ENDO INTERNATIONAL PUBLIC LIMITED COMPANY

Directors' Report and Financial Statements

For the Year Ended December 31, 2022

ENDO INTERNATIONAL PLC
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DIRECTORS AND OTHER INFORMATION

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DIRECTORS' REPORT
For the Year Ended December 31, 2022

The directors present their report and audited Consolidated Financial Statements for the year ended December 31, 2022.

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, which previously traded on the Nasdaq Global Select Market under the ticker symbol "ENDP," are currently quoted on the over-the-counter market using the ticker symbol "ENDPQ." 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 this report under the heading "RESULTS OF OPERATIONS." Across all of our reportable business segments, we generated total turnover of $2.32 billion and $2.99 billion in 2022 and 2021, 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., first-to-file products refer to generic products for which the Abbreviated New Drug Applications (ANDAs) containing patent challenges (or Paragraph IV certifications) to the corresponding branded products' listed patents were 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. First-to-market products refer to products that are the first marketed generic equivalents of the corresponding branded products 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 revenues from external customers of our Branded Pharmaceuticals segment for the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Specialty Products:		
XIAFLEX®	$ 438,680	$ 432,344
SUPPRELIN® LA	113,011	114,374
Other Specialty (1)	70,009	86,432
Total Specialty Products	$ 621,700	$ 633,150
Established Products:		
PERCOCET®	$ 103,943	$ 103,788
TESTOPEL®	38,727	43,636
Other Established (2)	86,772	113,043
Total Established Products	$ 229,442	$ 260,467
Total Branded Pharmaceuticals (3)	$ 851,142	$ 893,617

(1) Products included within Other Specialty include AVEED®, NASCOBAL® Nasal Spray and QWO®.
(2) Products included within Other Established include, but are not limited to, EDEX®.
(3) Individual products presented above represent the top two performing products in each product category for the year ended December 31, 2022 and/or any product having turnover in excess of $25 million during any completed quarterly period in 2022 or 2021.

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 DC; and (iii) pediatric endocrinology treatments, which currently focus on central precocious puberty (CPP). 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.
- 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.
- NASCOBAL® Nasal Spray, which is a prescription nasal spray used as a supplement to treat vitamin B12 deficiency.

This portfolio has also included QWO® (collagenase clostridium histolyticum-aaes), an injectable treatment for moderate to severe cellulite in the buttocks of adult women launched in March 2021. However, in December 2022, the Group announced it would be ceasing the production and sale of QWO® in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration.

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.

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, 2022 and 2021 (in thousands):

	2022	2021
VASOSTRICT®	$ 253,696	$ 901,735
ADRENALIN®	114,304	124,630
Other Sterile Injectables (1)	221,633	239,732
Total Sterile Injectables (2)	$ 589,633	$ 1,266,097

(1) Products included within Other Sterile Injectables include APLISOL®, ertapenem for injection and others.
(2) Individual products presented above represent the top two performing products within the Sterile Injectables segment for the year ended December 31, 2022 and/or any product having turnover in excess of $25 million during any completed quarterly period in 2022 or 2021.

The Sterile Injectables segment includes a product portfolio of approximately 40 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.
- APLISOL®, which is a sterile aqueous solution of a purified protein derivative for intradermal administration as an aid in the diagnosis of tuberculosis.
- 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.
- 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 110 generic product families including solid oral extended-release products, solid oral immediate-release products, 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. From time to time, our authorized generics have included generic versions of our branded products. 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®).

International Pharmaceuticals

Our International Pharmaceuticals segment includes a variety of specialty pharmaceutical products, including over-the-counter (OTC) products, sold outside the U.S., primarily in Canada through our operating company Paladin Labs Inc. (Paladin).

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 indications). In early 2020, we announced that we had initiated our XIAFLEX® development program for the treatment of plantar fibromatosis, for which we anticipate Phase 2 top-line data by the end of the first quarter of 2023. We also initiated a proof-of-concept study in plantar fasciitis during the fourth quarter of 2022. We may in the future develop our XIAFLEX® product for potential additional indications, advancing our strategy of developing non-surgical orthopedic care interventions.

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

TLC599

In June 2022, we announced that our subsidiary had entered into an agreement with Taiwan Liposome Company, Ltd. (TLC) to commercialize TLC599. TLC599 is an injectable compound in Phase 3 development for the treatment of osteoarthritis knee pain.

In September 2022, we were informed by TLC of the top-line results from TLC's Phase 3 clinical study to evaluate the efficacy and safety of TLC599 in patients with pain from osteoarthritis of the knee. While study participants treated with TLC599 showed improvement on the primary endpoint (change from baseline to week 12 on the WOMAC pain scale) consistent with the level of improvement reported in the previously conducted TLC599 Phase 2 clinical study, the difference compared to those receiving placebo was not statistically significant. Based on these data, we are evaluating options for TLC599 with TLC.

Other

Our remaining pipeline consists mainly of a variety of product candidates in our Sterile Injectables and Generic Pharmaceuticals segments. As of December 31, 2022, within these two segments, we were actively pursuing approximately 70 product candidates, including: (i) approximately 30 ANDAs pending with the FDA, of which approximately 40% are associated with our Sterile Injectables segment, as well as (ii) approximately 40 additional projects in development, of which approximately 90% are associated with our Sterile Injectables segment, including RTU and other more differentiated product candidates.

We expect to continue to focus investments in RTU and other product candidates in our Sterile Injectables segment, potentially including acquisitions and/or license and commercialization agreements such as the 2022 Nevakar Agreement that is further described in Note 12. License, Collaboration and Asset Acquisition Agreements in the Consolidated Financial Statements included in this report.

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 revenues during the years ended December 31, 2022 and 2021 are as follows:

	2022	2021
AmerisourceBergen Corporation	35 %	36 %
McKesson Corporation	26 %	32 %
Cardinal Health, Inc.	20 %	22 %

Turnover 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 Viatris Inc. (Viatris), Jazz Pharmaceuticals plc, Takeda Pharmaceutical Company Limited and Horizon Therapeutics Public Limited Company, 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® 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, Viatris, Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals, Inc. (Amneal), Hikma Pharmaceuticals PLC, Sandoz 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 competitive generic alternatives to VASOSTRICT® were launched, beginning with a generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives entered the market, including authorized generics. The degree of generic and/or other competition facing this segment is expected to increase in the future.

Generic Products

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

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

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

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

Seasonality

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

Patents, Trademarks, Licenses and Proprietary Property

We regard the protection of patents and other enforceable intellectual property rights that we own or license as critical to our business and competitive position. Accordingly, we rely on patent, trade secret and copyright law, as well as nondisclosure and other contractual arrangements, to protect our intellectual property. We have a portfolio of patents and patent applications owned or licensed by us that cover aspects of our products. These patents and applications generally include claims directed to the compounds and/or methods of using the compounds, formulations of the compounds, pharmaceutical salt forms of the compounds or methods of manufacturing the compounds. Our policy is to pursue patent applications on inventions that we believe are commercially important to the development and growth of our business.

Certain patents relating to products that are the subject of approved NDAs are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book). The Orange Book does not include a listing of patents related to biological products approved pursuant to a BLA. 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.

As of February 27, 2023, we held approximately: 152 U.S. issued patents, 45 U.S. patent applications pending, 427 foreign issued patents and 119 foreign patent applications pending. In addition, as of February 27, 2023, we had licenses for approximately 73 U.S. issued patents, 14 U.S. patent applications pending, 167 foreign issued patents and 83 foreign patent applications pending. We are seeking additional patent protection for several products, including XIAFLEX®. We may also obtain further patents or additional regulatory or patent exclusivity for one or more indications for any of our products in the future.

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.

XIAFLEX® is a biological product. We own or have licensed rights to patents and patent applications related to XIAFLEX®, including drug product and methods of manufacture patents and patent applications that will expire into the late 2030s and methods of use patents and patent applications for uses such as plantar fibromatosis that will expire into the late 2030s/early 2040s.

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 Item 1A. 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 included in this report.

Governmental Regulation

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

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

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

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an Investigational New Drug application (IND) for human clinical testing, which must become effective before human clinical trials may begin in the U.S.;

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

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

- Phase 1 trials generally involve testing the product for safety, adverse effects, dosage, tolerance, absorption, distribution, metabolism, excretion and other elements of clinical pharmacology.
- Phase 2 trials typically involve a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential adverse effects.
- Phase 3 trials are undertaken in an expanded patient population, typically at dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials, clinical investigators and the trial sponsor are also subject to regulatory inspections by the FDA and other regulatory authorities to confirm compliance with applicable regulatory standards. The process of completing clinical trials for a new product may take many years and require the expenditures of substantial resources. See Item 1A. Principal risks - "The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business, including withdrawal or suspension of existing products."

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

For some products, the FDA may require a REMS to confirm that a drug's benefits outweigh its risks. REMS could include medication guides, physician communication plans or other elements. See Item 1A. Principal risks - "The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business, including withdrawal or suspension of existing products."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Government Benefit Programs

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

The federal government may continue to pursue legislation aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. State governments also may continue to enact similar cost containment or transparency legislation. These efforts could have material consequences for the pharmaceutical industry and the Company. From time to time, legislative changes are made to government healthcare programs that impact our business. The U.S. Congress continues to examine various Medicare and Medicaid policy proposals that may result in a downward pressure on the prices of prescription products in these programs, including, for example, as part of the Inflation Reduction Act of 2022 that was enacted in August 2022. See Item 1A. Principal risks - "The availability of third-party reimbursement for our products is uncertain, and we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third-party reimbursement is not adequately provided."

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

The PPACA has been subject to court challenges and repeal efforts. For example, the U.S. Tax Cuts and Jobs Act of 2017 (TCJA) repealed the requirement that individuals maintain health insurance coverage or face a penalty (known as the individual mandate). In June 2021, the U.S. Supreme Court held that state and individual plaintiffs did not have standing to challenge the minimum essential coverage provision of the PPACA; in so holding, the U.S. Supreme Court did not consider larger constitutional questions about the validity of this provision or the validity of the PPACA in its entirety. Ongoing efforts to repeal, substantially amend, eliminate or reduce funding for the PPACA may threaten the stability of the insurance marketplace and may have consequences for the coverage and accessibility of prescription drugs. The current administration has taken actions intended to strengthen and build upon the PPACA.

Healthcare Fraud and Abuse Laws

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

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

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

International Regulations

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

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

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

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

Environmental Matters

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

Service Agreements

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

Refer to Note 12. License, Collaboration and Asset Acquisition 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 inventory management and alternative sourcing strategies. However, some raw materials are only available from one source. We are required to identify the suppliers of all raw materials for our products in the drug applications that we file with the FDA. If the raw materials from an approved supplier for a particular product become unavailable, we would be required to qualify a substitute supplier with the FDA, which would likely interrupt manufacturing of the affected product. See Item 1A. 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, Collaboration and Asset Acquisition Agreements in the Consolidated Financial Statements included in this report for additional information.

Human Capital Resources

As of February 27, 2023, we have 2,861 employees, of which 423 are engaged in R&D and regulatory work, 356 in sales and marketing, 1,106 in manufacturing, 580 in quality assurance and 396 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.

Review of the Performance of the Business

EXECUTIVE SUMMARY

This executive summary provides 2022 highlights from the results of operations that follow:

- Total turnover in 2022 were $2,318.9 million compared to $2,993.2 million in 2021 as turnover decreases related to VASOSTRICT® and certain other products in our Sterile Injectables segment, as well as our Branded Pharmaceuticals and International Pharmaceuticals segments, were partially offset by increased turnover from our Generic Pharmaceuticals segment.
- Gross margin percentage in 2022 decreased to 52.9% from 59.2% in 2021, reflecting unfavorable changes in product mix resulting primarily from decreased VASOSTRICT® turnover.
- Asset impairment charges in 2022 increased to $2,142.7 million from $415.0 million in 2021.
- We reported Loss from continuing operations of $2,952.6 million in 2022 compared to Loss from continuing operations of $569.1 million in 2021.

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:

- Since 2019, developments related to COVID-19 have continued to evolve rapidly and are likely to continue to do so. The duration and severity of the direct and indirect effects of COVID-19 on our results remain difficult to anticipate and, in many instances, outside of our control. As such, the impacts from COVID-19 on our consolidated results and the results of our business segments to date may not be directly comparable to any historical year and are not necessarily indicative of its impact on our results for any future periods, and the evolving nature of the COVID-19 pandemic could increase the degree to which our results, including the results of our business segments, fluctuate in the future. Additionally, the numerous uncertainties related to COVID-19 have impacted our ability to forecast our future operations; however, any future impact could be material.
- In November 2020, we announced the initiation of several strategic actions, collectively referred to herein as the 2020 Restructuring Initiative, to further optimize operations and increase overall efficiency. We recorded certain charges to complete these actions in anticipation of realizing annualized cost savings. For further discussion of these actions, including a discussion of amounts recognized, refer to Note 5. Restructuring 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, which are further discussed in Note 14. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- In November 2021, our PSP LLC subsidiary entered into the U.S. Government Agreement (as defined below), which is 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. For further discussion, refer to Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report.
- During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® were launched, beginning with a generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives entered the market, including authorized generics. These launches began to significantly impact both Endo's market share and product price toward the middle of the first quarter of 2022, and the effects of competition have since increased. Additionally, beginning late in the first quarter of 2022, COVID-19-related hospital utilization levels began to decline, resulting in significantly decreased market volumes for both branded and competing generic alternatives to VASOSTRICT®.
- In February 2022, we launched VASOSTRICT® in an RTU bottle, representing the first and only RTU formulation of the drug. The bottle formulation now represents a meaningful portion of the overall vasopressin market. Nevertheless, the factors described in the preceding bullet point could have a material adverse effect on our business, financial condition, results of operations and cash flows.
- In April 2022, we communicated the initiation of certain actions to streamline and simplify certain functions, including our commercial organization, to increase our overall organizational effectiveness and better align with current and future needs. In December 2022, we announced we would be taking certain additional actions to cease the production and sale of QWO® in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration. QWO® had been launched for the treatment of moderate to severe cellulite in the buttocks of adult women in March 2021. These actions are collectively referred to herein as the 2022 Restructuring Initiative. We have recorded and may continue to record certain charges to complete these actions in anticipation of realizing annualized cost savings. For further discussion of these actions, including a discussion of amounts recognized and information about any expected future charges, refer to Note 5. Restructuring in the Consolidated Financial Statements included in this report.
- In May 2022, we announced that our EVL subsidiary had entered into an agreement to acquire six development-stage RTU injectable product candidates from Nevakar Injectables, Inc., a subsidiary of Nevakar, Inc., for an upfront cash payment of $35.0 million, which was recorded as an Acquired in-process research and development charge in the Consolidated Profit and loss account in the second quarter of 2022. For further discussion of this agreement, as well as a discussion of subsequent legal proceedings with Nevakar (as defined below) that affected both this agreement and a prior 2018 agreement with Nevakar, see Note 12. License, Collaboration and Asset Acquisition Agreements in the Consolidated Financial Statements included in this report.
- In June 2022, we announced that our EVL subsidiary had entered into an agreement with TLC to commercialize TLC599. During the second quarter of 2022, we made an upfront cash payment of $30.0 million to TLC, which was recorded as an Acquired in-process research and development charge in the Consolidated Profit and loss account in the second quarter of 2022. For further discussion of this agreement, see Note 12. License, Collaboration and Asset Acquisition Agreements in the Consolidated Financial Statements included in this report.
- Beginning in June 2022, we elected to enter certain 30-day grace periods related to senior notes interest payments that were originally due to be paid between June 30, 2022 and August 1, 2022. Certain of these payments were subsequently paid prior to the expiration of the applicable grace periods; others were not. Refer to Note 1. Description of Business and Note 14. Debt in the Consolidated Financial Statements included in this report for further discussion.
- On 16 August 2022 "the Petition Date", the Debtors filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. We are subject to risks and uncertainties associated with our ongoing bankruptcy proceedings, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. Refer to Note 1. Description of Business, Note 2. Bankruptcy Proceedings and Note 14. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion.

- The Group held an extraordinary general meeting (the "EGM") on October 6, 2022. The EGM was convened pursuant to Section 1111 of the Irish Companies Act 2014 which requires an extraordinary general meeting to be convened to consider whether any, and if so what, measures should be taken in a situation where the net assets of a public limited company are half or less of the amount of the public limited company's called-up share capital. No resolutions were proposed and no substantive matters were presented for a vote or otherwise acted upon at the EGM.
- During the first quarter of 2023, a competitor launched an alternative generic version of varenicline tablets. This launch began to impact both Endo's market share and product price toward the middle of the first quarter of 2023, resulting in a decline in turnover for our Generic Pharmaceuticals segment. The effects of competition are likely to increase in future periods.
- 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, which are further discussed herein. Notwithstanding any relief that may be available as a result of our bankruptcy proceedings, 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. For further discussion, refer to Note 1. Description of Business, Note 2. Bankruptcy Proceedings and Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report, as well as "Principal risks."

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 and expanding margin in our Established Products portfolio. 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, with a focus on non-surgical orthopedic care interventions.
- 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, 2022 and 2021 (dollars in thousands):

	2022	2021	% Change 2022 vs. 2021
Total turnover, net	$ 2,318,875	$ 2,993,206	(23)%
Cost of sales	1,092,499	1,221,064	(11)%
Gross margin	$ 1,226,376	$ 1,772,142	(31)%
Gross margin percentage	*52.9 %*	*59.2 %*	
Selling, general and administrative	777,169	861,760	(10)%
Research and development	128,033	123,440	4 %
Acquired in-process research and development	68,700	25,120	NM
Litigation-related and other contingencies, net	521,722	345,495	51 %
Asset impairment charges	2,142,746	414,977	NM
Acquisition-related and integration items, net	408	(8,379)	NM
Interest expense, net	349,776	562,353	(38)%
Loss on extinguishment of debt	—	13,753	(100)%
Reorganization items, net	202,978	—	NM
Other income, net	(34,054)	(19,774)	72 %
Loss from continuing operations before income tax	$ (2,931,102)	$ (546,603)	NM

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

Total turnover, net. Total turnover in 2022 were $2,318.9 million compared to $2,993.2 million in 2021 as turnover decreases related to VASOSTRICT® and certain other products in our Sterile Injectables segment, as well as our Branded Pharmaceuticals and International Pharmaceuticals segments, were partially offset by increased turnover from our Generic 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, 2022 and 2021, Cost of sales includes certain amounts that impact its comparability among periods, as well as the comparability of gross margin percentage, including amortization expense and amounts related to continuity and separation benefits, cost reductions and strategic review initiatives. The following table summarizes such amounts (in thousands):

	2022	2021
Amortization of intangible assets (1)	$ 337,311	$ 372,907
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (2)	$ 61,806	$ 9,058

(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 2022 was primarily driven by prior asset impairment charges and decreases in the rate of amortization expense for certain assets.

(2) Amounts include, among other things, certain accelerated depreciation charges, stock adjustments and net employee separation, continuity and other benefit-related costs, including amounts related to restructurings. For further discussion of our restructuring initiatives, including a discussion of amounts recognized and information about any expected future charges, refer to Note 4. Discontinued Operations and Asset Sales and Note 5. Restructuring in the Consolidated Financial Statements included in this report.

The decrease in Cost of sales in 2022 was primarily due to decreased turnover and decreased amortization expense, partially offset by unfavorable changes in product mix resulting primarily from decreased VASOSTRICT® turnover, as well as increased costs for amounts related to continuity and separation benefits, cost reductions and strategic review initiatives.

The decrease in gross margin percentage in 2022 was primarily due to unfavorable changes in product mix resulting primarily from decreased VASOSTRICT® turnover.

Selling, general and administrative expenses. The decrease in 2022 was primarily due to decreased costs associated with our commercial investment in QWO® and certain legal matters. Additionally, in 2022, Selling, general and administrative expenses reflected the recovery of certain previously-incurred opioid-related legal expenses. These decreases were partially offset by increased Selling, general and administrative expenses associated with our investment in consumer marketing efforts supporting XIAFLEX® and certain strategic review initiatives, restructuring and/or other cost reduction initiatives, including costs incurred in connection with our bankruptcy proceedings, which are included in Selling, general and administrative expenses until the Petition Date and in Reorganization items, net thereafter. Refer to Note 5. Restructuring in the Consolidated Financial Statements included in this report for further discussion of certain restructuring initiatives, including a discussion of amounts recognized and information about any expected future charges.

R&D expenses. Our R&D efforts are focused on the development of a diversified portfolio of innovative and clinically differentiated product candidates. The amount of R&D expense we record in any year varies depending on the nature and stage of development of our R&D programs, certain of which are further described below.

We continue to invest in our Branded Pharmaceuticals segment. In early 2020, we announced that we had initiated our XIAFLEX® development program for the treatment of plantar fibromatosis, for which we anticipate Phase 2 top-line data by the end of the first quarter of 2023. We also initiated a proof-of-concept study in plantar fasciitis during the fourth quarter of 2022. Additionally, until late 2022, we had been advancing our development programs for QWO®, which was launched in March 2021 for the treatment of moderate to severe cellulite in the buttocks of adult women. However, as further discussed in Note 5. Restructuring in the Consolidated Financial Statements included in this report, in December 2022, we announced we would be ceasing the production and sale of QWO® in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration.

We expect to continue to focus investments in RTU and other product candidates in our Sterile Injectables segment, potentially including acquisitions and/or license and commercialization agreements such as the 2022 Nevakar Agreement that is further described in Note 12. License, Collaboration and Asset Acquisition Agreements in the Consolidated Financial Statements included in this report.

The increase in R&D expense in 2022 was primarily driven by increased costs associated with our XIAFLEX® development programs, certain restructuring and other cost reduction initiatives and certain post-marketing commitments. These increases were partially offset by decreased costs associated with QWO®, including as a result of actions taken in connection with the discontinuation of QWO® discussed above. Refer to Note 5. Restructuring in the Consolidated Financial Statements included in this report for further discussion of certain restructuring initiatives, including a discussion of amounts recognized and information about any expected future charges.

As our development programs progress, it is possible that our R&D expenses could increase.

Acquired in-process research and development. Acquired in-process research and development charges are generally recognized in periods in which in-process research and development assets (with no alternative future use in other research and development projects) are acquired from third parties in connection with an asset acquisition, or when costs are incurred (up to the point of regulatory approval) for upfront or milestone payments to third parties associated with in-process research and development. The increase in Acquired in-process research and development charges in 2022 was primarily driven by the incurrence, during the second quarter of 2022, of expenses related to upfront payments associated with the 2022 Nevakar Agreement and the TLC Agreement of $35.0 million and $30.0 million, respectively, which are further described in Note 12. License, Collaboration and Asset Acquisition Agreements in the Consolidated Financial Statements included in this report. This increase was partially offset by the incurrence, during 2021, of approximately $25.1 million of expenses, which primarily related to upfront payments associated with various license agreements. To the extent we enter into agreements to acquire in-process research and development in the future and/or incur expenses related to upfront or milestone payments to third parties associated with existing or potential future agreements, Acquired in-process research and development charges could increase in the future, and the amounts of any increases could be material.

Litigation-related and other contingencies, net. Included within Litigation-related and other contingencies, net are changes to our accruals for litigation-related charges. 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. Notwithstanding any relief that may be available as a result of our bankruptcy proceedings, 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. For further discussion, refer to Note 1. Description of Business, Note 2. Bankruptcy Proceedings and Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report.

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

	2022	2021
Goodwill impairment charges	$ 1,845,000	$ 363,000
Other intangible asset impairment charges	288,701	7,811
Tangible fixed assets, impairment charges	9,045	2,011
Disposal group impairment charges	—	42,155
Total asset impairment charges	$ 2,142,746	$ 414,977

For additional information, refer to Note 4. Discontinued Operations and Asset Sales, Note 5. Restructuring, Note 7. Fair Value Measurements, Note 9. Leases, Note 10. Tangible fixed assets and Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in this report, as well as the "CRITICAL ACCOUNTING ESTIMATES" section herein.

Acquisition-related and integration items, net. Acquisition-related and integration items, net primarily consist of the net expense (benefit) from changes in the fair value of acquisition-related contingent consideration liabilities resulting from changes to our estimates regarding the timing and amount of the future 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, 2022 and 2021 are as follows (in thousands):

	2022	2021
Interest expense	$ 350,740	$ 562,937
Interest income	(964)	(584)
Interest expense, net	$ 349,776	$ 562,353

The decrease in interest expense in 2022 was primarily attributable to the fact that we ceased the recognition of interest expense related to our indebtedness beginning on the Petition Date as a result of the Chapter 11 Cases. Additionally, when compared to the prior year period, there have been decreases to interest expense resulting from reductions in the aggregate principal amount of our indebtedness, which were primarily attributable to the partial repayment of the Revolving Credit Facility in October 2021, the January 2022 Senior Notes Repayments and certain quarterly payments made on the Term Loan Facility. These decreases in interest expense were partially offset by increases in the weighted average interest rate applicable to our total indebtedness through the Petition Date. Beginning during the third quarter of 2022, we also became obligated to make certain adequate protection payments as a result of the Chapter 11 Cases, which are currently being accounted for as a reduction of the carrying amount of the related debt instruments. Some or all of the adequate protection payments may later be recharacterized as interest expense depending upon certain developments in the Chapter 11 Cases, which could result in increases in interest expense in future periods that may be material. Refer to Note 14. Debt in the Consolidated Financial Statements included in this report for further discussion.

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

Loss on extinguishment of debt. The amount 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.

Reorganization items, net. Amounts relate to the net expense or profit recognized during our bankruptcy proceedings required to be presented as Reorganization items, net under *Accounting Standards Codification Topic 852, Reorganizations* (ASC 852). Refer to Note 2. Bankruptcy Proceedings in the Consolidated Financial Statements included in this report for further details. Costs related to our bankruptcy proceedings that were incurred prior to the Petition Date are generally reflected as Selling, general and administrative expenses in our Consolidated Profit and loss account. We expect to continue to incur significant expenses in connection with our ongoing bankruptcy proceedings and certain related transactions and it is possible that such costs will increase over time, particularly if we incur certain associated success-related and/or other contingent fees, which could be significant. In addition, the longer the Chapter 11 Cases continue, the higher our expenses for these matters could be.

Other income, net. The components of Other income, net for the years ended December 31, 2022 and 2021 are as follows (in thousands):

	2022	2021
Net gain on sale of business and other assets	$ (26,183)	$ (4,516)
Foreign currency (gain) loss, net	(2,087)	1,253
Net loss from our investments in the equity of other companies	378	453
Other miscellaneous, net	(6,162)	(16,964)
Other income, net	$ (34,054)	$ (19,774)

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 and Effective tax rate for the years ended December 31, 2022 and 2021 (dollars in thousands):

	2022	2021
Loss from continuing operations before income tax	$ (2,931,102)	$ (546,603)
Income tax expense	$ 21,516	$ 22,478
Effective tax rate	*(0.7)%*	*(4.1)%*

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 profit 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 year to year.

The change in income tax expense in 2022 compared to the 2021 income tax expense primarily relates to an increase in accrued interest on uncertain tax positions and changes in the geographic mix of pre-tax earnings. For additional discussion of the effective tax rate, see Note 20. Income Taxes in the Consolidated Financial Statements included in this report.

As previously disclosed, the Group concluded that there was substantial doubt about its ability to continue as a going concern within one year after the date of issuance of the Condensed Consolidated Financial Statements included in the Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022 filed with the SEC on August 9, 2022 (the Second-Quarter 2022 Form 10-Q). The Group considered this in determining that certain net deferred tax assets were no longer more likely than not realizable. As a result, an immaterial increase in valuation allowance on the Group's net deferred tax assets was recorded in various jurisdictions during the second quarter of 2022.

The Group maintains a full valuation allowance against the net deferred tax assets in the U.S., Luxembourg, Ireland and certain other foreign tax jurisdictions as of December 31, 2022. It is possible that within the next 12 months there may be sufficient positive evidence to release a portion or all of the valuation allowance. Release of these valuation allowances would result in a benefit to income tax expense for the year 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 of this report.

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

Additionally, as further discussed in Note 20. Income Taxes in the Consolidated Financial Statements included in this report, the IRS has filed multiple proofs of claim against several of the Debtors in connection with our ongoing bankruptcy proceedings.

For additional information on our income taxes, 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, 2022 and 2021 (in thousands):

	2022	2021
Litigation-related and other contingencies, net	$ —	$ 25,000
Loss from discontinued operations before income taxes	$ (15,543)	$ (49,594)
Income tax benefit	$ (2,056)	$ (5,430)
Discontinued operations, net of tax	$ (13,487)	$ (44,164)

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 2022 and 2021 were primarily related to mesh-related legal defense costs and certain other items. For additional discussion of mesh-related matters, refer to Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report.

Business Segment Results Review

Turnover, net. The following table displays our turnover by reportable segment for the years ended December 31, 2022 and 2021 (dollars in thousands):

	2022	2021	% Change 2022 vs. 2021
Branded Pharmaceuticals	$ 851,142	$ 893,617	(5)%
Sterile Injectables	589,633	1,266,097	(53)%
Generic Pharmaceuticals	795,457	740,586	7 %
International Pharmaceuticals (1)	82,643	92,906	(11)%
Total net turnover from external customers	$ 2,318,875	$ 2,993,206	(23)%

(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, 2022 and 2021 (dollars in thousands):

	2022	2021	% Change 2022 vs. 2021
Specialty Products:			
XIAFLEX®	$ 438,680	$ 432,344	1 %
SUPPRELIN® LA	113,011	114,374	(1)%
Other Specialty (1)	70,009	86,432	(19)%
Total Specialty Products	$ 621,700	$ 633,150	(2)%
Established Products:			
PERCOCET®	$ 103,943	$ 103,788	— %
TESTOPEL®	38,727	43,636	(11)%
Other Established (2)	86,772	113,043	(23)%
Total Established Products	$ 229,442	$ 260,467	(12)%
Total Branded Pharmaceuticals (3)	$ 851,142	$ 893,617	(5)%

(1) Products included within Other Specialty include AVEED®, NASCOBAL® Nasal Spray and QWO®.
(2) Products included within Other Established include, but are not limited to, EDEX®.
(3) Individual products presented above represent the top two performing products in each product category for the year ended December 31, 2022 and/or any product having turnover in excess of $25 million during any completed quarterly period in 2022 or 2021.

Specialty Products

Certain of our products that are physician administered, including XIAFLEX®, generally experienced decreased sales volumes during the COVID-19 pandemic due to reduced physician office activity and patient office visits because of the COVID-19 pandemic. While these products have generally been recovering since early 2020, they have at times continued to be impacted by COVID-19-related and, more recently, other market conditions for specialty product office-based procedures, including medical and administrative staff shortages in physicians' offices, reduced physician office activity and lower numbers of in-person patient office visits. The pandemic and other market conditions also created a high backlog of demand for non-elective urology procedures, which has in certain cases reduced the utilization of XIAFLEX® by healthcare providers. Additionally, we believe that concerns by healthcare providers regarding economic uncertainty have impacted purchasing patterns of XIAFLEX®. Changes in market conditions and certain other factors could result in turnover decreases or otherwise impact future periods, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The increase in XIAFLEX® turnover in 2022 was primarily attributable to increased net price, partially offset by lower volumes. The decrease in volumes was primarily driven by continued challenging market conditions as further described above and the ongoing impact from a disruption experienced by our third-party specialty pharmacy provider during the third quarter of 2022. While we have since seen some recovery in volumes related to this disruption, volumes have not yet returned to pre-disruption levels.

The decrease in SUPPRELIN® LA turnover in 2022 was primarily attributable to decreased volumes, partially offset by increased net price.

The decrease in Other Specialty turnover in 2022 was primarily attributable to decreased NASCOBAL® Nasal Spray turnover, partially offset by increased AVEED® turnover.

Established Products

The decrease in TESTOPEL® turnover in 2022 was primarily attributable to decreased volumes.

The decrease in Other Established turnover in 2022 was primarily attributable to ongoing competitive pressures impacting this product portfolio and certain other factors.

Our Established Products portfolio is likely to continue to be affected by ongoing competitive pressures. This could result in turnover decreases or otherwise impact future periods, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

	2022	2021	% Change 2022 vs. 2021
VASOSTRICT®	$ 253,696	$ 901,735	(72)%
ADRENALIN®	114,304	124,630	(8)%
Other Sterile Injectables (1)	221,633	239,732	(8)%
Total Sterile Injectables (2)	$ 589,633	$ 1,266,097	(53)%

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

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

The decrease in VASOSTRICT® turnover in 2022 was primarily driven by decreases to both net price and volumes, which were primarily attributable to the impact of generic competition as well as lower overall market demand as COVID-19-related hospital utilization levels declined. During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® were launched, beginning with a generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives entered the market, including authorized generics. These launches began to significantly impact both Endo's market share and product price toward the middle of the first quarter of 2022, and the effects of competition have since increased. Additionally, beginning late in the first quarter of 2022, COVID-19-related hospital utilization levels began to decline, resulting in significantly decreased market volumes for both branded and competing generic alternatives to VASOSTRICT®. In February 2022, we launched VASOSTRICT® in an RTU bottle, representing the first and only RTU formulation of the drug. The bottle formulation now represents a meaningful portion of the overall vasopressin market. Nevertheless, the factors described above 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 "Patent Matters."

The decrease in ADRENALIN® turnover in 2022 was primarily attributable to decreased net price and volumes.

The decrease in Other Sterile Injectables turnover in 2022 was primarily attributable to decreased price, partially offset by increased volumes.

Our Sterile Injectables segment is likely to continue to be affected by ongoing competitive pressures. This could result in turnover decreases or otherwise impact future periods, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

During the first quarter of 2023, a competitor launched an alternative generic version of varenicline tablets. This launch began to impact both Endo's market share and product price toward the middle of the first quarter of 2023, resulting in a decline in turnover for our Generic Pharmaceuticals segment. The effects of competition are likely to increase in future periods. Other products in our Generic Pharmaceuticals segment are also likely to continue to be affected by ongoing competitive pressures. These factors could result in turnover decreases or otherwise impact future periods, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

International Pharmaceuticals. The decrease in International Pharmaceuticals turnover in 2022 was primarily attributable to competitive pressures and the expiration of a product agreement. This segment is likely to continue to be affected by ongoing competitive pressures. This could result in turnover decreases or otherwise impact future periods, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

	2022	2021	% Change 2022 vs. 2021
Branded Pharmaceuticals	$ 366,554	$ 384,186	(5)%
Sterile Injectables	$ 349,424	$ 998,453	(65)%
Generic Pharmaceuticals	$ 336,133	$ 160,046	NM
International Pharmaceuticals	$ 19,920	$ 30,325	(34)%

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

Branded Pharmaceuticals. The decrease in Segment adjusted profit from continuing operations before income tax in 2022 was primarily attributable to the gross margin effects of the decreased segment turnover further described above, as well as increased costs associated with our investment in consumer marketing efforts supporting XIAFLEX® and certain legal matters, partially offset by decreased costs associated with our commercial investment in QWO®.

Sterile Injectables. The decrease in Segment adjusted profit from continuing operations before income tax in 2022 was primarily attributable to the gross margin effects of the decreased segment turnover further described above.

Generic Pharmaceuticals. The increase in Segment adjusted profit from continuing operations before income tax in 2022 was primarily attributable to the gross margin effects of the increased segment turnover further described above, as well as the favorable changes in product mix, which primarily related to varenicline tablets.

International Pharmaceuticals. The decrease in Segment adjusted profit from continuing operations before income tax in 2022 was primarily attributable to the gross margin effects of the decreased segment turnover further described above.

Endo International PLC Standalone Company results.

The Parent Company recorded a loss of $3,692.4 million for the year ended 31 December 2022 (2021: loss of $387.0 million). The increase was primarily attributed to a non cash financial guarantee provision of $2,324.3 million and impairment charge of $1,149.9 million (2021: $297.9 million). This provision is further described in Note 12. Financial Guarantee Liabilities and the impairment is further described in Note 3. Investment in Subsidiaries of the Standalone Company Financial Statements. This provision and impairment are eliminated in consolidation and therefore has no impact to the Consolidated Results.

LIQUIDITY AND CAPITAL RESOURCES

On the Petition Date, the Debtors filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. Refer to Note 1. Description of Business, Note 2. Bankruptcy Proceedings and Note 14. Debt in the Consolidated Financial Statements included in this report for further discussion.

Our principal source of liquidity is cash generated from operations. Cash at bank and on-hand, which primarily consisted of bank deposits and money market accounts, totaled $1,018.9 million at December 31, 2022 compared to $1,507.2 million at December 31, 2021. Our principal liquidity requirements are primarily for working capital for operations, licenses, capital expenditures, mergers and acquisitions (including upfront and milestone payments to third parties), income taxes, litigation-related and other contingent liabilities, debt service payments (including adequate protection payments on our First Lien Debt Instruments (as defined below)) and other amounts related to our bankruptcy proceedings.

Our business is exposed to a variety of material risks as further described herein. For example, we may face decreased turnover as a result of COVID-19 and, 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, such increase could be temporary. We may face unexpected costs in connection with our business operations, our ongoing and future legal proceedings, governmental investigations and other contingent liabilities (including potential costs related to settlements and judgments, as well as legal defense costs), our ongoing bankruptcy proceedings and the implementation of our COVID-19 related policies and procedures. On a longer-term basis, we may not be able to accurately predict the effect of certain developments on our sales and gross margins, such as the degree of market acceptance, patent protection and exclusivity of our products, pricing pressures (including those due to the impact of competition), the effectiveness of our sales and marketing efforts and the outcome of our current efforts to develop, receive approval for and successfully launch our product candidates. Furthermore, we may not be successful in implementing, or may face unexpected changes or expenses in connection with, our strategic direction, including the potential for opportunistic corporate development transactions. Additionally, as further discussed in Note 1. Description of Business in the Consolidated Financial Statements included in this report, management has concluded that there is substantial doubt regarding our ability to continue as a going concern. 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 we are required or choose to seek third-party financing in the future, there can be no assurance that we would be able to obtain any such required financing on a timely basis or at all, particularly in light of our ongoing bankruptcy proceedings and the corresponding event of default on our existing debt instruments. Additionally, any future financing arrangements could include terms that are not commercially beneficial to us, which could further restrict our operations and exacerbate any impact on our results of operations and liquidity that may result from any of the factors described herein or other factors.

Refer to Note 20. Income Taxes in the Consolidated Financial Statements included in this report for a discussion of our indefinite reinvestment assertion relating to undistributed earnings of certain of our subsidiaries.

Indebtedness. The Group and certain of its subsidiaries are party to the Credit Agreement (as defined below) governing the Credit Facilities (as defined below) and the indentures governing our various senior secured and senior unsecured notes. Refer to Note 2. Bankruptcy Proceedings and Note 14. Debt in the Consolidated Financial Statements included in this report for additional information about our indebtedness, including information about amounts currently outstanding, maturities, interest rates, security, priority, certain recent debt financing transactions and the effects of bankruptcy-related proceedings and the corresponding event of default.

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

	December 31, 2022	December 31, 2021
Total current assets	$ 2,076,768	$ 2,714,586
Less: total current liabilities	689,627	1,629,962
Working capital	$ 1,387,141	$ 1,084,624
Current ratio (total current assets divided by total current liabilities)	3.0:1	1.7:1

Net working capital increased by $302.5 million from December 31, 2021 to December 31, 2022. During this period, working capital benefited from the favorable impacts to net current assets resulting from turnover and gross margins, which are further described above. These benefits were partially offset by, among other things, the following current year activity: (i) Capital expenditures, excluding capitalized interest, net of Proceeds from the U.S. Government Agreement, of $81.1 million; (ii) Acquired in-process research and development charges of $68.7 million; and (iii) certain expenses incurred in connection with our bankruptcy proceedings and certain restructuring and other cost reduction initiatives.

Our bankruptcy proceedings have also resulted in adjustments to the classification of certain assets and liabilities in our Consolidated Balance Sheets during 2022, which have resulted in significant changes to our working capital. For example, many liabilities previously included in current liabilities have been reclassified as Liabilities subject to compromise and are therefore no longer part of our working capital. The classification of our assets and liabilities in our Consolidated Balance Sheets may continue to change significantly during bankruptcy proceedings, which could result in material changes to our working capital in future periods. Refer to Note 2. Bankruptcy Proceedings and Note 14. Debt in the Consolidated Financial Statements included in this report for additional information.

The following table summarizes our Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Net cash flow provided by (used in):		
Operating activities	$ 269,193	$ 411,050
Investing activities	(133,147)	(59,544)
Financing activities	(513,873)	(105,481)
Effect of foreign exchange rate	(4,242)	285
Net (decrease) increase in cash, cash equivalents, restricted cash and restricted cash equivalents	$ (382,069)	$ 246,310

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, MCOs, 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, reorganization items, income taxes and certain other items.

The $141.9 million decrease in Net cash provided by operating activities in 2022 compared to the prior year period was primarily due to reduced VASOSTRICT® turnover, partially offset by decreased payments to settle a variety of liabilities resulting from payment delays and/or other reductions related to our contingency planning and bankruptcy proceedings. Additionally, as further discussed in Note 14. Debt in the Consolidated Financial Statements included in this report, we are not currently making interest payments (which have historically been reflected as operating cash flows) on most of our debt instruments; we have instead begun making certain adequate protection payments related to our First Lien Debt Instruments, which are currently being reflected as financing cash flows.

It is possible that our operating cash flows could decline in the future as a result of, among other things, reductions to turnover and payments in future periods related to liabilities for which payment has been delayed as part of our contingency planning and bankruptcy proceedings. Additionally, it is possible that some or all of the adequate protection payments described above may later be recharacterized as interest expense depending upon certain developments in the Chapter 11 Cases, which could result adequate protection payments being reflected as operating cash flows in future periods, which could in turn lead to decreases to our operating cash flows that may be material.

Investing activities. The $73.6 million increase in Net cash used in investing activities in 2022 compared to the prior year period was primarily attributable to: (i) an increase in Acquisitions, including in-process research and development, net of cash and restricted cash acquired of $85.3 million and (ii) an increase in Capital expenditures, excluding capitalized interest of $21.8 million. The changes were partially offset by: (i) an increase in Proceeds from the U.S. Government Agreement of $18.6 million and (ii) an increase in Proceeds from sale of business and other assets, net of $11.1 million.

Financing activities. During 2022, Net cash used in financing activities primarily related to: (i) Adequate protection payments of $313.1 million; (ii) Repayments of notes of $180.3 million; and (iii) Repayments of term loans of $10.0 million.

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.

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, collaboration and asset acquisition agreements. We could become obligated to make certain contingent payments pursuant to our license, collaboration and asset acquisition agreements. Except for upfront payments, 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.

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, 2022, 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) payments related to our debt, including principal and interest and/or adequate protection payments; (ii) lease payments; (iii) obligations related to license and collaboration agreements; (iv) commitments for capital expenditures; (v) other purchase obligations, which represent enforceable and legally binding obligations for purchases of goods and services, including minimum inventory contracts, that specify all significant terms, including fixed or minimum quantities to be purchased, fixed, minimum or variable price provisions and timing; and (vi) contractual payments for certain legal liability settlements.

Refer to Note 9. Leases, Note 12. License, Collaboration and Asset Acquisition 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.

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 year of related future payments, if any.

The Chapter 11 Cases have affected and are likely to continue to affect certain of the obligations described above, as further discussed herein. As the Chapter 11 Cases progress, certain of our contractual arrangements could be amended or rejected, which could result in changes to our cash requirements for such obligations.

Additionally, we have made significant cash payments to date as a direct result of our ongoing bankruptcy proceedings, including payments for related professional fees. We expect to continue to incur significant expenditures in the future as a result of our bankruptcy proceedings and certain related transactions. It is possible that our expenditures will increase over time, particularly if we incur certain associated success-related and/or other contingent fees, which could be significant. In addition, the longer the Chapter 11 Cases continue, the higher our expenditures for these matters could be.

For additional discussion of our bankruptcy proceedings, refer to Note 2. Bankruptcy Proceedings in the Consolidated Financial Statements included in this report.

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; changing inflation and interest rates; 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; bankruptcy proceedings and strategic review initiatives; financing activities; COVID-19; acquired in-process research and development charges; asset impairment charges; share-based and other long-term incentive compensation; and changes in the fair value of financial instruments. Additionally, a substantial portion of our total turnover are through three wholesale distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

Inflation. 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. While we do not believe that inflation had a material adverse effect on our financial statements for the periods presented, if these types of events or disruptions continue to occur, they could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Financial Risk Management

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

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate indebtedness associated with our Credit Facilities. Borrowings under the Credit Facilities may from time to time require payments calculated using variable rates, in certain cases subject to a floor. At December 31, 2022 and December 31, 2021, a hypothetical 1% increase in the applicable rate over any applicable floor would have resulted in the incurrence of $22.5 million and $22.6 million, respectively, of incremental payments (representing the annual rate of incurrence) related to our variable-rate debt borrowings.

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

Foreign Currency Exchange Rate Risk

We operate and transact business in various foreign countries and are therefore subject to risks associated with foreign currency exchange rate fluctuations. The 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 (gain) 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, 2022 and December 31, 2021. A 10% change at December 31, 2022 and December 31, 2021 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 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.

Principal Risk Summary

The following is a summary of the principal risks contained in this Annual Report 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.

Risks Related to Bankruptcy and Our Ordinary Shares

- We are subject to risks and uncertainties associated with the Chapter 11 Cases (as defined below).
- Delays in the Chapter 11 Cases may occur.
- The RSA (as defined below) is subject to significant conditions and milestones that may be difficult for us to satisfy.
- If the RSA is terminated, our ability to confirm and consummate the Sale (as defined below) could be materially and adversely affected.
- Even if the Sale or an alternative restructuring transaction is consummated, we may not be able to achieve our stated goals or continue as a going concern.
- Our ability to prosecute the Chapter 11 Cases and consummate the Sale may be contested by third parties with litigation.
- In certain instances, a chapter 11 case may be converted to a case under chapter 7 of the Bankruptcy Code.
- Alternative plans of reorganization may be introduced, which could have less favorable terms than currently anticipated or result in significant litigation and expenses.
- As a result of the Chapter 11 Cases, our historical financial information may not be indicative of our future performance, which may be volatile.
- We may be subject to claims that will not be discharged in the Chapter 11 Cases.
- If we consummate the Sale with the Stalking Horse Bidder (as defined below), we may not have sufficient liquidity to implement an orderly wind-down process.
- The pursuit of the Chapter 11 Cases has consumed, and will continue to consume, a substantial portion of the time and attention of our management and could cause us to experience increased levels of employee attrition.
- Our current sources of financing may be insufficient to fund our cash requirements through emergence from bankruptcy.
- We may be unable to comply with restrictions imposed by the Cash Collateral Order (as defined below).
- Aspects of the Chapter 11 Cases limit the flexibility of our management team in running our business.
- 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.
- Our ordinary shares are quoted on the over-the-counter market, and thus may have a limited market and lack of liquidity.
- We believe it is likely that our ordinary shares will continue to decrease in value as a result of the Chapter 11 Cases.

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.
- 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 about our ability to bring new products to market and imposes substantial compliance costs on our business, including withdrawal or suspension of existing products.
- We are subject to complex reporting and payment obligations under Medicaid and other governmental 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 our products or face interruptions in the 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.

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 tax attributes to offset U.S. taxable profit 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. 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 this report "Business" under the caption "Patents, Trademarks, Licenses and Proprietary Property." Generic products we currently sell with generic exclusivity could in the future be subject to competition from other generic competitors. Some of our other branded and generic products, such as VASOSTRICT®, already face generic competition and are at risk of additional generic competitors entering the market. During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® were launched, beginning with a generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives entered the market, including authorized generics.

Manufacturers of generic products typically invest far less in R&D than research-based companies. Additionally, generic competitors, including Asian or other overseas generic competitors, may be able to manufacture products at costs lower than us. For these reasons, competitors may price their products lower than ours, and such differences could be significant. Due to lower prices, generic versions, where available, may be substituted by pharmacies or required in preference to branded versions under third-party reimbursement programs. As a result, generic competition could have a material adverse effect on our business, financial condition, results of operations and cash flows. Legislation encouraging early and rapid approval of generic drugs could also increase the degree of generic competition we face. See the risk factor "If other pharmaceutical companies use litigation and regulatory means to obtain approval for generic, biosimilar, OTC or other competing versions of our products, our sales may suffer" for more information.

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

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

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

Various manufacturers have filed ANDAs seeking FDA approval for generic versions of certain of our key pharmaceutical products including, but not limited to, 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.

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.

For example, 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 and other companies advising of the filing by such companies of ANDAs/NDAs for generic versions of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/ml and/or 200 units/10 ml. Beginning in May 2018, PSP LLC, PPI and Endo Par Innovation Company, LLC (EPIC) filed lawsuits against Eagle and other generic filers in the U.S. District Court for the District of Delaware or New Jersey. We reached settlements and voluntarily dismissed the suits against many of these filers. The remaining Delaware cases against Eagle and Amneal Pharmaceuticals LLC were consolidated and a trial was held in July 2021. In August 2021, the court issued an opinion holding that Eagle's proposed generic product would not infringe PPI's asserted patent claims. The court made no finding regarding the validity of the patents. We appealed the ruling. In August 2022, the Federal Circuit affirmed the District of Delaware's decision: (i) that Eagle's proposed generic product would not infringe PPI's asserted patent claims and (ii) denying the issuance of a declaratory judgment that Eagle's planned sale of generic product would infringe under 35 U.S.C. § 271(a) and (b). During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® 20 units/ml 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 entered the market, including authorized generics. These launches began to significantly impact both Endo's market share and product price toward the middle of the first quarter of 2022, and the effects of competition have since increased. This competition could have a material adverse effect on our business, financial condition, results of operations and cash flows.

There are currently pending 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 FFDCA or the 180-day exclusivity for competitive generic therapies established by the FDA Reauthorization Act of 2017, for such product candidates. Even if we were to secure such exclusivities, risks associated with securing timely approval, as well as risks of unfavorable litigation dispositions, put such exclusivities at risk of being forfeited. The approval of our ANDAs may also be stayed by the FDA for up to 30 months if such ANDAs become the subject of patent litigation. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants or with authorized generics that are not prohibited from sale during the 180-day marketing exclusivity period. Our 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.

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 group 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 group 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 group 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.

In addition to our efforts to consummate the Sale, and subject to any required approvals of the Bankruptcy Court, 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 4. Discontinued Operations and Asset Sales in the Consolidated Financial Statements included in this report, in both 2021 and 2022, we divested of certain assets related to our retail generics business. We have also divested of certain intellectual property rights throughout each of the past three years. We intend to continue to explore the sale of certain non-core assets, subject to any limitations imposed as a result of our bankruptcy proceedings. 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.

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.

In addition, in August 2022, the U.S. enacted the Inflation Reduction Act of 2022. Subject to subsequent rulemaking, this act, among other changes: (i) gives HHS the ability and authority to directly negotiate with manufacturers the price that Medicare will pay for certain drugs; (ii) requires manufacturers of certain Part B and Part D drugs to issue rebates to HHS based on certain calculations and triggers, such as when drug price increases outpace the rate of inflation; (iii) places certain limitations on out-of-pocket spending for Medicare Part D enrollees; (iv) implements a 15% corporate alternative minimum tax on book profit on corporations whose average annual adjusted financial statement profit during the most recently-completed three-year period exceeds $1.0 billion; (v) implements a 1% excise tax on net stock repurchases; and (vi) implements several tax incentives to promote clean energy. While the impact of the Inflation Reduction Act of 2022 was not material to us in 2022, we are continuing to evaluate the act and its requirements, as well as any potential impact on our business. It is possible that the act will have a material adverse effect on our business, financial condition, results of operations and cash flows in the future.

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, recent legislation, including the Inflation Reduction Act of 2022, seeks to reduce prescription drug costs in a variety of ways.

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. If we or our partners, suppliers or brands are negatively impacted by publicity, media coverage, market perception or consumer preference, it could impact the commercial viability of our products, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, in December 2022, we announced we would be taking certain actions to cease the production and sale of QWO® in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration.

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.

In October 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act was enacted in response to the opioid abuse epidemic. State laws have been enacted such as the New York Opioid Stewardship Act enacted in April 2018 which provides for certain manufacturers and distributors to make payments to an opioid stewardship fund. In April 2019, New York enacted an excise tax on the first sale of every opioid unit in New York. 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." These statutes, and 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 that came into force on July 1, 2022 made a number of changes to the regulation of Canadian drug prices by the PMPRB. The application of new price tests under the PMPRB 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 payments to the Canadian government to offset turnover deemed by the PMPRB to be excessive, which could ultimately impact the commercial viability of products we sell in Canada, reduce the turnover and cash flows of our International Pharmaceuticals segment and/or 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, 2022 and 2021 are as follows:

	2022	2021
AmerisourceBergen Corporation	35 %	36 %
McKesson Corporation	26 %	32 %
Cardinal Health, Inc.	20 %	22 %

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 inventory objectives or other factors. In addition, if we were to lose the business of any of these customers, or if any were to fail to pay us on a timely basis, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Third-party manufacturers currently manufacture a significant amount of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of our products. For example, Teikoku Seiyaku Co., Ltd. is our sole source of our lidocaine patch 5% product. As a result of the sale of certain of our manufacturing facilities and related assets, as further discussed in Note 4. Discontinued Operations and Asset Sales 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, mistake or failure by 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, shipping, 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, mistake 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®, in our Horsham, Pennsylvania facility, we have limited experience in manufacturing biologic products. Biologics such as CCH require processing steps that are highly complex and generally more difficult than those required for most chemical pharmaceuticals. In addition, TESTOPEL® is manufactured using a unique, proprietary process. If the manufacturing processes are disrupted at the facilities where our biologic products are manufactured, it may be difficult to find alternate manufacturing sites. We may encounter difficulties with the manufacture of CCH and the active ingredient of TESTOPEL®, which could delay, disrupt or halt our manufacture of such products and/or product candidates, result in supply disruption or delay, product recalls or product liability claims, require write-offs or otherwise have a material adverse effect on our business, financial condition, results of operations and cash flows.

The DEA limits the availability of the active ingredients used in many of our products as well as the production of these products, and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or complete clinical trials.

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

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

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

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 2022, approximately 4% 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 our manufacturing site in Indore. A disruption in our Indian operations could have a material adverse effect on our business, financial condition, results of operations and cash flows. These risks include, among others:

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

- difficulties in enforcing or defending intellectual property rights; and
- exposure to different legal and political standards due to our conducting business in foreign countries.

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

Widespread health problems 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, the supply of goods and services worldwide may be adversely affected as a result of increased pressure on global logistics network infrastructure and capacity or otherwise, which could result in interruptions of supply and/or increased costs based upon inability to obtain, and/or delayed deliveries of, raw materials and/or critical supplies necessary to continue our manufacturing activities and/or those of our third-party suppliers. See the risk factor "Supply chain and other manufacturing disruptions could negatively impact our businesses" for more information.

Due to these disruptions and other factors, including changes in our workforce availability and increased demand for some of our critical care products, our ability to meet our obligations to third-party distribution partners may be negatively impacted. 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. For example, certain of our products that are physician administered, including XIAFLEX®, generally experienced decreased sales volumes during the COVID-19 pandemic due to reduced physician office activity and patient office visits because of the COVID-19 pandemic. While these products have generally been recovering since early 2020, they have at times continued to be impacted by COVID-19-related and, more recently, other market conditions for specialty product office-based procedures, including medical and administrative staff shortages in physicians' offices, reduced physician office activity and lower numbers of in-person patient office visits. The pandemic and other market conditions also created a high backlog of demand for non-elective urology procedures, which has in certain cases reduced the utilization of XIAFLEX® by healthcare providers. Additionally, we believe that concerns by healthcare providers regarding economic uncertainty have impacted purchasing patterns of XIAFLEX®.

Economic crises and increases in unemployment rates resulting from widespread health problems 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. We are unable to predict the impact that widespread health problems 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 widespread health problems 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 epidemics, pandemics and other widespread health problems. Public health directives may 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.

Widespread health problems 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, 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.

Any of the risks described herein could also apply in the event of future outbreaks. 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.

Risks Related to Bankruptcy and Our Ordinary Shares

We are subject to risks and uncertainties associated with the Chapter 11 Cases.

The Chapter 11 Cases could have a material adverse effect on our business, financial condition, results of operations and cash flows. So long as the Chapter 11 Cases continue, our senior management may be required to spend a significant amount of time and effort dealing with bankruptcy proceedings instead of focusing on our business operations. The bankruptcy proceedings also may make it more difficult to retain management and the key personnel necessary to the success and growth of our business. In addition, during the period of time we are involved in the Chapter 11 Cases, our customers and suppliers may lose confidence in our ability to restructure our business and may seek to establish alternative commercial relationships.

Other significant risks associated with the Chapter 11 Cases that could have a material adverse effect on our business, financial condition, results of operations and cash flows include or relate to the following, among others:

- our ability to obtain approval from the Bankruptcy Court (as defined below) with respect to motions or other requests made to the Bankruptcy Court in the Chapter 11 Cases, including maintaining control as debtors-in-possession;
- our ability to consummate the Sale or another restructuring transaction, including in light of the currently outstanding objections relating to the Sale and proposed marketing process filed by certain stakeholders in the Chapter 11 Cases;
- the effects of the filing of the Chapter 11 Cases on our business and the interests of various constituents, including our shareholders;
- the high costs of the Chapter 11 Cases and related fees;
- our ability to maintain relationships with suppliers, customers, employees and other third parties as a result of the Chapter 11 Cases;
- Bankruptcy Court rulings in the Chapter 11 Cases as well as the outcome of other pending litigation and the outcome of the Chapter 11 Cases in general;
- the length of time that we will operate with chapter 11 protection and any resulting risk that we will not satisfy the milestones specified in the RSA and in our agreement with our secured lenders with respect to our use of their cash collateral;
- the availability of operating capital during the pendency of the Chapter 11 Cases, including any event that could terminate our right to continued access to the cash collateral of our lenders to use as operating capital;
- third-party motions in the Chapter 11 Cases, which may interfere with our ability to consummate the Sale or another restructuring transaction;
- the impact on our business following the Sale in light of possible changes in our business and its prospects;
- the adequacy of our cash balances at the time of the Sale and our projected exit from the Chapter 11 Cases; and
- our ability to continue as a going concern.

Because of the risks and uncertainties associated with the Chapter 11 Cases, we may not be able to accurately predict or quantify the ultimate impact the Chapter 11 Cases may have on our business, financial condition, results of operations and cash flows, nor can we accurately predict the ultimate impact the Chapter 11 Cases may have on our corporate or capital structure.

Delays in the Chapter 11 Cases may increase the risks of our being unable to consummate the Sale and increase our costs associated with the Chapter 11 Cases.

The RSA contemplates the consummation of the Sale, but there can be no assurance that we will be able to consummate the Sale. A prolonged chapter 11 proceeding could adversely affect our relationships with customers, suppliers and employees, among other parties, which in turn could have a material adverse effect on our business, financial condition, results of operations and cash flows, as well as our ability to continue as a going concern. A weakening of our business, financial condition, results of operations and cash flows could adversely affect our ability to implement the Sale (or any alternative restructuring transaction). If we are unable to consummate the Sale (or an alternative restructuring transaction), we may be forced to liquidate our assets.

The RSA is subject to significant conditions and milestones that may be difficult for us to satisfy.

There are certain material conditions we must satisfy under the RSA, including the timely satisfaction of milestones in the Chapter 11 Cases, which include the consummation of the Sale. Our ability to timely complete such milestones is subject to risks and uncertainties, many of which are beyond our control. Failure to meet such milestones could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If the RSA is terminated, our ability to confirm and consummate the Sale could be materially and adversely affected.

The RSA contains a number of termination events, upon the occurrence of which certain parties to the RSA may terminate the agreement. If the RSA is terminated as to all parties thereto, each of the parties thereto will be released from its obligations in accordance with the terms of the RSA. Such termination may result in the loss of support for the Sale by the parties to the RSA, which could adversely affect our ability to consummate the Sale. If the Sale is not consummated, there can be no assurance that the Chapter 11 Cases would not be converted to chapter 7 liquidation cases or that an alternative restructuring transaction would be as favorable to holders of claims against us as the Sale transaction.

Even if the Sale or an alternative restructuring transaction is consummated, we may not be able to achieve our stated goals or continue as a going concern.

Even if the Sale or an alternative restructuring transaction is consummated, we may continue to face a number of risks, such as changes in economic conditions, changes in our industry, changes in demand for our products and increasing expenses. Some of these risks become more acute when cases under the Bankruptcy Code continue for a protracted period without indication of how or when the cases may be completed. As a result of these risks and others, we cannot guarantee that the Sale or an alternative restructuring transaction will achieve our stated goals or that our business will be able to continue as a going concern.

Furthermore, even if our debts and other liabilities are reduced or discharged through the chapter 11 process, we may need to raise additional funds through public or private debt or equity financing or other various means to fund our business after the completion of the Chapter 11 Cases. Our access to additional financing may be limited, if it is available at all. Therefore, adequate funds may not be available when needed or may not be available on favorable terms, or at all.

Our ability to prosecute the Chapter 11 Cases and consummate the Sale may be contested by third parties with litigation.

Certain of our creditors and other parties in interest may bring litigation against us during the course of the Chapter 11 Cases, the outcome of which is uncertain. Such litigation may prolong the Chapter 11 Cases and may make it difficult for us to reach the contractual milestones for the Chapter 11 Cases within the timeframe set out in the RSA. Failure to meet such milestones could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In certain instances, a chapter 11 case may be converted to a case under chapter 7 of the Bankruptcy Code.

Upon a showing of cause, the Bankruptcy Court may convert the Chapter 11 Cases to cases under chapter 7 of the Bankruptcy Code. In such event, a chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the Bankruptcy Code. We believe that liquidation under chapter 7 would diminish recoveries for our creditors because of: (i) the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern; (ii) additional administrative expenses involved in the appointment of a chapter 7 trustee; and (iii) additional expenses and claims, some of which would be entitled to priority, that would be generated during the liquidation and from the rejection of leases and other executory contracts in connection with a cessation of operations.

Termination of our exclusive right to file a chapter 11 plan and the exclusive right to solicit acceptances could result in other parties in interest filing plans of reorganization, which could have less favorable terms than under the Sale transaction or result in significant litigation and expenses.

Following the commencement of the Chapter 11 Cases, we had the exclusive right to file a chapter 11 plan through and including December 14, 2022, and the exclusive right to solicit acceptances of any such plan through February 13, 2023. Deadlines such as these may be extended from time to time by the Bankruptcy Court for cause as permitted by section 1121(d) of the Bankruptcy Code. It is also possible that: (i) parties in interest could seek to shorten or terminate such exclusive plan filing and solicitation periods "for cause" (as permitted by section 1121(d) of the Bankruptcy Code) or seek to oppose any requested extension or (ii) that such periods could expire without extension.

On December 14, 2022, we filed a motion with the Bankruptcy Court seeking extensions of our initial exclusive filing and solicitation periods. Several parties in interest have filed objections to the requested extensions. While certain of these objections have been consensually resolved in principle, others remain outstanding. The Bankruptcy Court hearing on the exclusivity extension motion has been adjourned to an undetermined date, and in the interim, our exclusive periods have been extended to March 20, 2023 and may be subject to further extension based on when the hearing on the exclusivity extension motion is scheduled.

If our exclusive filing and solicitation periods expire or are terminated, other parties in interest will be permitted to file plans of reorganization. There can be no assurances that recoveries under any such plans would be more favorable to creditors than under the Sale or an alternative restructuring transaction. In addition, such plans of reorganization may entail significant litigation and significantly increase the expenses of administration of the Debtors' cases, which could deplete creditor recoveries. Furthermore, if the Bankruptcy Court does not extend the Debtors' exclusive periods, the Ad Hoc First Lien Group (as defined below) could contend that such failure to obtain an extension gives rise to a default under the Cash Collateral Order. If the Ad Hoc First Lien Group seeks to terminate our use of cash collateral, such action could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As a result of the Chapter 11 Cases, our historical financial information may not be indicative of our future performance, which may be volatile.

During the Chapter 11 Cases, we expect our financial results to continue to be volatile as restructuring activities and expenses, potential contract terminations and/or rejections and claims assessments significantly impact our Consolidated Financial Statements. As a result, our historic financial performance is likely not indicative of our financial performance after the Petition Date. In addition, if we emerge from chapter 11, the amounts reported in subsequent periods may materially change relative to historic amounts. We also may be required to adopt fresh start accounting, in which case our assets and liabilities would generally be recorded at fair value as of the fresh start reporting date, which may differ materially from the recorded values of assets and liabilities currently included in our Consolidated Balance Sheets. Our financial results after the application of fresh start accounting could also differ significantly from historic trends.

We may be subject to claims that will not be discharged in the Chapter 11 Cases, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

With certain exceptions, the Bankruptcy Code provides that the confirmation of a plan of reorganization generally discharges a debtor from claims arising prior to consummation of a plan of reorganization. Any claims not ultimately discharged pursuant to a plan of reorganization could be asserted against the reorganized entities and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, if we do not pursue a plan of reorganization following consummation of the Sale, there is a risk that claims against us will not be discharged upon our exit from chapter 11.

If we consummate the Sale with the Stalking Horse Bidder, we may not have sufficient liquidity to implement an orderly wind-down process.

The RSA contemplates a marketing process and auction that will be conducted under the supervision of the Bankruptcy Court. The purchaser pursuant to the auction shall be responsible for, among other things, providing cash for the Wind-Down Amount (as defined below) to fund an orderly wind down process, as further discussed in Note 2. Bankruptcy Proceedings in the Consolidated Financial Statements included in this report. The Wind-Down Amount relies on certain assumptions, including a nine-month wind-down process. It also reflects an estimate of anticipated costs to fund various items, such as director fees, professional fees, liquidation proceedings in non-U.S. jurisdictions and other administrative expenses arising after consummation of the Sale. However, there is no guarantee that the assumptions or estimates taken into account in calculating the Wind-Down Amount will result in the provision of sufficient funds to implement an orderly wind-down process.

The pursuit of the Chapter 11 Cases has consumed, and will continue to consume, a substantial portion of the time and attention of our management, which could have a material adverse effect on our business, financial condition, results of operations and cash flows, and could cause us to experience increased levels of employee attrition.

While the Chapter 11 Cases continue, our management will be required to spend a significant amount of time and effort focusing on the Chapter 11 Cases instead of focusing exclusively on our business operations. This diversion of attention could have a material adverse effect on our business, financial condition, results of operations and cash flows, particularly if the Chapter 11 Cases are protracted.

Furthermore, during the pendency of the Chapter 11 Cases, we may experience increased levels of employee attrition and our employees may face considerable distraction and uncertainty. A prolonged period of operating under Bankruptcy Court protection also may make it more difficult to retain management and other key personnel necessary to the success and growth of our business. A loss of key personnel or material erosion of employee morale could adversely affect our business and results of operations. The loss of services of members of our senior management team could also impair our ability to execute our strategy and implement operational initiatives, which would be likely to have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, the longer the Chapter 11 Cases continue, the more likely it is that vendors and employees will lose confidence in our ability to reorganize our business successfully.

Our current operations and future growth may require significant additional capital, and the amount and terms of our indebtedness could impair our ability to fund our capital requirements. Our current sources of financing may be insufficient to fund our cash requirements through emergence from bankruptcy.

Our business requires substantial capital. We may require additional capital in the event of growth opportunities, unanticipated maintenance requirements or significant departures from our current business plan. Additional financing may not be available on a timely basis or on terms acceptable to us, or at all.

Failure to obtain additional financing, should the need for it develop, could impair our ability to fund capital expenditure requirements and meet debt service requirements and could have a material adverse effect on our business, financial condition, results of operations and cash flows. Further, for the duration of the Chapter 11 Cases, we will be subject to various risks, including but not limited to: (i) the inability to maintain or obtain sufficient financing sources for operations or to fund the Chapter 11 Cases and meet future obligations and (ii) increased legal and/or professional costs associated with the Chapter 11 Cases and our reorganization.

We may be unable to comply with restrictions imposed by the Cash Collateral Order.

The Cash Collateral Order imposes a number of restrictions on us. For example, the Cash Collateral Order requires the Debtors to maintain at least $600.0 million of "liquidity," calculated at the end of each week as unrestricted cash at bank and on-hand plus certain specified amounts of restricted cash associated with the TLC Agreement (as defined below). The Cash Collateral Order also requires compliance with variance covenants that compare actual operating disbursements and receipts and capital expenditures to the budgeted amounts set forth in the cash collateral budgets delivered thereunder from time to time pursuant to the terms of the Cash Collateral Order. The Ad Hoc First Lien Group may also contend that the Cash Collateral Order requires the Debtors to obtain extensions to our exclusive plan filing and solicitation periods, as described in more detail herein. Our ability to comply with these provisions may be affected by events beyond our control and our failure to comply could result in an event of default under the Cash Collateral Order, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Aspects of the Chapter 11 Cases limit the flexibility of our management team in running our business.

While we operate our business under supervision by the Bankruptcy Court, we are required to obtain approval by the Bankruptcy Court, and in some cases certain other parties, prior to engaging in activities or transactions outside the ordinary course of business. Bankruptcy Court approval of non-ordinary course activities entails preparation and filing of appropriate motions with the Bankruptcy Court, negotiation with various parties in interest and one or more hearings. Parties in interest may be heard at any Bankruptcy Court hearing and may raise objections with respect to these motions. This process may delay major transactions and limit our ability to respond quickly to opportunities and events in the marketplace. Furthermore, in the event the Bankruptcy Court does not approve a proposed activity or transaction, we would be prevented from engaging in such activities or transactions, even if we believed they would be beneficial. Delays in receiving approvals or failures to receive approvals could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, as noted above, the Cash Collateral Order imposes a number of restrictions on us that may limit the flexibility of our management team in running our business.

We also may become subject to operating covenants that apply to substantially all of our business under the purchase and sale agreement that we anticipate entering into in connection with the Sale. These covenants may require us to operate in the ordinary course of business, to refrain from taking certain enumerated actions and to affirmatively take other enumerated actions. Such covenants may limit the flexibility of our management to respond to various events and circumstances that may arise from time to time, including as a result of the Chapter 11 Cases. If those covenants apply to our business, there can be no assurances that we will be able to obtain appropriate waivers from such covenants as may be necessary or advisable, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 2022, our ordinary shares were quoted at prices between approximately $0.06 and $3.98 per share. The following factors, in addition to other principal risks described in this section, may have caused and may in the future cause the market value of our securities to fluctuate:

- Developments related to our bankruptcy proceedings and certain related transactions;
- 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;
- year-to-year 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; 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 and our ability to do so is restricted during the pendency of the Chapter 11 Cases. Additionally, while our Board of Directors (the 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, 2022, 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 (including restrictions imposed by the Bankruptcy Code and related rules and guidelines during the pendency of the Chapter 11 Cases) 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.

Our ordinary shares are quoted on the over-the-counter market, and thus may have a limited market and lack of liquidity.

The delisting of our ordinary shares from the Nasdaq Global Select Market could result in significantly lower trading volumes and reduced liquidity for investors seeking to buy or sell ordinary shares. Our ordinary shares are currently quoted on the over-the-counter market, which may have an unfavorable impact on our share price and liquidity. The over-the-counter market is a significantly more limited market than the Nasdaq Global Select Market. The quotation of our shares on the over-the-counter market may result in a less liquid market available for existing and potential shareholders to trade our ordinary shares, could further depress the trading price of our ordinary shares and could have a long-term adverse impact on our ability to raise capital in the future. There can be no assurance that there will be an active market for our ordinary shares, either now or in the future, or that shareholders will be able to liquidate their investments or the price at which they may be liquidated. Accordingly, we urge extreme caution with respect to existing and future investments in our equity and other securities.

We believe it is likely that our ordinary shares will continue to decrease in value as a result of the Chapter 11 Cases.

We have a significant amount of indebtedness that is senior to our ordinary shares in our capital structure. Our existing ordinary shares have substantially decreased in value leading up to and during the Chapter 11 Cases. The proposed Sale transaction to the Stalking Horse Bidder does not contemplate the distribution of any value with respect to our shares, and we do not foresee a market for our existing ordinary shares after any emergence from the Chapter 11 Cases. Accordingly, any trading in our ordinary shares during the pendency of the Chapter 11 Cases is highly speculative and poses substantial risks to purchasers of our ordinary shares.

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.

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.

As further discussed in Note 2. Bankruptcy Proceedings and Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report, on the Petition Date, the Debtors filed voluntary petitions for relief under the Bankruptcy Code. Under the Bankruptcy Code, third-party actions to collect pre-petition indebtedness owed by the Debtors, as well as most litigation pending against the Debtors as of the Petition Date, are generally subject to an automatic stay. However, under the Bankruptcy Code, certain legal proceedings, such as those involving the assertion of a governmental entity's police or regulatory powers, may not be subject to the automatic stay and may continue unless otherwise ordered by the Bankruptcy Court. As a result, some proceedings may continue (or certain parties may attempt to argue that such proceedings should continue) notwithstanding the automatic stay. It is possible that legal proceedings such as those described herein and/or other matters could in the future cause us to take one or more additional significant corporate transactions or other remedial measures, including on a preventative or proactive basis.

As an example of our legal proceedings, we, as well as various other manufacturers, distributors, pharmacies and/or others, are the subject of numerous lawsuits consisting of cases filed by or on behalf of a wide variety of plaintiffs asserting claims relating to the defendants' alleged sales, marketing and/or distribution practices with respect to prescription opioid medications. In these cases, plaintiffs seek 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. Notwithstanding any relief that may be available as a result of our bankruptcy proceedings, 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. Refer to Note 15. Commitments and Contingencies in the Consolidated Financial Statements included in this report for more information.

As a result of the Chapter 11 Cases and the associated automatic stay, we are no longer actively pursuing our prior integrated settlement and litigation strategy to seek resolution of unsettled cases that have been stayed. Nevertheless, at any given time, we may be engaged in settlement or similar discussions regarding various legal matters including those that arise in connection with the Chapter 11 Cases; 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.

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. To the extent that any litigation arises or proceeds during the pendency of the Chapter 11 Cases, 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 and approval of the Bankruptcy Court during the pendency of the Chapter 11 Cases, which 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.

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. As a result of our ongoing bankruptcy proceedings, we could see an increase in the number of adverse events reported, which could increase costs and have other negative impacts.

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

If we are found liable in any lawsuits, including the 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.

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, plaintiffs have from time to time sought similar relief and may do so in the future. Any future default judgments or other sanctions relating to discovery matters could result in the imposition of material damages or other costs.

The August 16, 2022 bankruptcy filings by the Debtors constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. Refer to Note 14. Debt in the Consolidated Financial Statements included in this report for additional 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. 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 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. 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. Notwithstanding any relief that may be available as a result of our bankruptcy proceedings, 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. 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 risk factor “Our business and financial condition may be adversely affected by existing or future legislation and regulations” for more information.

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

Financial and Liquidity Related Risks

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

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

- causing a substantial portion of our cash flows from operations to be dedicated to the payment of legal or related expenses and therefore unavailable for other purposes, including the payment of principal and interest on our indebtedness, our operations, capital expenditures and future business opportunities;
- limiting our ability to adjust to changing market conditions, causing us to be more vulnerable to periods of negative or slow growth in the general economy or in our business, causing us to be unable to carry out capital spending that is important to our growth and placing us at a competitive disadvantage;
- limiting our ability to attract and retain key personnel;

- causing us to be unable to maintain compliance with or making it more difficult for us to satisfy our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt and long-term corporate ratings (which could increase our cost of capital) and exposing us to potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries' outstanding indebtedness;
- limiting our ability to incur additional borrowings under the covenants in our then-existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness; and/or
- causing a significant reduction in our short-term and long-term 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.

These risks have been and are likely to continue to be exacerbated by our ongoing bankruptcy proceedings and the corresponding event of default on our existing debt instruments, as further discussed herein.

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, 2022 and 2021, goodwill and other intangibles comprised approximately 54% and 63%, 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, 2022 and 2021, we recorded asset impairment charges of $2.1 billion and $0.4 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, 2022 and 2021. 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, 2022, we have total debt of approximately $8.1 billion in aggregate contractual principal amount. Our substantial indebtedness may:

- make it difficult for us to satisfy our financial obligations, including making any applicable scheduled principal, interest and/or adequate protection payments on our indebtedness as further discussed herein;
- 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 these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

These risks have been and are likely to continue to be exacerbated by our ongoing bankruptcy proceedings and the corresponding event of default on our existing debt instruments, as further discussed herein. To the extent we are required or choose to seek third-party financing in the future, there can be no assurance that we would be able to obtain any such required financing on a timely basis or at all, particularly in light of our ongoing bankruptcy proceedings and the corresponding event of default on our existing debt instruments. Additionally, any future financing arrangements could include terms that are not commercially beneficial to us, which could further restrict our operations and exacerbate any impact on our results of operations and liquidity that may result from any of the factors described herein or other factors.

At December 31, 2022, 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 (as defined below), respectively, bear interest and/or adequate protection payments at variable rates that are affected by benchmark interest rates. Additionally, the amounts of interest and/or adequate protection payments we are required to make on our various debt instruments are subject to changes based on contractual terms set forth in the applicable agreements and/or court orders. Recent increases in benchmark interest rates and certain other developments, including those related to our bankruptcy proceedings, have resulted in increases in the rates used to calculate the interest and/or adequate protection payments we are required to make, and such rates could further increase in future periods. Any future borrowings could also be subject to such risks.

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 in November 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 our commercial, operations and research and development functions. There can be no assurance that we will achieve the benefits and savings of actions such as these in the expected amounts and/or 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 intended 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.

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

The FFDCA and FDA regulations and guidance restrict the ability of healthcare companies, such as our 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. See "Governmental Regulation".

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

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

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

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

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

The ANDA approval process for a new product varies in time, generally requiring a minimum of 10 months following submission of the ANDA to the 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, 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 stock related to products under development. These 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 U.S. Drug Supply Chain Security Act (DSCSA), 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 becomes effective incrementally over a 10-year period from its enactment on November 27, 2013. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements could require significant capital expenditures, increase our operating costs and impose significant administrative burdens.

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

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

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

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

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

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

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

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. Further, we are continuing to evaluate the Inflation Reduction Act of 2022 and its requirements, as well as any potential impact on our business. Based on our current analysis of the act, we do not believe this legislation will have a material impact on our provision for income taxes.

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

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.

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.

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 tax attributes to offset U.S. taxable profit 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 (NOLs) 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.

In addition, our tax attributes and future tax deductions may be reduced or significantly limited as a result of our voluntary petitions for relief under the Bankruptcy Code. Generally, any discharge of our external or internal debt obligations as a result of our chapter 11 filing for an amount less than the adjusted issue price may give rise to cancellation of indebtedness income, which must either be included in our taxable profit or result in a reduction to our tax attributes. Certain tax attributes otherwise available and of value to the Group may be reduced, in most cases by the principal amount of the indebtedness forgiven. U.S. and non U.S. tax attributes subject to reduction include: (i) NOLs and NOL carryforwards; (ii) credit carryforwards; (iii) capital losses and capital loss carryforwards; and (iv) the tax basis of the Group's depreciable, amortizable and other assets.

To the extent, if any, that U.S. NOL carryforwards, other losses and credits generated by us during or prior to our bankruptcy proceedings are available as deductions following our bankruptcy proceedings, our ability to utilize such deductions may be limited by Section 382 of the Code. Section 382 provides rules limiting the utilization of a corporation's NOLs and other losses, deductions and credits following a more than 50% change in ownership of a corporation's equity (an "ownership change"). An ownership change may occur with respect to the Group in connection with bankruptcy, unless the Section 382(l)(5) exception applies. This exception is not easily met as it requires a majority of the holders of the Company's stock after bankruptcy to meet certain specific and narrow conditions. Therefore, the Group's U.S. NOLs may be significantly limited by Section 382 of the Code. The amount of the Group's post-ownership-change annual U.S. taxable profit that can be offset by the pre-ownership-change U.S. NOLs generally cannot exceed an amount equal to the product of: (i) the applicable federal long-term tax exempt rate in effect on the date of the ownership change and (ii) the value of the Group's U.S. affiliate stock (the Annual Limitation). However, if the value of the Group's U.S. affiliate stock is zero, if the Group does not continue its historic business or use a significant portion of its assets in a new business for two years after the ownership change, the Annual Limitation resulting from the ownership change is zero and the Group may be significantly limited in its ability to use any of its U.S. NOLs that originated during or prior to its bankruptcy proceedings. In addition, if the Group has a net unrealized built-in loss at the time of an ownership change, future deductions for items such as amortization, depreciation and settlement liabilities may also be significantly limited.

Further, if we or any of our affiliates undertake sales of any of our assets in connection with the bankruptcy, such sales may result in: (i) a reduction in our available tax attributes; (ii) an inability for us to proactively use our tax attributes; and (iii) us incurring a material amount of tax.

Any loss of or limitations on our ability to use any of the tax attributes described above or any other tax attributes could have 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 Group, 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 group are generally owed to the group only. As a result, shareholders of Irish companies generally do not have a personal right of action against the directors or officers of a group and may pursue a right of action on behalf of the group 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 group 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.

Bankruptcy Proceedings

On August 16, 2022 (the Petition Date), Endo International plc, together with certain of its direct and indirect subsidiaries (the Debtors), filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. As a result of these conditions and events, management continues to believe there is substantial doubt about our ability to continue as a going concern within one year after the date of issuance of the Consolidated Financial Statements included in this report. Additional information regarding our ongoing bankruptcy proceedings is included throughout this report including, without limitation, information about recent and potential future developments related to our bankruptcy proceedings and certain related transactions, the effects of our ongoing bankruptcy proceedings and certain related transactions on our business and financial statements to date and the potential future effects of such proceedings and transactions, including discussions of related risks and uncertainties.

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 August 10, 2023 the date this report is approved by the Audit & Finance Committee of the Board of Directors and the Board of Directors. For further details on significant events since year end refer to Note 31. Significant events in the Consolidated Financial Statements and Note 14. in the Company Financial Statements.

Directors and Secretary

The names of the persons who were directors at any time during the year ended December 31, 2022 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	(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)
Secretary	
Matthew Maletta	(Appointed 12 June 2020)
Assistant Secretary	
Deanna Voss	(Appointed 28 February 2014)
Brian Morrissey	(Appointed 10 October 2020)

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, 2022 in the share capital of Endo International plc were as follows:

	Ordinary Shares at 31 December 2022 (1)			Ordinary Shares at 31 December 2021 (or date of appointment if later) (1)		
Directors	**Shares**	**Options (2)**	**Other Share Units (3)**	**Shares**	**Options (2)**	**Other Share Units (3)**
Blaise Coleman	422,066	360,129	1,569,098	293,472	360,129	1,801,905
Shane M. Cooke	100,034	—	—	100,034	—	—
Nancy J. Hutson, Ph.D.	109,625	—	6,515	109,625	—	6,515
Michael Hyatt	355,560	—	—	355,560	—	—
Mark G. Barberio	38,187	—	—	38,187	—	—
William P. Montague	98,917	—	23,108	98,917	—	23,108
M. Christine Smith, Ph.D.	32,819	—	—	32,819	—	—
Jennifer M. Chao	24,921	—	—	24,921	—	—
Secretary						
Matthew J. Maletta	351,085	382,631	473,174	287,903	382,631	615,640

(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 2022.

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, environmental, 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 and work to embed a culture of compliance throughout the Company.

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. In 2022, in an effort to enhance our already robust compliance program, Endo created the Office of Integrity. The Office of Integrity serves as a centralized, confidential and objective resource for all Endo employees. Should team members have any questions and/or concerns they would like to report, they can work with the Office of Integrity in a confidential manner and without fear of retaliation.

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, our Compliance department or Office of Integrity if they do not feel comfortable going to their direct manager or supervisor. The Office of Integrity oversees the process for receiving and triaging reports for investigation and/or corrective action and conducts compliance investigations.

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.

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. 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 these principles, which serve as the foundation for the Endo Supplier Code of Conduct.

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 2022 and 2021. 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 2022	Calendar Year 2021
Energy Consumption			
Electricity	Gigajoules	318,505	341,216
Natural Gas	Centum Cubic Feet	1,620,693	2,248,129
Diesel Fuel	Gallons	237,826	448,148
GHG Emissions			
Scope 1 greenhouse gas (GHG)	Metric Tons CO2e	12,718	16,872
Scope 2 greenhouse gas (GHG)	Metric Tons CO2e	36,208	43,967
Water Consumption	Gallons	144,893,725	157,833,375
Waste Generation			
Hazardous Waste	Tons	354	446
Non-Hazardous Incineration	Tons	531	1,133
Recycling			
Cardboard, Metal and Plastic	Tons	713	640

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. We seek to create a culture where everyone feels a sense of belonging and where unique perspectives fuel innovation and drive our success. 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 dimensions of diversity.

Our global DEI Council, chaired by the Chief Human Resources Officer and Global DEI Head, is focused on three strategic priorities: talent, culture and community.

To build a strong, diverse and inclusive team, we are focused on talent acquisition, retention, professional development, and equitable HR practices, including pay equity. We measure and hold ourselves accountable for recruiting and engaging team members that are representative of the diverse communities we serve, including historically underrepresented communities and women. We continually monitor our practices, and also field pay equity surveys every other year and use external benchmarks to analyze our pay practices. Our leaders are focused on advancing our diversity recruiting strategies and know the importance of on-boarding talent. We have expanded our internal systems and our partnerships with diversity-focused organizations to extend and improve our outreach.

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. In 2022, Endo launched a Learning and Development Center of Excellence to spearhead enterprise-wide training, as well as learning and development strategies to address the specific needs of teams across the globe. Endo also has a robust new hire onboarding program, trainings and leadership development courses that are customized to various career pathways within the Company, including Research and Development (R&D), Commercial, Technical Operations, Engineering, Manufacturing and Quality, among others.

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. In 2022, our established leadership training programs—the Peer Trainer Program and the Emerging Leader Program—tripled in enrollment. In addition, the Company further invested in ASPIRE—a comprehensive program designed for high-potential female leaders, as well as the Clinical Development and Scientist Onboarding and Training Program.

Employee Wellness Safety & Privacy

At Endo, 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 put a great deal of effort into developing and maintaining a competitive suite of Total Rewards programs, which are focused on team members' physical, personal and financial well-being.

Workforce flexibility has increasingly become an important driver of employee satisfaction. The Company maintains a formal Flexible Work Arrangement (FWA) policy, which allows individuals to work with their leaders to determine the time and the place that they can be most productive and effective in helping Endo to achieve its goals. Since the launch of this policy in 2021, team members have shared an increased sense of trust, empowerment and level of productivity, and they appreciate that their input was sought on this critical topic. Embracing flexibility has given Endo access to a broader and more diverse talent pool that is not limited to specific geographic locations.

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 2022	Calendar Year 2021
Safety			
OSHA Injury Rate	Per 100 Employees	0.4	0.7
Days Away, Restricted and Transferred	Rate	0.3	0.6
Recordable Injuries	Number	16	22
Total Manhours Site Worked	Hours	8,510,432	9,327,014
Number of Employees	Employees	2,810	3,144

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 2022, Endo donated approximately 640,000 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.

The Information Technology Security (ITS) office develops Endo’s information security vision, strategy and program. Reporting to the Chief Information Officer, the ITS office leader provides monthly updates to the Senior Executive Team and quarterly updates to the Board Audit and Finance Committee. Endo’s Information Security Policy is maintained and championed by the ITS office through trainings, testing and awareness efforts provided to all team members.

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 Executive Summary 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 different 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 Financial Statements have been prepared on a going concern basis as required by U.S. GAAP and do not include adjustments that might be necessary should we be unable to continue as a going concern.

The Company Financial Statements have been prepared on a basis other than that of going concern 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, the Group's directors have taken into account various uncertainties as further discussed herein, thousands of governmental and private plaintiffs have filed suit against us and/or certain of our subsidiaries alleging opioid-related claims, most of which we have not been able to settle. As a result of the possibility or occurrence of an unfavorable outcome with respect to these proceedings, other legal proceedings and certain other risks and uncertainties, we explored a wide array of potential actions as part of our contingency planning.

On the August 16, 2022 Petition Date, the Debtors filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. Refer to Note 2. Bankruptcy Proceedings and Note 14. Debt for additional information. As a result of these conditions and events, the Group's directors have formed an opinion that most likely outcome from Bankruptcy Proceedings is the eventual liquidation and winding up of the Company and its subsidiaries after closing of the Sale to Stalking Horse Bidder. The uncertainties arising from the chapter 11 procedures are further described in Note 2. Bankruptcy Proceedings, these events and conditions indicate the existence of a material uncertainty which may cast substantial doubt about the group's ability to continue as a going concern. The accompanying Consolidated Financial Statements have been prepared under the going concern basis of accounting as required by U.S. GAAP and do not include any adjustments that might be necessary should we be unable to continue as a going concern.

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, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, on September 07, 2023.

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	/s/ Blaise Coleman
Mark G Barberio	Blaise Coleman
Chairman	*Director*

August 10, 2023

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.

As explained in note 1 of the Company financial statements, the directors do not believe that is appropriate to prepare the Company financial statements on a going concern basis.

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.

pwc

Independent auditors' report to the members of Endo International public limited company

Report on the audit of the financial statements

Opinion

In our opinion:

- Endo International public limited company'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 2022 and of the group's loss and cash flows for the year then ended;
- the consolidated 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 consolidated 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 2022;
- the Company Balance Sheet as at 31 December 2022;
- 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.

Emphasis of matter - Basis of preparation - Company

In forming our opinion on the company financial statements, which is not modified, we have considered the adequacy of the disclosure made in note 1 to the company financial statements concerning the basis of accounting. As described in note 1 of the company financial statements, the going concern basis of accounting is no longer appropriate and the company financial statements have been prepared on a basis other than going concern.

Material uncertainty relating to going concern - Group

We draw attention to note 3 to the group financial statements that describes the events and conditions that indicate the existence of a material uncertainty which may cast significant doubt about the group's ability to continue as a going concern. Our Report is not modified in respect of this matter.

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

- reviewing documentation relating to the voluntary petitions filed under Chapter 11 of the U.S. Bankruptcy Code, including the Restructuring Support Agreement, details of which are included in note 2;

- obtaining management's going concern assessment for a period of twelve months from the date of the financial statements are authorised for issue, which included an assessment of the current and forecasted financial statement position and forecasted liquidity;

- evaluating the key assumptions underpinning the group's forecasted cash flows and assessing how these forecasts are compiled;

- holding discussions with management on the directors' going concern assessment, the current proposed plans in respect of the Chapter 11 proceedings and understanding the current status of the those plans and their feasibility where a liquidation event is not imminent;

- evaluating the going concern disclosures included in the note 3 in order to assess whether the disclosures were appropriate.

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 in accordance with US GAAP is appropriate.

However, because not all future events or conditions can be predicted, this conclusion is not a guarantee as to the group'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.

Our audit approach

Overview

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<td>Overall materiality

● $20.0 million (2021: $33.0 million) - Consolidated financial statements
● Equates to circa 2.3% of EBITDA from continuing operations adjusted for non-recurring charges. These non-recurring charges include asset impairment charges, net litigation-related and other contingency, net reorganization items, separation benefits, and other restructuring charges (2021: 2.5% of EBITDA from continuing operations, adjusted for asset impairment charges, litigation-related settlement charges, and separation benefits and other restructuring charges).

● $2.2 million (2021: $12.0 million) - Company financial statements
● Based on c. 1.0% of total operating expenses before impairment and financial guarantee liability charges (2021: Based on c. 1.0% of total assets).

Performance materiality

● $15.0 million (2021: $24.8 million) - Consolidated financial statements.
● $1.6 million (2021: $9.0 million) - Company financial statements.</td>
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	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 centralized group functions and balances, including treasury, taxation, equity, 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 90.0% of group revenues and group total assets.
	Key audit matters ● Bankruptcy Proceedings (Group). ● Goodwill Impairment Assessments – Sterile Injectables segment (Group). ● Provisions for Sales Deductions (Group). ● Financial Guarantee Liabilities (Company).

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. In addition to going concern, described in the Material uncertainty relating to going concern section above, we determined the matters described below to be key audit matters to be communicated in our report. This is not a complete list of all risks identified by our audit.

Key audit matter	***How our audit addressed the key audit matter***
Bankruptcy Proceedings (Group) *Refer to Notes 2 (Bankruptcy Proceedings), Notes 3 (Summary of Significant Accounting Policies) and 15 (Commitments and Contingencies) to the consolidated financial statements.* As described above and in Notes 2 and 15 to the consolidated financial statements, the company initiated bankruptcy proceedings during the third quarter of 2022. As disclosed by management, on August 16, 2022, Endo International public limited company, together with certain of its direct and indirect subsidiaries (the Debtors), filed voluntary petitions for relief under chapter 11 of title 11 of the United States Code (the Bankruptcy Code). As a result of the bankruptcy proceedings, management has applied generally accepted accounting principles in the	We tested the operating effectiveness of controls related to management's accounting for and disclosure of the bankruptcy proceedings. We read the restructuring support agreement. We engaged professionals with specialized skill and knowledge to assist in evaluating the completeness and accuracy of amounts classified as "liabilities subject to compromise" and "reorganization items, net". We tested the completeness and accuracy of the classification of transactions as "liabilities subject to compromise" or "reorganization items, net".

Key audit matter	*How our audit addressed the key audit matter*
United States of America applicable to reorganizations in preparing the consolidated financial statements. These accounting principles require that, for periods including and after the filing of a chapter 11 petition, the consolidated financial statements distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. For periods beginning with the third quarter of 2022, pre-petition unsecured claims and undersecured claims related to the Debtors that may be impacted by the bankruptcy reorganization process in the amount of $9,211.8 million have been classified as liabilities subject to compromise in the consolidated balance sheet as of December 31, 2022. Additionally, certain expenses, gains and losses resulting from and recognized during the bankruptcy proceedings in the amount of $203.0 million are recorded in "reorganization items, net" in the consolidated profit and loss account for the year ended December 31, 2022. As further described in Note 2, in connection with the Restructuring Support Agreement entered into on August 16, 2022 with an ad hoc group of certain creditors (the Purchaser) among other things, one or more entities, formed in a manner acceptable to the Purchaser, will serve as stalking horse bidder as the Company seeks to sell all or substantially all of its assets in a sale pursuant to section 363 of the Bankruptcy Code. The Purchaser's bid, along with certain resolutions as filed with the Bankruptcy Court on March 24, 2023, provides for the establishment by the Purchaser of voluntary opioid trusts for the benefit of certain public, tribal and private opioid claimants in exchange for certain releases to be provided to (among others) the Purchaser and the company, its subsidiaries and affiliated entities and persons. The trusts would distribute up to a total of $611.4 million to eligible claimants that opt into the trust agreements by specified participation deadlines. Although the proposed voluntary opioid trusts would be funded by the Purchaser, and not by the company or any of its subsidiaries, management believes the proposed funding amount represents the best estimate of liability relating to the contingencies associated with various opioid claims against the Company and its subsidiaries. As a result, approximately $480.0 million in charges were recorded during the year ended December 31, 2022 to adjust the Company's aggregate opioid liability accrual to approximately $611.4 million as of December 31, 2022. We determined the bankruptcy proceedings to be a key audit matter given the judgment and complexity in relation to determination of the amount of liabilities subject to compromise, the audit effort involved and the level of auditors' subjectivity required in the selection of the appropriate procedures and in the evaluation of the relevant audit evidence obtained as well as the consideration of the relevant disclosures and the need to use professionals with specialized skill and knowledge.	We evaluated, on a sample basis, management's accounting for claims submitted to the bankruptcy court. We obtained and evaluated letters of audit inquiry with internal and external legal counsel related to opioid litigation and the bankruptcy proceedings and we evaluated the reasonableness of management's assessment of the probable loss in relation to the opioid litigation matters. We evaluated the accuracy of the Company's disclosures in notes 2, 3, and 15 with respect to the bankruptcy proceedings.

Key audit matter	*How our audit addressed the key audit matter*
Goodwill Impairment Assessments - Sterile Injectables Segment (Group) *Refer to Notes 3 (Summary of Significant Accounting Policies) and 11 (Goodwill and Other Intangibles) to the consolidated financial statements.* As described in Notes 3 and 11 to the financial statements the goodwill balance for the Sterile Injectables reporting unit was $523.2 million as of December 31, 2022 after recording impairment charges of $1,845.0 million during the year ended December 31, 2022 as described in Note 11 to the financial statements. The impairment charges were recorded as a result of impairment tests performed during the second and third quarters. 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 utilizes a discounted cash flow model. 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, discount rate, and the probability of achieving the estimated cash flows. The Goodwill impairment assessments for the Sterile Injectables segment was determined to be a key audit matter as there was significant judgement by management when developing the fair value estimate of the reporting unit, including determining significant assumptions related to future sales, long-term growth rates, gross margins, operating expenses and discount rates and the probability of achieving the estimated cash flows.	We tested the effectiveness of controls relating to goodwill impairment assessments, including controls over valuation of the Sterile Injectables reporting unit. We also tested the assignment of assets and liabilities to the Sterile Injectables reporting unit. We tested management's process for developing the fair value estimate, which included evaluating the appropriateness of the discounted cash flow model. We tested the completeness and accuracy of underlying data used in the discounted cash flow models related to cash flow projections. We evaluated whether the assumptions used to estimate fair value, including future sales, long-term growth rates, gross margins, operating expenses and discount rates and the probability of achieving the estimated cash flows were reasonable, which included considering historical performance of the reporting unit against forecasts, and industry and economic forecasts. Our procedures included the involvement of our PwC professionals with specialized skills and knowledge to assist us in evaluating the appropriateness of the discounted cash flow models and evaluating the reasonableness of the discount rates.
Provisions for Sales Deductions (Group) *Refer to Notes 3 (Summary of Significant Accounting Policies) and 24 (Provisions and Creditors) to the consolidated financial statements.* As described in Note 3 to the consolidated financial statements, the amount of revenue recognised by the company is determined by adjusting 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. As of December 31, 2022, provisions for sales deductions totalled $600.2 million. These amounts relate primarily to	We tested the effectiveness of controls over sales deductions, including controls over the assumptions used to estimate the provisions for the sales deductions at December 31, 2022. We developed an independent estimate for these provisions at December 31, 2022. 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, and current contract sales terms with direct and indirect customers. We compared this expectation to the provisions recorded by management. 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.

Key audit matter	*How our audit addressed the key audit matter*
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. Management estimates the provisions for sales deductions based on factors such as direct and indirect customers' direct and indirect 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, and current contract sales terms with direct and indirect customers. 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, and current contract sales terms with direct and indirect customers.	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.
Financial Guarantee Liabilities (Company) *Refer to Note 1 (Summary of Significant Accounting Policies), Note 11 (Guarantees) and Note 12 (Financial Guarantee Liabilities) to the company financial statements.* As set out in Note 12 to the company financial statements, Endo International public limited company has co-guaranteed various secured and unsecured debt instruments that were issued by certain subsidiary undertakings within the Endo International public limited company Group. As at December 31, 2022 the guaranteed debt amounted to $8,147.8 million. As further described in Note 1 of the company financial statements, the company together with certain of its direct and indirect subsidiaries filed voluntary petitions for relief under Chapter 11 of the U.S. Bankruptcy Code. This constituted an event of default that accelerated the obligations under substantially all of the group's outstanding third-party debt agreements. Consequently, financial guarantee liabilities of $2,324.4 million has been recorded in the Company Balance Sheet at December 31, 2022 based on management's estimate of the unavoidable cost of settling the related obligations for which the company was deemed contractually liable as a co-guarantor. The financial guarantee liabilities represent the shortfall between the group's contractual obligation to settle the third party debt of $8,147.8 million and the collective recoverable value of the group's pledge assets and the value of the company's own assets. The collective	We obtained management's accounting assessment and analysis supporting the liability which was recorded in the company financial statements relating to the group cross-guarantees. We read the cross-guarantee agreements to understand the contractual arrangements applicable to the obligation for which the company is deemed to be contractually liable as of December 31, 2022. We obtained and considered the Stalking Horse Bid documentation which underpinned the estimate of fair value of the total group pledged assets and the collective recoverable value. We considered the adequacy of the relevant disclosures including those relating to the judgements applied by management in arriving at the amount booked as a liability at year-end.

Key audit matter	*How our audit addressed the key audit matter*
recoverable value is determined based on the Stalking Horse Bid price which represents significant judgement. We determined the measurement of the financial guarantee liabilities to be a key audit matter as it is a material element of the company financial statements and due to complexity and judgements in measuring the guarantee amount.	

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 centralized 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:

	Consolidated financial statements	*Company financial statements*
Overall materiality	$20.0 million (2021: $33.0 million).	$2.2 million (2021: $12.0 million).
	Equates to circa 2.3% of EBITDA from continuing operations adjusted for non-recurring charges. These non-recurring charges include asset impairment charges, net litigation-related and other contingency, net reorganization items, separation benefits, and other restructuring charges (2021: 2.5% of EBITDA from continuing operations, adjusted for asset impairment charges, litigation-related settlement charges, and separation benefits and other restructuring charges).	c. 1.0% of total operating expenses before impairment and financial guarantee liability charges (2021: Based on c. 1.0% of total assets).

	Consolidated financial statements	*Company financial statements*
Rationale for benchmark applied	In determining our current year materiality, we considered a number of materiality benchmarks including "net revenue", "EBITDA from continuing operations", "EBITDA adjusted for non recurring charges", "pre-tax loss", and "pretax income adjusted for non recurring charges". In considering the materiality levels calculated by reference to the various benchmarks, we considered a materiality level of $20 million to be appropriate which equates to c. 2.3% of EBITDA from continuing operations adjusted for non-recurring charges. We also considered the reasonableness of the amount of overall materiality calculated by references to the materiality used in the prior year.	The company is the holding company of the group. As described in note 3 to the company financial statements, the carrying amount of the investment in subsidiaries, which represented the majority of the gross assets, was fully impaired in the current year. In the current year the company mainly incurred charges related to reorganization items and legal expenses. Consequently, we believe that total operating expenses is the most relevant metric for users of the company financial statements.

We use performance materiality to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds overall materiality. Specifically, we use performance materiality in determining the scope of our audit and the nature and extent of our testing of account balances, classes of transactions and disclosures, for example in determining sample sizes. Our performance materiality was c. 75% of overall materiality, amounting to $15 million (group audit) and $1.6 million (company audit).

In determining the performance materiality, we considered a number of factors - the history of misstatements, risk assessment and aggregation risk and the effectiveness of controls - and concluded that an amount at the upper end of our normal range was appropriate.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above $1.75 million (group audit) (2021: $2.5 million) and $100,000 (company audit) (2021: $600,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

Reporting on other information

The other information comprises all of the information in the Directors' Report and Financial Statements 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 2022 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 78, 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.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

Based on our understanding of the group and industry, we identified that the principal risks of non-compliance with laws and regulations related to the U.S Foreign Corrupt Practices Act, pharmaceutical regulations, and anti-bribery legislation, and we considered the extent to which non-compliance might have a material effect on the financial statements. We also considered those laws and regulations that have a direct impact on the preparation of the financial statements such as the Companies Act 2014 and relevant tax legislation. We evaluated management's incentives and opportunities for fraudulent manipulation of the financial statements (including the risk of override of controls), and determined that the principal risks were related to posting inappropriate journal entries to manipulate financial results and potential management bias in accounting estimates. Audit procedures performed by the engagement team included:

- Discussions with the Audit & Finance Committee, senior management, internal legal counsel and internal audit in respect of the risk of fraud, any known or suspected instance of fraud or non-compliance with laws and regulations;
- Reading the minutes of meetings of the Board of Directors and the Audit & Finance Committee;
- Inspection of internal audit reports in so far as they related to the financial statements;
- Challenging assumptions made by management in its significant accounting estimates, including assumptions in relation to the key audit matters above;
- Identifying and testing selected journal entries, including unusual account combinations related to manual revenue entries and consolidation journals based on our risk assessment; and
- Designing and incorporating elements of unpredictability around the nature, timing or extent of audit procedures performed.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

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
10 August 2023

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED PROFIT AND LOSS ACCOUNT
YEAR ENDED DECEMBER 31, 2022
(In thousands, except per share data)

	Note	2022	2021
TURNOVER	6	$ 2,318,875	$ 2,993,206
Cost of sales	4	1,092,499	1,221,064
GROSS PROFIT		1,226,376	1,772,142
Selling, general and administrative expenses		777,169	861,760
Research and development expenses		128,033	123,440
Acquired in-process research and development		68,700	25,120
Litigation-related and other contingency, net	4,6,15	521,722	345,495
Asset impairment charges	10,11	2,142,746	414,977
Acquisition-related and integration items	6	408	(8,379)
OPERATING PROFIT		$ (2,412,402)	$ 9,729
INTEREST RECEIVABLE AND SIMILAR INCOME	4	(964)	(584)
INTEREST PAYABLE AND SIMILAR CHARGES	4	350,740	562,937
LOSS ON EXTINGUISHMENT OF DEBT	4	—	13,753
REORGANIZATION ITEMS, NET		202,978	—
OTHER INCOME, NET	19	(34,054)	(19,774)
LOSS FROM CONTINUING OPERATIONS BEFORE TAXATION		$ (2,931,102)	$ (546,603)
TAX EXPENSE (BENEFIT) FROM CONTINUING OPERATIONS	20	21,516	22,478
(LOSS) PROFIT FROM CONTINUING OPERATIONS		$ (2,952,618)	$ (569,081)
LOSS FROM DISCONTINUED OPERATIONS, NET OF TAX	4	(13,487)	(44,164)
(LOSS) PROFIT FOR THE FINANCIAL YEAR		$ (2,966,105)	$ (613,245)
(LOSS) PROFIT PER SHARE - BASIC:			
Continuing operations		$ (12.57)	$ (2.44)
Discontinued operations		(0.06)	(0.19)
Basic		$ (12.63)	$ (2.63)
(LOSS) PROFIT PER SHARE - DILUTED:			
Continuing operations		$ (12.57)	$ (2.44)
Discontinued operations		(0.06)	(0.19)
Diluted		$ (12.63)	$ (2.63)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:			
Basic	21	234,840	232,785
Diluted	21	234,840	232,785

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
YEAR ENDED DECEMBER 31, 2022
(In thousands)

	Note	2022	2021
(LOSS) INCOME FOR THE FINANCIAL YEAR		$ (2,966,105)	$ (613,245)
Net unrealized loss on securities	16	—	—
Foreign currency translation (gain) / loss	16	(10,496)	1,308
TOTAL COMPREHENSIVE INCOME		$(2,976,601)	$(611,937)

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED BALANCE SHEET
AS AT DECEMBER 31, 2022
(In thousands)

	Note	December 31, 2022	December 31, 2021
ASSETS			
Non-current Assets			
Intangible assets-Goodwill	11	$ 1,352,011	$ 3,197,011
Intangible assets-Other	11	1,732,935	2,362,823
Tangible assets	10	438,314	396,712
Operating Lease Assets	9	28,070	34,832
Other	23	129,839	61,451
Current Assets			
Stock	8	274,499	283,552
Debtors	23	638,028	799,724
Cash at bank and in-hand		1,018,883	1,507,196
Restricted cash		145,358	124,114
TOTAL ASSETS		$ 5,757,937	$ 8,767,415
EQUITY AND LIABILITIES			
Capital and Reserves			
Called up share capital presented as equity	17	$ 67	$ 68
Share premium account		6,140,397	6,140,397
Other reserves		(9,450,844)	(9,455,764)
Profit and loss account		(894,792)	2,071,313
Total equity shareholders' funds		$ (4,205,172)	$ (1,243,986)
Creditors: amounts falling due within one year			
Debenture loans-current portion	14	$ —	$ 200,342
Operating lease liabilities	9	903	10,992
Trade and other creditors	24	353,472	1,074,608
		$ 354,375	$ 1,285,942
Creditors: amounts falling due after more than one year			
Debenture loans	14	$ —	$ 8,048,980
Operating lease liabilities	9	5,129	33,727
Liabilities subject to compromise	2	9,211,782	—
Trade and other creditors	24	56,571	284,404
Total for creditors: amounts falling due after more than one year		$ 9,273,482	$ 8,367,111
Provision for liabilities	24	$ 335,252	$ 358,348
TOTAL EQUITY AND LIABILITIES		$ 5,757,937	$ 8,767,415

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 August 10, 2023 and signed on its behalf by:

/s/ Mark G. Barberio	/s/ Blaise Coleman
Mark G Barberio	Blaise Coleman
Chairman	*Director*

ENDO INTERNATIONAL PLC
CONSOLIDATED STATEMENT OF CASH FLOWS
YEAR ENDED DECEMBER 31, 2022
(In thousands)

	2022	2021
OPERATING ACTIVITIES:		
Consolidated net (loss) profit	$ (2,966,105)	$(613,245)
Adjustments to reconcile consolidated net profit (loss) to Net cash provided by operating activities:		
Depreciation and amortization	391,629	457,098
Share-based compensation	17,314	30,046
Amortization of debt issuance costs and discount	9,406	14,437
Deferred income taxes	(7,303)	(3,157)
Change in fair value of contingent consideration	408	(8,793)
Loss on extinguishment of debt	—	13,753
Acquired in-process research and development charges	68,700	25,120
Asset impairment charges	2,142,746	414,977
Non-cash reorganization and other assets	89,197	—
Gain on sale of business and other assets	(26,183)	(4,516)
Other	2,776	—
Changes in assets and liabilities which (used) provided cash:		
Debtors	105,912	(82,052)
Stock	(4,359)	48,978
Prepaid and other assets	80,350	(34,002)
Accounts payable, accrued expenses and other liabilities	364,055	84,391
Income taxes payable/receivable	650	68,015
Net cash provided by operating activities	$269,193	$411,050
INVESTING ACTIVITIES:		
Purchases of tangible fixed assets	(99,722)	(77,929)
Capitalized interest payments	(3,140)	(2,721)
Proceeds from the U.S Government Agreement	18,635	—
Acquisitions including in-process research and development, net of cash and restricted cash acquired.	(90,320)	(5,000)
Proceeds from sale of marketable securities and investments	—	—

	2022	2021
Product acquisition costs and license fees	—	(4,177)
Proceeds from sale of business and other assets, net	41,400	30,283
Net cash used in investing activities	$(133,147)	$(59,544)
FINANCING ACTIVITIES:		
Proceeds from issuance of notes	—	1,279,978
Proceeds from issuance of term loans	—	1,980,000
Repayment of notes	(180,342)	—
Principal payments on term loans	(10,000)	(3,310,475)
Repayments of revolving debt	—	(22,800)
Adequate protection payments	(313,109)	—
Principal payments on other indebtedness	(6,062)	(5,448)
Payments for debt issuance and extinguishment costs	—	(8,574)
Payments for contingent consideration	(2,462)	(4,010)
Payments of tax withholding for restricted shares	(1,898)	(14,774)
Proceeds from exercise of options	—	622
Net cash used in financing activities	$(513,873)	$(105,481)
Effect of foreign exchange rate	(4,242)	285
NET INCREASE (DECREASE) IN CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND	$(382,069)	$246,310
CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND, BEGINNING OF YEAR	1,631,310	1,385,000
CASH AT BANK AND ON-HAND AND RESTRICTED CASH AT BANK AND ON-HAND, END OF YEAR	$1,249,241	$1,631,310
SUPPLEMENTAL INFORMATION:		
Cash paid for interest	$289,664	$538,424
Cash paid for income taxes	$14,101	$10,019
Cash refunds from income taxes, gross	$3,092	$57,801
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, 2022
(In thousands)

	Endo International plc Shareholders				
	Share Capital	Share Premium	Profit and Loss Account	Other Reserves	Total
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 profit	—	—	(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 share capital and other reserves	(4)	—	—	—	(4)
BALANCE, DECEMBER 31, 2021	$ 68	$ 6,140,397	$ 2,071,313	$ (9,455,764)	$ (1,243,986)
BALANCE, January 1, 2022	$ 68	$ 6,140,397	$ 2,071,313	$ (9,455,764)	$ (1,243,986)
Net loss	—	—	(2,966,105)	—	(2,966,105)
Other comprehensive loss	—	—	—	(10,496)	(10,496)
Compensation related to share-based awards	—	—	—	17,314	17,314
Ordinary shares issued	1	—	—	(1)	—
Tax withholding for restricted shares	—	—	—	(1,898)	(1,898)
Other	(2)	—	—	1	(1)
BALANCE, DECEMBER 31, 2022	$ 67	$ 6,140,397	$ (894,792)	$ (9,450,844)	$ (4,205,172)

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. BANKRUPTCY PROCEEDINGS

Chapter 11 Filing

As noted above, on the Petition Date, certain of the Debtors filed voluntary petitions for relief under the Bankruptcy Code. Certain additional Debtors filed voluntary petitions for relief under the Bankruptcy Code on May 25, 2023 and May 31, 2023. The Debtors have received approval from the U.S. Bankruptcy Court for the Southern District of New York (the Bankruptcy Court) to jointly administer their chapter 11 cases (the Chapter 11 Cases) for administrative purposes only pursuant to Rule 1015(b) of the Federal Rules of Bankruptcy Procedure under the caption *In re Endo International plc, et al*. Certain entities consolidated by Endo International plc and included in these Consolidated Financial Statements are not party to the Chapter 11 Cases. These entities are collectively referred to herein as the Non-Debtor Affiliates.

The Debtors will continue to operate their businesses and manage their properties as debtors-in-possession pursuant to sections 1107 and 1108 of the Bankruptcy Code. As debtors-in-possession, the Debtors are generally permitted to continue to operate as ongoing businesses and pay debts and honor obligations arising in the ordinary course of their businesses after the Petition Date. However, the Debtors generally may not pay third-party claims or creditors on account of obligations arising before the Petition Date or engage in transactions outside the ordinary course of business without approval of the Bankruptcy Court. Under the Bankruptcy Code, third-party actions to collect pre-petition indebtedness owed by the Debtors, as well as most litigation pending against the Debtors as of the Petition Date, are generally subject to an automatic stay. However, under the Bankruptcy Code, certain legal proceedings, such as those involving the assertion of a governmental entity's police or regulatory powers, may not be subject to the automatic stay and may continue unless otherwise ordered by the Bankruptcy Court.

Among other requirements, chapter 11 proceedings must comply with the priority scheme established by the Bankruptcy Code, under which certain post-petition and secured or "priority" pre-petition liabilities generally need to be satisfied before general unsecured creditors and shareholders are entitled to receive any distribution.

Under the Bankruptcy Code, the Debtors may assume, modify, assign or reject certain executory contracts and unexpired leases, including, without limitation, leases of real property and equipment, subject to the approval of the Bankruptcy Court and certain other conditions. Generally, the rejection of an executory contract or unexpired lease is treated as a pre-petition breach of such executory contract or unexpired lease and, subject to certain exceptions, relieves the Debtors from performing their future obligations under such executory contract or unexpired lease but entitles the contract counterparty or lessor to a pre-petition general unsecured claim for damages caused by such deemed breach. Generally, the assumption of an executory contract or unexpired lease requires the Debtors to cure existing monetary defaults under such executory contract or unexpired lease and provide adequate assurance of future performance. Accordingly, any description of an executory contract or unexpired lease in this report, including, where applicable, the express termination rights thereunder or a quantification of obligations, must be read in conjunction with, and is qualified by, any overriding rejection rights the Debtors have under the Bankruptcy Code.

To ensure their ability to continue operating in the ordinary course of business, the Debtors have filed with the Bankruptcy Court a variety of motions seeking "first day" relief, including the authority to access cash collateral, continue using their cash management system, pay employee wages and benefits and pay vendors in the ordinary course of business. At a hearing held on August 18, 2022, the Bankruptcy Court generally approved the relief sought in these motions on an interim basis. Following subsequent hearings held on September 28, 2022, October 13, 2022 and October 19, 2022, the Bankruptcy Court entered orders approving substantially all of the relief sought on a final basis.

Events of Default

The August 16, 2022 bankruptcy filings by the Debtors constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. Refer to Note 14. Debt for additional information.

Restructuring Support Agreement

On August 16, 2022, we entered into a Restructuring Support Agreement (the RSA) with an ad hoc group (the Ad Hoc First Lien Group) of certain creditors holding in excess of 50% of the aggregate outstanding principal amount of Secured Debt (as defined in that certain collateral trust agreement, dated as of April 27, 2017, among Endo International plc, certain subsidiaries of Endo International plc, the other grantors from time to time party thereto, JPMorgan Chase Bank, N.A., as administrative agent under the Credit Agreement (as defined below), and Wells Fargo Bank, National Association, as indenture trustee, and Wilmington Trust, National Association, as collateral trustee (the Collateral Trust Agreement)), pursuant to which, among other things, one or more entities formed in a manner acceptable to the Ad Hoc First Lien Group (the Stalking Horse Bidder or the Purchaser) will serve as stalking horse bidder as we seek to sell all or substantially all of our assets in a sale pursuant to section 363 of the Bankruptcy Code (the Sale).

As described in the RSA, the Stalking Horse Bidder's bid (the Stalking Horse Bid), which was subject to higher or otherwise better bids from other parties, includes an offer to purchase substantially all of our assets for an aggregate purchase price including: (i) a credit bid in full satisfaction of the Prepetition First Lien Indebtedness (as defined in the RSA); (ii) $5 million in cash on account of certain unencumbered assets; (iii) $122 million to wind-down our operations following the Sale closing date (the Wind-Down Amount); (iv) pre-closing professional fees; and (v) the assumption of certain liabilities. As part of the Stalking Horse Bid, the Stalking Horse Bidder will also make offers of employment to all of our active employees. The proposed purchase and sale agreement with respect to the Stalking Horse Bid as filed with the Bankruptcy Court on November 23, 2022, and as amended and subsequently filed with the Bankruptcy Court on March 24, 2023 and July 7, 2023, includes customary representations and warranties and customary covenants by the parties thereto.

On November 23, 2022, we filed: (i) a motion seeking Bankruptcy Court approval of bidding procedures in connection with the Sale and (ii) a motion seeking to set deadlines (bar dates) for all claimants to file claims against the Debtors. At a hearing on December 15, 2022, the Bankruptcy Court directed the Debtors and certain key parties in interest in the Chapter 11 Cases to participate in a mediation process to attempt to resolve certain objections and contested issues relating to the bidding procedures motion, the Sale and other critical matters in the Chapter 11 Cases.

In March 2023, the Debtors announced that, as a result of the mediation process, the Ad Hoc First Lien Group (and Stalking Horse Bidder) reached certain resolutions in principle with both the unsecured creditors' committee (the UCC) and opioid claimants' committee (the OCC) appointed in the Chapter 11 Cases and certain ad hoc groups of debtholders. These resolutions, documented in the stipulation filed with the Bankruptcy Court on March 24, 2023 (and described in further detail below), are supported by the Debtors. In connection with such resolutions, the Company agreed in principle with the Ad Hoc First Lien Group to reduce the Wind-Down Amount associated with the Stalking Horse Bid from $122 million to approximately $116 million, subject to definitive documentation. Following a hearing, the Bankruptcy Court entered orders on April 3, 2023 approving the bidding procedures motion (the Bidding Procedures Order) and the bar date motion.

As part of the Bidding Procedures Order, the Bankruptcy Court also approved certain internal restructuring transactions under Irish law that will allow us to pursue the Sale in a tax efficient manner (the Reconstruction Steps). The Reconstruction Steps were completed on May 31, 2023, and involved, among other things: (i) the conversion from private limited companies to private unlimited companies under Irish law of our subsidiaries Endo Ventures Limited and Endo Global Biologics Limited and their re-registration as Endo Ventures Unlimited (EVU) and Endo Global Biologics Unlimited (EGBU), respectively; and (ii) the transfer of the business and assets of EVU and EGBU to our newly-formed subsidiaries Operand Pharmaceuticals II Limited and Operand Pharmaceuticals III Limited.

As contemplated by the RSA , the bidding procedures order approved a marketing process and auction that was conducted under the supervision of the Bankruptcy Court, during which interested parties had an opportunity to conduct due diligence and determine whether to submit a bid to acquire the Debtors' assets.In the months following the entry of the Bidding Procedures Order, the Company conducted a robust marketing process. Following the passing of the deadline for potential bidders to submit indications of interest, on June 20, 2023, in accordance with the Bidding Procedures Order, the Company filed with the Bankruptcy Court a notice of termination of the sale and marketing process (the Sale Acceleration Election), naming the Stalking Horse Bidder as the Successful Bidder (as defined in the Bidding Procedures Order) and accelerating the hearing to approve the sale from August 31, 2023 to July 28, 2023 (which was thereafter adjourned to August 14, 2023).

Now that the Stalking Horse Bid has been selected as the highest or otherwise best offer following said marketing process, the Ad Hoc First Lien Group will direct the Collateral Trustee (as defined in the Collateral Trust Agreement) to assign

its rights to credit bid, on behalf of the Secured Parties (as defined in the Collateral Trust Agreement), to the Stalking Horse Bidder, so as to enable the Stalking Horse Bidder to credit bid for all or substantially all of our assets in exchange for the extinguishment of the obligations to the Secured Parties.

Pursuant to the RSA, each of the parties agreed to, among other things, take all actions as are necessary and appropriate to facilitate the implementation and consummation of the Restructuring (as defined in the RSA), negotiate in good faith certain definitive documents relating to the Restructuring and obtain required approvals. In addition, we agreed to conduct our business in the ordinary course, provide notice and certain materials relating to the Restructuring to the consenting creditors' advisors and pay certain fees and expenses of the consenting creditors. The RSA further contemplates that the Purchaser will fund one or more trusts for parties with opioid-related claims against us, as further discussed in Note 15. Commitments and Contingencies.

The RSA provides certain milestones for the Restructuring. If we fail to satisfy these milestones and such failure is not the result of a breach of the RSA by the Required Consenting First Lien Creditors (as defined in the RSA), the Required Consenting First Lien Creditors will have the right to terminate the RSA. These milestones, as modified since we entered into the RSA (and which may be further modified from time to time) and as adjusted to reflect our exercise of the Sale Acceleration Election, include: (i) not later than 11:59 p.m. prevailing Eastern Time on October 25, 2022, the Bankruptcy Court shall have entered the Cash Collateral Order (as defined below) on a final basis; (ii) not later than 11:59 p.m. prevailing Eastern Time on April 11, 2023, the Bankruptcy Court shall have entered an order approving the bidding procedures; (iii) not later than 11:59 p.m. prevailing Eastern Time on September 13, 2023, the Bankruptcy Court shall have entered an order approving the Sale; (the Sale Order Date); and (iv) not later than the earlier of (x) 11:59 p.m. prevailing Eastern Time on September 13, 2023 and (y) the date that is thirty (30) calendar days after the date the order approving the sale is entered (the Outside Date), the closing of the Sale shall have occurred, in which case the Outside Date is subject to certain extensions as a result of the Sale Acceleration Election as set forth in the RSA, including: (a) for extensions of prior milestones; (b) to close the Sale transaction with a backup bidder; and (c) for delays in obtaining regulatory or third-party approvals or consents. As of the date of this report, milestones (i) and (ii) referenced above have been satisfied. Each of the parties to the RSA may terminate the agreement (and thereby their support for the Sale) under certain limited circumstances, including for material breaches and materially untrue representations and warranties by their counterparties, if a governmental agency enjoins the Sale or if the purchase and sale agreement with respect to the Sale is terminated under certain circumstances.

The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated.

The Chapter 11 Proceedings

Cash Collateral

As part of the RSA, the Company and the Ad Hoc First Lien Group agreed on the terms of a proposed order authorizing the Company's use of cash collateral (as modified and entered by the Bankruptcy Court on a final (amended) basis in October 2022, the Cash Collateral Order) in connection with the Chapter 11 Cases on certain terms and conditions set forth therein. The Debtors intend to use the cash collateral to, among other things, permit the orderly continuation of their businesses, pay the costs of administration of their estates and satisfy other working capital and general corporate purposes.

The Cash Collateral Order: (i) obligates the Debtors to make certain adequate protection payments during the bankruptcy proceedings, which are further discussed in Note 14. Debt of this report and Note 14. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of the Annual Report; (ii) establishes a budget for the Debtors' use of cash collateral; (iii) establishes certain informational rights for the Debtors' secured creditors ; (iv) provides for the waiver of certain Bankruptcy Code provisions. ; and (v) requires the Debtors to maintain at least $600.0 million of "liquidity," calculated at the end of each week as unrestricted cash and cash equivalents plus certain specified amounts of restricted cash associated with the TLC Agreement, which is defined and further discussed below in Note 12. License, Collaboration and Asset Acquisition Agreements.

The foregoing description of the Cash Collateral Order does not purport to be complete and is qualified in its entirety by reference to the Cash Collateral Order entered by the Bankruptcy Court in the Chapter 11 Cases.

Potential Claims

In November 2022, the Debtors filed with the Bankruptcy Court schedules and statements, subject to further amendment or modification, which set forth, among other things, the assets and liabilities of each of the Debtors, subject to the assumptions filed in connection therewith.

As part of the Chapter 11 Cases, persons and entities believing that they have claims or causes of action against the Debtors may file proofs of claim evidencing such claims. As noted above, the Debtors have filed a motion seeking to set a bar date (deadline) for holders of claims to file proofs of claim (including general claims and claims of governmental units). On April 3, 2023, the Bankruptcy Court entered an order, as subsequently amended on June 23, 2023 and July 14, 2023 (the Bar

Date Order) setting July 7, 2023 as the general bar date (deadline) for persons and non-governmental entities to file proofs of claim against the Debtors. The Bankruptcy Court also set May 31, 2023 as the bar date for governmental entities to file claims other than certain claims relating to opioids against the Debtors. Certain claims, including most governmental claims relating to opioids, are subject to separate bar date procedures as set forth in more detail in the Bar Date Order.

As of August 1, 2023, more than 829,000 claims, totaling more than $924 billion, have been filed against the Debtors, including, in certain cases, duplicate claims across multiple Debtors. For example, the IRS has filed multiple proofs of claim against several of the Debtors, as further discussed in Note 20. Income Taxes. We expect that the Debtors may continue to receive a number of claims in the future. As claims are filed, they are being evaluated for validity and compared to amounts recorded in our accounting records. As of the date of this report, the amounts of certain of the claims received exceed the amounts of the corresponding liabilities, if any, that we have recorded based on our assessments of the purported liabilities underlying such claims, and it is likely this will continue to be the case in future periods. We are not aware of any claims that we currently expect will require a material adjustment to the accounts and balances as reported as of December 31, 2022.

Differences in amounts recorded and claims filed by creditors will continue to be investigated and resolved, including through the filing of objections with the Bankruptcy Court, where appropriate. The Debtors may ask the Bankruptcy Court to disallow claims that the Debtors believe are duplicative, have been later amended or superseded, are without merit, are overstated or should be disallowed for other reasons. In addition, as a result of this process, the Debtors may identify additional liabilities that will need to be recorded or reclassified to Liabilities subject to compromise in the Consolidated Balance Sheets. In light of the substantial number of claims that have been filed as of the date of this report and may be filed in the future, the claims resolution process may take considerable time to complete and may continue for the duration of the Debtors' bankruptcy proceedings.

Resolutions in the Chapter 11 Cases

In March 2023, the Debtors announced that, in connection with the mediation process and as referenced in an amended RSA, the Ad Hoc First Lien Group (and Stalking Horse Bidder) reached certain resolutions in principle with the UCC and the OCC appointed in the Chapter 11 Cases and certain ad hoc groups of debtholders. In July 2023, the Debtors announced an additional resolution between the Stalking Horse Bidder and the Future Claimants' Representative (the FCR). These resolutions, which are set forth in greater detail in filings with the Bankruptcy Court dated as of March 24, 2023 and July 13, 2023, respectively, are supported by the Debtors.

The resolution reached between the Ad Hoc First Lien Group and the UCC provides that, upon the consummation of the Sale, the Stalking Horse Bidder will create a trust for the benefit of eligible general unsecured creditors. As consideration, the trust will receive, among other things, (i) $60 million in cash; (ii) 4.25% of equity in the Stalking Horse Bidder (subject to dilution by equity issued pursuant to rights offerings and under the management incentive plan); (iii) a litigation trust, which will have the right to pursue certain estate claims and causes of action against (1) non-continuing directors and former officers (as against certain specified insurance policies and proceeds), (2) certain third-party advisors to the Debtors, and (3) certain additional third parties, including parties to certain pre-petition transactions with the Debtors; and (iv) a rights offering for certain eligible trust beneficiaries, subject to certain subscription requirements, for up to $160 million of equity in the Stalking Horse Bidder. The resolution also contemplates a fee cap of $15 million for the UCC professionals for any work done after April 1, 2023.

The resolution reached between the Ad Hoc First Lien Group and the OCC provides that, upon the consummation of the Sale, the Stalking Horse Bidder will create a trust for the benefit of certain private present opioid claimants (such as non-governmental entities). As consideration, the trust will receive, among other things, $119.7 million of gross cash consideration payable in three installments (subject to the Stalking Horse Bidder's exercise of certain prepayment options and triggers) to be distributed to eligible private present opioid claimants. As set forth in the amended RSA, the Stalking Horse Bidder has agreed, upon the consummation of the Sale, to fund a trust for the benefit of certain public and tribal opioid claimants. The trust to be created pursuant to the resolution reached with the OCC is intended to be structured similarly to the public/tribal opioid trust and includes prepayment obligations triggered upon certain prepayments made to the public/tribal opioid trust. The resolution also contemplates a fee cap of $8.5 million for opioid claimants' committee hourly professionals.

The resolution reached between the Ad Hoc First Lien Group and the FCR provides that, upon the consummation of the Sale, the Stalking Horse Bidder will create trusts (the Future Trusts) for the benefit of certain private opioid and mesh claimants whose first injury did not arise until after the general bar date. As consideration, the Future Trusts will receive, among other things, $12 million of gross cash consideration payable in installments to be distributed to eligible private future opioid and mesh claimants.

In connection with the resolutions, the UCC, the OCC, the FCR and the ad hoc groups of debtholders party thereto have agreed to support the Sale.

Bankruptcy Accounting

As a result of the Chapter 11 Cases, we have applied the provisions of ASC 852 in preparing the accompanying Consolidated Financial Statements. ASC 852 requires that, for periods including and after the filing of a chapter 11 petition, the Consolidated Financial Statements distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business.

Accordingly, for periods beginning with the third quarter of 2022, pre-petition unsecured and undersecured claims related to the Debtors that may be impacted by the bankruptcy reorganization process have been classified as Liabilities subject to compromise in the Consolidated Balance Sheets. Liabilities subject to compromise include pre-petition liabilities for which there is uncertainty about whether such pre-petition liabilities could be impaired as a result of the Chapter 11 Cases. Liabilities subject to compromise are recorded at the expected amount of the total allowed claim, even if they may ultimately be settled for different amounts. The following table sets forth, as of December 31, 2022, information about the amounts presented as Liabilities subject to compromise in our Consolidated Balance Sheets (in thousands):

	December 31, 2022
Accounts payable	$ 30,317
Accrued interest	160,617
Debt	7,834,717
Litigation accruals	863,805
Uncertain tax positions	235,176
Other (1)	87,150
Total	$ 9,211,782

(1) Amounts include operating and finance lease liabilities as further described in Note 9. Leases, acquisition-related contingent consideration liabilities as further described in Note 7. Fair Value Measurements and a variety of other miscellaneous liabilities.

The determination of how liabilities will ultimately be settled or treated cannot be made until approved by the Bankruptcy Court. Therefore, the amounts in the table above are preliminary and may be subject to future adjustments as a result of, among other things, the possibility or occurrence of certain Bankruptcy Court actions, further developments with respect to disputed claims, any rejection by us of executory contracts and/or any payments by us of amounts classified as Liabilities subject to compromise, which may be allowed in certain limited circumstances. Amounts are also subject to adjustments if we make changes to our assumptions or estimates related to claims as additional information becomes available to us including, without limitation, those related to the expected amounts of allowed claims, the value of any collateral securing claims and the secured status of claims. Such adjustments may be material. Additionally, as a result of our ongoing bankruptcy proceedings, we may sell or otherwise dispose of or liquidate assets or settle liabilities for amounts other than those reflected in the accompanying Consolidated Financial Statements. The possibility or occurrence of any such actions could materially impact the amounts and classifications of such assets and liabilities reported in our Consolidated Balance Sheets and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Certain expenses, gains and losses resulting from and recognized during our bankruptcy proceedings are now being recorded in Reorganization items, net in our Consolidated Statements of Operations. The following table sets forth, for the year ended December 31, 2022, information about the amounts presented as Reorganization items, net in our Consolidated Statements of Operations (in thousands):

	2022
Professional fees	$ 113,781
Debt valuation adjustments	89,197
Total	$ 202,978

Since the Petition Date, our operating cash flows included net cash outflows of $53.7 million related to amounts classified or expected to be classified as Reorganization items, net, which primarily consisted of payments for professional fees.

Refer also to Note 15. Debt for information about how our bankruptcy proceedings and certain related developments have affected our debt service payments and how such payments are being reflected in our Consolidated Financial Statements.

Nasdaq Delisting

On August 17, 2022, we received a letter (the Notice) from The Nasdaq Stock Market LLC (Nasdaq) stating that, in accordance with Nasdaq Listing Rules 5101, 5110(b) and IM-5101-1, Nasdaq had determined that Endo's ordinary shares would be delisted. In accordance with the Notice, trading of Endo's ordinary shares was suspended at the opening of business on August 26, 2022. As a result, Endo's ordinary shares began trading exclusively on the over-the-counter market on August 26, 2022. On the over-the-counter market, Endo's ordinary shares, which previously traded on the Nasdaq Global Select Market under the symbol ENDP, began to trade under the symbol ENDPQ. On September 14, 2022, Nasdaq filed a Form 25-NSE with the SEC and Endo's ordinary shares were subsequently delisted from the Nasdaq Global Select Market. On December 13, 2022, Endo's ordinary shares were deregistered under Section 12(b) of the Exchange Act.

NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Significant Accounting Policies

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

Going Concern. 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 as further discussed herein, thousands of governmental and private plaintiffs have filed suit against us and/or certain of our subsidiaries alleging opioid-related claims, most of which we have not been able to settle. As a result of the possibility or occurrence of an unfavorable outcome with respect to these proceedings, other legal proceedings and certain other risks and uncertainties, we explored a wide array of potential actions as part of our contingency planning.

On the August 16, 2022 Petition Date, the Debtors filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. Refer to Note 2. Bankruptcy Proceedings and Note 14. Debt for additional information.

As a result of these conditions and events, the Group's directors have formed an opinion that most likely outcome from Bankruptcy Proceedings is the eventual liquidation and winding up of the Company and its subsidiaries after closing of the Sale to Stalking Horse Bidder. The uncertainties arising from the chapter 11 procedures are, further described in Note 2. Bankruptcy Proceedings and, these events and conditions indicate the existence of a material uncertainty which may cast substantial doubt about the group's ability to continue as a going concern. The accompanying Consolidated Financial Statements have been prepared under the going concern basis of accounting as required by U.S. GAAP and do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Reclassifications. Certain prior year amounts have been reclassified to conform to the current year presentation. The reclassification adjustments primarily relate to changes to the presentation of certain costs and expenses in our Consolidated Profit and loss account. Specifically, effective with the first quarter of 2022, the Group has added a new financial statement line item labeled Acquired in-process research and development. Any prior year amounts of acquired in-process research and development charges presented in this report have been reclassified to this line item from the existing financial statement line item labeled Research and development.

Bankruptcy Accounting. Refer to Note 2. Bankruptcy Proceedings under the heading "Bankruptcy Accounting" for a discussion of accounting considerations related to our ongoing bankruptcy proceedings.

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, share-based compensation, liabilities subject to compromise and reorganization items, net, 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. Additionally, as a result of our ongoing bankruptcy proceedings, we may sell or otherwise dispose of or liquidate assets or settle liabilities for amounts other than those reflected in the accompanying Consolidated Financial Statements. The possibility or occurrence of any such actions could materially impact the amounts and classifications of such assets and liabilities reported in our Consolidated Balance Sheets. Furthermore, our ongoing bankruptcy proceedings and planned sale process have resulted in and are likely to continue to result in significant changes to our business, 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, 2022 and 2021 are as follows:

	2022	2021
AmerisourceBergen Corporation	35 %	36 %
McKesson Corporation	26 %	32 %
Cardinal Health, Inc.	20 %	22 %

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

XIAFLEX® accounted for 19% and 14% of our 2022 and 2021 net turnover, respectively. Varenicline tablets (our generic version of Pfizer Inc.'s Chantix®) accounted for 13% of our 2022 net turnover. VASOSTRICT® accounted for 11%, and 30% of our 2022 and 2021 net turnover, respectively. No other products accounted for 10% or more of our net turnover during any of the years ended December 31, 2022 and 2021.

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 Group 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, 2022 and 2021, our reserves for sales deductions totaled $600.2 million and $588.7 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 our right to consideration in exchange for goods or services that we have transferred when that right is conditioned on something other than the passage of time. We record income and a corresponding contract asset when we fulfill a contractual performance obligation, but must also fulfill one or more additional performance obligations before being entitled to payment. Once our right to consideration becomes unconditional, the contract asset amount is reclassified as Accounts receivable.

Contract liabilities represent our obligation to transfer goods or services to a customer. We record a contract liability generally upon receipt of consideration in advance of fulfilling one or more of our contractual performance obligations. Upon completing each performance obligation, the corresponding contract liability amount is reversed and income 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.

The accounting for costs associated with acquiring in-process research and development assets, including contractual upfront and milestone payments to third parties, is further discussed below.

R&D. Expenditures for R&D are expensed as incurred and included as Research and development in the Consolidated Profit and loss account. Such expenses include, among other things, the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials, materials and medical support of marketed products. R&D spending also includes enterprise-wide costs which support our overall R&D infrastructure. Tangible fixed assets 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. The accounting for costs associated with acquiring in-process research and development assets, including contractual upfront and milestone payments to third parties, is further discussed below.

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, 2022 and 2021, 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. 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 83% and 91% of our gross trade accounts receivable balances represent amounts due from three customers (Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation) at December 31, 2022 and December 31, 2021, 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, 2022 or December 31, 2021, 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 year 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, 2022, 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. 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 year 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.

Cloud Computing Arrangements. The Group may from time to time incur costs in connection with hosting arrangements that are service contracts. 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 and to be held and used, it is 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 6 years to 16 years, with a weighted average useful life of approximately 12 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. Prior to disposal, 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.

Acquired in-Process Research and Development Assets. Acquired in-process research and development charges are generally recognized in periods in which in-process research and development assets (with no alternative future use in other research and development projects) are acquired from third parties in connection with an asset acquisition, or when costs are incurred (up to the point of regulatory approval) for upfront or milestone payments to third parties associated with in-process research and development. 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, as of October 1, and when events or changes in circumstances indicate that the asset might be impaired. 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 are generally 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 $130.4 million and $136.8 million for the years ended December 31, 2022 and 2021, 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* 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* 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. From time to time, 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 PSUs where the ultimate payout is performance-based. For these awards, at each reporting period, the Group generally 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 income and expenses are generally remeasured using average exchange rates in effect during the year. In the case of nonmonetary assets and liabilities such as 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. Profit 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 (loss) income. Upon the sale or liquidation of an investment in a foreign operation, the Group records a reclassification adjustment out of Other comprehensive (loss) 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 profit 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 generally recognizes changes in UTPs, interest and penalties in the Income tax expense line in the Consolidated Profit and loss account. Refer to Note 20. Income Taxes for information about the classification of liabilities related to UTPs, including interest and penalties, in the Consolidated Balance Sheets.

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 profit as these amounts are recorded directly as an adjustment to shareholders' equity.

Government Assistance Transactions. Our PSP LLC subsidiary is party to the U.S. Government Agreement. 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.

The Group has concluded that reimbursements it receives pursuant to the U.S. Government Agreement, which are further described below, are not within the scope of *Accounting Standards Codification Topic 606, Revenue from Contracts with Customers* (ASC 606) because the U.S. government does not meet the definition of a "customer" as defined by ASC 606. We are instead accounting for the U.S. Government Agreement under other guidance including, for elements of the contract for which there is no authoritative guidance under U.S. GAAP, by applying the relevant accounting principles contained in *International Accounting Standards 20—Accounting for Government Grants and Disclosure of Government Assistance* by analogy.

Under this model, reimbursements we receive from the U.S. government for qualifying capital expenditures meet the definition of grants related to assets as the primary purpose for the reimbursements is to fund the purchase and construction of capital assets to increase production capacity. We recognize these reimbursements as deferred income in the Consolidated Balance Sheets as either Accounts payable and accrued expenses (for any current portion) or Other liabilities (for any noncurrent portion) when there is reasonable assurance the conditions of the grant will be met and the grant will be received. Refer to Note 15. Commitments and Contingencies for additional discussion of this agreement.

NOTE 4. 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, 2022 and 2021 (in thousands):

	2022	2021
Litigation-related and other contingencies, net	$ —	$ 25,000
Loss from discontinued operations before income taxes	$ (15,543)	$ (49,594)
Income tax benefit	$ (2,056)	$ (5,430)
Discontinued operations, net of tax	$ (13,487)	$ (44,164)

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 $13.5 million and $44.2 million for the years ended December 31, 2022 and 2021, 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 (the 2020 Restructuring Initiative), which are further discussed in Note 5. Restructuring. These actions include an initiative to exit certain of our manufacturing and other sites to optimize our retail generics business cost structure.

Certain of these sites and certain corresponding assets and liabilities were sold in 2021 to subsidiaries of Strides Pharma Science Limited and certain other entities. The assets sold included 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. As a result of these sales, we became entitled to aggregate cash consideration of approximately $25.6 million, substantially all of which was received by December 31, 2021, as well as certain non-cash consideration of approximately $5.8 million. In connection with these sales, we recognized the following amounts in 2021: (i) a pre-tax disposal loss of $42.2 million 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, and (ii) a pre-tax net reversal of $25.4 million of expense, primarily related to avoided severance costs for employees that transitioned to the purchasers in connection with these 2021 sales.

In 2022, we entered into a definitive agreement to sell certain additional assets located in Chestnut Ridge, New York to Ram Ridge Partners BH LLC. The assets primarily consisted of tangible fixed assets. In October 2022, the Bankruptcy Court approved the sale of the assets. The sale closed during the fourth quarter of 2022. As a result of this sale, we became entitled to aggregate cash consideration of approximately $18.5 million, substantially all of which was received by December 31, 2022. In connection with this sale, we recognized a pre-tax disposal gain of approximately $8.4 million in 2022, which we recorded in Other income, net in the Consolidated Profit and loss account.The assets described in this section, which primarily related to the Group's Generic Pharmaceuticals segment, did not meet the requirements for treatment as a discontinued operation. The amounts described in this section that were recognized in our Consolidated Profit and loss account are included in the quantitative disclosures of the 2020 Restructuring Initiative included in Note 5. Restructuring.

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 group for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31, 2022		
	Continuing Operations	Discontinued Operations	Global Company
TURNOVER	$ 2,318,875	$ —	$ 2,318,875
Cost of sales	1,092,499	—	1,092,499
GROSS PROFIT	$ 1,226,376	$ —	$ 1,226,376
Selling, general and administrative expenses	777,169	16,564	793,733
Research and development expenses	128,033	—	128,033
Litigation-related and other contingency expenses	521,722	—	521,722
Acquired in process research and development	68,700	—	68,700
Asset impairment charges	2,142,746	—	2,142,746
Acquisition-related and integration items	408	—	408
OPERATING PROFIT (LOSS)	$ (2,412,402)	$ (16,564)	$ (2,428,966)
INTEREST RECEIVABLE AND SIMILAR INCOME	(964)	—	(964)
INTEREST PAYABLE AND SIMILAR CHARGES	350,740	—	350,740
REORGANIZATION ITEMS, NET	202,978	—	202,978
LOSS ON EXTINGUISHMENT OF DEBT	—	—	—
OTHER INCOME, NET	(34,054)	(1,021)	(35,075)
LOSS FROM CONTINUING AND DISCONTINUING OPERATIONS BEFORE TAXATION	$ (2,931,102)	$ (15,543)	$ (2,946,645)
TAX EXPENSE/(BENEFIT) FROM CONTINUING AND DISCONTINUING OPERATIONS	21,516	(2,056)	19,460
(LOSS) FROM CONTINUING OPERATIONS AND DISCONTINUING	$ (2,952,618)	$ (13,487)	$ (2,966,105)
(LOSS) PROFIT DISCONTINUED OPERATIONS, NET OF TAX	(13,487)	13,487	—
(LOSS) FOR THE FINANCIAL YEAR	$ (2,966,105)	$ —	$ (2,966,105)

	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	123,440	—	123,440
Acquired in-process research and development	25,120	—	25,120
Litigation-related and other contingency (credits)/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
GAIN ON EXTINGUISHMENT OF DEBT	13,753	—	13,753
OTHER (PROFIT) LOSS, NET	(19,774)	(1,192)	(20,966)
LOSS FROM CONTINUING AND DISCONTINUING OPERATIONS BEFORE TAXATION	$ (546,603)	$ (49,594)	$ (596,197)
TAX BENEFIT FROM CONTINUING AND DISCONTINUING OPERATIONS	22,478	(5,430)	17,048
PROFIT (LOSS) FROM CONTINUING AND DISCONTINUING OPERATIONS	$ (569,081)	$ (44,164)	$ (613,245)
(LOSS) PROFIT DISCONTINUED OPERATIONS, NET OF TAX	(44,164)	44,164	—
PROFIT FOR THE FINANCIAL YEAR	$ (613,245)	$ —	$ (613,245)

The Group did not have held for sale assets and liabilities as of December 31, 2022 or 2021.

NOTE 5. RESTRUCTURING

2020 Restructuring Initiative

As noted above, in November 2020, the Group announced the initiation of several strategic actions to further optimize the Group's operations and increase overall efficiency. These actions were initiated with the expectation of, among other things, 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 included the following:

- Optimizing the Group's retail generics business cost structure by exiting manufacturing and other sites in Irvine, California, Chestnut Ridge, New York and India.
- 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.

As a result of the 2020 Restructuring Initiative, the Group's global workforce was reduced by approximately 300 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 turnover 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. Future costs associated with the 2020 Restructuring Initiative are not expected to be material.

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, 2022 and 2021 (in thousands):

	2022	2021
Net restructuring charges (charge reversals) related to:		
Accelerated depreciation	$ 3,773	$ 24,718
Asset impairments	—	42,155
Stock adjustments	1,494	6,968
Employee separation, continuity and other benefit-related costs	1,216	(7,384)
Certain other restructuring costs	795	2,012
Total	$ 7,278	$ 68,469

These pre-tax net amounts were primarily attributable to our Generic Pharmaceuticals segment, which incurred $5.4 million and $49.9 million of pre-tax net charges during the years ended December 31, 2022 and 2021, respectively. The remaining amounts related to our other segments and certain corporate unallocated costs.

As of December 31, 2022, cumulative amounts incurred to date include charges related to accelerated depreciation of approximately $51.0 million, asset impairments related to certain identifiable intangible assets, operating lease assets and disposal groups totaling approximately $49.5 million, stock adjustments of approximately $11.6 million, employee separation, continuity and other benefit-related costs, net of approximately $53.9 million and certain other restructuring costs of approximately $3.5 million. Of these amounts, approximately $134.3 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, 2022 and, 2021 (in thousands):

	2022	2021
Net restructuring charges (charge reversals) included in:		
Cost of sales	$ 3,966	$ 6,244
Selling, general and administrative	208	20,788
Research and development	3,104	1,367
Asset impairment charges	—	42,155
Other income, net	—	(2,085)
Total	$ 7,278	$ 68,469

In addition to the pre-tax net amounts summarized above, as part of the 2020 Restructuring Initiative, we recognized a pre-tax disposal gain of approximately $8.4 million during the fourth quarter of 2022 as a result of the Chestnut Ridge, New York sale transaction, which is further described in Note 4. Discontinued Operations and Asset Sales. The assets sold primarily related to our Generic Pharmaceuticals segment.

Changes to the liability for the 2020 Restructuring Initiative during the years ended December 31, 2022 and 2021 were as follows (in thousands):

	Employee Separation, Continuity and Other Benefit-Related Costs	Certain Other Restructuring Costs	Total
Liability balance as of January 1, 2021	$ 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
Net charges	1,216	796	2,012
Cash payments	(11,926)	(1,001)	(12,927)
Liability balance as of December 31, 2022	$ 269	$ —	$ 269

2022 Restructuring Initiative

In April 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. In December 2022, the Group announced it would be taking certain additional actions to cease the production and sale of QWO® in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration. These actions, which are collectively referred to herein as the 2022 Restructuring Initiative, were initiated with the expectation of, among other things, generating cost savings, with a portion to be reinvested to support the Group's key strategic priority to expand and enhance its product portfolio. In December 2022, the Bankruptcy Court approved an order authorizing the Group to cease the production and commercialization of QWO® and granting related relief.

As a result of the 2022 Restructuring Initiative, the Group's global workforce is ultimately expected to be reduced by up to approximately 190 net full-time positions. The Group expects to realize annualized pre-tax cash savings (without giving effect to the costs described below) of approximately $105 million to $125 million by the end of 2023, primarily related to reductions in Selling, general and administrative expenses and Cost of sales. Future costs associated with the 2022 Restructuring Initiative are not expected to be material.

The following pre-tax net amounts related to the 2022 Restructuring Initiative are included in the Group's Consolidated Profit and loss account during the year ended December 31, 2022 (in thousands):

	2022
Net restructuring charges related to:	
Asset impairments	$ 180,248
Stock adjustments	34,870
Employee separation, continuity and other benefit-related costs	28,345
Certain other restructuring costs	8,656
Total	$ 252,119

These pre-tax net amounts were primarily attributable to our Branded Pharmaceuticals segment, which incurred $238.6 million of pre-tax net charges during the year ended December 31, 2022. The remaining amounts related to our Generic Pharmaceuticals segment and certain corporate unallocated costs.

The following pre-tax net amounts related to the 2022 Restructuring Initiative are included in the Group's Consolidated Profit and loss account during the year ended December 31, 2022 (in thousands):

	2022
Net restructuring charges included in:	
Cost of sales	$ 49,078
Selling, general and administrative	18,692
Research and development	4,101
Asset impairment charges	180,248
Total	$ 252,119

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

	Employee Separation, Continuity and Other Benefit-Related Costs	Certain Other Restructuring Costs	Total
Liability balance as of December 31, 2021	$ —	$ —	$ —
Net charges	28,345	1,102	29,447
Cash payments	(13,348)	(1,102)	(14,450)
Liability balance as of December 31, 2022	$ 14,997	$ —	$ 14,997

The liability at December 31, 2022 is classified as current and is included in Accounts payable and accrued expenses in the Consolidated Balance Sheets.

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

Certain 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 Company'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 and bariatrics, among others. Products in this segment include XIAFLEX®, SUPPRELIN® LA, AVEED®, NASCOBAL® Nasal Spray, PERCOCET®, TESTOPEL® and EDEX®, 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's Invanz®) and ephedrine sulfate injection, among others.

Generic Pharmaceuticals

Our Generic Pharmaceuticals segment consists of a product portfolio including solid oral extended-release products, solid oral immediate-release products, 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, including OTC products, sold outside the U.S., primarily in Canada through our operating company Paladin.

The following represents selected information for the Group's reportable segments for the years ended December 31, 2022 and, 2021 (in thousands):

	2022	2021
Net turnover from external customers:		
Branded Pharmaceuticals	$ 851,142	$ 893,617
Sterile Injectables	589,633	1,266,097
Generic Pharmaceuticals	795,457	740,586
International Pharmaceuticals (1)	82,643	92,906
Total net turnover from external customers	$ 2,318,875	$ 2,993,206
Segment adjusted profit from continuing operations before income tax:		
Branded Pharmaceuticals	$ 381,554	$ 384,186
Sterile Injectables	349,424	998,453
Generic Pharmaceuticals	336,133	160,046
International Pharmaceuticals	19,920	30,325
Total segment adjusted profit from continuing operations before income tax	$ 1,087,031	$ 1,573,010

(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, 2022 and 2021 (in thousands):

	2022	2021
Total consolidated loss from continuing operations before income tax	$ (2,931,102)	$ (546,603)
Interest expense, net	349,776	562,353
Corporate unallocated costs (1)	182,335	180,866
Amortization of intangible assets	337,311	372,907
Acquired in-process research and development charges	68,700	25,120
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (2)	198,381	90,912
Certain litigation-related and other contingencies, net (3)	521,722	345,495
Certain legal costs (4)	46,756	136,148
Asset impairment charges (5)	2,142,746	414,977
Acquisition-related and integration items, net (6)	408	(8,379)
Loss on extinguishment of debt	—	13,753
Foreign currency impact related to the remeasurement of intercompany debt instruments	(5,328)	797
Reorganization items, net (7)	202,978	—
Other, net (8)	(27,652)	(15,336)
Total segment adjusted profit from continuing operations before income tax	$ 1,087,031	$ 1,573,010

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

(2) Amounts in 2022 include net employee separation, continuity and other benefit-related charges of $85.6 million, accelerated depreciation charges of $3.8 million, stock charges related to restructurings of $36.4 million and other net charges, including those related to strategic review initiatives, of $72.7 million. 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. These amounts relate primarily to our restructuring activities as further described in Note 5. Restructuring, certain continuity and transitional compensation arrangements, certain other cost reduction initiatives and certain strategic review initiatives, including costs incurred in connection with our bankruptcy proceedings, which are included in this row until the Petition Date and in the Reorganization items, net row thereafter.

(3) Amounts include adjustments to our accruals for litigation-related settlement charges. Our material legal proceedings and other contingent matters are described in more detail in Note 15. Commitments and Contingencies.

(4) Amounts relate to opioid-related legal expenses. The amount in 2022 reflects the recovery of certain previously-incurred opioid-related legal expenses.

(5) 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 4. Discontinued Operations and Asset Sales, Note 5. Restructuring, Note 7. Fair Value Measurements, Note 9. Leases, Note 10. tangible fixed assets and Note 11. Goodwill and Other Intangibles.

(6) Amounts primarily relate to changes in the fair value of contingent consideration.
(7) Amounts relate to the net expense or profit recognized during our bankruptcy proceedings required to be presented as Reorganization items, net under ASC 852. Refer to Note 2. Bankruptcy Proceedings for further details.
(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. Other amounts in this row relate to gains and losses on sales of businesses and other assets and certain other items.

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

During the years ended December 31, 2022 and 2021, 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.

	2022	2021
Branded Pharmaceuticals:		
Specialty Products:		
XIAFLEX®	$ 438,680	$ 432,344
SUPPRELIN® LA	113,011	114,374
Other Specialty (1)	70,009	86,432
Total Specialty Products	$ 621,700	$ 633,150
Established Products:		
PERCOCET®	$ 103,943	$ 103,788
TESTOPEL®	38,727	43,636
Other Established (2)	86,772	113,043
Total Established Products	$ 229,442	$ 260,467
Total Branded Pharmaceuticals (3)	$ 851,142	$ 893,617
Sterile Injectables:		
VASOSTRICT®	$ 253,696	$ 901,735
ADRENALIN®	114,304	124,630
Other Sterile Injectables (4)	221,633	239,732
Total Sterile Injectables (3)	$ 589,633	$ 1,266,097
Total Generic Pharmaceuticals (5)	$ 795,457	$ 740,586
Total International Pharmaceuticals (6)	$ 82,643	$ 92,906
Total turnover, net	$ 2,318,875	$ 2,993,206

(1) Products included within Other Specialty include AVEED®, NASCOBAL® Nasal Spray and QWO®.
(2) Products included within Other Established include, but are not limited to, EDEX®.
(3) Individual products presented above represent the top two performing products in each product category for the year ended December 31, 2022 and/or any product having turnover in excess of $25 million during any completed quarterly period in 2022 or 2021.
(4) Products included within Other Sterile Injectables include APLISOL®, ertapenem for injection 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 limited or no intellectual property protection and are sold within the U.S. During 2022, varenicline tablets (Endo's generic version of Pfizer Inc.'s Chantix®), which launched in September 2021, made up 13% of consolidated total turnover. No other individual product within this segment has exceeded 5% of consolidated total turnover for the periods presented.
(6) The International Pharmaceuticals segment, which accounted for less than 5% of consolidated total turnovers for each of the periods presented, includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through Endo's operating company Paladin.

The following represents depreciation expense for our reportable segments for the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Branded Pharmaceuticals	$ 9,862	$ 10,632
Sterile Injectables	20,224	17,796
Generic Pharmaceuticals	16,952	47,343
International Pharmaceuticals	3,638	4,242
Corporate unallocated	3,642	4,178
Total depreciation expense	$ 54,318	$ 84,191

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

The following table presents current and noncurrent restricted cash and cash equivalent balances at December 31, 2022 and December 31, 2021 (in thousands):

	Balance Sheet Line Items	December 31, 2022	December 31, 2021
Restricted cash at bank and on-hand—current (1)	Restricted cash at bank and on-hand	$ 145,358	$ 124,114
Restricted cash at bank and on-hand—noncurrent (2)	Other assets	85,000	—
Total restricted cash at bank and on-hand		$ 230,358	$ 124,114

(1) Amounts at December 31, 2022 and December 31, 2021 include: (i) restricted cash at bank and on-hand associated with litigation-related matters, including $50.7 million and $78.4 million, respectively, held in Qualified Settlement Funds (QSFs) for mesh- and/or opioid-related matters, and (ii) approximately $86.0 million and $45.0 million, respectively, of restricted cash at bank and on-hand related to certain insurance-related matters. See Note 15. Commitments and Contingencies for further information about litigation-related matters.

(2) The amount at December 31, 2022 relates to the TLC Agreement. See Note 12. License, Collaboration and Asset Acquisition Agreements for further information about this amount.

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, 2022 and December 31, 2021 were as follows (in thousands):

	Fair Value Measurements at December 31, 2022 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
Assets:				
Money market funds (1)	$ 12,226	$ —	$ —	$ 12,226
Liabilities:				
Acquisition-related contingent consideration (2)	$ —	$ —	$ 16,571	$ 16,571

	Fair Value Measurements at December 31, 2021 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
Assets:				
Money market funds (1)	$ 134,847	$ —	$ —	$ 134,847
Liabilities:				
Acquisition-related contingent consideration (2)	$ —	$ —	$ 20,076	$ 20,076

(1) At December 31, 2022 and December 31, 2021, money market funds include $12.2 million and $16.2 million, respectively, in QSFs. Amounts in QSFs are considered restricted cash equivalents. See Note 15. Commitments and Contingencies for further discussion of our litigation. At December 31, 2022 and December 31, 2021, the differences between the amortized cost and the fair value of our money market funds were not material, individually or in the aggregate.

(2) At December 31, 2022, the balance of the Group's liability for acquisition-related contingent consideration, which is governed by executory contracts and recorded at the expected amount of the total allowed claim, is classified within Liabilities subject to compromise in the Consolidated Balance Sheets. At December 31, 2021, this amount is classified in the Consolidated Balance Sheets as follows: $5.7 million is classified as a current liability and included within Accounts payable and accrued expenses and $14.3 million is classified as a noncurrent liability and included within Other liabilities.

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, 2022 and 2021 (in thousands):

	2022	2021
Beginning of period	$ 20,076	$ 36,249
Amounts settled	(3,127)	(7,449)
Changes in fair value recorded in earnings	408	(8,793)
Effect of currency translation	(786)	69
End of period (1)	$ 16,571	$ 20,076

(1) At December 31, 2022, the balance of the Group's liability for acquisition-related contingent consideration, which is governed by executory contracts and recorded at the expected amount of the total allowed claim, is classified within Liabilities subject to compromise in the Consolidated Balance Sheets.

At December 31, 2022, the fair value measurements of the contingent consideration obligations were determined using risk-adjusted discount rates ranging from 10.0% to 15.0% (weighted average rate of approximately 10.7%, 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.

The following table presents changes to the Group's liability for acquisition-related contingent consideration during the year ended December 31, 2022 by acquisition (in thousands):

	Balance as of January 1, 2022	Changes in Fair Value Recorded in Earnings	Amounts Settled and Other	Balance as of December 31, 2022 (1)
Auxilium acquisition	$ 9,038	$ 2,116	$ (536)	$ 10,618
Lehigh Valley Technologies, Inc. acquisitions	3,600	(635)	(665)	2,300
Other	7,438	(1,073)	(2,712)	3,653
Total	$ 20,076	$ 408	$ (3,913)	$ 16,571

(1) At December 31, 2022, the balance of the Group's liability for acquisition-related contingent consideration, which is governed by executory contracts and recorded at the expected amount of the total allowed claim, is classified within Liabilities subject to compromise in the 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

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, 2022 and 2021 were as follows (in thousands):

	Fair Value Measurements during the Year Ended December 31, 2022 (1) using:			Total Expense for the Year Ended December 31, 2022
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	
Intangible assets, excluding goodwill (2)(3)	$ —	$ —	$ 67,082	$ (288,701)
Certain tangible fixed assets	—	—	—	(9,045)
Total	$ —	$ —	$ 67,082	$ (297,746)

	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	$ —	$ —	$ 5,011	$ (9,822)

(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 2022, these fair value measurements were determined using risk-adjusted discount rates ranging from 9.5% to 12.0% (weighted average rate of approximately 11.8%, weighted based on relative fair value). 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).

(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 consisted of the following at December 31, 2022 and December 31, 2021 (in thousands):

	December 31, 2022	December 31, 2021
Raw materials (1)	$ 105,975	$ 90,453
Work-in-process (1)	43,057	82,728
Finished goods (1)	125,467	110,371
Total	$ 274,499	$ 283,552

(1) The components of stock shown in the table above are net of allowances.

Stock 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, 2022 and December 31, 2021, $23.0 million and $10.7 million, respectively, of noncurrent stock was included in Other assets in the Consolidated Balance Sheets. As of December 31, 2022 and December 31, 2021, the Group's Consolidated Balance Sheets included approximately $5.8 million and $12.2 million, respectively, of capitalized pre-launch stock related to products that were not yet available to be sold.

As of December 31, 2022 and 2021, $18.1 million and $31.5 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, 2022 and December 31, 2021 (in thousands):

	Balance Sheet Line Items	December 31, 2022	December 31, 2021
Right-of-use assets:			
Operating lease right-of-use assets	Operating lease assets	$ 28,070	$ 34,832
Finance lease right-of-use assets	Tangible fixed assets, net	26,761	38,365
Total right-of-use assets		$ 54,831	$ 73,197
Operating lease liabilities (1):			
Current operating lease liabilities	Current portion of operating lease liabilities	$ 903	$ 10,992
Noncurrent operating lease liabilities	Operating lease liabilities, less current portion	5,129	33,727
Total operating lease liabilities		$ 6,032	$ 44,719
Finance lease liabilities (1):			
Current finance lease liabilities	Accounts payable and accrued expenses	$ —	$ 6,841
Noncurrent finance lease liabilities	Other liabilities	1,392	18,374
Total finance lease liabilities		$ 1,392	$ 25,215

(1) Amounts at December 31, 2022 exclude operating lease liabilities of $28.4 million and finance lease liabilities of $17.1 million that are classified as Liabilities subject to compromise in the Consolidated Balance Sheets.

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

	Statement of Operations Line Items	2022	2021
Operating lease cost	Various (1)	$ 10,959	$ 13,892
Finance lease cost:			
Amortization of right-of-use assets	Various (1)	$ 8,479	$ 9,244
Interest on lease liabilities	Interest expense, net	$ 1,127	$ 1,480
Other lease costs and income:			
Variable lease costs (2)	Various (1)	$ 11,707	$ 13,202
Finance lease right-of-use asset impairment charges	Asset impairment charges	$ 3,063	$ —
Operating lease right-of-use asset impairment charges	Asset impairment charges	$ —	$ —
Sublease income	Various (1)	$ (6,436)	$ (3,793)

(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, 2022 and 2021 (in thousands):

	2022	2021
Cost of sales	$ 6,189	$ 11,316
Selling, general and administrative	$ 18,305	$ 21,013
Research and development	$ 215	$ 216

(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, 2022 for each of the five years subsequent to December 31, 2022 and thereafter, as well as a reconciliation of such undiscounted cash flows to our lease liabilities at December 31, 2022 (in thousands):

	Operating Leases	Finance Leases
2023	$ 11,518	$ 7,881
2024	6,599	8,038
2025	5,381	896
2026	5,337	896
2027	5,345	896
Thereafter	4,630	9,303
Total future lease payments	$ 38,810	$ 27,910
Less: amounts representing interest	4,391	9,440
Present value of future lease payments (lease liabilities, including amounts classified as Liabilities subject to compromise)	$ 34,419	$ 18,470
Less: amounts classified as Liabilities subject to compromise	28,387	17,078
Lease liabilities, excluding amounts classified as Liabilities subject to compromise	$ 6,032	$ 1,392

The following table provides the weighted average remaining lease term and weighted average discount rates for our leases as of December 31, 2022 and December 31, 2021:

	December 31, 2022	December 31, 2021
Weighted average remaining lease term (years), weighted based on lease liability balances:		
Operating leases	4.9 years	5.1 years
Finance leases	9.9 years	9.5 years
Weighted average discount rate (percentages), weighted based on the remaining balance of lease payments:		
Operating leases	6.1 %	5.9 %
Finance leases	7.5 %	7.6 %

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

	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash payments for operating leases	$ 13,152	$ 14,478
Operating cash payments for finance leases	$ 1,673	$ 2,256
Financing cash payments for finance leases	$ 6,062	$ 5,448
Lease liabilities arising from obtaining right-of-use assets:		
Operating leases (1)	$ 1,296	$ 5,807

(1) The amount in 2022 primarily relates to a new lease agreement. 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, 2022 are set forth in the table below (in thousands).

Cost:	Land and Buildings	Machinery and Equipment	Leasehold Improvements	Computer Equipment and Software	Furniture and Fixtures	Assets under Construction	Total
At January 1, 2022	$ 234,219	$ 206,971	$ 55,020	$ 118,959	$ 11,939	$ 120,483	$ 747,591
Additions (1)	35,008	43,389	1,283	8,152	188	27,770	115,790
Disposals, transfers, impairments and other	(30,020)	(8,342)	(1,827)	(34,238)	(2,982)	(5,693)	(83,102)
Effect of currency translation	—	(88)	(88)	(307)	(16)	—	(499)
At December 31, 2022	$ 239,207	$ 241,930	$ 54,388	$ 92,566	$ 9,129	$ 142,560	$ 779,780
Accumulated Depreciation:							
At January 1, 2022	$ (110,141)	$ (99,449)	$ (36,764)	$ (94,947)	$ (9,578)	$ —	$ (350,879)
Additions	(15,441)	(22,333)	(4,782)	(9,513)	(2,249)	—	(54,318)
Disposals, transfers and other	16,162	8,188	1,320	33,476	4,145	—	63,291
Effect of currency translation	—	61	77	287	15	—	440
At December 31, 2022	$ (109,420)	$ (113,533)	$ (40,149)	$ (70,697)	$ (7,667)	$ —	$ (341,466)
Net Book Amount:							
At December 31, 2022	$ 129,787	$ 128,397	$ 14,239	$ 21,869	$ 1,462	$ 142,560	$ 438,314
At December 31, 2021	$ 124,078	$ 107,522	$ 18,256	$ 24,012	$ 2,361	$ 120,483	$ 396,712

(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 $54.3 million and $84.2 million for the years ended December 31, 2022 and 2021, respectively. During the years ended December 31, 2022 and 2021, the Group recorded tangible fixed assets impairment charges totaling $9.0 million and $2.0 million, respectively. These charges are included in the Asset impairment charges line item in our Consolidated Profit and loss account and primarily reflect the write-off of certain tangible fixed assets.

At December 31, 2022 and December 31, 2021, $205.2 million and $162.1 million of the Group's Tangible fixed assets, net, representing net book amounts, were located in India. At December 31, 2022 and December 31, 2021, 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, 2022	$ 3,998,138	$ —	$ 442,107	$ 6,409	$ 6,226,139	$ 10,672,793
Additions	—	—	—	—	—	—
Impairments	(1,845,000)	—	—	—	(288,701)	(2,133,701)
Other	—	—	—	—	—	—
Effect of currency translations	—	—	—	—	(17,417)	(17,417)
At December 31, 2022	$ 2,153,138	$ —	$ 442,107	$ 6,409	$ 5,920,021	$ 8,521,675
Accumulated Amortization:						
At January 1, 2022	$ (801,127)	$ —	$ (419,932)	$ (6,409)	$ (3,885,491)	$ (5,112,959)
Charge	—	—	(4,576)	—	(332,735)	(337,311)
Other (1)	—	—	—	—	—	—
Effect of currency translations	—	—	—	—	13,541	13,541
At December 31, 2022	$ (801,127)	$ —	$ (424,508)	$ (6,409)	$ (4,204,685)	$ (5,436,729)
Net Book Amount:						
At December 31, 2022	$ 1,352,011	$ —	$ 17,599	$ —	$ 1,715,336	$ 3,084,946
At December 31, 2021	$ 3,197,011	$ —	$ 22,175	$ —	$ 2,340,648	$ 5,559,834

Amortization expense for the years ended December 31, 2022 and 2021 totaled $337.3 million and $372.9 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, 2022 is as follows (in thousands):

2023	$ 255,869
2024	$ 245,751
2025	$ 232,668
2026	$ 209,532
2027	$ 134,364

Changes in the carrying amount of our goodwill for the years ended December 31, 2022 and 2021 were as follows (in thousands):

	Branded Pharmaceuticals	Sterile Injectables	Generic Pharmaceuti	International Pharmaceutica	Total
Goodwill as of January 1, 2021	$ 828,818	$ 2,731,193	—	—	$ 3,560,011
Effect of currency translation	—	—	—	—	—
Goodwill impairment charges	—	(363,000)	—	—	(363,000)
Goodwill as of December 31, 2021	$ 828,818	$ 2,368,193	—	—	$ 3,197,011
Goodwill impairment charges	—	(1,845,000)	—	—	(1,845,000)
Goodwill as of December 31, 2022	$ 828,818	$ 523,193	—	—	$ 1,352,011

Impairments

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

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 reflect 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 rates and the probability of achieving the estimated cash flows, and (ii) future economic conditions. These assumptions are based on significant inputs and judgments not observable in the market, and thus represent Level 3 measurements within the fair value hierarchy. The discount rates used in the determination of fair value reflect our judgments regarding the risks and uncertainties inherent in the estimated future cash flows and may differ over time depending on the risk profile of the particular assets and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those 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.

Annual Goodwill Impairment Tests

The Group performed its annual goodwill impairment tests as of October 1, 2022 and 2021. For the purposes of these annual tests, the Group had two reporting units with goodwill: Branded Pharmaceuticals and Sterile Injectables. The discount rates used for the Branded Pharmaceuticals reporting units in these annual tests were 15.0% and 14.5%, respectively, and the discount rates used for the Sterile Injectables reporting units in these annual tests were 19.5% and 11.0%, respectively.

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.

We did not record any other goodwill impairment charges as a result of our October 1, 2022 and 2021 annual impairment tests.

Second-Quarter 2022 Interim Goodwill Impairment Tests

Beginning in May 2022, our share price and the aggregate estimated fair value of our debt experienced significant declines. We believe these declines, which persisted through the end of the second quarter of 2022, were predominantly attributable to continuing and increasing investor and analyst uncertainty with respect to: (i) ongoing opioid and other litigation matters for which we had been unable to reach a broad-based resolution of outstanding claims and (ii) speculation surrounding the possibility of a bankruptcy filing. Further, rising inflation and interest rates unfavorably affected the cost of borrowing, which is one of several inputs used in the determination of the discount rates used in our discounted cash flow models. For example, the U.S. Federal Reserve raised its benchmark interest rate by 50 basis points in May 2022 and by an additional 75 basis points in June 2022. Taken together, we determined that these factors represented triggering events that required the performance of interim goodwill impairments tests for both our Sterile Injectables and Branded Pharmaceuticals reporting units as of June 30, 2022.

When performing these goodwill impairment tests, we estimated the fair values of our reporting units taking into consideration management's continued commitment to Endo's strategic plans and the corresponding projected cash flows, as well as the fact that management's views on litigation risk had not materially changed since our annual goodwill impairment tests performed on October 1, 2021. However, when analyzing our aggregated estimated internal valuation of our reporting units as of June 30, 2022 compared to our market capitalization and the aggregate estimated fair value of our debt, we also considered the increased level of investor and analyst uncertainty described above, coupled with our belief that investors and analysts were unlikely to modify their projections or valuation models unless or until we could demonstrate significant progression on the resolution of outstanding litigation matters and/or demonstrate that the risks of potential future strategic alternatives, including the possibility of a future bankruptcy filing, were no longer applicable. After performing this analysis, we made certain adjustments to incorporate these factors into the valuations of our reporting units, primarily through adjustments to the discount rate resulting from an increase in the group-specific risk premium (CSRP), and determined that: (i) the estimated fair value of our Sterile Injectables reporting unit was less than its carrying amount, resulting in a pre-tax non-cash goodwill impairment charge of $1,748.0 million, and (ii) while the estimated fair value declined, there was no goodwill impairment for our Branded Pharmaceuticals reporting unit, for which the estimated fair value exceeded the carrying amount by more than 10%. The discount rates used in the June 30, 2022 goodwill tests were 13.5% and 18.5% for the Branded Pharmaceuticals and Sterile Injectables reporting units, respectively.

Third-Quarter 2022 Interim Goodwill Impairment Tests

As further described in Note 2. Bankruptcy Proceedings, during the third quarter of 2022, in connection with the Sale, we received the Stalking Horse Bid, subject to higher or otherwise better bids from other parties. The value of the bid, as well as our market capitalization and the aggregate estimated fair value of our debt, was considered when determining whether it was more likely than not that the carrying amounts of one or more of our reporting units exceeded their respective fair values. Further, rising inflation and interest rates unfavorably affected the cost of borrowing, which is one of several inputs used in the determination of the discount rates used in our discounted cash flow models. For example, the U.S. Federal Reserve raised its benchmark interest rate by 75 basis points in July 2022 and by an additional 75 basis points in September 2022. Taken together, we determined that these factors represented triggering events that required the performance of interim goodwill impairments tests for both our Sterile Injectables and Branded Pharmaceuticals reporting units as of September 30, 2022.

When performing these goodwill impairment tests, we estimated the fair values of our reporting units taking into consideration management's continued commitment to Endo's strategic plans and the corresponding projected cash flows. However, when analyzing our aggregated estimated internal valuation of our reporting units as of September 30, 2022 compared to our market capitalization and the aggregate estimated fair value of our debt, as well as the par value and fair value of the Stalking Horse Bid, we made adjustments to reflect certain risks and uncertainties, including those related to the Chapter 11 Cases and the Sale, into the valuations of our reporting units, primarily through adjustments to the discount rate resulting from an increase in the CSRP, and determined that: (i) the estimated fair value of our Sterile Injectables reporting unit was less than its carrying amount, resulting in a pre-tax non-cash goodwill impairment charge of $97.0 million, and (ii) the estimated fair value of our Branded Pharmaceuticals reporting unit exceeded the carrying amount by more than 10%. The discount rates used in the September 30, 2022 goodwill tests were 15.0% and 19.5% for the Branded Pharmaceuticals and Sterile Injectables reporting units, respectively.

Fourth-Quarter 2022 Interim Goodwill Impairment Test

Beginning in late fourth-quarter 2022 and concluding in February 2023, the Group completed its annual enterprise-wide long-term strategic planning process, which resulted in updates to its projected future cash flows. Among other items, these updates primarily reflected the anticipated impacts on the Group's projected future cash flows resulting from: (i) the discontinuation of QWO®; (ii) the disruption to XIAFLEX® turnover that occurred in the second half of 2022; (iii) routine updates to our assumptions regarding anticipated competitive events for currently marketed products, as well as probabilities of success, launch timing and the anticipated competitive landscape surrounding new product launches, including with respect to TLC599 and certain product candidates in our Sterile Injectables reporting unit pipeline; (iv) expected changes in the Group's future manufacturing expense profile, including delays related to construction, FDA inspections and product transfers to our Sterile Injectables facility in Indore, India; and (v) changes in the Group's future operating expense profile. Due to the extent of the changes to the projected future cash flows, coupled with the fact that we had recorded impairments for our Sterile Injectables reporting unit during the second and third quarters of 2022, we concluded that it was more likely than not that the carrying amount of our Sterile Injectables reporting unit may exceed its fair value. As a result, an interim impairment test was performed as of December 31, 2022. The updates to the projected future cash flows did not result in an interim goodwill impairment test for our Branded Pharmaceuticals reporting unit due to the significant headroom in this reporting unit.

When performing the goodwill impairment test, we estimated the fair value of our Sterile Injectables reporting unit taking into consideration management's updated forecasts of projected cash flows, as further discussed above. The updated forecast of projected future cash flows was reduced in comparison to the prior 2022 tests. However, in reducing the cash flows, we believe the level of risk and uncertainty of the cash flows also decreased resulting in a corresponding decrease in the CSRP and, in turn, the discount rate used in the determination of fair value of our Sterile Injectables reporting unit. The discount rate used in the December 31, 2022 goodwill impairment test was 14.5%. We believe this discount rate and the other inputs and assumptions used to estimate fair value were consistent with those that a market participant would have used in light of the degree of risk associated with the updated estimated future cash flows. Consistent with the goodwill impairment tests performed earlier in 2022, we compared our aggregated estimated internal valuation of our reporting units as of December 31, 2022 to our market capitalization and the aggregate estimated fair value of our debt, as well as the par value and fair value of the Stalking Horse Bid. As a result of the December 31, 2022 test, we determined that there was no impairment of goodwill.

Other Intangible Asset Impairments

With respect to other intangible assets, we recorded asset impairment charges of $288.7 million and $7.8 million during the years ended December 31, 2022 and 2021, respectively. These pre-tax non-cash asset impairment charges related primarily to certain developed technology intangible assets that were tested for impairment following changes in market conditions and certain other factors impacting recoverability. The amount recorded in 2022 included charges related to the 2022 Restructuring Initiative, as further discussed in Note 5. Restructuring.

NOTE 12. LICENSE COLLABORATION AND ASSET ACQUISITION AGREEMENT

We have entered into certain license, collaboration and asset acquisition agreements with third parties. Generally, these agreements require us to share in the costs of developing, manufacturing, commercializing and/or selling product candidates and/or products with third parties, who in turn grant us marketing rights for such product candidates and/or products. Under these agreements we are generally required to: (i) make upfront payments and/or other payments upon successful completion of regulatory, sales and/or other milestones and/or (ii) pay royalties on sales and/or other costs arising from these agreements. We have also, from time to time, entered into agreements to directly acquire certain assets from third parties.

BioSpecifics

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 Group (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, 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.

The operating results of BioSpecifics are included in the accompanying Consolidated Profit and loss account as of December 31, 2022 and 2021 and the assets and liabilities of BioSpecifics are included in the Consolidated Balance Sheets as of December 31, 2022 and 2021.

Prior to the Merger, BioSpecifics was a biopharmaceutical company involved in the development of injectable CCH that generated turnover primarily from a 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®. Specifically, 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, of certain specified products. This royalty applied to net sales by us and/or any of our sublicensees. In addition, we 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®). Our December 2020 acquisition of BioSpecifics eliminated this third-party relationship, which had the effect of reducing royalty payments recognized in Cost of sales. The BioSpecifics acquisition also eliminated 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 development program.

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

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

(1) Represents cash consideration paid for 6,159,975 shares tendered and 1,184,980 remaining shares not tendered, but automatically cancelled and funded in an escrow account.
(2) In accordance with BioSpecifics' stock plan and employment arrangements, certain unvested options and employee bonus compensation immediately vested and accelerated, with no future service requirement, upon change in control. We have accounted for the accelerated vestings as a component of consideration transferred.
(3) Represents the total reduction to the base purchase price for the pre-acquisition accrued and unpaid royalty liability discharged on the date of closing.

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

	December 2, 2020
Cash 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 Acquired in-process 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 were the periods over which the assets were 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. Immediately 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 Group began to amortize the corresponding intangible assets prospectively on a straight-line basis over their then-anticipated useful lives, which approximated the periods of economic benefits expected to be realized from future cash flows from sales of XIAFLEX® and QWO®. The Group's accounting for these intangible assets has since been affected by certain subsequent developments, including the Group's plans announced in December 2022 that it would be ceasing the production and sale of QWO® in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration. Refer to Note 5. Restructuring for additional information.

Nevakar Agreements

In May 2022, we announced that our EVL subsidiary had entered into an agreement to acquire six development-stage RTU injectable product candidates from Nevakar Injectables, Inc., a subsidiary of Nevakar, Inc., for an upfront cash payment of $35.0 million (the 2022 Nevakar Agreement). The acquisition closed during the second quarter of 2022. The acquired set of assets and activities did not meet the definition of a business. As a result, we accounted for the transaction as an asset acquisition. Upon closing, the upfront payment was recorded as Acquired in-process research and development in the Consolidated Profit and loss account.

The product candidates, which relate to our Sterile Injectables segment, are in various stages of development. The first commercial launch is expected in 2025; however, there can be no assurance this will occur within this timeframe or at all. With this acquisition, the Group will control all remaining development, regulatory, manufacturing and commercialization activities for the acquired product candidates.

In August 2022, within the ongoing bankruptcy proceedings, EVL filed an adversary proceeding (the Nevakar Litigation) against Nevakar, Inc. and Nevakar Injectables Inc. (collectively, Nevakar) to enforce: (i) a 2018 development, license and commercialization agreement (the 2018 Nevakar Agreement) and (ii) the 2022 Nevakar Agreement. In September 2022, Nevakar filed counterclaims against EVL. In December 2022, EVL and Nevakar reached a settlement with respect to the Nevakar Litigation (the Nevakar Settlement) subject to Bankruptcy Court approval. The Nevakar Settlement provided for the amendment of the 2018 Nevakar Agreement to revoke EVL's license of two products covered by the 2018 Nevakar Agreement, modify EVL's license to the remaining three products covered by the 2018 Nevakar Agreement to reduce the royalty owed to Nevakar, terminate any obligations of EVL to make payments to Nevakar upon achievement of contingent milestones and eliminate Nevakar's ability to terminate the remaining licenses for EVL's breach or material breach. The Nevakar Settlement also provided that EVL and Nevakar would agree to a mutual release of certain claims under both the 2018 Nevakar Agreement and the 2022 Nevakar Agreement. The Nevakar Settlement was approved by the Bankruptcy Court in January 2023. The Nevakar Settlement had no effect on our Consolidated Financial Statements in 2022.

In the first quarter of 2023, the Company concluded that the Nevakar Amendment met the definition of a nonmonetary exchange. The Nevakar Amendment did not result in the sale or acquisition of additional rights by the Company. The Company determined that the estimated value of the product rights revoked is approximately equal to the estimated reduction in the future royalty costs associated with the three products retained. There was no carrying value associated with the revoked product rights as the associated payments to Nevakar were previously expensed as Acquired in-process research and development. Based on these factors, the Nevakar Amendment had no effect on our Condensed Consolidated Financial Statements for the three months ended March 31, 2023.

TLC Agreement

In June 2022, we announced that our EVL subsidiary had entered into an agreement with TLC to commercialize TLC599 (the TLC Agreement). We are accounting for the agreement as an asset acquisition. TLC599 is an injectable compound in Phase 3 development for the treatment of osteoarthritis knee pain.

Under the terms of the TLC Agreement, TLC is primarily responsible for the development of the product and we are primarily responsible for obtaining regulatory approval and for commercialization of the product in the U.S. Upon receipt of regulatory approval, if obtained, we will have exclusive rights to manufacture, market, sell and distribute the product in the U.S.

During the second quarter of 2022, we made an upfront payment of $30.0 million to TLC and recorded a corresponding charge to Acquired in-process research and development in the Consolidated Profit and loss account. TLC is also eligible to receive: (i) payments of up to an additional $110.0 million based on the achievement of certain development, regulatory and manufacturing milestones related to the initial indication for the treatment of osteoarthritis knee pain; (ii) payments of up to an additional $30.0 million based on the achievement of certain development and regulatory milestones related to certain potential future indications; (iii) payments of up to an additional $500.0 million based on the achievement of certain commercial milestones; and (iv) tiered royalties based on net sales of TLC599 in the U.S. Unless terminated earlier or extended, the term of the TLC Agreement generally extends until the 20-year anniversary of the first commercial sale of TLC599.

Pursuant to the terms of the TLC Agreement, we have deposited approximately $85.0 million of cash into a bank account which may be used to fund certain future obligations under the TLC Agreement or returned to us upon satisfaction of certain conditions. As further described in Note 7. Fair Value Measurements, this amount is considered restricted cash as of December 31, 2022 and is included in our Consolidated Balance Sheets at December 31, 2022 as Other assets.

In September 2022, we were informed by TLC of the top-line results from TLC's Phase 3 clinical study to evaluate the efficacy and safety of TLC599 in patients with pain from osteoarthritis of the knee. While study participants treated with TLC599 showed improvement on the primary endpoint (change from baseline to week 12 on the WOMAC pain scale) consistent with the level of improvement reported in the previously conducted TLC599 Phase 2 clinical study, the difference compared to those receiving placebo was not statistically significant. Based on these data, we are evaluating options for TLC599 with TLC.

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, 2022, the unfulfilled performance obligations for these types of contracts relate to ordered but undelivered products. We generally expect to fulfill the performance obligations and recognize 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 income-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, 2022	December 31, 2021	$ Change	% Change
Contract assets (1)	$ 8,193	$ 13,005	$ (4,812)	(37)%
Contract liabilities (2)	$ 4,099	$ 4,663	$ (564)	(12)%

(1) At December 31, 2022 and December 31, 2021, approximately $1.5 million and $2.8 million, respectively, of these contract asset amounts are classified as current and are included in Prepaid expenses and other current assets in the Group's Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other assets. The net decrease in contract assets during the year ended December 31, 2022 primarily relates to: (i) reclassifications of certain amounts to receivables as a result of rights to consideration becoming unconditional and (ii) net changes in estimates with respect to amounts of consideration expected to be received from sales of certain intellectual property rights.

(2) At December 31, 2022 and December 31, 2021, approximately $0.6 million and $0.6 million, respectively, of these contract liability amounts are classified as current and are included in Accounts payable and accrued expenses in the Group's Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other liabilities. During the year ended December 31, 2022, approximately $0.6 million of turnover was recognized that was included in the contract liability balance at December 31, 2021.

During the year ended December 31, 2022, we recognized turnover of $11.9 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, 2022 and December 31, 2021 (dollars in thousands):

	December 31, 2022			December 31, 2021		
	Effective Interest Rate (1)	Principal Amount (2)	Carrying Amount (2)	Effective Interest Rate	Principal Amount	Carrying Amount
7.25% Senior Notes due 2022		$ —	$ —	7.25 %	$ 8,294	$ 8,294
5.75% Senior Notes due 2022		—	—	5.75 %	172,048	172,048
5.375% Senior Notes due 2023	5.38 %	6,127	6,127	5.62 %	6,127	6,111
6.00% Senior Notes due 2023	6.00 %	56,436	56,436	6.28 %	56,436	56,203
5.875% Senior Secured Notes due 2024	6.88 %	300,000	286,375	6.14 %	300,000	297,928
6.00% Senior Notes due 2025	6.00 %	21,578	21,578	6.27 %	21,578	21,413
7.50% Senior Secured Notes due 2027	8.50 %	2,015,479	1,894,774	7.70 %	2,015,479	1,997,777
9.50% Senior Secured Second Lien Notes due 2027	9.50 %	940,590	940,590	9.68 %	940,590	933,330
6.00% Senior Notes due 2028	6.00 %	1,260,416	1,260,416	6.11 %	1,260,416	1,252,667
6.125% Senior Secured Notes due 2029	7.13 %	1,295,000	1,230,799	6.34 %	1,295,000	1,278,718
Term Loan Facility	13.50 %	1,975,000	1,871,894	6.12 %	1,985,000	1,947,633
Revolving Credit Facility	11.00 %	277,200	265,728	2.63 %	277,200	277,200
Total (3)		$ 8,147,826	$ 7,834,717		$ 8,338,168	$ 8,249,322

(1) As noted below, beginning on the Petition Date, we ceased recognition of interest expense related to all of our debt instruments and began to incur "adequate protection payments" (further discussed below) related to our First Lien Debt Instruments (representing all of our debt instruments except for our senior unsecured notes and the 9.50% Senior Secured Second Lien Notes due 2027). The December 31, 2022 "effective interest rates" included in the table above represent the rates in effect on such date used to calculate: (i) future adequate protection payments related to our First Lien Debt Instruments and (ii) future contractual interest related to our other debt instruments, notwithstanding the fact that such interest is not currently being recognized. These rates are expressed as a percentage of the contractual principal amounts outstanding as of such date and, with respect to our First Lien Debt Instruments, without consideration of any reductions related to adequate protection payments made through such date.

(2) The December 31, 2022 principal amounts represent the amount of unpaid contractual principal owed on the respective instruments. During the third quarter of 2022, in accordance with ASC 852, we adjusted the carrying amounts of all unsecured and potentially undersecured debt instruments to equal the expected amount of the allowed claim by expensing (within Reorganization items, net in the Consolidated Profit and loss account) $89.2 million of previously-deferred and unamortized costs associated with these instruments. The December 31, 2022 carrying amounts of our First Lien Debt Instruments also reflect reductions for certain adequate protection payments made since the Petition Date, as further discussed herein.

(3) As of December 31, 2022, the entire carrying amount our debt, as well as any related remaining accrued and unpaid interest that existed as of the Petition Date, is included in the Liabilities subject to compromise line in the Consolidated Balance Sheets. As of December 31, 2021, $200.3 million of the carrying amount of our debt is classified as a current liability and is included in the Current portion of long-term debt line in the Consolidated Balance Sheets. The remaining carrying amount of our debt as of December 31, 2021 is included in the Long-term debt, less current portion, net line in the Consolidated Balance Sheets.

General Information

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, 2022. The obligations under: (i) the 5.875% Senior Secured Notes due 2024; (ii) the 7.50% Senior Secured Notes due 2027; (iii) the 6.125% Senior Secured Notes due 2029; and (iv) the Credit Agreement 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 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 $4.9 billion and $8.0 billion at December 31, 2022 and December 31, 2021, respectively. Based on this valuation methodology, we determined these debt instruments represent Level 2 measurements within the fair value hierarchy.

Credit Facilities

The Group and certain of its subsidiaries are party to the Credit Agreement, which immediately following the March 2021 Refinancing Transactions 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, 2022 under the Credit Facilities are set forth in the table above.

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, at which time the remaining principal amount outstanding is payable. Based on the Group's borrowings under the Revolving Credit Facility outstanding at December 31, 2022, $74.6 million generally matures in 2024, with the remainder generally maturing in 2026.

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 London Interbank Offered Rate (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.

The foregoing summary, which does not purport to be complete, is based on the terms of the Credit Agreement. Refer to the "Covenants, Events of Default and Bankruptcy-Related Matters" section below for a discussion of the effects of the ongoing bankruptcy proceedings and the related event of default on the Credit Facilities.

Senior Notes and Senior Secured Notes

The various senior notes and senior secured notes outstanding as of December 31, 2022 generally mature between 2023 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. The foregoing summary, which does not purport to be complete, is based on the terms of the indentures governing our various senior notes and senior secured notes. Refer to the "Covenants, Events of Default and Bankruptcy-Related Matters" section below for a discussion of the effects of the ongoing bankruptcy proceedings and the related event of default on our various senior notes and senior secured notes.

Covenants, Events of Default and Bankruptcy-Related Matters

The agreements relating to our outstanding indebtedness contain certain covenants and events of default.

Beginning during the second quarter of 2022, we elected to not make the following interest payments on or prior to their scheduled due dates: (i) approximately $38 million that was due on June 30, 2022 with respect to our outstanding 6.00% Senior Notes due 2028; (ii) approximately $2 million that was due on July 15, 2022 with respect to our outstanding 5.375% Senior Notes due 2023 and 6.00% Senior Notes due 2023; (iii) approximately $45 million that was due on July 31, 2022 with respect to our outstanding 9.50% Senior Secured Second Lien Notes due 2027; and (iv) approximately $1 million that was due on August 1, 2022 with respect to our outstanding 6.00% Senior Notes due 2025. Under each of the indentures governing these notes, we had a 30-day grace period from the respective due dates to make these interest payments before such non-payments constituted events of default with respect to such notes. We chose to enter these grace periods while continuing discussions with certain creditors in connection with our evaluation of strategic alternatives. Our decision to enter these grace periods was not driven by liquidity constraints. We made the interest payment of approximately $38 million that became due on June 30, 2022 with respect to our outstanding 6.00% Senior Notes due 2028 on July 28, 2022, which was prior to the end of the applicable grace period. We also made the interest payments totaling approximately $2 million that became due on July 15, 2022 with respect to our outstanding 5.375% Senior Notes due 2023 and 6.00% Senior Notes due 2023 on August 11, 2022, which was prior to the end of the applicable grace periods.

On the Petition Date, the Debtors filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code.

As a result of the Chapter 11 Cases, since the Petition Date, we have not made, and we are not currently making, any scheduled principal or interest payments on the Credit Facilities or our various senior notes and senior secured notes. We are however making certain adequate protection payments as further discussed below. Additionally, as a result of the Chapter 11 Cases, all remaining commitments under the Revolving Credit Facility have been terminated.

The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated. Because the Group has not yet obtained approval by the Bankruptcy Court regarding such transactions, there remains uncertainty with respect to the ability of our creditors, including our secured and unsecured debt holders, to recover the full amount of their claims against us. As a result, all secured and unsecured debt instruments have been classified as Liabilities subject to compromise in our Consolidated Balance Sheets as of December 31, 2022 and we ceased the recognition of interest expense related to these instruments as of the Petition Date. During 2022, we did not recognize approximately $231 million of contractual interest expense that would have been recognized if not for the Chapter 11 Cases.

As part of the RSA that is further discussed in Note 2. Bankruptcy Proceedings, the Group and the Ad Hoc First Lien Group agreed on the terms of a proposed order authorizing the Group's use of cash collateral (as modified and entered by the Bankruptcy Court on a final (amended) basis in October 2022, the Cash Collateral Order) in connection with the Chapter 11 Cases on certain terms and conditions set forth therein.

Pursuant to the Cash Collateral Order, we are obligated to make certain adequate protection payments during our bankruptcy proceedings on each of our First Lien Debt Instruments. These adequate protection payments include the payment of amounts equal to any accrued and unpaid interest that existed as of the Petition Date by no later than eight business days after entry of the interim Cash Collateral Order, as well as the following payments, to be paid on the last business day of each calendar month, calculated based upon a rate of:

- with respect to the Revolving Credit Facility and the Term Loan Facility, 200 basis points plus: (i) if denominated in dollars, ABR plus the Applicable Rate (each as defined in the Credit Agreement), or (ii) if denominated in Canadian dollars, the Canadian Prime Rate plus the Applicable Rate (each as defined in the Credit Agreement); and
- with respect to the applicable senior secured notes, 100 basis points plus the applicable rate of interest set forth on the face of the applicable note.

The rates in the foregoing bullet points, which are used to calculate any applicable adequate protection payments, are expressed as a percentage of the contractual principal amounts outstanding without consideration of any reductions related to adequate protection payments. On a cumulative basis through December 31, 2022, we made the following adequate protection payments pursuant to the Cash Collateral Order:

- $11.5 million with respect to the Revolving Credit Facility;
- $103.1 million with respect to the Term Loan Facility; and
- $198.5 million with respect to the applicable senior secured notes.

As required by ASC 852, these adequate protection payments are recorded as a reduction of the carrying amount of the respective First Lien Debt Instruments, which are classified as Liabilities subject to compromise. This accounting treatment is due to the aforementioned uncertainties with respect to the ultimate outcome of the bankruptcy proceedings, including the proposed Sale transaction, which in turn creates uncertainties surrounding the first lien debt holders' ability to recover in full the amount of outstanding principal associated with those instruments. Some or all of the adequate protection payments may later be recharacterized as interest expense depending upon certain developments in the Chapter 11 Cases.

In addition to the terms described above, the Cash Collateral Order, among other things, establishes a budget for the Debtors' use of cash collateral, establishes certain informational rights for the Debtors' secured creditors and provides for the waiver of certain Bankruptcy Code provisions. The foregoing description of the Cash Collateral Order does not purport to be complete and is qualified in its entirety by reference to the Cash Collateral Order entered by the Bankruptcy Court in the Chapter 11 Cases.

Debt Financing Transactions

Set forth below are certain disclosures relating to debt financing transactions that occurred during the years ended December 31, 2022, 2021 and 2020.

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 began to be amortized over the respective terms of the new notes; this continued until the initiation of our bankruptcy proceedings during the third quarter of 2022, at which time the remaining unamortized costs were expensed as Reorganization items, net in the Consolidated Profit and loss account. 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 in aggregate principal of 5.75% Senior Notes due 2022 pursuant to a 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 $2,000.0 million portion of the Term Loan Refinancing associated with the new term loan was accounted for as a debt modification, while the $1,295.0 million portion associated with the new notes issued was accounted for as an extinguishment. During the first quarter of 2021, in connection with the Term Loan Refinancing, $7.8 million of deferred and unamortized costs associated with the Existing Term Loans, representing the portion associated with the extinguishment, was charged to expense and is included in the Loss on extinguishment of debt line item in the 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 were initially deferred to be amortized as interest expense over the terms of the Term Loan Facility and the newly issued 6.125% Senior Secured Notes due 2029, respectively; (ii) $6.0 million was considered debt extinguishment costs and was charged to expense in the first quarter of 2021 and is included in the Loss on extinguishment of debt line item in the 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 is included in the Selling, general and administrative expense line item in the Consolidated Profit and loss account. The deferred amounts were being amortized as interest expense until the initiation of our bankruptcy proceedings during the third quarter of 2022, at which time the remaining unamortized costs were expensed as Reorganization items, net 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 and January 2022 Senior Notes Repayments

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

As noted above, the initiation of our bankruptcy proceedings constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. The following table presents, as of December 31, 2022, for each of the five fiscal years subsequent to December 31, 2022, the stated maturities on our long-term debt that would have been applicable if not for such acceleration (in thousands):

	Maturities (1)
2023	$ 82,563
2024 (2)	$ 394,600
2025	$ 41,578
2026 (2)	$ 222,600
2027	$ 2,976,069

(1) The terms of the Credit Agreement provide that 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. The amounts in this maturities table do not reflect any potential early repayments or refinancings.

(2) Based on the Group's borrowings under the Revolving Credit Facility that were outstanding at December 31, 2022, $74.6 million would have matured in 2024, with the remainder maturing in 2026.

As discussed above, as a result of the Chapter 11 Cases, since the Petition Date, we have not made, and we are not currently making, any scheduled principal or interest payments on the Credit Facilities or our various senior notes and senior secured notes. Therefore, the timing and amount of any future principal and interest payments is uncertain. The table above excludes $10.0 million of principal outstanding on our Term Loan Facility that, pursuant to the terms of the Credit Agreement, matured on or before December 31, 2022 but has not yet been paid as a result of the Chapter 11 Cases.

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). 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. Certain qualifying costs are eligible for reimbursement by the U.S. government under a cost share arrangement, generally within 30 days of us submitting requests for reimbursement. The Group must generally incur the costs before subsequently seeking reimbursement of qualifying costs from the U.S. government. Amounts reimbursed are subject to audit and may be recaptured by the U.S. government in certain circumstances.

Construction is currently in progress. During the year ended December 31, 2022, we incurred approximately $39.0 million of costs associated with the U.S. Government Agreement. Additional information about such costs is included below:

- Approximately $34.9 million has been capitalized and recorded as tangible fixed assets, net in our Consolidated Balance Sheets as of December 31, 2022. We have also recorded deferred income of approximately $26.5 million, representing the reimbursable portion of the costs incurred, which is included in Other liabilities in our Consolidated Balance Sheets as of December 31, 2022.
- Approximately $1.0 million has been charged to expense during the year ended December 31, 2022, with the majority of such expense included within Selling, general and administrative expenses and Cost of sales in our Consolidated Profit and loss account. This amount is net of approximately $3.1 million, representing the reimbursable portion of costs incurred.

Amounts included in our Consolidated Financial Statements as of and for the year ended December 31, 2021 were not material.

We currently estimate that between approximately one-quarter and one-third of our expected capital expenditures related to this agreement, as well as the corresponding reimbursements from the U.S. government, have occurred through December 31, 2022. We currently anticipate that facility readiness will occur in 2025, but there can be no assurance this will occur.

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 HHS 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. Refer to Note 3. Summary of Significant Accounting Policies for additional information about our accounting for the U.S. Government Agreement.

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. An adverse outcome in certain proceedings described herein could have a material adverse effect on our business, financial condition, results of operations and cash flows. We are also 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.

As further discussed in Note 2. Bankruptcy Proceedings, on the Petition Date, certain of the Debtors filed voluntary petitions for relief under the Bankruptcy Code. Certain additional Debtors filed voluntary petitions for relief under the Bankruptcy Code on May 25, 2023 and May 31, 2023. Under the Bankruptcy Code, third-party actions to collect pre-petition indebtedness owed by the Debtors, as well as most litigation pending against the Debtors as of the Petition Date, are generally subject to an automatic stay. However, under the Bankruptcy Code, certain legal proceedings, such as those involving the assertion of a governmental entity's police or regulatory powers, may not be subject to the automatic stay and may continue unless otherwise ordered by the Bankruptcy Court. As a result, some proceedings may continue (or certain parties may attempt to argue that such proceedings should continue) notwithstanding the automatic stay. Where no stay is in place or expected, and in the event the stays in place were to be lifted, we intend to vigorously prosecute or defend our position as appropriate. We cannot predict the outcome of any proceeding, and there can be no assurance that we will be successful or obtain any requested relief.

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. 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. 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. 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.

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. 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. The failure to generate sufficient cash flow or to obtain other financing could affect our ability to pay 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. Finally, as set forth in the stipulation filed with the Bankruptcy Court on March 24, 2023 (see Note 2. Bankruptcy Proceedings), our ability to access certain insurance proceeds may be impacted by the resolution reached between the Ad Hoc First Lien Group and the UCC.

As of December 31, 2022, our accrual for loss contingencies totaled $863.8 million, the most significant components of which relate to: (i) various opioid-related matters as further described herein and (ii) product liability and related matters associated with transvaginal surgical mesh products, which we have not sold since March 2016. Although we believe there is a possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. As of December 31, 2022, our entire accrual for loss contingencies is classified as Liabilities subject to compromise in the Consolidated Balance Sheets. As a result of the automatic stay under the Bankruptcy Code and the uncertain treatment of these liabilities pursuant to a chapter 11 plan or otherwise, the timing and amount of payment, if any, related to the amounts accrued for loss contingencies is uncertain.

As part of the Chapter 11 Cases, persons and entities believing that they have claims or causes of action against the Debtors, including litigants, may file proofs of claim evidencing such claims. On April 3, 2023, the Bankruptcy Court entered the Bar Date Order, as subsequently amended on June 23, 2023 and July 14, 2023, setting July 7, 2023 as the general bar date (deadline) for persons and non-governmental entities to file proofs of claim against the Debtors. The Bankruptcy Court also set May 31, 2023 as the bar date for governmental entities to file claims other than certain claims relating to opioids against the Debtors. Certain claims, including most governmental claims relating to opioids, are subject to separate bar date procedures as set forth in more detail in the Bar Date Order.

At the Debtors' request, the Bankruptcy Court has appointed the FCR in the Chapter 11 Cases. As further described in the applicable Bankruptcy Court filings, the FCR represents the rights of individuals who may in the future assert one or more personal injury claims against the Debtors or a successor of the Debtors' businesses relating to the Debtors' opioid, or transvaginal mesh, , but who could not assert such claims in the Chapter 11 Cases because, among other reasons, such individuals were unaware of the alleged injury, had a latent manifestation of the alleged injury or were otherwise unable to assert or incapable of asserting claims based on the alleged injury. Although the FCR was initially appointed to represent the rights of individuals who may in the future assert one or more personal injury claims against the Debtors or a successor of the Debtors' businesses relating to the Debtors' ranitidine products, in August 2023 the Bankruptcy Court entered an order terminating the FCR's appointment with respect to claims relating to the Debtors' ranitidine products.

Vaginal Mesh Matters

Since 2008, we and certain of our subsidiaries, including American Medical Systems Holdings, Inc. (AMS) (which subsequently converted to Astora Women's Health Holdings, LLC and merged into Astora Women's Health LLC (Astora)), have been named as defendants in multiple lawsuits in various state and federal courts in the U.S., and in the United Kingdom, 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.

At various times from June 2013 through the Petition Date, the Group and/or certain of its subsidiaries entered into various Master Settlement Agreements (MSAs) and other agreements intended to resolve approximately 71,000 filed and unfiled U.S. mesh claims. These MSAs and other agreements 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 were subject to a process that included guidelines and procedures for administering the settlements and the release of funds. In certain cases, the MSAs provided for the creation of QSFs into which settlement funds were deposited, established participation requirements and allowed for a reduction of the total settlement payment in the event participation thresholds were not met. In certain circumstances, participation requirements or other conditions for payment were not satisfied prior to the Petition Date. Funds deposited in QSFs are considered restricted cash and/or restricted cash equivalents. Distribution of funds to any individual claimant was 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 was required to represent and warrant that liens, assignment rights or other claims identified in the claims administration process have been or will be satisfied by the individual claimant. Confidentiality provisions applied 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, 2022 (in thousands):

	Mesh Qualified Settlement Funds	Mesh Liability Accrual
Balance as of December 31, 2021	$ 78,402	$ 258,137
Cash received for reversionary interests, net of cash contributions to Qualified Settlement Funds	(367)	—
Cash distributions to settle disputes from Qualified Settlement Funds	(28,159)	(28,159)
Other cash distributions to settle disputes	—	(6,499)
Other (1)	463	(507)
Balance as of December 31, 2022 (2)	$ 50,339	$ 222,972

(1) Amounts deposited in the QSFs earn interest from time to time that is reflected in the table above as an increase to the QSF and Mesh Liability Accrual balances. Subject to any restrictions on making payments as a result of the Chapter 11 Cases, such interest is generally used to pay administrative costs of the funds and 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.

(2) As of December 31, 2022, this balance is classified as Liabilities subject to compromise in the Consolidated Balance Sheets.

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, 2022, the Group has made total cumulative mesh liability payments of approximately $3.6 billion, $50.3 million of which remains in the QSFs as of December 31, 2022. In light of the filing of petitions for relief under the Bankruptcy Code, we do not expect to make new payments under 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.

On June 29, 2023, the Group filed a motion in the Bankruptcy Court seeking: (i) confirmation that the automatic stay does not apply to certain distributions to mesh claimants under the QSFs and (ii) authorization to request the return of the QSF funds to relevant parties (the QSF Motion). On July 25, 2023, the Bankruptcy Court entered an order confirming that the automatic stay does not apply to certain distributions from QSFs for mesh claimants for whom the Group does not have a reversionary interest, as scheduled in the QSF Motion, and authorizing the Group to request the return of the QSF funds for the mesh claimants who did not object to the QSF Motion. Objecting mesh claimants will have until August 17, 2023 to file a formal objection to the QSF Motion unless otherwise agreed by the Group and such claimants.

As of the Petition Date, mesh personal injury claims against AMS and Astora in the U.S., became subject to the automatic stay applicable under the Bankruptcy Code, and stays of mesh litigation have been obtained in the United Kingdom and Australia. In certain other countries where no stay is in place, and in the event the stays in place were to be lifted, we will continue to vigorously defend any unresolved claims and to explore other options as appropriate in our best interests.

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.

The resolution reached between the Stalking Horse Bidder and the UCC contemplates the creation and funding of a trust by the Purchaser for the benefit of certain unsecured creditors and sub-trusts established thereunder, one of which shall be established for the benefit of certain mesh claimants. Additionally, on April 13, 2023, the Stalking Horse Bidder and the FCR filed a resolution with the Bankruptcy Court that contemplates that, after the Sale, the Purchaser will establish and fund, with an aggregate amount of $0.5 million, a trust for certain future mesh claimants in exchange for certain releases to be provided to (among others) the Purchaser and Endo International plc, its subsidiaries and affiliated entities and persons. As previously noted, the Stalking Horse Bid is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed sale transaction to the Purchaser, and the funding of the voluntary mesh claims-related sub-trusts (including the trusts for certain future mesh claimants) by the Purchaser, will actually occur. Additionally, similar matters to the foregoing 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 allowed claim amount associated with all mesh-related matters as of the date of this report, it is reasonably possible 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 EVU, 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 August 1, 2023, pending cases in the U.S. of which we were aware include, but are not limited to, approximately 15 cases filed by or on behalf of states; approximately 2,570 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 220 cases filed by individuals, including but not limited to legal guardians of children born with neonatal abstinence syndrome. Certain of the U.S. cases are putative class actions. 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 on behalf of a proposed class of all local or municipal governments in Canada; an action filed in Saskatchewan on behalf of a proposed class of all First Nations communities and local or municipal governments in Canada; and three additional putative class actions, filed in British Columbia, 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 seek 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. Following the Petition Date, litigation activity against the Group and its subsidiaries ceased in nearly all pending cases as a result of the automatic stay and a November 2022 preliminary injunction order issued by the Bankruptcy Court. In June 2023, the Company requested that the Bankruptcy Court extend the preliminary injunction by a further 180 days. The Bankruptcy Court is expected to rule on the Company's request in August 2023. A similar cessation of litigation activity is in place in Canada.

In June 2020, the New York State Department of Financial Services (DFS) commenced an administrative action against the Company, EPI, EHSI, PPI and PPCI alleging violations of the New York Insurance Law and New York Financial Services Law. In July 2021, DFS filed an amended statement of charges. The amended statement of charges alleges that fraudulent or otherwise wrongful conduct in the marketing, sale and/or distribution of opioid medications caused false claims to be submitted to insurers. DFS 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 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 petition, which the court granted in June 2022. The Group's subsidiaries, among others, appealed that ruling in July 2022. Both the appeal and the DFS administrative matter were stayed following commencement of the Chapter 11 Cases.

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

- In September 2019, EPI, EHSI, PPI and PPCI executed a settlement agreement with two Ohio counties providing for payments totaling $10 million and up to $1 million of VASOSTRICT® and/or ADRENALIN®. The settlement amount was paid during the third quarter of 2019.
- In January 2020, EPI and PPI executed a settlement agreement with the state of Oklahoma providing for a payment of $8.75 million. The settlement amount was paid during the first quarter of 2020.
- 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. The settlement amount was paid during the third quarter of 2021.
- 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. The settlement amount was paid during the third quarter of 2021.
- 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, subject to certain participation thresholds. The settlement amount was not paid as of the Petition Date and, as a result of the Chapter 11 Cases, it is not known when or if such amount will be paid.
- 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, subject to certain participation thresholds. The settlement amount was deposited into a QSF during the first quarter of 2022.
- 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, subject to certain participation thresholds. The settlement amount was deposited into a QSF during the second quarter of 2022.
- 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, subject to certain participation thresholds. The settlement amount was not paid as of the Petition Date and, as a result of the Chapter 11 Cases, it is not known when or if such amount will be paid.
- 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, subject to certain participation thresholds. The settlement amount was not paid as of the Petition Date and, as a result of the Chapter 11 Cases, it is not known when or if such amount will be paid.
- In June 2022, EPI and EHSI executed a settlement agreement with the Arkansas Attorney General's office and certain Arkansas local governments intended to resolve opioid-related cases and claims of the state and other Arkansas governmental persons and entities in exchange for a total payment of $9.75 million, subject to certain participation thresholds. With the exception of certain amounts held back pursuant to an MDL common benefit fund order, the settlement amount was paid during the third quarter of 2022.

- In July 2022, EPI and EHSI executed a settlement agreement with the Mississippi Attorney General's office intended to resolve opioid-related cases and claims of the state and other Mississippi governmental persons and entities in exchange for a total payment of $9 million, subject to certain participation thresholds. The settlement amount was not paid as of the Petition Date and, as a result of the Chapter 11 Cases, it is not known when or if such amount will be paid.
- In July 2022, EPI, EHSI, PPI and PPCI executed a settlement agreement with the City and County of San Francisco providing for an initial payment of $5 million and subsequent payments of $500,000 a year over ten years. The settlement amount was not paid as of the Petition Date and, as a result of the Chapter 11 Cases, it is not known when or if such amount will be paid.

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

Certain of the settlement agreements described above provide for injunctive relief. The RSA also provides for certain voluntary injunctive terms that bind the Debtors during the course of the bankruptcy proceedings and would apply to any purchaser of our opioid business in conjunction with the bankruptcy proceedings. The Bankruptcy Court also approved certain injunctive terms in connection with its November 2022 preliminary injunction against the continued litigation of opioid actions brought by public plaintiffs.

The Stalking Horse Bid provides for the establishment by the Purchaser of voluntary opioid trusts for the benefit of certain public, tribal and private present and future opioid claimants in exchange for certain releases to be provided to (among others) the Purchaser and Endo International plc, its subsidiaries and affiliated entities and persons. In particular, under the RSA (as amended), the opioid trusts would distribute up to a total of $611 million over ten years to eligible claimants that opt into the trusts by specified participation deadlines. Under the proposed public claimant opioid trust, states which previously entered into settlement agreements and received payments from us may elect to participate in the trust. In doing so, those states would agree to return the amounts previously received under the prior settlement agreement(s), net of the amounts allocated to them by the trust, and would receive in return a release from any claim for the return of settlement funds under the applicable section of the Bankruptcy Code. The Debtors would have no obligation or liability with respect to the voluntary trusts, which would be funded exclusively by the Purchaser following the consummation of the Sale. As previously noted, the Sale to the Stalking Horse Bidder is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed sale transaction to the Purchaser, and the funding of the voluntary opioid trusts by the Purchaser, (including the trusts for certain future opioid claimants), will actually occur.

Although the proposed voluntary opioid trusts would be funded by the Purchaser, and not by the Group or any of its subsidiaries, we previously concluded that the proposed funding amount in the Stalking Horse Bid represented the best estimate of the allowed claims related to the contingencies associated with various opioid claims against the Group and its subsidiaries. As such, during the third quarter of 2022, we recorded charges of approximately $419 million to adjust our aggregate opioid liability accrual to approximately $550 million based on the terms set forth in the public opioid trust term sheet attached to the original RSA. In March 2023, the Ad Hoc First Lien Group (and Stalking Horse Bidder) reached certain resolutions in principle with both the UCC and OCC appointed in the Chapter 11 Cases and certain ad hoc groups of debtholders. These resolutions, documented in the stipulation filed with the Bankruptcy Court on March 24, 2023 (and discussed in additional detail under "Resolutions in the Chapter 11 Cases" in Note 2. Bankruptcy Proceedings), are supported by the Debtors. The resolutions include, among other things, a $34 million increase to the funding amount for the proposed voluntary private opioid trust. In addition, the Ad Hoc First Lien Group agreed to a $15 million increase to the funding amount for the proposed voluntary public opioid trust. The agreement to increase the funding amount for the proposed voluntary private opioid trust was announced prior to the filing of the Annual Report; accordingly, we recorded an additional charge of $34 million in the fourth quarter of 2022 to increase our aggregate opioid liability accrual to approximately $584 million. The agreement to increase the funding amount for the proposed voluntary public opioid trust was not announced until after the filing of the Annual 10-K Report. Therefore, we recorded an additional charge of $15 million in the first quarter of 2023 to increase our aggregate opioid liability accrual to approximately $599 million. This $15million was reflected on the Consolidated Irish Financial Statements at 31-December 2022 see subsequent events disclosure for this change between the 10 K Annual Report and the Irish Consolidated Financial Statements. On July 13, 2023, the Stalking Horse Bidder and the FCR filed with the Bankruptcy Court both a term sheet for a proposed resolution among such parties (the FCR Term Sheet) and an amended term sheet for the proposed voluntary private opioid trust. The resolution with the FCR provides that, in exchange for certain releases to be provided to (among others) the Purchaser and the Company and its affiliates, the Purchaser will agree to fund a trust of $11.5 million to be established for the benefit of certain future opioid claimants. The amended term sheet for the proposed voluntary private opioid trust provides for a $0.5 million increase to the funding amount for the proposed voluntary private opioid trust. Accordingly, we recorded an additional charge of $12 million to increase our aggregate opioid liability to approximately $611 million in the Consolidated Irish Financial Statements at 31-December 2022. Refer to subsequent events disclosure for this change between the 10 K Annual Report and the Irish Consolidated Financial Statements. The Group believes this modified proposed funding amount represents the best estimate of the allowed claims related to the contingencies associated with various opioid claims against the Group and its subsidiaries. Certain interested parties, including the U.S. Department of Justice (DOJ), continue to engage in the mediation in an effort to resolve their claims and/or objections relating to the sale process. The ongoing mediation, which is currently extended to August 14, 2023, could result in additional valuations or estimates in the future that may result in further adjustments to our estimated aggregate opioid liability accrual, which could be material.

To the extent unresolved, and in the event stays in place were to be lifted, we will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests, which may include 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 additional losses that could be incurred. Adjustments to the expected amount of the allowed claim 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. Some of these state attorneys general subsequently filed lawsuits against the Group and/or its subsidiaries and/or have indicated their support for the opioid trusts described above. To the extent any state attorney general investigations are continuing, we are cooperating with them.

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

In December 2020, the Group received a 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 the expected amount of the allowed claim 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 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 but not limited to California, Illinois and Pennsylvania. Neither PPI nor its subsidiaries have 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 a third-party payer pursuing class action claims, appealed the dismissal orders . PPI was dismissed from the third-party payer appeal in September 2022. In November 2022, the U.S. Court of Appeals for the Eleventh Circuit. affirmed the dismissal of the third-party payer complaint and dismissed the other appeals on procedural grounds.

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. At various times thereafter, certain MDL plaintiffs appealed the July 2021 dismissal order and/or the November 2021 judgment. These appeals generally remain pending, although PPI has been dismissed from certain of them.

In December 2022, the MDL court granted summary judgment in favor of certain remaining defendants with respect to five "designated cancers" (bladder, esophageal, gastric, liver and pancreatic), holding that plaintiffs had failed to provide sufficient evidence of causation. Various MDL plaintiffs subsequently appealed this order. Voluntary motions to dismiss PPI are pending in certain of those appeals.

On May 15, 2023, the MDL court issued orders extending its December 2022 summary judgment ruling to all MDL defendants. In July 2023, the MDL court entered an order dismissing plaintiffs' non-designated cancer claims, for failure to produce expert reports,as well as a tentative order that would enter final judgments in all cases asserting designated-cancer claims in which judgment had not previously been entered.

In July 2022, claimants alleging non-designated cancer claims were "exited" from the MDL census registry. Some of these claimants subsequently filed lawsuits in various courts. Following the MDL court's December 2022 summary judgment order, the MDL court closed the census registry, and the registry-related tolling of the statute of limitations for registry participants remaining in the census registry at the time of its closure expired in April 2023.

As of the Petition Date, the claims against PPI (including new complaints and related appeals) became subject to the automatic stay. ; PPI was subsequently voluntarily dismissed from several pending matters, including the appeal from the MDL court's dismissal of the third-party payer class action complaint.

In the event the stays in place were to be lifted, we will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests.

The resolution reached between the Stalking Horse Bidder and the UCC contemplates the creation and funding by the Purchaser of a trust for the benefit of certain unsecured creditors and sub-trusts established thereunder, one of which shall be established for the benefit of certain ranitidine claimants. As previously noted, the Stalking Horse Bid is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed sale transaction to the Purchaser, and the funding of the voluntary ranitidine claims-related sub-trust by the Purchaser, will actually occur. Additionally, similar matters to the foregoing 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. Adjustments to the expected amount of the allowed claim 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; three cases commenced by writ of summons in Pennsylvania state court are in deferred status. 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 generally seek damages, treble damages, civil penalties, disgorgement, declaratory and injunctive relief, costs and attorneys' fees. Some claims are based on alleged product-specific conspiracies; other claims allege broader, multiple-product conspiracies. Under their 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 in whole or in part, and discovery is ongoing.

As of the Petition Date, the claims against the Group and its subsidiaries in the U.S. became subject to the automatic stay. A similar cessation of litigation activity is in place in Canada. In the event the stays in place were to be lifted, 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 the expected amount of the allowed claim may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

In May 2018, we and our subsidiary PPCI each received a CID from the DOJ in relation to a U.S. False Claims Act an 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.

The resolution reached between the Stalking Horse Bidder and the UCC contemplates the creation and funding by the Purchaser of a trust for the benefit of certain unsecured creditors and sub-trusts established thereunder, one of which shall be established for the benefit of certain holders of generic drug pricing claims. As previously noted, the Stalking Horse Bid is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed sale transaction to the Purchaser, and the funding of the voluntary generic drug pricing claims-related sub-trust by the Purchaser, will actually occur. Additionally, similar investigations to the foregoing 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 additional losses that could be incurred. Adjustments to the expected amount of the allowed claim 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; Penwest Pharmaceuticals Co. (Penwest), which our subsidiary EPI had acquired; and Impax Laboratories, LLC (formerly Impax Laboratories, Inc. and referred to herein as Impax), alleging among other things violations of antitrust law arising out of an agreement between EPI and Impax to settle certain patent infringement litigation. Some cases were filed on behalf of putative classes of direct and indirect purchasers; others were non-class action suits. The cases were consolidated and/or coordinated in a federal MDL pending in the U.S. District Court for the Northern District of Illinois. The various complaints asserted claims under Sections 1 and 2 of the Sherman Act, state antitrust and consumer protection statutes and/or state common law. Plaintiffs generally sought damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. In June 2021, the court certified a direct purchaser class and an end-payer class; in August 2021, following an appeal, the district court amended its class certification order to certify a narrower end-payer class. Trial on all plaintiffs' claims began in June 2022. In July 2022, the jury returned a verdict in favor of EHSI, EPI and Penwest (Impax settled during trial). Later that month, plaintiffs filed a motion for judgment as a matter of law or in the alternative for a new trial. As of the Petition Date, the matter became subject to the automatic stay.

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. Between November 2019 and April 2021, PPI and PPCI entered into settlement agreements with all of the plaintiffs remaining in the MDL. 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 against PPI and other pharmaceutical companies 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. As of the Petition Date, the claims against PPI became subject to the automatic stay.

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; the retailer plaintiffs later did the same. PPI filed a partial motion to dismiss certain claims in September 2018; the court granted the motion in August 2019. In March 2022, the putative class plaintiffs filed motions for class certification. In May 2022, defendants filed motions for summary judgment. As of the Petition Date, the claims against PPI became subject to the automatic stay. In January 2023, certain direct purchaser plaintiffs dismissed their claims against PPI, EPI and us with prejudice and, in February 2023, certain indirect purchaser plaintiffs agreed to do the same. In July 2023, the court dismissed the remaining claims filed against PPI, EPI and us.

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 August 2020, the litigation was transferred to the U.S. District Court for the District of Delaware. In July 2022, the court dismissed certain claims asserted under state law but otherwise denied defendants' motions to dismiss. As of the Petition Date, the claims against PPI became subject to the automatic stay.

Beginning in June 2020, multiple complaints were filed against Jazz Pharmaceuticals (Jazz) and other pharmaceutical companies, including PPI, alleging violations of state and/or 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 generally 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; Aetna Inc (Aetna) filed a similar case in May 2022 in California state court. 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 MDL complaints that had been filed as of that time. In August 2021, the MDL court issued an order dismissing certain aspects of the plaintiffs' claims but otherwise denying the motions to dismiss. In July 2022, PPI, among others, filed a motion to quash the Aetna action for lack of personal jurisdiction; the defendants also filed a demurrer, motion to strike and motion to stay Aetna's action. As of the Petition Date, the claims against PPI became subject to the automatic stay. In December 2022, the California state court overseeing the Aetna action granted the motion to quash for lack of personal jurisdiction and, in January 2023, Aetna filed an amended complaint that did not name PPI as a defendant.

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). In particular, 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 plaintiffs asserted claims under Section 1 and Section 2 of the Sherman Act and sought damages, treble damages and attorneys' fees and costs. In November 2021, the plaintiffs dismissed all claims against EPI and in December 2021, the court dismissed the complaint for failure to state a claim. In January 2022, the plaintiffs 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. As of the Petition Date, the claims against PPI became subject to the automatic stay. In September 2022, the plaintiffs voluntarily dismissed all claims against PPI with prejudice, and PPI agreed to provide certain limited discovery as a non-party. In March 2023, the court denied the plaintiffs' motion for class certification. In April 2023, the court authorized the filing of an amended complaint adding certain additional plaintiffs and combining the litigation with the proceedings from which PPI was dismissed. The amended complaint names PPI as a defendant. Such claims against PPI are subject to the automatic stay.

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. The FTC filed a notice of appeal in May 2022. Briefing on the appeal has concluded and oral argument took place in May 2023. The appeal is pending.

To the extent unresolved, and in the event the stays in place were to be lifted, we will continue to vigorously defend the foregoing matters and to explore other options as appropriate in our best interests. The resolution reached between the Stalking Horse Bidder and the UCC contemplates the creation and funding by the Purchaser of a trust for the benefit of certain unsecured creditors and sub-trusts established thereunder, one of which shall be established for the benefit of certain antitrust claimants. As previously noted, the Stalking Horse Bid is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed sale transaction to the Purchaser, and the funding of the voluntary antitrust claims-related sub-trust by the Purchaser, will actually occur. Additionally, 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. Adjustments to the expected amount of the allowed claim may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Securities Litigation

In June 2020, a putative class action entitled Benoit Albiges v. Endo International plc, Paul V. Campanelli, Blaise Coleman, and Mark T. Bradley was filed in the U.S. District Court for the District of New Jersey by an individual shareholder on behalf of himself and all similarly situated shareholders. The lawsuit alleged 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 DFS's administrative action against the Group, EPI, EHSI, PPI and PPCI. In September 2020, the court appointed Curtis Laakso lead plaintiff in the action. In November 2020, the plaintiffs filed an amended complaint that among other things added Matthew J. Maletta as a defendant. 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. As of the Petition Date, the claims against the Group became subject to the automatic stay. In August 2022, the court granted the motion and dismissed the case with prejudice. Due to the automatic stay, the plaintiffs' time to appeal the dismissal as to the Company is tolled. The automatic stay does not apply to the individual defendants, and the plaintiffs' time to appeal the ruling as to those defendants has run.

Similar matters may be brought by others. We are unable to predict the outcome of any such matters or to estimate the possible range of any losses that could be incurred. Adjustments to the expected amount of the allowed claim may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Miscellaneous 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 the expected amount of the allowed claim may be required in the future, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Patent Matters

Beginning in April 2018, PSP LLC and PPI received notice letters from Eagle and other companies advising of the filing by such companies of ANDAs/NDAs for generic versions of VASOSTRICT® (vasopressin IV solution (infusion)) 20 units/ml and/or 200 units/10 ml. Beginning in May 2018, PSP LLC, PPI and EPIC filed lawsuits against Eagle and other generic filers in the U.S. District Court for the District of Delaware or New Jersey. We reached settlements and voluntarily dismissed the suits against many of these filers. The remaining Delaware cases against Eagle and Amneal Pharmaceuticals LLC were consolidated and a trial was held in July 2021. In August 2021, the court issued an opinion holding that Eagle's proposed generic product would not infringe PPI's asserted patent claims. The court made no finding regarding the validity of the patents. We appealed the ruling. In August 2022, the Federal Circuit affirmed the District of Delaware's decision: (i) that Eagle's proposed generic product would not infringe PPI's asserted patent claims and (ii) denying the issuance of a declaratory judgment that Eagle's planned sale of generic product would infringe under 35 U.S.C. § 271(a) and (b).

During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® 20 units/ml 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 entered the market, including authorized generics. These launches began to significantly impact both Endo's market share and product price toward the middle of the first quarter of 2022, and the effects of competition have since increased. This competition could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In March 2022, PSP LLC, PPI and Endo Par Innovation Company, LLC (EPIC) received a notice letter from Cipla Limited (Cipla) advising of its filing of an Abbreviated New Drug Application (ANDA) for generic versions of VASOSTRICT® (vasopressin injection) for IV use 40 units/100 ml and 60 units/100 ml. In May 2022, PSP LLC, PPI and EPIC filed a complaint against Cipla in the U.S. District Court for the District of New Jersey, which triggered a 30-month stay of U.S. Food and Drug Administration (FDA) approval of Cipla's ANDA; that stay expires in September 2024. In January 2023, PSP LLC, PPI and EPIC received another notice letter from Cipla advising of its ANDA filing for a generic version of VASOSTRICT® (vasopressin injection) for IV use 20 units/100 ml. In February 2023, PSP LLC, PPI and EPIC filed a complaint against Cipla concerning this ANDA in the U.S. District Court for the District of New Jersey. The 30-month stay on FDA approval of Cipla's 20 units/100 ml ANDA expires in July 2025. Both lawsuits against Cipla have been consolidated to the same schedule.

In January 2023, PSP LLC, PPI and EPIC received a notice letter from Baxter Healthcare Corporation (Baxter) pursuant to 505(b)(3)(B)-(D) of the U.S. Federal Food, Drug, and Cosmetic Act of its New Drug Application (NDA) submitted under 21 U.S.C. §355(b)(2) seeking FDA approval for vasopressin injection products in 20 units/100 ml and 40 units/100 ml strengths. In March 2023, PSP LLC, PPI and EPIC filed a complaint against Baxter in the U.S. District Court for the District of Delaware asserting infringement of three patents. These patents are not listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book); therefore, the patent infringement suit does not trigger a 30-month stay on FDA approval of Baxter's NDA. Baxter's answer to the complaint is due in August 2023.

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 in 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, 2022 and 2021, there were no tax effects allocated to any component of Other comprehensive (loss) income and there were no reclassifications out of Accumulated other comprehensive loss. Substantially all of the Group's Accumulated other comprehensive loss balances at December 31, 2022 and December 31, 2021 consist of Foreign currency translation gain and loss respectively.

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, 2022 and 2021 (in thousands):

	2022	2021
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 (235,208,039 issued and outstanding) (2021 233,690,816 issued and outstanding)	100	100
Total share capital	$ 140	$ 140
Allotted, called-up and fully paid equity:		
BALANCE, JANUARY 01, 2021		$ 72
Other		(4)
BALANCE, DECEMBER 31, 2021		$ 68
Other		(1)
BALANCE, DECEMBER 31, 2022		$ 67

Share Repurchase Program

Pursuant to Article 11 of the Company's Articles of Association, the Company has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. The Company's authority to repurchase ordinary shares is subject to legal limitations, including restrictions imposed by the Bankruptcy Code and related rules and guidelines during the pendency of the Chapter 11 Cases, 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. In addition, our existing debt instruments restrict or prevent us from conducting ordinary share repurchases. Agreements governing any future indebtedness, in addition to those governing our current indebtedness, may not permit us to conduct ordinary share repurchases. Unless we are able to generate sufficient distributable reserves or create distributable reserves by reducing our share premium account, we will not be able to repurchase our ordinary shares. As permitted by Irish Law and the Company's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption.

The Board has approved the 2015 Share Buyback Program that authorizes the Company to redeem, in the aggregate, $2.5 billion of its outstanding ordinary shares. To date, the Company has redeemed and cancelled approximately 4.4 million of its ordinary shares under the 2015 Share Buyback Program for $250.0 million, not including related fees.

NOTE 18. SHARE-BASED COMPENSATION

Stock Incentive Plans

In June 2015, the Company's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan), which has subsequently been amended, as approved by the Company's shareholders, on multiple occasions. 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, 2022, approximately 11.4 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2022, stock options, restricted stock awards, PSUs, RSUs, long-term cash incentive awards and certain other cash-based awards have been granted under the stock incentive plans.

In February 2023, the Group filed post-effective amendments to its Form S-8 registration statements with respect to the 2015 Plan in order to deregister all remaining unissued securities.

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 generally 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, 2022 and 2021 (in thousands).

	2022	2021
Selling, general and administrative expenses	$ 16,019	$ 23,400
Research and development expenses	1,059	1,378
Cost of sales	1,136	5,268
Total share-based compensation expense	$ 18,214	$ 30,046

As of December 31, 2022, 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, 2022 amounted to $10.1 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. As of December 31, 2022, stock options outstanding generally had expiration dates that extended ten years from the respective grant dates.

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, 2022 and 2021 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding as of January 1, 2021	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		
Expired	(1,304,602)	$ 20.04		
Outstanding as of December 31, 2022 (2)	5,079,312	$ 15.84	2.01	$ —
Vested and expected to vest as of December 31, 2022 (2)	5,079,312	$ 15.84	2.01	$ —
Exercisable as of December 31, 2022 (2)	5,079,312	$ 15.84	2.01	$ —

(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.

(2) On March 3, 2023, the Bankruptcy Court entered orders authorizing the Group to reject outstanding stock option agreements, restricted stock award agreements and performance award agreements.

The range of exercise prices for the above stock options outstanding at December 31, 2022 is from $7.55 to $86.54.

The total intrinsic value of options exercised during the year ended December 31, 2021 was $0.1 million. There were no material tax benefits from stock option exercises realized during any of the periods presented above.

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.

As of December 31, 2022: (i) unvested RSUs were subject to three-year vesting periods, with ratable vesting on the first, second and third anniversaries of the respective grant dates, and (ii) unvested PSUs were subject to three-year service periods, after which the awards would vest in full (conditioned upon the achievement of performance and/or market conditions established by the Compensation & Human Capital Committee of the Board and certain continued employment conditions), with the actual number of shares awarded adjusted to between zero and 200% of the target award amount based upon the level of achievement of the performance criteria described below.

No PSUs were awarded in 2022. PSUs awarded in 2021 and 2020 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 PSUs upon issuance, with TSR performance being measured against the three-year TSR of a custom index of companies and FCF performance being measured against a target covering a three-year performance period. 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, 2022 and 2021 is presented below:

	Number of Shares	Aggregate Intrinsic Value (1)
Non-vested as of January 1, 2021	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	
Granted	280,373	
Forfeited	(1,116,960)	
Vested	(2,324,696)	
Non-vested as of December 31, 2022 (2)	4,979,827	$ 348,588
Vested and expected to vest as of December 31, 2022 (2)	4,751,674	$ 332,617

(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.

(2) On March 3, 2023, the Bankruptcy Court entered orders authorizing the Group to reject outstanding stock option agreements, restricted stock award agreements and performance award agreements. In connection with the rejection of these agreements, the Group currently expects to recognize any remaining unrecognized compensation cost associated with these agreements during the first quarter of 2023.

As of December 31, 2022, the weighted average remaining requisite service period of the units presented in the table above was 0.8 years and the corresponding total remaining unrecognized compensation cost amounted to $3.5 million in the case of RSUs and $6.6 million in the case of PSUs.

The weighted average grant-date fair value of the units granted during the years ended December 31, 2022 and 2021 was $3.21 and $7.39 per unit, respectively.

NOTE 19. OTHER INCOME, NET

the components of Other income, net for the years ended December 31, 2022 and 2021 are as follows (in thousands):

	2022	2021
Net gain on sale of business and other assets (1)	$ (26,183)	$ (4,516)
Foreign currency (gain) loss, net (2)	(2,087)	1,253
Net loss (gain) from our investments in the equity of other companies (3)	378	453
Other miscellaneous, net (4)	(6,162)	(16,964)
Other income, net	$ (34,054)	$ (19,774)

(1) Amounts primarily relate to the sales of certain intellectual property rights and certain other assets including, in 2022 and 2021, assets associated with the sale transactions that are further discussed in Note 4. Discontinued Operations and Asset Sales.

(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, 2022 and 2021 are as follows (in thousands):

	2022	2021
U.S.	$ (2,472,315)	$ 4,792,852
International	(458,787)	(5,339,455)
Total loss from continuing operations before income tax	$ (2,931,102)	$ (546,603)

Income tax from continuing operations consists of the following for the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Current:		
U.S. Federal	$ 21,057	$ 13,649
U.S. State	1,731	1,491
International	6,031	10,495
Total current income tax	$ 28,819	$ 25,635
Deferred:		
U.S. Federal	$ (622)	$ 118
U.S. State	1,065	(564)
International	(7,746)	(2,711)
Total deferred income tax	$ (7,303)	$ (3,157)
Total income tax	$ 21,516	$ 22,478

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, 2022 and 2021 is as follows (in thousands):

	2022	2021
Notional U.S. federal income tax provision at the statutory rate	$ (606,502)	$ (114,787)
State income tax, net of federal benefit	(9,517)	6,750
U.S. tax reform impact	—	—
Uncertain tax positions	21,930	42,415
Residual tax on non-U.S. net earnings	(32,257)	(181,739)
Non-deductible goodwill impairment	385,459	76,230
Change in valuation allowance	306,497	495,565
Base erosion minimum tax	—	—
Non-deductible expenses	47,221	39,791
Executive compensation limitation	5,580	6,215
Equity based compensation	3,247	2,695
Financing activities (1)	73,629	(287,012)
Investment activities (2)	(178,018)	(68,943)
Other	4,247	5,298
Income tax	$ 21,516	$ 22,478

(1) The amount in 2022 primarily relates to non-deductible foreign currency adjustments on intercompany debt. 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 amounts in 2022 and 2021 primarily relate 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 2022 compared to the 2021 income tax expense primarily relates to an increase in accrued interest on uncertain tax positions and changes in the geographic mix of pre-tax earnings. 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.

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 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, 2022 and 2021 are as follows (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Accrued expenses and reserves	$ 220,415	$ 144,573
Deferred interest deduction	421,552	347,501
Fixed assets, intangible assets and deferred amortization	560,257	512,584
Loss on capital assets	23,511	64,503
Net operating loss carryforward	9,214,688	9,258,122
Other	49,943	50,694
Research and development and other tax credit carryforwards	7,777	8,254
Total gross deferred income tax assets	$ 10,498,143	$ 10,386,231
Deferred tax liabilities:		
Other	$ (3,156)	$ (8,586)
Investments	(107)	(124,311)
Intercompany notes	(72,286)	(104,530)
Total gross deferred income tax liabilities	$ (75,549)	$ (237,427)
Valuation allowance	(10,436,419)	(10,169,294)
Net deferred income tax liability	$ (13,825)	$ (20,490)

As of December 31, 2022, 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	$ 79,617	Indefinite
Luxembourg	$ 8,934,046	2034
U.S.:		
Federal-ordinary losses	$ 19,105	2037
Federal-capital losses	$ 13,699	2023
Federal-tax credits	$ 14,081	2025
State-ordinary losses	$ 227,587	2023
State-capital losses	$ 11,871	2023
State-tax credits	$ 3,256	2037

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, 2022 and 2021, the total valuation allowance was $10,436.4 million and $10,169.3 million, respectively. During the years ended December 31, 2022 and 2021, the Group increased its valuation allowance by $267.1 million and $500.7 million, respectively, which was primarily driven by taxable losses in Luxembourg related to investments in consolidated subsidiaries. As previously disclosed, the Group concluded that there was substantial doubt about its ability to continue as a going concern within one year after the date of issuance of the Condensed Consolidated Financial Statements included in the Second-Quarter 2022 Form 10-Q. The Group considered this in determining that certain net deferred tax assets were no longer more likely than not realizable. As a result, an immaterial increase in valuation allowance on the Group's net deferred tax assets was recorded in various jurisdictions during the second quarter of 2022.

As of December 31, 2022, the Group had the following significant valuation allowances (in thousands):

Jurisdiction	December 31, 2022
Ireland	$ 289,500
Luxembourg	$ 8,862,060
U.S.	$ 1,278,026

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

We 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. As a result of the bankruptcy filing, we have reassessed our historical indefinite reinvestment assertion with respect to undistributed earnings. Based on that reassessment, we have determined that the undistributed earnings of certain subsidiaries will continue to be indefinitely reinvested. Those entities for which we will continue to assert indefinite reinvestment have an accumulated earnings deficit as of December 31, 2022. No additional provision has been made for Irish and non-Irish income taxes on those undistributed earnings that we are not asserting indefinite reinvestment as no tax is expected to be incurred with respect to those earnings. 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, 2022, the Group had total UTPs, including accrued interest and penalties, of $646.4 million. If recognized in future years, $251.4 million of such amounts would impact the income tax provision and effective tax rate. 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 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, 2022 and 2021 (in thousands):

	Unrecognized Tax Positions Federal, State and Foreign Tax
UTP Balance at January 1, 2021	$ 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
Gross additions for current year positions	20,061
Decrease due to lapse of statute of limitations	(4,451)
Currency translation adjustment	(2,419)
UTP Balance at December 31, 2022	$ 579,630
Accrued interest and penalties	66,736
Total UTP balance including accrued interest and penalties	$ 646,366

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 $66.7 million and $53.6 million as of December 31, 2022 and 2021, respectively.

During the year ended December 31, 2022, the Group recognized net expense of $16.2 million associated with UTPs, primarily related to interest and penalties. 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. At December 31, 2022, the Group's UTP liability is included in the Consolidated Balance Sheets within Liabilities subject to compromise, Other liabilities and, where appropriate, as a reduction to Deferred tax assets. At December 31, 2021, the Group's UTP liability is included in the Consolidated Balance Sheets within Other liabilities and, where 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 2018 tax years by the IRS.

It is expected that the amount of UTPs will change during the next 12 months; however, we do 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) 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. In April 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, 2022, we may be subject to examination in the following major tax jurisdictions:

Jurisdiction	Open Years
Canada	2016 through 2022
India	2012 through 2022
Ireland	2016 through 2022
Luxembourg	2015 through 2022
U.S. - federal, state and local	2006 through 2022

Bankruptcy-Related Developments

In connection with our ongoing bankruptcy proceedings, the IRS has filed multiple proofs of claim against several of the Debtors. The total amount of the claims filed by the IRS, which relate to tax years ended 2006 through 2014, 2016 through 2018 and 2020 through 2021, is approximately $18.7 billion. A number of the claims are in respect of the same proposed tax liability but are filed against multiple subsidiary members of our U.S. consolidated tax groups. After excluding the repetitive claims filed to different members of our U.S. consolidated tax groups, the net claims are approximately $2.6 billion. We did not receive from the IRS calculations or support for the amount of the claims filed; however, through our discussions with the IRS following the submission of the claims, we understand that the claims primarily relate to the IRS's challenges of our historic tax positions discussed above for 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. We disagree with the IRS's claims and, if necessary, intend to contest any additional tax determined to be owed with respect to the claims.

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, 2022 and 2021 (in thousands):

	2022	2021
Numerator:		
(Loss) profit from continuing operations	$ (2,952,618)	$ (569,081)
Profit (loss) from discontinued operations, net of tax	(13,487)	(44,164)
Net (loss) profit	$ (2,966,105)	$ (613,245)
Denominator:		
For basic per share data—weighted average shares	234,840	232,785
Dilutive effect of ordinary share equivalents	—	—
For diluted per share data—weighted average shares	234,840	232,785

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

	2022	2021
Stock options	5,453	6,584
Stock awards	5,789	9,256

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 $6.5 million and $7.6 million for the years ended December 31, 2022 and 2021, respectively.

NOTE 23. DEBTORS

The components of Debtors as at December 31, 2022 and 2021 (in thousands) were as follows:

	2022	2021
Amounts falling due within one year:		
Trade debtors	$ 493,988	$ 592,019
Prepayments and other debtors	136,923	200,484
Income taxes receivable	7,117	7,221
	$ 638,028	$ 799,724
Amounts falling due after more than one year:		
Deferred tax asset	$ —	$ 1,138
Other debtors	129,839	60,313
	$ 129,839	$ 61,451

NOTE 24. PROVISIONS AND CREDITORS

The components of Provisions and Creditors as at December 31, 2022 and 2021 (in thousands) were as follows:

	Note	2022	2021
Provisions for liabilities:			
Amounts falling due within one year:			
Returns and allowances, rebates, chargebacks and other sales deductions (1)		$ 335,252	$ 338,272
Acquisition-related contingent consideration—short-term	7	—	5,748
		$ 335,252	$ 344,020
Amounts falling due after more than one year:			
Acquisition-related contingent consideration—long-term	7	—	14,328
		$ 335,252	$ 358,348
Creditors:			
Amounts falling due within one year:			
Trade accounts payable		$ 109,033	$ 123,129
Accrued expenses		242,898	369,749
Current portion of legal settlement accrual	15	—	580,994
Income taxes payable	20	1,541	736
		$ 353,472	$ 1,074,608
Amounts falling due after more than one year:			
Deferred income taxes	20	13,825	21,628
Income taxes payable	20	6,900	228,110
Other creditors		35,846	34,666
		$ 56,571	$ 284,404
		$ 410,043	$ 1,359,012

(1) The following table summarizes changes in the ending balances for our product sales provisions for the years ended December 31, 2022 and 2021 (in thousands): The amounts in the table above do not include amounts classified as Liabilities subject to compromise in our Consolidated Balance Sheets. Refer to Note 2 Bankruptcy Proceedings for additional information about Liabilities subject to compromise.

	Returns and Allowances	Rebates	Chargebacks	Other Sales Deductions	Total
Balance, December 31, 2021	$ 183,116	$ 150,039	$ 2,617	$ 2,500	$ 338,272
Current year provision	77,451	394,734	6,946	6,694	485,825
Prior year provision	(5,367)	(4,169)	(965)	(64)	(10,565)
Payments or credits	(88,034)	(374,129)	(4,173)	(2,933)	(469,269)
Balance, December 31, 2022	$ 167,166	$ 166,475	$ 4,425	$ 6,197	$ 344,263

Total product sales deductions amount to $600,157 as at 31 December 2022 (2021 $588,723) which consists of the $347,263 (2021: $338,272) as presented in the table above and $252,894 (2021: 250,450) which has been deducted from the Trade Debtor balance as included in Note 23. Debtors. The amounts in the table above do not include amounts classified as Liabilities subject to compromise in our Consolidated Balance Sheets ($9,011). Refer to Note 2 Bankruptcy Proceedings for additional information about Liabilities subject to compromise.

NOTE 25. CAPITAL EXPENDITURE COMMITMENTS

The directors have authorized the Group to spend $65.0 million for capital expenditures in the year ended December 31, 2023.

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, 2022 and 2021 were as follows:

	2022	2021
Manufacturing	1,743	1,972
Research and development	448	445
Selling, general and administrative	843	942
Total employees	3,034	3,359

Employee costs for the years ended December 31, 2022 and 2021 (in thousands) were as follows:

	2022	2021
Wages and salaries	$ 371,597	$ 364,685
Benefits (1)	45,174	54,725
Share-based compensation	17,314	30,046
Total employee cost	$ 434,085	$ 449,456

(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 2022, 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 2022) of certain incentive compensation components which, had they adhered to the normal compensation timeline, would have been reportable in 2023 and beyond. Specifically, had these amounts not been prepaid, total 2022 compensation for Mr. Blaise Coleman would have been reduced by ($11,850 thousand). 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).

	2022	2021
Emoluments	$ 16,898	$ 25,602
Benefits under long-term incentive schemes	$ 432	$ 3,198
Contributions to retirement benefit schemes:	$ 12	$ —
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, 2022 and 2021. The table below summarizes the aggregate fees for services PricewaterhouseCoopers Ireland and its affiliated firms provided during years 2022 and 2021, respectively (in thousands).

	2022	2021
Audit fees (1)	7,183	$ 5,646
Audit-related fees (2)	1,350	3,083
Tax fees (3)	333	972
All other fees (4)	11	10
Total auditors' remuneration	$ 8,877	$ 9,711

(1) Fees for audit services in 2022 and 2021 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 2022 and 2021 consisted of:
- Attestation services requested by management, including carve-out audit services of certain business units;
- 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 2022 and 2021 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 2022 and 2021 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:

	2022	2021
Audit of the Group financials statements	$ 316	$ 288
Other assurance services	579	313
Tax advisory services	71	241
Total auditors' remuneration	$ 966	$ 842

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 2022:

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 August 10, 2023 the date this report is approved by the Audit & Finance Committee of the Board of Directors and the Board of Directors.

Refer to Note 2. Bankruptcy Proceedings of the Consolidated Statements for details of the ongoing Chapter 11 bankruptcy proceedings, including event which occurred since the end of the financial year.

In September 2020, PSP LLC entered into a manufacturing and services agreement with Novavax, Inc. (Novavax), pursuant to which PSP LLC would provide fill-finish manufacturing services at its plant in Rochester, Michigan for Novavax's COVID-19 vaccine candidate. In April 2023, PSP LLC executed, and the Bankruptcy Court approved, a Settlement Agreement and Release of Claims with Novavax (the Novavax Settlement Agreement) to resolve a dispute under the manufacturing and services agreement. In connection with the effective date of the Novavax Settlement Agreement, Novavax paid $27 million of cash and certain other non-cash consideration. Provided certain conditions are met, this agreement will be accounted for in the second quarter of 2023.

Legal Accruals

Subsequent to December 31, 2022, adjustments were made to recognize litigation charges related to probable and estimable damages for matters that existed at December 31, 2022. The following adjustments were made to balances previously reported in the Consolidated Statements of Operations included in Endo International plc's Annual Report on Form 10-K (10-K) filed with the Securities and Exchange Commission on March 06, 2023. For further information on these legal proceedings refer to Note 15. Commitment and Contingencies.

(in thousands)	As reported in Form 10-K	Litigation adjustment	Adjusted balance
Litigation-related and other contingency credits	$ 478,722	$ 43,000	$ 521,722

The following adjustments were made to balances previously reported in the Consolidated Balance Sheets included in Endo International plc's Annual Report on Form 10-K (10-K) filed with the Securities and Exchange Commission on March 06, 2023. For further information on these legal proceedings refer to Note 15. Commitment and Contingencies.

(in thousands)	As reported in Form 10-K	Litigation adjustment	Adjusted balance
Liabilities subject to compromise	$ 9,168,782	$ 43,000	$ 9,211,782

NOTE 32. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved by the directors on August 10, 2023.

ENDO INTERNATIONAL PLC
COMPANY RECONCILIATION OF SHAREHOLDERS' FUNDS
FOR THE YEAR ENDED DECEMBER 31, 2022
(In thousands)

	Share Capital Presented as Equity	Share Premium	Profit and Loss Account	Other Reserves	Total Equity
BALANCE, January 1, 2021	$ 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 excercises	—	—	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
Net loss	—	—	(3,690,510)	—	(3,690,510)
Share-based payment activity	—	—	—	14,834	14,834
Option exercises	—	—	—	—	—
Receipt of Endo International's shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	—	—	(1,898)	—	(1,898)
Other	(1)	—	—	—	(1)
BALANCE, DECEMBER 31, 2022	$ 67	$ 6,156,266	$ (9,443,663)	$ 437,162	$ (2,850,168)

ENDO INTERNATIONAL PLC
COMPANY BALANCE SHEET AS AT
DECEMBER 31, 2022
(In thousands)

	Note	December 31, 2022	December 31, 2021
ASSETS			
Financial Fixed Assets			
Investment in subsidiaries	3	$ —	$ 1,134,514
Current Assets			
Debtors - Prepayments and other debtors	5	26,410	86,920
Debtors - Amounts due from subsidiaries	4	8,137	859
Cash at bank and in hand		11,926	7,129
TOTAL ASSETS		$ 46,473	$ 1,229,422
EQUITY AND LIABILITIES			
Capital and Reserves			
Called up share capital presented as equity, $0.01 par value Euro deferred shares	9	$ 43	$ 45
Called up share capital presented as equity, $0.0001 par value ordinary shares	9	24	23
Share premium account	9	6,156,266	6,156,266
Other reserves	9	437,162	422,328
Profit and loss account		(9,443,663)	(5,751,255)
Total equity		$ (2,850,168)	$ 827,407
Creditors (amounts falling due within one year)			
Intercompany loan payable	6	$ 276,353	$ 167,316
Amounts due to subsidiaries	7	232,201	165,180
Accruals and other creditors	8	63,701	69,519
Financial guarantee liabilities	12	2,324,386	—
Total for creditors		$ 2,896,641	$ 402,015
TOTAL EQUITY AND LIABILITIES		$ 46,473	$ 1,229,422

The Parent Company recorded a loss of $3,692.4 million for the year ended 31 December 2022 (2021: loss of $387.0 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 August 10, 2023 and signed on its behalf by:

/s/ Mark G. Barberio	/s/ Blaise Coleman
Mark G Barberio	Blaise Coleman
Chairman	*Director*

NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation and Going Concern

The financial statements have been prepared on a basis other than going concern 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, the Company's directors have taken into account various uncertainties as further discussed herein, thousands of governmental and private plaintiffs have filed suit against us and/or certain of our subsidiaries alleging opioid-related claims, most of which we have not been able to settle. As a result of the possibility or occurrence of an unfavorable outcome with respect to these proceedings, other legal proceedings and certain other risks and uncertainties, we explored a wide array of potential actions as part of our contingency planning. On the August 16, 2022 Petition Date, Endo International Plc, together with certain of its direct and indirect subsidiaries (together the "Debtors") filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors' rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. Refer to Note 2. Bankruptcy Proceedings and Note 15. Debt on the consolidated statements for additional information. As a result of these conditions and events, the Company's directors have formed the opinion that the most likely outcome from Bankruptcy Proceedings is the eventual liquidation and winding up of the Company after closing of the Sale to Stalking Horse Bidder. Accordingly, the directors have concluded it is appropriate to prepare the Company financial statements on a basis other than going concern.

Due consideration was given to the recognition and measurement requirements of FRS 102 as a result of this decision and the conclusion was to prepare these financial statements under FRS 102 framework with no deviations required. The "other than going concern basis of preparation" could include adjustments in relation to reclassification of non-current assets and long-term/non-current liabilities as current assets and liabilities; and/or writing down of assets to their recoverable value. Liabilities continue to be recognised if the obligation exists at the balance sheet date. No adjustments were necessary in these financial statements to reduce assets to their realisable values, to provide for liabilities arising from the preparation of the financial statements on a basis other than going concern or to reclassify non current assets and long-term liabilities as current assets and liabilities. Due to the chapter 11 filing and the related circumstances impacting the Company and wider Group, the directors have considered indicators of impairment under both Section 27 Impairment of assets and Section 11 / Section 12 Financial instruments. Certain impairment charges have been recognised in these Company financial statements, as detailed in Note 3 and 4. Additionally and as result of the Chapter 11 filing as further described in Note 12, a provision has been recorded in light of current facts and circumstances, to reflect management's best estimate of the probable outflow of resources, pertaining to the financial guarantees provided on the Group's third party debt, for which the Company is a joint and several guarantor.

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, 2022. The Company has taken advantage of the following disclosure exemptions under FRS 102:

- the requirements of section 4 Statement of Financial Position - reconciliation of number of shares outstanding 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 33.1A
- the requirements of Section 33 Related Party Disclosures, paragraph 33.7, and
- the requirements of Section 304 of the Companies Act 2014, paragraph A3.15

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.

Going concern

Directors' judgement is required to determine the appropriate basis of preparation of the financial statements. The financial statements should be prepared on a going concern basis, unless management intends either to liquidate the entity or cease trading or has no realistic alternative but to do so. Refer to Note 1 for details of key management judgements in this regard.

Impairment of financial assets

At the end of each reporting period, the Company assesses whether there is objective evidence that a financial asset is impaired, meaning one or more events have occurred which have an impact on the estimated future cash flows that can be reliably evaluated. Impairments are measured as the excess of the cost over the fair value. Impairment losses are recognised in the profit and loss account in the period they are incurred. Refer note 4 for impairment of intercompany receivables.

Investment in subsidiaries

Investments in subsidiaries are stated at cost less any return of capital unless the investment has been impaired, in which case it is carried at cost less impairment losses. Judgement is exercised by the directors to determine whether an impairment triggering event has occurred and to estimate the relevant recoverable amount, where applicable – see Note 3 for impairment of investment in subsidiaries.

Joint and several guarantees

The Company is jointly and severally liable for various secured and unsecured debt instruments ("obligations") that were issued by certain subsidiary undertakings. The part of the obligation that is expected to be met by other group companies is treated as a contingent liability. The Company recognises a provision for that part of the obligation for which an outflow of resources embodying economic benefits is probable. Judgment is exercised by the directors to determine whether an amount is probable and whether such amount can be reasonably estimated – see Note 12. Financial Guarantee for further details. Judgement is also exercised in determining that the fair value of the Groups assets, is equal to the Stalking Horse Bid price. The use of the Stalking horse bid is a judgement and there is estimation uncertainty as to the amount which is dependent on the final outcome of the Stalking horse bid.

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, 2022 and 2021 were $3,690.5 million and $387.0 million, respectively. No other comprehensive profit or losses were applicable for the years ended December 31, 2022 and 2021.

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%.

On August 16, 2022 (the Petition Date), Endo International plc, together with certain of its direct and indirect subsidiaries (the Debtors), filed voluntary petitions for relief under the Bankruptcy Code, which constituted an event of default that accelerated our obligations under substantially all of our then-outstanding debt instruments. However, section 362 of the Bankruptcy Code stays creditors from taking any action to enforce the related financial obligations and creditors’ rights of enforcement in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. Additional information regarding the Group's ongoing bankruptcy proceedings is included refer to Note 2. Bankruptcy Proceedings of the consolidated statements.

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, Simmonscourt 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, 2021 to December 31, 2022 is as follows (in thousands):

	Investment in Subsidiaries
Balance - January 01, 2021, at cost	$ 1,401,425
Capital contribution in respect of share-based payment plans	26,289
Impairment	(297,991)
Capital Contribution	4,791
Balance - December 31, 2021, at cost	$ 1,134,514
Capital contribution in respect of share-based payment plans	13,898
Impairment	(1,149,952)
Capital Contribution	1,540
Balance - December 31, 2022, at cost	$ —

Financial assets of the Company are pledged against third party debts taken by subsidiaries of the Company. Refer note 12 for more details.

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, 2022 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 2022. As a result of this analysis, the Company determined that the net book value of its Investment in subsidiaries asset exceeded its recoverable amount. As further discussed in Note 2. History and Description of the Company and Note 11. Guarantees, the equity value of Endo International Plc as of December 31, 2022 no longer reflects the recoverable value of Endo International Plc's subsidiaries given the low trading volumes while in Bankruptcy. Furthermore, the proposed sale to the Stalking Horse Bidder does not does not contemplate the distribution of any value to the shareholders or foresee a market for the existing ordinary shares after the completion of the Sale. The recoverable amount of the Investment in subsidiaries was determined by reference to the carrying value of the Company's subsidiaries debt, including guarantees recognized by subsidiaries in 2022, compared to the value of the Group's assets as of December 31, 2022.

The Company made capital contributions of $1,540 thousand and $4,791 thousand during the year ended December 31, 2022 and December 31, 2021, respectively, to its subsidiary Endo Designated Activity Company therefore increasing the carrying amount of its Investment in Subsidiary.

As part of the impairment analysis, the Company recorded a non-cash impairment charge in the Profit and loss accounts for the year ended 2022 of $1,149 million (2021: $297.9 million), to reduce the carrying amount of the Company’s investment to its recoverable amount. The 2022 impairment was driven by the recognition of joint and several guarantee liabilities by the subsidiaries of the Company which are ultimately in excess of the value Endo International Plc's assets.

During the year ended December 31, 2021 certain trigger events, described in more detail below, indicated that the net book value of the Investment in subsidiaries balance exceeded its recoverable amount. The recoverable amount as at December 31, 2021 has been determined by reference to the number of outstanding shares multiplied by the closing stock price of Endo International Plc as of that day, adjusted for a control premium which has been determined by analysis of historical pharmaceutical industry deal activity.

The 2021 impairment of $297.9 million was driven by a combination of factors, including a decrease in Endo's stock price compared to the share price as at December 31, 2021, 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.

NOTE 4. AMOUNTS DUE FROM SUBSIDIARIES

Amounts due from subsidiaries of $8.1 million and $0.9 million at December 31, 2022 and 2021, respectively, are non-interest bearing and payable on demand.

Financial assets of the Company are pledged against third party debts taken by subsidiaries of the Company. Refer note 12 for more details.

NOTE 5. PREPAYMENTS AND OTHER DEBTORS

Amounts for prepayments and other debtors of $26.4 million and $86.9 million at December 31, 2022 and 2021, respectively. The decrease 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. This was settled in February 2022 resulting in a decrease to its insurance receivable and decrease in its accruals and other creditors. In addition the Company has other reimbursable legal expenses under Insurance policies at December 31, 2022 and 2021 respectively included in Prepayments and Other Debtors.

Financial assets of the Company are pledged against third party debts taken by subsidiaries of the Company. Refer note 12 for more details.

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.

On August 12, 2022, the Company issued $30.0 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 thirty years from the issuance date or upon written demand by the affiliate.

During 2022 the Company drew an additional $79.1 million against the revolver balance with an affiliate.

NOTE 7. AMOUNTS DUE TO SUBSIDIARIES

Amounts due to subsidiaries of $232.2 million and $165.2 million at December 31, 2022 and 2021, respectively, are non-interest bearing and payable on demand.

NOTE 8. ACCRUALS AND OTHER CREDITORS

Amounts for accruals and other creditors of $63.7 million and $69.5 million at December 31, 2022 and 2021, respectively.

The decrease 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. This was settled in February 2022 resulting in a decrease to its insurance receivable and decrease in its accruals and other creditors. In 2022 the Company had increases in its legal expenses accruals primarily driven by the Groups Bankruptcy filing offset against the Pelletier settlement resulting in net decrease in accruals and other creditors of $5.8 million.

NOTE 9. CALLED UP SHARE CAPITAL

Share Capital consists of the following for the year ended December 31, 2022 (in thousands):

	2022	
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 (235,208,039 issued and outstanding) (2021 233,690,816 issued and outstanding)		100
Total share capital	$	140
Allotted, called-up and fully paid equity:		
BALANCE, JANUARY 01, 2021	$	72
Other		(4)
BALANCE, DECEMBER 31, 2021	$	68
Other		(1)
BALANCE, DECEMBER 31, 2022	$	67

Called up Share Capital

The Company has two classes of equity shares, being (a) ordinary shares with a nominal value of $0.0001 each; and (b) euro deferred shares with a nominal value of €0.01 each.

At any general meeting of the Company, each holder of an ordinary share is entitled to one vote per share held by him/her/it. Each holder of an ordinary share is: (a) entitled to dividends on a pro rata basis in accordance with the relevant provisions of the Company's Articles of Association; and (b) entitled to participate pro rata in the distribution of the total assets of the Company in a solvent liquidation, after the payment of the company’s debts and any other preferential amounts. Except in the case of an interim dividend, any dividend recommended by the Board of Directors of the Company is considered a final dividend, which is subject to the approval of the holders of ordinary shares in the ensuing Annual General Meeting of the Company. All ordinary shares shall rank pari passu with each other in all respects.

The euro deferred shares carry no voting rights and are not entitled to receive any dividend or distribution.

Share Repurchase Program

Pursuant to Article 11 of the Company's Articles of Association, the Company is permitted to conduct ordinary share repurchases by way of redemptions. The Company's authority to repurchase ordinary shares is subject to legal limitations, including (a) restrictions imposed by the Bankruptcy Code and related rules and guidelines during the pendency of the Chapter 11 Cases, (b) the existence of sufficient distributable reserves, and (c) the existence of sufficient net assets. For example, the Companies Act requires (a) Irish companies to have distributable reserves equal to or greater than the amount of any proposed ordinary share repurchase amount and (b) that, following any proposed share repurchase, Irish public limited companies must have net assets which equal or exceed the aggregate of their called up share capital and their undistributable reserves. In addition, our existing debt instruments restrict or prevent us from conducting ordinary share repurchases. Agreements governing any future indebtedness, in addition to those governing our current indebtedness, may not permit us to conduct ordinary share repurchases. Unless we are able to generate sufficient distributable reserves or create distributable reserves by way of a capital reduction, we will not be able to repurchase our ordinary shares. As permitted by Irish Law and the Company's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption.

The Board has approved the 2015 Share Buyback Program that authorizes the Company to redeem, in the aggregate, $2.5 billion of its outstanding ordinary shares. To date, the Company has redeemed and cancelled approximately 4.4 million of its ordinary shares under the 2015 Share Buyback Program for $250.0 million, not including related fees.

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. Under the 2015 Plan, stock options (including incentive stock options), stock appreciation rights, restricted stock awards, performance awards and other share- or cash-based awards may be issued at the discretion of the Compensation & Human Capital Committee of the Board from time to time. No ordinary shares are to be granted under previously approved plans, including the Company's 2000, 2004, 2007, 2010 and Assumed Stock Incentive Plans. Any awards previously granted and outstanding under these prior plans remain subject to the terms of those prior plans.

At December 31, 2022, approximately 11.4 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2022, stock options, restricted stock awards, PSUs, RSUs, long-term cash incentive awards and certain other cash-based awards have been granted under the stock incentive plans.

In February 2023, the Company filed post-effective amendments to its Form S-8 registration statements with respect to the 2015 Plan in order to deregister all remaining unissued securities.

Generally, the grant-date fair value of each award is recognized as expense over the requisite service period. However, expense recognition differs in the case of certain PSUs where the ultimate payout is performance-based. For these awards, at each reporting period, the Company generally estimates the ultimate payout and adjusts the cumulative expense based on its estimate and the percent of the requisite service year that has elapsed. Refer to Note 14 Subsequent events for further details on stock options and stock exercise awards in 2023.

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, 2022 and 2021 (in thousands).

	2022	2021
Selling, general and administrative expenses	$ 16,019	$ 23,400
Research and development expenses	1,059	1,378
Cost of sales	1,136	5,268
Total share-based compensation expense	$ 18,214	$ 30,046

As of December 31, 2022, 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, 2022 amounted to $10.1 million.

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.

Contingent Success Fees

In connection with our ongoing bankruptcy proceedings and certain related transactions, it is possible that we will incur certain success-related and/or other contingent fees, which could be significant.

Financial Guarantees

Certain subsidiaries of Endo International plc entered into a credit facility upon the closing of the Paladin acquisition on 28 February 2014. The Company is a guarantor along with other Group undertakings of that credit facility.

In the prior year statutory financial statements, the Company disclosed as a contingent liability that it had co–guaranteed various secured and unsecured senior notes that were issued by certain subsidiary undertakings within the Endo International Plc Group on a senior secured and unsecured basis.

The Company considers these financial guarantee contracts to fall within the scope of Section 21 Provisions and Contingencies and accounts for them as such. The Company accounts for these guarantee contracts as contingent liabilities until such times as it becomes probable that a payment will be required under such guarantees.

In the notes to the financial statements for the year ended 31 December 2021, these guarantees were disclosed as contingent liabilities as it was not considered probable, at that point in time, that these guarantees would be called upon by the holders of the obligation.

Following the petition for Chapter 11 bankruptcy proceedings filed on 16 August 2022, which represented an event of default of the Group's senior notes, the Company now considers it probable that a payment will be required under these guarantees and have recognised a provision of $ 2,324 million at 31 December 2022 – see Note 12 for further details.

As set out in further detail in Note 1, the principal value of the outstanding senior notes of $8,147 million, is greater than the recoverable value of the Group’s collective pledged assets, which is estimated at $5,823 million based on the Stalking Horse Bid value.

As set out in Note 1, the Company has prepared its financial statements on a non–going concern basis and is not expected to have sufficient assets to settle all liabilities, including intercompany debt obligations, intercompany milestone obligations, or the surplus portion of the Group's third–party debt obligations for which the Company may be deemed liable, under the relevant accounting standards, as a joint and several guarantor of such obligations given the event of default which occurred on the Petition Date which is not satisfied by the other guarantors to the debt agreements.

The Company has recorded a provision in the current year which reflects management’s best estimate of the expenditure required to settle the present obligation at the end of the reporting period in relation to the third–party debt arrangements for which it is a co–guarantor. This provision has been calculated based on (i) the expected recoverable value of the Company's pledged assets over which the Group's senior secured debt holders have a right of lien; and (ii) the shortfall amount between the recoverable value of the Group’s collective pledged assets and the contractual obligation to settle the third party debt of $8.1 billion at 31 December 2022. Given the deficit amount will not be met by subsidiary undertakings in their capacity as co-guarantors, it has been recorded by the parent undertaking, Plc.

While the provision represents management's best estimate of the likely outflow of resources from the Company as determined at the reporting date, the Company is one of several guarantors of the senior notes and therefore, remains liable for the full contractual amount until such times as all outstanding third-party debts have been settled in full to the satisfaction and approval of the Bankruptcy Courts.

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.

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. FINANCIAL GUARANTEE LIABILITIES

Financial Guarantee Liabilities consists of the following for the year ended December 31, 2022 (in thousands):

	Joint and several guarantees	Total
Opening balance	$ —	
Charge for the year Utilized	2,324,386	2,324,386
At 31 December 2022	$ 2,324,386	$ 2,324,386
To be settled within one year	2,324,386	2,324,386
To be settled after one year	—	—
At 31 December 2022	$ 2,324,386	$ 2,324,386

Joint and several liability guarantees

Joint and several liability arises when a number of entities are liable for a single obligation, both individually and collectively. The holder of the obligation in these circumstances can collect the entire amount from any single member of the group or from any and all members in various amounts until the liability is settled in full.

At 31 December 2022, the Company has co-guaranteed various secured and unsecured debt instruments (the "Debt instruments") issued by certain fellow subsidiary undertakings within the Endo International Group (the "Group") which amounted to $8,147 million (2021: $8,338 million) on a senior secured and unsecured basis as follows:

Credit Agreement:

i. $1,955 million term loan facility

ii. $297 million revolving credit facility

Senior secured debt:

i. $3,610 million first lien

ii. $940 million second lien

Unsecured debt:

i. $1,345 million

The Company considers these financial guarantee contracts to be within the scope of Section 21 Provisions and Contingencies. The Company accounts for these guarantee contracts as contingent liabilities until such times as it becomes probable that a payment will be required under such guarantees.

In the notes to the financial statements for the year ended 31 December 2021, these guarantees were disclosed as contingent liabilities as it was not considered probable, at that point in time, that these guarantees would be called upon by the holders of the obligation.

As described further in Note 2 of consolidated financial statements , on 16 August 2022 (the "Petition Date"), Endo International Plc ("Plc") together with certain of its direct and indirect subsidiaries (together "the Debtors") filed voluntary petitions for relief under Chapter 11 of the U.S. Bankruptcy Code (the "Bankruptcy Code), which constituted an event of default that accelerated the obligations of Plc and its affiliates under substantially all of its then-outstanding third-party debt agreements. However, Section 362 of the Bankruptcy Code stays the creditors from taking any action to enforce the related financial obligations. The creditors' rights of enforcement in respect of the Debt Instruments are subject to the applicable provisions of the Bankruptcy Code and to the supervision of the presiding bankruptcy court.

As set out in further detail in Note 2 of consolidated financial statements, on the Petition Date the Group also entered into a Restructuring Support Agreement (the initial "RSA") with an ad hoc group (the "Ad Hoc First Lien Group") of certain creditors holding in excess of 50% of the aggregate outstanding principal amount of the Group's first lien secured debt. Pursuant to the Initial RSA, among other things, one or more entities formed in a manner acceptable to the Ad Hoc First Lien Group (the "Stalking Horse Bidder" or the "Purchaser") will serve as the Stalking Horse Bidder as the Debtors seek to sell all or

substantially all of their assets pursuant to Section 363 of the Bankruptcy Code (the “Sale”), which will require the approval of the Bankruptcy Court. The Initial RSA was amended and restated on 24 March 2023 (the “Amended RSA”). Additional first-lien lenders acceded to the Amended RSA following a Bankruptcy-Court ordered mediation process.

The Debtors filed a motion for approval of proposed sale procedures (the "Bidding Procedures Motion") to the Bankruptcy Court for approval on 23 November 2022. The Bidding Procedures Motion was heard and approved by the Bankruptcy Court on 28 and 29 March 2023. The Bankruptcy Court entered the order approving the Bidding Procedures Motion on 3 April 2023 (the "Bidding Procedures Order").

The Stalking Horse Bidder’s bid, which was subject to higher or otherwise better bids from other parties pursuant to the sale procedures set out in the Bidding Procedures Order, includes an offer to purchase substantially all of the Debtor’s assets for an aggregate purchase price of approximately $5,823 million, including a credit bid in full satisfaction of the Prepetition First Lien Indebtedness (as defined in the Amended RSA) and certain other amounts described in the Amended RSA. The Amended RSA further contemplates that the Purchaser will fund one or more trusts for (i) parties with opioid-related claims against the Debtors; and (ii) the Debtors’ non-opioid related general unsecured creditors.

The Sale process set forth in the Bidding Procedures Order contemplates a marketing process and auction will be conducted under the supervision of the Bankruptcy Court, during which interested parties will have an opportunity to conduct due diligence and determine whether to submit a bid to acquire some or all of the Debtor’s assets.

The Sale contemplated by the Amended RSA remains subject to final Bankruptcy Court approval at a further hearing (the “Sale Hearing”).

Through a mediation process ordered by the Bankruptcy Court, the Debtors have made substantial progress towards the Sale, having obtained support for the Sale from several of their key constituencies, including an official committee appointed in the Bankruptcy Court proceedings to represent the interests of unsecured creditors generally (the “UCC”), an official committee to represent the interests of opioid claimants generally (the “OCC”), certain holders of the Debtors’ unsecured notes, certain holders of the Group’s secured debt who were not signatories to the Initial RSA (but who have since acceded to the Amended RSA) (the “Other First Lien Lenders”), and others. However, other parties in interest, including the United States Trustee, and the United States Department of Justice, continue to oppose the Sale on various grounds. Accordingly, no assurance can be given that the transactions described in the Amended RSA will be consummated.

The marketing process for the Sale began in earnest in early May 2023. Initial indications of interest were due on 13 June 2023 (the “IOI Deadline”). The Debtors, in their reasonable business judgment and in consultation with the Consultation Parties and the Multi-State Endo Executive Committee (each as defined in the Bidding Procedures Order), determined that no indications of interest received prior to the IOI Deadline, viewed individually or together with other indications of interest, were reasonably likely to result in the submission of a Qualified Bid (as defined in the Bidding Procedures Order). The Debtors therefore decided to terminate the remainder of the sale and marketing process (including Phase B (as defined in the Bidding Procedures Order), the bid deadline, and the auction); the Stalking Horse Bidder will be the sole successful bidder in the sale for the Debtors’ assets; and the Debtors intend to seek final Bankruptcy Court approval for the sale of substantially all of their assets to the Stalking Horse Bidder at an accelerated Sale Hearing, which is currently scheduled for 4 August 2023.

Given the termination of the marketing process and the identification of the Stalking Horse Bidder as the only successful bidder, the anticipated outcome of the Debtors’ bankruptcy process will be a Sale to the Stalking Horse Bidder.

As noted above, certain parties in interest continue to engage in mediation in an effort to resolve various objections to the Sale. There are no assurances that the parties will successfully resolve these matters via mediation and, accordingly, no assurance can be given that the Debtors will complete the Sale to the Stalking Horse Bidder, as currently contemplated.

It is currently unclear when the Sale, if approved at the Sale Hearing, will close, although it will likely be the fourth quarter of 2023. Following the closing of the Sale, the Group’s Irish entities are expected to go through a local liquidation process in Ireland which would take approximately 9-12 months to complete, from commencement to dissolution, for a very straightforward liquidation, and longer for a more complex liquidation. The liquidation process for the Irish entities would commence after closing of the Sale.

The principal value of the outstanding debt of $8,147 million, is greater than the recoverable value of Endo group’s assets, which is estimated at $5,823 million. This represents a shortfall on the principal amount of the third-party debt obligations of approximately $2.3 billion.

As set out in Note 1, the Company has prepared its accounts on a non-going concern basis and is not expected to have assets sufficient to settle all liabilities, including intercompany debt obligations, intercompany milestone obligations, or the surplus portion of the Group’s third-party debt obligations for which the Company may be deemed liable, under the relevant accounting standards, as a joint and several guarantor of such obligations given the event of default which occurred on the Petition Date which is not satisfied by the other guarantors to the debt agreements.

The Company has recorded a provision in the current year which reflects management's best estimate of the probable outflow of resources pertaining to the third–party debt arrangements for which it is a co–guarantor. This provision has been calculated based on the expected recoverable value of the Company's pledged assets over which the Group's senior secured debt holders have a right of lien. All of the Company's assets are considered pledged, unless otherwise noted below.

The Company, as ultimate parent undertaking of the group, has recorded an additional provision of $2.3 billion which represents management's best estimate of the deficit amount which will not be serviced by other guarantors/subsidiary undertakings plus the recoverable value of the standalone entities pledged assets. The joint and several guarantors of the Endo Group are contractually liable to settle the third-party debt as the holder of the obligation can call upon the individual guarantors to provide in satisfying (or partially satisfying) the outstanding debt until the liability is settled in full. The provision recorded by Plc represents the value of their pledged assets plus the calculated shortfall between the collective recoverable value of the group's pledged assets and the group's contractual obligation to settle the third party debt of $8.1 billion as at the reporting date.

Management has taken a bottom-up approach in quantifying and recognising provisions across the joint and several guarantors, such that the total contractual liability of $8,147 million is provided for at 31 December 2022.

In arriving at this provision, the recoverable value of each of the Company's pledged assets has been calculated as outlined below.

Financial assets

The recoverable value of the Company's financial assets, comprising cash at bank and on hand, investments in subsidiaries (which have been fully impaired – see Note 4) and accounts receivable, are considered approximate to their carrying values as at 31 December 2022.

As noted above, the Group's secured third-party debt amounts to $6,802 million with $4,550 million of the debt secured with a first ranking lien charge over the Company's assets as it is a co-guarantor of the debt. The provision which has been recorded of $2,324.4 million is reflective of (i) the estimated recoverable value of the Company's pledged assets; and (ii) the shortfall amount between the recoverable value of the group's collective pledged assets and its contractual obligation to settle the third party debt of $8.1 billion at 31 December 2022. Given the deficit amount will not be met by subsidiary undertakings in their capacity as co-guarantors, it has been recorded by the parent undertaking, Plc.

The estimates of the recoverable value of the Company's assets are uncertain and changes in any of the estimated inputs used could result in significant adjustments to the recoverable value of the Company's assets, which could, in turn, result in a material adjustment to the quantum of the liability recognised for the financial guarantee.

As such the financial guarantee liability which has been recorded is subject to significant estimation uncertainty and there is a significant risk of material adjustment to the liability recorded in the next financial year. In the event the Sale is approved to the Stalking Horse Bidder in the Sale Hearing, the guarantee will be extinguished and the outstanding third-party debt will be satisfied at approximately $5,823 million which is equivalent to the recoverable value of the Endo group's assets. The Company would then reverse its provision for any estimated shortfall between the recoverable value of the Group's pledged assets and the Group's contractual obligation to settle the third party debt of $8.1 billion, in the financial year in which the sale is approved and third-party debt satisfied.

NOTE 13. AUDITORS' REMUNERATION

Total auditors' remuneration paid to PricewaterhouseCoopers and its affiliated firms for the years ended December 31, 2022 and 2021 were as follows (in thousands):

	2022	2021
Audit of the Company's individual financials	$ 65	$ 25
Audit-related fees	—	—
Tax fees	—	—
Total auditors' remuneration	$ 65	$ 25

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 14. SUBSEQUENT EVENTS

Subsequent events have been evaluated through August 10, 2023 the date this report is approved by the Audit & Finance Committee of the Board of Directors and the Board of Directors.

Refer to Note 2 Bankruptcy Proceedings of the Consolidated Statements for details of the ongoing Chapter 11 bankruptcy proceedings, including event which occurred since the end of the financial year.

On March 3, 2023, in connection with the Company's ongoing bankruptcy proceedings, the Company took action to reject all outstanding award agreements associated with stock options and stock awards. In connection with the rejection of these agreements, the Company recorded a charge of approximately $9.2 million during the first quarter of 2023 to recognize all remaining unrecognized compensation cost associated with these agreements.

During 2023 the Company entered into a new loan revolver agreement with its affiliate entity for $650 million. During 2023 the Company has drawn down a total of $230.9 million during 2023 against this revolver.

During 2023 the Company increased its existing revolver loan drawdown limit with its affiliate entity from $250 to $350 million during the year. During 2023 the Company has drawn down a total of $206 million during 2023 against this revolver.

NOTE 15. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved and authorized for issue by the directors on August 10, 2023.