linked securities, loans and other financial obligations or extensions of credit held by or due to us or on our overall financial condition or results of operations.

Covenants in our debt agreements restrict our business in many ways, a default of which may result in acceleration of certain of our indebtedness.

We are subject to various covenants in the instruments governing our debt that limit our and/or our subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- incur judgments above certain thresholds;
- issue redeemable stock and preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase debt;
- make loans, investments and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

A breach of any of these covenants could result in a default under our indebtedness. If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately, terminate all commitments to extend further credit, foreclose against all the assets comprising the collateral securing or otherwise supporting the debt and pursue other legal remedies. The instruments governing our debt may contain cross-default or cross-acceleration provisions that may cause all of the debt issued under such instruments to become immediately due and payable as a result of a default under an unrelated debt instrument. Our assets and cash flows may be insufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder were accelerated upon an event of default. We may need to conduct asset sales or pursue other alternatives, including proceedings under applicable insolvency laws relating to some or all of our business. The covenants are also subject to a number of exceptions, including the ability to incur certain additional amounts of secured and unsecured indebtedness, which could exacerbate any of these risks. Any or all of the above could have a material adverse effect on our business, financial condition, results of operations and cash flows. For a description of our indebtedness, see Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

We may not realize the anticipated benefits from our strategic actions.

We continuously seek to optimize our operations and increase our overall efficiency through strategic actions. These actions may involve decisions to exit manufacturing or research sites, transfer the manufacture of products to other internal and external sites within our manufacturing network and simplify business process activities. For example, we announced plans on November 5, 2020 to optimize our retail generics business cost structure, transfer certain transaction processing activities to third-party global business process service providers and further integrate the Company's commercial, operations and research and development functions. There can be no assurance that we will achieve the benefits and savings of such actions in the amounts and with the expected timing, if at all. We will also incur certain charges in connection with such actions and future costs could also be incurred. It is also possible that charges and cash expenditures associated with such actions could be higher than estimated. Any of these risks could ultimately have a material adverse effect on our business, financial condition, results of operations and cash flows.

Legal and Regulatory Related Risks

Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny and we may be subject to additional investigations or litigation.

We are and may in the future be involved in patent litigations in which generic companies challenge the validity or enforceability of our products' listed patents and/or the applicability of these patents to the generic applicant's products. Likewise, we are and may in the future be involved in patent litigations in which we challenge the validity or enforceability of innovator companies' listed patents and/or their applicability to our generic products. Therefore, settling patent litigations has been and is likely to continue to be part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the U.S. Federal Trade Commission (FTC) and the Antitrust Division of the DOJ for review. In some instances, the FTC has brought actions against brand and generic companies that have entered into such agreements, alleging that they violate antitrust laws. Even in the absence of an FTC challenge, other governmental or private litigants may assert antitrust or other claims relating to such agreements. We may receive formal or informal requests from the FTC or other governmental entities for information about any such settlement agreement we enter into or about other matters, and there is a risk that the FTC or other governmental or private litigants may commence an action against us alleging violation of antitrust laws or other claims. For example, in December 2021, in response to a citizen petition filed on behalf of PSP LLC regarding vasopressin ANDA products referencing VASOSTRICT®, the FDA denied the petition and stated that it intends to refer the matter to the FTC.

The U.S. Supreme Court, in *FTC v. Actavis*, determined that patent settlement agreements between generic and brand companies should be evaluated under the rule of reason, but provided limited guidance beyond the selection of this standard. Because the U.S. Supreme Court did not articulate the full range of criteria upon which a determination of the legality of such settlements would be based, or provide guidance on the precise circumstances under which such settlements would qualify as legal, there has been and may continue to be extensive litigation over what constitutes a reasonable and lawful patent settlement between a brand and generic company. The Company and/or its subsidiaries have been named in several such lawsuits. For example, 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). See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

There have been federal and state legislative efforts to overturn the *FTC v. Actavis* decision and make certain terms in patent settlement agreements *per se* unlawful. For example, some members of the U.S. Congress have proposed legislation that would limit the types of settlement agreements generic manufacturers and brand companies can enter into. The state of California enacted legislation, effective January 1, 2020, that deems a settlement of a patent infringement claim to be presumptively anticompetitive and allows the California Attorney General to seek monetary penalties if a generic company receives anything of value from the branded company and the generic company agrees to delay research and development, manufacturing, marketing or sales of the generic product for any period of time. The California law carves out from the definition of "anything of value" certain types of settlement terms and it allows the settling parties to rebut the presumption of anticompetitive harm. In December 2021, a federal district court enjoined enforcement of the California law pending resolution of a lawsuit challenging its constitutionality; however, there has been no final determination of the merits of the legal challenge.

We are subject to various laws and regulations pertaining to the marketing of our products and services.

The marketing and pricing of our products and services, including product promotion, educational activities, support of continuing medical education programs and other interactions with healthcare professionals, are governed by various laws and regulations, including FDA regulations and the Anti-Kickback Statute. Additionally, many states have adopted laws similar to the Anti-Kickback Statute, without identical exceptions or exemptions. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs. Any such regulations or requirements could be difficult and expensive for us to comply with, could delay our introduction of new products and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from federally funded healthcare programs such as Medicare and Medicaid, as well as potential liability under the False Claims Act and applicable state false claims acts. There can be no assurance that our practices will not be challenged under these laws in the future, that changes in these laws or interpretation of these laws would not give rise to new challenges of our practices or that any such challenge would not have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, in December 2021, the Attorney General of Texas announced an investigation of EPI and AbbVie Inc. under the Texas Deceptive Trade Practices Act for allegedly advertising and promoting hormone (puberty) blockers for unapproved uses without disclosing potential risks. Law enforcement agencies sometimes initiate investigations into sales, marketing and/or pricing practices based on preliminary information or evidence, and such investigations can be and often are closed without any enforcement action. Nevertheless, these types of investigations and any related litigation can result in: (i) large expenditures of cash for legal fees, payment of penalties and compliance activities; (ii) limitations on operations; (iii) diversion of management resources; (iv) injury to our reputation; and (v) decreased demand for our products.

The FFDCA and FDA regulations and guidance restrict the ability of healthcare companies, such as our company, to communicate with patients, physicians and other third parties about uses of prescription pharmaceuticals or devices that are not cleared or approved by the FDA, which are commonly referred to as "off-label" uses. Prohibitions on the promotion of off-label uses and against promotional practices deemed false or misleading are actively enforced by various parties at both the federal and state levels. A company that is found to have improperly promoted its products under these laws may be subject to significant liability, such as significant administrative, civil and criminal sanctions including, but not limited to, significant civil damages, criminal fines and exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Applicable laws governing product promotion also provide for administrative, civil and criminal liability for individuals, including, in some circumstances, potential strict vicarious liability. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by such conduct.

We have established and implemented a corporate compliance program designed to prevent, detect and correct violations of state and federal healthcare laws, including laws related to advertising and promotion of our products. Nonetheless, governmental agencies or private parties may take the position that we are not in compliance with such requirements and, if such non-compliance is proven, the Company and, in some cases, individual employees, may be subject to significant liability, including the aforementioned administrative, civil and criminal sanctions.

In February 2014, EPI entered into a Deferred Prosecution Agreement and a Corporate Integrity Agreement (CIA) with HHS to resolve allegations regarding the promotion of LIDODERM®. In March 2013, our subsidiary Par Pharmaceutical Companies, Inc. (PPCI) entered into a CIA and plea agreement with the DOJ to resolve allegations regarding the promotion of MEGACE® ES, which was subsequently subsumed by EPI's CIA. Those agreements placed certain obligations on us related to the marketing of our pharmaceutical products and our healthcare regulatory compliance program, including reporting requirements to the U.S. government, detailed requirements for our compliance program, code of conduct and policies and procedures and the requirement to engage an Independent Review Organization. We implemented procedures and practices to comply with the CIAs, including the engagement of an Independent Review Organization. In February 2020, Endo was notified that it had satisfied its CIA requirements and the 5-year term of Endo's CIA has now concluded.

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.

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. For example, 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 cGMP. We also may experience delays in obtaining, or we may not obtain, required initial and continuing approval of our clinical trials from institutional review boards. We may experience delays or undesired results in any of our clinical trials. These risks could be further exacerbated by the impact of COVID-19.

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. Even if we receive approval for an NDA under section 505(b)(2) of the 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, BLA or 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 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 oxymorphone ER and oxymorphone 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 APIs, 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 TRT 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 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 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.

Our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

We are subject to federal and state laws prohibiting the presentation (or the causing to be presented) of claims for payment (by Medicare, Medicaid or other third-party payers) that are determined to be false or fraudulent, including presenting a claim for an item or service that was not provided. These false claims statutes include the federal civil False Claims Act, which permits private persons to bring suit in the name of the government alleging false or fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as *qui tam* actions, have increased significantly in the healthcare industry in recent years. These actions against pharmaceutical companies, which do not require proof of a specific intent to defraud the government, may result in payment of fines to and/or administrative exclusion from the Medicare, Medicaid and/or other government healthcare programs.

We are subject to laws that require us to enter into a Medicaid Drug Rebate Agreement, a 340B Pharmaceutical Pricing Agreement and agreements with the Department of Veterans Affairs as a condition for having our products eligible for payment under Medicare Part B and Medicaid. We have entered into such agreements. In addition, we are required to report certain pricing information to CMS, the Health Resources and Services Administration and the Department of Veterans Affairs on a periodic basis to facilitate rebate payments to the State Medicaid Programs, to set Medicare Part B reimbursement levels and to establish the prices that can be charged to certain purchasers, including 340B-covered entities and certain government entities. Any failure to comply with these laws and agreements could have a material adverse effect on our business, financial condition, results of operations and cash flows.

With regard to the Medicaid Drug Rebate Program, on February 1, 2016, CMS issued a Final Rule implementing the Medicaid Drug Rebate provisions incorporated into the PPACA, effective April 1, 2016 in most instances. Ongoing compliance with these program rules, including the requirement that we adopt reasonable assumptions where law, regulation and guidance do not address specific participation issues, may impact the level of rebates that we owe under the program. The 2016 Final Rule also expanded the scope of the Medicaid Drug Rebate program to apply to U.S. territories (which pursuant to further rulemaking is now scheduled to become effective on January 1, 2023), which will require operational adjustments and may result in additional rebate liability. Additionally, in December 2020, CMS issued a Final Rule for the Medicaid Drug Rebate Program that makes changes with regard to: (i) the calculation of Medicaid Best Price for certain value- or outcomes-based discounting arrangements; (ii) the standard for excluding the value of manufacturer copayment assistance and other patient support arrangements from the calculation of Average Manufacturer Price and Best Price; (iii) the identification of "line extension" drugs that are subject to higher Medicaid rebate liability; and (iv) establishment of additional drug utilization review requirements for opioids. Depending on how these changes are implemented, they could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We and other pharmaceutical companies have been named as defendants in a number of lawsuits filed by various government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain products that are reimbursable by state Medicaid programs, which are partially funded by the federal government. There is a risk we will be subject to similar investigations or litigations in the future, that we will suffer adverse decisions or verdicts of substantial amounts or that we will enter into monetary settlements. Any unfavorable outcomes as a result of such proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Decreases in the degree to which individuals are covered by healthcare insurance could result in decreased use of our products.

Employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees. Job losses or other economic hardships, including any that may be related to COVID-19, may also result in reduced levels of coverage for some individuals, potentially resulting in lower levels of healthcare coverage for themselves or their families. Further, in addition to the fact that the TCJA eliminated the PPACA's requirement that individuals maintain insurance or face a penalty, additional steps to limit or end cost-sharing subsidies to lower-income Americans may increase instability in the insurance marketplace and the number of uninsured Americans. These economic conditions may affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations and lost healthcare insurance coverage or for other reasons. We believe such conditions could lead to changes in patient behavior and spending patterns that negatively affect usage of certain of our products, including some patients delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies or foregoing healthcare insurance coverage. Such changes may result in reduced demand for our products, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If our manufacturing facilities are unable to manufacture our products or the manufacturing process is interrupted due to failure to comply with regulations or for other reasons, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If any of our or our third party manufacturing facilities fail to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect our ability to supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products are subject to inspection by regulatory agencies at any time and must be operated in conformity with cGMP and, in the case of controlled substances, DEA regulations. Compliance with the FDA's cGMP and DEA requirements applies to both products for which regulatory approval is being sought and to approved products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, recordkeeping, quality assurance and quality control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects our or our third party manufacturing facilities to possible legal or regulatory action, including shutdown, which may adversely affect our ability to supply our products. Additionally, our facilities and our third party manufacturing facilities may face other significant disruptions due to labor strikes, failure to reach acceptable agreement with labor unions, infringement of intellectual property rights, vandalism, natural disaster, outbreak and spread of viral or other diseases, storm or other environmental damage, civil or political unrest, export or import restrictions or other events. If we are not able to manufacture products at our or our third party manufacturing facilities because of regulatory, business or any other reasons, the manufacture and marketing of these products could be interrupted. This could have a material adverse effect on our business, financial condition, results of operations and cash flows.

For example, the manufacturing facilities qualified to manufacture the enzyme CCH, which is included in XIAFLEX® and QWO®, are subject to such regulatory requirements and oversight. If such facilities fail to comply with cGMP requirements, we may not be permitted to sell our products or may be limited in the jurisdictions in which we are permitted to sell them. Further, if an inspection by regulatory authorities indicates that there are deficiencies, including non-compliance with regulatory requirements, we could be required to take remedial actions, stop production or close our facilities, which could disrupt the manufacturing processes and could limit the supply of CCH and/or delay clinical trials and subsequent licensure and/or limit the sale of commercial supplies. In addition, future noncompliance with any applicable regulatory requirements may result in refusal by regulatory authorities to allow use of CCH in clinical trials, refusal by the government to allow distribution of CCH within the U.S. or other jurisdictions, criminal prosecution, fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products, refusal to allow the entering into of federal and state supply contracts and civil litigation.

We purchase certain API and other materials used in our manufacturing operations from foreign and U.S. suppliers. The price and availability of API and other materials is subject to volatility for a number of reasons, many of which may be outside of our control. There is no guarantee that we will always have timely, sufficient or affordable access to critical raw materials or supplies from third parties. An increase in the price, or an interruption in the supply, of any API or raw material could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Non-U.S. regulatory requirements vary, including with respect to the regulatory approval process, and failure to obtain regulatory approval or maintain compliance with requirements in non-U.S. jurisdictions would prevent or impact the marketing of our products in those jurisdictions.

We have worldwide intellectual property rights to market many of our products and product candidates and may seek approval to market certain of our existing or potential future products outside of the U.S. Approval of a product by the regulatory authorities of a particular country is generally required prior to manufacturing or marketing that product in that country. The approval procedure varies among countries and can involve additional testing and the time required to obtain such approval may differ from that required to obtain FDA approval. Non-U.S. regulatory approval processes generally include risks similar to those associated with obtaining FDA approval, as further described herein. FDA approval does not guarantee approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country guarantee approval by regulatory authorities in other foreign countries or by the FDA.

Outside of the U.S., regulatory agencies generally evaluate and monitor the safety, efficacy and quality of pharmaceutical products and devices and impose regulatory requirements applicable to manufacturing processes, stability testing, recordkeeping and quality standards, among others. These requirements vary by jurisdiction. In certain countries, the applicable healthcare and drug regulatory regimes may continue to evolve and implement new requirements. Ensuring and maintaining compliance with these varying and evolving requirements is and will continue to be difficult, time-consuming and costly. In seeking regulatory approvals in non-U.S. jurisdictions, we must also continue to comply with U.S. laws and regulations, including those imposed by the FCPA. See the risk factor "The risks related to our global operations may adversely impact our revenues, results of operations and financial condition." If we fail to comply with these various regulatory requirements or fail to obtain and maintain required approvals, our target market will be reduced and our ability to generate non-U.S. revenue will be adversely affected.

If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and other efforts, our sales of generic products may suffer.

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of earlier patents, which could extend patent protection for additional years;
- using the Citizen Petition process (for example, under 21 C.F.R. § 10.30) to request amendments to FDA standards;
- attempting to use the legislative and regulatory process to have products reclassified or rescheduled or to set definitions of abuse-deterrent formulations to protect patents and profits; and
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic products.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products and our growth prospects may decline, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

New tariffs and evolving trade policy between the U.S. and other countries, including China, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We conduct business globally and our operations, including third party suppliers, span numerous countries outside the U.S. There is uncertainty about the future relationship between the U.S. and various other countries with respect to trade policies, treaties, government regulations and tariffs.

The U.S. government may seek to impose additional restrictions on international trade, such as increased tariffs on goods imported into the U.S. Such tariffs could potentially disrupt our existing supply chains and impose additional costs on our business, including costs with respect to raw materials upon which our business depends. Furthermore, if tariffs, trade restrictions or trade barriers are placed on products such as ours by foreign governments, it could cause us to raise prices for our products, which may result in the loss of customers. If we are unable to pass along increased costs to our customers, our margins could be adversely affected. Additionally, it is possible that further tariffs may be imposed that could affect imports of APIs and other materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by other countries, including restricted access to APIs or other materials used in our products, causing us to raise prices or make changes to our products. Further, the continued threats of tariffs, trade restrictions and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales. Given the volatility and uncertainty regarding the scope and duration of these tariffs and other aspects of U.S. international trade policy, the impact on our operations and results is uncertain and could be significant. Further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures could occur in the future. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We are subject to information privacy and data protection laws that include penalties for noncompliance. Our failure to comply with various laws protecting the confidentiality of personal information, patient health information or other data could result in penalties and reputational damage.

We are subject to a number of privacy and data protection laws and regulations globally. The legislative and regulatory landscape for privacy and data security continues to evolve. Certain countries in which we operate have, or are developing, laws protecting the confidentiality of individually identifiable personal information, including patient health information. This includes federal and state laws and regulations in the U.S. as well as in Europe and other markets.

For example, multiple U.S. states have passed data privacy legislation that provides new data privacy rights for consumers and new operational requirements for businesses. The California Consumer Privacy Act of 2018 (CCPA) went into effect on January 1, 2020 and established a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the state of California and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. In 2021, Virginia and Colorado passed laws similar in scope to the CCPA and California voters passed an update to the CCPA, the California Privacy Rights Act, which expanded on the existing consumer rights under the CCPA, imposed additional obligations on governed businesses and created a new state enforcement agency dedicated to enforcing California consumers' privacy rights. State legislatures can be expected to continue to regulate data privacy in the absence of legislation from the U.S. federal government. Many aspects of the CCPA and new state privacy laws have not been interpreted by courts and best practices are still being developed, all of which increase the risk of compliance failure and related adverse impacts.

In addition, data protection laws in other international jurisdictions impose restrictions on our authority to collect, analyze and transfer personal data, including health data, across international borders. For example, the EU's General Data Protection Regulation (GDPR), which became enforceable as of May 25, 2018, and related implementing laws in individual EU Member States strictly regulate our ability to collect, analyze and transfer personal data regarding persons in the EU, including health data from clinical trials and adverse event reporting. The GDPR, which has extra-territorial scope and substantial fines for breaches (up to 4% of global annual revenue or €20 million, whichever is greater) grants individuals whose personal data (which is very broadly defined) is collected or otherwise processed the right to access the data, request its deletion and control its use and disclosure. The GDPR also requires notification of a breach in the security of such data to be provided within 72 hours of discovering the breach. Although the GDPR itself is self-executing across all EU Member States, data protection authorities from different EU Member States may interpret and apply the regulation somewhat differently, which adds to the complexity of processing personal data in the EU. Uncertainty in the interpretation and enforcement of the regulation by the EU Member States' different data protection authorities contributes to liability exposure risk.

The GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the European Commission to provide an adequate level of data protection, and transfers of personal data to such countries may be made only in certain circumstances, such as where the transfer is necessary for important reasons of public interest or the individual to whom the personal data relates has given his or her explicit consent to the transfer after being informed of the risks involved. Even when certain circumstances are met, a July 2020 decision by the Court of Justice of the European Union (Schrems II), placed transfers of personal data from the EU to the U.S. under considerable uncertainty as the decision raised concerns about governmental entity access to personal data under U.S. national security laws. Transfers of personal data out of the EU to the U.S. remain an unresolved matter for political negotiation between the U.S. and EU representatives.

Similar international data privacy laws also impose stringent requirements on the collection, use of and ability to analyze and transfer personal data from each country and increase the complexity of our global operations. In all cases, enforcement of international data privacy laws and regulations is new, or priorities are shifting, which may constrain the implementation of global business processes and may impose additional costs for compliance.

We have policies and practices that we believe make us compliant with applicable privacy regulations. Nevertheless, there remains a risk of failure to comply with the rules arising from the GDPR or privacy laws in other jurisdictions in which we operate. Should a transgression be deemed to have occurred, it could lead to government enforcement actions and significant sanctions or penalties against us, adversely impact our results of operations and subject us to negative publicity. Such liabilities could materially affect our operations.

There has also been increased enforcement activity in the U.S. particularly related to data security breaches. A violation of these laws or regulations by us or our third party vendors could subject us to penalties, fines, liability and/or possible exclusion from Medicare or Medicaid. Such sanctions could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Intellectual Property Related Risks

Our ability to protect and maintain our proprietary and licensed third party technology, which is vital to our business, is uncertain.

Our success, competitive position and future income depend in part on our ability, and the ability of our partners and suppliers, to obtain and protect patent and other intellectual property rights relating to our current and future technologies, processes and products. The degree of protection any patents will afford is uncertain, including whether the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all the jurisdictions where we conduct business. That is, the issuance of a patent is not conclusive as to its claimed scope, validity or enforceability. Patent rights may be challenged, revoked, invalidated, infringed or circumvented by third parties. For example, if an invention qualifies as a joint invention, the joint inventor may have intellectual property rights in the invention, which might not be protected. A third party may also infringe upon, design around or develop uses not covered by any patent issued or licensed to us and our patents may not otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain and involves complex legal and factual questions. Even issued patents may later be modified or revoked by the PTO, by comparable foreign patent offices or by a court following legal proceedings. Laws relating to such rights may in the future also be changed or withdrawn.

There is no assurance that any of our patent claims in our pending non-provisional and provisional patent applications relating to our technologies, processes or products will be issued or, if issued, that any of our existing and future patent claims will be held valid and enforceable against third-party infringement. We could incur significant costs and management distraction if we initiate litigation against others to protect or enforce our intellectual property rights. Such patent disputes may be lengthy and a potential violator of our patents may bring a potentially infringing product to market during the dispute, subjecting us to competition and damages due to infringement of the competitor product. Upon the expiration or loss of intellectual property protection for a product, others may manufacture and distribute such patented product, which may result in the loss of a significant portion of our sales of that product.

We also rely on trade secrets and other unpatented proprietary information, which we generally seek to protect by confidentiality and nondisclosure agreements with our employees, consultants, advisors and partners. These agreements may not effectively prevent disclosure of confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure. Even if third parties misappropriate or infringe upon our proprietary rights, we may not be able to discover or determine the extent of any such unauthorized use and we may not be able to prevent third parties from misappropriating or infringing upon our proprietary rights. In addition, if our employees, scientific consultants or partners develop inventions or processes that may be applicable to our existing products or products under development, such inventions and processes will not necessarily become our property and may remain the property of those persons or their employers.

Any failure by us to adequately protect our technology, trade secrets or proprietary know-how or to enforce our intellectual property rights could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our competitors or other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to "at-risk" product launches, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Companies that produce branded pharmaceutical products routinely bring litigation against ANDA or similar applicants that seek regulatory approval to manufacture and market generic forms of branded products, alleging patent infringement or other violations of intellectual property rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling approved generic products. Litigation often involves significant expense. Additionally, if the patents of others are held valid, enforceable and infringed by our current products or future product candidates, we would, unless we could obtain a license from the patent holder, need to delay selling our corresponding generic product and, if we are already selling our product, cease selling and potentially destroy existing product stock. Additionally, we could be required to pay monetary damages or royalties to license proprietary rights from third parties and we may not be able to obtain such licenses on commercially reasonable terms or at all.

There may be situations in which we may make business and legal judgments to market and sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts based upon our belief that such patents are invalid, unenforceable or are not infringed by our marketing and sale of such products. This is commonly referred to in the pharmaceutical industry as an "at-risk" launch. The risk involved in an at-risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, damages calculated based on the profits lost by the patent holder, which can be significantly higher than the profits we make from selling the generic version of the product. Moreover, if a court determines that such infringement is willful, the damages could be subject to trebling. We could face substantial damages from adverse court decisions in such matters. We could also be at risk for the value of such inventory that we are unable to market or sell.

Risks Related to our Ordinary Shares

The trading prices of our securities have been volatile, and investments in our securities could decline in value.

The market prices for securities of Endo, and of pharmaceutical companies in general, have been highly volatile and may continue to be highly volatile in the future. For example, in 2021, our ordinary shares traded between $1.94 and $10.89 per share on the Nasdaq. The following factors, in addition to other risk factors described in this section, may cause the market value of our securities to fluctuate:

- FDA approval or disapproval of any of the drug applications we have submitted;
- the success or failure of our clinical trials;
- the success or failure of our ESG strategy and our ability to respond to increased stakeholder focus on ESG matters including climate change;
- new data or new analyses of older data that raise potential safety or effectiveness issues concerning our approved products;
- product recalls or withdrawals;
- competitors announcing technological innovations or new commercial products;
- introduction of generic, compounded or other substitutes for our products, including the filing of ANDAs with respect to generic versions of our branded products;
- developments concerning our or others' proprietary rights, including patents;
- competitors' publicity regarding actual or potential products under development or other activities affecting our competitors or the industry in general;
- regulatory developments in the U.S. and foreign countries, or announcements relating to these matters;
- period-to-period fluctuations in our financial results;
- new legislation, regulation, administrative guidance or executive orders, or changes in interpretation of existing legislation, regulation, administrative guidance or executive orders, including by virtue of new judicial decisions, that could affect the development, sale or pricing of pharmaceutical products, the number of individuals with access to affordable healthcare, the taxes we pay and/or other factors;
- a determination by a regulatory agency that we are engaging in or have engaged in inappropriate sales or marketing activities, including promoting off-label uses of our products;
- social and political pressure to lower the cost of pharmaceutical products;
- social and political scrutiny over increases in prices of shares of pharmaceutical companies that are perceived to be caused by a strategy of growth through acquisitions;
- litigation against us or others;
- reports of security analysts and rating agencies;
- judgments or settlements or reports of settlement negotiations concerning opioid-related litigation or claims;
- our ongoing contingency planning and strategic review that could ultimately result in our pursuing of one or more significant corporate transactions or other remedial measures, including a possible bankruptcy filing, potentially on a preventative or proactive basis; and
- changes in the political landscape, regulatory environment and international relations, including different policies that may be pursued by the current U.S. presidential administration.

We have no plans to pay regular dividends on our ordinary shares or to conduct ordinary share repurchases.

We currently do not intend to pay any cash dividends in the foreseeable future on our ordinary shares. Additionally, while our Board of Directors (Board) has approved a share buyback program (the 2015 Share Buyback Program), of which there is approximately $2.3 billion available as of December 31, 2021, we currently do not intend to conduct ordinary share repurchases in the foreseeable future. Any declaration and payment of future dividends to holders of ordinary shares as well as any repurchase of our ordinary shares under the 2015 Share Buyback Program will be at the sole discretion of the Board and will depend on many factors, including our financial condition, earnings, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of both cash and property dividends or share repurchases and other considerations that the Board deems relevant. In addition, our existing debt instruments restrict or prevent us from paying dividends on our ordinary shares and conducting ordinary share repurchases. Agreements governing any future indebtedness, in addition to those governing our current indebtedness, may not permit us to pay dividends on our ordinary shares or conduct ordinary share repurchases.

Our business and operations could be negatively affected by shareholder activism, which could cause us to incur significant expenses, hinder execution of our business strategy and impact our share price.

In recent years, shareholder activism involving corporate governance, strategic direction and operations has become increasingly prevalent. If we become the subject of such shareholder activism, their demands may disrupt our business and divert the attention of our management, employees and Board. Also, we may incur substantial costs, including legal fees and other expenses, related to such activist shareholder matters. Perceived uncertainties resulting from such activist shareholder matters may result in loss of potential business opportunities with our current and potential customers and business partners, be exploited by our competitors and make attracting and retaining qualified personnel more difficult. In addition, such shareholder activism may cause significant fluctuations in our share price based on temporary or speculative market perceptions, uncertainties or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Tax Related Risks

Future changes to tax laws could materially adversely affect us.

Under current law, we expect Endo International plc to be treated as a non-U.S. corporation for U.S. federal income tax purposes. However, changes to the rules in Section 7874 of the Internal Revenue Code (the Code) or regulations promulgated thereunder or other guidance issued by the Treasury or the IRS could adversely affect our status as a non-U.S. corporation for U.S. federal income tax purposes, and any such changes could have prospective or retroactive application to us, EHSI and/or their respective shareholders and affiliates. Consequently, there can be no assurance that there will not exist in the future a change in law that might cause us to be treated as a U.S. corporation for U.S. federal income tax purposes, including with retroactive effect.

In addition, Ireland's Department of Finance, Luxembourg's Ministry of Finance, the Organization for Economic Co-operation and Development, the European Commission and other government agencies in jurisdictions where we and our affiliates do business, including the U.S. Congress, have had an extended focus on issues related to the taxation of multinational corporations. There are several proposals pending in various jurisdictions in which we do business that, if enacted, would substantially change the taxation of multinational corporations. As a result, the tax laws in the jurisdictions in which we operate could change on a prospective or retroactive basis, and any such changes could affect recorded deferred tax assets and liabilities and increase our effective tax rate, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. The potential impact of changes in tax laws in such jurisdictions could have a material impact on the Company.

The IRS may not agree with the conclusion that we should be treated as a non-U.S. corporation for U.S. federal income tax purposes.

Although Endo International plc is incorporated in Ireland, the IRS may assert that it should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to Section 7874 of the Code. A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. Because we are an Irish incorporated entity, we would generally be classified as a non-U.S. corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a non-U.S. incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

Under Section 7874, we would be treated as a non-U.S. corporation for U.S. federal income tax purposes if the former shareholders of EHSI owned, immediately after the Paladin transactions (within the meaning of Section 7874), less than 80% (by both vote and value) of Endo shares by reason of holding shares in EHSI (the ownership test). The former EHSI shareholders owned less than 80% (by both vote and value) of the shares in Endo after the Paladin merger by reason of their ownership of shares in EHSI. As a result, under current law, we expect Endo International plc to be treated as a non-U.S. corporation for U.S. federal income tax purposes. There is limited guidance regarding the application of Section 7874, including with respect to the provisions regarding the application of the ownership test. Our obligation to complete the Paladin transactions was conditional upon receipt of a Section 7874 opinion from our counsel, Skadden, Arps, Slate, Meagher & Flom LLP (Skadden), dated as of the closing date of the Paladin transactions and subject to certain qualifications and limitations set forth therein, to the effect that Section 7874 and the regulations promulgated thereunder should not apply in such a manner so as to cause Endo to be treated as a U.S. corporation for U.S. federal income tax purposes from and after the closing date. However, an opinion of tax counsel is not binding on the IRS or a court. Therefore, there can be no assurance that the IRS will not take a position contrary to Skadden's Section 7874 opinion or that a court will not agree with the IRS in the event of litigation.

The effective rate of taxation upon our results of operations is dependent on multi-national tax considerations.

Our effective income tax rate in the future could be adversely affected by a number of factors, including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws, the outcome of income tax audits and the repatriation of earnings from our subsidiaries for which we have not provided for taxes. Cash repatriations are subject to restrictions in certain jurisdictions and may be subject to withholding and other taxes. We periodically assess our tax positions to determine the adequacy of our tax provisions, which are subject to significant discretion. Although we believe our tax provisions are adequate, the final determination of tax audits and any related disputes could be materially different from our historical income tax provisions and accruals. The results of audits and disputes could have a material adverse effect on our business, financial condition, results of operations and cash flows for the period or periods for which the applicable final determinations are made.

The IRS and other taxing authorities may continue to challenge our tax positions and we may not be able to successfully maintain such positions.

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 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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.

Responding to or defending any challenge or proposed adjustment to our tax positions is expensive, consumes time and other resources and diverts management's attention. We cannot predict whether taxing authorities will conduct an audit challenging any of our tax positions, the cost involved in responding to and defending any such audit and resulting litigation, or the outcome. If we are unsuccessful in any of these matters, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future or repay certain tax refunds, any of which could require us to reduce our operating costs, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our ability to use U.S. tax attributes to offset U.S. taxable income may be limited.

Existing and future tax laws and regulations may limit our ability to use U.S. tax attributes including, but not limited to, net operating losses and excess interest expense, to offset U.S. taxable income. For a period of time following the 2014 Paladin transactions, Section 7874 of the Code precludes our U.S. affiliates from utilizing U.S. tax attributes to offset taxable income if we complete certain transactions with related non-U.S. subsidiaries. The limitations on the use of certain tax attributes and deductions in these regulations are in addition to existing rules that could impose more restrictive limitations in the event that cumulative changes in our stock ownership within a three-year period exceeded certain thresholds. Such changes or the adoption of additional limitations could impact our overall utilization of deferred tax assets, potentially resulting in a material adverse effect on our business, financial condition, results of operations and cash flows.

Structural and Organizational Risks

We are incorporated in Ireland and Irish law differs from the laws in effect in the U.S. and may afford less protection to, or otherwise adversely affect, our shareholders.

Our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction of the U.S. As an Irish company, we are governed by Irish Companies Act 2014 (the Companies Act). The Companies Act and other relevant aspects of Irish law differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, the provisions relating to interested director and officer transactions, acquisitions, takeovers, shareholder lawsuits and indemnification of directors. For example, under Irish law, the duties of directors and officers of a company are generally owed to the company only. As a result, shareholders of Irish companies generally do not have a personal right of action against the directors or officers of a company and may pursue a right of action on behalf of the company only in limited circumstances. In addition, depending on the circumstances, the acquisition, ownership and/or disposition of our ordinary shares may subject individuals to different or additional tax consequences under Irish law including, but not limited to, Irish stamp duty, dividend withholding tax and capital acquisitions tax.

Any attempts to take us over will be subject to Irish Takeover Rules and subject to review by the Irish Takeover Panel.

We are subject to Irish Takeover Rules, under which the Board will not be permitted to take any action which might frustrate an offer for our ordinary shares once it has received an approach which may lead to an offer or has reason to believe an offer is imminent.

We are an Irish company and it may be difficult to enforce judgments against us or certain of our officers and directors.

We are incorporated in Ireland and a substantial portion of our assets are located in jurisdictions outside the U.S. In addition, some of our officers and directors reside outside the U.S., and some or all of their respective assets are or may be located in jurisdictions outside of the U.S. It may be difficult for investors to effect service of process against us or such officers or directors or to enforce against us or them judgments of U.S. courts predicated upon civil liability provisions of the U.S. federal securities laws.

There is no treaty between Ireland and the U.S. providing for the reciprocal enforcement of foreign judgments. The following requirements must be met before a foreign judgment will be deemed to be enforceable in Ireland:

- the judgment must be for a definite sum;
- the judgment must be final and conclusive; and
- the judgment must be provided by a court of competent jurisdiction.

An Irish court will also exercise its right to refuse judgment if the foreign judgment was obtained by fraud, if the judgment violated Irish public policy, if the judgment is in breach of natural justice or if it is irreconcilable with an earlier judgment. Further, an Irish court may stay proceedings if concurrent proceedings are being brought elsewhere. Judgments of U.S. courts of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts if deemed to be contrary to public policy in Ireland.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

This section provides information about the location and general character of the Company's principal physical properties at December 31, 2021.

The Company's global headquarters is located in Dublin, Ireland. The Company also conducts certain corporate functions at its Malvern, Pennsylvania location. Both properties are leased. The Malvern lease is described in more detail in Note 9. Leases in the Consolidated Financial Statements included in Part IV, Item 15 of this report. These locations support each of our reportable segments. For example, our global quality and supply chain functions are run from our global headquarters. The Company's segments conduct certain additional business functions, including manufacturing, distribution, quality assurance, R&D and administration, at locations throughout the U.S. and select global markets. Additional information about the properties of the Company's reportable segments is set forth below:

- Branded Pharmaceuticals: This segment also conducts certain operations in the U.S. through leased and owned manufacturing properties in Pennsylvania, New York, New Jersey and Michigan, as well as certain administrative and R&D functions through leased properties in Pennsylvania.
- Sterile Injectables: This segment also conducts certain manufacturing, quality assurance, R&D and administration functions in the U.S. through owned and leased properties in Michigan, as well as certain R&D and administration functions in New York and in India in the same facilities as our Generic Pharmaceuticals segment, as discussed below.
- Generic Pharmaceuticals: This segment also conducts certain administration functions through an owned property in New York, as well as significant R&D operations and manufacturing and administrative functions in India through owned and leased facilities in Chennai and Mumbai.
- International Pharmaceuticals: This segment's operations are currently conducted through Paladin's leased headquarters in Montreal, Canada.

As of December 31, 2021, our owned and leased properties consist of approximately 0.9 million and 1.1 million square feet, respectively. We believe our properties are suitable and adequate to support our current and projected operations in all material respects.

Item 3. *Legal Proceedings*

The disclosures under Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report are incorporated into this Part I, Item 3 by reference.

Item 4. *Mine Safety Disclosures*

Not applicable.

PART II

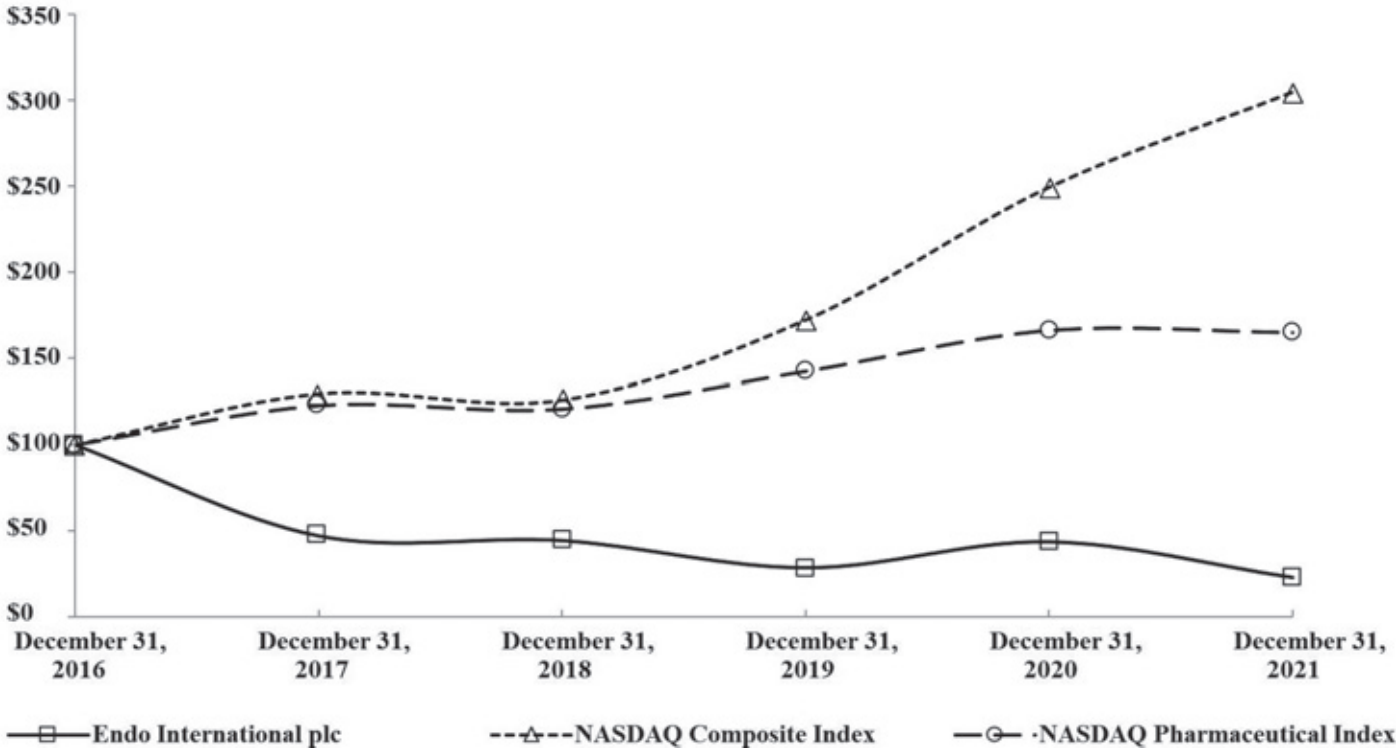
Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information. Our ordinary shares are traded on the Nasdaq under the ticker symbol "ENDP."

Holders. As of February 21, 2022, we estimate that there were approximately 63 holders of record of our ordinary shares.

Dividends. We have never declared or paid any cash dividends on our ordinary shares and we currently have no plans to declare a dividend. We are permitted to pay dividends subject to limitations imposed by Irish law, the various agreements and indentures governing our indebtedness and the existence of sufficient distributable reserves. For example, the Companies Act requires Irish companies to have distributable reserves equal to or greater than the amount of any proposed dividend. Unless we are able to generate sufficient distributable reserves or create distributable reserves by reducing our share premium account, we will not be able to pay dividends.

Performance Graph. The following graph provides a comparison of the cumulative total shareholder return on the Company's ordinary shares with that of the cumulative total shareholder return on both: (i) the NASDAQ Composite Index and (ii) the NASDAQ Pharmaceutical Index, commencing on December 31, 2016 and ending December 31, 2021. The graph assumes $100 invested on December 31, 2016 in the Company's ordinary shares and in each of the comparative indices, including reinvestment of any dividends. Our historic share price performance is not necessarily indicative of future share price performance.



	December 31,					
	2016	2017	2018	2019	2020	2021
Endo International plc	$ 100.00	$ 47.06	$ 44.32	$ 28.48	$ 43.59	$ 22.83
NASDAQ Composite Index	$ 100.00	$ 129.64	$ 125.96	$ 172.17	$ 249.51	$ 304.85
NASDAQ Pharmaceutical Index	$ 100.00	$ 122.85	$ 120.80	$ 142.53	$ 166.32	$ 165.08

Recent sales of unregistered securities; Use of proceeds from registered securities. There were no unregistered sales of equity securities by the Company during the three years ended December 31, 2021.

Purchase of Equity Securities by the issuer and affiliated purchasers. The following table reflects purchases of Endo International plc ordinary shares by the Company during the three months ended December 31, 2021:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plan (1)
October 1, 2021 to October 31, 2021	—	—	—	$ 2,250,000,000
November 1, 2021 to November 30, 2021	—	—	—	$ 2,250,000,000
December 1, 2021 to December 31, 2021	—	—	—	$ 2,250,000,000
Three months ended December 31, 2021	—	—	—	

(1) Pursuant to Article 11 of the Company's Articles of Association, the Company has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. As permitted by Irish Law and the Company's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption. The Board has approved the 2015 Share Buyback Program that authorizes the Company to redeem, in the aggregate, $2.5 billion of its outstanding ordinary shares. Redemptions under this program may be made from time to time in open market or negotiated transactions or otherwise, as determined by the Board. This program does not obligate the Company to redeem any particular amount of ordinary shares. To date, the Company has redeemed and cancelled approximately 4.4 million of its ordinary shares under the 2015 Share Buyback Program for $250.0 million, not including related fees. We currently do not intend to conduct ordinary share repurchases in the foreseeable future. Future redemptions, if any, will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, repayment of future debt, if any, the then current share price, market conditions, legal limitations, sufficient distributable reserves and other factors. For example, the Companies Act requires Irish companies to have distributable reserves equal to or greater than the amount of any proposed ordinary share repurchase amount. Unless we are able to generate sufficient distributable reserves or create distributable reserves by reducing our share premium account, we will not be able to repurchase our ordinary shares. The 2015 Share Buyback Program may be suspended, modified or discontinued at any time.

Item 6. ***Reserved***

Item 7. ***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 section omits discussions about 2019 items and comparisons between 2020 and 2019. Such discussions can be found in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2020.

The discussions in this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited Consolidated Financial Statements and the related Notes thereto. 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.

The operating results of the Company's Astora business are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. For additional information, see Note 3. Discontinued Operations in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

EXECUTIVE SUMMARY

This executive summary provides 2021 highlights from the results of operations that follow:

- Total revenues in 2021 were $2,993.2 million compared to $2,903.1 million in 2020 as revenue increases from the Specialty Products portfolio of our Branded Pharmaceuticals segment and from our Sterile Injectables segment were partially offset by decreased revenues from our Generic Pharmaceuticals segment, the Established Products portfolio of our Branded Pharmaceuticals segment and our International Pharmaceuticals segment.
- Gross margin percentage in 2021 increased to 59.2% from 50.3% in 2020, reflecting the reduction in royalty payments recognized in Cost of revenues resulting from the December 2020 BioSpecifics acquisition, favorable changes in product mix, decreased amortization expense and decreased expenses for amounts related to continuity and separation benefits, cost reductions and strategic review initiatives. The favorable change in product mix in 2021 primarily resulted from increased revenues from the Specialty Products portfolio of our Branded Pharmaceuticals segment and from our Sterile Injectables segment.
- Asset impairment charges in 2021 increased to $415.0 million from $120.3 million in 2020.
- We reported Loss from continuing operations of $569.1 million in 2021 compared to Income from continuing operations of $247.5 million in 2020.

Additionally, 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:

- In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Many countries and localities announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, suspending all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing shelter-in-place orders (subject to limited exceptions). Since then, developments have evolved rapidly and are likely to continue to do so. While some restrictions have been loosened, an increase in diagnosed cases may lead to the reinstatement of various restrictions. The impact on our results from COVID-19 and related changes in economic conditions, including changes to consumer spending, are highly uncertain and, in many instances, outside of our control. The duration and severity of the direct and indirect effects of COVID-19 are evolving rapidly and in ways that are difficult to anticipate. There are numerous uncertainties related to the COVID-19 pandemic that have impacted our ability to forecast our future operations. The extent to which COVID-19 will affect our business, financial position and operating results in the future cannot be predicted with certainty; however, any such impact could be material. In addition, 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. COVID-19 could also increase the degree to which our results, including the results of our business segments, fluctuate in the future.
- In June 2020, we completed a series of financing transactions, collectively referred to herein as the June 2020 Refinancing Transactions (as defined below), which are further discussed in Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- In September 2020, we announced that we had entered into a non-exclusive agreement with Novavax, Inc. to provide fill-finish manufacturing services for its COVID-19 vaccine candidate (NVX-CoV2373).
- 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 third quarter 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 3. Discontinued Operations and Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- In December 2020, we completed our acquisition of BioSpecifics. Prior to this acquisition, we had a strategic relationship with BioSpecifics since 2004 pursuant to which BioSpecifics was, among other things, entitled to a royalty stream from us related to our collagenase-based therapies, including XIAFLEX® and QWO®. Subsequent to the acquisition, BioSpecifics became our wholly-owned consolidated subsidiary. As a result, beginning in December 2020, the BioSpecifics acquisition had the effect of reducing royalty payments recognized in Cost of revenues. For additional information about the BioSpecifics acquisition, including information about the purchase consideration and our pre-acquisition royalty obligations, refer to Note 5. Acquisitions and Note 12. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- In March 2021, we completed a series of financing transactions, collectively referred to herein as the March 2021 Refinancing Transactions (as defined below), which are further discussed in Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- In July 2020, we received FDA approval for QWO® for the treatment of moderate to severe cellulite in the buttocks of adult women. During 2020, we put in place a U.S. aesthetics commercial team and the capabilities that enabled us to launch QWO® in March 2021.
- 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 (the U.S. Government Agreement). For additional information, refer to Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- During the first quarter of 2022, multiple competing generic alternatives to VASOSTRICT® were launched, beginning with Eagle's generic, which it launched at risk and began shipping toward the end of January 2022. Since then, additional competing alternatives have entered the market, including an authorized generic. We expect these launches to significantly impact both Endo's market share and product price beginning in the first quarter of 2022, and the effects of competition are likely to increase throughout 2022 and beyond. Additionally, to the extent hospitalizations related to COVID-19 decline, overall demand for both branded and generic versions of VASOSTRICT® could be reduced.

- 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" herein. For further discussion, see Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

CRITICAL ACCOUNTING ESTIMATES

The preparation of our Consolidated Financial Statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires us to make estimates and assumptions that affect the amounts and disclosures in our 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.

Accordingly, in order to understand our Consolidated Financial Statements, it is important to understand our critical accounting estimates. We consider an accounting estimate to be critical if both: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made and (ii) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition, results of operations or cash flows. Our most critical accounting estimates are described below.

Revenue recognition

With respect to contracts with commercial substance that establish payment terms and each party's rights regarding goods or services to be transferred, we recognize revenue when (or as) we satisfy our performance obligations for such contracts by transferring control of the underlying promised goods or services to our customers, to the extent collection of substantially all of the related consideration is probable. The amount of revenue we recognize reflects our estimate of the consideration we expect to be entitled to receive, subject to certain constraints, in exchange for such goods or services. This amount is referred to as the transaction price.

Our revenue consists almost entirely of sales of our products to customers, whereby we ship products to a customer pursuant to a purchase order. For contracts such as these, revenue is recognized when our contractual performance obligations have been fulfilled and control has been transferred to the customer pursuant to the contract's terms, which is generally upon delivery to the customer. The amount of revenue we recognize is equal to the fixed amount of the transaction price, adjusted for our estimates of a number of significant variable components including, but not limited to, estimates for chargebacks, rebates, sales incentives and allowances, DSA and other fees for services, returns and allowances, which we collectively refer to as sales deductions.

The Company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components and the most likely amount method when estimating the amount of variable consideration to include in the transaction price with respect to future potential milestone payments that do not qualify for the sales- and usage-based royalty exception. Variable consideration is included in the transaction price only to the extent it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved. The variable component of the transaction price is estimated based on factors such as our direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, specific known market events and estimated future trends, current contractual and statutory requirements, industry data, estimated customer inventory levels, current contract sales terms with our direct and indirect customers and other competitive factors. We subsequently review our estimates for sales deductions based on new or revised information that becomes available to us and make revisions to our estimates if and when appropriate. Refer to "Sales deductions" section below for additional information.

We believe that speculative buying of product, particularly in anticipation of possible price increases, has been the historical practice of certain of our customers. The timing of purchasing decisions made by wholesaler and large retail chain customers can materially affect the level of our sales in any particular period. Accordingly, our sales may not correlate to the number of prescriptions written for our products based on external third-party data.

We have entered into DSAs with certain of our significant wholesaler customers that obligate the wholesalers, in exchange for fees paid by us, to: (i) manage the variability of their purchases and inventory levels within specified limits based on product demand and (ii) provide us with specific services, including the provision of periodic retail demand information and current inventory levels for our pharmaceutical products held at their warehouse locations.

Sales deductions

As described above, the amount of revenue we recognize is equal to the fixed amount of the transaction price, adjusted for our estimates of variable consideration, including sales deductions. If the assumptions we use to calculate our estimates for sales deductions do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted. The following table presents the activity and ending balances, excluding Discontinued operations, for our product sales provisions for the years ended December 31, 2021 and 2020 (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Other Sales Deductions	Total
Balance, December 31, 2019	$ 206,248	$ 215,790	$ 205,168	$ 33,131	$ 660,337
Current year provision	99,001	614,923	2,117,251	154,660	2,985,835
Prior year provision	(5,857)	(10,049)	485	(3,674)	(19,095)
Payments or credits	(91,476)	(641,219)	(2,132,376)	(156,391)	(3,021,462)
Balance, December 31, 2020	$ 207,916	$ 179,445	$ 190,528	$ 27,726	$ 605,615
Current year provision	81,944	619,279	2,265,277	126,080	3,092,580
Prior year provision	(16,313)	(6,481)	(153)	(911)	(23,858)
Payments or credits	(90,431)	(595,775)	(2,270,469)	(128,939)	(3,085,614)
Balance, December 31, 2021	$ 183,116	$ 196,468	$ 185,183	$ 23,956	$ 588,723

Returns and Allowances

Consistent with industry practice, we maintain a return policy that allows our customers to return products within a specified period of time both subsequent to and, in certain cases, prior to the products' expiration dates. Our return policy generally allows customers to receive credit for expired products within six months prior to expiration and within between six months and one year after expiration. Our provision for returns and allowances consists of our estimates for future product returns, pricing adjustments and delivery errors. The primary factors we consider in estimating our potential product returns include:

- the shelf life or expiration date of each product;
- historical levels of expired product returns;
- external data with respect to inventory levels in the wholesale distribution channel;
- external data with respect to prescription demand for our products; and
- the estimated returns liability to be processed by year of sale based on analysis of lot information related to actual historical returns.

In determining our estimates for returns and allowances, we are required to make certain assumptions regarding the timing of the introduction of new products and the potential of these products to capture market share. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments, we utilize market data for similar products as analogs for our estimations. We use our best judgment to formulate these assumptions based on past experience and information available to us at the time. We continually reassess and make appropriate changes to our estimates and assumptions as new information becomes available to us.

Our estimate for returns and allowances may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. Where available, we utilize information received from our wholesaler customers about the quantities of inventory held, including the information received pursuant to DSAs, which we have not independently verified. For other customers, we have estimated inventory held based on buying patterns. In addition, we evaluate market conditions for products primarily through the analysis of wholesaler and other third party sell-through data, as well as internally-generated information, to assess factors that could impact expected product demand at the estimate date. As of December 31, 2021, we believe that our estimates of the level of inventory held by our customers is within a reasonable range as compared to both historical amounts and expected demand for each respective product.

When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine whether we believe the increase is temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns and allowances. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

- recently implemented or announced price increases for our products; and
- new product launches or expanded indications for our existing products.

Conversely, other-than-temporary increases in inventory levels may be an indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our provision for returns and allowances. Some of the factors that may be an indication that an increase in inventory levels will be other-than-temporary include:

- declining sales trends based on prescription demand;
- recent regulatory approvals to shorten the shelf life of our products, which could result in a period of higher returns related to older product still in the distribution channel;
- introduction of generic, OTC or other competing products;
- increasing price competition from competitors; and
- changes to the National Drug Codes (NDCs) of our products, which could result in a period of higher returns related to product with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

Rebates

Our provision for rebates, sales incentives and other allowances can generally be categorized into the following four types:

- direct rebates;
- indirect rebates;
- governmental rebates, including those for Medicaid, Medicare and TRICARE, among others; and
- managed-care rebates.

We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives, DSA fees and other allowances. Some customers receive rebates upon attaining established sales volumes. Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer's purchases from us, including fees paid to wholesalers under our DSAs, as described above. Indirect rebates are rebates paid to indirect customers that have purchased our products from a wholesaler or distributor under a contract with us.

We are subject to rebates on sales made under governmental and managed-care pricing programs based on relevant statutes with respect to governmental pricing programs and contractual sales terms with respect to managed-care providers and GPOs. For example, we are required to provide a discount on certain of our products to patients who fall within the Medicare Part D coverage gap, also referred to as the donut hole.

We participate in various federal and state government-managed programs whereby discounts and rebates are provided to participating government entities. For example, Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance and field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of this provision for several periods. Because Medicaid pricing programs involve particularly difficult interpretations of complex statutes and regulatory guidance, our estimates could differ from actual experience.

In determining our estimates for rebates, we consider the terms of our contracts and relevant statutes, together with information about sales mix (to determine which sales are subject to rebates and the amount of such rebates), historical relationships of rebates to revenues, past payment experience, estimated inventory levels of our customers and estimated future trends. Our provisions for rebates include estimates for both unbilled claims for end-customer sales that have already occurred and future claims that will be made when inventory in the distribution channel is sold through to end-customer plan participants. Changes in the level of utilization of our products through private or public benefit plans and GPOs will affect the amount of rebates that we owe.

Chargebacks

We market and sell products to both: (i) direct customers including wholesalers, distributors, warehousing pharmacy chains and other direct purchasing entities and (ii) indirect customers including independent pharmacies, non-warehousing chains, MCOs, GPOs, hospitals and other healthcare institutions and government entities. We enter into agreements with certain of our indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback.

Our provision for chargebacks consists of our estimates for the credits described above. The primary factors we consider in developing and evaluating our provision for chargebacks include:

- the average historical chargeback credits;
- estimated future sales trends; and
- an estimate of the inventory held by our wholesalers, based on internal analysis of a wholesaler's historical purchases and contract sales.

Other sales deductions

We offer prompt-pay cash discounts to certain of our customers. Provisions for such discounts are estimated and recorded at the time of sale. We estimate provisions for cash discounts based on contractual sales terms with customers, an analysis of unpaid invoices and historical payment experience. Estimated cash discounts have historically been predictable and less subjective due to the limited number of assumptions involved, the consistency of historical experience and the fact that we generally settle these amounts upon receipt of payment by the customer.

Shelf-stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer's inventory cost to better reflect current market prices. The primary factors we consider when deciding whether to record a reserve for a shelf-stock adjustment include:

- the estimated number of competing products being launched as well as the expected launch date, which we determine based on market intelligence;
- the estimated decline in the market price of our product, which we determine based on historical experience and customer input; and
- the estimated levels of inventory held by our customers at the time of the anticipated decrease in market price, which we determine based upon historical experience and customer input.

Valuation of long-lived assets

As of December 31, 2021, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is approximately $2.8 billion. Our finite-lived intangible assets consist of license rights and developed technology.

Long-lived assets are generally initially recorded at fair value if acquired in a business combination, or at cost if otherwise. To the extent any such asset is deemed to have a finite life, it is then amortized over its estimated useful life using either the straight-line method or, in the case of certain developed technology assets, an accelerated amortization model. The values of these various assets are subject to continuing scientific, medical and marketplace uncertainty. Factors giving rise to our initial estimate of useful lives are subject to change. Significant changes to any of these factors may result in adjustments to the useful life of the asset and an acceleration of related amortization expense, which could cause our net income and net income per share to decrease. Amortization expense is not recorded on assets held for sale.

Long-lived assets are assessed for impairment whenever events or changes in circumstances indicate the assets may not be recoverable. Recoverability of an asset that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying amount of the asset exceeds its undiscounted future cash flows and the carrying amount is not considered recoverable, impairment may exist. An impairment loss, if any, is measured as the excess of the asset's carrying amount over its fair value, generally based on a discounted future cash flow method, independent appraisals or offers from prospective buyers. An impairment loss would be recognized in the Consolidated Statements of Operations in the period that the impairment occurs.

In the case of long-lived assets to be disposed of by sale or otherwise, including assets held for sale, the assets and the associated liabilities to be disposed of together as a group in a single transaction (the disposal group) are measured at the lower of their carrying amount or fair value less cost to sell. Losses are recognized for any initial or subsequent write-down to fair value less cost to sell, while gains are recognized for any subsequent increase in fair value less cost to sell, but not in excess of any cumulative losses previously recognized. Any gains or losses not previously recognized that result from the sale of a disposal group shall be recognized at the date of sale.

As a result of the significance of our long-lived assets, any recognized losses could have a material adverse impact on our financial position and results of operations.

Our reviews of long-lived assets during the two years ended December 31, 2021 resulted in certain impairment charges. The majority of these charges related to finite-lived intangible assets and certain assets associated with disposal groups, which are further described in Note 11. Goodwill and Other Intangibles and Note 3. Discontinued Operations, respectively, in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Our impairment charges relating to long-lived assets were generally based on fair value estimates determined using discounted cash flow models or, in the case of disposal groups, a market approach. When testing a long-lived asset using a discounted cash flow model, we utilize assumptions related to the future operating performance of the corresponding product based on management's annual and ongoing budgeting, forecasting and planning processes, which represent our best estimate of future cash flows. These estimates are subject to many assumptions, such as the economic environment in which our segments operate, demand for our products, competitor actions and factors which could affect our tax rate. Estimated future pre-tax cash flows are adjusted for taxes using a market participant tax rate and discounted to present value using a market participant, weighted average cost of capital. Financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and our market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions would increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of our related impairments, if any. The discount rates applied to intangible long-lived assets impaired in 2021 ranged from 10.0% to 12.0%.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted with certainty. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a product line in relation to expectations, competitive events affecting the expected future performance of a product line, significant negative industry or economic trends and significant changes or planned changes in our use of the assets.

Each category of long-lived intangible assets is described further below.

Developed Technology. Our developed technology assets subject to amortization have useful lives ranging from 4 years to 20 years, with a weighted average useful life of approximately 11 years. We determine amortization periods and methods of amortization for developed technology assets based on our assessment of various factors impacting estimated useful lives and the timing and extent of estimated cash flows of the acquired assets, including the strength of the intellectual property protection of the product (if applicable), contractual terms and various other competitive and regulatory issues.

License Rights. Our license rights subject to amortization have useful lives ranging from 7 years to 15 years, with a weighted average useful life of approximately 14 years. We determine amortization periods for licenses based on our assessment of various factors including the expected launch date of the product, the strength of the intellectual property protection of the product (if applicable), contractual terms and various other competitive, developmental and regulatory issues.

Goodwill and indefinite-lived intangible assets

As of December 31, 2021, our goodwill balance is approximately $3.2 billion and we have no remaining indefinite-lived intangible assets.

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.

We perform the goodwill impairment test by estimating the fair value of the reporting units using an income approach that utilizes a discounted cash flow model or, where appropriate, a market approach. Any goodwill impairment charge we recognize for a reporting unit is equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value.

Similarly, if applicable, we perform our indefinite-lived intangible asset impairment tests by comparing the fair value of each intangible asset with its carrying amount. If the carrying amount of an indefinite-lived intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess.

We estimate the fair values of our reporting units and of any identified indefinite-lived 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, all of which may differ from actual future cash flows.

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes, which represent our best estimate of future cash flows. These estimates are subject to many assumptions, such as the economic environment in which our segments operate, demand for our products, competitor actions and factors which could affect our tax rate. Estimated future pre-tax cash flows are adjusted for taxes using a market participant tax rate and discounted to present value using a market participant, weighted average cost of capital. Financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and our market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions would increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of our related impairments, if any.

In order to assess the reasonableness of the calculated fair values of our reporting units, we also compare the sum of the reporting units' fair values to Endo's market capitalization and calculate an implied control premium (the excess sum of the reporting units' fair values over the market capitalization) or an implied control discount (the excess sum of total invested capital over the sum of the reporting units' fair values). The Company evaluates the implied control premium or discount by comparing it to control premiums or discounts of recent comparable market transactions, as applicable. If the control premium or discount is not reasonable in light of comparable recent transactions, or recent movements in the Company's share price, we reevaluate the fair value estimates of the reporting units to determine whether it is appropriate to adjust discount rates and/or other assumptions. This re-evaluation could correlate to different implied fair values for certain or all of the Company's reporting units.

As further described in Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report, Endo performed its annual impairment tests as of October 1, 2021. For the purpose of the 2021 annual tests, the Company had two reporting units with goodwill: Branded Pharmaceuticals and Sterile Injectables; the Company did not have any indefinite-lived intangible assets. The fair values of each of our reporting units were determined using an income approach utilizing discount rates determined based on the overall risk associated with the particular assets and other market factors.

The discount rates used in the October 1, 2021 goodwill tests were 14.5% and 11.0% for the Branded Pharmaceuticals and Sterile Injectables reporting units, respectively, compared to 15.0% and 10.0%, respectively, used in the October 1, 2020 goodwill tests. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. As a result of the October 1, 2021 tests, we did not record a goodwill impairment charge related to our Branded Pharmaceuticals reporting unit; however, we did record a pre-tax non-cash goodwill impairment charge of $363.0 million related to our Sterile Injectables reporting unit. A 50 basis point increase in the assumed discount rate utilized in the Branded Pharmaceuticals test would not have changed the outcome of that test; however, a 50 basis point increase in the assumed discount rate utilized in the Sterile Injectables test would have increased the goodwill impairment charge for this reporting unit by approximately $190 million.

Additional information about the impairment tests is provided in Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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 competition, including the effects of the competing generic alternatives to VASOSTRICT® that were introduced beginning in 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, which could relate to, among other things, our Sterile Injectables segment's remaining goodwill balance of approximately $2.4 billion and/or our Sterile Injectables segment's and/or our Generic Pharmaceuticals segment's long-lived and other assets.

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.

Income taxes

Our income tax expense, deferred tax assets and liabilities, income tax payable and reserves for unrecognized tax benefits reflect our best assessment of estimated current and future taxes to be paid. We are subject to income taxes in the U.S. and numerous other jurisdictions in which we operate. Significant judgments and estimates are required in determining the consolidated income tax expense or benefit for financial statement purposes. Deferred income taxes arise from temporary differences, which result in future taxable or deductible amounts, between the tax basis of assets and liabilities and the corresponding amounts reported in our Consolidated Financial Statements. In assessing the ability to realize deferred tax assets, we consider, when appropriate, future taxable income by tax jurisdiction and tax planning strategies. Where appropriate, we record a valuation allowance to reduce our net deferred tax assets to equal an amount that is more likely than not to be realized. In projecting future taxable income, we consider historical results, adjusted in certain cases for the results of discontinued operations, changes in tax laws or nonrecurring transactions. We incorporate assumptions about the amount of future earnings within a specific jurisdiction's pretax income, adjusted for material changes included in business operations. The assumptions about future taxable income require significant judgment and, while these assumptions rely heavily on estimates, such estimates are consistent with the plans we are using to manage the underlying business. Future changes in tax laws and rates, including administrative or regulatory guidance, could affect recorded deferred tax assets and liabilities. Any adjustments to these estimates will generally be recorded as an income tax expense or benefit in the period the adjustment is determined.

The calculation of our tax liabilities often involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations. A benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained on the basis of the technical merits upon examination, including resolutions of any related appeals or litigation processes. We first record unrecognized tax benefits as liabilities and then adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available at the time of establishing the liability. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment, potentially including interest and penalties, that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences, along with any related interest and penalties, will generally be reflected as increases or decreases to income tax expense in the period in which new information becomes available.

We make an evaluation at the end of each reporting period as to whether or not some or all of the undistributed earnings of our subsidiaries are indefinitely reinvested. While we currently have no intention to distribute such earnings and consider them indefinitely reinvested, facts and circumstances may change in the future. Changes in facts and circumstances may include changes in the estimated capital needs of our subsidiaries or in our corporate liquidity requirements. Such changes could result in our management determining that some or all of such undistributed earnings are no longer indefinitely reinvested. In that event, we would be required to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely reinvested outside the relevant tax jurisdiction. For additional information, refer to Note 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Contingencies

The Company is subject to various patent challenges, product liability claims, government investigations and other legal proceedings in the ordinary course of business. Material legal proceedings are discussed in Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Contingent accruals and legal settlements are recorded in the Consolidated Statements of Operations as Litigation-related and other contingencies, net (or as Discontinued operations, net of tax in the case of vaginal mesh matters) when the Company determines that a loss is both probable and reasonably estimable. Legal fees and other expenses related to litigation are expensed as incurred and included in Selling, general and administrative expenses in the Consolidated Statements of Operations (or as Discontinued operations, net of tax in the case of vaginal mesh matters).

Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our estimates of the probability and amount of any such liabilities involve significant judgment regarding future events. The factors we consider in developing our liabilities for legal proceedings include the merits and jurisdiction of the proceeding, the nature and the number of other similar current and past proceedings, the nature of the product and the current assessment of the science subject to the proceeding, if applicable, and the likelihood of the conditions of settlement being met.

In order to evaluate whether a claim is probable of loss, we may rely on certain information about the claim. Without access to and review of such information, we may not be in a position to determine whether a loss is probable. Further, the timing and extent to which we obtain any such information, and our evaluation thereof, is often impacted by items outside of our control including, without limitation, the normal cadence of the litigation process and the provision of claim information to us by plaintiff's counsel. The amount of our liabilities for legal proceedings may change as we receive additional information and/or become aware of additional asserted or unasserted claims. Additionally, there is a possibility that we will suffer adverse decisions or verdicts of substantial amounts or that we will enter into additional monetary settlements, either of which could be in excess of amounts previously accrued for. Any changes to our liabilities for legal proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As of December 31, 2021, our accrual for loss contingencies totaled $581.0 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; (ii) various opioid-related matters as further described herein; and (iii) a settlement relating to the *Pelletier* securities case further described herein, which has been funded by the Company's insurers. 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.

RESULTS OF OPERATIONS

COVID-19 Update and Other Key Trends

We are closely monitoring the 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 R&D programs and regulatory approval processes and our liquidity and access to capital. In addition to our existing business continuity plans, our Senior Executive Team has developed and implemented a range of proactive measures to address the risks, uncertainties and operational challenges associated with COVID-19. We continue to closely monitor the rapidly 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. Actions we have taken to date and expected key trends are further described below.

Workforce. We have taken, and will continue to take, proactive measures to provide for the well-being of our workforce around the globe while continuing to safely produce products upon which patients and their healthcare providers rely. We implemented alternative working practices and work-from-home requirements for appropriate employees, inclusive of our Senior Executive Team. We limited international and domestic travel, increased our already-thorough cleaning protocols throughout our facilities and prohibited non-essential visitors from our sites. We also implemented temperature screenings, health questionnaires, social distancing, modified schedules, shift rotation and/or other similar policies at our manufacturing facilities. We have continued to pay full wages to our workforce. Certain of these measures have resulted in increased costs and, as further described below, resulted in the prioritization of certain products in our production plans from time to time.

We have since begun to adjust certain of these practices, reflecting the evolved guidelines from health and other governmental authorities, including the elimination of certain social distancing requirements for fully vaccinated team members. We launched a hybrid approach selling model in June 2020 for our field employees, which allows virtual and/or live engagement with healthcare providers and other customers. Additionally, where conditions allowed, we transitioned from our work-from-home requirements during the third quarter of 2021 and implemented flexible work options for our employees. We intend to continue to evaluate our practices as circumstances and governmental guidance evolve.

Customers and the Patients They Serve. We have experienced, and expect to continue to experience, changes in customer demand as the COVID-19 pandemic continues to evolve, which are difficult to predict.

Beginning in late first-quarter 2020 and into early second-quarter 2020, we experienced an increase in sales volumes for some of our critical care products, including VASOSTRICT®. These higher volumes resulted from significant channel inventory stocking of these products in anticipation of treating certain patients infected with COVID-19 including, in the case of VASOSTRICT®, for the treatment of patients with vasodilatory shock. The increase in sales volumes for VASOSTRICT® was followed by significant inventory destocking for the remainder of the second quarter of 2020 and a continued decline in sales volumes toward pre-COVID-19 levels during the third quarter of 2020. Beginning in the fourth quarter of 2020 and continuing into 2021, we experienced increased sales volumes based on a resurgence of COVID-19 cases in certain parts of the U.S. While sales volumes began to decline toward more normal pre-COVID-19 levels in the second quarter of 2021, we again experienced increased sales volumes during the second half of 2021 based on increased utilization levels. Despite these quarterly fluctuations, VASOSTRICT® has generally continued to experience increased sales volumes during the COVID-19 pandemic as compared to pre-COVID-19 levels.

Additionally, during the last two weeks of the first quarter of 2020 and continuing into the second quarter of 2020, certain of our products that are physician administered, including XIAFLEX® and SUPPRELIN® LA, began experiencing significantly decreased sales volumes due to reduced physician office activity and patient office visits because of the COVID-19 pandemic. Since then, sales volumes for these products have generally been recovering. However, these products continue 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 significantly lower numbers of in-person patient office visits. These conditions have contributed to some 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.

Manufacturing and Supply Chain Operations. As of the date of this report, our business has not experienced any material supply issues related to COVID-19 and our manufacturing facilities across the globe have continued to operate. We have taken, and plan to continue to take, commercially practical measures to keep these facilities open as they are critical to our ability to reliably supply required critical care and medically necessary products. These measures, as further described above, as well as changes in our workforce availability, have impacted our manufacturing and supply chain productivity at certain of our facilities and have, from time to time, resulted in the prioritization of certain products, such as VASOSTRICT®, in our production plans to provide for their continued availability during and after the pandemic. We believe that our diversified manufacturing footprint, which includes a combination of facilities located in the U.S. and India, supply agreements and strong business relationships with numerous contract manufacturing organizations throughout the world, including in the U.S., Canada, Europe and India, and our proven ability to be a preferred partner of choice to large pharmaceutical companies seeking authorized generic distributors for their branded products, is a critical factor to mitigate significant risks related to manufacturing and supply chain disruption. This footprint, overseen by our global quality and supply chain teams in Ireland, combined with a skilled management team with significant experience in manufacturing and supply chain operations, has enabled us to respond quickly and effectively to the evolving COVID-19 pandemic to date. However, as the pandemic continues to impact the supply of goods and services worldwide, we face the risk of increased pressure on global logistics network infrastructure and capacity, which could result in interruptions of supply and/or increased costs based upon inability to obtain, and/or delayed deliveries of, raw materials and/or critical supplies necessary to continue our manufacturing activities and/or those of our third party suppliers.

Clinical and Development Programs. We have a number of ongoing clinical trials. We are committed to the safety of our patients, employees and others involved in these trials. We are monitoring COVID-19 closely and continue to partner with the FDA on our ongoing clinical trials, regulatory applications and other R&D activities. Based on an assessment of our R&D programs, including our clinical trials, we have developed a plan and timeline for each study in order to enhance communication with patients, sites and vendors. To date, the impacts of COVID-19 have resulted in modest delays and could continue to cause delays to certain of our clinical trials and product development and commercialization programs, including obtaining adequate patient enrollment, receiving regulatory approvals and successfully bringing product candidates to market. Additionally, as a result of COVID-19 and its impact on medical aesthetics physician office closures and consumer spending, we moved the product launch of QWO® to March 2021.

Key Trends. Since the first quarter of 2020, we, and our industry as a whole, have been impacted by COVID-19 and may continue to experience an impact going forward. The most significant trends we face as a result of the COVID-19 pandemic include: (i) decreases in demand for certain of our physician administered products due to physician office closures and a decline in patients electing to be treated because of the COVID-19 pandemic, (ii) potential temporary decreases to the supply of certain of our products due to measures we may implement from time to time in response to COVID-19, workforce availability and/or an inability to obtain, and/or delayed deliveries of, raw materials and/or critical supplies necessary to continue our manufacturing activities and/or those of our third party suppliers, (iii) potential idle capacity charges based on the impact of any of the conditions described above and (iv) potential delays in our ability to launch certain new products due to production prioritization and economic conditions and other factors outside of our control.

Due to uncertainties in certain key assumptions related to COVID-19 (including the rate and extent to which the market for specialty product office-based procedures recovers from COVID-19-related market challenges) and other factors (including the timing and impact of VASOSTRICT® generic competition), the Company is only providing information about estimated revenue trends through 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 first quarter of 2022, we expect XIAFLEX® revenues to continue to be impacted by COVID-19-related market conditions, which could result in XIAFLEX® revenues remaining consistent with or declining compared to the first quarter of 2021. We also expect an overall decline in revenues from our Branded Pharmaceuticals segment, primarily driven by expected competitive and other pricing pressures impacting this segment.
- For the first quarter of 2022, we expect revenues from our Sterile Injectables segment to decline significantly as compared to the first quarter of 2021, primarily driven by competition for VASOSTRICT®, as further described herein.
- For the first 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 revenue decreases as compared to the first quarter of 2021, which are expected to be partially or fully offset by the impact of certain 2021 product launches.

Consolidated Results Review

The following table displays our revenue, gross margin, gross margin percentage and other pre-tax expense or income for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020	% Change 2021 vs. 2020
Total revenues, net	$ 2,993,206	$ 2,903,074	3 %
Cost of revenues	1,221,064	1,442,511	(15)%
Gross margin	$ 1,772,142	$ 1,460,563	21 %
Gross margin percentage	*59.2 %*	*50.3 %*	
Selling, general and administrative	861,760	698,506	23 %
Research and development	148,560	158,902	(7)%
Litigation-related and other contingencies, net	345,495	(19,049)	NM
Asset impairment charges	414,977	120,344	NM
Acquisition-related and integration items, net	(8,379)	16,549	NM
Interest expense, net	562,353	532,939	6 %
Loss (gain) on extinguishment of debt	13,753	—	NM
Other (income) expense, net	(19,774)	(21,110)	(6)%
Loss from continuing operations before income tax	$ (546,603)	$ (26,518)	NM

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

Total revenues, net. Total revenues in 2021 were $2,993.2 million compared to $2,903.1 million in 2020 as revenue increases from the Specialty Products portfolio of our Branded Pharmaceuticals segment and from our Sterile Injectables segment were partially offset by decreased revenues from our Generic Pharmaceuticals segment, the Established Products portfolio of our Branded Pharmaceuticals segment and our International 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 years ended December 31, 2021 and 2020, Cost of revenues includes certain amounts that impact comparability, 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):

	2021	2020
Amortization of intangible assets (1)	$ 372,907	$ 427,543
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (2)	$ 9,058	$ 55,413

(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 in 2021 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 primarily relate to certain employee separation, continuity and other benefit-related costs, excess inventory reserves and accelerated depreciation. As further discussed in Note 3. Discontinued Operations and Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report, amounts in 2021 include a net pre-tax reversal of expense, primarily related to avoided severance costs for employees that transitioned to the purchasers in connection with certain site sales. For further discussion of our material restructuring initiatives, including a discussion of amounts recognized and expected future charges, refer to Note 4. Restructuring.

The decrease in Cost of revenues in 2021 was primarily due to decreased amortization expense, decreased expenses for amounts related to continuity and separation benefits, cost reductions and strategic review initiatives, the reduction in royalty payments recognized in Cost of revenues resulting from the December 2020 BioSpecifics acquisition and favorable changes in product mix as described below, partially offset by increased revenues.

Gross margin percentage increased in 2021 as a result of the reduction in royalty payments recognized in Cost of revenues resulting from the December 2020 BioSpecifics acquisition, favorable changes in product mix, decreased amortization expense and decreased expenses for amounts related to continuity and separation benefits, cost reductions and strategic review initiatives. The favorable change in product mix in 2021 primarily resulted from increased revenues from the Specialty Products portfolio of our Branded Pharmaceuticals segment and from our Sterile Injectables segment.

Selling, general and administrative expenses. The increase in 2021 was primarily due to increased costs associated with our commercial launch of QWO®, our investment and promotional efforts behind XIAFLEX®, certain legal matters and certain strategic review initiatives, partially offset by decreased costs associated with both the debt financing transactions that are further discussed in Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report and the 2020 Restructuring Initiative, which is further discussed in Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Selling, general and administrative expenses may continue to be impacted by the 2020 Restructuring Initiative. Refer to Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report for discussion of this initiative, including a discussion of amounts recognized and expected future charges.

R&D expenses. 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 and can also vary in periods in which we incur significant upfront or milestone charges related to agreements with third parties.

Our R&D efforts are focused on the development of a diversified portfolio of innovative and clinically differentiated product candidates. We have been progressing and expect to continue to progress our cellulite treatment development programs for QWO®, which was approved by the FDA in July 2020 for the treatment of moderate to severe cellulite in the buttocks of adult women. 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 also expect to continue to focus investments in RTU and other product candidates in our Sterile Injectables segment, potentially including license and commercialization agreements such as our Nevakar, Inc. agreement. As our development programs progress, it is possible that our R&D expenses could increase.

The decrease in R&D expense in 2021 was primarily driven by the fact that the prior year period's amount included a $28.6 million charge related to in-process research and development assets that were expensed in connection with the 2020 acquisition of BioSpecifics, which is further described in Note 5. Acquisitions in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Additionally, R&D expense in 2021 decreased as a result of lower costs associated with both our Generic Pharmaceuticals segment and the 2020 Restructuring Initiative, which is further discussed in Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report. These decreases were partially offset by 2021 charges related to upfront payments associated with certain license agreements entered into in 2021 and increased costs associated with our XIAFLEX® development programs.

R&D expenses may continue to be impacted by the 2020 Restructuring Initiative. Refer to Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report for discussion of this initiative, including a discussion of amounts recognized and expected future charges.

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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report. 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 years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Goodwill impairment charges	$ 363,000	$ 32,786
Other intangible asset impairment charges	7,811	79,917
Property, plant and equipment impairment charges	2,011	1,249
Operating lease right-of-use asset impairment charges	—	6,392
Disposal group impairment charges	42,155	—
Total asset impairment charges	$ 414,977	$ 120,344

The factors leading to our material goodwill and intangible asset impairment tests, as well as the results of these tests, are further described in Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report. A discussion of critical accounting estimates made in connection with certain of our impairment tests is included under the caption "CRITICAL ACCOUNTING ESTIMATES." For further discussion of the disposal group impairment charges, refer to Note 3. Discontinued Operations in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Acquisition-related and integration items, net. Acquisition-related and integration items, net primarily consist of the net (benefit) expense 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 7. Fair Value Measurements in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion of our acquisition-related contingent consideration.

Interest expense, net. The components of Interest expense, net for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	2021	2020
Interest expense	$ 562,937	$ 537,109
Interest income	(584)	(4,170)
Interest expense, net	$ 562,353	$ 532,939

The increase in interest expense in 2021 was primarily attributable to the increases to the weighted average interest rates applicable to: (i) our notes following the June 2020 Refinancing Transactions and (ii) our total indebtedness following the March 2021 Refinancing Transactions. These increases were partially offset by net decreases to LIBOR that impacted our variable-rate debt and the reduction to the amount of our indebtedness associated with the June 2020 Refinancing Transactions. Refer to Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report 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 (gain) on extinguishment of debt. The amount in 2021 relates to the March 2021 Refinancing Transactions. Refer to Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion.

Other (income) expense, net. The components of Other (income) expense, net for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	2021	2020
Net gain on sale of business and other assets	$ (4,516)	$ (16,353)
Foreign currency loss, net	1,253	2,466
Net loss (gain) from our investments in the equity of other companies	453	(2,160)
Other miscellaneous, net	(16,964)	(5,063)
Other (income) expense, net	$ (19,774)	$ (21,110)

For additional information on the components of Other (income) expense, net, refer to Note 20. Other (Income) Expense, Net in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Income tax expense (benefit). The following table displays our Loss from continuing operations before income tax, Income tax expense (benefit) and Effective tax rate for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020
Loss from continuing operations before income tax	$ (546,603)	$ (26,518)
Income tax expense (benefit)	$ 22,478	$ (273,982)
Effective tax rate	*(4.1)%*	*1,033.2 %*

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 expense in 2021 compared to the 2020 income tax benefit primarily relates to the 2020 tax benefit for the CARES Act and changes in deferred tax liabilities following the BioSpecifics acquisition during 2020. For additional discussion of the effective tax rate, see Note 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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 December 31, 2021. 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 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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 of this report for more information.

For additional information on our income taxes, including information about the impact of the CARES Act, see Note 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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 Consolidated Statements of Operations for all periods presented. The following table provides the operating results of Astora Discontinued operations, net of tax, for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Litigation-related and other contingencies, net	$ 25,000	$ 41,097
Loss from discontinued operations before income taxes	$ (49,594)	$ (67,847)
Income tax benefit	$ (5,430)	$ (4,327)
Discontinued operations, net of tax	$ (44,164)	$ (63,520)

Amounts included in the Litigation-related and other contingencies, net line of the table above are for mesh-related litigation. The remaining pre-tax amounts in 2021 and 2020 were primarily related to mesh-related legal defense costs and certain other items. For additional discussion of mesh-related matters, refer to Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Business Segment Results Review

Refer to Note 6. Segment Results in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further details regarding our reportable segments and Segment adjusted income from continuing operations before income tax (the measure we use to evaluate segment performance), as well as reconciliations of Total consolidated loss 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.

We refer to Segment adjusted income from continuing operations before income tax, a financial measure not defined by U.S. GAAP, in making operating decisions because we believe it provides meaningful supplemental information regarding our operational performance. For instance, we believe that this measure facilitates internal comparisons to our historical operating results and comparisons to competitors' results. We believe this measure is useful to investors in allowing for greater transparency related to supplemental information used in our financial and operational decision-making. Further, we believe that Segment adjusted income from continuing operations before income tax may be useful to investors as we are aware that certain of our significant shareholders utilize Segment adjusted income from continuing operations before income tax to evaluate our financial performance. Finally, Segment adjusted income from continuing operations before income tax is utilized in the calculation of other financial measures not determined in accordance with U.S. GAAP that are used by the Compensation & Human Capital Committee of the Company's Board in assessing the performance and compensation of substantially all of our employees, including our executive officers.

There are limitations to using financial measures such as Segment adjusted income from continuing operations before income tax. Other companies in our industry may define Segment adjusted income from continuing operations before income tax differently than we do. As a result, it may be difficult to use Segment adjusted income from continuing operations before income tax or similarly named adjusted financial measures that other companies may use to compare the performance of those companies to our performance. Because of these limitations, Segment adjusted income from continuing operations before income tax is not intended to represent cash flow from operations as defined by U.S. GAAP and should not be used as an indicator of operating performance, a measure of liquidity or as alternative to net income, cash flows or any other financial measure determined in accordance with U.S. GAAP. We compensate for these limitations by providing, in Note 6. Segment Results in the Consolidated Financial Statements included in Part IV, Item 15 of this report, reconciliations of Total consolidated loss 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.

Revenues, net. The following table displays our revenue by reportable segment for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020	% Change 2021 vs. 2020
Branded Pharmaceuticals	$ 893,617	$ 781,780	14 %
Sterile Injectables	1,266,097	1,238,847	2 %
Generic Pharmaceuticals	740,586	783,110	(5)%
International Pharmaceuticals (1)	92,906	99,337	(6)%
Total net revenues from external customers	$ 2,993,206	$ 2,903,074	3 %

(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 years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020	% Change 2021 vs. 2020
Specialty Products:			
XIAFLEX®	$ 432,344	$ 316,234	37 %
SUPPRELIN® LA	114,374	88,182	30 %
Other Specialty (1)	86,432	92,662	(7)%
Total Specialty Products	$ 633,150	$ 497,078	27 %
Established Products:			
PERCOCET®	$ 103,788	$ 110,112	(6)%
TESTOPEL®	43,636	35,234	24 %
Other Established (2)	113,043	139,356	(19)%
Total Established Products	$ 260,467	$ 284,702	(9)%
Total Branded Pharmaceuticals (3)	$ 893,617	$ 781,780	14 %

(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 year ended December 31, 2021 and/or any product having revenues in excess of $25 million during any quarterly period in 2021 or 2020.

Specialty Products

As discussed above, during the last two weeks of the first quarter of 2020 and continuing into the second quarter of 2020, certain of our products that are physician administered, including XIAFLEX® and SUPPRELIN® LA, began experiencing significantly decreased sales volumes due to reduced physician office activity and patient office visits because of the COVID-19 pandemic. Since then, sales volumes for these products have generally been recovering. However, these products continue 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 significantly lower numbers of in-person patient office visits. These conditions have contributed to some 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 in 2021 was primarily attributable to increased demand-related volumes, including as a result of the recovery noted above and our increased investment and promotional efforts behind XIAFLEX®, as well as increased net price.

The increase in SUPPRELIN® LA revenues in 2021 was primarily attributable to increased volumes, including as a result of the recovery noted above, our investment and promotional efforts behind SUPPRELIN® LA and a temporary competitor supply disruption, partially offset by decreased price.

The decrease in Other Specialty Products revenues in 2021 was primarily attributable to net decreases in price and volumes for multiple products in this portfolio, partially offset by revenues from QWO®, which we launched in March 2021.

Established Products

The decrease in PERCOCET® revenues in 2021 was primarily attributable to decreased volumes, partially offset by increased price.

During the first half of 2020, TESTOPEL® experienced a temporary supply disruption that was resolved during the third quarter of 2020. The increase in TESTOPEL® revenues in 2021 was primarily attributable to higher sales in 2021 following the third-quarter 2020 resolution of the supply disruption.

The decrease in Other Established Products revenues in 2021 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 years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020	% Change 2021 vs. 2020
VASOSTRICT®	$ 901,735	$ 785,646	15 %
ADRENALIN®	124,630	152,074	(18)%
Other Sterile Injectables (1)	239,732	301,127	(20)%
Total Sterile Injectables (2)	$ 1,266,097	$ 1,238,847	2 %

(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 year ended December 31, 2021 and/or any product having revenues in excess of $25 million during any quarterly period in 2021 or 2020.

The increase in VASOSTRICT® revenues in 2021 was driven by increased sales volumes resulting primarily from increased utilization levels, as well as increased price. Despite quarterly fluctuations, VASOSTRICT® has generally continued to experience increased sales volumes during the COVID-19 pandemic as compared to pre-COVID-19 levels.

During the first quarter of 2022, multiple competing generic alternatives to VASOSTRICT® were launched, beginning with Eagle's generic, which it launched at risk and began shipping toward the end of January 2022. Since then, additional competing alternatives have entered the market, including an authorized generic. We expect these launches to significantly impact both Endo's market share and product price beginning in the first quarter of 2022, and the effects of competition are likely to increase throughout 2022 and beyond. Additionally, to the extent hospitalizations related to COVID-19 decline, overall demand for both branded and generic versions of VASOSTRICT® could be reduced. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows. For additional information, refer to Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report under the heading "VASOSTRICT® Related Matters."

The decrease in ADRENALIN® revenues in 2021 was primarily attributable to the impact of competitive entrants. The introduction of one or more additional competing versions of ADRENALIN® could result in further reductions to our market share and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The decrease in Other Sterile Injectables revenues in 2021 was primarily attributable to competitive pressures across multiple products within the product portfolio.

Generic Pharmaceuticals. The decrease in Generic Pharmaceuticals revenues in 2021 was primarily attributable to competitive pressures on certain generic products, partially offset by increased revenues from certain recent product launches.

International Pharmaceuticals. The decrease in International Pharmaceuticals revenues in 2021 was primarily attributable to competitive pressures in certain international markets and the impact of certain product discontinuation activities.

Segment adjusted income from continuing operations before income tax. The following table displays our Segment adjusted income from continuing operations before income tax by reportable segment for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020	% Change 2021 vs. 2020
Branded Pharmaceuticals	$ 384,186	$ 377,526	2 %
Sterile Injectables	$ 998,453	$ 950,145	5 %
Generic Pharmaceuticals	$ 160,046	$ 87,178	84 %
International Pharmaceuticals	$ 30,325	$ 41,022	(26)%

Branded Pharmaceuticals. The increase in Segment adjusted income from continuing operations before income tax in 2021 was primarily attributable to the gross margin effect of increased revenues, as further described above, the reduction to royalty payments relating to the BioSpecifics acquisition and favorable changes in product mix, partially offset by increased costs associated with our commercial launch of QWO® and our R&D investments in and promotional efforts behind XIAFLEX®.

Sterile Injectables. The increase in Segment adjusted income from continuing operations before income tax in 2021 was primarily attributable to the gross margin effect of the increased revenues further described above and favorable changes in product mix.

Generic Pharmaceuticals. The increase in Segment adjusted income from continuing operations before income tax in 2021 was primarily attributable to favorable changes in product mix, decreased R&D expenses and cost savings related to the restructuring activities further described in Note 4. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report, partially offset by the gross margin effect of the decreased revenues further described above.

International Pharmaceuticals. The decrease in Segment adjusted income from continuing operations before income tax in 2021 was primarily attributable to the gross margin effects of the decreased revenues further described above.

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, milestone payments, capital expenditures, mergers and acquisitions, contingent liabilities, debt service payments, income taxes and litigation-related matters. The Company's working capital was $1,084.6 million at December 31, 2021 compared to working capital of $1,159.4 million at December 31, 2020. The amounts at December 31, 2021 and December 31, 2020 include restricted cash and cash equivalents of $78.4 million and $127.0 million, respectively, held in Qualified Settlement Funds (QSFs) for mesh-related matters. Although these amounts in QSFs are included in working capital, they are required to be used for mesh product liability settlement agreements.

Cash and cash equivalents, which primarily consisted of bank deposits and money market accounts, totaled $1,507.2 million at December 31, 2021 compared to $1,213.4 million at December 31, 2020. 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, the extent to which COVID-19 could impact our business, financial condition, results of operations and cash flows in the short- and medium-term cannot be predicted with certainty, but such impact could be material. 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 as described above, such increase could be temporary. 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. We may also 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. 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. 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" herein. 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 COVID-19.

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.

We consider the undistributed earnings from the majority of our subsidiaries as of December 31, 2021 to be indefinitely reinvested outside of Ireland and, accordingly, neither income tax nor withholding taxes have been provided thereon. As of December 31, 2021, indefinitely reinvested earnings were approximately $119.7 million. We do not anticipate incurring tax in deploying funds to satisfy liquidity needs arising in the ordinary course of business.

Indebtedness. The Company and certain of its subsidiaries are party to the Credit Agreement governing the Credit Facilities (as defined below) and the indentures governing our various senior secured and senior unsecured notes. As of December 31, 2021, approximately $2.0 billion was outstanding under the Term Loan Facility, approximately $0.3 billion was outstanding under the Revolving Credit Facility and approximately $6.1 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 December 31, 2021. 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 December 31, 2021 and December 31, 2020, 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.

In addition, after each fiscal year-end, the Company is required to perform a calculation of Excess Cash Flow (as defined in the Credit Agreement), which could result in certain pre-payments of the outstanding loans under the Term Loan Facility in accordance with the terms of the Credit Agreement. No such payment is required at December 31, 2021.

Refer to Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information about our indebtedness, including our debt refinancing 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 December 31, 2021 and December 31, 2020 are below (dollars in thousands):

	December 31, 2021	December 31, 2020
Total current assets	$ 2,714,586	$ 2,413,258
Less: total current liabilities	1,629,962	1,253,824
Working capital	$ 1,084,624	$ 1,159,434
Current ratio (total current assets divided by total current liabilities)	1.7:1	1.9:1

In 2021, working capital benefited from the favorable impacts to net current assets resulting from our current period revenues and gross margins, which are further described above. However, this benefit was more than offset by the following current period activity, resulting in a net decrease to working capital of $74.8 million from December 31, 2020 to December 31, 2021: (i) net charges of $370.5 million related to litigation-related and other contingencies, which are further described in Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report; (ii) an increase in the Current portion of long-term debt of $166.2 million relating to debt expected to be paid within the next twelve months; (iii) the incurrence of costs and fees related to the March 2021 Refinancing Transactions, which are further described in Note 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report; and (iv) Capital expenditures, excluding capitalized interest, of $77.9 million.

The following table summarizes our Consolidated Statements of Cash Flows for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Net cash flow provided by (used in):		
Operating activities	$ 411,050	$ 397,392
Investing activities	(59,544)	(624,867)
Financing activities	(105,481)	(108,567)
Effect of foreign exchange rate	285	654
Net increase (decrease) in cash, cash equivalents, restricted cash and restricted cash equivalents	$ 246,310	$ (335,388)

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 $13.7 million increase in Net cash provided by operating activities in 2021 compared to the prior year period was primarily due to our results of operations as described above and the timing of cash collections and cash payments related to our operations. When compared to 2020, our 2021 Net cash provided by operating activities included a decrease of approximately $71.6 million in cash outflows for the settlement of certain mesh-related matters and an increase of approximately $76.3 million in cash outflows for the settlement of certain opioid-related matters. 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, as further discussed above, expected reductions in VASOSTRICT® revenues.

Investing activities. The $565.3 million decrease in Net cash used in investing activities in 2021 compared to the prior year period was primarily attributable to: (i) a decrease in Acquisitions, including in-process research and development, net of cash and restricted cash acquired of $644.5 million, which primarily relates to the 2020 BioSpecifics acquisition that is further discussed in Note 5. Acquisitions in the Consolidated Financial Statements included in Part IV, Item 15 of this report, and (ii) an increase in Proceeds from sale of business and other assets, net of $23.5 million, which primarily relates to the sale transactions that are further discussed in Note 3. Discontinued Operations in the Consolidated Financial Statements included in Part IV, Item 15 of this report. These items were partially offset by: (i) a decrease in Proceeds from sales and maturities of investments of $92.8 million, which primarily relates to investments acquired as part of the 2020 BioSpecifics acquisition that were fully liquidated in 2020, and (ii) an increase in Capital expenditures, excluding capitalized interest of $8.0 million.

Financing activities. During 2021, Net cash used in financing activities related primarily to: (i) the March 2021 Refinancing Transactions, including the payment of approximately $43.6 million of associated costs and fees; (ii) Repayments of revolving debt of $22.8 million; (iii) Repayments of term loans subsequent to the March 2021 Refinancing Transactions of $15.0 million; and (iv) Payments of tax withholding for restricted shares of $14.8 million.

During 2020, Net cash used in financing activities related primarily to: (i) Repayments of notes of $57.6 million associated with the June 2020 Refinancing Transactions and August 2020 Tender Offer (as defined below); (ii) Repayments of term loans of $34.2 million; and (iii) Payments of tax withholding for restricted shares of $8.0 million.

R&D. As further described above under the heading "RESULTS OF OPERATIONS," in recent years, we have incurred significant expenditures related to R&D. We expect to continue incur R&D expenditures related to the development and advancement of our current product pipeline and any additional product candidates we may add via license, acquisition or organically. There can be no assurance that the results of any ongoing or future nonclinical or clinical trials related to these projects will be successful, that additional trials will not be required, that any compound, product or indication under development will receive regulatory approval in a timely manner or at all or that such compound, product or indication could be successfully manufactured in accordance with local current good manufacturing practices or marketed successfully, or that we will have sufficient funds to develop or commercialize any of our products.

Manufacturing, supply and other service agreements. We contract with various third party manufacturers, suppliers and service providers to supply our products, or materials used in the manufacturing of our products, and to provide additional services such as packaging, processing, labeling, warehousing, distribution and customer service support. Any interruption to the goods or services provided for by these and similar contracts could have a material adverse effect on our business, financial condition, results of operations and cash flows.

License and collaboration agreements. We could become obligated to make certain contingent payments pursuant to our license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. Due to the fact that it is uncertain whether and when certain of these milestones will be achieved, they have not been recorded in our Consolidated Balance Sheets. In addition, we may be required to make sales-based royalty or similar payments under certain arrangements.

Acquisitions. Going forward, our primary focus will be on organic growth. However, we may consider and, as appropriate, make acquisitions of other businesses, products, product rights or technologies. Our cash reserves and other liquid assets may be inadequate to consummate such acquisitions and it may be necessary for us to issue ordinary shares or raise substantial additional funds in the future to complete future transactions. In addition, as a result of any acquisition efforts, we are likely to experience significant charges to earnings for merger and related expenses (whether or not our efforts are successful) that may include transaction costs, closure costs, integration costs and/or costs of restructuring activities.

Legal proceedings. We are subject to various patent challenges, product liability claims, government investigations and other legal proceedings in the ordinary course of business. Contingent accruals are recorded when we determine that a loss is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events. For additional discussion of legal proceedings, see Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Cash Requirements for Contractual and Other Obligations. As of December 31, 2021, we have various contractual and other obligations that we expect will require the use of cash in both the short-term and long-term. These include, without limitation, the following: (i) principal and interest payments related to our debt; (ii) lease payments; (iii) obligations related to license and collaboration agreements; (iv) commitments for capital expenditures; (v) other purchase obligations, which represent enforceable and legally binding obligations for purchases of goods and services, including minimum inventory contracts, that specify all significant terms, including fixed or minimum quantities to be purchased, fixed, minimum or variable price provisions and timing; and (vi) contractual payments for certain legal liability settlements.

Refer to Note 9. Leases, Note 12. License and Collaboration Agreements, Note 15. Debt and Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information about these obligations including, to the extent material, quantitative information about the related cash requirements.

Additionally, information about our unrecognized income tax positions is included in Note 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Due to the nature and timing of the ultimate outcome of these unrecognized income tax positions, we cannot make a reliable estimate of the amount and period of related future payments, if any.

Fluctuations. 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; upfront and milestone payments to partners; asset impairment charges; share-based and other long-term incentive compensation; and changes in the fair value of financial instruments. 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.

Growth opportunities. We continue to evaluate growth opportunities including investments, licensing arrangements, acquisitions of product rights or technologies, businesses and strategic alliances and promotional arrangements, any of which could require significant capital resources. We continue to focus our business development activities on further diversifying our revenue base through product licensing and company acquisitions, as well as other opportunities to enhance shareholder value. Through execution of our business strategy, we focus on developing new products both internally and with contract and collaborative partners; expanding our product lines by acquiring new products and technologies, increasing revenues and earnings through sales and marketing programs for our innovative product offerings and effectively using our resources; and providing additional resources to support our businesses.

Non-U.S. operations. Fluctuations in foreign currency rates resulted in a net loss of $1.3 million in 2021 and a net loss of $2.5 million in 2020.

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.

Item 7A. *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 December 31, 2021 and December 31, 2020, the aggregate principal amounts of such variable-rate indebtedness were $2,262.2 million and $3,595.5 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 December 31, 2021 and December 31, 2020, a hypothetical 1% increase in the applicable rate over the floor would have resulted in $22.6 million and $36.0 million, respectively, 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 December 31, 2021 and December 31, 2020, 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 (income) expense, net in the Consolidated Statements of Operations. Refer to Note 20. Other (Income) Expense, Net in the Consolidated Financial Statements included in Part IV, Item 15 of this report 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 December 31, 2021 and December 31, 2020. A 10% change at December 31, 2021 and December 31, 2020 would have resulted in approximately $11 million in incremental foreign currency losses on such dates.

Item 8. *Financial Statements and Supplementary Data*

The information required by this item is contained in the financial statements set forth in Item 15. under the caption "Consolidated Financial Statements" as part of this Annual Report on Form 10-K.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

(a) 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 Exchange Act, as of December 31, 2021. 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 December 31, 2021.

(b) Management's Report on Internal Control over Financial Reporting

The report of management of the Company regarding internal control over financial reporting is set forth in Item 15. of this Annual Report on Form 10-K under the caption "MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING" and incorporated herein by reference.

(c) Attestation Report of Independent Registered Public Accounting Firm

The attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting is set forth in Item 15. of this Annual Report on Form 10-K under the caption "REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM" and incorporated herein by reference.

(d) 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 December 31, 2021 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. ***Other Information***

None.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Directors

The information concerning our directors required under this item is incorporated herein by reference from our proxy statement relating to our 2022 Annual General Meeting (2022 Proxy Statement) to be filed with the SEC subsequent to the date hereof.

Executive Officers

For information concerning Endo's executive officers, see Part I, Item 1 of this report "Business" under the caption "Information about our Executive Officers" and our 2022 Proxy Statement.

Code of Ethics

The information concerning our Code of Conduct is incorporated herein by reference from our 2022 Proxy Statement and can be viewed on our website, the internet address for which is www.endo.com *(intended to be an inactive textual reference only)*.

Audit Committee

The information concerning our Audit & Finance Committee is incorporated herein by reference from our 2022 Proxy Statement.

Audit Committee Financial Experts

The information concerning our audit committee financial experts is incorporated herein by reference from our 2022 Proxy Statement.

Item 11. ***Executive Compensation***

The information required under this item is incorporated herein by reference from our 2022 Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Equity Compensation Plan Information

The following table sets forth aggregate information for the fiscal year ended December 31, 2021 regarding the Company's compensation plans, under which equity securities of Endo may be issued to employees and directors.

	Column A	Column B	Column C
Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights (1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
Equity compensation plans approved by security holders	14,837,068	$ 16.70	9,285,062
Equity compensation plans not approved by security holders	—	—	—
Total	14,837,068	$ 16.70	9,285,062

(1) Excludes shares of restricted stock units, performance share units and long-term cash incentive awards which will be settled in the Company's ordinary shares.

The other information required under this item is incorporated herein by reference from our 2022 Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required under this item is incorporated herein by reference from our 2022 Proxy Statement.

Item 14. ***Principal Accountant Fees and Services***

Information about the fees for 2021 and 2020 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2022 Proxy Statement. Our Audit & Finance Committee's policy on pre-approval of audit and permissible non-audit services of our independent registered public accounting firm is incorporated herein by reference from our 2022 Proxy Statement.

The information required under this item is incorporated herein by reference from our 2022 Proxy Statement.

PART IV

Item 15. ***Exhibit and Financial Statement Schedules***

(a) The following documents are filed as part of this report:

1. The Consolidated Financial Statements:

Management's Report on Internal Control Over Financial Reporting
Report of Independent Registered Public Accounting Firm (PCAOB ID 238)
Consolidated Balance Sheets as of December 31, 2021 and 2020
Consolidated Statements of Operations for the years ended December 31, 2021, 2020 and 2019
Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2021, 2020 and 2019
Consolidated Statements of Shareholders' Deficit for the years ended December 31, 2021, 2020 and 2019
Consolidated Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019
Notes to Consolidated Financial Statements

2. Financial Statement Schedules

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS
(in thousands)

	Balance at Beginning of Period	Additions, Costs and Expenses	Deductions, Write-offs	Other (1)	Balance at End of Period
Valuation Allowance For Deferred Tax Assets:					
Year Ended December 31, 2019	$ 9,877,617	$ 299,372	$ (9,078)	$ (338,952)	$ 9,828,959
Year Ended December 31, 2020	$ 9,828,959	$ 150,500	$ (316,474)	$ 5,571	$ 9,668,556
Year Ended December 31, 2021	$ 9,668,556	$ 504,499	$ (9)	$ (3,752)	$ 10,169,294

(1) Represents the remeasurement of net deferred tax assets due to changes in statutory tax rates.

All other financial statement schedules have been omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or the Notes thereto.

3. Exhibits:

		Incorporated by Reference from:		
Number	**Description**	**File Number**	**Filing Type**	**Filing Date**
2.1†	Agreement and Plan of Merger, dated as of October 19, 2020, by and among BioSpecifics Technologies Corp., Endo International plc, and Beta Acquisition Corp.	001-36326	Current Report on Form 8-K	October 19, 2020
3.1	Certificate of Incorporation on re-registration as a public limited company of Endo International plc	001-36326	Current Report on Form 8-K12B	February 28, 2014
3.2	Memorandum and Articles of Association of Endo International plc, dated as of October 31, 2013 and as amended as of June 8, 2017	001-36326	Quarterly Report on Form 10-Q	August 8, 2017
4.1	Description of Registrant's Securities	Not applicable; filed herewith		
4.2	Specimen Share Certificate of Endo International plc	333-194253	Form S-8	February 28, 2014
4.3	Indenture, dated January 27, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.00% Senior Notes due 2025 (including Form of 6.00% Senior Notes due 2025 and Form of Supplemental Indenture relating to the 6.00% Senior Notes due 2025)	001-36326	Current Report on Form 8-K	January 27, 2015
4.3.1	Supplemental Indenture, dated March 27, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated January 27, 2015	001-36326	Annual Report on Form 10-K	February 29, 2016

		Incorporated by Reference from:		
Number	Description	File Number	Filing Type	Filing Date
4.3.2	Supplemental Indenture, dated as of May 28, 2020, among Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated as of January 27, 2015, among Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.000% Senior Notes due 2025	001-36326	Current Report on Form 8-K	June 16, 2020
4.4	Registration Rights Agreement, dated January 27, 2015, by and among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and RBC Capital Markets, LLC and Citigroup Global Markets Inc., relating to the 6.00% Senior Notes due 2025 (including Form of Counterpart to the Registration Rights Agreement relating to the 6.00% Senior Notes due 2025)	001-36326	Current Report on Form 8-K	January 27, 2015
4.5	Indenture, dated July 9, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.000% Senior Notes due 2023 (including Form of 6.000% Notes due 2023 and Form of Supplemental Indenture relating to the 6.000% Notes due 2023)	001-36326	Current Report on Form 8-K	July 9, 2015
4.5.1	Supplemental Indenture, dated as of May 28, 2020, among Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated as of July 9, 2015, among Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.000% Senior Notes due 2023	001-36326	Current Report on Form 8-K	June 16, 2020
4.6	Indenture, dated as of March 28, 2019, among Par Pharmaceutical, Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 7.500% Senior Secured Notes due 2027 (including Form of 7.500% Senior Secured Notes due 2027)	001-36326	Current Report on Form 8-K	March 28, 2019
4.6.1	First Supplemental Indenture, dated as of June 16, 2020, among Par Pharmaceutical, Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated as of March 28, 2019, among Par Pharmaceutical, Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 7.500% Senior Secured Notes due 2027	001-36326	Current Report on Form 8-K	June 16, 2020
4.7	Indenture, dated as of June 16, 2020, among Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 9.500% Senior Secured Second Lien Notes due 2027 (including Form of 9.500% Senior Secured Second Lien Notes due 2027)	001-36326	Current Report on Form 8-K	June 16, 2020
4.8	Indenture, dated as of June 16, 2020, among Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.000% Senior Notes due 2028 (including Form of 6.000% Senior Notes due 2028)	001-36326	Current Report on Form 8-K	June 16, 2020
4.9	Indenture, dated as of March 25, 2021, among Endo Luxembourg Finance Company I S.à r.l., Endo U.S. Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.125% Senior Secured Notes due 2029 (including Form of 6.125% Senior Secured Notes due 2029)	001-36326	Current Report on Form 8-K	March 25, 2021
10.1	Amended and Restated Executive Deferred Compensation Plan	001-36326	Quarterly Report on Form 10-Q	August 8, 2018
10.2	Amended and Restated 401(k) Restoration Plan	001-15989	Annual Report on Form 10-K	March 1, 2013

		Incorporated by Reference from:		
Number	**Description**	**File Number**	**Filing Type**	**Filing Date**
10.3	Directors Deferred Compensation Plan	001-15989	Annual Report on Form 10-K	March 1, 2013
10.4	Endo International plc Amended and Restated Employee Stock Purchase Plan	333-194253	Form S-8	February 28, 2014
10.5	Amendment and Restatement Agreement, dated as of March 25, 2021, by and among Endo International plc, Endo Luxembourg Finance Company I S.à r.l., Endo LLC, the lenders and other parties party thereto and JPMorgan Chase Bank, N.A. as administrative agent, issuing bank and swingline lender, which amends and restates the Credit Agreement, dated as of April 27, 2017	001-36326	Current Report on Form 8-K	March 25, 2021
10.6	Collateral Trust Agreement, dated as of April 27, 2017, by and among Endo International plc, certain subsidiaries of Endo International plc as borrowers, Par Pharmaceutical, Inc., certain other grantors party thereto, JPMorgan Chase Bank, N.A, as administrative agent, Wells Fargo Bank, National Association, as trustee, and Wilmington Trust, National Association, as collateral trustee	001-36326	Current Report on Form 8-K	June 16, 2020
10.7	Second Lien Collateral Trust Agreement, dated as of June 16, 2020, by and among Endo International plc, certain subsidiaries of Endo International plc as borrowers, Endo Designated Activity Company, Endo Finance LLC, Endo Finco Inc., certain other grantors party thereto, JPMorgan Chase Bank, N.A, as administrative agent, Wells Fargo Bank, National Association, as trustee, and Wilmington Trust, National Association, as collateral trustee	001-36326	Current Report on Form 8-K	June 16, 2020
10.8	Intercreditor Agreement, dated as of June 16, 2020, by and among Wilmington Trust, National Association, as first priority representative, Wilmington Trust, National Association, as second priority representative, and certain grantors party thereto	001-36326	Current Report on Form 8-K	June 16, 2020
10.9*	Supply Agreement, dated June 26, 2008, between Auxilium and Hollister-Stier Laboratories LLC	000-50855	Quarterly Report on Form 10-Q	August 8, 2008
10.10	Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Current Report on Form 8-K	June 11, 2020
10.11	Form of Stock Option Agreement under the Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	November 8, 2018
10.12	Form of Stock Award Agreement under the Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	May 7, 2021
10.13	Form of Performance Award Agreement under the Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	May 7, 2021
10.14	Form of Long-Term Cash Award Agreement under the Endo International plc Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	May 7, 2021
10.15	Form of Long-Term Cash Incentive Award Agreement under the Amended and Restated 2015 Stock Incentive Plan	001-36326	Quarterly Report on Form 10-Q	August 8, 2018
10.16	Form of Indemnification Agreement with Endo Health Solutions Inc.	001-36326	Annual Report on Form 10-K	February 29, 2016
10.17	Form of Indemnification Agreement with Endo International plc	001-36326	Quarterly Report on Form 10-Q	May 6, 2016
10.18	Executive Employment Agreement between Endo Health Solutions Inc. and Blaise Coleman, dated February 19, 2020 and effective March 6, 2020	001-36326	Annual Report on Form 10-K	February 26, 2020
10.19	Executive Employment Agreement between Endo Health Solutions Inc. and Patrick Barry, effective April 26, 2020	001-36326	Quarterly Report on Form 10-Q	May 7, 2020
10.20	Executive Employment Agreement between Endo Health Solutions Inc. and Mark T. Bradley, dated February 19, 2020 and effective March 6, 2020	001-36326	Annual Report on Form 10-K	February 26, 2020

		Incorporated by Reference from:		
Number	Description	File Number	Filing Type	Filing Date
10.21	Executive Employment Agreement between Endo Health Solutions Inc. and Matthew Maletta, effective February 13, 2021	001-36326	Quarterly Report on Form 10-Q	November 6, 2020
10.22	Retention Agreement between Endo and Blaise Coleman, dated November 1, 2021	Not applicable; filed herewith		
10.23	Retention Agreement between Endo and Mark T. Bradley, dated November 1, 2021	Not applicable; filed herewith		
10.24	Retention Agreement between Endo and Matthew J. Maletta, dated November 1, 2021	Not applicable; filed herewith		
10.25	Retention Agreement between Endo and Patrick Barry, dated November 1, 2021	Not applicable; filed herewith		
21.1	Subsidiaries of the Registrant	Not applicable; filed herewith		
23.1	Consent of PricewaterhouseCoopers LLP	Not applicable; filed herewith		
24.1	Power of Attorney	Not applicable; filed herewith		
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		

* Confidential portions of this exhibit (indicated by asterisks) have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

† Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

Item 16. ***Form 10-K Summary***

None.

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)

Date: March 1, 2022

Pursuant to the requirements of the Securities Exchange of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ BLAISE COLEMAN Blaise Coleman	Director, President and Chief Executive Officer (Principal Executive Officer)	March 1, 2022
/S/ MARK T. BRADLEY Mark T. Bradley	Executive Vice President, Chief Financial Officer (Principal Financial Officer)	March 1, 2022
/S/ FRANK B. RACITI Frank B. Raciti	Vice President, Controller, Chief Accounting Officer (Principal Accounting Officer)	March 1, 2022
* Mark G. Barberio	Chairman and Director	March 1, 2022
* Jennifer M. Chao	Director	March 1, 2022
* Shane M. Cooke	Director	March 1, 2022
* Nancy J. Hutson, Ph.D.	Director	March 1, 2022
* Michael Hyatt	Director	March 1, 2022
* William P. Montague	Director	March 1, 2022
* M. Christine Smith, Ph.D.	Director	March 1, 2022
*By: /S/ MATTHEW J. MALETTA Matthew J. Maletta	Attorney-in-fact pursuant to a Power of Attorney filed with this Report as Exhibit 24.1	March 1, 2022

INDEX TO FINANCIAL STATEMENTS

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Endo International plc is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as amended. Endo International plc's internal control over financial reporting was designed 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Endo International plc's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2021. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (2013)*. Based on management's assessment, as of December 31, 2021, the Company's internal control over financial reporting is effective based on those criteria.

Endo International plc's independent registered public accounting firm has issued its report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2021. This report appears on page F-3.

/S/ BLAISE COLEMAN

Blaise Coleman

President and Chief Executive Officer
(Principal Executive Officer)

/S/ MARK T. BRADLEY

Mark T. Bradley

Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

March 1, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Endo International plc

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Endo International plc and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations, of comprehensive (loss) income, of shareholders' deficit and of cash flows for each of the three years in the period ended December 31, 2021, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2021 appearing under Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Emphasis of Matter

As discussed in Note 16 to the consolidated financial statements, under the heading Legal Proceedings and Investigations, the Company and its subsidiaries are subject to risks and uncertainties as a result of ongoing litigation that could affect amounts and disclosures reported in the Company's consolidated financial statements in future periods. Management's plans in regard to these matters are described in Note 16.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sales Deduction Reserves

As described in Note 2 to the consolidated financial statements, the amount of revenue recognized by the Company is equal to the fixed amount of the transaction price, adjusted for management's estimates of a number of significant variable components including, but not limited to, estimates for chargebacks, rebates, sales incentives and allowances, DSA and other fees for services, returns and allowances, which management collectively refer to as sales deductions. As of December 31, 2021, reserves for sales deductions totaled $588.7 million. These amounts relate primarily to management's estimates of unsettled obligations for returns and allowances, rebates and chargebacks. The most significant sales deduction reserves relate to returns, wholesaler chargebacks and rebates for the Sterile Injectables and Generic Pharmaceuticals segments. Management estimates the reserves for sales deductions based on factors such as direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, specific known market events and estimated future trends, current contractual and statutory requirements, industry data, estimated customer inventory levels, current contract sales terms with direct and indirect customers and other competitive factors.

The principal considerations for our determination that performing procedures relating to reserves for sales deductions is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty in developing these reserves, which in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating the reserves, as the reserves are based on direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with direct and indirect customers and other competitive factors.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to sales deductions, including the Company's controls over the assumptions used to estimate the corresponding reserves for sales deductions. These procedures also included, among others, (i) developing an independent estimate of the reserves for sales deductions utilizing direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with direct and indirect customers and other competitive factors, (ii) comparing the independent estimates to the sales deduction reserves recorded by management, (iii) evaluating management's estimates in previous years by comparing historical reserves to rebate payments and credits processed in subsequent periods, and (iv) testing actual payments made and amounts credited to both direct and indirect customers to evaluate whether the payments and credits were made in accordance with the contractual and mandated terms of the Company's rebate programs and returns policy.

Goodwill Impairment Assessment - Sterile Injectables Reporting Unit

As described in Notes 2 and 11 to the consolidated financial statements, the Company's goodwill balance for the Sterile Injectables reporting unit was $2,368.2 million as of December 31, 2021. An impairment assessment is conducted as of October 1, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. Management performs the goodwill impairment test by estimating the fair value of the reporting units 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 management's 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. The Company recognized goodwill impairment charges of $363.0 million during the year ended December 31, 2021.

The principal considerations for our determination that performing procedures relating to the goodwill impairment assessment for the Sterile Injectables reporting unit is a critical audit matter are the significant judgment by management when determining the fair value of the reporting unit; this in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's cash flows and significant assumptions related to future sales, long-term growth rates, gross margins, operating expenses, discount rate and the probability of achieving the estimated cash flows and future economic conditions. In addition, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's goodwill impairment assessment, including controls over the identification of triggering events, the determination of the Sterile Injectables reporting unit's fair value, and the development of assumptions used to estimate fair value. These procedures also included, among others, testing management's process for determining the fair value estimate of the Sterile Injectables reporting unit. Testing management's process included evaluating the appropriateness of the discounted cash flow model related to cash flow projections, testing the completeness and accuracy of underlying data used in the model, evaluating the reasonableness of assumptions related to future sales, long-term growth rates, gross margins, operating expenses, discount rate and the probability of achieving the estimated cash flows and future economic conditions, and testing the assignment of assets and liabilities to the Sterile Injectables reporting unit. Evaluating management's assumptions related to future sales, long-term growth rates, gross margins, operating expenses, discount rate and the probability of achieving the estimated cash flows and future economic conditions involved evaluating whether the assumptions used were reasonable considering (i) historical performance, (ii) industry and economic forecasts and (iii) whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of the Company's discounted cash flow model and evaluating the appropriateness of the discount rate and long-term growth rate assumptions.

Opioid-Related Litigation

As described in Notes 2 and 16 to the consolidated financial statements, the Company is subject to various claims, legal proceedings and governmental investigations, including those related to opioids. 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 the Company and certain of its subsidiaries, asserting claims relating to the defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications. As of February 21, 2022, and as described by management, filed cases in the U.S. of which management was aware include, but are not limited to, approximately 20 cases filed by or on behalf of states; approximately 2,920 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 210 cases filed by individuals, including but not limited to legal guardians of children born with neonatal abstinence syndrome. The Company has recorded total charges for opioid-related matters of $343.5 million in 2021 and, as of December 31, 2021, the corresponding accrual totaled $258.7 million. Contingent accruals and legal settlements are recorded in the consolidated statements of operations as Litigation-related and other contingencies, net when management determines that a loss is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, management estimates of the probability and amount of any such liabilities involve significant judgment regarding future events.

The principal considerations for our determination that performing procedures relating to opioid-related litigation is a critical audit matter are the significant judgment by management when assessing the likelihood of losses being incurred and when determining whether reasonable estimates of the loss or range of losses can be made, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of litigation claims, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as financial statement disclosures. These procedures also included, among others, (i) gaining an understanding of management's process around the accounting and reporting for the opioid-related litigation; (ii) evaluating the status of significant known actual and potential litigation and ongoing settlement negotiations through discussion with the Company's in-house legal counsel; (iii) obtaining and evaluating the letters of audit inquiry with internal and external legal counsel for significant litigation; (iv) evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable; and (v) evaluating the sufficiency of the Company's litigation contingencies disclosures.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
March 1, 2022

We have served as the Company's auditor since 2014.

ENDO INTERNATIONAL PLC
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2021 AND 2020
(Dollars in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,507,196	$ 1,213,437
Restricted cash and cash equivalents	124,114	171,563
Accounts receivable, net	592,019	511,262
Inventories, net	283,552	352,260
Prepaid expenses and other current assets	200,484	100,899
Income taxes receivable	7,221	63,837
Total current assets	$ 2,714,586	$ 2,413,258
PROPERTY, PLANT AND EQUIPMENT, NET	396,712	458,471
OPERATING LEASE ASSETS	34,832	37,030
GOODWILL	3,197,011	3,560,011
OTHER INTANGIBLES, NET	2,362,823	2,740,808
DEFERRED INCOME TAXES	1,138	1,824
OTHER ASSETS	60,313	53,235
TOTAL ASSETS	$ 8,767,415	$ 9,264,637
LIABILITIES AND SHAREHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 836,898	$ 835,940
Current portion of legal settlement accrual	580,994	372,121
Current portion of operating lease liabilities	10,992	11,613
Current portion of long-term debt	200,342	34,150
Income taxes payable	736	—
Total current liabilities	$ 1,629,962	$ 1,253,824
DEFERRED INCOME TAXES	21,628	26,066
LONG-TERM DEBT, LESS CURRENT PORTION, NET	8,048,980	8,280,578
OPERATING LEASE LIABILITIES, LESS CURRENT PORTION	33,727	38,132
OTHER LIABILITIES	277,104	313,976
COMMITMENTS AND CONTINGENCIES (NOTE 16)		
SHAREHOLDERS' DEFICIT:		
Euro deferred shares, $0.01 par value; 4,000,000 shares authorized and issued at both December 31, 2021 and December 31, 2020	45	49
Ordinary shares, $0.0001 par value; 1,000,000,000 shares authorized; 233,690,816 and 230,315,768 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	23	23
Additional paid-in capital	8,953,906	8,938,012
Accumulated deficit	(9,981,515)	(9,368,270)
Accumulated other comprehensive loss	(216,445)	(217,753)
Total shareholders' deficit	$ (1,243,986)	$ (647,939)
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	$ 8,767,415	$ 9,264,637

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019
(Dollars and shares in thousands, except per share data)

	2021	2020	2019
TOTAL REVENUES, NET	$ 2,993,206	$ 2,903,074	$ 2,914,364
COSTS AND EXPENSES:			
Cost of revenues	1,221,064	1,442,511	1,569,338
Selling, general and administrative	861,760	698,506	632,420
Research and development	148,560	158,902	130,732
Litigation-related and other contingencies, net	345,495	(19,049)	11,211
Asset impairment charges	414,977	120,344	526,082
Acquisition-related and integration items, net	(8,379)	16,549	(46,098)
Interest expense, net	562,353	532,939	538,734
Loss (gain) on extinguishment of debt	13,753	—	(119,828)
Other (income) expense, net	(19,774)	(21,110)	16,677
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX	$ (546,603)	$ (26,518)	$ (344,904)
INCOME TAX EXPENSE (BENEFIT)	22,478	(273,982)	15,680
(LOSS) INCOME FROM CONTINUING OPERATIONS	$ (569,081)	$ 247,464	$ (360,584)
DISCONTINUED OPERATIONS, NET OF TAX (NOTE 3)	(44,164)	(63,520)	(62,052)
NET (LOSS) INCOME	$ (613,245)	$ 183,944	$ (422,636)
NET (LOSS) INCOME PER SHARE—BASIC:			
Continuing operations	$ (2.44)	$ 1.08	$ (1.60)
Discontinued operations	(0.19)	(0.28)	(0.27)
Basic	$ (2.63)	$ 0.80	$ (1.87)
NET (LOSS) INCOME PER SHARE—DILUTED:			
Continuing operations	$ (2.44)	$ 1.06	$ (1.60)
Discontinued operations	(0.19)	(0.27)	(0.27)
Diluted	$ (2.63)	$ 0.79	$ (1.87)
WEIGHTED AVERAGE SHARES:			
Basic	232,785	229,314	226,050
Diluted	232,785	233,653	226,050

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019
(Dollars in thousands)

	2021	2020	2019
NET (LOSS) INCOME	$ (613,245)	$ 183,944	$ (422,636)
OTHER COMPREHENSIVE INCOME:			
Net unrealized gain on foreign currency	$ 1,308	$ 1,337	$ 10,139
Total other comprehensive income	$ 1,308	$ 1,337	$ 10,139
COMPREHENSIVE (LOSS) INCOME	$ (611,937)	$ 185,281	$ (412,497)

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019
(Dollars in thousands, except share data)

	Ordinary Shares		Euro Deferred Shares				Accumulated Other Comprehensive Loss	Total Shareholders' Deficit
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit		
BALANCE, DECEMBER 31, 2018, prior to the adoption of ASC 842 (NOTE 18)	224,382,791	$ 22	4,000,000	$ 46	$ 8,855,810	$ (9,124,932)	$ (229,229)	$ (498,283)
Effect of adopting ASC 842 (NOTE 18)	—	—	—	—	—	(4,646)	—	(4,646)
BALANCE, DECEMBER 31, 2018	224,382,791	$ 22	4,000,000	$ 46	$ 8,855,810	$ (9,129,578)	$ (229,229)	$ (502,929)
Net loss	—	—	—	—	—	(422,636)	—	(422,636)
Other comprehensive income	—	—	—	—	—	—	10,139	10,139
Compensation related to share-based awards	—	—	—	—	59,142	—	—	59,142
Exercise of options	557	—	—	—	4	—	—	4
Ordinary shares issued	2,419,261	—	—	—	—	—	—	—
Tax withholding for restricted shares	—	—	—	—	(10,156)	—	—	(10,156)
Other	—	1	—	(1)	(108)	—	—	(108)
BALANCE, DECEMBER 31, 2019	226,802,609	$ 23	4,000,000	$ 45	$ 8,904,692	$ (9,552,214)	$ (219,090)	$ (866,544)
Net income	—	—	—	—	—	183,944	—	183,944
Other comprehensive income	—	—	—	—	—	—	1,337	1,337
Compensation related to share-based awards	—	—	—	—	41,357	—	—	41,357
Ordinary shares issued	3,513,159	—	—	—	—	—	—	—
Tax withholding for restricted shares	—	—	—	—	(8,036)	—	—	(8,036)
Other	—	—	—	4	(1)	—	—	3
BALANCE, DECEMBER 31, 2020	230,315,768	$ 23	4,000,000	$ 49	$ 8,938,012	$ (9,368,270)	$ (217,753)	$ (647,939)
Net loss	—	—	—	—	—	(613,245)	—	(613,245)
Other comprehensive income	—	—	—	—	—	—	1,308	1,308
Compensation related to share-based awards	—	—	—	—	30,046	—	—	30,046
Exercise of options	82,331	—	—	—	622	—	—	622
Ordinary shares issued	3,292,717	—	—	—	—	—	—	—
Tax withholding for restricted shares	—	—	—	—	(14,774)	—	—	(14,774)
Other	—	—	—	(4)	—	—	—	(4)
BALANCE, DECEMBER 31, 2021	233,690,816	$ 23	4,000,000	$ 45	$ 8,953,906	$ (9,981,515)	$ (216,445)	$ (1,243,986)

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019
(Dollars in thousands)

	2021	2020	2019
OPERATING ACTIVITIES:			
Net (loss) income	$ (613,245)	$ 183,944	$ (422,636)
Adjustments to reconcile Net (loss) income to Net cash provided by operating activities:			
Depreciation and amortization	457,098	518,807	612,862
Share-based compensation	30,046	41,357	59,142
Amortization of debt issuance costs and discount	14,437	15,606	18,107
Deferred income taxes	(3,157)	(163,558)	(5,561)
Change in fair value of contingent consideration	(8,793)	16,353	(46,098)
Loss (gain) on extinguishment of debt	13,753	—	(119,828)
Acquired in-process research and development charges	25,120	28,602	—
Asset impairment charges	414,977	120,344	526,082
Gain on sale of business and other assets	(4,516)	(16,353)	(6,367)
Changes in assets and liabilities which (used) provided cash:			
Accounts receivable	(82,052)	(45,792)	19,158
Inventories	48,978	(8,031)	(27,139)
Prepaid and other assets	(34,002)	(27,421)	11,370
Accounts payable, accrued expenses and other liabilities	84,391	(171,366)	(525,746)
Income taxes payable/receivable, net	68,015	(95,100)	4,706
Net cash provided by operating activities	$ 411,050	$ 397,392	$ 98,052
INVESTING ACTIVITIES:			
Capital expenditures, excluding capitalized interest	(77,929)	(69,971)	(63,854)
Capitalized interest payments	(2,721)	(2,892)	(3,833)
Acquisitions, including in-process research and development, net of cash and restricted cash acquired	(5,000)	(649,504)	—
Proceeds from sales and maturities of investments	—	92,763	—
Product acquisition costs and license fees	(4,177)	(2,000)	—
Proceeds from sale of business and other assets, net	30,283	6,737	6,577
Other investing activities	—	—	912
Net cash used in investing activities	$ (59,544)	$ (624,867)	$ (60,198)

	2021	2020	2019
FINANCING ACTIVITIES:			
Proceeds from issuance of notes, net	1,279,978	—	1,483,125
Proceeds from issuance of term loans, net	1,980,000	—	—
Repayments of notes	—	(57,649)	(1,501,788)
Repayments of term loans	(3,310,475)	(34,150)	(34,152)
Proceeds from draw of revolving debt	—	—	300,000
Repayments of revolving debt	(22,800)	—	—
Repayments of other indebtedness	(5,448)	(4,884)	(9,196)
Payments for debt issuance and extinguishment costs	(8,574)	—	(6,414)
Payments for contingent consideration	(4,010)	(3,848)	(16,822)
Payments of tax withholding for restricted shares	(14,774)	(8,036)	(10,156)
Proceeds from exercise of options	622	—	4
Net cash (used in) provided by financing activities	$ (105,481)	$ (108,567)	$ 204,601
Effect of foreign exchange rate	285	654	1,096
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS	$ 246,310	$ (335,388)	$ 243,551
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, BEGINNING OF PERIOD	1,385,000	1,720,388	1,476,837
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, END OF PERIOD	$ 1,631,310	$ 1,385,000	$ 1,720,388
SUPPLEMENTAL INFORMATION:			
Cash paid for interest, excluding capitalized interest	$ 538,424	$ 534,529	$ 559,528
Cash paid for income taxes, gross	$ 10,019	$ 11,669	$ 14,875
Cash refunds from income taxes, gross	$ 57,801	$ 31,897	$ 11,808
Cash paid into Qualified Settlement Funds for mesh legal settlements	$ 670	$ 7,215	$ 253,520
Cash paid out of Qualified Settlement Funds for mesh legal settlements	$ 49,287	$ 123,803	$ 314,266
Other cash distributions for mesh legal settlements	$ 47,360	$ 44,471	$ 15,330
SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:			
Acquisitions, including in-process research and development, accrued in the period but not yet paid	$ 20,120	$ —	$ —

See accompanying Notes to Consolidated Financial Statements.

NOTE 1. DESCRIPTION OF BUSINESS

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 Consolidated Financial Statements of Endo International plc and its subsidiaries have been prepared in accordance with U.S. GAAP.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Significant Accounting Policies

Consolidation and Basis of Presentation. The Consolidated Financial Statements include the accounts of wholly-owned subsidiaries after the elimination of intercompany accounts and transactions.

Reclassifications. Certain prior period amounts have been reclassified to conform to the current period presentation.

Use of Estimates. The preparation of our Consolidated Financial Statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts and disclosures in our 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.

We regularly evaluate our estimates and assumptions using historical experience and other factors, including the economic environment. As future events and their effects cannot be determined with precision, our estimates and assumptions may prove to be incomplete or inaccurate, or unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. Market conditions, such as illiquid credit markets, volatile equity markets, dramatic fluctuations in foreign currency rates and economic downturns, can increase the uncertainty already inherent in our estimates and assumptions. We also are subject to other risks and uncertainties that may cause actual results to differ from estimated amounts, such as changes in the healthcare environment, competition, litigation, legislation and regulations. We adjust our estimates and assumptions when facts and circumstances indicate the need for change. Those changes generally will be reflected in our Consolidated Financial Statements on a prospective basis.

Customer, Product and Supplier Concentration. We primarily sell our products to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and/or government agencies. Our wholesalers and/or distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies, hospitals, long-term care facilities, clinics, home infusion pharmacies, government facilities and MCOs. Net revenues from direct customers that accounted for 10% or more of our total consolidated net revenues during the years ended December 31, 2021, 2020 and 2019 are as follows:

	2021	2020	2019
AmerisourceBergen Corporation	36 %	33 %	34 %
McKesson Corporation	32 %	27 %	26 %
Cardinal Health, Inc.	22 %	24 %	25 %

Revenues from these customers are included within each of our segments.

VASOSTRICT® accounted for 30%, 27% and 18% of our 2021, 2020 and 2019 net revenues, respectively. XIAFLEX® accounted for 14%, 11% and 11% of our 2021, 2020 and 2019 net revenues, respectively. No other products accounted for 10% or more of our net revenues during the years ended December 31, 2021, 2020 or 2019.

We have agreements with certain third parties for the manufacture, supply and processing of certain of our existing pharmaceutical products. See Note 16. Commitments and Contingencies for information on any material manufacturing, supply and other service agreements.

We are subject to risks and uncertainties associated with these concentrations that could have a material adverse effect on our business, financial condition, results of operations and cash flows in future periods, including in the near term.

Revenue Recognition and Sales Deductions. With respect to contracts with commercial substance that establish payment terms and each party's rights regarding goods or services to be transferred, we recognize revenue when (or as) we satisfy our performance obligations for such contracts by transferring control of the underlying promised goods or services to our customers, to the extent collection of substantially all of the related consideration is probable. The amount of revenue we recognize reflects our estimate of the consideration we expect to be entitled to receive, subject to certain constraints, in exchange for such goods or services. This amount is referred to as the transaction price.

Our revenue consists almost entirely of sales of our products to customers, whereby we ship products to a customer pursuant to a purchase order. For contracts such as these, revenue is recognized when our contractual performance obligations have been fulfilled and control has been transferred to the customer pursuant to the contract's terms, which is generally upon delivery to the customer. The amount of revenue we recognize is equal to the fixed amount of the transaction price, adjusted for our estimates of a number of significant variable components including, but not limited to, estimates for chargebacks, rebates, sales incentives and allowances, DSA and other fees for services, returns and allowances, which we collectively refer to as sales deductions.

The Company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components and the most likely amount method when estimating the amount of variable consideration to include in the transaction price with respect to future potential milestone payments that do not qualify for the sales- and usage-based royalty exception. Variable consideration is included in the transaction price only to the extent it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved. Payment terms for these types of contracts generally fall within 30 to 120 days of invoicing.

At December 31, 2021 and 2020, our reserves for sales deductions totaled $588.7 million and $605.6 million, respectively. These amounts relate primarily to our estimates of unsettled obligations for returns and allowances, rebates and chargebacks. The most significant sales deduction reserves relate to returns, wholesaler chargebacks and rebates for the Sterile Injectables and Generic Pharmaceuticals segments. Our estimates are based on factors such as our direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, specific known market events and estimated future trends, current contractual and statutory requirements, industry data, estimated customer inventory levels, current contract sales terms with our direct and indirect customers and other competitive factors. Significant judgment and estimation is required in developing the foregoing and other relevant assumptions. The most significant sales deductions are further described below.

Returns and Allowances—Consistent with industry practice, we maintain a return policy that allows our customers to return products within a specified period of time both subsequent to and, in certain cases, prior to the products' expiration dates. Our return policy generally allows customers to receive credit for expired products within six months prior to expiration and within between six months and one year after expiration. Our provision for returns and allowances consists of our estimates for future product returns, pricing adjustments and delivery errors.

Rebates—Our provision for rebates, sales incentives and other allowances can generally be categorized into the following four types:

- direct rebates;
- indirect rebates;
- governmental rebates, including those for Medicaid, Medicare and TRICARE, among others; and
- managed-care rebates.

We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives, DSA fees and other allowances. Some customers receive rebates upon attaining established sales volumes. Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer's purchases from us, including fees paid to wholesalers under our DSAs, as described above. Indirect rebates are rebates paid to indirect customers that have purchased our products from a wholesaler or distributor under a contract with us.

We are subject to rebates on sales made under governmental and managed-care pricing programs based on relevant statutes with respect to governmental pricing programs and contractual sales terms with respect to managed-care providers and GPOs. For example, we are required to provide a discount on certain of our products to patients who fall within the Medicare Part D coverage gap, also referred to as the donut hole.

We participate in various federal and state government-managed programs whereby discounts and rebates are provided to participating government entities. For example, Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant.

Chargebacks—We market and sell products to both: (i) direct customers including wholesalers, distributors, warehousing pharmacy chains and other direct purchasing entities and (ii) indirect customers including independent pharmacies, non-warehousing chains, MCOs, GPOs, hospitals and other healthcare institutions and government entities. We enter into agreements with certain of our indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback.

Contract Assets and Contract Liabilities. Contract assets represent the Company's right to consideration in exchange for goods or services that the Company has transferred when that right is conditioned on something other than the passage of time. The Company records revenue and a corresponding contract asset when it fulfills a contractual performance obligation, but must also fulfill one or more additional performance obligations before being entitled to payment. Once the Company's right to consideration becomes unconditional, the contract asset amount is reclassified as Accounts receivable.

Contract liabilities represent the Company's obligation to transfer goods or services to a customer. The Company records a contract liability generally upon receipt of consideration in advance of fulfilling one or more of its contractual performance obligations. Upon completing each performance obligation, the corresponding contract liability amount is reversed and revenue is recognized.

Contract assets and liabilities related to rights and obligations arising from a single contract, or a series of contracts combined and accounted for as a single contract, are generally presented on a net basis. Contract assets and liabilities are further described in Note 13. Contract Assets and Liabilities.

Acquisitions. We evaluate acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If so, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not we have acquired inputs and processes that have the ability to create outputs, which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. We also evaluate which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. Assets acquired as part of an asset acquisition that are considered to be in-process research and development are immediately expensed and included in Research and development in the Consolidated Statements of Operations unless there is an alternative future use in other research and development projects.

R&D. Expenditures for R&D are expensed as incurred. Total R&D expenses include, among other things, the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials, materials, medical support of marketed products and certain upfront and milestone payments. R&D spending also includes enterprise-wide costs which support our overall R&D infrastructure. Property, plant and equipment that are acquired or constructed for R&D activities and that have alternate future uses are capitalized and depreciated over their estimated useful lives on a straight-line basis. From time to time, the Company has entered into licensing or collaborative agreements with third parties to develop new drug candidates. Contractual upfront and milestone payments made to third parties pursuant to these types of contracts are generally: (i) expensed as incurred up to the point of regulatory approval and (ii) capitalized and amortized over the related product's remaining useful life subsequent to regulatory approval. Amounts capitalized for such payments are included in Other intangibles, net in the Consolidated Balance Sheets.

Cash and Cash Equivalents. The Company considers all highly liquid money market instruments with an original maturities of three months or less when purchased to be cash equivalents. At December 31, 2021 and 2020, cash equivalents were deposited in financial institutions and consisted almost entirely of immediately available fund balances. The Company maintains its cash deposits and cash equivalents with financial institutions it believes to be well-known and stable.

Restricted Cash and Cash Equivalents. Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are excluded from Cash and cash equivalents in the Consolidated Balance Sheets. For additional information see Note 7. Fair Value Measurements.

Accounts Receivable. The Company adopted *Accounting Standards Codification Topic 326, Financial Instruments-Credit Losses* (ASC 326) on January 1, 2020. For further discussion of the adoption, refer to the "Recent Accounting Pronouncements Adopted or Otherwise Effective as of December 31, 2021" section below. Subsequent to the adoption of ASC 326, our accounts receivable balance is stated at amortized cost less an allowance determined using the expected credit loss model. In addition, our accounts receivable balance is reduced by certain sales deduction reserves where we have the right of offset with the customer. We generally do not require collateral.

Concentrations of Credit Risk and Credit Losses. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash equivalents, restricted cash equivalents and accounts receivable. From time to time, we invest our excess cash in high-quality, liquid money market instruments maintained by major banks and financial institutions. We have not experienced any losses on our cash equivalents.

With respect to our accounts receivable, we have no history of significant losses. Approximately 91% and 90% of our gross trade accounts receivable balances represent amounts due from three customers (Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation) at December 31, 2021 and December 31, 2020, respectively. We perform ongoing credit evaluations of these and our other customers based on information available to us. We consider these and other factors, including changes in the composition and aging of our accounts receivable, in developing our allowance for expected credit losses. The estimated allowance was not material to the Company's Consolidated Financial Statements at December 31, 2021 or December 31, 2020, nor were the changes to the allowance during any of the periods presented.

We do not currently expect our current or future exposures to credit losses to have a significant impact on us. However, our customers' ability to pay us on a timely basis, or at all, could be affected by factors specific to their respective businesses and/or by economic conditions, including those related to the COVID-19 pandemic, the extent of which cannot be fully predicted.

Inventories. Inventories consist of raw materials, work-in-process and finished goods. Inventory that is in excess of the amount expected to be sold within one year is classified as long-term inventory and is recorded in Other assets in the Consolidated Balance Sheets. The Company capitalizes inventory costs associated with certain products prior to regulatory approval and product launch when it is reasonably certain, based on management's judgment of future commercial use and net realizable value, that the pre-launch inventories will be saleable. The determination to capitalize is made on a product-by-product basis. The Company could be required to write down previously capitalized costs related to pre-launch inventories upon a change in such judgment, a denial or delay of approval by regulatory bodies, a delay in commercialization or other potential factors. Our inventories are stated at the lower of cost or net realizable value.

Cost is determined by the first-in, first-out method. It includes materials, direct labor and an allocation of overhead, but excludes certain period charges and unallocated overheads that are charged to expense in the period in which they are incurred. Unallocated overheads can occur as a consequence of abnormally low production or idle facilities.

Net realizable value is determined by the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. When necessary, we write-down inventories to net realizable value based on forecasted demand and market and regulatory conditions, which may differ from actual results.

Property, Plant and Equipment. Property, plant and equipment is generally stated at cost less accumulated depreciation. Major improvements are capitalized, while routine maintenance and repairs are expensed as incurred. Costs incurred during the construction or development of property, plant and equipment are capitalized as assets under construction. Once an asset has been placed into service, depreciation expense is taken on a straight-line basis over the estimated useful life of the related assets or, in the case of leasehold improvements and finance lease assets, over the shorter of the estimated useful life and the lease term. As of December 31, 2021, the useful lives of our property, plant and equipment range from 1 year to up to 30 years for buildings, 15 years for machinery and equipment, 10 years for computer equipment and software and 10 years for furniture and fixtures. Depreciation expense is not recorded on assets held for sale. Gains and losses on disposals are included in Other (income) expense, net in the Consolidated Statements of Operations. As further described below under the heading "Long-Lived Asset Impairment Testing," our property plant and equipment assets are also subject to impairment reviews.

Computer Software. The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software, including external direct costs of material and services, and payroll costs for employees directly involved with the software development. Capitalized software costs are included in Property, plant and equipment, net in the Consolidated Balance Sheets and depreciated beginning when the software project is substantially complete and the asset is ready for its intended use. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Lease Accounting. The Company adopted *Accounting Standards Codification Topic 842, Leases* (ASC 842) on January 1, 2019 using the modified retrospective approach with an effective date of January 1, 2019 for leases that existed on that date. The Company elected to apply certain practical expedients permitted under the transition guidance within ASC 842 to leases that commenced before January 1, 2019, including the package of practical expedients, as well as the practical expedient permitting the Company to not assess whether certain land easements contain leases. Due to the Company's election of these practical expedients, the Company carried forward certain historical conclusions for existing contracts, including conclusions relating to initial direct costs and to the existence and classification of leases. ASC 842 applies to a number of arrangements to which the Company is party.

Whenever the Company enters into a new arrangement, it must determine, at the inception date, whether the arrangement is or contains a lease. This determination generally depends on whether the arrangement conveys to the Company the right to control the use of an explicitly or implicitly identified asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset.

If a lease exists, the Company must then determine the separate lease and nonlease components of the arrangement. Each right to use an underlying asset conveyed by a lease arrangement should generally be considered a separate lease component if it both: (i) can benefit the Company without depending on other resources not readily available to the Company and (ii) does not significantly affect and is not significantly affected by other rights of use conveyed by the lease. Aspects of a lease arrangement that transfer other goods or services to the Company but do not meet the definition of lease components are considered nonlease components. The consideration owed by the Company pursuant to a lease arrangement is generally allocated to each lease and nonlease component for accounting purposes. However, the Company has elected, for all of its leases, to not separate lease and nonlease components. Each lease component is accounted for separately from other lease components, but together with the associated nonlease components.

For each lease, the Company must then determine the lease term, the present value of lease payments and the classification of the lease as either an operating or finance lease.

The lease term is the period of the lease not cancellable by the Company, together with periods covered by: (i) renewal options the Company is reasonably certain to exercise, (ii) termination options the Company is reasonably certain not to exercise and (iii) renewal or termination options that are controlled by the lessor.

The present value of lease payments is calculated based on:

- Lease payments—Lease payments include fixed and certain variable payments, less lease incentives, together with amounts probable of being owed by the Company under residual value guarantees and, if reasonably certain of being paid, the cost of certain renewal options and early termination penalties set forth in the lease arrangement. Lease payments exclude consideration that is not related to the transfer of goods and services to the Company.
- Discount rate—The discount rate must be determined based on information available to the Company upon the commencement of a lease. Lessees are required to use the rate implicit in the lease whenever such rate is readily available; however, as the implicit rate in the Company's leases is generally not readily determinable, the Company generally uses the hypothetical incremental borrowing rate it would have to pay to borrow an amount equal to the lease payments, on a collateralized basis, over a timeframe similar to the lease term.

In making the determination of whether a lease is an operating lease or a finance lease, the Company considers the lease term in relation to the economic life of the leased asset, the present value of lease payments in relation to the fair value of the leased asset and certain other factors, including the lessee's and lessor's rights, obligations and economic incentives over the term of the lease.

Generally, upon the commencement of a lease, the Company will record a lease liability and a right-of-use asset. However, the Company has elected, for all underlying assets with initial lease terms of twelve months or less (known as short-term leases), to not recognize a lease liability or right-of-use asset. Lease liabilities are initially recorded at lease commencement as the present value of future lease payments. Right-of-use assets are initially recorded at lease commencement as the initial amount of the lease liability, together with the following, if applicable: (i) initial direct costs incurred by the lessee and (ii) lease payments made by the lessor, net of lease incentives received, prior to lease commencement.

Over the lease term, the Company generally increases its lease liabilities using the effective interest method and decreases its lease liabilities for lease payments made. For finance leases, amortization expense and interest expense are recognized separately in the Consolidated Statements of Operations, with amortization expense generally recorded on a straight-line basis over the lease term and interest expense recorded using the effective interest method. For operating leases, a single lease cost is generally recognized in the Consolidated Statements of Operations on a straight-line basis over the lease term unless an impairment has been recorded with respect to a leased asset. Lease costs for short-term leases not recognized in the Consolidated Balance Sheets are recognized in the Consolidated Statements of Operations on a straight-line basis over the lease term. Variable lease costs not initially included in the lease liability and right-of-use asset impairment charges are expensed as incurred. Right-of-use assets are assessed for impairment, similar to other long-lived assets.

Prior to the adoption of ASC 842, the Company accounted for leases under *Accounting Standards Codification Topic 840, Leases* (ASC 840).

Cloud Computing Arrangements. The Company may from time to time incur costs in connection with hosting arrangements that are service contracts. Subsequent to the Company's January 1, 2019 adoption of *Accounting Standards Update (ASU) No. 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (ASU 2018-15), the Company capitalizes any such implementation costs, expenses them over the terms of the respective hosting arrangements and subjects them to impairment testing consistent with other long-lived assets.

Finite-Lived Intangible Assets. Our finite-lived intangible assets consist of license rights and developed technology. Upon acquisition, intangible assets are generally initially recorded at fair value if acquired in a business combination, or at cost if otherwise. There are several methods that can be used to determine fair value. For intangible assets, we typically use an income approach. This approach starts with our forecast of all of the expected future net cash flows. Revenues are estimated based on relevant market size and growth factors, expected industry trends, individual project life cycles and, if applicable, the life of any estimated period of marketing exclusivity, such as that granted by a patent. The pricing, margins and expense levels of similar products are considered if available. For certain licensed assets, our estimates of future cash flows consider periods covered by renewal options to the extent we have the intent and ability, at the date of the estimate, to renew the underlying license agreements. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams.

To the extent an intangible asset is deemed to have a finite life, it is then amortized over its estimated useful life using either the straight-line method or, in the case of certain developed technology assets, an accelerated amortization model. The values of these various assets are subject to continuing scientific, medical and marketplace uncertainty. Factors giving rise to our initial estimate of useful lives are subject to change. Significant changes to any of these factors may result in adjustments to the useful life of the asset and an acceleration of related amortization expense, which could cause our net income and net income per share to decrease. Amortization expense is not recorded on assets held for sale.

As further described under the heading "Long-Lived Asset Impairment Testing," our finite-lived intangible assets are also subject to impairment reviews.

Developed Technology. Our developed technology assets subject to amortization have useful lives ranging from 4 years to 20 years, with a weighted average useful life of approximately 11 years. We determine amortization periods and methods of amortization for developed technology assets based on our assessment of various factors impacting estimated useful lives and the timing and extent of estimated cash flows of the acquired assets, including the strength of the intellectual property protection of the product (if applicable), contractual terms and various other competitive and regulatory issues.

License Rights. Our license rights subject to amortization have useful lives ranging from 7 years to 15 years, with a weighted average useful life of approximately 14 years. We determine amortization periods for licenses based on our assessment of various factors including the expected launch date of the product, the strength of the intellectual property protection of the product (if applicable), contractual terms and various other competitive, developmental and regulatory issues.

Long-Lived Asset Impairment Testing. Long-lived assets, including property, plant and equipment and finite-lived intangible assets, are assessed for impairment whenever events or changes in circumstances indicate the assets may not be recoverable. Recoverability of an asset that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying amount of the asset exceeds its undiscounted future cash flows and the carrying amount is not considered recoverable, impairment may exist. An impairment loss, if any, is measured as the excess of the asset's carrying amount over its fair value, generally based on a discounted future cash flow method, independent appraisals or offers from prospective buyers. An impairment loss would be recognized in the Consolidated Statements of Operations in the period that the impairment occurs.

In the case of long-lived assets to be disposed of by sale or otherwise, including assets held for sale, the assets and the associated liabilities to be disposed of together as a group in a single transaction (the disposal group) are measured at the lower of their carrying amount or fair value less cost to sell. Losses are recognized for any initial or subsequent write-down to fair value less cost to sell, while gains are recognized for any subsequent increase in fair value less cost to sell, but not in excess of any cumulative losses previously recognized. Any gains or losses not previously recognized that result from the sale of a disposal group shall be recognized at the date of sale.

In-Process Research and Development Assets. In-process research and development assets acquired in an asset acquisition are immediately expensed and included in Research and development in the Consolidated Statements of Operations unless there is an alternative future use in other research and development projects. Otherwise, acquired in-process research and development assets are generally recognized as indefinite-lived intangible assets. Such assets are generally initially recorded at fair value if acquired in a business combination, or at cost if otherwise. Any indefinite-lived intangible assets are not subject to amortization. Instead, they 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. If the fair value of the intangible assets is less than its carrying amount, an impairment loss is recognized for the difference. Assets that receive regulatory approval are reclassified and accounted for as finite-lived intangible assets.

Goodwill. While amortization expense is not recorded on goodwill, goodwill is subject to impairment reviews. An impairment assessment is conducted as of October 1, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired.

We perform the goodwill impairment test by estimating the fair value of the reporting units using an income approach that utilizes a discounted cash flow model or, where appropriate, a market approach. Any goodwill impairment charge we recognize for a reporting unit is equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value.

Contingencies. The Company is subject to various patent challenges, product liability claims, government investigations and other legal proceedings in the ordinary course of business. Contingent accruals and legal settlements are recorded in the Consolidated Statements of Operations as Litigation-related and other contingencies, net (or as Discontinued operations, net of tax in the case of vaginal mesh matters) when the Company determines that a loss is both probable and reasonably estimable. Legal fees and other expenses related to litigation are expensed as incurred and included in Selling, general and administrative expenses in the Consolidated Statements of Operations (or as Discontinued operations, net of tax in the case of vaginal mesh matters).

Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our estimates of the probability and amount of any such liabilities involve significant judgment regarding future events. The Company records receivables from its insurance carriers only when the realization of the potential claim for recovery is considered probable.

Contingent Consideration. Certain of the Company's acquisitions involve the potential for future payment of consideration that is contingent upon the occurrence of a future event, such as (i) the achievement of specified regulatory, operational and/or commercial milestones or (ii) royalty payments, such as those relating to future product sales. Contingent consideration liabilities related to an asset acquisition are initially recorded when considered probable and reasonably estimable, which may occur subsequent to the acquisition date. Subsequent changes in the recorded amounts are generally recorded as adjustments to the cost of the acquired assets. Contingent consideration liabilities related to a business combination are initially recorded at fair value on the acquisition date using unobservable inputs. 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 Company remeasures its contingent consideration liabilities to their current estimated fair values, with changes recorded in earnings. Changes to any of the inputs used in determining fair value may result in fair value adjustments that differ significantly from the actual remeasurement adjustments recognized.

Share Repurchases. The Company accounts for the repurchase of ordinary shares, if any, at par value. Under applicable Irish law, ordinary shares repurchased are retired and not displayed separately as treasury stock. Upon retirement of the ordinary shares, the Company records the difference between the weighted average cost of such ordinary shares and the par value of the ordinary shares as an adjustment to Accumulated deficit in the Consolidated Balance Sheets.

Advertising Costs. Advertising costs are expensed as incurred and included in Selling, general and administrative expenses in the Consolidated Statements of Operations. Advertising costs amounted to $136.8 million, $76.0 million and $63.1 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Cost of Revenues. Cost of revenues includes all costs directly related to bringing both purchased and manufactured products to their final selling destination. Amounts include purchasing and receiving costs, direct and indirect costs to manufacture products including direct materials, direct labor and direct overhead expenses necessary to acquire and convert purchased materials and supplies into finished goods, royalties paid or owed by Endo on certain in-licensed products, inspection costs, depreciation of certain property, plant and equipment, amortization of intangible assets, lease costs, warehousing costs, freight charges, costs to operate our equipment and other shipping and handling costs, among others.

Restructuring. Restructuring charges related to nonretirement postemployment benefits that fall under *Accounting Standards Codification Topic 712, Compensation—Nonretirement Postemployment Benefits* (ASC 712) are recognized when the severance liability is determined to be probable of being paid and reasonably estimable. One-time benefits related to restructurings, if any, are recognized in accordance with *Accounting Standards Codification Topic 420, Exit or Disposal Cost Obligations* (ASC 420) when the programs are approved, the affected employees are identified, the terms of the arrangement are established, it is determined changes to the plan are unlikely to occur and the arrangements are communicated to employees. Other restructuring costs are generally expensed as incurred.

Share-Based Compensation. The Company grants share-based compensation awards to certain employees and non-employee directors. Generally, the grant-date fair value of each award is recognized as expense over the requisite service period. However, expense recognition differs in the case of certain performance share units (PSUs) where the ultimate payout is performance-based. For these awards, at each reporting period, the Company estimates the ultimate payout and adjusts the cumulative expense based on its estimate and the percent of the requisite service period that has elapsed. Share-based compensation expense is reduced for estimated future forfeitures. These estimates are revised in future periods if actual forfeitures differ from the estimates. Changes in forfeiture estimates impact compensation expense in the period in which the change in estimate occurs. New ordinary shares are generally issued upon the exercise of stock options or vesting of stock awards by employees and non-employee directors. Refer to Note 19. Share-based Compensation for additional discussion.

Foreign Currency. The Company operates in various jurisdictions both inside and outside of the U.S. While the Company's reporting currency is the U.S. dollar, the Company has concluded that certain of its distinct and separable operations have functional currencies other than the U.S. dollar. Further, certain of the Company's operations hold assets and liabilities and recognize income and expenses denominated in various local currencies, which may differ from their functional currencies.

Assets and liabilities are first remeasured from local currency to functional currency, generally using end-of-period exchange rates. Foreign currency income and expenses are generally remeasured using average exchange rates in effect during the year. In the case of nonmonetary assets and liabilities such as inventories, prepaid expenses, property, plant and equipment, goodwill and other intangible assets, and related income statement amounts, such as depreciation expense, historical exchange rates are used for remeasurement. The net effect of remeasurement is included in Other (income) expense, net in the Consolidated Statements of Operations.

As part of the Company's consolidation process, assets and liabilities of entities with functional currencies other than the U.S. dollar are translated into U.S. dollars at end-of-period exchange rates. Income and expenses are translated using average exchange rates in effect during the year. The net effect of translation, as well as any foreign currency gains or losses on intercompany transactions considered to be of a long-term investment nature, are recognized as foreign currency translation, a component of Other comprehensive income. Upon the sale or liquidation of an investment in a foreign operation, the Company records a reclassification adjustment out of Other comprehensive income for the corresponding accumulated amount of foreign currency translation gain or loss.

Income Taxes. The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company records net deferred tax assets to the extent it believes these assets will more likely than not be realized. In making such a determination, the Company considers all available positive and negative evidence, including projected future taxable income, tax-planning strategies and results of recent operations. In the event that the Company were to determine that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income tax.

The Company records unrecognized income tax positions (UTPs) on the basis of a two-step process whereby the Company first determines whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position and then measures those tax positions that meet the more-likely-than-not recognition threshold. The Company recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the tax authority. The Company recognizes changes in UTPs, interest and penalties in the Income tax expense (benefit) line in the Consolidated Statements of Operations. The Company recognizes liabilities related to UTPs, including interest and penalties, in the Consolidated Balance Sheets as Accounts payable and accrued expenses (for any current portion) and/or Other liabilities (for any noncurrent portion).

Comprehensive Income. Comprehensive income or loss includes all changes in equity during a period except those that resulted from investments by or distributions to a company's shareholders. Other comprehensive income or loss refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to shareholders' equity.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Adopted or Otherwise Effective as of December 31, 2021

In June 2016, the Financial Accounting Standards Board (FASB) issued *ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments* (ASU 2016-13). ASU 2016-13, together with a series of subsequently-issued related ASUs, has been codified in ASC 326. ASC 326 establishes new requirements for companies to estimate expected credit losses when measuring certain financial assets, including accounts receivable. The Company adopted ASC 326 using a modified retrospective approach with an effective date of January 1, 2020. The adoption of ASC 326 did not have a material impact on the Company's Consolidated Financial Statements.

In November 2021, the FASB issued *ASU No. 2021-10, Disclosures by Business Entities about Government Assistance* (ASU 2021-10). ASU 2021-10 added *Accounting Standards Codification Topic 832, Government Assistance* (ASC 832), which requires annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The Company early adopted ASC 832 during the fourth quarter of 2021 and is complying with the related disclosure requirements.

NOTE 3. DISCONTINUED OPERATIONS

Astora

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 Consolidated Statements of Operations for all periods presented. The following table provides the operating results of Astora Discontinued operations, net of tax, for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Litigation-related and other contingencies, net	$ 25,000	$ 41,097	$ 30,400
Loss from discontinued operations before income taxes	$ (49,594)	$ (67,847)	$ (62,052)
Income tax benefit	$ (5,430)	$ (4,327)	$ —
Discontinued operations, net of tax	$ (44,164)	$ (63,520)	$ (62,052)

Loss from discontinued operations before income taxes includes Litigation-related and other contingencies, net, 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 $44.2 million, $63.5 million and $62.1 million for the years ended December 31, 2021, 2020 and 2019, 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.

Certain Assets and Liabilities of Endo's Retail Generics Business

In November 2020, we announced the initiation of several strategic actions to further optimize the Company's operations and increase overall efficiency, which are collectively referred to as the 2020 Restructuring Initiative and are further discussed in Note 4. Restructuring. These actions include an initiative to exit certain of our manufacturing and other sites to optimize our retail generics business cost structure. As part of this initiative, 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, to subsidiaries of Strides Pharma Science Limited (Strides) and certain other entities. These sales closed in the fourth quarter of 2021. As a result of these sales, we became entitled to aggregate cash consideration of approximately $25.6 million, substantially all of which has been received as of December 31, 2021, as well as certain non-cash consideration of approximately $5.8 million. The assets sold include certain of our manufacturing facilities and related fixed assets in Chestnut Ridge, New York and Irvine, California, as well as certain U.S. retail generics products and certain related product inventory. Under the terms of the agreements, the purchasers are providing Endo with certain contract manufacturing and other services on a transitional basis and Endo provided Strides with certain transitional services, which were substantially completed by the end of February 2022.

During 2021, these assets and liabilities first met the criteria to be classified as held for sale in the Consolidated Balance Sheets, at which time we ceased depreciating the related long-lived assets. We recognized a pre-tax disposal loss of $42.2 million in 2021 to write down the carrying amount of the disposal group to fair value, less cost to sell, which we recorded in Asset impairment charges in the Consolidated Statements of Operations. Additionally, in 2021, we recognized a net pre-tax reversal of $25.4 million of expense, primarily related to avoided severance costs for employees that transitioned to the purchasers in connection with the transactions summarized above. These amounts are included in the quantitative disclosures of the 2020 Restructuring Initiative included in Note 4. Restructuring.

As of December 31, 2021, the corresponding assets and liabilities, which were primarily part of the Company's Generic Pharmaceuticals segment, have been fully divested. These assets and liabilities did not meet the requirements for treatment as a discontinued operation.

NOTE 4. RESTRUCTURING

Set forth below are disclosures relating to any restructuring initiatives for which amounts recognized or cash expenditures during the years ended December 31, 2021, 2020 or 2019 were material or that had material restructuring liabilities at either December 31, 2021 or December 31, 2020.

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 active pharmaceutical ingredient manufacturing and bioequivalence study sites in India. Certain of the sites have already been exited as a result of the sale transactions that are further discussed in Note 3. Discontinued Operations and certain products historically manufactured at these sites have been transferred to other internal and external sites within the Company's manufacturing network. The remaining sites are currently expected to be exited by the second half of 2022; however, the ultimate timing remains uncertain.
- 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.

The amounts in this footnote related to the 2020 Restructuring Initiative include the sale transactions that are further discussed in Note 3. Discontinued Operations.

As a result of the 2020 Restructuring Initiative, the Company's global workforce is ultimately expected to be reduced by 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, which have been updated to reflect the effects of the sale transactions that are further discussed in Note 3. Discontinued Operations, 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. The Company anticipates these actions will be substantially completed by the end of 2022, with substantially all cash payments made by then.

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

	2021	2020
Net restructuring charges (charge reversals) related to:		
Accelerated depreciation	$ 24,718	$ 22,459
Asset impairments	42,155	7,391
Excess inventory reserves	6,968	3,097
Employee separation, continuity and other benefit-related costs	(7,384)	60,025
Certain other restructuring costs	2,012	664
Total	$ 68,469	$ 93,636

These pre-tax net amounts were primarily attributable to our Generic Pharmaceuticals segment, which incurred $49.9 million and $79.0 million of pre-tax net charges during the years ended December 31, 2021 and 2020, respectively. The remaining amounts related to our other segments and certain corporate unallocated costs.

As of December 31, 2021, cumulative amounts incurred to date include charges related to accelerated depreciation of approximately $47.2 million, asset impairments related to identifiable intangible assets, certain operating lease assets and the disposal group that is further discussed in Note 3. Discontinued Operations of approximately $49.5 million, excess inventory reserves of approximately $10.1 million, employee separation, continuity and other benefit-related costs, net of approximately $52.6 million and certain other restructuring costs of approximately $2.7 million. Of these amounts, approximately $128.8 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 Consolidated Statements of Operations during the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Net restructuring charges (charge reversals) included in:		
Cost of revenues	$ 6,244	$ 53,297
Selling, general and administrative	20,788	27,857
Research and development	1,367	5,091
Asset impairment charges	42,155	7,391
Other (income) expense, net	(2,085)	—
Total	$ 68,469	$ 93,636

Changes to the liability for the 2020 Restructuring Initiative during the years ended December 31, 2021 and 2020 were as follows (in thousands):

	Employee Separation, Continuity and Other Benefit-Related Costs	Certain Other Restructuring Costs	Total
Liability balance as of December 31, 2019	$ —	$ —	$ —
Net charges	60,025	664	60,689
Cash payments	(1,687)	—	(1,687)
Liability balance as of December 31, 2020	$ 58,338	$ 664	$ 59,002
Net (charge reversals) charges	(7,384)	3,711	(3,673)
Cash payments	(39,975)	(4,170)	(44,145)
Liability balance as of December 31, 2021	$ 10,979	$ 205	$ 11,184

Of the liability at December 31, 2021, approximately $10.6 million is classified as current and is included in Accounts payable and accrued expenses in the Consolidated Balance Sheets, with the remaining amount classified as noncurrent and included in Other liabilities.

NOTE 5. ACQUISITIONS

BioSpecifics Acquisition

On October 19, 2020, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Beta Acquisition Corp., a Delaware corporation and wholly-owned indirect subsidiary of the Company (Merger Sub) and BioSpecifics. Pursuant to the Merger Agreement, and on the terms and subject to the conditions thereof, Merger Sub commenced a tender offer (the Offer) on November 2, 2020 to acquire all of BioSpecifics' issued and outstanding shares of common stock (BioSpecifics Shares) at a purchase price of $88.50 per BioSpecifics Share (Offer Price), net to the holder thereof in cash, subject to reduction for any applicable withholding taxes and without interest.

Through the expiration of the Offer on December 1, 2020, approximately 6,159,975 BioSpecifics Shares were validly tendered and not validly withdrawn in accordance with the terms of the Offer. With all conditions to the Offer satisfied, on December 2, 2020, Merger Sub accepted for purchase all of the BioSpecifics Shares that were validly tendered and not validly withdrawn in accordance with the terms of the Offer.

Following consummation of the Offer, on December 2, 2020, Merger Sub merged with and into BioSpecifics (the Merger) in accordance with Section 251(h) of the Delaware General Corporation Law without a vote on the adoption of the Merger Agreement by BioSpecifics' stockholders, with BioSpecifics continuing as the surviving corporation in the Merger and thereby becoming a wholly-owned, indirect subsidiary of the Company.

As a result of the Merger, the BioSpecifics Shares ceased to be traded on the Nasdaq, effective as of market open on December 2, 2020.

Prior to the Merger, BioSpecifics was a biopharmaceutical company involved in the development of injectable CCH that generated revenue primarily from its license agreement with us. We had a strategic relationship with BioSpecifics since 2004 pursuant to which BioSpecifics was, among other things, entitled to a royalty stream from us related to our collagenase-based therapies, including XIAFLEX® and QWO®. Subsequent to the acquisition, BioSpecifics became our wholly-owned consolidated subsidiary.

The operating results of BioSpecifics are included in the accompanying Consolidated Statements of Operations from December 2, 2020 and the assets and liabilities of BioSpecifics are included in the Consolidated Balance Sheets as of December 31, 2021 and 2020. Additionally, beginning in December 2020, the BioSpecifics acquisition had the effect of reducing royalty payments recognized in Cost of revenues. The BioSpecifics acquisition also eliminates certain milestones and royalties we may otherwise have been required to pay for potential future indications of products or product candidates containing CCH, including those associated with our plantar fibromatosis and adhesive capsulitis development programs.

The acquired set of BioSpecifics assets and activities did not meet the definition of a business based on our assessment that the acquired set of activities lacks substantive processes that significantly contribute to the conversion of inputs into outputs. As a result, we accounted for the transaction as an asset acquisition. The consideration transferred in the asset acquisition was measured at cost, including transaction costs, assets transferred by the Company and royalty obligations discharged by the seller. The following table represents the costs accumulated to acquire BioSpecifics (in thousands):

	December 2, 2020
Base purchase price (1)	$ 650,029
Vested employee options and benefits (2)	10,280
Transaction costs	10,268
Less: royalty obligations discharged (3)	(14,909)
Total acquisition consideration	$ 655,668

(1) Represents cash consideration paid for 6,159,975 shares tendered and 1,184,980 remaining shares not tendered, but automatically cancelled and funded in an escrow account.

(2) In accordance with BioSpecifics' stock plan and employment arrangements, certain unvested options and employee bonus compensation immediately vested and accelerated, with no future service requirement, upon change in control. We have accounted for the accelerated vestings as a component of consideration transferred.

(3) Represents the total reduction to the base purchase price for the pre-acquisition accrued and unpaid royalty liability discharged on the date of closing.

The following table summarizes the allocation of consideration transferred on a relative fair value basis to identifiable tangible and intangible assets and other information about the assets and liabilities acquired at the BioSpecifics acquisition date (in thousands):

	December 2, 2020
Cash and cash equivalents	$ 21,073
Investments (1)	89,050
Intangible assets—developed technology	673,796
Intangible assets—in-process research and development	28,602
Other acquired assets	3,089
Deferred tax liability	(156,441)
Other assumed liabilities	(3,501)
Net identifiable assets acquired	$ 655,668

(1) Investments acquired primarily consisted of debt securities acquired from BioSpecifics on December 2, 2020. Investments acquired were fully liquidated prior to December 31, 2020. No material gains or losses were recognized upon liquidation.

The in-process research and development assets noted in the table above were expensed on the acquisition date and are included in Research and development in the Consolidated Statements of Operations. The Company concluded that the consideration allocable to developed technology acquired represented incremental costs associated with the Company's existing XIAFLEX® and QWO® intangible assets (the Existing Intangible Assets). The Existing Intangible Assets were acquired by the Company as part of its acquisition of Auxilium Pharmaceuticals, Inc. (Auxilium), accounted for as a business combination at fair value during 2015. Auxilium had a pre-existing development and license agreement with BioSpecifics. The following table summarizes changes to the gross carrying amount, accumulated amortization and net book amount of the Existing Intangible Assets and the new intangible assets resulting from the BioSpecifics acquisition (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Book Amount
Asset balances immediately prior to BioSpecifics acquisition	$ 1,580,600	$ (725,123)	$ 855,477
Additional costs incurred in connection with BioSpecifics acquisition	673,796	—	673,796
Asset balances immediately following BioSpecifics acquisition	$ 2,254,396	$ (725,123)	$ 1,529,273

Prior to the BioSpecifics acquisition, the Company had been amortizing the Existing Intangible Assets over their respective useful lives, which are the periods over which the assets are expected to contribute directly or indirectly to the future cash flows of the Company. The BioSpecifics acquisition significantly impacted the timing and amount of estimated future cash flows from sales of XIAFLEX® and QWO® and, therefore, the Company considered the acquisition to be a triggering event to remeasure the expected useful lives of the XIAFLEX® and QWO® intangible assets. Following the BioSpecifics acquisition, the Company determined that the weighted average useful life for the XIAFLEX® and QWO® intangible assets was approximately 13.6 years from the closing date of the BioSpecifics acquisition and, accordingly, the intangible assets will be amortized prospectively on a straight-line basis over their revised useful lives, which approximate the periods of economic benefits expected to be realized from future cash flows from sales of XIAFLEX® and QWO®.

NOTE 6. 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 from continuing operations before income tax and before certain upfront and milestone payments to partners; 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. 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 years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Net revenues from external customers:			
Branded Pharmaceuticals	$ 893,617	$ 781,780	$ 855,402
Sterile Injectables	1,266,097	1,238,847	1,063,131
Generic Pharmaceuticals	740,586	783,110	879,882
International Pharmaceuticals (1)	92,906	99,337	115,949
Total net revenues from external customers	$ 2,993,206	$ 2,903,074	$ 2,914,364
Segment adjusted income from continuing operations before income tax:			
Branded Pharmaceuticals	$ 384,186	$ 377,526	$ 426,677
Sterile Injectables	998,453	950,145	780,799
Generic Pharmaceuticals	160,046	87,178	159,716
International Pharmaceuticals	30,325	41,022	44,758
Total segment adjusted income from continuing operations before income tax	$ 1,573,010	$ 1,455,871	$ 1,411,950

(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 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 years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Total consolidated loss from continuing operations before income tax	$ (546,603)	$ (26,518)	$ (344,904)
Interest expense, net	562,353	532,939	538,734
Corporate unallocated costs (1)	180,866	157,723	168,136
Amortization of intangible assets	372,907	427,543	543,862
Upfront and milestone payments to partners (2)	26,451	35,075	6,623
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (3)	90,912	126,282	34,598
Certain litigation-related and other contingencies, net (4)	345,495	(19,049)	11,211
Certain legal costs (5)	136,148	67,819	65,282
Asset impairment charges (6)	414,977	120,344	526,082
Acquisition-related and integration items, net (7)	(8,379)	16,549	(46,098)
Loss (gain) on extinguishment of debt	13,753	—	(119,828)
Foreign currency impact related to the remeasurement of intercompany debt instruments	797	1,919	4,362
Other, net (8)	(16,667)	15,245	23,890
Total segment adjusted income from continuing operations before income tax	$ 1,573,010	$ 1,455,871	$ 1,411,950

(1) Amounts include certain corporate overhead costs, such as headcount, facility and corporate litigation expenses and certain other income and expenses.
(2) Amounts in 2021 primarily relate to upfront payments associated with certain license agreements. Amounts in 2020 include a $28.6 million charge related to in-process research and development assets expensed in connection with the acquisition of BioSpecifics.
(3) Amounts in 2021 include net employee separation, continuity and other benefit-related charges of $8.8 million, accelerated depreciation charges of $24.7 million and other net charges, including those related to strategic review initiatives, of $57.4 million. Amounts in 2020 include net employee separation, continuity and other benefit-related charges of $86.9 million, accelerated depreciation charges of $22.5 million and other net charges, including those related to strategic review initiatives, of $16.9 million. Amounts in 2019 include net employee separation, continuity and other benefit-related charges of $23.6 million and other net charges, including those related to strategic review initiatives, of $11.0 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.
(4) 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 16. Commitments and Contingencies.
(5) Amounts relate to opioid-related legal expenses.

(6) Amounts primarily relate to charges to impair goodwill and intangible assets, property, plant and equipment, operating lease right-of-use assets and certain disposal group assets. For additional information, refer to Note 3. Discontinued Operations, Note 4. Restructuring, Note 7. Fair Value Measurements, Note 9. Leases, Note 10. Property, Plant and Equipment and Note 11. Goodwill and Other Intangibles.

(7) Amounts primarily relate to changes in the fair value of contingent consideration.

(8) Amounts in 2021 include gains of $15.5 million associated with the termination of certain contracts, partially offset by $3.9 million of third party fees incurred in connection with the March 2021 Refinancing Transactions, which were accounted for as debt modification costs as further discussed in Note 15. Debt. Amounts in 2020 include $31.1 million of third party fees incurred in connection with the June 2020 Refinancing Transactions, which were accounted for as debt modification costs as further discussed in Note 15. Debt. Amounts in 2019 include $17.5 million for contract termination costs incurred as a result of certain product discontinuation activities in our International Pharmaceuticals segment and $14.1 million for a premium associated with an extended reporting period endorsement on an expiring insurance program. Other amounts in this row primarily relate to gains or losses on sales of businesses and other assets, as further described in Note 20. Other (Income) Expense, Net.

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 years ended December 31, 2021, 2020 and 2019, 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.

	2021	2020	2019
Branded Pharmaceuticals:			
Specialty Products:			
XIAFLEX®	$ 432,344	$ 316,234	$ 327,638
SUPPRELIN® LA	114,374	88,182	86,797
Other Specialty (1)	86,432	92,662	105,241
Total Specialty Products	$ 633,150	$ 497,078	$ 519,676
Established Products:			
PERCOCET®	$ 103,788	$ 110,112	$ 116,012
TESTOPEL®	43,636	35,234	55,244
Other Established (2)	113,043	139,356	164,470
Total Established Products	$ 260,467	$ 284,702	$ 335,726
Total Branded Pharmaceuticals (3)	$ 893,617	$ 781,780	$ 855,402
Sterile Injectables:			
VASOSTRICT®	$ 901,735	$ 785,646	$ 531,737
ADRENALIN®	124,630	152,074	179,295
Other Sterile Injectables (4)	239,732	301,127	352,099
Total Sterile Injectables (3)	$ 1,266,097	$ 1,238,847	$ 1,063,131
Total Generic Pharmaceuticals (5)	$ 740,586	$ 783,110	$ 879,882
Total International Pharmaceuticals (6)	$ 92,906	$ 99,337	$ 115,949
Total revenues, net	$ 2,993,206	$ 2,903,074	$ 2,914,364

(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 year ended December 31, 2021 and/or any product having revenues in excess of $25 million during any quarterly period in 2021 or 2020.

(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 year ended December 31, 2019, colchicine tablets (the authorized generic of Takeda Pharmaceuticals U.S.A., Inc.'s Colcrys®) made up 6% 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.

The following represents depreciation expense for our reportable segments for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Branded Pharmaceuticals	$ 10,632	$ 11,758	$ 12,573
Sterile Injectables	17,796	17,400	14,287
Generic Pharmaceuticals	47,343	52,614	32,689
International Pharmaceuticals	4,242	4,530	4,234
Corporate unallocated	4,178	4,962	5,217
Total depreciation expense	$ 84,191	$ 91,264	$ 69,000

NOTE 7. 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 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 Consolidated Balance Sheets primarily relate to litigation-related matters, including approximately $78.4 million and $127.0 million held in QSFs for mesh-related matters at December 31, 2021 and December 31, 2020, respectively. See Note 16. Commitments and Contingencies for further information about mesh-related and other litigation-related matters. Additionally, at December 31, 2021 and December 31, 2020, approximately $45.0 million and $25.0 million, respectively, 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 December 31, 2021 and December 31, 2020 were as follows (in thousands):

	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

	Fair Value Measurements at December 31, 2020 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
Assets:				
Money market funds	$ 214,120	$ —	$ —	$ 214,120
Liabilities:				
Acquisition-related contingent consideration—current	$ —	$ —	$ 8,566	$ 8,566
Acquisition-related contingent consideration—noncurrent	$ —	$ —	$ 27,683	$ 27,683

At December 31, 2021 and December 31, 2020, money market funds include $16.2 million and $26.5 million, respectively, in QSFs to be disbursed to mesh-related or other product liability claimants. Amounts in QSFs are considered restricted cash equivalents. See Note 16. Commitments and Contingencies for further discussion of our product liability cases. At December 31, 2021 and December 31, 2020, 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 years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Beginning of period	$ 36,249	$ 29,657
Amounts settled	(7,449)	(9,885)
Changes in fair value recorded in earnings	(8,793)	16,353
Effect of currency translation	69	124
End of period	$ 20,076	$ 36,249

At December 31, 2021, 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 10.9%, weighted based on relative fair value). Changes in fair value recorded in earnings related to acquisition-related contingent consideration are included in our 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 Consolidated Balance Sheets.

The following table presents changes to the Company's liability for acquisition-related contingent consideration during the year ended December 31, 2021 by acquisition (in thousands):

	Balance as of December 31, 2020	Changes in Fair Value Recorded in Earnings	Amounts Settled and Other	Balance as of December 31, 2021
Auxilium acquisition	$ 14,484	$ (3,471)	$ (1,975)	$ 9,038
Lehigh Valley Technologies, Inc. acquisitions	13,100	(6,061)	(3,439)	3,600
Other	8,665	739	(1,966)	7,438
Total	$ 36,249	$ (8,793)	$ (7,380)	$ 20,076

The following table presents changes to the Company's liability for acquisition-related contingent consideration during the year ended December 31, 2020 by acquisition (in thousands):

	Balance as of December 31, 2019	Changes in Fair Value Recorded in Earnings	Amounts Settled and Other	Balance as of December 31, 2020
Auxilium acquisition	$ 13,207	$ 2,921	$ (1,644)	$ 14,484
Lehigh Valley Technologies, Inc. acquisitions	6,800	12,337	(6,037)	13,100
Other	9,650	1,095	(2,080)	8,665
Total	$ 29,657	$ 16,353	$ (9,761)	$ 36,249

Nonrecurring Fair Value Measurements

The Company's financial assets and liabilities measured at fair value on a nonrecurring basis during the years ended December 31, 2021 and 2020 were as follows (in thousands):

	Fair Value Measurements during the Year Ended December 31, 2021 (1) using:			Total Expense for the Year Ended December 31, 2021
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	
Intangible assets, excluding goodwill (2)(3)	$ —	$ —	$ 5,011	$ (7,811)
Certain property, plant and equipment	—	—	—	(2,011)
Total	$ —	$ —	$ 5,011	$ (9,822)

	Fair Value Measurements during the Year Ended December 31, 2020 (1) using:			Total Expense for the Year Ended December 31, 2020
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	
Intangible assets, excluding goodwill (2)(3)	$ —	$ —	$ 15,463	$ (79,917)
Certain property, plant and equipment	—	—	—	(1,249)
Operating lease right-of-use assets	—	—	—	(6,392)
Total	$ —	$ —	$ 15,463	$ (87,558)

(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) For 2021, these fair value measurements were determined using risk-adjusted discount rates ranging from 10.0% to 12.0% (weighted average rate of approximately 11.1%, weighted based on relative fair value). For 2020, these fair value measurements were determined using risk-adjusted discount rates ranging from 10.0% to 12.0% (weighted average rate of approximately 11.3%, weighted based on relative fair value).

(3) The Company also performed fair value measurements in connection with its goodwill impairment tests. Refer to Note 11. Goodwill and Other Intangibles for additional information on goodwill and other intangible asset impairment tests, including information about the valuation methodologies used.

NOTE 8. INVENTORIES

Inventories consist of the following at December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021	December 31, 2020
Raw materials (1)	$ 90,453	$ 99,495
Work-in-process (1)	82,728	98,753
Finished goods (1)	110,371	154,012
Total	$ 283,552	$ 352,260

(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 December 31, 2021 and December 31, 2020, $10.7 million and $13.2 million, respectively, of noncurrent inventory was included in Other assets in the Consolidated Balance Sheets. As of December 31, 2021 and December 31, 2020, the Company's Consolidated Balance Sheets included approximately $12.2 million and $37.5 million, respectively, of capitalized pre-launch inventories related to products that were not yet available to be sold.

NOTE 9. LEASES

We have entered into contracts with third parties to lease a variety of assets, including certain real estate, machinery, equipment, automobiles and other assets.

Our leases frequently allow for lease payments that could vary based on factors such as inflation or the degree of utilization of the underlying asset and the incurrence of contractual charges such as those for common area maintenance or utilities.

Renewal and/or early termination options are common in our lease arrangements, particularly with respect to our real estate leases. Our right-of-use assets and lease liabilities generally exclude periods covered by renewal options and include periods covered by early termination options (based on our conclusion that it is not reasonably certain that we will exercise such options).

Our most significant lease is for our Malvern, Pennsylvania location. The initial term of the lease is through 2024 and includes three renewal options, each for an additional 60-month period. These renewal options are not considered reasonably certain of exercise and are therefore excluded from the right-of-use asset and lease liability.

We are party to certain sublease arrangements, primarily related to our real estate leases, where we act as the lessee and intermediate lessor. For example, we sublease portions of our Malvern, Pennsylvania facility to multiple tenants through sublease arrangements ending in 2024, with certain limited renewal and early termination options.

The following table presents information about the Company's right-of-use assets and lease liabilities at December 31, 2021 and December 31, 2020 (in thousands):

	Balance Sheet Line Items	December 31, 2021	December 31, 2020
Right-of-use assets:			
Operating lease right-of-use assets	Operating lease assets	$ 34,832	$ 37,030
Finance lease right-of-use assets	Property, plant and equipment, net	38,365	47,549
Total right-of-use assets		$ 73,197	$ 84,579
Operating lease liabilities:			
Current operating lease liabilities	Current portion of operating lease liabilities	$ 10,992	$ 11,613
Noncurrent operating lease liabilities	Operating lease liabilities, less current portion	33,727	38,132
Total operating lease liabilities		$ 44,719	$ 49,745
Finance lease liabilities:			
Current finance lease liabilities	Accounts payable and accrued expenses	$ 6,841	$ 6,227
Noncurrent finance lease liabilities	Other liabilities	18,374	25,027
Total finance lease liabilities		$ 25,215	$ 31,254

The following table presents information about lease costs and expenses and sublease income for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Statement of Operations Line Items	2021	2020	2019
Operating lease cost	Various (1)	$ 13,892	$ 14,175	$ 13,648
Finance lease cost:				
Amortization of right-of-use assets	Various (1)	$ 9,244	$ 9,244	$ 9,407
Interest on lease liabilities	Interest expense, net	$ 1,480	$ 1,716	$ 1,986
Other lease costs and income:				
Variable lease costs (2)	Various (1)	$ 13,202	$ 10,305	$ 9,653
Operating lease right-of-use asset impairment charges	Asset impairment charges	$ —	$ 6,392	$ —
Sublease income	Various (1)	$ (3,793)	$ (3,803)	$ (3,689)

(1) Amounts are included in the 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 years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Cost of revenues	$ 11,316	$ 11,610	$ 11,168
Selling, general and administrative	$ 21,013	$ 18,108	$ 17,648
Research and development	$ 216	$ 203	$ 203

(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 the undiscounted amount of future cash flows included in our lease liabilities at December 31, 2021 for each of the five years subsequent to December 31, 2021 and thereafter, as well as a reconciliation of such undiscounted cash flows to our lease liabilities at December 31, 2021 (in thousands):

	Operating Leases	Finance Leases
2022	$ 13,150	$ 7,738
2023	12,217	7,892
2024	6,760	8,049
2025	5,103	907
2026	5,151	907
Thereafter	9,959	11,187
Total future lease payments	$ 52,340	$ 36,680
Less: amount representing interest	7,621	11,465
Present value of future lease payments (lease liability)	$ 44,719	$ 25,215

The following table provides the weighted average remaining lease term and weighted average discount rates for our leases as of December 31, 2021 and December 31, 2020:

	December 31, 2021	December 31, 2020
Weighted average remaining lease term (years), weighted based on lease liability balances:		
Operating leases	5.1 years	5.1 years
Finance leases	9.5 years	9.5 years
Weighted average discount rate (percentages), weighted based on the remaining balance of lease payments:		
Operating leases	5.9 %	5.9 %
Finance leases	7.6 %	5.6 %

The following table provides certain cash flow and supplemental noncash information related to our lease liabilities for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash payments for operating leases	$ 14,478	$ 14,598	$ 14,940
Operating cash payments for finance leases	$ 2,256	$ 2,666	$ 2,000
Financing cash payments for finance leases	$ 5,448	$ 4,884	$ 9,196
Lease liabilities arising from obtaining right-of-use assets:			
Operating leases (1)	$ 5,807	$ —	$ 623
Finance leases	$ —	$ —	$ 5,953

(1) The amount in 2021 primarily relates to an increase in lease liabilities and right-of-use assets related to a lease modification.

NOTE 10. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net consists of the following at December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021	December 31, 2020
Land and buildings	$ 234,219	$ 291,212
Machinery and equipment	206,971	275,846
Leasehold improvements	55,020	74,506
Computer equipment and software	118,959	126,437
Furniture and fixtures	11,939	13,886
Assets under construction	120,483	84,759
Total property, plant and equipment, gross	$ 747,591	$ 866,646
Less: accumulated depreciation	(350,879)	(408,175)
Total property, plant and equipment, net	$ 396,712	$ 458,471

Depreciation expense was $84.2 million, $91.3 million and $69.0 million for the years ended December 31, 2021, 2020 and 2019, respectively. During the years ended December 31, 2021, 2020 and 2019, the Company recorded property, plant and equipment impairment charges totaling $2.0 million, $1.2 million and $6.5 million, respectively. These charges are included in the Asset impairment charges line item in our Consolidated Statement of Operations and primarily reflect the write-off of certain property, plant and equipment. Additionally, the balances at December 31, 2021 reflect reductions compared to December 31, 2020 related to the sale transactions that are further discussed in Note 3. Discontinued Operations.

At December 31, 2021 and December 31, 2020, $162.1 million and $141.4 million of the Company's Property, plant and equipment, representing net book amounts, were located in India. At December 31, 2021 and December 31, 2020, there were no other material tangible long-lived assets located outside of the U.S., individually or in the aggregate.

NOTE 11. GOODWILL AND OTHER INTANGIBLES

Goodwill

Changes in the carrying amounts of our goodwill for the years ended December 31, 2021 and December 31, 2020 were as follows (in thousands):

	Branded Pharmaceuticals	Sterile Injectables	Generic Pharmaceuticals	International Pharmaceuticals	Total
Goodwill as of December 31, 2019	$ 828,818	$ 2,731,193	$ —	$ 35,173	$ 3,595,184
Effect of currency translation	—	—	—	(2,387)	(2,387)
Goodwill impairment charges	—	—	—	(32,786)	(32,786)
Goodwill as of December 31, 2020	$ 828,818	$ 2,731,193	$ —	$ —	$ 3,560,011
Goodwill impairment charges	—	(363,000)	—	—	(363,000)
Goodwill as of December 31, 2021	$ 828,818	$ 2,368,193	$ —	$ —	$ 3,197,011

The carrying amounts of goodwill at December 31, 2021 and December 31, 2020 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, 2020	$ 855,810	$ —	$ 3,142,657	$ 546,251	$ 4,544,718
Accumulated impairment losses as of December 31, 2021	$ 855,810	$ 363,000	$ 3,142,657	$ 550,355	$ 4,911,822

Other Intangible Assets

Changes in the amounts of other intangible assets for the year ended December 31, 2021 are set forth in the table below (in thousands). This table excludes changes related to assets classified as held for sale to the extent such changes occurred after the assets were classified as held for sale.

Cost basis:	Balance as of December 31, 2020	Acquisitions	Impairments	Other (1)	Effect of Currency Translation	Balance as of December 31, 2021
Indefinite-lived intangibles:						
In-process research and development	$ 3,000	$ —	$ —	$ (3,000)	$ —	$ —
Total indefinite-lived intangibles	$ 3,000	$ —	$ —	$ (3,000)	$ —	$ —
Finite-lived intangibles:						
Licenses (weighted average life of 14 years)	$ 439,230	$ 4,177	$ (1,300)	$ —	$ —	$ 442,107
Tradenames	6,409	—	—	—	—	6,409
Developed technology (weighted average life of 11 years)	6,442,734	—	(6,511)	(212,043)	1,959	6,226,139
Total finite-lived intangibles (weighted average life of 12 years)	$ 6,888,373	$ 4,177	$ (7,811)	$ (212,043)	$ 1,959	$ 6,674,655
Total other intangibles	$ 6,891,373	$ 4,177	$ (7,811)	$ (215,043)	$ 1,959	$ 6,674,655

Accumulated amortization:	Balance as of December 31, 2020	Amortization	Impairments	Other (1)	Effect of Currency Translation	Balance as of December 31, 2021
Finite-lived intangibles:						
Licenses	$ (415,193)	$ (4,739)	$ —	$ —	$ —	$ (419,932)
Tradenames	(6,409)	—	—	—	—	(6,409)
Developed technology	(3,728,963)	(368,168)	—	212,764	(1,124)	(3,885,491)
Total other intangibles	$ (4,150,565)	$ (372,907)	$ —	$ 212,764	$ (1,124)	$ (4,311,832)
Net other intangibles	$ 2,740,808					$ 2,362,823

(1) Amounts include: (i) reclassification adjustments of $3.0 million for certain developed technology intangible assets, previously classified as in-process research and development, that were placed in service during the year ended December 31, 2021; (ii) the transfer, during the third quarter of 2021, of certain developed technology intangible assets with a cost basis of $213.5 million and accumulated amortization of $211.2 million to assets held for sale, as further discussed in Note 3. Discontinued Operations; and (iii) the removal of certain fully amortized developed technology intangible assets.

Amortization expense for the years ended December 31, 2021, 2020 and 2019 totaled $372.9 million, $427.5 million and $543.9 million, respectively. Amortization expense is included in Cost of revenues in the Consolidated Statements of Operations. For intangible assets subject to amortization, estimated amortization expense for the five fiscal years subsequent to December 31, 2021 is as follows (in thousands):

2022	$ 357,119
2023	$ 314,955
2024	$ 280,325
2025	$ 258,660
2026	$ 230,644

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 for the Company's October 1, 2021, 2020 and 2019 annual goodwill and indefinite-lived intangible assets impairment tests ranged from 11.0% to 14.5%, from 10.0% to 15.0% and from 9.5% to 13.5%, respectively, 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 Consolidated Statements of Operations.

During the years ended December 31, 2021, 2020 and 2019, the Company incurred the following goodwill and other intangible asset impairment charges (in thousands):

	2021	2020	2019
Goodwill impairment charges	$ 363,000	$ 32,786	$ 171,908
Other intangible asset impairment charges	$ 7,811	$ 79,917	$ 347,706

Except as described below, pre-tax non-cash asset impairment charges related primarily to certain in-process research and development and/or developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability.

Annual Goodwill Impairment Tests

As a result of our annual tests performed as of October 1, 2021, the Company determined that the carrying amount of the Sterile Injectables reporting unit exceeded its estimated fair value; therefore, the Company recorded a pre-tax non-cash goodwill impairment charge of $363.0 million during the fourth quarter of 2021. The Sterile Injectables impairment was primarily a result of changes in assumptions related to competition, including assumptions related to competing generic alternatives to VASOSTRICT®, which were subsequently introduced beginning with Eagle's at-risk launch in January 2022.

As a result of our annual tests performed as of October 1, 2019, the Company determined that the carrying amount of the Paladin reporting unit exceeded its estimated fair value; therefore, the Company recorded a pre-tax non-cash goodwill impairment charge of $20.8 million during the fourth quarter of 2019. The Paladin impairment was primarily a result of certain anticipated product discontinuation activities. The impairment also reflects the estimated impact of Canadian pricing regulations that were issued in the second half of 2019.

We did not record any other goodwill impairment charges as a result of our October 1, 2021, 2020 and 2019 annual impairment tests.

Other Impairment Tests

As a result of certain business decisions that occurred during the first quarter of 2020, we tested the goodwill of our Paladin reporting unit for impairment as of March 31, 2020. The fair value of the reporting unit was estimated using an income approach that utilized a discounted cash flow model. The discount rate utilized in this test was 9.5%. This goodwill impairment test resulted in a pre-tax non-cash goodwill impairment charge of $32.8 million during the three months ended March 31, 2020, representing the remaining carrying amount. This impairment was primarily attributable to portfolio decisions and updated market expectations during the quarter.

As a result of certain competitive events that occurred during the first quarter of 2019, we tested the goodwill of our Generic Pharmaceuticals reporting unit for impairment as of March 31, 2019. The fair value of the reporting unit was estimated using an income approach that utilized a discounted cash flow model. The discount rate utilized in this test was 10.5%. This goodwill impairment test resulted in a pre-tax non-cash goodwill impairment charge of $86.0 million during the three months ended March 31, 2019, representing the excess of this reporting unit's carrying amount over its estimated fair value. This Generic Pharmaceuticals impairment can be primarily attributed to the impact of the competitive events referenced above and an increase in the discount rate used in the determination of fair value.

During the second quarter of 2019, unfavorable competitive and pricing events occurred that caused us to update certain assumptions from those used in our first-quarter 2019 Generic Pharmaceuticals goodwill impairment test. We considered these events, together with the fact that this reporting unit's carrying amount equaled its fair value immediately subsequent to the first-quarter 2019 goodwill impairment charge, as part of our qualitative assessment of goodwill triggering events for the second quarter of 2019. As a result, we concluded that it was more likely than not that the fair value of this reporting unit was below its carrying amount as of June 30, 2019 and a goodwill impairment test was required. After performing this quantitative test, we determined that this reporting unit's carrying amount exceeded its estimated fair value. The fair value of the reporting unit was estimated using an income approach that utilized a discounted cash flow model. The discount rate utilized in this test was 10.5%. Based on the excess of this reporting unit's carrying amount over its estimated fair value, we recorded a pre-tax non-cash goodwill impairment charge of $65.1 million during the three months ended June 30, 2019, representing the entire remaining amount of this reporting unit's goodwill.

NOTE 12. LICENSE AND COLLABORATION AGREEMENTS

Our subsidiaries have entered into certain license, collaboration and discovery agreements with third parties for product development. These agreements require our subsidiaries to share in the development costs of such products and the third parties grant marketing rights to our subsidiaries for such products.

Generally, under these agreements: (i) we are required to make upfront payments and other payments upon successful completion of regulatory or sales milestones and/or (ii) we are required to pay royalties on sales of the products arising from these agreements.

BioSpecifics

Until the acquisition of BioSpecifics in December 2020, the Company, through an affiliate, was party to a development and license agreement, as amended (the BioSpecifics License Agreement) with BioSpecifics. The BioSpecifics License Agreement was originally entered into in June 2004 to obtain exclusive worldwide rights to develop, market and sell certain products containing BioSpecifics' enzyme CCH. The Company's licensed rights concerned the development and commercialization of products, other than dermal formulations labeled for topical administration, including the indications of DC, Dupuytren's nodules, PD, adhesive capsulitis, cellulite, plantar fibromatosis, lateral hip fat and other potential indications.

Until the acquisition of BioSpecifics in December 2020, we were required to, among other things, pay BioSpecifics on a country-by-country and product-by-product basis a specified percentage within a range of 5% to 15% of net sales for products covered by the BioSpecifics License Agreement. This royalty applied to net sales by the Company and/or any of its sublicensees. In addition, the Company and its affiliates were required to pay BioSpecifics an amount equal to a specified mark-up on certain cost of goods related to supply of XIAFLEX® (which mark-up was capped at a specified percentage within the range of 5% to 15% of the cost of goods of XIAFLEX®) for products sold by the Company and its affiliates.

In December 2020, we acquired BioSpecifics, which eliminated this third-party relationship. See Note 5. Acquisitions for further discussion of the BioSpecifics acquisition.

NOTE 13. 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 December 31, 2021, 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):

	December 31, 2021	December 31, 2020	$ Change	% Change
Contract assets, net (1)	$ 13,005	$ 13,525	$ (520)	(4)%
Contract liabilities, net (2)	$ 4,663	$ 6,028	$ (1,365)	(23)%

(1) At December 31, 2021 and December 31, 2020, approximately $2.8 million and $3.2 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 Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other assets.

(2) At December 31, 2021 and December 31, 2020, approximately $0.6 million and $1.4 million, respectively, of these contract liability amounts are classified as current and are included in Accounts payable and accrued expenses in the Company's Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other liabilities. During the year ended December 31, 2021, approximately $0.6 million of revenue was recognized that was included in the contract liability balance at December 31, 2020.

During the year ended December 31, 2021, we recognized revenue of $23.9 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 14. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021	December 31, 2020
Trade accounts payable	$ 123,129	$ 94,408
Returns and allowances	183,116	207,916
Rebates	150,039	126,644
Chargebacks	2,617	2,177
Other sales deductions	2,500	—
Accrued interest	106,735	98,105
Accrued payroll and related benefits	90,029	130,092
Accrued royalties and other distribution partner payables	58,422	59,745
Acquisition-related contingent consideration—current	5,748	8,566
Other	114,563	108,287
Total	$ 836,898	$ 835,940

NOTE 15. DEBT

The following table presents information about the Company's total indebtedness at December 31, 2021 and December 31, 2020 (dollars in thousands):

	December 31, 2021			December 31, 2020		
	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	7.25 %	$ 8,294	$ 8,294
5.75% Senior Notes due 2022	5.75 %	172,048	172,048	5.75 %	172,048	172,048
5.375% Senior Notes due 2023	5.62 %	6,127	6,111	5.62 %	6,127	6,098
6.00% Senior Notes due 2023	6.28 %	56,436	56,203	6.28 %	56,436	56,063
5.875% Senior Secured Notes due 2024	6.14 %	300,000	297,928	6.14 %	300,000	297,267
6.00% Senior Notes due 2025	6.27 %	21,578	21,413	6.27 %	21,578	21,366
7.50% Senior Secured Notes due 2027	7.70 %	2,015,479	1,997,777	7.70 %	2,015,479	1,995,142
9.50% Senior Secured Second Lien Notes due 2027	9.68 %	940,590	933,330	9.68 %	940,590	932,395
6.00% Senior Notes due 2028	6.11 %	1,260,416	1,252,667	6.11 %	1,260,416	1,251,725
6.125% Senior Secured Notes due 2029	6.34 %	1,295,000	1,278,718		—	—
Term Loan Facility	6.12 %	1,985,000	1,947,633	5.21 %	3,295,475	3,274,330
Revolving Credit Facility	2.63 %	277,200	277,200	2.69 %	300,000	300,000
Total long-term debt, net		$ 8,338,168	$ 8,249,322		$ 8,376,443	$ 8,314,728
Less: current portion, net		200,342	200,342		34,150	34,150
Total long-term debt, less current portion, net		$ 8,137,826	$ 8,048,980		$ 8,342,293	$ 8,280,578

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 December 31, 2021. 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 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 $8.0 billion and $8.4 billion at December 31, 2021 and December 31, 2020, 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 (as defined below), 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 December 31, 2021 under the Credit Facilities are set forth in the table above. As of December 31, 2021, $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 December 31, 2021. 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 contains affirmative and negative covenants and events of default that the Company believes to be customary for a senior secured credit facility of this type. The negative covenants include, among other things, limitations on asset sales, mergers and acquisitions, indebtedness, liens, dividends and other restricted payments, investments and transactions with the Company's affiliates. As of December 31, 2021 and December 31, 2020, we were in compliance with all such covenants. The events of default include, among other things, non-payment of principal or interest, breach of covenants, certain bankruptcies, cross default with respect to certain debt having a principal amount in excess of $150.0 million and the entry of certain non-appealable judgments by a court for the payment of money in excess of $150.0 million (net of amounts covered by insurance) that have not been paid or discharged within certain specified time periods and during which time execution has not been stayed. The events of default are subject to certain grace periods, may require the administrative agent or lenders to take certain action to accelerate the outstanding loans and other secured obligations under the Credit Agreement and may be waived, cured or amended in a number of circumstances.

In addition, after each fiscal year-end, the Company is required to perform a calculation of Excess Cash Flow (as defined in the Credit Agreement), which could result in certain pre-payments of the outstanding loans under the Term Loan Facility in accordance with the terms of the Credit Agreement. No such payment is required at December 31, 2021.

The remaining commitments under the Revolving Credit Facility generally mature as follows: (i) approximately $248.7 million in March 2024 and (ii) approximately $675.3 million in March 2026.

Principal payments on the Term Loan Facility equal to 0.25% of the initial $2,000.0 million principal amount are generally payable quarterly, beginning on June 30, 2021 and extending until the Term Loan Facility's maturity date in March 2028 (which may spring to an earlier date as described below), at which time the remaining principal amount outstanding will be payable. The maturity date of the Term Loan Facility will be accelerated to: (i) December 2026, if the 7.50% Senior Secured Notes due 2027 have not been repaid or refinanced prior to the date that is 91 days prior to their April 1, 2027 maturity date and the related principal amount of such notes outstanding on such date is at least $500.0 million, or (ii) May 2027, if the 9.50% Senior Secured Second Lien Notes due 2027 have not been repaid or refinanced prior to the date that is 91 days prior to their July 31, 2027 maturity date and the related principal amount of such notes outstanding on such date is at least $500.0 million.

Borrowings under the Revolving Credit Facility bear interest, at the borrower's election, at a rate per annum equal to (i) an applicable margin between 1.50% and 3.00% depending on the Company's Total Net Leverage Ratio plus the Adjusted LIBO Rate (as defined in the Credit Agreement) or (ii) an applicable margin between 0.50% and 2.00% depending on the Company's Total Net Leverage Ratio plus the Alternate Base Rate (as defined in the Credit Agreement). In addition, borrowings under our Term Loan Facility bear interest, at the borrower's election, at a rate per annum equal to (i) 5.00% plus the Adjusted LIBO Rate, subject to a LIBOR floor of 0.75%, or (ii) 4.00% plus the Alternate Base Rate, subject to an Alternate Base Rate floor of 1.75%. Interest on these instruments is generally payable at the end of each interest period but at least every three months.

On November 29, 2021, in connection with the phase-out of LIBOR, the Company entered into a Suspension of Rights Agreement which, among other provisions, suspends the Company's ability to make non-USD currency borrowings under the Revolving Credit Facility until LIBOR is replaced with an alternative benchmark for such non-USD currency borrowings under the Credit Agreement.

Senior Notes and Senior Secured Notes

Our various senior notes and senior secured notes outstanding as of December 31, 2021 mature between 2022 and 2029. Interest on these notes is generally payable semiannually in arrears. The indentures governing these notes generally allow for redemption prior to maturity, in whole or in part, subject to certain restrictions and limitations described therein, in the following ways:

- Until a date specified in each indenture (the Non-Call Period), the notes may be redeemed, in whole or in part, by paying the sum of: (i) 100% of the principal amount being redeemed, (ii) an applicable make-whole premium as described in each indenture and (iii) accrued and unpaid interest to, but excluding, the redemption date. As of December 31, 2021, the Non-Call Period has expired for each of our notes except for the 7.50% Senior Secured Notes due 2027 (expires April 1, 2022), the 9.50% Senior Secured Second Lien Notes due 2027 (expires July 31, 2023), the 6.00% Senior Notes due 2028 (expires June 30, 2023) and the 6.125% Senior Secured Notes due 2029 (expires April 1, 2024).
- After the Non-Call Period specified in each indenture, the notes may be redeemed, in whole or in part, at redemption prices set forth in each indenture, plus accrued and unpaid interest to, but excluding, the redemption date. The redemption prices for each of our notes vary over time and generally decrease to 100% of the principal amount of the applicable notes as the notes approach maturity pursuant to a step-down schedule.
- Until a date specified in each indenture, the notes may be redeemed, in part (up to 35% or 40% of the principal amount outstanding as specified in each indenture), with the net cash proceeds from specified equity offerings at redemption prices set forth in each indenture, plus accrued and unpaid interest to, but excluding, the redemption date. As of December 31, 2021, this clause has expired for each of our notes except for the 7.50% Senior Secured Notes due 2027, the 9.50% Senior Secured Second Lien Notes due 2027, the 6.00% Senior Notes due 2028 and the 6.125% Senior Secured Notes due 2029, for which the specified redemption premiums are price plus the coupon.

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.

The indentures governing our various senior secured notes and the 6.00% Senior Notes due 2028 contain affirmative and negative covenants and events of default that the Company believes to be customary for similar indentures. Under these indentures, the negative covenants, among other things, restrict the Company's ability and the ability of its restricted subsidiaries (as defined in the indentures) to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; enter into sale and leaseback transactions; agree to certain restrictions on the ability of restricted subsidiaries to make certain payments to the Company or any of its restricted subsidiaries; create certain liens; merge, consolidate or sell all or substantially all of the Company's assets; enter into certain transactions with affiliates or designate subsidiaries as unrestricted subsidiaries. These covenants are subject to a number of exceptions and qualifications, including the fall away or revision of certain of these covenants and release of collateral in the case of the senior secured notes, upon the notes receiving investment grade credit ratings. At December 31, 2021 and December 31, 2020, we were in compliance with all covenants contained in the indentures governing our various senior notes and senior secured notes. Under these indentures, the events of default include, among other things, non-payment of principal or interest, breach of covenants, certain bankruptcies, failure to make any required payment at maturity on certain debt having a principal amount in excess of $150.0 million, or the acceleration of such debt, and the entry of certain judgments by a court for the payment of money in excess of $150.0 million (net of amounts covered by insurance or bonded) that have not been satisfied, stayed, rescinded or annulled or subject to certain other events within certain specified time periods. The events of default are subject to certain grace periods, may require the trustee or holders to take certain action to accelerate the notes and may be waived or amended in a number of circumstances.

Debt Financing Transactions

Set forth below are certain disclosures relating to debt financing transactions that occurred during the years ended December 31, 2021, 2020 and 2019.

March 2019 Refinancing

In March 2019, the Company executed certain transactions (the March 2019 Refinancing Transactions) that included:

- entry into an amendment (the Revolving Credit Facility Amendment) to the Prior Credit Agreement (as defined below);
- issuance of $1,500.0 million of 7.50% Senior Secured Notes due 2027;
- repurchase of $1,642.2 million aggregate principal amount ($1,624.0 million aggregate carrying amount) of certain of the Company's senior unsecured notes for $1,500.0 million in cash, excluding accrued interest (the Notes Repurchases); and
- solicitation of consents from the holders of the existing 7.25% Senior Notes due 2022 and 5.75% Senior Notes due 2022 to certain amendments to the indentures governing such notes, which eliminated substantially all of the restrictive covenants, certain events of default and other provisions contained in each such indenture.

The difference between the cash paid and the carrying amount of notes repurchased in the Notes Repurchases resulted in a $124.0 million gain. In connection with the March 2019 Refinancing Transactions, we also incurred costs and fees totaling $26.2 million, of which $4.2 million related to the Notes Repurchases, $19.1 million related to the 7.50% Senior Secured Notes due 2027 issuance and $2.9 million related to the Revolving Credit Facility Amendment. The costs incurred in connection with the Notes Repurchases were charged to expense in the first quarter of 2019 and recorded as a partial offset to the gain. The costs incurred in connection with the 7.50% Senior Secured Notes due 2027 issuance and the Revolving Credit Facility Amendment, together with previously deferred debt issuance costs associated with the Revolving Credit Facility, have been deferred to be amortized as interest expense over the terms of the respective instruments. The net gain resulting from the March 2019 Refinancing Transactions was included in the Loss (gain) on extinguishment of debt line item in the Consolidated Statements of Operations.

June 2019 Revolving Credit Facility Borrowing

In June 2019, the Company borrowed $300.0 million under the Revolving Credit Facility to be used for purposes consistent with the Company's capital allocation priorities, including for general corporate purposes.

June 2020 Refinancing

In June 2020, the Company executed certain transactions (the June 2020 Refinancing Transactions) that included, among other things, the exchanges by certain of the Company's wholly-owned subsidiaries of certain series of senior notes for certain newly issued senior secured notes and senior notes and $47.2 million in cash paid by the Company. The June 2020 Refinancing Transactions were accounted for as debt modifications. Following the June 2020 Refinancing Transactions, previously deferred and unamortized amounts associated with the old notes exchanged are now being amortized over the respective terms of the new notes. In connection with the June 2020 Refinancing Transactions, we incurred fees to third parties of approximately $31.1 million, substantially all of which were charged to expense during the second quarter of 2020 and were included in Selling, general and administrative expenses in the Consolidated Statements of Operations.

August 2020 Tender Offer

In August 2020, the Company repurchased and retired approximately $10 million aggregate principal of 5.75% Senior Notes due 2022 pursuant to a tender offer (the August 2020 Tender Offer).

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 6.125% Senior Secured Notes due 2029 were issued in March 2021 in a private offering to "qualified institutional buyers" (as defined in Rule 144A under the Securities Act) and outside the U.S. to non-U.S. persons in compliance with Regulation S under the Securities Act. These notes, along with the Company's other first lien obligations, are secured on a *pari passu* basis by a first priority lien on the collateral securing these notes. They are guaranteed on a senior secured basis by the Company and its subsidiaries that also guarantee the Credit Agreement and the Company's other senior secured notes. Interest on these notes is payable semiannually in arrears on April 1 and October 1 of each year, beginning on October 1, 2021. These notes will mature on April 1, 2029 but may be redeemed earlier, in whole or in part, subject to limitations as described in the indenture.

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 included in the Loss (gain) on extinguishment of debt line item in the 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 included in the Loss (gain) on extinguishment of debt line item in the 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 included in the Selling, general and administrative expense line item in the 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

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.

Maturities

The following table presents, as of December 31, 2021, the maturities on our long-term debt for each of the five fiscal years subsequent to December 31, 2021 (in thousands):

	Maturities (1)
2022	$ 200,342
2023	$ 82,563
2024 (2)	$ 394,600
2025	$ 41,578
2026 (2)	$ 222,600

(1) Per the terms of the Credit Agreement, certain amounts borrowed pursuant to the Credit Facilities could mature prior to their scheduled maturity date if certain of our senior notes are not refinanced or repaid prior to the date that is 91 days prior to the respective stated maturity dates thereof. Accordingly, we may seek to repay or refinance certain senior notes prior to their stated maturity dates or otherwise may be required to repay certain amounts borrowed pursuant to the Credit Facilities prior to their scheduled maturity dates. The amounts in this maturities table do not generally reflect any potential early repayments or refinancings, except for any that have already been triggered as of the date this report was issued. For additional information, refer to the discussion above under the heading "Credit Facilities."

(2) Based on the Company's borrowings under the Revolving Credit Facility that were outstanding at December 31, 2021, $74.6 million will mature in 2024, with the remainder maturing in 2026.

NOTE 16. COMMITMENTS AND CONTINGENCIES

Manufacturing, Supply and Other Service Agreements

Our subsidiaries contract with various third party manufacturers, suppliers and service providers to provide raw materials used in our subsidiaries' products and semi-finished and finished goods, as well as certain packaging, labeling services, customer service support, warehouse and distribution services. If, for any reason, we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products or services needed to conduct our business, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition to the manufacturing and supply agreements described above, we have agreements with various companies for clinical development and certain other services. Although we have no reason to believe that the parties to these agreements will not meet their obligations, failure by any of these third parties to honor their contractual obligations may have a material adverse effect on our business, financial condition, results of operations and cash flows.

U.S. Government Agreement

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. The U.S. Government Agreement is part of the U.S. government's efforts, authorized under the Defense Production Act, to address potential vulnerabilities in critical product supply chains and strengthen the advancement of domestic manufacturing capabilities critical to the national defense, including essential medicines production. Under the terms of the U.S. Government Agreement, our Rochester facility will establish new sterile fill-finish manufacturing assets capable of processing liquid or lyophilized products requiring Biosafety Level (BSL) 2 containment in order to establish and sustain BSL 2 sterile fill-finish production capacity to create and maintain industrial base capabilities for the national defense. Although subject to change, we currently expect that construction will begin in 2022 and that facility readiness will occur in early 2025.

Pursuant to the U.S. Government Agreement, we currently expect to incur estimated capital expenditures of approximately $120 million, of which approximately one-third is expected to be made in 2022. Because the grant is a cost reimbursement type award, the Company must generally incur the costs before subsequently seeking reimbursement of qualifying costs from the U.S. government. We currently expect that approximately $90 million will be reimbursed by the U.S. government under a cost share arrangement, generally within 30 days of us submitting requests for reimbursement. Amounts reimbursed are subject to audit and may be recaptured by the U.S. government in certain circumstances.

The new sterile fill-finish manufacturing assets will be available to support our future commercial operations, subject to the U.S. government's conditional priority access and certain preferred pricing obligations under the U.S. Government Agreement. The U.S. government will have conditional priority access to the facility for an initial period of ten years from the completion of the expansion project, which could be extended in the future after good faith negotiation and on commercially reasonable terms and conditions. Specifically, the U.S. government (or a third-party U.S. government supporting entity) will have priority access to utilize the new sterile fill-finish manufacturing assets for the production of a medical countermeasure if a determination is made in writing by the Secretary of the U.S. Department of Health and Human Services that the priority access is needed to respond to a disease, health condition or other threat to the public health that causes a public health emergency or a credible risk of such an emergency. The U.S. Government Agreement also contemplates the establishment of separate supply agreements to be negotiated in good faith on mutually-acceptable commercially reasonable terms.

Amounts included in our Consolidated Financial Statements as of and for the year ended December 31, 2021 were not material.

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 December 31, 2021, our accrual for loss contingencies totaled $581.0 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; (ii) various opioid-related matters as further described herein; and (iii) a settlement relating to the *Pelletier* securities case further described herein, which has been funded by the Company's insurers. 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. While the timing of the resolution of certain of the matters accrued for as loss contingencies remains uncertain and could extend beyond 12 months, as of December 31, 2021, the entire liability accrual amount is classified in the Current portion of legal settlement accrual in the Consolidated Balance Sheets.

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 POP and 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 December 31, 2021. 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 QSFs and mesh liability accrual balances during the year ended December 31, 2021 (in thousands):

	Qualified Settlement Funds	Mesh Liability Accrual
Balance as of December 31, 2020	$ 126,998	$ 330,921
Additional charges	—	25,000
Cash contributions to Qualified Settlement Funds	670	—
Cash distributions to settle disputes from Qualified Settlement Funds	(49,287)	(49,287)
Cash distributions to settle disputes	—	(47,360)
Other (1)	21	(1,137)
Balance as of December 31, 2021	$ 78,402	$ 258,137

(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 Consolidated Statements of Operations.

As of December 31, 2021, the Company has made total cumulative mesh liability payments of approximately $3.6 billion, $78.4 million of which remains in the QSFs as of December 31, 2021. 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 July 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 EHSI, EPI, PPI, PPCI, Endo Generics Holdings, Inc. (EGHI), Vintage Pharmaceuticals, LLC, Generics Bidco I, LLC, DAVA Pharmaceuticals, 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 February 21, 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 2,920 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 210 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; 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 EHSI, 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. The next trial is currently set for April 2022. 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, EHSI, 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, EHSI, 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, EHSI, 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; a hearing is currently scheduled for March 2022.

In February 2022, the court in *Dunaway, et al. v. Purdue Pharma, L.P., 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 *Dunaway* court also severed EPI and EHSI from the remaining defendants, set a damages trial to begin in April 2023 and 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.

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 during the years ended December 31, 2021, 2020 and 2019 include but are not limited 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, 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.

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 and Texas 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. Certain settlement agreements provide for the creation of QSFs into which the 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 may 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. As of December 31, 2021, no amounts had been deposited into the QSFs.

We recorded total charges for opioid-related matters of $343.5 million in 2021 and, as of December 31, 2021, our corresponding accrual totaled $258.7 million. In addition to the developments described above, our accrual for opioid-related matters as of December 31, 2021 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 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 oxymorphone 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, 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 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. Trial is currently scheduled for June 2022; however, the timing of trials is uncertain due to the impact of COVID-19 and other factors.

Beginning in February 2009, the 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. Trial is currently scheduled for 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, which the defendants, including PPI, moved to dismiss in February 2022.

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) constitutes unfair competition in violation of Section 5(a) of the FTC Act. The complaint generally seeks injunctive and equitable monetary relief. In April 2021, the defendants filed motions to dismiss, which remain pending.

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 November 2017, a putative class action entitled *Pelletier v. Endo International plc, Rajiv Kanishka Liyanaarchchie De Silva, Suketu P. Upadhyay and Paul V. Campanelli* was filed in the U.S. District Court for the Eastern District of Pennsylvania 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 pricing of various generic pharmaceutical products. In September 2018, the defendants filed a motion to dismiss, which the court granted in part and denied in part in February 2020. In particular, the court granted the motion and dismissed the claims with prejudice insofar as they were based on an alleged price-fixing conspiracy; the court otherwise denied the motion to dismiss, allowing other aspects of the lead plaintiff's claims to proceed. In May 2021, the court granted plaintiffs' motion for class certification, and in June 2021, defendants moved for summary judgment on certain grounds. In October 2021, while the motion for summary judgment was pending, the parties entered into a settlement providing for a payment of $63.4 million to the investor class in exchange for a release of their claims. The settlement was solely by way of compromise and settlement and was not in any way an admission of wrongdoing, fault or liability of any kind. As a result of the settlement, during the third quarter of 2021, the Company recorded: (i) an increase of approximately $63.4 million to its accrual for loss contingencies and (ii) a corresponding insurance receivable of approximately $63.4 million. The insurance receivable is recorded as Prepaid expenses and other current assets in the Consolidated Balance Sheets. In February 2022, the court approved the settlement and dismissed the action with prejudice as to the plaintiffs and all class members.

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 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.

VASOSTRICT® Related Matters

Beginning in April 2018, PSP LLC and PPI received notice letters from Eagle, Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent, Fresenius, Dr. Reddy's Laboratories, Inc., Aurobindo Pharma Limited and Gland Pharma Limited advising of the filing by such companies of ANDAs/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 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 competing generic alternatives to VASOSTRICT® were launched, beginning with Eagle's generic, which it launched at risk and began shipping toward the end of January 2022. Since then, additional competing alternatives have entered the market, including an authorized generic. We expect these launches to significantly impact both Endo's market share and product price beginning in the first quarter of 2022, and the effects of competition are likely 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 17. OTHER COMPREHENSIVE INCOME

During the years ended December 31, 2021, 2020 and 2019, 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 December 31, 2021 and December 31, 2020 consist of Foreign currency translation loss.

NOTE 18. SHAREHOLDERS' DEFICIT

The Company has issued 4,000,000 euro deferred shares of $0.01 each at par. The euro deferred shares are held by nominees in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro and to have at least seven registered shareholders. The euro deferred shares carry no voting rights and are not entitled to receive any dividend or distribution.

Effect of Change in Accounting Principle

As further discussed in Note 2. Summary of Significant Accounting Policies, the Company adopted ASC 842 on January 1, 2019. This adoption resulted in a net increase of $4.6 million to the Company's Accumulated deficit at January 1, 2019.

Share Repurchase Program

Pursuant to Article 11 of the Company's Articles of Association, the Company has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. The Company's authority to repurchase ordinary shares is subject to legal limitations and the existence of sufficient distributable reserves. For example, the Companies Act requires Irish companies to have distributable reserves equal to or greater than the amount of any proposed ordinary share repurchase amount. Unless we are able to generate sufficient distributable reserves or create distributable reserves by reducing our share premium account, we will not be able to repurchase our ordinary shares. As permitted by Irish Law and the Company's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption.

The Board has approved the 2015 Share Buyback Program that authorizes the Company to redeem, in the aggregate, $2.5 billion of its outstanding ordinary shares. To date, the Company has redeemed and cancelled approximately 4.4 million of its ordinary shares under the 2015 Share Buyback Program for $250.0 million, not including related fees.

NOTE 19. SHARE-BASED COMPENSATION

Stock Incentive Plans

In June 2015, the Company's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan), which has subsequently been amended, as approved by the Company's shareholders, on multiple occasions, including in 2019 and 2020. Under the 2015 Plan, stock options (including incentive stock options), stock appreciation rights, restricted stock awards, performance awards and other share- or cash-based awards may be issued at the discretion of the Compensation & Human Capital Committee of the Board from time to time. No ordinary shares are to be granted under previously approved plans, including the Company's 2000, 2004, 2007, 2010 and Assumed Stock Incentive Plans. Any awards previously granted and outstanding under these prior plans remain subject to the terms of those prior plans.

At December 31, 2021, approximately 9.3 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2021, stock options, restricted stock awards, PSUs, restricted stock units (RSUs), long-term cash incentive awards and certain other cash-based awards have been granted under the stock incentive plans.

Generally, the grant-date fair value of each award is recognized as expense over the requisite service period. However, expense recognition differs in the case of certain PSUs where the ultimate payout is performance-based. For these awards, at each reporting period, the Company estimates the ultimate payout and adjusts the cumulative expense based on its estimate and the percent of the requisite service period that has elapsed.

Presented below are the components of total share-based compensation as recorded in our Consolidated Statements of Operations for the years ended December 31, 2021, 2020 and 2019 (in thousands).

	2021	2020	2019
Selling, general and administrative expenses	$ 23,400	$ 32,368	$ 44,159
Research and development expenses	1,378	2,504	4,501
Cost of revenues	5,268	6,485	10,482
Total share-based compensation expense	$ 30,046	$ 41,357	$ 59,142

As of December 31, 2021, the total remaining unrecognized compensation cost related to non-vested share-based compensation awards for which a grant date has been established as of December 31, 2021 amounted to $24.7 million.

Stock Options

From time to time, the Company grants stock options to its employees as part of their annual share compensation awards and, in certain circumstances, on an ad hoc basis or upon their commencement of service with the Company.

Although we have not granted employee stock options since 2018, previous grants have generally vested ratably, in equal amounts, over a three or four-year service period. Stock options outstanding as of December 31, 2021 generally expire ten years from the grant date. We estimate the fair value of stock option grants at the date of grant using the Black-Scholes option-pricing model. This model utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's share price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. We estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors.

A summary of the activity for each of the years ended December 31, 2021, 2020 and 2019 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding as of December 31, 2018	8,072,718	$ 20.62		
Exercised	(557)	$ 7.55		
Forfeited	(125,739)	$ 14.38		
Expired	(665,883)	$ 40.37		
Outstanding as of December 31, 2019	7,280,539	$ 18.93		
Forfeited	(16,953)	$ 11.81		
Expired	(347,000)	$ 35.56		
Outstanding as of December 31, 2020	6,916,586	$ 18.11		
Exercised	(82,331)	$ 7.55		
Forfeited	(11,887)	$ 13.19		
Expired	(438,454)	$ 40.76		
Outstanding as of December 31, 2021	6,383,914	$ 16.70	4.07	$ —
Vested and expected to vest as of December 31, 2021	6,383,914	$ 16.70	4.07	$ —
Exercisable as of December 31, 2021	6,383,914	$ 16.70	4.07	$ —

(1) The intrinsic value of a stock option is the excess, if any, of the closing price of the Company's ordinary shares on the last trading day of the fiscal year over the exercise price. The aggregate intrinsic values presented in the table above represent sum of the intrinsic values of all corresponding stock options that are "in-the-money," if any.

The range of exercise prices for the above stock options outstanding at December 31, 2021 is from $7.55 to $86.54.

The total intrinsic values of options exercised during the years ended December 31, 2021 and 2019 were $0.1 million and less than $0.1 million, respectively. There were no material tax benefits from stock option exercises realized during the years ended December 31, 2021, 2020 and 2019.

Restricted Stock Units and Performance Share Units

From time to time, the Company grants RSUs and PSUs to its employees as part of their annual share compensation awards and, in certain circumstances, on an ad hoc basis or upon their commencement of service with the Company.

RSUs vest ratably, in equal amounts, over a three-year service period. PSUs vest in full after a three-year service period and are conditional upon the achievement of performance and/or market conditions established by the Compensation & Human Capital Committee of the Board.

PSUs awarded in 2021, 2020 and 2019 were based upon two discrete measures: relative total shareholder return (TSR) and an adjusted free cash flow performance metric (FCF), each accounting for 50% of the PSU awards upon issuance. TSR performance is measured against the three-year TSR of a custom index of companies. For PSUs awarded in 2021, 2020 and 2019, FCF performance is measured against a target covering a single three-year performance period, which is generally established at the grant date. Upon the completion of the three-year performance period, the PSUs vest and the actual number of shares awarded is adjusted to between zero and 200% of the target award amount based upon the performance criteria described above. In addition to meeting the performance conditions, grant recipients are also generally subject to being employed by the Company until the conclusion of the three-year vesting period in order to receive the awards. TSR is considered a market condition under applicable authoritative guidance, while FCF is considered performance condition.

RSUs are valued based on the closing price of Endo's ordinary shares on the date of grant. PSUs with TSR conditions are valued using a Monte-Carlo variant valuation model, while those with FCF conditions are valued taking into consideration the probability of achieving the specified performance goal. The Monte-Carlo variant valuation model used considers a variety of potential future share prices for Endo as well as our peer companies in a selected market index.

A summary of our non-vested RSUs and PSUs for the years ended December 31, 2021, 2020 and 2019 is presented below:

	Number of Shares	Aggregate Intrinsic Value (1)
Non-vested as of December 31, 2018	11,019,472	
Granted	6,687,695	
Forfeited	(918,425)	
Vested	(3,872,453)	
Non-vested as of December 31, 2019	12,916,289	
Granted	3,761,648	
Forfeited	(824,299)	
Vested	(5,513,359)	
Non-vested as of December 31, 2020	10,340,279	
Granted	4,483,385	
Forfeited	(1,302,292)	
Vested	(5,380,262)	
Non-vested as of December 31, 2021	8,141,110	$ 30,610,574
Vested and expected to vest as of December 31, 2021	7,547,762	$ 28,379,585

(1) The aggregate intrinsic values presented in the table above were calculated by multiplying the closing price of the Company's ordinary shares on the last trading day of the fiscal year by the corresponding quantities above.

As of December 31, 2021, the weighted average remaining requisite service period of the units presented in the table above was 1.5 years and the corresponding total remaining unrecognized compensation cost amounted to $10.4 million in the case of RSUs and $14.3 million in the case of PSUs. The weighted average grant-date fair value of the units granted during the years ended December 31, 2021, 2020 and 2019 was $7.39, $5.54 and $7.72 per unit, respectively.

NOTE 20. OTHER (INCOME) EXPENSE, NET

The components of Other (income) expense, net for the years ended December 31, 2021, 2020 and 2019 are as follows (in thousands):

	2021	2020	2019
Net gain on sale of business and other assets (1)	$ (4,516)	$ (16,353)	$ (6,367)
Foreign currency loss, net (2)	1,253	2,466	5,247
Net loss (gain) from our investments in the equity of other companies (3)	453	(2,160)	2,346
Other miscellaneous, net (4)	(16,964)	(5,063)	15,451
Other (income) expense, net	$ (19,774)	$ (21,110)	$ 16,677

(1) Amounts primarily relate to the sales of certain intellectual property rights as well as, in 2021, the sale transactions that are further discussed in Note 3. Discontinued Operations.
(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.
(4) Amounts in 2021 include gains of $15.5 million associated with the termination of certain contracts. Amounts in 2019 primarily relate to $17.5 million of contract termination costs incurred as a result of certain product discontinuation activities in our International Pharmaceuticals segment.

NOTE 21. INCOME TAXES

Loss from Continuing Operations before Income Tax

Our operations are conducted through our various subsidiaries in numerous jurisdictions throughout the world. We have provided for income taxes based upon the tax laws and rates in the jurisdictions in which our operations are conducted.

The components of our Loss from continuing operations before income tax by geography for the years ended December 31, 2021, 2020 and 2019 are as follows (in thousands):

	2021	2020	2019
U.S.	$ 4,792,852	$ (375,262)	$ (688,224)
International	(5,339,455)	348,744	343,320
Total loss from continuing operations before income tax	$ (546,603)	$ (26,518)	$ (344,904)

Income tax from continuing operations consists of the following for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Current:			
U.S. Federal	$ 13,649	$ (108,866)	$ 15,317
U.S. State	1,491	(434)	(3,002)
International	10,495	(1,124)	8,926
Total current income tax	$ 25,635	$ (110,424)	$ 21,241
Deferred:			
U.S. Federal	$ 118	$ (143,411)	$ (515)
U.S. State	(564)	(11,773)	(482)
International	(2,711)	(8,374)	(4,564)
Total deferred income tax	$ (3,157)	$ (163,558)	$ (5,561)
Total income tax	$ 22,478	$ (273,982)	$ 15,680

Tax Rate

A reconciliation of income tax from continuing operations at the U.S. federal statutory income tax rate to the total income tax provision from continuing operations for the years ended December 31, 2021, 2020 and 2019 is as follows (in thousands):

	2021	2020	2019
Notional U.S. federal income tax provision at the statutory rate	$ (114,787)	$ (5,569)	$ (72,430)
State income tax, net of federal benefit	6,750	(17,311)	(4,455)
U.S. tax reform impact	—	(129,599)	—
Uncertain tax positions	42,415	35,941	43,273
Residual tax on non-U.S. net earnings	(181,739)	(83,550)	(67,987)
Non-deductible goodwill impairment	76,230	7,490	27,493
Change in valuation allowance	495,565	(97,752)	30,123
Base erosion minimum tax	—	77,438	13,662
Non-deductible expenses	39,791	8,875	21,299
Executive compensation limitation	6,215	5,857	4,547
Equity based compensation	2,695	6,495	6,014
Financing activities (1)	(287,012)	(33,217)	—
Investment activities (2)	(68,943)	(44,964)	—
Other	5,298	(4,116)	14,141
Income tax	$ 22,478	$ (273,982)	$ 15,680

(1) The amount in 2021 primarily relates to a net tax benefit of approximately $1.2 billion related to non-taxable intercompany cancellation of indebtedness income, which was partially offset by a net tax expense of approximately $465 million related to non-deductible bad debt expense and a net tax expense of approximately $427 million related to non-deductible intercompany interest expense. The net tax benefit is fully offset by an increase to the valuation allowance.

(2) The amount in 2021 primarily relates to tax deductible losses associated with the investment in consolidated subsidiaries. The tax benefit is fully offset by an increase to the valuation allowance.

The change in income tax expense in 2021 compared to the 2020 income tax benefit primarily relates to the 2020 tax benefit for the CARES Act as discussed in more detail below and changes in deferred tax liabilities following the BioSpecifics acquisition during 2020. The change in income tax benefit in 2020 compared to the 2019 income tax expense primarily relates to the 2020 tax benefit from the CARES Act and changes in deferred tax liabilities following the BioSpecifics acquisition.

On March 27, 2020, the CARES Act was enacted by the U.S. government in response to the COVID-19 pandemic. The CARES Act, among other things, permits net operating loss (NOL) carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. During the year ended December 31, 2020, the Company recorded a discrete tax benefit in continuing operations of $129.6 million as a result of the change in the NOL carryback period.

Deferred Tax Assets and Liabilities

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The significant components of the net deferred income tax liability shown on the balance sheets as of December 31, 2021 and 2020 are as follows (in thousands):

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Accrued expenses and reserves	$ 144,573	$ 109,595
Deferred interest deduction	347,501	290,658
Fixed assets, intangible assets and deferred amortization	512,584	515,683
Loss on capital assets	64,503	66,159
Net operating loss carryforward	9,258,122	9,659,130
Other	50,694	54,540
Research and development and other tax credit carryforwards	8,254	15,176
Total gross deferred income tax assets	$ 10,386,231	$ 10,710,941
Deferred tax liabilities:		
Other	$ (8,586)	$ (9,469)
Investments	(124,311)	—
Intercompany notes	(104,530)	(1,057,158)
Total gross deferred income tax liabilities	$ (237,427)	$ (1,066,627)
Valuation allowance	(10,169,294)	(9,668,556)
Net deferred income tax liability	$ (20,490)	$ (24,242)

As of December 31, 2021, the Company had significant deferred tax assets for tax credits, net operating and capital loss carryforwards, net of unrecognized tax positions, as presented below (in thousands):

Jurisdiction	Amount	Begin to Expire
Ireland	$ 54,802	Indefinite
Luxembourg	$ 8,981,499	2034
U.S.:		
Federal-ordinary losses	$ 32,726	2037
Federal-capital losses	$ 41,636	2022
Federal-tax credits	$ 13,339	2025
State-ordinary losses	$ 237,414	2022
State-capital losses	$ 28,390	2022
State-tax credits	$ 3,256	2036

A valuation allowance is required when it is more likely than not that all or a portion of a deferred tax asset will not be realized. The Company assesses the available positive and negative evidence to estimate whether the existing deferred tax assets will be realized.

The Company has recorded a valuation allowance against certain jurisdictional NOL carryforwards and other tax attributes. As of December 31, 2021 and 2020, the total valuation allowance was $10,169.3 million and $9,668.6 million, respectively. During the year ended December 31, 2021, the Company increased its valuation allowance by $500.7 million, which was primarily driven by taxable losses in Luxembourg related to investments in consolidated subsidiaries. During the year ended December 31, 2020, the Company decreased its valuation allowance by $160.4 million, which was primarily driven by deferred tax liabilities recognized as part of the BioSpecifics acquisition.

As of December 31, 2021, the Company had the following significant valuation allowances (in thousands):

Jurisdiction	December 31, 2021
Ireland	$ 230,913
Luxembourg	$ 8,736,985
U.S.	$ 1,195,810

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 December 31, 2021. 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 have provided for any applicable income taxes associated with current year distributions, as well as any earnings that are expected to be distributed in the future, in the calculation of the income tax provision. No additional provision has been made for Irish and non-Irish income taxes on the undistributed earnings of subsidiaries as such earnings are expected to be indefinitely reinvested. As of December 31, 2021, certain subsidiaries had approximately $119.7 million of cumulative undistributed earnings that have been deemed permanently reinvested. A liability could arise if our intention to indefinitely reinvest such earnings were to change and amounts are distributed by such subsidiaries or if such subsidiaries are ultimately disposed. The potential tax implications of unremitted earnings are driven by the facts at the time of the distribution. It is not practicable to estimate the additional income taxes related to indefinitely reinvested earnings or the basis differences related to investments in subsidiaries.

Uncertain Tax Positions

The Company and its subsidiaries are subject to income taxes in the U.S., various states and numerous foreign jurisdictions with varying statutes as to which tax years are subject to examination by the tax authorities. The Company has taken positions on its tax returns that may be challenged by various tax authorities. The Company believes it has appropriately established reserves for tax-related uncertainties. The Company endeavors to resolve matters with a tax authority at the examination level and could reach agreement with a tax authority at any time. The accruals for tax-related uncertainties are based on the Company's best estimate of the potential tax exposures. When particular matters arise, a number of years may elapse before such matters are audited and finally resolved. The final outcome with a tax authority may result in a tax liability that is more or less than that reflected in our financial statements. Favorable resolution of such matters could be recognized as a reduction of the Company's effective tax rate in the year of resolution, while a resolution that is not favorable could increase the effective tax rate and may require the use of cash. Uncertain tax positions are reviewed quarterly and adjusted as necessary when events occur that affect potential tax liabilities, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, identification of new issues and issuance of new legislation, regulations or case law.

As of December 31, 2021, the Company had total UTPs, including accrued interest and penalties, of $620.0 million. If recognized in future years, $241.0 million of such amounts would impact the income tax provision and effective tax rate. As of December 31, 2020, the Company had total UTPs, including accrued interest and penalties, of $576.8 million. If recognized in future years, $230.8 million of such amounts would have impacted the income tax provision and effective tax rate. The following table summarizes the activity related to UTPs during the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Unrecognized Tax Positions Federal, State and Foreign Tax
UTP Balance at December 31, 2018	$ 451,690
Gross additions for current year positions	35,766
Gross reductions for prior period positions	(2,377)
Gross additions for prior period positions	880
Decrease due to lapse of statute of limitations	(1,006)
Currency translation adjustment	1,528
UTP Balance at December 31, 2019	$ 486,481
Gross additions for current year positions	33,402
Gross reductions for prior period positions	(577)
Gross additions for prior period positions	16,914
Decrease due to lapse of statute of limitations	(7,033)
Currency translation adjustment	588
UTP Balance at December 31, 2020	$ 529,775
Gross additions for current year positions	36,662
Gross reductions for prior period positions	(702)
Gross additions for prior period positions	1,203
Decrease due to lapse of statute of limitations	(475)
Currency translation adjustment	(24)
UTP Balance at December 31, 2021	$ 566,439
Accrued interest and penalties	53,569
Total UTP balance including accrued interest and penalties	$ 620,008

The Company records accrued interest and penalties, where applicable, related to uncertain tax positions as part of the provision for income taxes. The cumulative accrued interest and penalties related to uncertain tax positions were $53.6 million and $47.0 million as of December 31, 2021 and 2020, respectively.

During the year ended December 31, 2021, the Company recognized net expense of $10.6 million associated with UTPs, primarily related to interest and penalties. During the year ended December 31, 2020, the Company recognized a net benefit of $78.2 million as a reduction to our net UTP liability, primarily related to the CARES Act. During the year ended December 31, 2019, the Company recognized net expense of $13.8 million associated with UTPs, primarily related to interest and penalties. The UTP liability is included in our Consolidated Balance Sheet as Other liabilities or, if and to the extent appropriate, as a reduction to Deferred tax assets.

Our subsidiaries file income tax returns in the countries in which they have operations. Generally, these countries have statutes of limitations ranging from 3 to 5 years. Certain subsidiary tax returns are currently under examination by taxing authorities, including U.S. tax returns for the 2006 through 2019 tax years by the IRS.

It is expected that the amount of UTPs will change during the next 12 months; however, the Company does not currently anticipate any adjustments that would lead to a material impact on our results of operations or our financial position.

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.

As of December 31, 2021, we may be subject to examination in the following major tax jurisdictions:

Jurisdiction	Open Years
Canada	2015 through 2021
India	2012 through 2021
Ireland	2016 through 2021
Luxembourg	2015 through 2021
U.S. - federal, state and local	2006 through 2021

NOTE 22. 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 years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Numerator:			
(Loss) income from continuing operations	$ (569,081)	$ 247,464	$ (360,584)
Loss from discontinued operations, net of tax	(44,164)	(63,520)	(62,052)
Net (loss) income	$ (613,245)	$ 183,944	$ (422,636)
Denominator:			
For basic per share data—weighted average shares	232,785	229,314	226,050
Dilutive effect of ordinary share equivalents	—	4,339	—
For diluted per share data—weighted average shares	232,785	233,653	226,050

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 years ended December 31, 2021, 2020 and 2019, 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):

	2021	2020	2019
Stock options	6,584	7,073	7,681
Stock awards	9,256	5,197	13,418

NOTE 23. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS

Savings and Investment Plan

The Company maintains a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all U.S.-based eligible employees. The Company matches 100% of the first 3% of eligible cash compensation that a participant contributes to the Endo 401(k) Plan plus 50% of the next 2% for a total of up to 4%, subject to statutory limitations. The Company's matching contributions generally vest ratably over a two-year period.

Costs incurred for contributions made by the Company to the Endo 401(k) Plan amounted to $7.6 million, $7.6 million and $7.4 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Directors Stock Election Plan

The Company maintains a directors stock election plan. The purpose of this plan is to provide non-employee directors the opportunity to have their cash retainer fees, or a portion thereof, delivered in the form of Endo ordinary shares. The amount of shares will be determined by dividing the portion of cash fees elected to be received as shares by the closing price of the shares on the day the payment would have otherwise been paid in cash.

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