

ENDO INTERNATIONAL PUBLIC LIMITED COMPANY
Directors' Report and Financial Statements
For the Year Ended December 31, 2021

ENDO INTERNATIONAL PLC
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DIRECTORS AND OTHER INFORMATION

DIRECTORS	Mark G. Barberio (United States) Blaise Coleman (United States) Shane M. Cooke (Ireland) Nancy J. Hutson, Ph.D. (United States) Michael Hyatt (United States) William P. Montague (United States) M. Christine Smith, Ph.D. (United States) Jennifer M. Chao (United States)
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DIRECTORS' REPORT
For the Year Ended December 31, 2021

The directors present their report and audited Consolidated Financial Statements for the year ended December 31, 2021.

Principal Activities

Unless otherwise indicated or required by the context, references throughout to “Endo,” the “Group,” “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 report. The results of operations of our reportable business segments are discussed in the heading “RESULTS OF OPERATIONS.” Across all of our reportable business segments, we generated total turnover of \$2.99 billion and \$2.90 billion in 2021 and 2020, 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.

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.

Products Overview

Branded Pharmaceuticals

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

	2021	2020
<i>Specialty Products:</i>		
XIAFLEX®	\$ 432,344	\$ 316,234
SUPPRELIN® LA	114,374	88,182
Other Specialty (1)	86,432	92,662
Total Specialty Products	\$ 633,150	\$ 497,078
<i>Established Products:</i>		
PERCOCET®	\$ 103,788	\$ 110,112
TESTOPEL®	43,636	35,234
Other Established (2)	113,043	139,356
Total Established Products	\$ 260,467	\$ 284,702
Total Branded Pharmaceuticals (3)	\$ 893,617	\$ 781,780

(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 turnover 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 Group'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 Group announced the elimination of its entire U.S. pain product field sales force.

Sterile Injectables

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

	<u>2021</u>	<u>2020</u>
VASOSTRICT®	\$ 901,735	\$ 785,646
ADRENALIN®	124,630	152,074
Other Sterile Injectables (1)	239,732	301,127
Total Sterile Injectables (2)	<u>\$ 1,266,097</u>	<u>\$ 1,238,847</u>

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

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

Turnovers 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 Stock 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 Viatrix Inc. (Viatrix), 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), Viatriis, 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, Viatriis, 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 turnover 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 Principal risks - "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 turnover. See Note 15. Commitments and Contingencies in the Consolidated Financial Statements.

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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 stock 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. Principal risks for further discussion on the risks associated with the sourcing of our raw materials.

License and 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 Group enters into strategic alliances and collaborative arrangements with third parties, which give the Group 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 turnover-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 Group not opted for a development partner. Refer to Note 12. License and Collaboration Agreements in the Consolidated Financial Statements included in this report for additional information.

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 and we do not believe that future compliance will have a material adverse effect on our business, financial condition, results of operations or cash flows.

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 Group 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.

Review of the Performance of the Business

EXECUTIVE SUMMARY

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

- Total turnover in 2021 were \$2,993.2 million compared to \$2,903.1 million in 2020 as turnover increases from the Specialty Products portfolio of our Branded Pharmaceuticals segment and from our Sterile Injectables segment were partially offset by decreased turnover 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 sales 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 turnover 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 Profit 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 14. Debt in the Consolidated Financial Statements included in 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 Divestitures and Note 4. Restructuring in the Consolidated Financial Statements included in 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 sales. 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 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 14. Debt in the Consolidated Financial Statements included in 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 "Principal risks" herein. For further discussion, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report.

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.

Results of Operations

Consolidated Results Review

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

	2021	2020	% Change 2021 vs. 2020
Total turnover, net	\$ 2,993,206	\$ 2,903,074	3 %
Cost of sales	1,221,064	1,442,511	(15)%
Gross margin	\$ 1,772,142	\$ 1,460,563	21 %
<i>Gross margin percentage</i>	<i>59.2 %</i>	<i>50.3 %</i>	
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	(1,549)	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 on extinguishment of debt	13,753	—	NM
Other income, net	(19,774)	(21,110)	(6)
Loss from continuing operations before income tax	\$ (546,603)	\$ (44,018)	NM

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

Total turnover, net. Total turnover in 2021 were \$2,993.2 million compared to \$2,903.1 million in 2020 as turnover increases from the Specialty Products portfolio of our Branded Pharmaceuticals segment and from our Sterile Injectables segment were partially offset by decreased turnover from our Generic Pharmaceuticals segment, the Established Products portfolio of our Branded Pharmaceuticals segment and our International Pharmaceuticals segment. Our turnover are further disaggregated and described below under the heading “Business Segment Results Review.”

Cost of sales and gross margin percentage. During the years ended December 31, 2021 and 2020, Cost of sales 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 stock reserves and accelerated depreciation. As further discussed in Note 3. Discontinued Operations and Divestitures and Note 4. Restructuring in the Consolidated Financial Statements included in 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 sales 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 sales resulting from the December 2020 BioSpecifics acquisition and favorable changes in product mix as described below, partially offset by increased turnover.

Gross margin percentage increased in 2021 as a result of the reduction in royalty payments recognized in Cost of sales 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 turnover 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 XI AFLEX[®], 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 14. Debt in the Consolidated Financial Statements included in this report and the 2020 Restructuring Initiative, which is further discussed in Note 4. Restructuring in the Consolidated Financial Statements included in 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 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 XI AFLEX[®] 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 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 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 XI AFLEX[®] 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 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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
Tangible fixed assets impairment charges, 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	<u>\$ 414,977</u>	<u>\$ 120,346</u>

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 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 and Divestitures in the Consolidated Financial Statements included in 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 turnover 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 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	<u>\$ 562,353</u>	<u>\$ 532,939</u>

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 14. Debt in the Consolidated Financial Statements included in 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 14. Debt in the Consolidated Financial Statements included in this report for further discussion.

Other income, net. The components of Other income, 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, net	<u>\$ (19,774)</u>	<u>\$ (21,110)</u>

For additional information on the components of Other income, net, refer to Note 19. Other Income, Net in the Consolidated Financial Statements included in 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)	\$ (44,018)
Income tax expense/(benefit)	\$ 22,478	\$ (273,982)
Effective tax rate	(4.1)%	622.4 %

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 20. Income Taxes in the Consolidated Financial Statements included in this report.

The Group 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 20. Income Taxes in the Consolidated Financial Statements included in 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 principal risks "The IRS and other taxing authorities may continue to challenge our tax positions and we may not be able to successfully maintain such positions.

For additional information on our income taxes, including information about the impact of the CARES Act, see Note 20. Income Taxes in the Consolidated Financial Statements included in this report.

Discontinued operations, net of tax. The operating results of the Group's Astora business, which the Board resolved to wind down in 2016, are reported as Discontinued operations, net of tax in the Consolidated Profit and loss account 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report.

Business Segment Results Review

Refer to Note 6. Segment Results in the Consolidated Financial Statements included in this report for further details regarding our reportable segments and Segment adjusted profit 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 profit from continuing operations before income tax.

We refer to Segment adjusted profit 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 profit from continuing operations before income tax may be useful to investors as we are aware that certain of our significant shareholders utilize Segment adjusted profit from continuing operations before income tax to evaluate our financial performance. Finally, Segment adjusted profit 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 Group'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 profit from continuing operations before income tax. Other companies in our industry may define Segment adjusted profit from continuing operations before income tax differently than we do. As a result, it may be difficult to use Segment adjusted profit 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 profit 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 profit, 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 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 profit from continuing operations before income tax.

Turnover, net. The following table displays our turnover 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 turnover from external customers	<u>\$ 2,993,206</u>	<u>\$ 2,903,074</u>	3 %

(1) Turnover 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 turnover from external customers for the years ended December 31, 2021 and 2020 (dollars in thousands):

	2021	2020	% Change 2021 vs. 2020
<i>Specialty Products:</i>			
XIAFLEX®	\$ 432,344	\$ 316,234	37 %
SUPPRELIN® LA	114,374	88,182	30 %
Other Specialty (1)	86,432	92,662	(7)%
Total Specialty Products	<u>\$ 633,150</u>	<u>\$ 497,078</u>	27 %
<i>Established Products:</i>			
PERCOCET®	\$ 103,788	\$ 110,112	(6)%
TESTOPEL®	43,636	35,234	24 %
Other Established (2)	113,043	139,356	(19)%
Total Established Products	<u>\$ 260,467</u>	<u>\$ 284,702</u>	(9)%
Total Branded Pharmaceuticals (3)	<u>\$ 893,617</u>	<u>\$ 781,780</u>	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 turnover 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 turnover. 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® turnover 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 turnover 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 turnover in 2021 was primarily attributable to net decreases in price and volumes for multiple products in this portfolio, partially offset by turnover from QWO®, which we launched in March 2021.

Established Products

The decrease in PERCOCET® turnover 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[®] turnover 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 turnover 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 turnover 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)	<u>\$ 1,266,097</u>	<u>\$ 1,238,847</u>	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 turnover in excess of \$25 million during any quarterly period in 2021 or 2020.

The increase in VASOSTRICT[®] turnover 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report under the heading "VASOSTRICT[®] Related Matters."

The decrease in ADRENALIN[®] turnover 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 turnover in 2021 was primarily attributable to competitive pressures across multiple products within the product portfolio.

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

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

Segment adjusted profit from continuing operations before income tax. The following table displays our Segment adjusted profit 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 profit from continuing operations before income tax in 2021 was primarily attributable to the gross margin effect of increased turnover, 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 XIAPLEX[®].

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

Generic Pharmaceuticals. The increase in Segment adjusted profit 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 report, partially offset by the gross margin effect of the decreased turnover further described above.

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

Endo International PLC Standalone Company results.

The Parent Company recorded a loss of \$387.0 million for the year ended 31 December 2021 (2020: loss of \$49.5 million). The increase was primarily attributed to a non cash impairment charge of \$297.9 million. This impairment is further described in Note 3. Investment in Subsidiaries of the Standalone Company Financial Statements. This impairment is eliminated in consolidation and therefore has no impact to the Consolidated Results.

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 Group'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 at bank and on-hand 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 at bank and on-hand, 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 at bank and on-hand, including as a result of any increase in turnover 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 "Principal risks" 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 profit 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 Group 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 Group's outstanding debt agreements contain a number of restrictive covenants, including certain limitations on the Group'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 Group 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 Group 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 14. Debt in the Consolidated Financial Statements included in 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 Group'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	<u>\$ 1,084,624</u>	<u>\$ 1,159,434</u>
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 turnover 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 14. Debt in the Consolidated Financial Statements included in 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	<u>\$ 246,310</u>	<u>\$ (335,388)</u>

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

The \$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[®] turnover.

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 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 and Divestitures in the Consolidated Financial Statements included in 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 stock 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 14. Debt and Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 20. Income Taxes in the Consolidated Financial Statements included in 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 turnover 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 turnover 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 turnover 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.

Financial Risk Management

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 Group manages this foreign currency risk, in part, through operational means including managing foreign currency turnover in relation to same-currency costs and foreign currency assets in relation to same-currency liabilities. The Group 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 Group'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, net in the Consolidated Profit and loss account. Refer to Note 19. Other Income, Net in the Consolidated Financial Statements included in this report for the amounts of Foreign currency loss, net.

Based on the Group'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.

Principal Risks

Principal risk Summary

The following is a summary of the principal risks 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 principal risks 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.
- **Principal risks**

The following principal risks could adversely affect our business, financial condition, results of operations and cash flows. These are not the only risks facing the Group. 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 "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 principal risk "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 turnover 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 turnover 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/NDA's 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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". 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 turnover, 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 turnover 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 FDCA 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 turnover 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 profit 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 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 two 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 turnover and future profitability.

We may experience downward pricing pressure on our products due to social or political pressures, which would reduce our turnover 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 turnover 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 turnover 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, group 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 turnover 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 turnover deemed by the PMPRB to be excessive, which could ultimately reduce the turnover 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”.

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

	<u>2021</u>	<u>2020</u>
AmerisourceBergen Corporation	36 %	33 %
McKesson Corporation	32 %	27 %
Cardinal Health, Inc.	22 %	24 %

Turnover from these customers are included within each of our segments. Accordingly, our turnover, 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 stock 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 and Divestitures in the Consolidated Financial Statements included in 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 group, 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 group, 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 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 stock 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 Group 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 Group'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 group 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 turnover, results of operations and financial condition.

In 2021, approximately 3% of our total turnover 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 principal risk “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 turnover, 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 principal risk “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 group, 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 group 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 turnover, 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 group.

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 Group or the expansion of ongoing litigation against the Group. See Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 Group 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 turnover. 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 principal risk "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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 principal risk "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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 Group. 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 Group.

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 principal risk “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 turnover 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 and 2020, we recorded asset impairment charges of \$0.4 billion and \$0.1 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 this report for examples and a discussion of material impairment tests and impairment charges during the years ended December 31, 2021 and 2020. The procedures and assumptions used in our goodwill and other intangible assets impairment testing are discussed in 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 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 turnover 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 Group 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 14. Debt in the Consolidated Financial Statements included in 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 Group'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 Group 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 15. Commitments and Contingencies in the Consolidated Financial Statements included in 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 FDCA and FDA regulations and guidance restrict the ability of healthcare companies, such as our group, 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 Group 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.

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. Even if we receive approval for an NDA under section 505(b)(2) of the FDCA, the FDA may not take timely enforcement action against companies marketing unapproved versions of the product; therefore, we cannot be sure 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 turnover. We could also be at risk for the value of any capitalized pre-launch stocks 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 Group 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 Group'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 turnover 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 turnover, 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 principal risk “The risks related to our global operations may adversely impact our turnover, 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. turnover 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 turnover 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 profit 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 stock 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 principal risks 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 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 Cooperation 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 Group.

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 20. Income Taxes in the Consolidated Financial Statements included in 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 profit 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.

Likely Future Developments

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 turnover.

Future changes in the COVID-19 pandemic could further impact future turnover 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 Group is only providing information about estimated turnover trends through March 31, 2022 at this time. These estimated turnover 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[®] turnover to continue to be impacted by COVID-19-related market conditions, which could result in XIAFLEX[®] turnover remaining consistent with or declining compared to the first quarter of 2021. We also expect an overall decline in turnover 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 turnover 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 turnover to continue to be impacted by competitive pressures for certain products in this portfolio, resulting in turnover 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.

Accounting Records

The directors are responsible for ensuring that Endo International plc (Group) and its subsidiaries keep accounting records and appropriate accounting systems. To achieve this, the directors have appointed a Chief Financial Officer who makes regular reports to the Board of Directors and ensures compliance with the requirements of Section 281 to 285 of the Companies Act, 2014. The Chief Financial Officer makes regular reports to the Audit & Finance Committee of the Board of Directors. The Audit & Finance Committee, in turn, briefs the full Board of Directors on significant financial matters arising from reports of the Chief Financial Officer and the external auditor. The measures taken by the directors to secure compliance with the Group's obligation to keep accounting records and the use of appropriate systems and procedures and employment of competent persons. The accounting records are kept at 1400 Atwater Drive, Malvern, PA 19355.

Significant Events Since Year End

Subsequent events have been evaluated through May 06, 2022 the date this report is approved by the Audit & Finance Committee of the Board of Directors and the Board of Directors.

2022 Restructuring Initiative

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

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

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

Nevakar Injectables, Inc. Acquisition

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

Directors and Secretary

The names of the persons who were directors at any time during the year ended December 31, 2021 are set out below. Unless indicated otherwise, they served as directors for the entire year.

Directors	Date of Service as Director or Secretary
Blaise Coleman	(Appointed 06 March 2020)
Mark G. Barberio ⁽²⁾	(Appointed 19 February 2020)
Shane M. Cooke	(Appointed 29 July 2014)
Nancy J. Hutson, Ph.D.	(Appointed 28 February 2014)
Michael Hyatt	(Appointed 28 February 2014)
William P. Montague	(Appointed 28 February 2014)
M Christine Smith, Ph.D.	(Appointed 29 July 2020)
Jennifer M. Chao ⁽¹⁾	(Appointed 17 February 2021)
Roger H. Kimmel ⁽³⁾	(Appointed 28 February 2014, Retired 10 June 2021)
Paul Campanelli ⁽²⁾	(Appointed 23 September 2016. Retired 10 June 2021)

Secretary

Matthew Maletta (Appointed 12 June 2020)

Assistant Secretary

Deanna Voss (Appointed 28 February 2014)

Brian Morrissey (Appointed 10 October 2020)

(1) On February 17, 2021 the Group announced Jennifer M. Chao has been appointed to serve as director. Ms Chao has been appointed to Endo's Audit & Finance Committee and its Compliance Committee and becomes its eighth independent director.

(2) On April 27, 2021 the Group announced Mark G. Barberio will be appointed Chairman of the Board effective at the Group's June 2021 Annual General Meeting. In addition, Paul Campanelli, who served as Chairman of the Board since 2019 and who served as President and Chief Executive Officer from 2016 to 2020 will retire from the Board upon the expiration of his current term at the Group's June 2021 Annual General Meeting.

(3) On April 27, 2021 the Group announced Roger H. Kimmel, who has been Senior Independent Director since 2019 and who served as Chairman of the Board from 2014 to 2019, will also retire from the Board upon the expiration of his current term at the Group's June 2021 Annual General Meeting.

Directors' and Secretary's Interests

No director, the secretary or any member of their immediate families had any interest in shares or debentures of any subsidiary. Directors' remuneration is set forth in Note 28. Directors' Remuneration of the accompanying Consolidated Financial Statements included in this report. The beneficial interests, including the interests of spouses and minor children, of the directors and secretary in office at December 31, 2021 in the share capital of Endo International plc were as follows:

Directors	Ordinary Shares at 31 December 2021 (1)			Ordinary Shares at 31 December 2020 (or date of appointment if later) (1)		
	Shares	Options (2)	Other Share Units (3)	Shares	Options (2)	Other Share Units (3)
Blaise Coleman	293,472	360,129	1,801,905	207,498	360,129	921,606
Shane M. Cooke	100,034	—	—	94,320	—	—
Nancy J. Hutson, Ph.D.	109,625	—	6,515	84,704	—	6,515
Michael Hyatt	355,560	—	—	330,639	—	—
Mark G. Barberio	38,187	—	—	13,266	—	—
William P. Montague	98,917	—	23,108	83,029	—	23,108
M. Christine Smith, Ph.D.	32,819	—	—	5,655	—	—
Jennifer M. Chao	24,921	—	—	—	—	—
Secretary						
Matthew J. Maletta	287,903	382,631	615,640	204,383	382,631	502,337

(1) All interests declared are in the ordinary shares of \$0.0001 par value of Endo International plc.

(2) Amounts include vested and unvested options.

(3) Amounts include vested and unvested restricted share units and performance share units.

Dividends

The Group did not pay any dividends to ordinary shareholders and minority interests during 2021.

Political Donations

The electoral (Amendment) (Political Funding) Act 2012 requires companies to disclose all political donations over 200 euro in aggregate made during the financial year. The Directors, on inquiry, have satisfied themselves that no such donations have been made by the Group during the financial year.

NON-FINANCIAL STATEMENT

Endo's Business Model

A description of Endo's business model can be found under "Principal Activities" within this Report.

Our Commitment to Environmental, Social and Governance-Related Business Practices ("ESG")

At Endo, we believe that a commitment to positive environmental, social and governance-related business practices strengthens our group, increases our connection with our stakeholders and helps to create sustainable value for our shareholders, our employees, our customers and the communities in which we live and work across the world. As a global group, Endo faces a range of risks, including general economic, credit and capital market conditions risks, regulatory risk, social and employee matters. A description of Endo's risks, including those related to environmental, social and governance issues can be found under "Principal Risks" within this Report.

We govern our enterprise risks and opportunities through a robust risk management and mitigation program. Our Board of Directors' (Board's) role in risk oversight is consistent with our leadership structure, with management having day-to-day responsibility for identifying, assessing and managing our risk exposure. The Board and its committees providing oversight in connection with those efforts, with particular focus on the most significant risks we face, with the Nominating, Governance and Corporate Responsibility Committee having oversight of our overall ESG strategy. The Board performs its risk oversight role in several ways. Board meetings regularly include strategic overviews by the CEO that describe the most significant issues, including risks, affecting Endo. In addition, the Board is regularly provided with business updates from our business and functional leaders. The Board reviews the risks associated with our financial forecast, business plan and operations. These risks are identified and managed in connection with Endo's enterprise risk management (ERM) process.

As part of our ERM approach to risk management and our strategies for long-term value creation, our Board and our management monitor long-term risks and opportunities that may be impacted by environmental, social and governance issues, set policies relating to these issues, and monitor the results of those policies. We monitor certain key metrics including those presented in this report.

The following is a summary of Endo's key policies and actions in the areas of (i) Environmental Matters, (ii) Human Capital Matters, (iii) Social Matters, (iv) Information Security, (v) Human Rights, (vi) Bribery and Corruption and (vii) Business Continuity. These policies and actions aim to confirm Endo's risk management in these areas and achieve its goals.

Focus on Ethics

Endo's reputation - as a company, as leaders and as individuals - depends on our adherence to high ethical standards. Today's compliance environment is highly dynamic and our approach to ethics and compliance is unwavering, proactive and strategic as regulatory and public expectations continue to evolve. Operating with integrity and delivering our products with a quality mindset are shared values across Endo. We expect team members to do the right thing, even when no one is watching, and to be accountable for their actions. These foundational behaviors are key to maintaining a culture of compliance and ethics. Endo has a strong Corporate Compliance Program and Employee Code of Conduct ("Code") to guide our team members to make sound and ethical decisions, which is the foundation for how we do business. This enables us to earn and keep the trust and confidence of our healthcare customers, patients, regulators, employees and shareholders.

Code of Conduct

Endo's Code of Conduct (the "Code") governs the Group's internal and external interactions, including with patients, healthcare providers, payors, suppliers, government officials, the healthcare community and shareholders. The Code applies to every person conducting business for Endo and to all Endo locations, subsidiaries and affiliates. Due to local law, some Code provisions may be supplemented by policies or standards to address local requirements.

The Code details, among other things, the role of Endo's Compliance Department. The Compliance Department, which directly oversees Endo's compliance program, establishes clear rules of business conduct, educates and trains employees, and conducts ongoing monitoring to confirm that the compliance program is operating as intended and to enhance its effectiveness. Endo also maintains a Global Compliance Committee comprised of members of the Senior Executive Team "SET" and other senior leaders who oversee, assess and enhance Endo's compliance program as needed. The Compliance Committee is supported by a management-level Executive Reporting Group.

Endo is also committed to a culture of openness with clear channels to ask questions or report potential concerns in a confidential and anonymous manner without fear of retaliation. Endo maintains a 24-hour Ethics Hotline that is operated by an independent third-party vendor and allows callers to report concerns or ask questions confidentially and anonymously. Employees, suppliers, customers and third parties can report concerns or ask questions either by phone or through a website, via our Ethics Hotline. Concerns reported, or questions asked via the Ethics Hotline are routed to the appropriate function or business unit for handling and response. Our Ethics Hotline statistics are reviewed quarterly by our Executive Reporting Group and by our Compliance Committee of the Board of Directors.

The Ethics Hotline is only one of several communication vehicles. Most often, employees discuss such issues directly with their supervisor. This reflects the fact that most day-to-day questions are handled at the local plant or office level with local managers and supervisors. Employees are encouraged to reach out to their Human Resources representative, our Legal department or our Compliance department if they do not feel comfortable going to their direct manager or supervisor.

Annually, all employees, full time contractors and select part time contractors and vendors complete training on Endo's Code of Conduct. Any employee who violates the Code, Group policy, or applicable laws is subject to disciplinary action up to and included termination. The Code is publicly available at www.endo.com. Endo's Code of Conduct (the "Code") governs the Group's internal and external interactions, including with patients, healthcare providers, payors, suppliers, government officials, the healthcare community and shareholders. The Code applies to every person conducting business for Endo and to all Endo

locations, subsidiaries and affiliates. Due to local law, some Code provisions may be supplemented by policies or standards to address local requirements.

Environmental Matters

Endo strives to act in an environmentally responsible way. All employees are responsible for compliance with applicable legal and regulatory requirements on environmental matters.

Endo recognizes that its activities can have an impact on the environment, including as a result of the manner in which Endo sources materials and manufactures products, consumes energy and generates waste. Endo is committed to operating its business in an environmentally responsible manner that seeks to minimize environmental risks and impacts and promotes the safe, efficient and responsible use of global resources. Endo’s products and services also support our customers’ efforts to make their products more efficient and more environmentally friendly. Specifically, it is Endo's policy to:

- Source our materials, provide our products and services, and manage our facilities in an environmentally responsible manner.
- Minimize material usage, energy consumption and waste generation in the manufacturing of our products for the good of the environment and to minimize overall production costs.
- Research and identify materials and manufacturing methods that minimize impact to the environment through air and water emissions, waste generation, and energy and water consumption.

Through our manufacturing leaders, we engage employees to drive world-class manufacturing and operational excellence and grow our business. All employees are responsible for compliance with applicable legal and regulatory requirements on environmental matters. More broadly, Endo recognizes the relevance and importance of environmental risks and impacts in our wider supply chain.

Endo continues to monitor, review and assess its environmental impact and the outcomes of its environmental policies. The following table shows the data collected for 2021 and 2020. Key performance indicators covering energy consumption, water consumption, waste generation and recycling have been included because they represent the key areas of Endo's environmental impact. Endo will continue to monitor the key performance indicators below and develop targets for those key performance indicators with the aim of reducing its overall environmental impact.

Key Performance Indicator	Units	Calendar Year 2021	Calendar Year 2020
<i>Energy Consumption</i>			
Electricity	Gigajoules	341,216	349,850
Natural Gas	Centum Cubic Feet	2,248,129	2,819,714
Diesel Fuel	Gallons	448,148	414,455
<i>Water Consumption</i>	Gallons	157,833,375	147,126,115
<i>Waste Generation</i>			
Hazardous Waste	Tons	446	341
Non-Hazardous Incineration	Tons	1,133	670
<i>Recycling</i>			
Cardboard, Metal and Plastic	Tons	640	345

Human Capital Matters

Endo’s culture strives to instill a focus on integrity, quality and empathy while enabling innovation, embracing change, promoting collaboration and rewarding high performance. The group’s ability to deliver sustainable business results depends upon effectively achieving the desired culture, as well as retaining and attracting diverse enterprise leadership and talent. These critical goals are fundamentally accomplished by developing and deploying robust plans to attract, assess, develop and inspire current and future leaders and employees at all levels of the group, while providing clear opportunities for professional growth. Endo must also develop and maintain the leadership capacity and workforce with the necessary collective skills and experiences to execute its strategic plan and deliver its operating objectives. Organizational change resulting in unplanned future leadership transitions and/or corporate initiatives, including restructuring actions, could result in talent gaps caused by increased employee turnover. Additionally, organizational disruptions or inability to attract and retain key employees could have a negative effect on Endo's business operations and operating results. The following sections summarize material aspects of Endo's policies relating to social and employee matters and management of the risks outlined above.

Diversity 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 also support the important work of advocacy groups that are advancing diversity, equity and inclusion across our industry and beyond.

Anti-Harassment: No Tolerance Environment

Our employees are expected to exhibit the highest standards of professionalism and integrity. Any behavior that constitutes unlawful harassment or discrimination will be thoroughly investigated and not tolerated.

Endo requires that management of each facility implements equal opportunity and no harassment policies in accordance with national, state or provincial law. Employees, temporary employees, visitors and other non-employees are encouraged to immediately report situations of harassment committed by anyone without fear of reprisal, including visitors and other non-employees. Actions taken as a result of an investigation may include discipline and warnings to employees, employee counseling, leadership training, and Equal Employment Opportunity Commission/Harassment training.

We also expect our suppliers to treat their employees with dignity and to maintain workplaces free of discrimination and harassment in all forms.

Employee Development, Training and Education

We want the best and brightest people at Endo to help us with our mission to develop and deliver life-enhancing products through focused execution. Endo supports and facilitates the continued development of its people and 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. Across the organization, employees are encouraged to embrace professional development opportunities and our leaders monitor the progress of the growth of their respective teams. The group also has well established succession planning and talent review processes, focused on the development and growth of our people with an emphasis on advancing diverse talent. The Senior Executive Team as well as business unit and functional leadership, discuss top talent regularly during their scheduled meetings to confirm that they are up-to-date on progress and gaps. To build a robust talent pipeline, organizational and individual development plans are used to accelerate the growth of high-potential employees by distinguishing key strengths and areas for growth, and identifying key events and experiences needed for development.

High performance at Endo is an outcome of an individual embracing the group's values and doing things the right way. Performance is enhanced by a person's aspiration and ability to learn, adapt, and grow throughout an individual's career. At Endo, the emphasis is on the value of on-the-job, real-time learning that enables a person to meet the demands of challenging and changing work. Our approach to learning focuses on reinforcing key principles that are designed to support an individual's effectiveness in his or her current job, and in future situations.

Endo is committed to providing leadership and learning opportunities for talent at all levels in their careers. Training is provided in a number of formats to accommodate the learner's style and pace, location and technological knowledge and access. Endo offers programmatic and individual development courses and opportunities across the organization in a variety of delivery methods. To help achieve these objectives, the Group recently launched a Learning and Development Center of Excellence whose purpose is to establish an enterprise-wide training, learning and development strategy and program to address the specific needs of our teams across the globe.

Employee Safety & Privacy

Endo is committed to maintaining a work environment free from any substance that could impair our ability to safely and professionally execute our job responsibilities. Violence in the workplace will not be tolerated.

The following table sets out key performance indicators related to the safety of our employees:

Key Performance Indicator	Units	Calendar Year 2021	Calendar Year 2020
Safety			
OSHA Injury Rate	Per 100 Employees	0.7	0.8
Days Away, Restricted and Transferred	Rate	0.6	0.5
Recordable Injuries	Number	22	27
Total Manhours Site Worked	Hours	9,327,014	7,272,844
Number of Employees	Employees	3,144	2,668

The safety of our team members at our manufacturing facilities, labs and offices is of the utmost importance. We have a robust safety program that is designed to monitor our work zones, educate team members about best practices and record and/or report any safety issues so that we can learn from them and continuously improve.

Social Matters

Corporate Social Responsibility

Endo values our role in giving back to the patients we serve and the communities where we work. Our corporate giving focuses on the following areas:

Corporate Giving

Employee Matching Gifts - Matching U.S. employee donation dollar for dollar up to \$1,000 per employee per calendar year.

Community Support - Endo believes good health is the foundation to living your best life, and as a healthcare company, is dedicated to reducing healthcare disparities and promoting a healthier global community. Endo provides funding to community non-profit organizations endeavoring to reduce healthcare disparities. We also support organizations providing educational programs to disadvantaged children, programs advancing Science, Technology, Engineering & Math (STEM) education. Endo also provides charitable grants to organizations that work to protect and improve the quality of care for the patients we serve.

Disease Education - Through unrestricted grants, Endo supports projects which cultivate awareness of the Group's therapeutic areas; seek to improve patient health through disease state education and foster advocacy efforts aimed towards protecting and improving access to quality care for patients.

Disaster Relief - Endo supports humanitarian efforts including recovery from flood or fire through our Disaster Relief program.

Patient Assistance Program

Endo supports patient assistance through third parties, which provide support based on patient need and cover any FDA approved or compendia listed product for specified diseases. These organizations independently develop approval criteria and shield any patient or product specific information from Endo.

Product Donation

In addition to financial support, Endo donates product to help people in need around the globe. In 2021, Endo donated approximately 500,000 units of medicines. All product donations are made through third-party partnerships that adhere to the World Health Organization (WHO) guidelines on product donations.

Safety, Performance and Quality

Patient health and safety are top priorities. Maintaining the quality of our products and the continued monitoring of their performance is paramount to protecting the safety of patients. We have a responsibility to detect and report adverse events and quality complaints associated with our products, including unfavorable side effects, dosing errors, misuse, malfunctions and concerns about performance or efficacy of a product. Team members go through a significant level of training and certification process annually and are rewarded for improving the quality and effectiveness of their processes and procedures.

Information Security

Our business depends on the efficient and uninterrupted operation of our communications systems, networks and other information technology. As a global company, our strategy and daily operations necessitate the collection, use and, at times, sharing of personal information about patients as well as our customers, shareholders and employees as permitted by local laws. We follow local data protection and privacy laws. We continuously invest resources to maintain, enhance, develop, replace and add to our information technology infrastructure, and we protect it with industry-leading cyber security systems and tools. We ask our suppliers to maintain similar commitments to protecting our data and that of our customers and employees

Endo continues to monitor, review and assess the outcomes of its policies on social and employee matters to confirm that they are having the desired impact.

Human Rights

Endo is committed to respecting human rights. At Endo, we believe that it is our responsibility to respect and uphold the human rights of our people and any other individuals we are in contact with across the globe. We believe this is evident in all our policies and practices, including HR, Safety and Procurement.

Endo enforces the following specific policies with respect to the protection of and respect for our global employee workforce:

- General conduct policy with rules pertaining to an employee's responsibilities and conduct.
- Complies with minimum legal working age requirements.
- Sets work hours to comply with local law.
- Complies with applicable wage laws, regulations, and relevant collective bargaining agreements, including those relating to minimum wages, overtime hours and legally mandated benefits.
- Maintains workplaces free of harassment and abuse.
- Recruits, hires, trains and promotes employees without regard to their race, color, religion, gender, age, national origin, citizenship, caste, marital status, sexual orientation, gender identity, genetic information, disability, veteran status or other protected characteristic.
- Respects employees' voluntary freedom of association, including the right to organize and bargain collectively.

All suppliers working with or on behalf of Endo are expected to share in our commitment to operate in an ethical, social and environmentally responsible manner by abiding by the Pharmaceutical Supply Chain Initiative (PSCI) guidelines, which serve as the foundation for the Endo Supplier Code of Conduct.

As discussed above, Endo employees are trained on our Code of Conduct and educated on how to report potential ethical violations or claims of harassment or discrimination without fear of retaliation. All complaints of alleged human rights violations, ethical concerns, or claims of harassment or discrimination are thoroughly investigated and appropriate disciplinary action is taken if warranted.

Bribery and Corruption

Endo provides annual training to its employees on a variety of anti-corruption and related matters, including the Foreign Corrupt Practices Act, anti-bribery, conflicts of interest, statements from our Code of Conduct and our Code of Conduct more broadly.

As regulators, payers, or purchasers of our products, government officials are integral to our business. Healthcare professionals who are public employees may be considered government officials in many countries. Through our research and development, regulatory, manufacturing and import/export activities, we may interact with government officials or entities that are state owned. Payments, gifts or services should not be given to government employees or healthcare providers that are intended to or appear to influence their actions. In short, Endo does not permit bribery of any kind.

Business Continuity

Knowing how to respond in a time of emergency or disaster is critical to ensuring the continued safety of our employees and the ongoing sustainability of our business. At Endo, we have a comprehensive plan for preventing, responding to, and recovering from potential disruptions across the group. This includes procedures and practices to ensure safety and mitigate business disruptions and an overarching framework that governs how crises are managed. These plans were leveraged as part of the Endo's response to COVID-19. See Likely Future Developments for discussion of Endo's response to COVID-19.

Disclaimer: The information in Endo's Non-Financial Statement is shared based on the best available data at publication. In some cases, data is estimated. Endo cautions that our statements with respect to current and future potential implications of corporate social responsibility and sustainability topics are subject to numerous important risks, uncertainties, assumptions and other factors, some of which are beyond Endo's control, which could cause Endo's actual results and business implications to differ materially from those expressed or implied by the information in this report. For additional information on Endo's ESG report refer to www.endo.com.

Subsidiary Companies and Branches

Information regarding subsidiary undertakings and associates is provided in Note 30. Subsidiaries of the accompanying Consolidated Financial Statements included in this report. The Group does not operate any branches outside of the State.

Going Concern

The Consolidated and the Company Financial Statements have been prepared on a going concern basis. In arriving at its conclusion, the Group's directors have taken into account various uncertainties, including those relating to pending or threatened litigation.

As outlined in Note 15. Commitments and Contingencies, 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, as well as various other manufacturers, distributors, pharmacies and/or others, asserting claims relating to defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications, including certain of our products. The outcome of this litigation is inherently uncertain and 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. To the extent unresolved, the Group will continue to vigorously defend the foregoing matters and to explore other options as appropriate in its best interests, including entering into settlement negotiations and settlements even in circumstances where we believe we have meritorious defenses. The board has formed a judgment at the time of approving the Consolidated and Company Financial Statements that the Group's existing cash resources and cash expected to be generated from the Group's operations will be sufficient to fund the Group's and Company's operating and capital needs for a twelve-month period from the date of issuance of the financial statements.

Disclosure of Information to the Auditors

For the purposes of section 330 of the Companies Act 2014, each of the persons who are Directors at the date of approval of this report individually confirm that:

- In so far as they are aware, there is no relevant audit information, as defined in section 330, of which the Group's auditors are unaware; and
- That they have taken all the steps that they ought to have taken as a Director in order to make themselves aware of any relevant audit information and to establish that the Group's auditors are aware of such information.

Audit & Finance Committee

In accordance with Section 167 of the Companies Act 2014, Endo has an Audit & Finance committee, which meets the requirements of the Companies Act.

Annual Compliance Statement of Endo International Plc (the Company)

The Directors acknowledge that they are responsible for securing compliance by the Company with its Relevant Obligations as defined in Section 225 of the Companies Act, 2014 (the Relevant Obligations).

The Directors confirm that they have drawn up and adopted a compliance policy statement setting out the Company's policies that, in the Directors' opinion, are appropriate to the Company respecting compliance with its Relevant Obligations.

The Directors further confirm the Company has put in place appropriate arrangements or structures that are, in the Directors' opinion, designed to secure material compliance with its Relevant Obligations including reliance on the advice of persons employed by the Company and external legal and tax advisers as considered appropriate from time to time and that they have reviewed the effectiveness of these arrangements or structures during the financial year to which this report relates.

Annual General Meeting

The Annual General Meeting of the Group will take place at First Floor, Minerva House, Simonscourt Road, Ballsbridge, Dublin 4, Ireland, on June 09, 2022.

Statutory Auditors

The statutory auditors, PricewaterhouseCoopers (PwC) have indicated their willingness to continue in office, and a resolution that they be reappointed will be proposed at the Annual General Meeting.

On behalf of the Directors

/s/ Mark G. Barberio
Mark G Barberio
Chairman

/s/ Blaise Coleman
Blaise Coleman
Director

May 06, 2022

ENDO INTERNATIONAL PLC
STATEMENT OF DIRECTORS' RESPONSIBILITIES

The directors are responsible for preparing the directors' report and the group and company financial statements in accordance with Irish law.

Irish law requires the directors to prepare group and company financial statements for each financial year giving a true and fair view of the group and company's assets, liabilities and financial position at the end of the financial year and the profit or loss of the group and company for the financial year. Under that law the directors have prepared the financial statements in accordance with Irish Generally Accepted Accounting Practice (accounting standards issued by the UK Financial Reporting Council, including Financial Reporting Standard 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* and Irish law).

Under Irish law, the directors shall not approve the group and company financial statements unless they are satisfied that they give a true and fair view of the group and company's assets, liabilities and financial position as at the end of the financial year and the profit or loss of the group and company for the financial year.

In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with applicable accounting standards and identify the standards in question, subject to any material departures from those standards being disclosed and explained in the notes to the financial statements; and
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that the group and company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to:

- correctly record and explain the transactions of the group and company;
- enable, at any time, the assets, liabilities, financial position and profit or loss of the group and company to be determined with reasonable accuracy; and
- enable the directors to ensure that the financial statements comply with the Companies Act 2014 and enable those financial statements to be audited.

The directors are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the Group's website. Legislation in Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.



Independent auditors' report to the members of Endo International plc

Report on the audit of the financial statements

Opinion

In our opinion:

- Endo International plc's consolidated financial statements and company financial statements (the "financial statements") give a true and fair view of the group's and the company's assets, liabilities and financial position as at 31 December 2021 and of the group's loss and cash flows for the year then ended;
- the group financial statements have been properly prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of group financial statements does not contravene any provision of Part 6 of the Companies Act 2014;
- the company financial statements have been properly prepared in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council of the UK, including Financial Reporting Standard 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" and Irish law); and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

We have audited the financial statements, included within the Directors' Report and Financial Statements (the "Annual Report"), which comprise:

- the Consolidated Balance Sheet as at 31 December 2021;
- the Company Balance Sheet as at 31 December 2021;
- the Consolidated Profit and Loss Account and the Consolidated Statement of Comprehensive Income for the year then ended;
- the Consolidated Statement of Cash Flows for the year then ended;
- the Consolidated Reconciliation of Shareholders' Funds for the year then ended;
- the Company Reconciliation of Shareholders' Funds for the year then ended; and
- the notes to the financial statements, which include a description of the significant accounting policies.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) ("ISAs (Ireland)") and applicable law. Our responsibilities under ISAs (Ireland) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We remained independent of the group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, which includes IAASA's Ethical Standard as applicable to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.



Our audit approach

Overview



Materiality

- \$33 million (2020: \$32 million) - Consolidated financial statements
- Based on 2.5% of EBITDA from continuing operations, adjusted for asset impairment charges, litigation-related settlement charges, and separation benefits and other restructuring charges.
- \$12 million (2020: \$14 million) - Company financial statements
- Based on 1% of total assets.



Audit scope

- We performed full scope audits over two components. We paid particular attention to these components due to their size or characteristics and to ensure appropriate audit coverage.
- Specified audit procedures were performed in respect of two components.
- Certain centralised group functions and balances, including treasury, taxation, equity and stock compensation, goodwill and intangible assets and contingent consideration were subject to full scope audit procedures.
- Taken together, through the performance of full scope audits and specified audit procedures, we obtained coverage in excess of 90% of group revenues and group total assets.



Key audit matters

- Opioid-Related Litigation.
- Provisions for Sales Deductions.
- Goodwill Impairment Assessment - Sterile Injectables segment.

The scope of our audit

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

Key audit matters

Key audit matters are those matters that, in the auditors' professional judgement, were of most significance in the audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by the auditors, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters, and any comments we make on the results of our procedures thereon, were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

<i>Key audit matter</i>	<i>How our audit addressed the key audit matter</i>
<i>Opioid-Related Litigation</i>	We gained an understanding of management's process around the accounting and reporting for the opioid-related litigation.



<i>Key audit matter</i>	<i>How our audit addressed the key audit matter</i>
<p data-bbox="233 422 826 509"><i>Refer to Notes 2 (Basis of Presentation and Significant Accounting Principles) and 15 (Commitments and Contingencies) to the consolidated financial statements.</i></p> <p data-bbox="233 561 826 675">The Company and its subsidiaries are subject to risks and uncertainties as a result of ongoing litigation that could affect amounts and disclosures in the financial statements in future periods.</p> <p data-bbox="233 727 826 1355">As described in Notes 2 and 15 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. The majority of cases are in the U.S. As of April 28, 2022, and set out in Note 15, 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 2,925 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 310 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers and approximately 215 cases filed by individuals, including but not limited to legal guardians of children born with neonatal abstinence syndrome.</p> <p data-bbox="233 1406 826 1520">The company has recorded total settlement charges for opioid-related matters of \$343.5 million in 2021 and, as of December 31, 2021, the corresponding accrual totalled \$258.7 million.</p> <p data-bbox="233 1572 826 1810">Contingent accruals and legal settlements are recorded in the consolidated statement of comprehensive income 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’s estimates of the probability and amount of any such liabilities involve significant judgement regarding future events.</p> <p data-bbox="233 1862 826 1910">We determined provisions for opioid related litigation to be a key audit matter as there is significant judgement by</p>	<p data-bbox="850 464 1461 609">We tested 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.</p> <p data-bbox="850 660 1461 774">We evaluated the status of significant known actual and potential litigation and ongoing settlement negotiations through discussion with the company’s in-house legal counsel.</p> <p data-bbox="850 826 1461 878">We obtained and evaluated the letters of audit inquiry with internal and external legal counsel for significant litigation.</p> <p data-bbox="850 930 1461 1023">We evaluated the reasonableness of management’s assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable.</p> <p data-bbox="850 1075 1461 1127">We evaluated the sufficiency of the company’s litigation contingencies disclosures.</p>



<i>Key audit matter</i>	<i>How our audit addressed the key audit matter</i>
<p>management when assessing the likelihood of losses being incurred, determining whether reasonable estimates of the loss or range of losses can be made and the amount of such estimates.</p>	
<p><i>Provisions for Sales Deductions</i> <i>Refer to Notes 2 (Basis of Presentation and Significant Accounting Principles) and 24 (Provisions and Creditors) to the consolidated financial statements.</i></p> <p>As described in Note 2 to the consolidated financial statements, the amount of revenue recognised by the company is determined by adjusting the fixed amount of the transaction price for management’s estimates of a number of significant variable components including, but not limited to, estimates for chargebacks, rebates, sales incentives and allowances, fees payable under Distribution Sale Agreements (“DSA”) and other fees for services, returns and allowances, which management collectively refer to as sales deductions.</p> <p>As of December 31, 2021, provisions for sales deductions totalled \$588.7 million. These amounts relate primarily to the company’s estimates of unsettled obligations for chargebacks, rebates, returns and allowances. The most significant sales deductions relate to returns, wholesaler chargebacks and rebates for the Sterile Injectables and Generic Pharmaceuticals segments.</p> <p>Management estimates the provisions 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, 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.</p> <p>We determined provisions for sales deductions to be a key audit matter as there is significant judgement exercised by management in developing these provisions, including determining appropriate assumptions related to customers’ direct and indirect 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.</p>	<p>We tested the effectiveness of controls over sales deductions, including controls over the assumptions used to estimate the provisions for the sales deductions balance at year-end.</p> <p>We developed an independent estimate for these provisions at December 31, 2021. This included using 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. We compared this expectation to the provisions recorded by management.</p> <p>We considered the historical accuracy of management’s estimates in previous years by comparing historical provisions to rebate payments and credits processed in subsequent periods.</p> <p>We tested a sample of 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 group’s rebate programs and returns policy.</p>
<p><i>Goodwill Impairment Assessment - Sterile Injectables Segment</i> <i>Refer to Notes 2 (Basis of Presentation and Significant Accounting Principles) and 11 (Goodwill and Other Intangibles) to the consolidated financial statements.</i></p>	<p>We tested the effectiveness of controls relating to goodwill impairment assessment, including controls over the identification of triggering events, determination of the Sterile Injectables reporting unit and the estimation of the Sterile Injectables reporting unit’s fair value including the development of assumptions used to estimate fair value.</p>



<i>Key audit matter</i>	<i>How our audit addressed the key audit matter</i>
<p>As described in Notes 2 and 11 to the financial statements the goodwill balance for the Sterile Injectables reporting unit was \$2,368.2 million as of December 31, 2021.</p>	<p>We tested the assignment of assets and liabilities to the reporting unit.</p>
<p>An impairment assessment is conducted as of October 1 each year or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. Management performs the goodwill impairment test by comparing the fair value and carrying amount of each reporting unit. Management estimated the fair values of its reporting units using an income approach that utilises a discounted cash flow model.</p>	<p>We tested management’s process for determining the fair value estimate, which included evaluating the appropriateness of the discounted cash flow model.</p>
<p>The discounted cash flow models are dependent upon management’s estimates of future cash flows and other factors such as estimates of future operating performance, including future sales, long-term growth rates, gross margins, operating expenses and discount rate.</p>	<p>We tested the completeness and accuracy of underlying data used in the discounted cash flow model related to cashflow projections.</p>
<p>As described within Note 11 to the consolidated financial statements, the company recognised an impairment related to the Sterile Injectables reporting unit of \$363.0 million during the year ended December 31, 2021. The impairment charge was recorded following the Group’s annual goodwill impairment test.</p>	<p>We evaluated whether the assumptions used to estimate fair value, including future sales, long-term growth rates, gross margins, operating expenses and discount rate and the probability of achieving the estimated cash flows were reasonable, which included considering historical performance and industry and economic forecasts.</p>
<p>The Goodwill impairment assessment for the Sterile Injectables segment was determined to be a key audit matter as there was significant judgement by management when determining the fair value of the reporting unit, including determining significant assumptions related to future sales, long-term growth rates, gross margins, operating expenses and discount rate and the probability of achieving the estimated cash flows.</p>	<p>Our procedures also included the involvement of our PwC professionals with specialised skills and knowledge to assist us in evaluating the appropriateness of the discount rate and long-term growth rate assumptions.</p>

How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the group, the accounting processes and controls, and the industry in which the group operates.

The consolidated financial statements are a consolidation of four reportable segments (Generic Pharmaceuticals, Branded Pharmaceuticals, Sterile Injectables and International Pharmaceuticals) comprising a number of components.

In determining our audit scope we focused on individual components and determined the type of work that needed to be performed at four components by us, as the Irish group engagement team, PwC US as the global engagement team, or other component auditors within other PwC network firms.

Two components were identified as significant components and full scope audits were performed at these components. In addition, another two components were subject to specified audit procedures. Certain centralised group functions and balances, including treasury, taxation, equity and stock compensation, goodwill and intangible assets and contingent consideration were subject to full scope audit procedures by the PwC US global engagement team.



Through the performance of full scope audits and specified procedures, we obtained coverage in excess of 90% of group revenues and group total assets. This, together with additional procedures performed at group level, gave us the evidence we needed for our opinion on the financial statements as a whole.

The group team was responsible for the scope and direction of the audit process. Where the work was performed by component auditors, we determined the level of involvement the group team needed to have to be able to conclude whether sufficient appropriate audit evidence had been obtained as a basis for our opinion on the consolidated financial statements as a whole. The supervision of the component teams included a combination of regular calls with the senior members of the component audit teams and review of detailed memoranda of work performed by component teams. In addition to this, the group engagement team reviewed certain of the audit working papers of significant components.

Materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

	<i>Consolidated financial statements</i>	<i>Company financial statements</i>
<i>Overall materiality</i>	\$33 million (2020: \$32 million).	\$12 million (2020: \$14 million).
<i>How we determined it</i>	2.5% of EBITDA from continuing operations, adjusted for asset impairment charges, litigation-related settlement charges and separation benefits and other restructuring charges.	1% of total assets.
<i>Rationale for benchmark applied</i>	We believe that EBITDA from continuing operations, adjusted for asset impairment charges, litigation-related settlement charges and separation benefits and other restructuring charges provides us with a consistent year on year basis for determining materiality and is the most relevant metric for the users of the financial statements.	As the Company is a holding company, we believe that total assets are the most appropriate benchmark to calculate materiality.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above \$2.5 million (group audit) (2020: \$2.5 million) and \$600,000 (company audit) (2020: \$700,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

Conclusions relating to going concern

Our evaluation of the directors’ assessment of the group and company’s ability to continue to adopt the going concern basis of accounting included:

- > Obtaining and reviewing management’s going concern assessment for the going concern period of twelve months from the date on which the financial statements are authorised for issue;
- > Understanding the process undertaken by management to perform the going concern assessment;
- > Evaluating the current liquidity and financial position;
- > Evaluating the key assumptions underpinning the group’s forecasts, including the projected cash flow impact of litigation, as disclosed note 15, and assessing how these forecasts are compiled;
- > Assessing management’s sensitivities performed over the group’s cash flow forecasts and evaluating if these sensitivities appropriately considered the relevant risks facing the business as set out in “Consolidation and Basis of Preparation” within Note 2 for the going concern period.



Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's or the company's ability to continue as a going concern for a period of at least twelve months from the date on which the financial statements are authorised for issue.

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

However, because not all future events or conditions can be predicted, this conclusion is not a guarantee as to the group's or the company's ability to continue as a going concern.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Reporting on other information

The other information comprises all of the information in the Annual Report other than the financial statements and our auditors' report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Directors' Report, we also considered whether the disclosures required by the Companies Act 2014 (excluding the information included in the "Non Financial Statement" as defined by that Act on which we are not required to report) have been included.

Based on the responsibilities described above and our work undertaken in the course of the audit, ISAs (Ireland) and the Companies Act 2014 require us to also report certain opinions and matters as described below:

- In our opinion, based on the work undertaken in the course of the audit, the information given in the Directors' Report (excluding the information included in the "Non Financial Statement" on which we are not required to report) for the year ended 31 December 2021 is consistent with the financial statements and has been prepared in accordance with the applicable legal requirements.
- Based on our knowledge and understanding of the group and company and their environment obtained in the course of the audit, we have not identified any material misstatements in the Directors' Report (excluding the information included in the "Non Financial Statement" on which we are not required to report).

Responsibilities for the financial statements and the audit

Responsibilities of the directors for the financial statements

As explained more fully in the Statement of Directors' Responsibilities set out on page 73, the directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view.

The directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and the company's ability to continue as a going concern, disclosing as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the company or to cease operations, or have no realistic alternative but to do so.

Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered



material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Our audit testing might include testing complete populations of certain transactions and balances, possibly using data auditing techniques. However, it typically involves selecting a limited number of items for testing, rather than testing complete populations. We will often seek to target particular items for testing based on their size or risk characteristics. In other cases, we will use audit sampling to enable us to draw a conclusion about the population from which the sample is selected.

A further description of our responsibilities for the audit of the financial statements is located on the IAASA website at:

https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description_of_auditors_responsibilities_for_audit.pdf

This description forms part of our auditors' report.

Use of this report

This report, including the opinions, has been prepared for and only for the company's members as a body in accordance with section 391 of the Companies Act 2014 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

Other required reporting

Companies Act 2014 opinions on other matters

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the company financial statements to be readily and properly audited.
- The Company Balance Sheet is in agreement with the accounting records.

Other exception reporting

Directors' remuneration and transactions

Under the Companies Act 2014 we are required to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by sections 305 to 312 of that Act have not been made. We have no exceptions to report arising from this responsibility.

Prior financial year Non Financial Statement

We are required to report if the company has not provided the information required by Regulation 5(2) to 5(7) of the European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 in respect of the prior financial year. We have nothing to report arising from this responsibility.

Gareth Hynes
for and on behalf of PricewaterhouseCoopers
Chartered Accountants and Statutory Audit Firm
Dublin
6 May 2022

ENDO INTERNATIONAL PLC
CONSOLIDATED PROFIT AND LOSS ACCOUNT
YEAR ENDED DECEMBER 31, 2021
(In thousands, except per share data)

	Note	2021	2020
TURNOVER	6	\$ 2,993,206	\$ 2,903,074
Cost of sales	3	1,221,064	1,442,511
GROSS PROFIT		1,772,142	1,460,563
Selling, general and administrative expenses		861,760	698,506
Research and development expenses		148,560	158,902
Litigation-related and other contingency credits	3,6,15	345,495	(1,549)
Asset impairment charges	10,11	414,977	120,344
Acquisition-related and integration items	6	(8,379)	16,549
OPERATING PROFIT		\$ 9,729	\$ 467,811
INTEREST RECEIVABLE AND SIMILAR INCOME	3	(584)	(4,170)
INTEREST PAYABLE AND SIMILAR CHARGES	3	562,937	537,109
LOSS ON EXTINGUISHMENT OF DEBT	3	13,753	—
OTHER INCOME, NET	19	(19,774)	(21,110)
LOSS FROM CONTINUING OPERATIONS BEFORE TAXATION		\$ (546,603)	\$ (44,018)
TAX EXPENSE (BENEFIT) FROM CONTINUING OPERATIONS	20	22,478	(273,982)
(LOSS) PROFIT FROM CONTINUING OPERATIONS		\$ (569,081)	\$ 229,964
LOSS FROM DISCONTINUED OPERATIONS, NET OF TAX	3	(44,164)	(33,520)
(LOSS) PROFIT FOR THE FINANCIAL YEAR		\$ (613,245)	\$ 196,444
(LOSS) PROFIT PER SHARE - BASIC:			
Continuing operations		\$ (2.44)	\$ 1.00
Discontinued operations		(0.19)	(0.15)
Basic		\$ (2.63)	\$ 0.85
(LOSS) PROFIT PER SHARE - DILUTED:			
Continuing operations		\$ (2.44)	\$ 0.98
Discontinued operations		(0.19)	(0.14)
Diluted		\$ (2.63)	\$ 0.84
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:			
Basic	21	232,785	229,314
Diluted	21	232,785	233,653

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
YEAR ENDED DECEMBER 31, 2021
(In thousands)

	<u>Note</u>	<u>2021</u>	<u>2020</u>
(LOSS) INCOME FOR THE FINANCIAL YEAR		\$ (613,245)	\$ 196,444
Net unrealized loss on securities	16	—	—
Foreign currency translation gain	16	1,308	1,337
TOTAL COMPREHENSIVE INCOME		<u>\$(611,937)</u>	<u>\$197,781</u>

ENDO INTERNATIONAL PLC
CONSOLIDATED BALANCE SHEET
AS AT DECEMBER 31, 2021
(In thousands)

	Note	December 31, 2021	December 31, 2020
ASSETS			
<i>Non-current Assets</i>			
Intangible assets-Goodwill	11	\$ 3,197,011	\$ 3,560,011
Intangible assets-Other	11	2,362,823	2,740,808
Tangible assets	10	396,712	458,471
Operating Lease Assets	9	34,832	37,030
Other	23	61,451	55,059
<i>Current Assets</i>			
Stock	8	283,552	352,260
Debtors	23	799,724	675,998
Cash at bank and in-hand		1,507,196	1,213,437
Restricted cash		124,114	171,563
TOTAL ASSETS		\$ 8,767,415	\$ 9,264,637
EQUITY AND LIABILITIES			
<i>Capital and Reserves</i>			
Called up share capital presented as equity	17	\$ 68	\$ 72
Share premium account		6,140,397	6,140,397
Other reserves		(9,455,764)	(9,472,966)
Profit and loss account		2,071,313	2,684,558
Total equity shareholders' funds		\$ (1,243,986)	\$ (647,939)
<i>Creditors: amounts falling due within one year</i>			
Debenture loans-current portion	14	\$ 200,342	\$ 34,150
Operating lease liabilities	9	10,992	11,613
Trade and other creditors	24	1,074,608	862,758
		\$ 1,285,942	\$ 908,521
<i>Creditors: amounts falling due after more than one year</i>			
Debenture loans	14	\$ 8,048,980	\$ 8,280,578
Operating lease liabilities	9	33,727	38,132
Trade and other creditors	24	284,404	312,359
Total for creditors: amounts falling due after more than one year		\$ 8,367,111	\$ 8,631,069
Provision for liabilities	24	\$ 358,348	\$ 372,986
TOTAL EQUITY AND LIABILITIES		\$ 8,767,415	\$ 9,264,637

The Notes to the Consolidated Balance Sheet are an integral part of this statement.

The financial statements were approved by the Board of Directors on May 06, 2022 and signed on its behalf by:

/s/ Mark G. Barberio

Mark G Barberio
Chairman

/s/ Blaise Coleman

Blaise Coleman
Director

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENT OF CASH FLOWS
YEAR ENDED DECEMBER 31, 2021
(In thousands)

	2021	2020
OPERATING ACTIVITIES:		
Consolidated net (loss) profit	\$ (613,245)	\$196,444
Adjustments to reconcile consolidated net profit (loss) to Net cash provided by operating activities:		
Depreciation and amortization	457,098	518,807
Share-based compensation	30,046	41,357
Amortization of debt issuance costs and discount	14,437	15,606
Deferred income taxes	(3,157)	(163,558)
Change in fair value of contingent consideration	(8,793)	16,353
Loss on extinguishment of debt	13,753	—
Acquired in-process research and development charges	25,120	28,602
Asset impairment charges	414,977	120,344
Gain on sale of business and other assets	(4,516)	(16,353)
Changes in assets and liabilities which (used) provided cash:		
Debtors	(82,052)	(45,792)
Stock	48,978	(8,031)
Prepaid and other assets	(34,002)	(27,421)
Accounts payable, accrued expenses and other liabilities	84,391	(183,866)
Income taxes payable/receivable	68,015	(95,100)
Net cash provided by operating activities	<u>\$411,050</u>	<u>\$397,392</u>
INVESTING ACTIVITIES:		
Purchases of tangible fixed assets	(77,929)	(69,971)
Capitalized interest payments	(2,721)	(2,892)
Acquisitions including in-process research and development, net of cash and restricted cash acquired.	(5,000)	(649,504)
Proceeds from sale of marketable securities and 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

	2021	2020
Other investing activities	—	—
Net cash used in investing activities	\$(59,544)	\$(624,867)
FINANCING ACTIVITIES:		
Proceeds from issuance of notes	1,279,978	—
Proceeds from issuance of term loans	1,980,000	—
Principal payments on notes	—	(57,649)
Principal payments on term loans	(3,310,475)	(34,150)
Proceeds from draw of revolving debt	—	—
Repayments of revolving debt	(22,800)	—
Principal payments on other indebtedness	(5,448)	(4,884)
Payments for debt issuance and extinguishment costs	(8,574)	—
Payments for contingent consideration	(4,010)	(3,848)
Payments of tax withholding for restricted shares	(14,774)	(8,036)
Proceeds from exercise of options	622	—
Net cash used in financing activities	\$(105,481)	\$(108,567)
Effect of foreign exchange rate	285	654
NET INCREASE (DECREASE) IN CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND	\$246,310	\$(335,388)
CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND, BEGINNING OF YEAR	1,385,000	1,720,388
CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND, END OF YEAR	<u>\$1,631,310</u>	<u>\$1,385,000</u>
SUPPLEMENTAL INFORMATION:		
Cash paid for interest	\$538,424	\$534,529
Cash paid for income taxes	\$10,019	\$11,669
Cash paid into Qualified Settlement Funds for mesh legal settlements	\$670	\$7,215
Cash refunds from income taxes, gross	\$57,801	\$31,897
Cash paid out of Qualified Settlement Funds for mesh legal settlements	\$49,287	\$123,803
Other cash distributions for mesh legal settlements	\$47,360	\$44,471
SCHEDULE OF NON CASH INVESTING AND FINANCING ACTIVITIES		
Acquisitions, including in-process research and development, accrued in the period but not yet paid	\$ 20,120	\$ —

ENDO INTERNATIONAL PLC
CONSOLIDATED RECONCILIATION OF SHAREHOLDERS' FUNDS
YEAR ENDED DECEMBER 31, 2021
(In thousands)

	Endo International plc Shareholders				Total
	Share Capital	Share Premium	Profit and Loss Account	Other Reserves	
BALANCE, DECEMBER 31, 2019	\$ 68	\$ 6,140,397	\$ 2,488,114	\$ (9,507,623)	\$ (879,044)
BALANCE, January 1, 2020	\$ 68	\$ 6,140,397	\$ 2,488,114	\$ (9,507,623)	\$ (879,044)
Net profit	—	—	196,444	—	196,444
Other comprehensive income	—	—	—	1,337	1,337
Compensation related to share-based awards	—	—	—	41,357	41,357
Exercise of options	—	—	—	—	—
Tax withholding for restricted shares	—	—	—	(8,036)	(8,036)
Other share capital and other reserves	4	—	—	(1)	3
BALANCE, DECEMBER 31, 2020	\$ 72	\$ 6,140,397	\$ 2,684,558	\$ (9,472,966)	\$ (647,939)
BALANCE, January 1, 2021	\$ 72	\$ 6,140,397	\$ 2,684,558	\$ (9,472,966)	\$ (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	—	—	—	622	622
Tax withholding for restricted shares	—	—	—	(14,774)	(14,774)
Other	(4)	—	—	—	(4)
BALANCE, DECEMBER 31, 2021	\$ 68	\$ 6,140,397	\$ 2,071,313	\$ (9,455,764)	\$ (1,243,986)

ENDO INTERNATIONAL PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEAR ENDED DECEMBER 31, 2021

NOTE 1. DESCRIPTION OF BUSINESS

Endo International plc is an Ireland-domiciled specialty branded and generics pharmaceutical company that conducts business through its operating subsidiaries. Unless otherwise indicated or required by the context, references throughout to “Endo,” the “Group,” “we,” “our” or “us” refer to financial information and transactions of 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. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING PRINCIPLES

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.

The Consolidated Financial Statements have been prepared on a going concern basis. In arriving at its conclusion, the Group's directors have taken into account various uncertainties, including those relating to pending or threatened litigation.

As outlined in Note 15. Commitments and Contingencies, 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, as well as various other manufacturers, distributors, pharmacies and/or others, asserting claims relating to defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications, including certain of our products. The outcome of this litigation is inherently uncertain and 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. To the extent unresolved, the Group will continue to vigorously defend the foregoing matters and to explore other options as appropriate in its best interests, including entering into settlement negotiations and settlements even in circumstances where we believe we have meritorious defenses. The board has formed a judgment at the time of approving the Consolidated Financial Statements that the Group's existing cash resources and cash expected to be generated from the Group's operations will be sufficient to fund the Group's operating and capital needs for a twelve-month period from the date of issuance of the financial statements.

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

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

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

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

We have agreements with certain third parties for the manufacture, supply and processing of certain of our existing pharmaceutical products. See Note 15. 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.

Turnover 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 turnover 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 turnover 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 turnover 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, turnover 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 turnover 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 turnover 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 stock 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 Group's right to consideration in exchange for goods or services that the Group has transferred when that right is conditioned on something other than the passage of time. The Group records turnover 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 Group's right to consideration becomes unconditional, the contract asset amount is reclassified as Accounts receivable.

Contract liabilities represent the Group's obligation to transfer goods or services to a customer. The Group 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 turnover 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 Profit and loss account 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. Tangible fixed assets, 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 Group 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 at bank and on-hand. The Group 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 Group maintains its cash deposits and cash equivalents with financial institutions it believes to be well-known and stable.

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

Accounts Receivable. The Group 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 Group'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.

Stock. *Stock* consist of raw materials, work-in-process and finished goods. Stock that is in excess of the amount expected to be sold within one year is classified as long-term stock and is recorded in Other assets in the Consolidated Balance Sheets. The Group capitalizes stock 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 stock will be saleable. The determination to capitalize is made on a product-by-product basis. The Group could be required to write down previously capitalized costs related to pre-launch stock upon a change in such judgment, a denial or delay of approval by regulatory bodies, a delay in commercialization or other potential factors. Our stock 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 stock to net realizable value based on forecasted demand and market and regulatory conditions, which may differ from actual results.

Tangible Fixed Assets. *Tangible fixed assets* 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 tangible fixed assets 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 tangible fixed assets 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, net in the Consolidated Profit and loss account. 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 Group 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 Tangible fixed assets, 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 Group 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 Group 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 Group to not assess whether certain land easements contain leases. Due to the Group's election of these practical expedients, the Group 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 Group is party.

Whenever the Group 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 Group 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 Group if the Group 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 Group 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 Group without depending on other resources not readily available to the Group 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 Group but do not meet the definition of lease components are considered nonlease components. The consideration owed by the Group pursuant to a lease arrangement is generally allocated to each lease and nonlease component for accounting purposes. However, the Group 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 Group 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 Group, together with periods covered by: (i) renewal options the Group is reasonably certain to exercise, (ii) termination options the Group 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 Group 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 Group.
- Discount rate—The discount rate must be determined based on information available to the Group 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 Group's leases is generally not readily determinable, the Group 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 Group 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 Group will record a lease liability and a right-of-use asset. However, the Group 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 Group 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 Profit and loss account, 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 Profit and loss account 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 Profit and loss account 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 Group accounted for leases under *Accounting Standards Codification Topic 840, Leases* (ASC 840).

Cloud Computing Arrangements. The Group may from time to time incur costs in connection with hosting arrangements that are service contracts. Subsequent to the Group'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 Group 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. Turnover 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 principal risks 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 profit and net profit 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 tangible fixed assets 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 Profit and loss account 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 Profit and loss account 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.

Irish company law requires goodwill to be written off over a time period which does not exceed its useful life. Consistent with U.S. GAAP, the Group does not amortize goodwill over an arbitrary period as it is considered to have an indefinite life.

Contingencies. The Group 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 Profit and loss account as Litigation-related and other contingencies, net (or as Discontinued operations, net of tax in the case of vaginal mesh matters) when the Group 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 Profit and loss account (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 Group records receivables from its insurance carriers only when the realization of the potential claim for recovery is considered probable.

Contingent Consideration. Certain of the Group'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 Group 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 Group 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 Group 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 Profit and loss account . 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 Sales. *Cost of Sales* 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 tangible fixed assets , 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 Group 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 Group 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 18. Share-based Compensation for additional discussion.

Foreign Currency. The Group operates in various jurisdictions both inside and outside of the U.S. While the Group's reporting currency is the U.S. dollar, the Group has concluded that certain of its distinct and separable operations have functional currencies other than the U.S. dollar. Further, certain of the Group's operations hold assets and liabilities and recognize profit 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 profit and expenses are generally remeasured using average exchange rates in effect during the year. In the case of nonmonetary assets and liabilities such as stock, prepaid expenses, tangible fixed assets, 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, net in the Consolidated Profit and loss account

As part of the Group'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 Group records a reclassification adjustment out of Other comprehensive income for the corresponding accumulated amount of foreign currency translation gain or loss.

Income Taxes. The Group 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 Group 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 Group 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 Group 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 Group would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income tax.

The Group records unrecognized income tax positions (UTPs) on the basis of a two-step process whereby the Group 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 Group recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the tax authority. The Group recognizes changes in UTPs, interest and penalties in the Income tax expense (benefit) line in the Consolidated Profit and loss account. The Group 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 group's shareholders. Other comprehensive income or loss refers to turnover, 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 Group 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 Group'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 Group early adopted ASC 832 during the fourth quarter of 2021 and is complying with the related disclosure requirements.

NOTE 3. DISCONTINUED OPERATIONS AND DIVESTITURES

Astora

The operating results of the Group's Astora business, which the Board resolved to wind down in 2016, are reported as Discontinued operations, net of tax in the Consolidated Profit and loss account 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	\$ 11,097
Loss from discontinued operations before income taxes	\$ (49,594)	\$ (37,847)
Income tax benefit	\$ (5,430)	\$ (4,327)
Loss from discontinued operations, net of tax	\$ (44,164)	\$ (33,520)

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 and \$33.5 million for the years ended December 31, 2021 and 2020, 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 Group'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 stock. 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 Profit and loss account

. 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 Group's Generic Pharmaceuticals segment, have been fully divested. These assets and liabilities did not meet the requirements for treatment as a discontinued operation. Loss from discontinued operations before income taxes includes Litigation-related and other contingencies, net, mesh-related legal defense costs and certain other items.

Continuing Operations and Discontinued Operations

The Group is presenting a bridge of the continuing operations financial statements presented with the financial statements of the group. Treatment of discontinued operations presented are in accordance with U.S. GAAP.

The following profit and loss accounts show reconciliations of continuing operations and discontinued operations to the global company for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31, 2021		
	Continuing Operations	Discontinued Operations	Global Company
TURNOVER	\$ 2,993,206	\$ —	\$ 2,993,206
Cost of sales	1,221,064	—	1,221,064
GROSS PROFIT	\$ 1,772,142	\$ —	\$ 1,772,142
Selling, general and administrative expenses	861,760	25,786	887,546
Research and development expenses	148,560	—	148,560
Litigation-related and other contingency expenses	345,495	25,000	370,495
Asset impairment charges	414,977	—	414,977
Acquisition-related and integration items	(8,379)	—	(8,379)
OPERATING PROFIT (LOSS)	\$ 9,729	\$ (50,786)	\$ (41,057)
INTEREST RECEIVABLE AND SIMILAR INCOME	(584)	—	(584)
INTEREST PAYABLE AND SIMILAR CHARGES	562,937	—	562,937
LOSS ON EXTINGUISHMENT OF DEBT	13,753	—	13,753
OTHER INCOME, NET	(19,774)	(1,192)	(20,966)
LOSS FROM CONTINUING AND DISCONTINUING OPERATIONS BEFORE TAXATION	\$ (546,603)	\$ (49,594)	\$ (596,197)
TAX EXPENSE/(BENEFIT) FROM CONTINUING AND DISCONTINUING OPERATIONS	22,478	(5,430)	17,048
(LOSS) FROM CONTINUING OPERATIONS AND DISCONTINUING OPERATIONS	\$ (569,081)	\$ (44,164)	\$ (613,245)
(LOSS) PROFIT DISCONTINUED OPERATIONS, NET OF TAX	(44,164)	44,164	—
(LOSS) FOR THE FINANCIAL YEAR	\$ (613,245)	\$ —	\$ (613,245)

	Year Ended December 31, 2020		
	Continuing Operations	Discontinued Operations	Global Company
TURNOVER	\$ 2,903,074	\$ —	\$ 2,903,074
Cost of sales	1,442,511	—	1,442,511
GROSS PROFIT	\$ 1,460,563	\$ —	\$ 1,460,563
Selling, general and administrative expenses	698,506	25,195	723,701
Research and development expenses	158,902	—	158,902
Litigation-related and other contingency (credits)/expenses	(1,549)	11,097	9,548
Asset impairment charges	120,344	—	120,344
Acquisition-related and integration items	16,549	—	16,549
OPERATING PROFIT (LOSS)	\$ 467,811	\$ (36,292)	\$ 431,519
INTEREST RECEIVABLE AND SIMILAR INCOME	(4,170)	—	(4,170)
INTEREST PAYABLE AND SIMILAR CHARGES	537,109	4	537,113
GAIN ON EXTINGUISHMENT OF DEBT	—	—	—
OTHER (PROFIT) LOSS, NET	(21,110)	1,551	(19,559)
LOSS FROM CONTINUING AND DISCONTINUING OPERATIONS BEFORE TAXATION	\$ (44,018)	\$ (37,847)	\$ (81,865)
TAX BENEFIT FROM CONTINUING AND DISCONTINUING OPERATIONS	(273,982)	(4,327)	(278,309)
PROFIT (LOSS) FROM CONTINUING AND DISCONTINUING OPERATIONS	\$ 229,964	\$ (33,520)	\$ 196,444
(LOSS) PROFIT DISCONTINUED OPERATIONS, NET OF TAX	(33,520)	33,520	—
PROFIT FOR THE FINANCIAL YEAR	<u>\$ 196,444</u>	<u>\$ —</u>	<u>\$ 196,444</u>

The Group did not have held for sale assets and liabilities as of December 31, 2021 or 2020.

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 Group announced the initiation of several strategic actions to further optimize the Group'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 Group's key strategic priority to expand and enhance its product portfolio. These actions, which we have been progressing, include the following:

- Optimizing the Group'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 Group'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 Group's commercial, operations and research and development functions, respectively, to support the Group'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 and Divestitures.

As a result of the 2020 Restructuring Initiative, the Group's global workforce is ultimately expected to be reduced by approximately 500 net full-time positions. The Group 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 Sales 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 Group 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 and Divestitures, 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 Group 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 Group's Consolidated Profit and loss account 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 stock 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 and Divestitures of approximately \$49.5 million, excess stock 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 Group's Consolidated Profit and loss account during the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Net restructuring charges (charge reversals) included in:		
Cost of Sales	\$ 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 (profit) 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 January 1, 2020	\$ —	\$ —	\$ —
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 (December 31, 2020 \$36.4 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 Group 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 Group.

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 turnover 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 Profit and loss account 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 Sales. 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 Group 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 at bank and on-hand	\$ 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 Profit and loss account. The Group concluded that the consideration allocable to developed technology acquired represented incremental costs associated with the Group's existing XIAFLEX[®] and QWO[®] intangible assets (the Existing Intangible Assets). The Existing Intangible Assets were acquired by the Group 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 Group 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 Group. The BioSpecifics acquisition significantly impacted the timing and amount of estimated future cash flows from sales of XIAFLEX[®] and QWO[®] and, therefore, the Group 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 Group 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 Group'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 turnover from the sales or licensing of its respective products and is discussed in more detail below.

We evaluate segment performance based on Segment adjusted profit 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; stock 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 Group are not directly attributable to any specific segment. Accordingly, these costs are not allocated to any of the Group'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 Group's segments. The Group's Total segment adjusted profit 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 Group's reportable segments for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Net turnover from external customers:		
Branded Pharmaceuticals	\$ 893,617	\$ 781,780
Sterile Injectables	1,266,097	1,238,847
Generic Pharmaceuticals	740,586	783,110
International Pharmaceuticals (1)	92,906	99,337
Total net turnover from external customers	<u>\$ 2,993,206</u>	<u>\$ 2,903,074</u>
Segment adjusted profit from continuing operations before income tax:		
Branded Pharmaceuticals	\$ 384,186	\$ 377,526
Sterile Injectables	998,453	950,145
Generic Pharmaceuticals	160,046	87,178
International Pharmaceuticals	30,325	41,022
Total segment adjusted profit from continuing operations before income tax	<u>\$ 1,573,010</u>	<u>\$ 1,455,871</u>

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

There were no material turnover 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 profit from continuing operations before income tax for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Total consolidated loss from continuing operations before income tax	\$ (546,603)	\$ (44,018)
Interest expense, net	562,353	532,939
Corporate unallocated costs (1)	180,866	157,723
Amortization of intangible assets	372,907	427,543
Upfront and milestone payments to partners (2)	26,451	35,075
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (3)	90,912	126,282
Certain litigation-related and other contingencies, net (4)	345,495	(1,549)
Certain legal costs (5)	136,148	67,819
Asset impairment charges (6)	414,977	120,344
Acquisition-related and integration items, net (7)	(8,379)	16,549
Loss on extinguishment of debt	13,753	—
Foreign currency impact related to the remeasurement of intercompany debt instruments	797	1,919
Other, net (8)	(16,667)	15,245
Total segment adjusted profit from continuing operations before income tax	<u>\$ 1,573,010</u>	<u>\$ 1,455,871</u>

(1) Amounts include certain corporate overhead costs, such as headcount, facility and corporate litigation expenses and certain other profit 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 15. Commitments and Contingencies.

(5) Amounts relate to opioid-related legal expenses.

- (6) Amounts primarily relate to charges to impair goodwill and intangible assets, tangible fixed assets, operating lease right-of-use assets and certain disposal group assets. For additional information, refer to Note 3. Discontinued Operations and Divestitures, Note 4. Restructuring, Note 7. Fair Value Measurements, Note 9. Leases, Note 10. Tangible fixed assets 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 14. 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 14. Debt. Other amounts in this row primarily relate to gains or losses on sales of businesses and other assets, as further described in Note 19. Other Income, Net.

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

During the years ended December 31, 2021 and 2020, the Group disaggregated its turnover from contracts with customers into the categories included in the table below (in thousands). The Group believes these categories depict how the nature, timing and uncertainty of turnover and cash flows are affected by economic factors.

	2021	2020
<i>Branded Pharmaceuticals:</i>		
<i>Specialty Products:</i>		
XIAFLEX®	\$ 432,344	\$ 316,234
SUPPRELIN® LA	114,374	88,182
Other Specialty (1)	86,432	92,662
Total Specialty Products	<u>\$ 633,150</u>	<u>\$ 497,078</u>
<i>Established Products:</i>		
PERCOCET®	\$ 103,788	\$ 110,112
TESTOPEL®	43,636	35,234
Other Established (2)	113,043	139,356
Total Established Products	<u>\$ 260,467</u>	<u>\$ 284,702</u>
Total Branded Pharmaceuticals (3)	<u>\$ 893,617</u>	<u>\$ 781,780</u>
<i>Sterile Injectables:</i>		
VASOSTRICT®	\$ 901,735	\$ 785,646
ADRENALIN®	124,630	152,074
Other Sterile Injectables (4)	239,732	301,127
Total Sterile Injectables (3)	<u>\$ 1,266,097</u>	<u>\$ 1,238,847</u>
Total Generic Pharmaceuticals (5)	<u>\$ 740,586</u>	<u>\$ 783,110</u>
Total International Pharmaceuticals (6)	<u>\$ 92,906</u>	<u>\$ 99,337</u>
Total turnover, net	<u><u>\$ 2,993,206</u></u>	<u><u>\$ 2,903,074</u></u>

- (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 turnover 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.
- (6) The International Pharmaceuticals segment, which accounted for less than 5% of consolidated total turnover 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 and 2020(in thousands):

	2021	2020
Branded Pharmaceuticals	\$ 10,632	\$ 11,758
Sterile Injectables	17,796	17,400
Generic Pharmaceuticals	47,343	52,614
International Pharmaceuticals	4,242	4,530
Corporate unallocated	4,178	4,962
Total depreciation expense	<u>\$ 84,191</u>	<u>\$ 91,264</u>

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

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 at bank and on-hand, restricted cash at bank and on-hand, accounts receivable, accounts payable and accrued expenses, acquisition-related contingent consideration and debt obligations. Included in cash at bank and on-hand and restricted cash at bank and on-hand 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 at bank and on-hand (including money market funds), accounts receivable, accounts payable and accrued expenses approximate their fair values.

Restricted Cash at bank and on-hand

Amounts reported as Restricted cash at bank and on-hand 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 15. 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 at bank and on-hand 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 Group'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
<i>Assets:</i>				
Money market funds	\$ 134,847	\$ —	\$ —	\$ 134,847
<i>Liabilities:</i>				
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
<i>Assets:</i>				
Money market funds	\$ 214,120	\$ —	\$ —	\$ 214,120
<i>Liabilities:</i>				
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 15. 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 Group'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 Profit and loss account 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 Group's liability for acquisition-related contingent consideration during the year ended December 31, 2021 by acquisition (in thousands):

	Balance as of January 1, 2021	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 Group's liability for acquisition-related contingent consideration during the year ended December 31, 2020 by acquisition (in thousands):

	Balance as of January 1, 2020	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	<u>\$ 29,657</u>	<u>\$ 16,353</u>	<u>\$ (9,761)</u>	<u>\$ 36,249</u>

Nonrecurring Fair Value Measurements

The Group'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 tangible fixed assets	—	—	—	(2,011)
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,011</u>	<u>\$ (9,822)</u>
	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 tangible fixed assets	—	—	—	(1,249)
Operating lease right-of-use assets	—	—	—	(6,392)
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 15,463</u>	<u>\$ (87,558)</u>

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

Stock 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	<u>\$ 283,552</u>	<u>\$ 352,260</u>

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

Stock that is in excess of the amount expected to be sold within one year is classified as noncurrent stock 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 stock was included in Other assets in the Consolidated Balance Sheets. As of December 31, 2021 and December 31, 2020, the Group's Consolidated Balance Sheets included approximately \$12.2 million and \$37.5 million, respectively, of capitalized pre-launch stock related to products that were not yet available to be sold.

As of December 31, 2021 and 2020, \$31.5 million and \$45.6 million, respectively, of employee costs were capitalized as part of stock.

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 Group'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	Tangible fixed assets, 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 and 2020 (in thousands):

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

(1) Amounts are included in the Consolidated Profit and loss account 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 and 2020 (in thousands):

	2021	2020
Cost of Sales	\$ 11,316	\$ 11,610
Selling, general and administrative	\$ 21,013	\$ 18,108
Research and development	\$ 216	\$ 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	<u>\$ 52,340</u>	<u>\$ 36,680</u>
Less: amount representing interest	7,621	11,465
Present value of future lease payments (lease liability)	<u>\$ 44,719</u>	<u>\$ 25,215</u>

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 and 2020 (in thousands):

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

- (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. TANGIBLE ASSETS

Changes in the amount of Tangible Assets for the year ended December 31, 2021 are set forth in the table below (in thousands).

<i>Cost:</i>	Land and Buildings	Machinery and Equipment	Leasehold Improvements	Computer Equipment and Software	Furniture and Fixtures	Assets under Construction	Total
At January 1, 2021	\$ 291,212	\$ 275,846	\$ 74,506	\$ 126,437	\$ 13,886	\$ 84,759	\$ 866,646
Additions (1)	1,774	25,793	5,610	6,732	100	37,654	77,663
Disposals, transfers, impairments and other	(58,767)	(94,678)	(25,106)	(14,243)	(2,049)	(1,930)	(196,773)
Effect of currency translation	—	10	10	33	2	—	55
At December 31, 2021	<u>\$ 234,219</u>	<u>\$ 206,971</u>	<u>\$ 55,020</u>	<u>\$ 118,959</u>	<u>\$ 11,939</u>	<u>\$ 120,483</u>	<u>\$ 747,591</u>
<i>Accumulated Depreciation:</i>							
At January 1, 2021	\$ (114,543)	\$ (139,036)	\$ (49,179)	\$ (95,699)	\$ (9,718)	\$ —	\$ (408,175)
Additions	(26,670)	(31,481)	(11,251)	(12,841)	(1,948)	—	(84,191)
Disposals, transfers and other	31,072	71,072	23,672	13,615	2,090	—	141,521
Effect of currency translation	—	(4)	(6)	(22)	(2)	—	(34)
At December 31, 2021	<u>\$ (110,141)</u>	<u>\$ (99,449)</u>	<u>\$ (36,764)</u>	<u>\$ (94,947)</u>	<u>\$ (9,578)</u>	<u>\$ —</u>	<u>\$ (350,879)</u>
<i>Net Book Amount:</i>							
At December 31, 2021	<u>\$ 124,078</u>	<u>\$ 107,522</u>	<u>\$ 18,256</u>	<u>\$ 24,012</u>	<u>\$ 2,361</u>	<u>\$ 120,483</u>	<u>\$ 396,712</u>
At December 31, 2020	<u>\$ 176,669</u>	<u>\$ 136,810</u>	<u>\$ 25,327</u>	<u>\$ 30,738</u>	<u>\$ 4,168</u>	<u>\$ 84,759</u>	<u>\$ 458,471</u>

(1) Costs incurred during the construction or development of tangible fixed assets are initially recorded as additions to Assets under Construction. Once an asset has been placed into service, the cost of that asset is transferred from Assets under Construction to one of the other classes of assets.]

Depreciation expense was \$84.2 million and \$91.3 million for the years ended December 31, 2021 and 2020, respectively.

During the years ended December 31, 2021 and 2020, the Group recorded tangible fixed assets impairment charges totaling \$2.0 million and \$1.2 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 tangible fixed assets. 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 and Divestitures.

At December 31, 2021 and December 31, 2020, \$162.1 million and \$141.4 million of the Group's Tangible fixed assets, 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 and intangible assets consist of the following:

	Goodwill	In-process Research and Development	Licenses	Tradenames	Developed Technology	Total
	(In thousands)					
Cost:						
At January 1, 2021	\$ 4,361,138	\$ 3,000	\$ 439,230	\$ 6,409	\$ 6,442,734	\$ 11,252,511
Additions	—	—	4,177	—	—	4,177
Impairments	(363,000)	—	(1,300)	—	(6,511)	(370,811)
Other (1)	—	(3,000)	—	—	(212,043)	(215,043)
Effect of currency translations	—	—	—	—	1,959	1,959
At December 31, 2021	\$ 3,998,138	\$ —	\$ 442,107	\$ 6,409	\$ 6,226,139	\$ 10,672,793
Accumulated Amortization:						
At January 1, 2021	\$ (801,127)	\$ —	\$ (415,193)	\$ (6,409)	\$ (3,728,963)	\$ (4,951,692)
Charge	—	—	(4,739)	—	(368,168)	(372,907)
Other (1)	—	—	—	—	212,764	212,764
Effect of currency translations	—	—	—	—	(1,124)	(1,124)
At December 31, 2021	\$ (801,127)	\$ —	\$ (419,932)	\$ (6,409)	\$ (3,885,491)	\$ (5,112,959)
Net Book Amount:						
At December 31, 2021	\$ 3,197,011	\$ —	\$ 22,175	\$ —	\$ 2,340,648	\$ 5,559,834
At December 31, 2020	\$ 3,560,011	\$ 3,000	\$ 24,037	\$ —	\$ 2,713,771	\$ 6,300,819

(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 Divestitures; and (iii) the removal of certain fully amortized developed technology intangible assets.

Amortization expense for the years ended December 31, 2021 and 2020 totaled \$372.9 million and \$427.5 million, respectively. Amortization expense is included in Cost of Sales in the Consolidated Profit and loss account. 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

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

	Branded Pharmaceuticals	Sterile Injectables	Generic Pharmaceuti	International Pharmaceutica	Total
Goodwill as of January 1, 2020	\$ 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

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 Group'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 Profit and loss account

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

	2021	2020
Goodwill impairment charges	\$ 363,000	\$ 32,786
Other intangible asset impairment charges	\$ 7,811	\$ 79,917

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 Group determined that the carrying amount of the Sterile Injectables reporting unit exceeded its estimated fair value; therefore, the Group 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 Group determined that the carrying amount of the Paladin reporting unit exceeded its estimated fair value; therefore, the Group 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 and 2020 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 Group, 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 Group'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 Group and/or any of its sublicensees. In addition, the Group 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 Group 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 turnover consists almost entirely of sales of our products to customers, whereby we ship products to a customer pursuant to a purchase order. Turnover 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 turnover 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 turnover-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 Group'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 Group'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 turnover was recognized that was included in the contract liability balance at December 31, 2020.

During the year ended December 31, 2021, we recognized turnover of \$23.9 million relating to performance obligations satisfied, or partially satisfied, in prior periods. Such turnover generally relates to changes in estimates with respect to our variable consideration.

NOTE 14. DEBT

The following table presents information about the Group'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 Group and its subsidiaries, with certain customary exceptions, guarantee or serve as issuers or borrowers of the debt instruments representing substantially all of the Group'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 Group'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 Group 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 Group's outstanding debt agreements contain a number of restrictive covenants, including certain limitations on the Group's ability to incur additional indebtedness.

The Credit Agreement contains affirmative and negative covenants and events of default that the Group 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 Group'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 Group 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 Group'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 Group'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 Group entered into a Suspension of Rights Agreement which, among other provisions, suspends the Group'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 Group believes to be customary for similar indentures. Under these indentures, the negative covenants, among other things, restrict the Group'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 Group or any of its restricted subsidiaries; create certain liens; merge, consolidate or sell all or substantially all of the Group'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 Group 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 Group'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 Profit and loss account.

June 2019 Revolving Credit Facility Borrowing

In June 2019, the Group borrowed \$300.0 million under the Revolving Credit Facility to be used for purposes consistent with the Group's capital allocation priorities, including for general corporate purposes.

June 2020 Refinancing

In June 2020, the Group executed certain transactions (the June 2020 Refinancing Transactions) that included, among other things, the exchanges by certain of the Group'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 Group. 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 Profit and loss account

August 2020 Tender Offer

In August 2020, the Group 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 Group 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 Group 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 Group'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 Group and its subsidiaries that also guarantee the Credit Agreement and the Group'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 Profit and loss account. The Group 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 Profit and loss account; 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 Profit and loss account.

During the first quarter of 2021, the Group 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 Group 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 Group'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 15. 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 Group 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 Group'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 pelvic organ prolapse (POP) and stress urinary incontinence (SUI). We have not sold such products since March 2016. Plaintiffs claim a variety of personal injuries, including chronic pain, incontinence, inability to control bowel function and permanent deformities, and seek compensatory and punitive damages, where available.

Various Master Settlement Agreements (MSAs) and other agreements have resolved approximately 71,000 filed and unfiled U.S. mesh claims as of 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 mesh related QSFs and 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	<u>\$ 78,402</u>	<u>\$ 258,137</u>

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

Charges related to vaginal mesh liability and associated legal fees and other expenses for all periods presented are reported in Discontinued operations, net of tax in our Consolidated Profit and loss account

As of December 31, 2021, the Group 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 at bank and on-hand.

In addition, we may pay cash distributions to settle disputes separate from the QSFs, which will also decrease the liability accrual and decrease cash at bank and on-hand.

We were contacted in October 2012 regarding a civil investigation initiated by various U.S. state attorneys general into mesh products, including transvaginal surgical mesh products designed to treat POP and SUI. In November 2013, we received a subpoena relating to this investigation from the state of California, and we subsequently received additional subpoenas from California and other states. We are cooperating with the investigations.

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

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

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

Opioid-Related Matters

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

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

Many of the U.S. cases have been coordinated in a federal multidistrict litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio; however, in April 2022, the Judicial Panel on Multidistrict Litigation issued an order suggesting that, based on the progress of the MDL, it would no longer transfer new cases filed in or removed to federal court to the MDL. Other cases are pending in various federal or state courts. A case in Superior Court in Orange County, California, *People of the State of California v. Purdue Pharma L.P., et al.*, has been tried to verdict. The plaintiffs in the case, Orange, Santa Clara and Los Angeles Counties and the City of Oakland, asserted claims against EPI and 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. Certain cases have been stayed pending settlement discussions; excluding such cases the next trial is currently set to begin in early 2023. Trials may occur earlier or later than currently scheduled, as timing remains uncertain due to the impact of COVID-19 and other factors.

In September 2019, EPI, 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 Group, 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; which remains pending.

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

Since 2019, the Group 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 to the following:

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

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

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

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

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

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

Certain settlement agreements provide for the creation of QSFs into which settlement funds will be deposited and/or provide for the repayment of some or all of the settlement amount under certain conditions. Depending on the terms of the respective agreements, funds deposited in QSFs 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 Group believes a loss is probable and can reasonably be estimated. As further described below, the Group 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 Group and/or its subsidiaries have received certain subpoenas, civil investigative demands (CIDs) and informal requests for information concerning the sale, marketing and/or distribution of prescription opioid medications, including but not limited to the following:

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

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

In December 2020, the Group 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 Group 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 Group, Generics Bidco I, LLC, DAVA Pharmaceuticals, LLC, DAVA International LLC, EPI, EHSI and/or PPCI, as well as other pharmaceutical manufacturers and, in some instances, other corporate and/or individual defendants, alleging price-fixing and other anticompetitive conduct with respect to generic pharmaceutical products. These cases, which include proposed class actions filed on behalf of direct purchasers, end-payers and indirect purchaser resellers, as well as non-class action suits, have generally been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Eastern District of Pennsylvania. There is also a proposed class action filed in the Federal Court of Canada on behalf of a proposed class of Canadian purchasers.

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

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

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

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

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

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

Other Antitrust Matters

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

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

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

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

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

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

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

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

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

Securities Litigation

In 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 Group 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 Group, EPI, EHSI, PPI and PPCI. In September 2020, the court appointed Curtis Laakso lead plaintiff in the action. The plaintiffs filed an amended complaint in November 2020. In January 2021, the defendants filed a motion to dismiss, which the court granted in August 2021. In November 2021, the plaintiffs filed a second amended complaint, which among other things added allegations about discovery issues in certain opioid-related lawsuits. In January 2022, the defendants moved to dismiss the second amended complaint.

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

Other Government Investigations

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

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

VASOSTRICT® Related Matters

Beginning in April 2018, PSP LLC and PPI received notice letters from Eagle Pharmaceuticals, Inc. (Eagle), Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent, Fresenius, Kabi USA, LLC (Fresenius), Dr. Reddy's Laboratories, Inc., Aurobindo Pharma Limited and Gland Pharma Limited advising of the filing by such companies of Abbreviated New Drug Applications (ANDAs)/New Drug Applications (NDAs) for generic versions of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/ml and/or 200 units/10 ml. Beginning in May 2018, PSP LLC, PPI and Endo Par Innovation Company, LLC filed lawsuits against Eagle, Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, American Regent and Fresenius in the U.S. District Court for the District of Delaware or New Jersey within the 45-day deadline to invoke a 30-month stay of U.S. Food and Drug Administration (FDA) approval pursuant to the Hatch-Waxman legislative scheme. In December 2020, we separately filed suit against Eagle, Amneal Pharmaceuticals LLC, Dr. Reddy's Laboratories, Inc. and Aurobindo Pharma Limited in the U.S. District Court for the District of New Jersey in connection with a newly issued VASOSTRICT® genotyping patent. Beginning in May 2020 through January 2021, we reached settlements with American Regent, Sandoz, Inc., Amphastar Pharmaceuticals, Inc., Fresenius, Aurobindo Pharma Limited and Dr. Reddy's Laboratories, Inc. We have voluntarily dismissed all cases pending against those defendants. The remaining Delaware cases against Eagle and Amneal Pharmaceuticals LLC have been consolidated and a trial was held in July 2021. In August 2021, the court issued an opinion holding that Eagle's proposed generic product will not infringe PPI's asserted patent claims. We have appealed the ruling. The court made no finding regarding the validity of the patents. During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® were launched, beginning with Eagle's generic, that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives have entered the market, including an authorized generic. These launches began to significantly impact both Endo's market share and product price 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 16. OTHER COMPREHENSIVE INCOME (LOSS)

During the years ended December 31, 2021 and 2020, 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 Group's Accumulated other comprehensive loss balances for the year ended December 31, 2021 and December 31, 2020 consist of Foreign currency translation loss.

NOTE 17. CALLED UP SHARE CAPITAL

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.

Share Capital consists of the following as at December 31, 2021 and 2020 (in thousands):

	2021	2020
Authorized:		
4,000,000 Euro deferred shares of \$0.01 par value (4,000,000 issued and outstanding)	\$ 40	\$ 40
1,000,000,000 ordinary shares of \$0.0001 par value (233,690,816 issued and outstanding) (2020 230,315,768 issued and outstanding)	100	100
Total share capital	<u>\$ 140</u>	<u>\$ 140</u>
Allotted, called-up and fully paid equity:		
BALANCE, JANUARY 01, 2020		\$ 68
Other		4
BALANCE, DECEMBER 31, 2020		<u>\$ 72</u>
Other		(4)
BALANCE, DECEMBER 31, 2021		<u>\$ 68</u>

Share Repurchase Program

Pursuant to Article 11 of the Group's Articles of Association, the Group has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. The Group'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 Group'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 Group to redeem, in the aggregate, \$2.5 billion of its outstanding ordinary shares. To date, the Group 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 18. SHARE-BASED COMPENSATION

Stock Incentive Plans

In June 2015, the Group's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan), which has subsequently been amended, as approved by the Group'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 Group'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 Group 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 Profit and loss account for the years ended December 31, 2021 and 2020 (in thousands).

	2021	2020
Selling, general and administrative expenses	\$ 23,400	\$ 32,368
Research and development expenses	1,378	2,504
Cost of sales	5,268	6,485
Total share-based compensation expense	<u>\$ 30,046</u>	<u>\$ 41,357</u>

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 Group 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 Group.

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 Group 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 Group'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 and 2020 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding as of January 1 2020	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 Group'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 2020 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 Group 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 Group.

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 Group 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 and 2020 is presented below:

	Number of Shares	Aggregate Intrinsic Value (1)
Non-vested as of January 1, 2020	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 Group'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 and 2020 was \$7.39 and \$5.54 per unit, respectively.

NOTE 19. OTHER INCOME, NET

The components of Other income, 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 (1)	\$ (4,516)	\$ (16,353)
Foreign currency loss, net (2)	1,253	2,466
Net loss (gain) from our investments in the equity of other companies (3)	453	(2,160)
Other miscellaneous, net (4)	(16,964)	(5,063)
Other income, net	\$ (19,774)	\$ (21,110)

- (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 Group'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.

NOTE 20. 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 and 2020 are as follows (in thousands):

	2021	2020
U.S.	\$ 4,792,852	\$ (392,762)
International	(5,339,455)	348,744
Total loss from continuing operations before income tax	<u>\$ (546,603)</u>	<u>\$ (44,018)</u>

Income tax from continuing operations consists of the following for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Current:		
U.S. Federal	\$ 13,649	\$ (108,866)
U.S. State	1,491	(434)
International	10,495	(1,124)
Total current income tax	<u>\$ 25,635</u>	<u>\$ (110,424)</u>
Deferred:		
U.S. Federal	\$ 118	\$ (143,411)
U.S. State	(564)	(11,773)
International	(2,711)	(8,374)
Total deferred income tax	<u>\$ (3,157)</u>	<u>\$ (163,558)</u>
Total income tax	<u>\$ 22,478</u>	<u>\$ (273,982)</u>

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 and 2020 is as follows (in thousands):

	2021	2020
Notional U.S. federal income tax provision at the statutory rate	\$ (114,787)	\$ (5,569)
State income tax, net of federal benefit	6,750	(17,311)
U.S. tax reform impact	—	(129,599)
Uncertain tax positions	42,415	35,941
Residual tax on non-U.S. net earnings	(181,739)	(83,550)
Non-deductible goodwill impairment	76,230	7,490
Change in valuation allowance	495,565	(97,752)
Base erosion minimum tax	—	77,438
Non-deductible expenses	39,791	8,875
Executive compensation limitation	6,215	5,857
Equity based compensation	2,695	6,495
Financing activities (1)	(287,012)	(33,217)
Investment activities (2)	(68,943)	(44,964)
Other	5,298	(4,116)
Income tax	<u>\$ 22,478</u>	<u>\$ (273,982)</u>

- (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 Group 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	<u>\$ 10,386,231</u>	<u>\$ 10,710,941</u>
Deferred tax liabilities:		
Other	\$ (8,586)	\$ (9,469)
Investments	(124,311)	—
Intercompany notes	(104,530)	(1,057,158)
Total gross deferred income tax liabilities	<u>\$ (237,427)</u>	<u>\$ (1,066,627)</u>
Valuation allowance	(10,169,294)	(9,668,556)
Net deferred income tax liability	<u>\$ (20,490)</u>	<u>\$ (24,242)</u>

As of December 31, 2021, the Group 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 Group assesses the available positive and negative evidence to estimate whether the existing deferred tax assets will be realized.

The Group 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 Group 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 Group 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 Group 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 Group 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 Group 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 Group has taken positions on its tax returns that may be challenged by various tax authorities. The Group believes it has appropriately established reserves for tax-related uncertainties. The Group 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 Group'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 Group'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 Group 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 Group 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 and 2020 (in thousands):

	Unrecognized Tax Positions Federal, State and Foreign Tax
UTP Balance at January 1, 2020	\$ 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 Group 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 Group recognized net expense of \$10.6 million associated with UTPs, primarily related to interest and penalties. During the year ended December 31, 2020, the Group 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 Group 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 Group 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 21. NET (LOSS) PROFIT PER SHARE

The following is a reconciliation of the numerator and denominator of basic and diluted net (loss) profit per share for the years ended December 31, 2021 and 2020 (in thousands):

	2021	2020
Numerator:		
(Loss) profit from continuing operations	\$ (569,081)	\$ 229,964
Loss from discontinued operations, net of tax	(44,164)	(33,520)
Net (loss) profit	<u>\$ (613,245)</u>	<u>\$ 196,444</u>
Denominator:		
For basic per share data—weighted average shares	232,785	229,314
Dilutive effect of ordinary share equivalents	—	4,339
For diluted per share data—weighted average shares	<u>232,785</u>	<u>233,653</u>

Basic per share amounts are computed based on the weighted average number of ordinary shares outstanding during the period. Diluted per share amounts are computed based on the weighted average number of ordinary shares outstanding and, if there is net profit 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 and 2020, 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
Stock options	6,584	7,073
Stock awards	9,256	5,197

NOTE 22. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS

Savings and Investment Plan

The Group maintains a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all U.S.-based eligible employees. The Group 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 Group's matching contributions generally vest ratably over a two-year period.

Costs incurred for contributions made by the Group to the Endo 401(k) Plan amounted to \$7.6 million and \$7.6 million for the years ended December 31, 2021 and 2020, respectively.

Directors Stock Election Plan

The Group 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.

NOTE 23. DEBTORS

The components of Debtors as at December 31, 2021 and 2020 (in thousands) were as follows:

	2021	2020
<i>Amounts falling due within one year:</i>		
Trade debtors	\$ 592,019	\$ 511,262
Prepayments and other debtors	200,484	100,899
Income taxes receivable	7,221	63,837
	<u>\$ 799,724</u>	<u>\$ 675,998</u>
<i>Amounts falling due after more than one year:</i>		
Deferred tax asset	\$ 1,138	\$ 1,824
Other debtors	60,313	53,235
	<u>\$ 61,451</u>	<u>\$ 55,059</u>

NOTE 24. PROVISIONS AND CREDITORS

The components of Provisions and Creditors as at December 31, 2021 and 2020 (in thousands) were as follows:

	Note	2021	2020
<i>Provisions for liabilities:</i>			
<i>Amounts falling due within one year:</i>			
Returns and allowances, rebates, chargebacks and other sales deductions ⁽¹⁾		\$ 338,272	\$ 336,737
Acquisition-related contingent consideration—short-term	7	5,748	8,566
		<u>\$ 344,020</u>	<u>\$ 345,303</u>
<i>Amounts falling due after more than one year:</i>			
Acquisition-related contingent consideration—long-term	7	14,328	27,683
		<u>\$ 358,348</u>	<u>\$ 372,986</u>
<i>Creditors:</i>			
<i>Amounts falling due within one year:</i>			
Trade accounts payable		\$ 123,129	\$ 94,408
Accrued expenses		369,749	396,229
Current portion of legal settlement accrual	15	580,994	372,121
Income taxes payable	20	736	—
		<u>\$ 1,074,608</u>	<u>\$ 862,758</u>
<i>Amounts falling due after more than one year:</i>			
Deferred income taxes	20	21,628	26,066
Income taxes payable	20	228,110	217,268
Other creditors		34,666	69,025
		<u>\$ 284,404</u>	<u>\$ 312,359</u>
		<u>\$ 1,359,012</u>	<u>\$ 1,175,117</u>

(1) The following table summarizes changes in the ending balances 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, 2020	\$ 207,916	\$ 126,644	\$ 2,177	\$ —	\$ 336,737
Current year provision	82,171	363,618	12,506	3,226	461,521
Prior year provision	(16,540)	(6,564)	—	(253)	(23,357)
Payments or credits	(90,431)	(333,659)	(12,066)	(473)	(436,629)
Balance, December 31, 2021	<u>\$ 183,116</u>	<u>\$ 150,039</u>	<u>\$ 2,617</u>	<u>\$ 2,500</u>	<u>\$ 338,272</u>

Total product sales deductions amount to \$588,722 as at 31 December 2021 (2020 \$605,614) which consists of the \$338,272 (2020: \$336,737) as presented in the table above and \$250,450 (2020: 268,877) which has been deducted from the Trade Debtor balance as included in Note 23. Debtors.

NOTE 25. CAPITAL EXPENDITURE COMMITMENTS

The directors have authorized the Group to spend \$94.6 million for capital expenditures in the year ended December 31, 2022.

NOTE 26. RELATED PARTY DISCLOSURES

The principal related party relationships requiring disclosure in the Consolidated Financial Statements pertain to the existence of subsidiaries and associates and transactions with these entities entered into by the Group and the identification of key management personnel as addressed in greater detail below.

Subsidiaries and Associates

The Consolidated Financial Statements include the results of operations, financial positions and cash flows of the Group and its subsidiaries and associates over which the Group has control. A listing of principal subsidiaries and associates is provided in Note 30. Subsidiaries.

Trading Transactions

There were no transactions requiring disclosure under Sch. 3, Part IV, 67 of the Irish Companies Act, 2014.

Compensation of Key Management Personnel of the Group

Key management personnel are the Group's executive and non-executive directors and their compensation is disclosed in Note 28. Directors' Remuneration.

NOTE 27. EMPLOYEES

The average number of persons employed by the Group for the years ended December 31, 2021 and 2020 were as follows:

	2021	2020
Manufacturing	1,972	1,922
Research and development	445	377
Selling, general and administrative	942	932
Total employees	<u>3,359</u>	<u>3,231</u>

Employee costs for the years ended December 31, 2021 and 2020 (in thousands) were as follows:

	2021	2020
Wages and salaries	\$ 364,685	\$ 419,500
Benefits (1)	54,725	48,135
Share-based compensation	30,046	41,357
Total employee cost	<u>\$ 449,456</u>	<u>\$ 508,992</u>

(1) Benefits include social security costs, employer paid payroll taxes and other employee benefits paid by the Group.

NOTE 28. DIRECTORS' REMUNERATION

Directors' remuneration is set forth in the table below (in thousands). The amounts below include compensation for Mr. Blaise Coleman as President and Chief Executive Officer and compensation for all non-employee directors in their capacity as such. Mr. Blaise Coleman, the President and Chief Executive Officer, was not provided additional compensation for his service as a director. There were no contributions made to retirement benefit schemes or compensation paid for loss of office to non-executive directors during the years presented. In 2021, Directors' remuneration include prepayments of certain incentive compensation components for Mr. Blaise Coleman, the substantial majority of which relate to amounts that normally would have been earned, paid or granted, and thus reportable in the Directors Remuneration Note, in future years. Therefore, these prepayments resulted in the acceleration of reporting (into 2021) of certain incentive compensation components which, had they adhered to the normal compensation timeline, would have been reportable in 2022 and beyond. Specifically, had these amounts not been prepaid, total 2021 compensation for Mr. Blaise Coleman would have been reduced by (\$15,242 thousand).

	2021	2020
Emoluments	\$ 25,602	\$ 10,418
Benefits under long-term incentive schemes	\$ 3,198	\$ 5,201
Contributions to retirement benefit schemes:		
Defined contribution	\$ —	\$ —
Defined benefit	\$ —	\$ —
	\$ —	\$ —
Compensation for loss of office paid by the company and other termination payments	\$ —	\$ —

NOTE 29. AUDITORS' REMUNERATION

PricewaterhouseCoopers served as the Group's independent registered public accounting firm for the years ended December 31, 2021 and 2020. The table below summarizes the aggregate fees for services PricewaterhouseCoopers Ireland and its affiliated firms provided during years 2021 and 2020, respectively (in thousands).

	2021	2020
Audit fees (1)	\$ 5,646	\$ 6,833
Audit-related fees (2)	3,083	350
Tax fees (3)	972	1,575
All other fees (4)	10	85
Total auditors' remuneration	\$ 9,711	\$ 8,843

- (1) Fees for audit services in 2021 and 2020 consisted of:
- Audit of the Group's annual financial statements;
 - Evaluation and reporting on the effectiveness of the Group's internal controls over financial reporting;
 - Reviews of the Group's quarterly financial statements;
 - Statutory audits for the Group and certain of its subsidiaries; and
 - Comfort letters, consents and other services related to debt issuances and other SEC matters.
- (2) Fees for audit-related services in 2021 and 2020 consisted of:
- Attestation services requested by management;
 - Due diligence services; and
 - Pre- or post- implementation reviews of processes or systems, and
 - Other services related to accounting and financial reporting.
- (3) Fees for tax services in 2021 and 2020 consisted of tax compliance and tax planning and advice.
- Tax compliance;
 - Statutory tax return preparation and review; and
 - Tax planning and advice, including advice related to the impact of changes in tax laws.
- (4) All other fees in 2021 and 2020 principally includes compliance advisory services and subscriptions to knowledge tools.

Auditors' remuneration (including expenses) for all professional services rendered by the statutory auditor

PricewaterhouseCoopers Ireland was as follows:

	2021	2020
Audit of the Group financials statements	\$ 288	\$ 251
Other assurance services	313	277
Tax advisory services	241	406
Total auditors' remuneration	\$ 842	\$ 934

NOTE 30. SUBSIDIARIES

The subsidiaries of Endo International plc are wholly-owned by Endo International plc or one of its subsidiaries. The following is a list of the subsidiaries that principally affect the Group's statutory financial statements as at 31 December 2021:

Subsidiary	Jurisdiction of Incorporation or Organization	Ownership by Endo International plc	Percent Ownership
Actient Pharmaceuticals LLC	Delaware	Indirect	100%
Actient Therapeutics, LLC	Delaware	Indirect	100%
Astora Women's Health, LLC	Delaware	Indirect	100%
Auxilium Pharmaceuticals, LLC	Delaware	Indirect	100%
BioSpecifics Technologies LLC	Delaware	Indirect	100%
Endo Designated Activity Company	Ireland	Direct	100%
Endo Eurofin Unlimited Company	Ireland	Indirect	100%
Endo Finance IV Unlimited Company	Ireland	Indirect	100%
Endo Finance LLC	Delaware	Indirect	100%
Endo Finance Operations LLC	Delaware	Indirect	100%
Endo Global Aesthetics Limited	Ireland	Indirect	100%
Endo Global Biologics Limited	Ireland	Indirect	100%
Endo Health Solutions Inc.	Delaware	Indirect	100%
Endo Luxembourg Finance Company I S.a r.l.	Luxembourg	Indirect	100%
Endo Luxembourg Holding Company S.a r.l.	Luxembourg	Indirect	100%
Endo Management Limited	Ireland	Indirect	100%
Endo Par Innovation Company, LLC	Delaware	Indirect	100%
Endo Pharmaceuticals Inc.	Delaware	Indirect	100%
Endo Pharmaceuticals Valera Inc.	Delaware	Indirect	100%
Endo TopFin Limited	Ireland	Indirect	100%
Endo U.S. Inc.	Delaware	Indirect	100%
Endo US Holdings Luxembourg I S.a r.l.	Luxembourg	Indirect	100%
Endo Ventures Limited	Ireland	Indirect	100%
Generics Bidco I, LLC (doing business as Par Pharmaceutical)	Delaware	Indirect	100%
Generics International (US) 2, Inc.	Delaware	Indirect	100%
Hawk Acquisition Ireland Limited	Ireland	Indirect	100%
Luxembourg Endo Specialty Pharmaceuticals Holding I S.a r.l.	Luxembourg	Indirect	100%
Paladin Labs Canadian Holding Inc.	Canada	Indirect	100%
Paladin Labs Inc.	Canada	Indirect	100%
Par Pharmaceutical 2, Inc.	Delaware	Indirect	100%
Par Pharmaceutical Companies, Inc.	Delaware	Indirect	100%
Par Pharmaceutical Holdings, Inc.	Delaware	Indirect	100%
Par Pharmaceutical, Inc. (doing business as Par Pharmaceutical)	New York	Indirect	100%
Par Sterile Products, LLC	Delaware	Indirect	100%

NOTE 31. SUBSEQUENT EVENTS

Subsequent events have been evaluated through May 06, 2022 the date this report is approved by the Audit & Finance Committee of the Board of Directors and the Board of Directors.

2022 Restructuring Initiative

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

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

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

Nevakar Injectables, Inc. Acquisition

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

NOTE 32. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved by the directors on May 06, 2022.

ENDO INTERNATIONAL PLC
COMPANY RECONCILIATION OF SHAREHOLDERS' FUNDS
FOR THE YEAR ENDED DECEMBER 31, 2021
(In thousands)

	Share Capital Presented as Equity	Share Premium	Profit and Loss Account	Other Reserves	Total Equity
BALANCE, January 1, 2020	\$ 68	\$ 6,156,265	\$ (5,292,595)	\$ 346,582	\$ 1,210,320
Net loss	—	—	(49,485)	—	(49,485)
Share-based payment activity	—	—	—	48,016	48,016
Receipt of Endo International's shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	—	—	(8,036)	—	(8,036)
Other	4	1	—	—	5
BALANCE, DECEMBER 31, 2020	\$ 72	\$ 6,156,266	\$ (5,350,116)	\$ 394,598	\$ 1,200,820
Net loss	—	—	(386,987)	—	(386,987)
Share-based payment activity	—	—	—	27,730	27,730
Option exercises	—	—	622	—	622
Receipt of Endo International's shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	—	—	(14,774)	—	(14,774)
Other	(4)	—	—	—	(4)
BALANCE, DECEMBER 31, 2021	\$ 68	\$ 6,156,266	\$ (5,751,255)	\$ 422,328	\$ 827,407

ENDO INTERNATIONAL PLC
COMPANY BALANCE SHEET AS AT
DECEMBER 31, 2021
(In thousands)

	Note	December 31, 2021	December 31, 2020
ASSETS			
<i>Financial Fixed Assets</i>			
Investment in subsidiaries	3	\$ 1,134,514	\$ 1,401,425
<i>Current Assets</i>			
Debtors - Prepayments and other debtors	5	86,920	15,156
Debtors - Amounts due from subsidiaries	4	859	1,980
Cash at bank and in hand		7,129	5,677
TOTAL ASSETS		\$ 1,229,422	\$ 1,424,238
EQUITY AND LIABILITIES			
<i>Capital and Reserves</i>			
Called up share capital presented as equity, \$0.01 par value Euro deferred shares ...	9	\$ 45	\$ 49
Called up share capital presented as equity, \$0.0001 par value ordinary shares	9	23	23
Share premium account	9	6,156,266	6,156,266
Other reserves	9	422,328	394,598
Profit and loss account		(5,751,255)	(5,350,116)
Total equity		\$ 827,407	\$ 1,200,820
<i>Creditors (amounts falling due within one year)</i>			
Intercompany loan payable	6	\$ 167,316	\$ 131,921
Amounts due to subsidiaries	7	165,180	83,666
Accruals and other creditors	8	69,519	7,831
Total for creditors		\$ 402,015	\$ 223,418
TOTAL EQUITY AND LIABILITIES		\$ 1,229,422	\$ 1,424,238

The Parent Company recorded a loss of \$387.0 million for the year ended 31 December 2021 (2020: loss of \$49.5 million)

The Notes to the Company Balance Sheet are an integral part of this statement.

The financial statements were approved by the Board of Directors on May 06, 2022 and signed on its behalf by:

/s/ Mark G. Barberio

Mark G Barberio

Chairman

/s/ Blaise Coleman

Blaise Coleman

Director

ENDO INTERNATIONAL PLC
NOTES TO COMPANY FINANCIAL STATEMENTS
YEAR ENDED DECEMBER 31, 2021

NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

The financial statements have been prepared on a going concern basis and in accordance with the Companies Act 2014, and Financial Reporting Standard 102 The Financial Reporting Standard applicable in the UK and Republic of Ireland. In arriving at its conclusion in respect of going concern, the Company's directors have taken into account various uncertainties, including those relating to pending or threatened litigation against the Group.

As outlined in Note 15 to the Group financial statements Commitments and Contingencies, 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, as well as various other manufacturers, distributors, pharmacies and/or others, asserting claims relating to defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications, including certain of our products. The outcome of this litigation is inherently uncertain and 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. To the extent unresolved, the Group will continue to vigorously defend the foregoing matters and to explore other options as appropriate in its best interests, including entering into settlement negotiations and settlements even in circumstances where we believe we have meritorious defenses. The board has formed a judgment at the time of approving the Company Financial Statements that the Group's existing cash resources and cash expected to be generated from the Group's operations will be sufficient to fund the Company's operating and capital needs for a twelve-month period from the date of issuance of the financial statements.

The accompanying balance sheet of Endo International plc (the Company) is presented on a stand-alone basis, including related party transactions. The financial statements are presented in United States (U.S.) dollars, which is the Company's functional and presentation currency. All values are rounded to the nearest thousand U.S. dollars except when otherwise indicated.

The financial statements are prepared under the historical cost convention. The accounting policies which follow set out those policies which apply in preparing the financial statements for the year ended December 31, 2021. The Company has taken advantage of the following disclosure exemptions under FRS 102:

- the requirements of section 4 Statement of Financial Position - Paragraph 4.12 (a) (iv),
- the requirements of section 7 Statement of Cash Flows and Section 3 Financial Statement Presentation paragraph 3.17(d),
- the requirements of Section 26 Share based Payment: paragraph 26.18 (b), 26.19 to 26.21 and 26.23
- the requirements of Section 33 Related Party Disclosures, paragraph 33.7, and
- the requirements of Section 304 of the Companies Act 2014

Critical Accounting Judgments and Estimation Uncertainty

The preparation of the Company's financial statements requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, turnover and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to its investments in subsidiaries and share-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

In particular, the Company identifies a significant judgement in respect to the recoverability and valuation of its investment in subsidiaries. As further explained in Note 3. Investment in Subsidiaries, the recoverable amount of investment in subsidiaries is determined by reference to the outstanding number of shares at the end of each reporting period multiplied by the closing stock price of Endo International plc, adjusted for an expected control premium. The control premium is calculated based on selected historical pharmaceutical deal activities. The utilization of this valuation methodology, including the application of a control premium, to determine the recoverable amount of the investment in subsidiary and the magnitude of impairment, if applicable, is subject to estimates, judgements and assumptions by management.

Employees and Directors

The Company had no employees during the year. The Company's directors are not employees but are remunerated for their service by the parent company. See Note 28. Directors' Remuneration of the accompanying Consolidated Financial Statements included in this report for a summary of their remuneration.

Related Party Transactions

The Company has not disclosed any other related party transactions as it has availed of the exemption available under the provisions of FRS 102 Section 33.1A "Related Party Disclosures" which exempts disclosure of transactions entered into between two or more members of a group, provided that any subsidiary which is a party to the transaction is wholly owned by a member of that group.

Investment in Subsidiaries

Investment in subsidiaries is stated in the Company's Balance Sheet at cost less any return of capital, unless it has been impaired in which case it is carried at net of any impairment loss recognized.

Contingencies

Provisions are recognized in the Profit and loss account as Litigation-related and other contingencies, net when the Company determines that a present obligation exists to a third party as a result of past events and a future outflow of resources is reliably estimable. Contingent liabilities are only recognized if the outflow of resources with economic benefits has become probable and the amount can be reliably estimated. If the criteria for recognizing a provision are not met, but the outflow of resources with economic benefits is not remote, such obligations are disclosed in the notes to the Company Financial Statements. Legal fees and other expenses related to litigation are expensed as incurred and included in the Profit and loss account.

The Company has guaranteed certain liabilities and credit arrangements of the group. The Company reviews the status of these guarantees at each reporting date and considers whether it is required to make a provision for payment on those guarantees based on the probability of the commitment being called.

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.

Reimbursement rights

When the Company expects some or all of an expenditure to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain and the amount of the receivable can be measured reliably. The expense relating to the provision is presented net of any reimbursement.

Share Based Payments

Endo International plc and its subsidiaries operate a number of share based payment plans, the details of which are presented in Note 18. Share-Based Compensation to the Consolidated Financial Statements. The share based payment expense associated with the share plans is recognized as an expense by the group entity, which employs and receives the services in exchange for the share based compensation. In these Company only Financial Statements, the profit and loss account is charged with only the expense related to the services received directly by the Company. The cost for equity awards granted to the Company's subsidiaries' employees represents additional capital contributions by the Company to its subsidiaries. An additional investment in subsidiaries has been recorded in respect of those equity awards granted to the Company's subsidiaries' employees, with a corresponding increase in the Company's shareholder funds. The additional capital contribution is based on the fair value at the grant date of the equity awards issued, allocated over the life of the underlying grant's vesting period.

Share Premium

The difference between the proceeds received on issue of shares and the nominal value of the shares is credited to the share premium account.

Profit and loss account

In accordance with Section 304 of the Companies Act 2014, the Company is availing of the exemption from presenting the individual profit and loss account. Endo International plc's losses for the years ended December 31, 2021 and 2020 were \$387.0 million and \$49.5 million, respectively. No other comprehensive profit or losses were applicable for the years ended December 31, 2021 and 2020.

Share Repurchases

The Company accounts for the repurchase of ordinary shares 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 weighted average cost of such ordinary shares as an adjustment to its consolidated Profit and loss account in the Company's Balance Sheet.

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income, net" in the Consolidated Profit and Loss Account.

Taxation

Deferred tax is recognised in respect of all timing differences which are differences between taxable profits and total comprehensive income that arise from the inclusion of profit and expenses in tax assessments in periods different from those in which they are recognised in the financial statements, except that unrelieved tax losses and other deferred tax assets are recognised only to the extent that the directors consider that it probable that they will be recovered against the reversal of deferred tax liabilities or other future taxable profits. Deferred tax is measured on an undiscounted basis at the tax rates that are expected to apply in the periods in which timing differences reverse, based on tax rates and laws enacted or substantively enacted at the balance sheet date. The Company accounts for uncertain tax positions using a "more-likely-than-not" threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on a quarterly basis. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

NOTE 2. HISTORY AND DESCRIPTION OF THE COMPANY

Endo International plc was incorporated in Ireland on October 31, 2013 as a private limited company and re-registered effective February 18, 2014 as a public limited company registered number 534814. It was established for the purpose of facilitating the business combination between Endo Health Solutions Inc. (EHSI) and Paladin Labs Inc. (Paladin).

On February 28, 2014, pursuant to an arrangement agreement, dated November 5, 2013 (the Arrangement Agreement), among EHSI, Endo International Limited, Endo Limited (formerly known as Sportwell II Limited), Endo U.S. Inc. (formerly known as ULU Acquisition Corp.), RDS Merger Sub, LLC (Merger Sub), 8312214 Canada Inc. and Paladin (a) Endo International Limited indirectly acquired all of the outstanding common shares of Paladin pursuant to a plan of arrangement under Canadian law (the Arrangement); and (b) Merger Sub merged with and into EHSI, with EHSI as the surviving corporation in the merger (the Merger and, together with the Arrangement, the Transactions). Following consummation of the Transactions, each of EHSI and Paladin became indirect wholly owned subsidiaries of Endo International plc.

Pursuant to the Arrangement, (a) former Paladin shareholders received C\$1.16 in cash, 1,6331 newly issued Endo International ordinary shares and one common share of Knight Therapeutics Inc., a newly formed corporation incorporated under the laws of Canada that was separated from Paladin as part of the Transactions, in exchange for each Paladin common share held by such former shareholders; (b) all options to acquire Paladin common shares were settled on a cashless exercise basis for Endo International ordinary shares and common shares of Knight Therapeutics Inc. in an amount reflecting the arrangement consideration; and (c) unvested rights to receive additional common shares under Paladin's share purchase plan were settled for a cash amount based on the Paladin common share price immediately prior to the effective time of the Arrangement. At the effective time of the Merger, each share of EHSI common stock was cancelled and automatically converted into the right to receive one Endo International plc ordinary share. Immediately following the closing of the transaction, former EHSI shareholders owned approximately 79% of Endo International plc, and former Paladin shareholders owned approximately 21%.

Endo International plc is an Ireland-domiciled, global specialty pharmaceutical company focused on branded and generic pharmaceuticals. Endo International plc aims to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of branded and generic drugs to meet patients' needs. The Company's corporate headquarters are located at First Floor, Minerva House, Simmons Court Road, Ballsbridge, Dublin 4, Ireland. The Company's headquarters for its United States operations is based in Malvern, Pennsylvania.

NOTE 3. INVESTMENT IN SUBSIDIARIES

A reconciliation of the change in the Investment in Subsidiaries balance from January 01, 2020 to December 31, 2021 is as follows (in thousands):

	Investment in Subsidiaries
Balance - January 01, 2020, at cost	\$ 1,354,359
Capital contribution in respect of share-based payment plans	47,066
Impairment	—
Balance - December 31, 2020, at cost	<u>\$ 1,401,425</u>
Capital contribution in respect of share-based payment plans	26,289
Impairment	(297,991)
Capital Contribution	4,791
Balance - December 31, 2021, at cost	<u>\$ 1,134,514</u>

The Company was re-registered as a public limited company effective February 18, 2014 and Endo International plc was formed. Refer to Note 2. History and Description of the Company for a description of this transaction.

On January 29, 2015, the Company, through an indirect wholly owned subsidiary, acquired all of the outstanding shares of common stock of Auxilium. The consideration included 18,609,835 ordinary shares valued at \$1.52 billion. On June 10, 2015, the Company completed the sale of 27,627,628 ordinary shares for gross proceeds of \$2.24 billion, including fees, in order to finance a portion of the Par acquisition. On September 25, 2015, the Company, through an indirectly wholly owned subsidiary, acquired Par. The consideration included 18,069,899 ordinary shares valued at \$1.33 billion.

During the year ended December 31, 2021 the Company identified certain trigger events indicating a potential impairment of its Investment in subsidiaries balance and initiated an Investment in subsidiaries impairment analysis as of 2021. As a result of this analysis, the Company determined that the net book value of its Investment in subsidiaries asset exceeded its recoverable amount. The recoverable amount has been determined by reference to the number of outstanding shares multiplied by the closing stock price of Endo International Plc as of December 31 (or the last trading day of the applicable calendar year), adjusted for a control premium which has been determined by analysis of historical pharmaceutical industry deal activity.

The Company made a capital contribution of \$4,791 thousand to Endo Designated Activity Company its subsidiary therefore increasing the carrying amount of its Investment in Subsidiary as it is included as an addition for the year ended 31 December 2021 above.

As part of the impairment analysis, the Company recorded a non-cash impairment charge in the Profit and loss accounts for the year ended 2021 of \$297.9 million, to reduce the carrying amount of the Company's investment to its recoverable amount. The 2021 impairment was driven by a combination of factors, including a decrease in Endo's stock price compared to the share price as at December 31, 2020, driven by approval of generic version of VASOSTRICT®, various ongoing litigation, as well as, continued pricing pressures and unfavorable competitive events primarily affecting the Group's Generic Pharmaceuticals and International Pharmaceuticals business segments, among others. If the estimated control premium for the impairment analysis had increased or decreased from management's estimate by 1 percentage point, the impairment of the Investment in subsidiaries balance would have changed by \$9 million for the year ended December 31, 2021. The Company did not identify any impairments or reversal of impairment in the year 2020.

NOTE 4. AMOUNTS DUE FROM SUBSIDIARIES

Amounts due from subsidiaries of \$0.9 million and \$2.0 million at December 31, 2021 and 2020, respectively, are non-interest bearing and payable on demand.

NOTE 5. PREPAYMENTS AND OTHER DEBTORS

Amounts for prepayments and other debtors of \$86.9 million and \$15.1 million at December 31, 2021 and 2020, respectively. The increase in the Companies prepayments is primarily as a result of the settlement case entitled *Pelletier v. Endo International plc, Rajiv Kanishka Liyanaarchchie De Silva, Suketu P. Upadhyay and Paul V. Campanelli*, during the third quarter of 2021, the Company recorded: (i) an increase of approximately \$63.4 million to its insurance receivable and (ii) a corresponding increase in its accrual and other creditors of approximately \$63.4 million. The insurance receivable is recorded as prepayments and other debtors as further described in Note 15. Commitment and Contingencies of the Consolidated Financial Statements. In addition the Company has other reimbursable legal expenses under Insurance policies at December 31, 2021 and 2020 respectively included in Prepayments and Other Debtors.

NOTE 6. INTERCOMPANY LOAN PAYABLES

On February 28, 2014, the Company issued \$24.7 million in aggregate principal amount of a non-interest bearing note payable to an affiliate. The loan is due upon the earlier of the expiration of five years from the issuance date or upon written demand by the affiliate. The maturity date of this loan was extended in 2018 to the earlier of ten years from the issuance date or upon written demand by the affiliate. On December 18, 2019, the Company novated its \$24.7 million non-interest bearing note from one affiliate Company to another affiliate.

On December 20, 2017, the Company issued \$17.9 million in aggregate principal amount of a non-interest bearing note payable to an affiliate. The loan is due upon the earlier of the expiration of thirty years from the issuance date or upon written demand by the affiliate.

On June 22, 2018, the Company issued \$30.1 million in aggregate principal amount of a non-interest bearing note payable to an affiliate. The loan is due upon the earlier of the expiration of thirty years from the issuance date or upon written demand by the affiliate.

On December 24, 2018, the Company issued \$25.0 million in aggregate principal amount of a non-interest bearing note payable to an affiliate. The loan is due up on the earlier of the expiration of thirty years from the issuance date or upon written demand by the affiliate.

On December 18, 2019, the Company issued \$17.2 million in aggregate principal amount of a non-interest bearing note payable to an affiliate. This loan is due upon the earlier of the expiration of twenty five years from the issuance date or upon written demand by the affiliate.

On June 24, 2020, the Company entered into a revolving loan agreement with an affiliate. The maximum loan amount is \$50.0 million and interest is to be accrued at the applicable federal rate as provided by the Internal Revenue Service. This loan is due upon the earlier of the expiration of ten years or any other earlier date upon written demand by the lender. On December 16, 2020, the Company drew \$17.0 million against this revolver balance.

In December 2021, the revolver limit was increased to \$250.0 million, with all other conditions remaining the same. During 2021, the Company drew an additional \$35.4 million against the revolver balance.

NOTE 7. AMOUNTS DUE TO SUBSIDIARIES

Amounts due to subsidiaries of \$165.2 million and \$83.7 million at December 31, 2021 and 2020, respectively, are non-interest bearing and payable on demand.

NOTE 8. ACCRUALS AND OTHER CREDITORS

Amounts for accruals and other creditors of \$69.5 million and \$7.8 million at December 31, 2021 and 2020, respectively.

The increase in the Companies accruals and other creditors is primarily as a result of the settlement case entitled *Pelletier v. Endo International plc, Rajiv Kanishka Liyanaarchchie De Silva, Suketu P. Upadhyay and Paul V. Campanelli*, during the third quarter of 2021, the Company recorded: (i) an increase of approximately \$63.4 million to its insurance receivable and (ii) a corresponding increase in its accrual and other creditors of approximately \$63.4 million. The insurance accrual is recorded as accrual and other creditors as further described in Note 15. Commitment and Contingencies of the Consolidated Financial Statements.

NOTE 9. CALLED UP SHARE CAPITAL

Share Capital consists of the following for the year ended December 31, 2021 (in thousands):

	2021
Authorized:	
4,000,000 Euro deferred shares of \$0.01 par value (4,000,000 issued and outstanding)	\$ 40
1,000,000,000 ordinary shares of \$0.0001 par value (233,690,816 issued and outstanding) (2020 230,315,768 issued and outstanding)	100
Total share capital	<u>\$ 140</u>
Allotted, called-up and fully paid equity:	
BALANCE, JANUARY 01, 2020	\$ 68
Other	4
BALANCE, DECEMBER 31, 2020	<u>\$ 72</u>
Other	(4)
BALANCE, DECEMBER 31, 2021	<u>\$ 68</u>

Share Repurchase Program

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. The Company has broad shareholder authority to conduct share repurchases of its ordinary shares, as its shareholders granted to the Company a general authority (the 2014 Share Buyback Authority) to make overseas market purchases (as defined by section 212 of the Irish Companies Act 1990 (the 1990 Act)) of shares of the Company on such terms and conditions as the Company's Board of Directors may approve, but subject to the provisions of the 1990 Act and certain other provisions.

Pursuant to the 2014 Share Buyback Authority, in April 2015, the Company's Board of Directors approved a share buyback program (the 2015 Share Buyback Program). The 2015 Share Buyback Program authorizes the Company to redeem in the aggregate \$2.5 billion of its outstanding ordinary shares. In accordance with Irish Law and the Company's Articles of Association, all ordinary shares redeemed shall be cancelled upon redemption.

In November 2015, the Company entered into a program to repurchase up to \$250.0 million of its ordinary shares under the 2015 Share Buyback Program. The Company purchased approximately 4.4 million of its ordinary shares during November 2015 totaling \$250.0 million, not including related fees.

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 2017 and 2018. 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 Board of Directors 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. All awards previously granted and outstanding under these prior plans remain subject to the terms of those prior plans.

At December 31, 2021, approximately 9.3million ordinary shares (2020 12.1 million ordinary shares) were reserved for future grants under the 2015 Plan. As of December 31, 2021 and December 31, 2020, stock options, restricted stock awards, performance stock units and restricted stock units have been granted under the stock incentive plans.

Share premium account

This reserve records the amount above the nominal value received for shares sold, less transaction costs.

Other reserves

This reserve is used to recognise the value of equity-settled share-based payments provided to employees of the group as part of their remuneration.

NOTE 10. CONTINGENCIES

The Company and certain of its subsidiaries are involved in various claims, legal proceedings and governmental investigations that arise from time to time in the ordinary course of business, including relating to product liability, intellectual property, regulatory compliance and commercial matters. While the Company cannot predict the outcome of these ongoing legal proceedings and the Company and its subsidiaries intend to defend vigorously its and their position, an adverse outcome in any of these proceedings could have a material adverse effect on the Company's current and future financial position, results of operations and cash flows. See Note 15. Commitments and Contingencies of the accompanying Consolidated Financial Statements included in this report for additional information.

NOTE 11. GUARANTEES

On February 28, 2014, Endo International plc became the ultimate parent company and EHSI became a stand-alone subsidiary in accordance with the Arrangement Agreement and as further described above in Note 2. History and Description of the Company. As part of the Arrangement Agreement, the guarantee structure was updated to reflect the newly created legal structure under which Endo International plc assumed the obligations of EHSI as issuer or guarantor under the various indentures covering the outstanding Convertible Notes of EHSI.

In accordance with the provisions of Section 357 of the Companies Act 2014, the Company has guaranteed the liabilities of certain of its Irish subsidiaries in respect of the year ended December 31, 2021 in order to avail of the exemption from the filing provisions under Section 347 and 348 of the Companies Act 2014. These Irish subsidiaries are Endo Ventures Limited and Endo DAC.

The Company is also a guarantor on its Dublin lease at Minerva House with an address at Simmonscourt Road, Dublin 4, Ireland.

The Company entered into a credit agreement (the 2017 Credit Agreement) on April 27, 2017 as a guarantor, together with its subsidiaries Endo Luxembourg Finance Company I S.à r.l. and Endo LLC as borrowers (the Borrowers), the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent, issuing bank and swingline lender. The 2017 Credit Agreement provided for (i) a five-year revolving credit facility in a principal amount of approximately \$1,000.0 million (the 2017 Revolving Credit Facility) and (ii) a seven-year term loan facility in a principal amount of approximately \$3,415.0 million (the 2017 Term Loan Facility); provided that each of the 2017 Revolving Credit Facility and the 2017 Term Loan Facility may mature prior to its respective stated maturity in the event that certain of our senior notes are not refinanced or repaid in full prior to the date that is 91 days before the stated maturity of such notes. In March 2019, the Company entered into an amendment (the Revolving Credit Facility Amendment) to the 2017 Credit Agreement (the 2017 Credit Agreement, as amended by the Revolving Credit Facility Amendment, the Existing Credit Agreement). The Revolving Credit Facility Amendment amended the 2017 Credit Agreement to, among other things, (i) extend the maturity of the commitments under the 2017 Revolving Credit Facility from April 2022 to March 2024 (with the exception of \$76.0 million of commitments that were not extended) and (ii) with respect to the financial covenant, (x) increase the maximum secured net leverage ratio from 3.50:1.00 to 4.50:1.00 and (y) provide that such financial covenant is tested only if, at the end of a fiscal quarter, the aggregate principal amount of revolving loans and letters of credit (excluding undrawn letters of credit up to \$20 million and letters of credit that have been backstopped or cash collateralized in accordance with the terms of the Existing Credit Agreement) outstanding exceeds 30% of the aggregate revolving commitments.

On April 27, 2017, Endo DAC, Endo Finance LLC and Endo Finco Inc. (collectively, the Issuers), each a wholly-owned subsidiary of the Company, issued \$300.0 million in aggregate principal amount of 5.875% senior secured notes due 2024 (the 2024 Notes). On March 14, 2019, Par Pharmaceutical, Inc. (PPI), a wholly-owned subsidiary of the Company, issued \$1,500.0 million in aggregate principal amount of 7.500% senior secured notes due 2027 (the 2027 First Lien Notes).

On June 16, 2020, in connection with exchange offers for three series of the Company's existing notes, PPI issued an additional \$515.5 million in aggregate principal amount of the 2027 First Lien Notes and the Issuers issued \$940.6 million in aggregate principal amount of 9.500% senior secured second lien notes due 2027 (the 2027 Second Lien Notes) and \$1,260.4 million in aggregate principal amount of 6.000% senior notes due 2028 (the 2028 Notes). Each of the 2024 Notes, the 2027 First Lien Notes, the 2027 Second Lien Notes and the 2028 Notes are guaranteed by the Company and its subsidiaries that also guarantee the 2017 Credit Agreement.

On March 25, 2021 (the Restatement Effective Date), the Group entered into an amendment and restatement agreement (the Restatement Agreement), together with the Borrowers, the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent, issuing bank and swingline lender, which amended and restated the Existing Credit Agreement (the Existing Credit Agreement, as amended and restated by the Restatement Agreement, the Restated Credit Agreement). The Restated Credit Agreement provides for, among other things, (i) a new seven-year senior secured term loan in an aggregate

principal amount of \$2,000.0 million (the New Term Loan) (subject to springing maturity if certain of our existing secured notes are not refinanced or repaid prior to the date that is 91 days prior to the stated maturity thereof), (ii) the extension of the maturity of \$675.2 million of the existing revolving commitments to a date that is five years from the Restatement Effective Date and (iii) certain other modifications to the Existing Credit Agreement. The net proceeds of the New Term Loan, together with cash on hand and the net proceeds of the 2029 Notes (as defined below), refinanced in full the term loans outstanding under the Existing Credit Agreement.

Furthermore, on March 25, 2021, Endo Luxembourg Finance Company I S.à r.l. and Endo U.S. Inc., each a wholly-owned subsidiary of the Group, issued \$1,295.0 million in aggregate principal amount of 6.125% senior secured notes due 2029 (the 2029 Notes). The 2029 Notes are guaranteed by the Group and its subsidiaries that also guarantee the 2017 Credit Agreement.

NOTE 12. AUDITORS' REMUNERATION

Total auditors' remuneration paid to PricewaterhouseCoopers and its affiliated firms for the years ended December 31, 2021 and 2020 were as follows (in thousands):

	<u>2021</u>	<u>2020</u>
Audit of the Company's individual financials	\$ 25	\$ 25
Audit-related fees	—	—
Tax fees	—	—
Total auditors' remuneration	<u>\$ 25</u>	<u>\$ 25</u>

See Note 29. Auditors' Remuneration of the accompanying Consolidated Financial Statements included in this report for additional information regarding fees paid to the auditors by the Company.

NOTE 13. SUBSEQUENT EVENTS

Subsequent events have been evaluated through May 06, 2022 the date this report is approved by the Audit & Finance Committee of the Board of Directors and the Board of Directors.

NOTE 14. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved and authorized for issue by the directors on May 06, 2022.