UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission file number 001-36326

Endo International plc

(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Act: None (1)

(1) On August 26, 2022, Endo International plc's ordinary shares, which previously traded on the Nasdaq Global Select Market under the symbol ENDP, began trading exclusively on the over-the-counter market under the symbol ENDPQ. On September 14, 2022, Nasdaq filed a Form 25-NSE with the United States Securities and Exchange Commission and Endo International plc's ordinary shares were subsequently delisted from the Nasdaq Global Select Market. On December 13, 2022, Endo International plc's ordinary shares were deregistered under Section 12(b) of the Securities Exchange Act of 1934, as amended.

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	Yes	☐	No	☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.	Yes	☒	No	☐
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.	Yes	☒	No	☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).	Yes	☒	No	☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.	☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.	☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.	☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b).	☐

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

The aggregate market value of the voting common equity (ordinary shares) held by non-affiliates as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) was $4,084,766 based on a closing sale price of $0.0175 per share as reported on the over-the-counter market on that date. Ordinary shares held by each officer and director have been excluded since such persons and beneficial owners may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no non-voting ordinary shares authorized or outstanding.

The number of ordinary shares, nominal value $0.0001 per share outstanding as of February 28, 2024 was 235,219,612.

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
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FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this document contain information that includes or is based on "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act) and the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, any statements relating to future financial results, cost savings, revenues, expenses, net income and income per share; the status, progress and/or outcome of litigation, proceedings under chapter 11 of title 11 of the United States (U.S.) Code (the Bankruptcy Code) and/or any other contingency planning initiatives, including the application and effect of the automatic stay thereunder; future financing activities; the impact of public health crises and epidemics on the health and welfare of our employees and on our business (including any economic impact, anticipated return to historical purchasing decisions by customers, changes in consumer spending, decisions to engage in certain medical procedures, future governmental orders that could impact our operations and the ability of our manufacturing facilities and suppliers to fulfill their obligations to us); the expansion of our product pipeline and any development, approval, launch or commercialization activities; and any other statements that refer to Endo's expected, estimated or anticipated future results. We have tried, whenever possible, to identify such statements with words such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "project," "forecast," "will," "may" or similar expressions. We have based these forward-looking statements on our current expectations, assumptions and projections about, among other things, the growth of our business, our financial performance and the development of our industry.

Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties including, without limitation, the timing or results of any pending or future litigation, investigations, claims, actual or contingent liabilities, settlement discussions, negotiations or other adverse proceedings, including proceedings involving opioid-related matters, antitrust matters and tax matters with the U.S. Internal Revenue Service (IRS); unfavorable publicity regarding the misuse of opioids; the status, progress and/or outcome of our ongoing bankruptcy proceedings; changing competitive, market and regulatory conditions; changes in legislation; our ability to obtain and maintain adequate protection for our intellectual property rights; the impacts of competition such as those related to the loss of VASOSTRICT® exclusivity; the timing and uncertainty of the results of both the research and development and regulatory processes, including regulatory decisions, product recalls, withdrawals and other unusual items; domestic and foreign health care and cost containment reforms, including government pricing, tax and reimbursement policies; technological advances and patents obtained by competitors; the performance, including the approval, introduction and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; our ability to develop or expand our product pipeline and to continue to develop the market for XIAFLEX® and other branded or unbranded products; the impact that known and unknown side effects may have on market perception and consumer preference; the success of any acquisition, licensing or commercialization; the effectiveness of advertising and other promotional campaigns; the timely and successful implementation of any strategic and/or optimization initiatives; the uncertainty associated with the identification of and successful consummation and execution of external corporate development initiatives and strategic partnering transactions; our ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner; and the other risks and uncertainties more fully described under the caption "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K and in other reports that we file with the Securities and Exchange Commission (SEC).

These risks and uncertainties, many of which are outside of our control, and any other risks and uncertainties that we are not currently able to predict or identify, individually or in the aggregate, could have a material adverse effect on our business, financial condition, results of operations and cash flows and could cause our actual results to differ materially and adversely from those expressed in forward-looking statements contained or referenced in this document, including with respect to opioid, tax or antitrust related proceedings or any other litigation; the effects of our ongoing bankruptcy proceedings and the related events of default under our indebtedness on our current and future liquidity and ability to fund our working capital, capital expenditures, business development, debt service requirements, acquisitions and any other obligations; our ability to attract and retain key personnel; our ability to adjust to changing market conditions; and/or the potential for a significant reduction in our short-term and long-term revenues and/or any other factor that could cause us to be unable to fund our operations and liquidity needs.

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

PART I

Item 1. *Business*

Overview

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

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

Our ordinary shares, 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 Part I. The results of operations of our reportable business segments are discussed in Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the heading "RESULTS OF OPERATIONS." Across all of our reportable business segments, we generated total revenues of $2.01 billion, $2.32 billion and $2.99 billion in 2023, 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. Additional information is included throughout this Part I, Item 1.

Generic products are the pharmaceutical and therapeutic equivalents of branded products and are generally sold under their generic (chemical) names rather than their brand names. For generic products, which we sell primarily through our Sterile Injectables and Generic Pharmaceuticals segments, our focus is on high-barrier-to-entry products, with an emphasis on complex sterile injectable products, such as ready-to-use (RTU) products, and first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges. In the U.S., 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. Additional information is included throughout this Part I, Item 1.

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 Part IV, Item 15 of 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.

As further described in this section and throughout this Annual Report on Form 10-K, the Debtors have made substantial progress in the chapter 11 proceedings, including reaching resolutions with substantially all stakeholders. The Debtors anticipate seeking confirmation of the Plan from the Bankruptcy Court in a hearing currently scheduled for March 19, 2024 and, subject to such confirmation, anticipate consummation of the transactions contemplated in the Plan in the second quarter of 2024. The Company, including the Debtors and its non-debtor affiliates, continues to plan for the execution of the transactions contemplated in the Plan and, further, the successful continued operation of its business by the Purchaser following the confirmation and consummation of the Plan. Notably, the Plan contemplates the resolution of various historical litigation matters facing the Company and a revised capital structure for the Purchaser, including a substantial reduction in the outstanding debt obligations compared to the historical debt obligations of the Company, which are expected to provide greater financial and operational flexibility for the Purchaser compared to that of the Company. While the Company anticipates that the Purchaser will continue to pursue the same or similar strategy and will continue to operate its businesses and utilize its assets in substantially the same or similar manner as the Company, the Purchaser may, either initially or over time, refine, enhance or otherwise make changes to the strategy, the manner in which it manages or operates its businesses, utilizes its assets or discharges its liabilities, or other matters following the consummation of the transactions contemplated in the Plan. Such changes, if any, will be made at the discretion of the Purchaser and are generally not contemplated or reflected herein.

Our Strategy

Endo International plc is a diversified 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 and non-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 Corporate Responsibility and Sustainability (CRS) strategy, we are committed to the adoption of more sustainable practices, including the promotion of Diversity, Equity and Inclusion (DE&I) in all that we do, and to operating our business in a responsible manner that seeks to minimize environmental impact, while promoting the safe, efficient and responsible use of global resources.

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

Our Competitive Strengths

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

Experienced and dedicated management team. We have a highly skilled and customer-focused management team in critical leadership positions across Endo. Our senior management team has extensive experience in the pharmaceutical industry, including improving business performance through organic revenue growth, operational and commercial excellence and through the identification, consummation and integration of licensing and acquisition opportunities. This experience is demonstrated through a proven track record of developing products and businesses.

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

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

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

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

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

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

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

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

In addition to advertising in professional journals, participating in medical meetings and conventions and utilizing direct mail and internet programs to provide descriptive product literature and scientific information, we have also utilized both branded and unbranded marketing and public relations campaigns across digital, social and television platforms to reach our target consumers. For example, during the fourth quarter of 2023, we launched a new Peyronie's disease (PD) condition awareness campaign featuring unscripted videos with real PD patients, during the first quarter of 2022, we launched a new Dupuytren's contracture (DC) condition awareness campaign featuring real DC patients and, during the fourth quarter of 2021, we launched a new multi-channel branded advertising campaign for XIAFLEX® for the treatment of PD, including our first-ever television commercial for XIAFLEX®.

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

Products Overview

Branded Pharmaceuticals

The following table displays the revenues from external customers of our Branded Pharmaceuticals segment for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Specialty Products:			
XIAFLEX®	$ 475,014	$ 438,680	$ 432,344
SUPPRELIN® LA	96,849	113,011	114,374
Other Specialty (1)	73,797	70,009	86,432
Total Specialty Products	$ 645,660	$ 621,700	$ 633,150
Established Products:			
PERCOCET®	$ 106,375	$ 103,943	$ 103,788
TESTOPEL®	42,464	38,727	43,636
Other Established (2)	64,588	86,772	113,043
Total Established Products	$ 213,427	$ 229,442	$ 260,467
Total Branded Pharmaceuticals (3)	$ 859,087	$ 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, 2023 and/or any product having revenues in excess of $25 million during any completed quarterly period in 2023 or 2022.

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 PD (for adult men with a collagen plaque and a penile curvature deformity of thirty degrees or greater at the start of therapy) and DC (for adult patients with an abnormal buildup of collagen in the fingers that limits or disables hand function).
- 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 Company 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 management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
- 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 Company's pain products, including opioid products, are managed as mature brands and are not and have not been actively promoted for years. In December 2016, the Company announced the elimination of its entire U.S. pain product field sales force.

Sterile Injectables

The following table displays the revenues from external customers of our Sterile Injectables segment for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
ADRENALIN®	$ 99,910	$ 114,304	$ 124,630
VASOSTRICT®	93,180	253,696	901,735
Other Sterile Injectables (1)	236,473	221,633	239,732
Total Sterile Injectables (2)	$ 429,563	$ 589,633	$ 1,266,097

(1) Products included within Other Sterile Injectables include, but are not limited to, APLISOL®.
(2) Individual products presented above represent the top two performing products within the Sterile Injectables segment for the year ended December 31, 2023 and/or any product having revenues in excess of $25 million during any completed quarterly period in 2023 or 2022.

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:

- ADRENALIN®, which is a non-selective alpha and beta adrenergic agonist indicated for emergency treatment of certain allergic reactions, including anaphylaxis.
- 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.
- APLISOL®, which is a sterile aqueous solution of a purified protein derivative for intradermal administration as an aid in the diagnosis of tuberculosis.

Generic Pharmaceuticals

The Generic Pharmaceuticals segment includes a product portfolio of approximately 85 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 April 2023, we launched posaconazole oral suspension (the authorized generic of Merck's Noxafil®).

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 (PFI). In March 2023, we announced top-line results from our Phase 2 clinical study of XIAFLEX® in participants with PFI and while the primary endpoint when analyzed with the overall study population did not meet statistical significance, a large patient sub-population showed statistically significant improvement across a majority of endpoints. We initiated the Phase 3 clinical program in the fourth quarter of 2023. We also completed a proof-of-concept study in plantar fasciitis (PFA) during the third quarter of 2023 and, based on encouraging proof-of-concept study results initiated the Phase 2 clinical study in the fourth quarter of 2023. We may in the future develop our XIAFLEX® product for potential additional indications, advancing our strategy of developing both non-surgical orthopedic and non-orthopedic care interventions.

Other

Our remaining pipeline consists mainly of a variety of product candidates in our Sterile Injectables and Generic Pharmaceuticals segments. As of December 31, 2023, within these two segments, we were actively pursuing approximately 60 product candidates, including: (i) approximately 16 ANDAs pending with the FDA, of which approximately 50% are associated with our Sterile Injectables segment, as well as (ii) approximately 44 additional projects in development, of which approximately 93% 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 differentiated product candidates in our Sterile Injectables segment, potentially including acquisitions and/or license and commercialization agreements.

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

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

Major Customers

We primarily sell our products to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and/or government agencies. Our wholesalers and/or distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies, hospitals, long-term care facilities, clinics, home infusion pharmacies, government facilities and managed care organizations (MCOs). Our current customer group reflects significant consolidation in recent years, marked by mergers and acquisitions and other alliances. Net revenues from direct customers that accounted for 10% or more of our total consolidated net revenues during the years ended December 31, 2023, 2022 and 2021 are as follows:

	2023	2022	2021
Cencora, Inc., previously known as AmerisourceBergen Corporation (1)	29 %	35 %	36 %
McKesson Corporation	25 %	26 %	32 %
Cardinal Health, Inc.	17 %	20 %	22 %
CVS Health Corporation (1)	16 %	4 %	— %

(1) During the second quarter of 2022, CVS Health Corporation finalized the acquisition of US Bioservices from Cencora, Inc. (known as AmerisourceBergen Corporation at the time).

Net revenues from these customers are generally included within each of our segments.

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

Competition

Branded Products

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

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

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

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

Branded Pharmaceuticals

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

Several of this segment's products, such as PERCOCET®, TESTOPEL® 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 Pfizer Hospital US, Fresenius Kabi USA, LLC, Viatris, Amphastar Pharmaceuticals, Inc., Amneal Pharmaceuticals, Inc. (Amneal), Hikma Pharmaceuticals PLC, Sandoz Group AG (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 ADRENALIN® and VASOSTRICT®, 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 28, 2024, we held approximately: 140 U.S. issued patents, 40 U.S. patent applications pending, 372 foreign issued patents and 124 foreign patent applications pending. In addition, as of February 28, 2024, we had licenses for approximately 60 U.S. issued patents, 14 U.S. patent applications pending, 130 foreign issued patents and 65 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 PFI 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 revenues for that product in a very short period of time that may never be reversed. In some cases, however, it is possible to obtain commercial benefits from product manufacturing trade secrets, patents on uses for products, patents on processes and intermediates for the economical manufacture of the active ingredients or patents for special formulations of the product or delivery mechanisms. There can also be no assurance that our confidentiality agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property.

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

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

Governmental Regulation

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

The pharmaceutical industry in the U.S. is subject to extensive and rigorous government regulation. The 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. Risk Factors - "The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business."

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

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

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. 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 pharmaceutical and biological product manufacturing operations. Compliance with the regulations requires a continuous commitment of time, money and effort in all operational areas.

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

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

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

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

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

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

In October 2018, the U.S. Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (H.R. 6). Intended to achieve sweeping reform to combat opioid abuse, H.R. 6, among other provisions, amends related laws administered by the FDA, DEA and the 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 Item 1A. Risk Factors, statutory and regulatory requirements for government healthcare programs such as Medicaid, Medicare and TRICARE govern access and provider reimbursement levels, and provide for other cost-containment measures such as requiring pharmaceutical companies to pay rebates or refunds for certain sales of products reimbursed by such programs, or subjecting products to certain price ceilings. In addition to the cost-containment measures described in Item 1A. Risk Factors, sales to retail pharmacies under the TRICARE Retail Pharmacy Program are subject to certain price ceilings which require manufacturers to, among other things, pay refunds for prescriptions filled based on the applicable ceiling price limits. Beginning in the first quarter of 2017, pursuant to the Bipartisan Budget Act of 2015, manufacturers are required to pay additional rebates to state Medicaid programs if the prices of their non-innovator products rise at a rate faster than inflation (as continues to be the case for innovator products); this requirement previously existed only as to branded or innovator products.

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 (IRA) that was enacted in August 2022. See Item 1A. Risk Factors - "The availability of third-party reimbursement for our products is uncertain, and we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third-party reimbursement is not adequately provided, and government-led efforts may seek to legislate or otherwise effect lower prices for our products."

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 Company regarding vaginal mesh devices previously sold by certain of our operating subsidiaries and investigations and litigation by certain government entities regarding the prior promotional practices of certain of our operating subsidiaries with respect to opioid products.

International Regulations

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

In Canada, the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)* (the Amendments) 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 revenues that were generated and/or the price of the medicine must be reduced. The PMPRB's authority to regulate the price of a drug product is linked to patent protection, specifically when there is a patent to an invention that is intended or capable of being used for medicine or for the preparation or production of medicine.

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 Environmental, Social and Governance (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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information.

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

License & Collaboration Agreements and Acquisitions

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

Human Capital Resources

As of February 28, 2024, we have 2,931 employees, of which 446 are engaged in R&D and regulatory work, 365 in sales and marketing, 1,153 in manufacturing, 620 in quality assurance and 347 in general and administrative capacities. With the exception of approximately 215 production personnel in our Rochester, Michigan manufacturing facility, our employees are generally not represented by unions. In March 2024, our collective bargaining agreement with United Steelworkers Local 176, which affects the production personnel in our Rochester, Michigan manufacturing facility, will expire, and negotiations for a replacement collective bargaining agreement are ongoing. We cannot predict the timing or outcome of the negotiations. We believe that our relations with our employees are good.

Information about our Executive Officers

The following table sets forth, as of March 6, 2024, information about our executive officers:

Name	Age	Position and Offices
Blaise Coleman	50	President and Chief Executive Officer
Patrick Barry	56	Executive Vice President and President, Global Commercial Operations
Mark T. Bradley	55	Executive Vice President and Chief Financial Officer
Matthew J. Maletta	52	Executive Vice President and Chief Legal Officer and Company Secretary
James P. Tursi, M.D.	59	Executive Vice President, Global Research & Development

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

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

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

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

James P. Tursi, M.D. was appointed Executive Vice President, Global Research & Development, effective January 2022. In this role, Dr. Tursi is responsible for leading global research & development, medical affairs and regulatory operations. Prior to joining Endo, he held senior leadership roles at Ferring Pharmaceuticals U.S., Antares Pharmaceuticals and Aralez Pharmaceuticals. Prior to Aralez, Dr. Tursi was Chief Medical Officer and Vice President of Clinical R&D at Auxilium Pharmaceuticals until its acquisition by Endo in 2015. Dr. Tursi practiced medicine and surgery for over 10 years and created a medical education company, I Will Pass®, which assisted physicians in the process of board certification. He performed his residency in Gynecology and Obstetrics at the Johns Hopkins Hospital, holds a Bachelor of Science degree in Chemistry and Biology from Ursinus College and a Doctor of Medicine degree from the Medical College of Pennsylvania. Dr. Tursi is a member of the Ideal Image and NueroBo Pharmaceuticals Boards of Directors. Previously, Dr. Tursi served as a member of the Agile Therapeutics, Inc. Board of Directors from October 2014 to October 2022.

We have employment agreements with each of our executive officers.

Available Information

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

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

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

Item 1A. ***Risk Factors***

Risk Factor Summary

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

Business Related Risks

- We operate in a highly competitive industry.
- Other pharmaceutical companies may obtain approval for competing versions of our products.
- Pharmacies or outsourcing facilities may produce compounded versions of our products.
- We may fail to successfully identify, develop, maintain or introduce products.
- Uncertainties exist regarding our acquisition and licensing strategy.
- Asset sales could adversely affect our prospects and opportunities for growth.
- Third-party reimbursement for our products is uncertain.
- Price levels may be reduced because of social or political pressures.
- Our business is highly dependent upon market perceptions of us, our brands and the safety and quality of our products.
- Our business and financial condition may be adversely affected by existing or future legislation and regulations.
- Our customer concentration may adversely affect us.
- We are currently dependent on outside manufacturers for the manufacture of a significant amount of our products.
- We are dependent on third parties to supply raw materials used in our products and to provide services.
- We have limited experience in manufacturing biologic products and may encounter difficulties in our manufacturing processes.
- The DEA could limit the availability of active ingredients and the production of products.
- We rely on our ability to retain our key personnel and to continue to attract additional professional staff.
- Our operations could be disrupted if our information systems fail or are not upgraded or 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 Plan (as defined below) could be adversely affected.
- Even if the Plan is consummated, we may not be able to achieve our goals or continue as a going concern.
- Our ability to prosecute the Chapter 11 Cases and confirm and consummate the Plan may be contested by third parties.
- 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 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.
- We may be subject to claims that will not be discharged in the Chapter 11 Cases.
- 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 significant expenses, hinder 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 and generic pharmaceutical companies are facing increased government scrutiny.
- We are subject to various laws, court orders 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; our failure to comply with these laws and regulations could have a material adverse impact.
- 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 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 technology, which is vital to our business, is uncertain.
- Allegations of intellectual property infringement, unfavorable 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 income may be limited.

Structural and Organizational Risks

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

Risk Factors

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

Business Related Risks

We operate in a highly competitive industry.

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

Certain of our branded products do not currently compete with on-market generic products but are likely to face generic competition in the future. The entrance of generic competitors can occur at any time and cannot be predicted with certainty. For additional information on our patent protection, refer to Part I, Item 1 of this report "Business" under the caption "Patents, Trademarks, Licenses and Proprietary Property." Generic products we currently sell with generic exclusivity could in the future be subject to competition from other generic competitors. Some of our other 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. For example, the U.S. federal government has taken numerous legislative and regulatory actions to expedite the development and approval of generic drugs and biosimilars. Congress, the FDA and other regulatory agencies are considering, and have enacted, various legislative and regulatory initiatives focused on drug competition, including legislation focused on drug patenting and provision of drug to generic applicants for testing. 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 revenue of such products, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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. 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®. 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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

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

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

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

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

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

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

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

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

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

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

- diversion of management's attention to integration matters;
- difficulties in achieving anticipated cost or tax savings, synergies, business opportunities and growth prospects from the combination of the businesses;
- difficulties in the integration of operations and systems;
- the impact of pre-existing legal and/or regulatory issues;
- difficulties in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the companies;
- difficulties in the assimilation of employees and retention of key personnel;
- difficulties in managing the expanded operations of a larger and more complex company;
- challenges in retaining existing customers and obtaining new customers;
- potential unknown liabilities or larger liabilities than projected;
- unforeseen increases to expenses or other adverse consequences; and
- difficulties in coordinating a geographically dispersed organization.

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

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

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

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

In addition to our efforts to consummate a sale transaction through our Plan, 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 Part IV, Item 15 of 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, and government-led efforts may seek to legislate or otherwise effect lower prices for our products.

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 and regulatory agencies 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, as well as the impact of any ongoing or future legal challenges to such 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 IRA. 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 income on corporations whose average annual adjusted financial statement income 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. These provisions started taking effect incrementally in late 2022 and currently are subject to various legal challenges. For example, as of the date of this report, CMS has released initial revised guidance addressing the Medicare Part B and Medicare Part D inflation rebate provisions of the IRA. In addition, in June 2023, CMS released revised guidance setting forth the requirements and procedures for implementing the Medicare Drug Price Negotiation Program for the first round of drug pricing evaluations, which occurred in 2023 and will continue in 2024, resulting in prices effective in 2026; our revenues may be significantly impacted if one or more of our products are eventually selected for evaluation under this program. While the impact of the IRA was not material to us in 2022 or 2023, 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 revenue and future profitability.

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

In addition, the federal government and a number of federal legislators continue to scrutinize pharmaceutical prices and seek ways to lower prices. For example, recent legislation, including the IRA, 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, company name and the safety and quality of our products. Our products and similar products are subject to market withdrawal or recall and may be claimed or proven to be ineffective or harmful to consumers.

Our products may cause known or unknown adverse or other side effects. 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 revenues and royalties, any of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

We cannot predict with any certainty how existing laws may be applied or how laws or legal standards may change in the future. Current or future legislation and regulations, whether state or federal, or in any of the non-U.S. jurisdictions with authority over our operations, may have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 revenues deemed by the PMPRB to be excessive, which could ultimately impact the commercial viability of products we sell in Canada, reduce the revenues 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" in Part I, Item 1.

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

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

Net revenues from direct customers that accounted for 10% or more of our total consolidated net revenues during the years ended December 31, 2023, 2022 and 2021 are as follows:

	2023	2022	2021
Cencora, Inc. (1)	29 %	35 %	36 %
McKesson Corporation	25 %	26 %	32 %
Cardinal Health, Inc.	17 %	20 %	22 %
CVS Health Corporation (1)	16 %	4 %	— %

(1) During the second quarter of 2022, CVS Health Corporation finalized the acquisition of US Bioservices from Cencora, Inc. (known as AmerisourceBergen Corporation at the time).

Net revenues from these customers are generally included within each of our segments.

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

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

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

We are dependent on third parties to supply raw materials used in our products and to provide services for certain core aspects of our business. Any interruption, 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 company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. We may also be unsuccessful in resolving any underlying issues with such suppliers, distributors and partners or replacing them within a reasonable time and on commercially reasonable terms.

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

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

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

The manufacture of biologic products requires significant expertise and capital investment. Although we manufacture CCH, which is included in XIAFLEX®, 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 or are not upgraded or are subject to cyber-attacks.

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

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

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

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

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

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

In 2023, approximately 4% of our total revenues were from customers outside the U.S. Some of these sales were to governmental entities and other organizations with extended payment terms. Conducting business internationally, including the sourcing, manufacturing, development, sale and distribution of our products and services across international borders, subjects us to extensive U.S. and foreign governmental trade regulations, such as various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act (FCPA), export control laws, customs and import laws and anti-boycott laws. The FCPA and similar anti-corruption laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. We cannot provide assurance that our internal controls and procedures will always protect us from criminal acts committed by our employees or third parties with whom we work. If we are found liable for violations of the FCPA or other applicable laws and regulations, either due to our own acts or out of inadvertence, or due to the acts or inadvertence of others, we could suffer significant criminal, civil and administrative penalties, including, but not limited to, imprisonment of individuals, fines, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting, as well as reputational harm. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, some countries where we source, develop, manufacture or sell products are subject to political, economic and/or social instability. Our non-U.S. R&D, manufacturing and sales operations expose us and our employees, representatives, agents and distributors to risks inherent in operating in non-U.S. jurisdictions. For example, we currently perform certain R&D and manufacturing operations in India and plan to expand these operations, including through investment in 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;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions including foreign exchange controls;
- supply disruptions and increases in energy and transportation costs;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- changes in global tax laws and/or the imposition by tax authorities of significant fines, penalties and additional taxes;
- pricing pressure that we may experience internationally;
- fluctuations in foreign currency exchange rates;
- competition from local, regional and international competitors;
- difficulties and costs of staffing and managing foreign operations, including cultural differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate;
- difficulties and costs of obtaining and maintaining labs, R&D sites, manufacturing facilities and other locations in which we operate;
- COVID-19 or other outbreaks, epidemics or pandemics as described in the risk factor "Widespread health problems, including the recent global coronavirus, could materially and adversely affect our business" set forth in this report;
- laws and business practices favoring local companies;
- difficulties in enforcing or defending intellectual property rights; and
- exposure to different legal and political standards due to our conducting business in foreign countries.

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

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

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

Public health outbreaks, epidemics or pandemics, such as the coronavirus, could materially and adversely impact our business. The effects of COVID-19, including public health directives and orders, impacted our business and similar public health outbreaks 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.

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 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 confirm and consummate the Plan or another restructuring transaction;
- 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 amended 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 confirm and consummate the Plan or another restructuring transaction;
- the impact on our business following the sale transaction contemplated by the Plan in light of possible changes in our business and its prospects;
- the adequacy of our cash balances at the time the Plan goes effective 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 confirm and consummate the Plan and increase our costs associated with the Chapter 11 Cases.

The RSA contemplates the confirmation and consummation of the Plan, but there can be no assurance that we will be able to confirm and consummate the Plan. 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 Plan (or any alternative restructuring transaction). If we are unable to confirm and consummate the Plan (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 confirmation and consummation of the Plan. 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 Plan could be 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 Plan by the parties to the RSA, which could adversely affect our ability to confirm and consummate the Plan. If the Plan is not confirmed and 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 Plan transaction.

Even if the Plan is consummated, we may not be able to achieve our goals or continue as a going concern.

Even if the Plan 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 Plan 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 and we are able to raise funds through exit financing and/or one or more rights offering in connection with the Plan, we will 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 confirm and consummate the Plan may be contested by third parties.

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 than under the Plan 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. The Bankruptcy Court has since extended our exclusive periods several times through and including February 16, 2024 and April 16, 2024, respectively. It is possible, however, 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 (ii) since the Bankruptcy Court has already authorized the maximum extension of our exclusive periods allowed under the Bankruptcy Code, that such periods could expire without extension before our Plan is confirmed or another restructuring transaction is consummated.

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 Plan 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.

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

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.

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 will 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, in addition to the potential exit financing and rights offerings contemplated by the Plan, 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 and cash equivalents plus certain specified amounts of restricted cash associated with the TLC Agreement (as defined and further discussed 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 Plan. 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 2023, our ordinary shares were quoted at prices between approximately $0.0001 and $0.1450 per share. The following factors, in addition to other risk factors 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;
- period-to-period fluctuations in our financial results;
- new legislation, regulation, administrative guidance or executive orders, or changes in interpretation of existing legislation, regulation, administrative guidance or executive orders, including by virtue of new judicial decisions, that could affect the development, sale or pricing of pharmaceutical products, the number of individuals with access to affordable healthcare, the taxes we pay and/or other factors;
- a determination by a regulatory agency that we are engaging in or have engaged in inappropriate sales or marketing activities, including promoting off-label uses of our products;
- social and political pressure to lower the cost of pharmaceutical products;
- social and political scrutiny over increases in prices of shares of pharmaceutical companies that are perceived to be caused by a strategy of growth through acquisitions;
- litigation against us or others;
- reports of security analysts and rating agencies;
- judgments or settlements or reports of settlement negotiations concerning opioid-related litigation or claims; 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, 2023, 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 significant expenses, hinder 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 has resulted 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 has and will continue to 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 has resulted 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 Plan 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 company.

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

As further discussed in Note 2. Bankruptcy Proceedings and Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report, 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. 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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of 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 revenues, injunctions and disruption of business. Additionally, we have received, and may continue to receive, claims or requests for indemnification from other persons or entities named in or subject to discovery in various lawsuits or other legal proceedings, including certain of our customers.

We and other manufacturers of prescription opioid medications have been, and will likely continue to be, subject to negative publicity and press, which could harm our brand and the demand for our products.

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

Any failure to effectively identify, analyze, report and protect adverse event data and/or to fully comply with relevant laws, rules and regulations around adverse event reporting could expose the Company to legal proceedings, penalties, fines and/or reputational damage. 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 revenue. Adverse publicity could also result in an increased number of additional product liability claims, whether or not these claims have a basis in scientific fact. See the risk factor "Public concern around the abuse of opioids or other products including, without limitation, law enforcement concerns over diversion or marketing practices, regulatory efforts to combat abuse and litigation could result in costs to our business and damage our reputation" for more information.

If we are found liable in any lawsuits, including the 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 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information.

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

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

We may not have and may be unable to obtain or maintain insurance on acceptable terms or with adequate coverage against potential liabilities or other losses, including costs, judgments, settlements and other liabilities incurred in connection with current or future legal proceedings, regardless of the success or failure of the claim. For example, we do not have insurance sufficient to satisfy all of the opioid claims that have been made against us. 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 Company. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of opioids, the limitations of abuse-deterrent formulations, the ability of abusers to discover previously unknown ways to abuse our products, public inquiries and investigations into drug abuse or litigation or regulatory or enforcement activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation, on the results of litigation and on our ability to attract or maintain relationships with third-party partners, including suppliers, vendors, advisors, distributors, manufacturers, collaboration partners, administrators and agents. As a result of the timing and schedule of certain legal proceedings against us, we will likely be subject to additional press for the foreseeable future.

Manufacturers of prescription opioid medications have been the subject of significant civil and criminal investigatory and enforcement actions even in cases where such medications have received approval from the FDA or similar regulatory authorities. Numerous governmental and private persons and entities are pursuing litigation against opioid manufacturers, including us, as well as distributors and others, asserting alleged violations of various laws and regulations relating to opioids and/or other prescription medicines, relying on common law theories, and seeking to hold the defendants accountable for, among other things, societal costs associated with the misuse and abuse of prescription opioid medications as well as non-prescription opioids. 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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

There have been proposals in certain legislatures to restrict the ability to compromise or release liability of certain parties in such cases, and we cannot assure you whether any such proposals will be made or adopted in the future or predict how any such proposals may affect the Company.

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

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

Financial and Liquidity Related Risks

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

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

- causing a substantial portion of our cash flows from operations to be dedicated to the payment of legal or related expenses and therefore unavailable for other purposes, including the payment of principal and interest on our indebtedness, our operations, capital expenditures and future business opportunities;
- limiting our ability to adjust to changing market conditions, causing us to be more vulnerable to periods of negative or slow growth in the general economy or in our business, causing us to be unable to carry out capital spending that is important to our growth and placing us at a competitive disadvantage;
- limiting our ability to attract and retain key personnel;
- causing us to be unable to maintain compliance with or making it more difficult for us to satisfy our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt and long-term corporate ratings (which could increase our cost of capital) and exposing us to potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries’ outstanding indebtedness;

- limiting our ability to incur additional borrowings under the covenants in our then-existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness; and/or
- causing a significant reduction in our short-term and long-term revenues and/or otherwise causing us to be unable to fund our operations and liquidity needs, such as future capital expenditures and payment of our indebtedness.

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, 2023 and 2022, goodwill and other intangibles comprised approximately 55% and 54%, 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 year ended December 31, 2023, we recorded a minimal amount of asset impairment charges. 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 Part IV, Item 15 of this report for examples and a discussion of material impairment tests and impairment charges during the years ended December 31, 2022 and 2021. The procedures and assumptions used in our goodwill and other intangible assets impairment testing are discussed in Part II, Item 7 of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "CRITICAL ACCOUNTING ESTIMATES" and in Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

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

We currently have a substantial amount of indebtedness. As of December 31, 2023, 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 revenues or increased costs and expenses related to the impact of COVID-19 on our business, as well as increased pricing pressures or otherwise, we may be required to refinance all or part of our then-existing indebtedness, sell assets, reduce or delay capital expenditures or seek to raise additional capital. Any of 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, including in connection with any exit financing or rights offerings contemplated by the Plan, 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, 2023, 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. 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 and generic pharmaceutical companies are facing increased government scrutiny.

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 Company and/or its subsidiaries have been named in several such lawsuits. For example, beginning in May 2018, multiple complaints were filed in the U.S. District Court for the Southern District of New York against PPI, EPI and/or us, as well as other pharmaceutical companies, alleging violations of antitrust law arising out of the settlement of certain patent litigation concerning the generic version of Exforge® (amlodipine/valsartan). See Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for more information.

There have been federal and state legislative efforts to overturn the *FTC v. Actavis* decision and make certain terms in patent settlement agreements *per se* unlawful. For example, some members of the U.S. Congress have proposed legislation that would limit the types of settlement agreements generic manufacturers and brand companies can enter into. The state of California enacted legislation, effective January 1, 2020, that deems a settlement of a patent infringement claim to be presumptively anticompetitive and allows the California Attorney General to seek monetary penalties if a generic company receives anything of value from the branded company and the generic company agrees to delay research and development, manufacturing, marketing or sales of the generic product for any period of time. The California law carves out from the definition of "anything of value" certain types of settlement terms and it allows the settling parties to rebut the presumption of anticompetitive harm.

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

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

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.

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

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

Clinical trials can be delayed for reasons outside of our control, which can lead to increased development costs and delays in regulatory approval. 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" in Part I, Item 1. Even if we receive approval for an NDA under section 505(b)(2) of the FFDCA, the FDA may not take timely enforcement action against companies marketing unapproved versions of the product; therefore, we cannot be sure that that we will receive the benefit of any de facto exclusive marketing period or that we will fully recoup the expenses incurred to obtain an approval. In addition, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, this could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

The ANDA approval process for a new product varies in time, generally requiring a minimum of 10 months following submission of the ANDA to 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 revenue. We could also be at risk for the value of any capitalized pre-launch inventories 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 Company to legal proceedings, penalties, fines and reputational damage. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. Meeting regulatory requirements and evolving government standards may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to other companies that compete against us.

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

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

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

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

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

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

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

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

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

In addition, we are subject to the 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 became effective incrementally over a 10-year period from its enactment on November 27, 2013. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements could require significant capital expenditures, increase our operating costs and impose significant administrative burdens.

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

Our reporting and payment obligations under 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 (VA) 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 VA 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. The inclusion of the additional territories did not have a material adverse effect on our business, financial condition, results of operations and cash flows.

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. These changes did not 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 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. In March 2024, our collective bargaining agreement for certain production personnel in our Rochester, Michigan manufacturing facility, which affects approximately 215 employees, will expire, and negotiations for a replacement collective bargaining agreement are expected to be completed prior to expiration. any failure to reach an agreement on a new collective bargaining agreement may result in strikes, boycotts or other labor disruptions. 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 revenues, results of operations and financial condition.” If we fail to comply with these various regulatory requirements or fail to obtain and maintain required approvals, our target market will be reduced and our ability to generate non-U.S. revenue will be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual Property Related Risks

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

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

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

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

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

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

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

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

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 IRA 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 Company.

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

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

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

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

Our effective income tax rate in the future could be adversely affected by a number of factors, including changes in the 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 period or periods for which the applicable final determinations are made.

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

We are incorporated in Ireland and also maintain subsidiaries in, among other jurisdictions, the U.S., Canada, India, the United Kingdom and Luxembourg. The IRS and other taxing authorities may continue to challenge our tax positions. The IRS presently is examining certain of our subsidiaries' U.S. income tax returns for fiscal years ended between December 31, 2011 and December 31, 2018 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 21. Income Taxes of the Consolidated Financial Statements included in Part IV, Item 15 of 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 income may be limited.

Existing and future tax laws and regulations may limit our ability to use U.S. tax attributes including, but not limited to, net operating losses (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 income 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 income or result in a reduction to our tax attributes. Certain tax attributes otherwise available and of value to the Company 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 Company'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 Company 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 Company's U.S. NOLs may be significantly limited by Section 382 of the Code. The amount of the Company's post-ownership-change annual U.S. taxable income 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 Company's U.S. affiliate stock (the Annual Limitation). However, if the value of the Company's U.S. affiliate stock is zero, if the Company 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 Company 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 Company 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.

It is anticipated that, upon the effectiveness of the U.S. Government resolutions, no existing tax attributes will transfer to the Purchaser upon consummation of the Plan.

Structural and Organizational Risks

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

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

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

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

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

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

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

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

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

Item 1B. ***Unresolved Staff Comments***

None.

Item 1C. ***Cybersecurity***

The Company has procedures and safeguards designed to detect and/or prevent unauthorized access to confidential information and defend against cyber-attacks, both internally and with the assistance and partnership of cybersecurity experts, with a view toward addressing the ever-evolving threat landscape and changing cybersecurity regulations. As part of its role in risk oversight, the Audit & Finance Committee of the Company's Board (Audit & Finance Committee) reviews the Company's program for managing information security risks, including data privacy and data protection. Our cybersecurity framework, which is based on the National Institute of Standards and Technology Cybersecurity Framework, includes risks and controls embedded into our processes and technology, and measured and monitored by cybersecurity subject matter specialists. All employees and contractors with access to our Company's systems must also complete mandatory comprehensive cybersecurity trainings periodically and participate in simulations which are deployed to educate and prepare users for cyber-attacks and similar risks.

Under the direction of the Chief Information Officer (CIO), who reports to the Company's Chief Executive Officer, and Chief Information Security Officer (CISO), who reports to the CIO, as well as certain other cybersecurity focused team members (the IT Security team), the IT Security team is responsible for addressing the dynamic threats against our electronic systems and assisting the workforce with handling system incidents, including by centralizing the reporting, detection and response to incidents to one functional team. The CIO and CISO have multiple decades of relevant IT experience. Incident management and response processes establish the recommended organization, actions and procedures needed to recognize and respond to an incident; assess the situation quickly and effectively; notify the appropriate individuals and organizations about the incident; organize the Company's response activities, including activating a command center; escalate the Company's response efforts based on the severity of the incident; and support the business recovery efforts being made in the aftermath of the incident. Additionally, third-party security experts are regularly engaged to monitor, assess, review and analyze the information technology landscape. The Company's incident response framework also defines the roles with respect to cybersecurity risk oversight and assigns responsibility to the IT Security Team. The IT Security team members have: (i) completed extensive cybersecurity training; (ii) have experience assessing cybersecurity incidents; (iii) actively participate in industry and government forums; and iv) collaborate with our peers to understand and improve cybersecurity intelligence, vulnerability management and defense strategies.

Our internal audit team performs audits of our information systems and network security. The audit scope, timing and frequency of our cybersecurity control framework is integrated into the Company's overall risk management process and the planning for, and results of, those audits are reviewed with the Audit and Finance Committee.

We regularly assess and monitor our cybersecurity risks and incidents and report them to our senior management and Audit and Finance Committee. Our Audit and Finance Committee oversees our cybersecurity strategy and governance and reviews our cybersecurity policies and practices on a periodic basis. Additionally, and as further discussed above, the Audit and Finance Committee is briefed multiple times a year or as needed by the CISO and/or CIO and, if applicable as determined by the Company's senior leadership, external advisors on the current and emerging cybersecurity threats and trends and the effectiveness of our cybersecurity controls and response capabilities.

We conduct due diligence security assessments of certain third-party providers before engagement, have contractual rights to and gather data on the effectiveness of vendor systems and protocols and monitor compliance with our cybersecurity standards. The monitoring includes periodic assessments and ongoing monitoring by the IT Security team. This approach is designed to mitigate risks related to data breaches or other security incidents originating from third-parties.

To date, cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected the Company, including our business strategy, results of operations, or financial condition. We do not believe that cybersecurity threats resulting from any previous cybersecurity incidents, of which we are aware, are reasonably likely to materially affect the Company. Refer to *"Our operations could be disrupted if our information systems fail or are not upgraded or are subject to cyber-attacks"* in Part I, Item 1A of this report for additional information on risks from cybersecurity threats.

Item 2. ***Properties***

This section provides information about the location and general character of the Company's principal physical properties at December 31, 2023.

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

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

As of December 31, 2023, our owned and leased properties consist of approximately 1.1 million and 0.9 million square feet, respectively. We believe our properties are suitable and adequate to support our current and projected operations in all material respects.

Item 3. ***Legal Proceedings***

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

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

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

Market Information. 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.

Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Holders. As of February 28, 2024, we estimate that there were approximately 199 holders of record of our ordinary shares.

Dividends. We have never declared or paid any cash dividends on our ordinary shares and we currently have no plans to declare a dividend. We are permitted to pay dividends subject to limitations imposed by Irish law, the Bankruptcy Code and related rules during the pendency of the Chapter 11 Cases, the various agreements and indentures governing our indebtedness and the existence of sufficient distributable reserves. For example, the Companies Act requires Irish companies to have distributable reserves equal to or greater than the amount of any proposed dividend. Unless we are able to generate sufficient distributable reserves or create distributable reserves by reducing our share premium account, we will not be able to pay dividends.

Recent sales of unregistered securities; Use of proceeds from registered securities. There were no unregistered sales of equity securities by the Company during the three years ended December 31, 2023.

Purchase of Equity Securities by the issuer and affiliated purchasers. The following table reflects purchases of Endo International plc ordinary shares by the Company during the three months ended December 31, 2023:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plan (1)
October 1, 2023 to October 31, 2023	—	—	—	$ 2,250,000,000
November 1, 2023 to November 30, 2023	—	—	—	$ 2,250,000,000
December 1, 2023 to December 31, 2023	—	—	—	$ 2,250,000,000
Three months ended December 31, 2023	—	—	—	

(1) Pursuant to Article 11 of the Company's Articles of Association, the Company has broad shareholder authority to conduct ordinary share repurchases by way of redemptions. As permitted by Irish Law and the Company's Articles of Association, any ordinary shares redeemed shall be cancelled upon redemption. Although 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, of which there is approximately $2.3 billion available as of December 31, 2023, we currently do not intend to conduct ordinary share repurchases in the foreseeable future and our ability to do so is restricted during the pendency of the Chapter 11 Cases. Redemptions under this program may be made from time to time in open market or negotiated transactions or otherwise, as determined by the Board. This program does not obligate the Company to redeem any particular amount of ordinary shares and 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. 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 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. 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. 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. The 2015 Share Buyback Program may be suspended, modified or discontinued at any time.

Item 6. *Reserved*

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following Management's Discussion and Analysis of Financial Condition and Results of Operations describes the principal factors affecting the results of operations, liquidity and capital resources and critical accounting estimates of Endo International plc.

This section omits discussions about 2021 items and comparisons between 2022 and 2021. Such discussions can be found in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2022.

The discussions in this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited Consolidated Financial Statements and the related Notes thereto. Except for the historical information contained in this report, including the following discussion, this report contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements" beginning on page i of this report.

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

The operating results of the Company's Astora business are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. For additional information, see Note 4. Discontinued Operations and Asset Sales in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

EXECUTIVE SUMMARY

This executive summary provides 2023 highlights from the results of operations that follow:

- Total revenues in 2023 were $2,011.5 million compared to $2,318.9 million in 2022 as competition resulted in revenue decreases in our Sterile Injectables segment, primarily related to VASOSTRICT®, as well as our Generic Pharmaceuticals segment, primarily related to varenicline tablets and lubiprostone capsules partially offset by increased revenues from dexlansoprazole delayed release capsules, which launched in November 2022.
- Gross margin percentage in 2023 increased to 53.0% from 52.9% in 2022, reflecting decreased costs associated with amortization expense, partially offset by unfavorable changes in product mix resulting primarily from decreased varenicline tablets and VASOSTRICT® revenues.
- Selling, general and administrative expenses in 2023 decreased to $567.7 million from $777.2 million in 2022 primarily due to decreased costs associated with certain litigation matters as a result of the automatic stay and restructuring and/or other cost reduction initiatives. In addition, costs associated with certain strategic review initiatives, including costs incurred in connection with our bankruptcy proceedings, are included in Selling, general and administrative expenses until the Petition Date. Following the Petition Date, such costs are required to be presented separately within Reorganization items, net to the extent such costs are incurred directly as a result of the Company's ongoing bankruptcy proceedings.
- Asset impairment charges in 2023 decreased to $0.5 million from $2,142.7 million in 2022.
- We reported Loss from continuing operations of $2,447.8 million in 2023 compared to Loss from continuing operations of $2,909.6 million in 2022.

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:

- From 2019 until the end of the public health emergency in May 2023, the effects of COVID-19 have had direct and indirect impacts on our consolidated results. These impacts on our consolidated results and the results of our business segments to date may not be directly comparable to any historical period and are not necessarily indicative of its impact on our results for any future periods.
- In November 2021, we entered into the U.S. Government Cooperative Agreement (as defined below) to expand our Sterile Injectables segment's fill-finish manufacturing production capacity and capabilities at our Rochester, Michigan plant to support the U.S. government's national defense efforts regarding production of critical medicines advancing pandemic preparation. Refer to Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional discussion of this agreement.
- During the first quarter of 2022, multiple competitive generic alternatives to VASOSTRICT® were launched, beginning with a generic that was launched at risk and began shipping toward the end of January 2022. Since then, additional competitive alternatives 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. 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 Company's key strategic priority to expand and enhance its product portfolio. For further discussion of this initiative, including a discussion of amounts recognized, refer to Note 5. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- In May 2022, we announced that we 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 Statements of Operations in the second quarter of 2022. For further discussion of this agreement, as well as a discussion of subsequent legal proceedings with Nevakar that affected both this agreement and a prior 2018 agreement with Nevakar, see Note 12. License, Collaboration and Asset Acquisition Agreements of the Consolidated Financial Statements included in Part IV, Item 15 of this report.
- In June 2022, we announced that we 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 Statements of Operations 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 Part IV, Item 15 of 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 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion.
- On the Petition Date, certain of 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 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion.
- During the year ended December 31, 2023, multiple competitors launched alternative generic versions of varenicline tablets. These launches began to impact both Endo's market share and product price toward the middle of the first quarter of 2023, and the effects of additional subsequent competition has accelerated both price and volume erosion within the overall market. The effects of competition are likely to increase in future periods, impacting our Generic Pharmaceuticals segment.
- In September 2020, we entered into a manufacturing and services agreement with Novavax, Inc. (Novavax), pursuant to which we would provide fill-finish manufacturing services at its plant in Rochester, Michigan for Novavax's COVID-19 vaccine candidate. In April 2023, we 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 cash and transferred certain other non-cash consideration, with a total value of $33 million, which was recorded as revenue in the Consolidated Statements of Operations in the second quarter of 2023 and is reflected in our Sterile Injectables segment.
- 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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report, as well as Part I, Item 1A. "Risk Factors."

CRITICAL ACCOUNTING ESTIMATES

The preparation of our Consolidated Financial Statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires us to make estimates and assumptions that affect the amounts and disclosures in our Consolidated Financial Statements, including the Notes thereto, and elsewhere in this report. For example, we are required to make significant estimates and assumptions related to revenue recognition, including sales deductions, long-lived assets, goodwill, other intangible assets, income taxes, contingencies, financial instruments, share-based compensation, estimated allowed claim amounts, liabilities subject to compromise and reorganization items, net, among others. Some of these estimates can be subjective and complex. Uncertainties related to the magnitude and duration of potential public health crises, like the recent COVID-19 pandemic, and epidemics, the extent to which it may impact our estimated future financial results, worldwide macroeconomic conditions including interest rates, employment rates, consumer spending and health insurance coverage, among others, 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 our anticipated sale process in connection with the Plan 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.

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

Revenue recognition

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

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

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

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

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

Sales deductions

As described above, the amount of revenue we recognize is equal to the fixed amount of the transaction price, adjusted for our estimates of variable consideration, including sales deductions. If the assumptions we use to calculate our estimates for sales deductions do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted. The following table presents the activity and ending balances, excluding Discontinued operations, for our product sales provisions for the years ended December 31, 2023 and 2022 (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Other Sales Deductions	Total
Balance, December 31, 2021	$ 183,116	$ 196,468	$ 185,183	$ 23,956	$ 588,723
Current year provision	77,698	634,439	2,229,131	137,758	3,079,026
Prior year provision	(5,614)	(5,031)	(965)	(272)	(11,882)
Payments or credits	(88,034)	(612,600)	(2,238,647)	(116,429)	(3,055,710)
Balance, December 31, 2022	$ 167,166	$ 213,276	$ 174,702	$ 45,013	$ 600,157
Current year provision	44,494	453,493	1,982,715	151,587	2,632,289
Prior year provision	(8,395)	(9,262)	100	(2,707)	(20,264)
Payments or credits	(76,912)	(523,336)	(2,016,436)	(161,546)	(2,778,230)
Balance, December 31, 2023	$ 126,353	$ 134,171	$ 141,081	$ 32,347	$ 433,952

Returns and Allowances

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

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

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

Our estimate for returns and allowances may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. Where available, we utilize information received from our wholesaler customers about the quantities of inventory held, including the information received pursuant to DSAs, which we have not independently verified. For other customers, we have estimated inventory held based on buying patterns. In addition, we evaluate market conditions for products primarily through the analysis of wholesaler and other third-party sell-through data, as well as internally-generated information, to assess factors that could impact expected product demand at the estimate date. As of December 31, 2023, we believe that our estimates of the level of inventory held by our customers is within a reasonable range as compared to both historical amounts and expected demand for each respective product.

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

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

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

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

Rebates

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

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

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

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

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

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

Chargebacks

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

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

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

Other sales deductions

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

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

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

Valuation of long-lived assets

As of December 31, 2023, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is approximately $2.0 billion. Our finite-lived intangible assets consist of license rights and developed technology.

Long-lived assets are generally initially recorded at fair value if acquired in a business combination, or at cost if otherwise. To the extent any such asset is deemed to have a finite life 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 income and net income per share to decrease. Amortization expense is not recorded on assets held for sale.

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

In the case of long-lived assets to be disposed of by sale or otherwise, including assets held for sale, the assets and the associated liabilities to be disposed of together as a group in a single transaction (the disposal group) are measured at the lower of their carrying amount or fair value less cost to sell. 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.

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

Our reviews of long-lived assets during the two years ended December 31, 2023 resulted in certain impairment charges. The majority of these charges related to finite-lived intangible assets and certain assets associated with disposal groups, which are further described in Note 11. Goodwill and Other Intangibles and Note 4. Discontinued Operations and Asset Sales, respectively, in the Consolidated Financial Statements included in Part IV, Item 15 of this report. Our impairment charges relating to long-lived assets were generally based on fair value estimates determined using discounted cash flow models or, in the case of disposal groups, a market approach. When testing a long-lived asset using a discounted cash flow model, we utilize assumptions related to the future operating performance of the corresponding product based on management's annual and ongoing budgeting, forecasting and planning processes, which represent our best estimate of future cash flows. These estimates are subject to many assumptions, such as the economic environment in which we operate, demand for our products, competitor actions and factors which could affect our tax rate. Estimated future pre-tax cash flows are adjusted for taxes using a market participant tax rate and discounted to present value using a market participant weighted average cost of capital. Financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and certain capital structure considerations. 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 use of different inputs and assumptions would increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of our related impairments, if any. There were no intangible long-lived assets impaired in 2023. The discount rates applied to intangible long-lived assets impaired in 2022 ranged from 9.5% to 12.0%.

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

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

Developed Technology. Our developed technology assets subject to amortization have useful lives ranging from 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.

As of December 31, 2023, the carrying amount of our intangible assets associated with developed technology and license rights totaled approximately $1.5 billion. As a result, if the assumptions used in our impairment tests change, it is possible that material impairment charges could be recorded in future periods.

Goodwill and indefinite-lived intangible assets

As of December 31, 2023, our goodwill balance is approximately $1.4 billion and we have no indefinite-lived intangible assets.

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.

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

Similarly, if applicable, we perform our indefinite-lived intangible asset impairment tests by comparing the fair value of each intangible asset with its carrying amount. We estimate the fair values of our indefinite-lived intangible assets using an income approach that utilizes a discounted cash flow model. If the carrying amount of an indefinite-lived intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess.

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, all of which may differ from actual future cash flows.

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes, which represent our best estimate of future cash flows. These estimates are subject to many assumptions, such as the economic environment in which we operate, demand for our products, competitor actions and factors which could affect our tax rate. Estimated future pre-tax cash flows are adjusted for taxes using a market participant tax rate and discounted to present value using a market participant weighted average cost of capital. Financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and certain capital structure considerations. Where appropriate, the weighted average cost of capital may also incorporate certain risk premiums, such as a company-specific risk premium (CSRP), which represents the incremental return that investors may require to compensate for the risks, uncertainties and variability in our estimated future cash flows. 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 use of different inputs and assumptions would increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of our related impairments, if any.

In order to assess the reasonableness of the calculated fair values of our reporting units, we also compare the sum of the reporting units' fair values to Endo's market capitalization, together with the aggregate estimated fair value of its debt, and/or other observable data points for the Company, such as various preliminary indications of value ranges within documents filed with the Bankruptcy Court (as further discussed in Note 2. Bankruptcy Proceedings in the Consolidated Financial Statements included in Part IV, Item 15 of this report). We use this comparison to calculate an implied control premium (the excess sum of the reporting units' fair values over Endo's market capitalization, together with the aggregate estimated fair value of its debt, and/or observable bids) or an implied control discount (the excess of Endo's market capitalization, together with the aggregate estimated fair value of its debt, and/or observable bids over the sum of the reporting units' fair values). The Company evaluates the implied control premium or discount by comparing it to control premiums or discounts of recent comparable market transactions, as applicable. If the control premium or discount is not reasonable in light of comparable recent transactions, or recent movements in the Company's share price and/or the aggregate estimated fair value of its debt, we reevaluate the fair value estimates of the reporting units to determine whether it is appropriate to adjust discount rates and/or other assumptions. This re-evaluation could correlate to different implied fair values for certain or all of the Company's reporting units.

As further described in Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report, Endo performed its annual impairment tests as of October 1, 2023. For the purposes of the 2023 annual tests, the Company had two reporting units with goodwill: Branded Pharmaceuticals and Sterile Injectables; the Company did not have any indefinite-lived intangible assets.

The discount rate used in the October 1, 2023 goodwill tests for the Branded Pharmaceuticals and Sterile Injectables reporting units was 14.5%, compared to 15.0% and 19.5%, respectively, used in the October 1, 2022 goodwill tests. 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 most recent estimated future cash flows used in this impairment test as compared to the October 1, 2022 tests.

No interim impairment tests were performed or charges recorded for our Branded Pharmaceuticals or Sterile Injectables reporting units during an interim period in 2023.

We completed our annual goodwill impairment tests on October 1, 2023; no impairments were recorded in connection with these tests. A 50 basis point increase in the assumed discount rate utilized in the Sterile Injectables or Branded Pharmaceuticals tests would not have changed the outcome.

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

As of December 31, 2023, our Branded Pharmaceuticals and Sterile Injectables reporting units had remaining goodwill of approximately $828.8 million and $523.2 million, respectively. As a result, if the assumptions used in our impairment tests change, it is possible that additional impairment charges could be recorded in future periods and that these charges could be material.

Each of our reporting units is subject to various risks and uncertainties, including those described above and in Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of this report. If actual results for our reporting units differ from our expectations, as a result of these or other risks and uncertainties, and/or if we make related changes to our assumptions for these reporting units, the estimated future revenues and cash flows could be significantly reduced, which could ultimately result in goodwill impairment charges that may be material.

Income taxes

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

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

We make an evaluation at the end of each reporting period as to whether or not some or all of the undistributed earnings of our subsidiaries are indefinitely reinvested. Refer to Note 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report for information about our evaluation for the current reporting period and certain associated risks and uncertainties.

Contingencies

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

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

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

As of December 31, 2023, our accrual for loss contingencies totaled $2,431.5 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, 2023, our entire accrual for loss contingencies is classified as Liabilities subject to compromise in the Consolidated Balance Sheets and recorded at the expected allowed claim amount, even if they may ultimately be settled for different amounts. 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.

Liabilities subject to compromise

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 determination of how liabilities will ultimately be settled or treated cannot be made until the Plan is confirmed by the Bankruptcy Court. Therefore, the amounts classified as Liabilities subject to compromise 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.

Please review our Plan and related disclosure statement for more information regarding the proposed treatment of different categories of prepetition claims.

RESULTS OF OPERATIONS

Consolidated Results Review

The following table displays our revenue, gross margin, gross margin percentage and other pre-tax expense or income for the years ended December 31, 2023 and 2022 (dollars in thousands):

	2023	2022	% Change 2023 vs. 2022
Total revenues, net	$ 2,011,518	$ 2,318,875	(13)%
Cost of revenues	946,415	1,092,499	(13)%
Gross margin	$ 1,065,103	$ 1,226,376	(13)%
Gross margin percentage	*53.0 %*	*52.9 %*	
Selling, general and administrative	567,727	777,169	(27)%
Research and development	115,462	128,033	(10)%
Acquired in-process research and development	—	68,700	(100)%
Litigation-related and other contingencies, net	1,611,090	478,722	NM
Asset impairment charges	503	2,142,746	(100)%
Acquisition-related and integration items, net	1,972	408	NM
Interest expense, net	—	349,776	(100)%
Reorganization items, net	1,169,961	202,978	NM
Other income, net	(9,688)	(34,054)	(72)%
Loss from continuing operations before income tax	$ (2,391,924)	$ (2,888,102)	(17)%

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

Total revenues, net. Total revenues in 2023 were $2,011.5 million compared to $2,318.9 million in 2022 as competition resulted in revenue decreases in our Sterile Injectables segment, primarily related to VASOSTRICT®, as well as our Generic Pharmaceuticals segment, primarily related to varenicline tablets and lubiprostone capsules partially offset by increased revenues from dexlansoprazole delayed release capsules, which launched in November 2022. Our revenues are further disaggregated and described below under the heading “Business Segment Results Review.”

Cost of revenues and gross margin percentage. During the years ended December 31, 2023 and 2022, Cost of revenues 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):

	2023	2022
Amortization of intangible assets (1)	$ 255,933	$ 337,311
Amounts related to continuity and separation benefits, cost reductions and strategic review initiatives (2)	$ 4,514	$ 61,806

(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 2023 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, inventory 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 Part IV, Item 15 of this report.

The decrease in Cost of revenues in 2023 was primarily due to decreased revenues, decreased costs associated with amortization expense and decreased costs for amounts related to continuity and separation benefits, cost reductions and strategic review initiatives.

The increase in gross margin percentage in 2023 was primarily due to decreased costs associated with amortization expense, partially offset by unfavorable changes in product mix resulting primarily from decreased varenicline tablets and VASOSTRICT® revenues.

Selling, general and administrative expenses. The decrease in 2023 was primarily due to decreased costs associated with certain litigation matters as a result of the automatic stay and restructuring and/or other cost reduction initiatives. In addition, costs associated with certain strategic review initiatives, including costs incurred in connection with our bankruptcy proceedings, are included in Selling, general and administrative expenses until the Petition Date. Following the Petition Date, such costs are required to be presented separately within Reorganization items, net to the extent such costs are incurred directly as a result of the Company's ongoing bankruptcy proceedings. Refer to Note 2. Bankruptcy Proceedings and Note 5. Restructuring of the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion of these items.

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 period varies depending on the nature and stage of development of our R&D programs. Total R&D expenses in 2023 and 2022 were $115.5 million and $128.0 million, respectively, of which $54.9 million and $70.6 million, respectively, related to our Branded Pharmaceuticals development projects, 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 PFI. In March 2023, we announced top-line results from our Phase 2 clinical study of XIAFLEX® in participants with PFI and while the primary endpoint when analyzed with the overall study population did not meet statistical significance, a large patient sub-population showed statistically significant improvement across a majority of endpoints. We initiated the Phase 3 clinical program in the fourth quarter of 2023. We also completed a proof-of-concept study in PFA during the third quarter of 2023 and, based on encouraging proof-of-concept study results initiated the Phase 2 clinical study in the fourth quarter of 2023. We may in the future develop our XIAFLEX® product for potential additional indications, advancing our strategy of developing both non-surgical orthopedic and non-orthopedic care interventions.

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 of the Consolidated Financial Statements included in Part IV, Item 15 of 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.

The remaining R&D expenses in 2023 and 2022 were primarily related to our Sterile Injectables segment where we expect to continue to focus investments in RTU and other differentiated product candidates, potentially including acquisitions and/or license and commercialization agreements. No individual development project in the Sterile Injectables segment has incurred direct R&D expenses that exceeded 5% of total R&D expenses for the periods presented. Refer to Part I, Item 1 of this report for further information about the Sterile Injectables pipeline.

The decrease in R&D expense in 2023 was primarily driven by decreased costs associated with certain restructuring and other cost reduction initiatives and certain post-marketing commitments, partially offset by increased costs associated with our Sterile Injectables segment. Refer to Note 5. Restructuring in the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion of certain restructuring initiatives, including a discussion of amounts recognized.

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 decrease in Acquired in-process research and development charges in 2023 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 Part IV, Item 15 of this report. 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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of 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 16. Commitments and Contingencies of the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Asset impairment charges. The following table presents the components of our total Asset impairment charges for the years ended December 31, 2023 and 2022 (in thousands):

	2023	2022
Goodwill impairment charges	$ —	$ 1,845,000
Other intangible asset impairment charges	—	288,701
Property, plant and equipment impairment charges	503	9,045
Total asset impairment charges	$ 503	$ 2,142,746

For additional information, refer to Note 7. Fair Value Measurements and Note 11. Goodwill and Other Intangibles in the Consolidated Financial Statements included in Part IV, Item 15 of 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 from changes in the fair value of acquisition-related contingent consideration liabilities resulting from changes to our estimates regarding the timing and amount of the future revenues of the underlying products and changes in other assumptions impacting the probability of incurring, and extent to which we could incur, related contingent obligations. See Note 7. Fair Value Measurements of the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion of our acquisition-related contingent consideration.

Interest expense, net. The components of Interest expense, net for the years ended December 31, 2023 and 2022 are as follows (in thousands):

	2023	2022
Interest expense	$ 991	$ 350,740
Interest income	(991)	(964)
Interest expense, net	$ —	$ 349,776

The decrease in interest expense in 2023 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. Beginning during the third quarter of 2022, we 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. Certain of the adequate protection payments may later be characterized 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 15. Debt of the Consolidated Financial Statements included in Part IV, Item 15 of 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.

Reorganization items, net. Amounts relate to the net expense or income 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 Part IV, Item 15 of 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 Statements of Operations. 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, 2023 and 2022 are as follows (in thousands):

	2023	2022
Net gain on sale of business and other assets	$ (10,392)	$ (26,183)
Foreign currency loss (gain), net	1,779	(2,087)
Net (gain) loss from our investments in the equity of other companies	(199)	378
Other miscellaneous, net	(876)	(6,162)
Other income, net	$ (9,688)	$ (34,054)

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

Income tax expense. 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, 2023 and 2022 (dollars in thousands):

	2023	2022
Loss from continuing operations before income tax	$ (2,391,924)	$ (2,888,102)
Income tax expense	$ 55,862	$ 21,516
Effective tax rate	*(2.3)%*	*(0.7)%*

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

The change in income tax expense in 2023 compared to the 2022 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 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

As previously disclosed, the Company 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 Company 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 Company's net deferred tax assets was recorded in various jurisdictions during the second quarter of 2022.

The Company 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, 2023. It is possible that in the future there may be sufficient positive evidence to release a portion or all of the valuation allowance. Release of these valuation allowances would result in a benefit to income tax expense for the period the release is recorded, which could have a material impact on net earnings. The timing and amount of the potential valuation allowance release are subject to significant management judgment and prospective earnings.

We are incorporated in Ireland and also maintain subsidiaries in, among other jurisdictions, the U.S., Canada, India, the United Kingdom and Luxembourg. The IRS and other taxing authorities may continue to challenge our tax positions. Where appropriate, we have established reserves for tax-related uncertainties. Uncertain tax positions are reviewed quarterly and adjusted as necessary when events occur that impact 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.

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, 2018 and, in connection with those examinations, is reviewing our tax positions related to, among other things, certain intercompany arrangements, including the level of profit earned by our U.S. subsidiaries pursuant to such arrangements, and a product liability loss carryback claim. For additional information, including a discussion of related recent developments and their potential impact on us, refer to Note 21. Income Taxes of the Consolidated Financial Statements included in Part IV, Item 15 of this report.

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

Additionally, as further discussed in Note 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of 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 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Discontinued operations, net of tax. The operating results of the Company's Astora business, which the Board resolved to wind down in 2016, are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. The following table provides the operating results of Astora Discontinued operations, net of tax, for the years ended December 31, 2023 and 2022 (in thousands):

	2023	2022
Litigation-related and other contingencies, net	$ 495	$ —
Loss from discontinued operations before income taxes	$ (2,329)	$ (15,543)
Income tax benefit	$ (308)	$ (2,056)
Discontinued operations, net of tax	$ (2,021)	$ (13,487)

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 2023 and 2022 were primarily related to mesh-related legal defense costs and certain other items. For additional discussion of mesh-related matters, refer to Note 16. Commitments and Contingencies of the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Business Segment Results Review

Revenues, net. The following table displays our revenue by reportable segment for the years ended December 31, 2023 and 2022 (dollars in thousands):

	2023	2022	% Change 2023 vs. 2022
Branded Pharmaceuticals	$ 859,087	$ 851,142	1 %
Sterile Injectables	429,563	589,633	(27)%
Generic Pharmaceuticals	650,352	795,457	(18)%
International Pharmaceuticals (1)	72,516	82,643	(12)%
Total net revenues from external customers	$ 2,011,518	$ 2,318,875	(13)%

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

Branded Pharmaceuticals. The following table displays the significant components of our Branded Pharmaceuticals revenues from external customers for the years ended December 31, 2023 and 2022 (dollars in thousands):

	2023	2022	% Change 2023 vs. 2022
Specialty Products:			
XIAFLEX®	$ 475,014	$ 438,680	8 %
SUPPRELIN® LA	96,849	113,011	(14)%
Other Specialty (1)	73,797	70,009	5 %
Total Specialty Products	$ 645,660	$ 621,700	4 %
Established Products:			
PERCOCET®	$ 106,375	$ 103,943	2 %
TESTOPEL®	42,464	38,727	10 %
Other Established (2)	64,588	86,772	(26)%
Total Established Products	$ 213,427	$ 229,442	(7)%
Total Branded Pharmaceuticals (3)	$ 859,087	$ 851,142	1 %

(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, 2023 and/or any product having revenues in excess of $25 million during any completed quarterly period in 2023 or 2022.

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. 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.

The increase in XIAFLEX® revenues in 2023 was primarily attributable to increased net price of approximately 7% and volumes. Increased volumes for 2023 were primarily driven by annual demand growth of approximately 2%, partially impacted by inventory destocking during the first quarter of 2023.

The decrease in SUPPRELIN® LA revenues in 2023 was primarily attributable to decreased volumes due to lower demand and overall market contraction.

The increase in Other Specialty revenues in 2023 was primarily attributable to increased net price, partially offset by decreased volumes.

Established Products

PERCOCET® revenues in 2023 were broadly in line with the prior year.

The increase in TESTOPEL® revenues in 2023 was primarily attributable to increased volumes as a result of increased demand.

The decrease in Other Established revenues in 2023 was primarily attributable to ongoing competitive pressures impacting this product portfolio, product discontinuations and certain other factors.

Our Established Products portfolio has been and is likely to continue to be affected by ongoing competitive pressures. The effects of competition could result in revenue 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 revenues from external customers for the years ended December 31, 2023 and 2022 (dollars in thousands):

	2023	2022	% Change 2023 vs. 2022
ADRENALIN®	$ 99,910	$ 114,304	(13)%
VASOSTRICT®	93,180	253,696	(63)%
Other Sterile Injectables (1)	236,473	221,633	7 %
Total Sterile Injectables (2)	$ 429,563	$ 589,633	(27)%

(1) Products included within Other Sterile Injectables include, but are not limited to, APLISOL®.

(2) Individual products presented above represent the top two performing products within the Sterile Injectables segment for the year ended December 31, 2023 and/or any product having revenues in excess of $25 million during any completed quarterly period in 2023 or 2022. No individual product within Other Sterile Injectables has exceeded 5% of consolidated total revenues for the periods presented.

The decrease in ADRENALIN® revenues in 2023 was primarily attributable to decreased net price and decreased volumes, both due to the impact of competition.

The decrease in VASOSTRICT® revenues in 2023 was primarily driven by decreases to both volumes and net price, which was 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. 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.

The increase in Other Sterile Injectables revenues in 2023 was primarily attributable to the Novavax Settlement Agreement, partially offset by decreased net price.

Our Sterile Injectables segment is likely to continue to be affected by ongoing competitive pressures. This could result in revenue 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 decrease in Generic Pharmaceuticals revenues in 2023 was primarily attributable to competitive pressures on certain generic products including varenicline tablets and lubiprostone capsules, partially offset by the revenues from dexlansoprazole delayed release capsules, which launched in November 2022.

During the year ended December 31, 2023, multiple competitors launched alternative generic versions of varenicline tablets. These launches began to impact both Endo's market share and product price toward the middle of the first quarter of 2023, and the effects of additional subsequent competition has accelerated both price and volume erosion within the overall market. The effects of competition are likely to increase in future periods, impacting our Generic Pharmaceuticals segment. Other products in our Generic Pharmaceuticals segment are also likely to continue to be affected by ongoing competitive pressures. These factors could result in revenue 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 income from continuing operations before income tax. The following table displays our Segment adjusted income from continuing operations before income tax (the measure we use to evaluate segment performance) by reportable segment for the years ended December 31, 2023 and 2022 (dollars in thousands):

	2023	2022	% Change 2023 vs. 2022
Branded Pharmaceuticals	$ 459,309	$ 366,554	25 %
Sterile Injectables	$ 157,179	$ 349,424	(55)%
Generic Pharmaceuticals	$ 237,870	$ 336,133	(29)%
International Pharmaceuticals	$ 16,733	$ 19,920	(16)%

Branded Pharmaceuticals. The increase in Segment adjusted income from continuing operations before income tax in 2023 was primarily attributable to decreased costs as a result of the 2022 Restructuring Initiative, decreased costs associated with certain legal matters and the gross margin effects of the increased revenues further described above.

Sterile Injectables. The decrease in Segment adjusted income from continuing operations before income tax in 2023 was primarily attributable to the gross margin effects of the decreased revenues further described above.

Generic Pharmaceuticals. The decrease in Segment adjusted income from continuing operations before income tax in 2023 was primarily attributable to the gross margin effects of the decreased revenues further described above, partially offset by lower Selling, general and administrative expenses resulting from reduced legal expenses and the impact of prior restructurings.

LIQUIDITY AND CAPITAL RESOURCES

On the Petition Date, certain of 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 15. Debt of the Consolidated Financial Statements included in Part IV, Item 15 of this report for further discussion.

Our principal source of liquidity is cash generated from operations. Cash and cash equivalents, which primarily consisted of bank deposits and money market accounts, totaled $777.9 million at December 31, 2023 compared to $1,018.9 million at December 31, 2022. 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. We may face unexpected costs in connection with our business operations, our ongoing and future legal proceedings, governmental investigations and other contingent liabilities (including potential costs related to settlements and judgments, as well as legal defense costs), and our ongoing bankruptcy proceedings. 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 Part IV, Item 15 of 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, including in connection with any exit financing or rights offerings contemplated by the Plan, 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 21. Income Taxes in the Consolidated Financial Statements included in Part IV, Item 15 of this report for a discussion of our indefinite reinvestment assertion relating to undistributed earnings of certain of our subsidiaries.

Indebtedness. The Company 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 15. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of 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, 2023 and December 31, 2022 are below (dollars in thousands):

	December 31, 2023	December 31, 2022
Total current assets	$ 1,668,501	$ 2,076,768
Less: total current liabilities	538,794	689,627
Working capital	$ 1,129,707	$ 1,387,141
Current ratio (total current assets divided by total current liabilities)	3.1:1	3.0:1

Net working capital decreased by $257.4 million from December 31, 2022 to December 31, 2023. During this period, working capital benefited from the favorable impacts to net current assets resulting from revenues and gross margins, which are further described above. These benefits were more than offset by, among other things, the following current period activity: (i) Adequate protection payments of $592.8 million; (ii) certain expenses incurred in connection with our bankruptcy proceedings and certain restructuring and other cost reduction initiatives; and (iii) Capital expenditures, excluding capitalized interest, net of Proceeds from the U.S. Government Cooperative Agreement (as defined below), of $54.9 million.

The classification of our assets and liabilities in our Consolidated Balance Sheets may 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 15. Debt of the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information.

The following table summarizes our Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022 (in thousands):

	2023	2022
Net cash flow provided by (used in):		
Operating activities	$ 435,098	$ 269,193
Investing activities	(49,794)	(133,147)
Financing activities	(604,628)	(513,873)
Effect of foreign exchange rate	704	(4,242)
Net decrease in cash, cash equivalents, restricted cash and restricted cash equivalents	$ (218,620)	$ (382,069)

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 $165.9 million increase in Net cash provided by operating activities in 2023 compared to the prior year was primarily due to reduced litigation costs, as a result of the automatic stay, reduced payments for opioid-related matters and reduced interest payments (which have historically been reflected as operating cash flows) on most of our debt instruments, further discussed in Note 2. Bankruptcy Proceedings and Note 15. Debt of the Consolidated Financial Statements included in Part IV, Item 15 of this report. As further discussed below, adequate protection payments related to our First Lien Debt Instruments are currently being reflected as financing cash flows. These increases were offset by reduced varenicline tablets and VASOSTRICT® revenues and increased payments for professional fees associated with our bankruptcy proceedings and certain related transactions.

It is possible that our operating cash flows could decline in the future as a result of, among other things, reductions in revenues and payments associated with our bankruptcy proceedings and certain related transactions. Additionally, it is possible that certain of the adequate protection payments described above may later be characterized as interest expense depending upon certain developments in the Chapter 11 Cases, which could result in 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 $83.4 million decrease in Net cash used in investing activities in 2023 compared to the prior year period was primarily attributable to: (i) a decrease in Acquisitions, including in-process research and development, net of cash and restricted cash acquired of $90.3 million and (ii) an increase in Proceeds from the U.S. Government Cooperative Agreement (as defined below) of $20.8 million. The changes were partially offset by: (i) a decrease in Proceeds from sale of business and other assets of $36.3 million.

Financing activities. During 2023, Net cash used in financing activities primarily related to Adequate protection payments of $592.8 million.

During 2022, Net cash used in financing activities related primarily 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.

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 to 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 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report.

Cash Requirements for Contractual and Other Obligations. As of December 31, 2023, 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 15. Debt and Note 16. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this report for additional information about these obligations including, to the extent material, quantitative information about the related cash requirements.

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

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 Part IV, Item 15 of 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; public health crises, like the recent COVID-19 pandemic, and epidemics; 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 revenues 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 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.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

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

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate indebtedness associated with our Credit Facilities. Borrowings under the Credit Facilities may from time to time require payments calculated using variable rates, in certain cases subject to a floor. At both December 31, 2023 and December 31, 2022, a hypothetical 1% increase in the applicable rate over any applicable floor would have resulted in the incurrence of $22.5 million of incremental payments (representing the annual rate of incurrence) related to our variable-rate debt borrowings.

As of December 31, 2023 and December 31, 2022, we had no other assets or liabilities with significant interest rate sensitivity.

Foreign Currency Exchange Rate Risk

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

The assets and liabilities of certain of our international subsidiaries are also translated to U.S. dollars at period-end exchange rates. Translation adjustments arising from the use of differing exchange rates are included in Accumulated other comprehensive loss. Gains and losses on foreign currency transactions and short-term intercompany receivables from foreign subsidiaries are included in Other income, net in the Consolidated Statements of Operations. Refer to Note 20. Other Income, Net of the Consolidated Financial Statements included in Part IV, Item 15 of this report for the amounts of Foreign currency loss (gain), net.

Based on the Company's significant foreign currency denominated intercompany loans, we separately considered the hypothetical impact of a 10% change in the underlying currencies of our foreign currency denominated intercompany loans, relative to the U.S. dollar, at December 31, 2023 and December 31, 2022. A 10% change at December 31, 2023 and December 31, 2022 would have resulted in approximately $11 million in incremental foreign currency losses on such dates.

Item 8. *Financial Statements and Supplementary Data*

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

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

Not applicable.

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

(a) Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Principal Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, as of December 31, 2023. Based on that evaluation, the Company's Chief Executive Officer and Principal Financial Officer concluded that the Company's disclosure controls and procedures were effective as of December 31, 2023.

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

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

(c) Attestation Report of Independent Registered Public Accounting Firm

Not applicable.

(d) Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the fiscal quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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

None.

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

None.

PART III

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

The information required under this item will be provided in an amendment filed on Form 10-K/A.

Item 11. ***Executive Compensation***

The information required under this item will be provided in an amendment filed on Form 10-K/A.

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

The information required under this item will be provided in an amendment filed on Form 10-K/A.

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

The information required under this item will be provided in an amendment filed on Form 10-K/A.

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

The information required under this item will be provided in an amendment filed on Form 10-K/A.

PART IV

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

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

1. *The Consolidated Financial Statements*

Management's Report on Internal Control Over Financial Reporting
Report of Independent Registered Public Accounting Firm (PCAOB ID 238)
Consolidated Balance Sheets as of December 31, 2023 and 2022
Consolidated Statements of Operations for the years ended December 31, 2023, 2022 and 2021
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2023, 2022 and 2021
Consolidated Statements of Shareholders' Deficit for the years ended December 31, 2023, 2022 and 2021
Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022 and 2021
Notes to Consolidated Financial Statements

2. *Financial Statement Schedules*

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS
(in thousands)

	Balance at Beginning of Period	Additions, Costs and Expenses	Deductions, Write-offs	Other (1)	Balance at End of Period
Valuation Allowance For Deferred Tax Assets:					
Year Ended December 31, 2021	$ 9,668,556	$ 504,499	$ (9)	$ (3,752)	$ 10,169,294
Year Ended December 31, 2022	$ 10,169,294	$ 273,538	$ (46)	$ (6,367)	$ 10,436,419
Year Ended December 31, 2023	$ 10,436,419	$ 6,431,095	$ —	$ 6,125	$ 16,873,639

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

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

3. *Exhibits*

		Incorporated by Reference from:		
Number	**Description**	**File Number**	**Filing Type**	**Filing Date**
2.1†	Agreement and Plan of Merger, dated as of October 19, 2020, by and among BioSpecifics Technologies Corp., Endo International plc, and Beta Acquisition Corp.	001-36326	Current Report on Form 8-K	October 19, 2020
3.1	Certificate of Incorporation on re-registration as a public limited company of Endo International plc	001-36326	Current Report on Form 8-K12B	February 28, 2014
3.2	Memorandum and Articles of Association of Endo International plc, dated as of October 31, 2013 and as amended as of June 8, 2017	001-36326	Quarterly Report on Form 10-Q	August 8, 2017
4.1	Specimen Share Certificate of Endo International plc	333-194253	Form S-8	February 28, 2014
4.2	Indenture, dated January 27, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, relating to the 6.00% Senior Notes due 2025 (including Form of 6.00% Senior Notes due 2025 and Form of Supplemental Indenture relating to the 6.00% Senior Notes due 2025)	001-36326	Current Report on Form 8-K	January 27, 2015
4.2.1	Supplemental Indenture, dated March 27, 2015, among Endo Designated Activity Company (formerly, Endo Limited), Endo Finance LLC, Endo Finco Inc., the guarantors named therein and Wells Fargo Bank, National Association, as trustee, to the Indenture, dated January 27, 2015	001-36326	Annual Report on Form 10-K	February 29, 2016

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

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

		Incorporated by Reference from:		
Number	Description	File Number	Filing Type	Filing Date
10.21	Executive Employment Agreement between Endo Health Solutions Inc. and Matthew Maletta, effective February 13, 2021	001-36326	Quarterly Report on Form 10-Q	November 6, 2020
10.22	Amendment, dated as of August 13, 2022, to Executive Employment Agreement between Endo Health Solutions Inc. and Blaise Coleman, effective March 6, 2020	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.23	Amendment, dated as of August 13, 2022, to Executive Employment Agreement between Endo Health Solutions Inc. and Patrick Barry, effective April 26, 2020	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.24	Amendment, dated as of August 13, 2022, to Executive Employment Agreement between Endo Health Solutions Inc. and Mark T. Bradley, effective March 6, 2020	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.25	Amendment, dated as of August 13, 2022, to Executive Employment Agreement between Endo Health Solutions Inc. and Matthew Maletta, effective February 13, 2021	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.26	Retention Agreement between Endo and Blaise Coleman, dated November 1, 2021	001-36326	Annual Report on Form 10-K	March 1, 2022
10.27	Retention Agreement between Endo and Mark T. Bradley, dated November 1, 2021	001-36326	Annual Report on Form 10-K	March 1, 2022
10.28	Retention Agreement between Endo and Matthew J. Maletta, dated November 1, 2021	001-36326	Annual Report on Form 10-K	March 1, 2022
10.29	Retention Agreement between Endo and Patrick Barry, dated November 1, 2021	001-36326	Annual Report on Form 10-K	March 1, 2022
10.30	Retention Agreement between Endo and Blaise Coleman, dated August 11, 2022	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.31	Retention Agreement between Endo and Mark T. Bradley, dated August 11, 2022	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.32	Retention Agreement between Endo and Matthew J. Maletta, dated August 11, 2022	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.33	Retention Agreement between Endo and Patrick Barry, dated August 11, 2022	001-36326	Quarterly Report on Form 10-Q	November 9, 2022
10.34	Restructuring Support Agreement, dated August 16, 2022, by and among the Debtors and the members of the Ad Hoc First Lien Group	001-36326	Current Report on Form 8-K	August 17, 2022
10.35	Executive Employment Agreement between Endo Health Solutions Inc. and James Tursi, dated December 15, 2021 and effective January 18, 2022	001-36326	Annual Report on Form 10-K/A (Amendment No. 1)	April 28, 2023
10.36	Retention Agreement between Endo and James Tursi, dated July 11, 2022	001-36326	Annual Report on Form 10-K/A (Amendment No. 1)	April 28, 2023
10.37	Notice of Filing of Second Amended and Restated Restructuring Support Agreement	001-36326	Current Report on Form 8-K	January 2, 2024
10.38	Global Settlement Agreement, dated February 28, 2024, by and among the United States of America, Endo Inc. and Endo International PLC	Not applicable; filed herewith		
10.39	Plea Agreement, dated February 27, 2024, between the United States and Endo Health Solutions Inc.	Not applicable; filed herewith		
10.40	Civil Settlement Agreement, dated February 20, 2024, among the United States, Endo Health Solutions Inc. and Loretta Reed	Not applicable; filed herewith		
21.1	Subsidiaries of the Registrant	Not applicable; filed herewith		
24.1	Power of Attorney	Not applicable; filed herewith		
31.1	Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Not applicable; filed herewith		
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Not applicable; filed herewith		

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

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

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

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

None.

SIGNATURES

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

ENDO INTERNATIONAL PLC
(Registrant)

/S/ BLAISE COLEMAN
Name: **Blaise Coleman**
Title: **President and Chief Executive Officer**
(Principal Executive Officer)

Date: March 6, 2024

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

	Signature	Title	Date
	/S/ BLAISE COLEMAN Blaise Coleman	Director, President and Chief Executive Officer (Principal Executive Officer)	March 6, 2024
	/S/ MARK T. BRADLEY Mark T. Bradley	Executive Vice President, Chief Financial Officer (Principal Financial Officer)	March 6, 2024
	/S/ FRANK B. RACITI Frank B. Raciti	Vice President, Controller, Chief Accounting Officer (Principal Accounting Officer)	March 6, 2024
	* Mark G. Barberio	Chairman and Director	March 6, 2024
	* Jennifer M. Chao	Director	March 6, 2024
	* Shane M. Cooke	Director	March 6, 2024
	* Nancy J. Hutson, Ph.D.	Director	March 6, 2024
	* Michael Hyatt	Director	March 6, 2024
	* William P. Montague	Director	March 6, 2024
	* M. Christine Smith, Ph.D.	Director	March 6, 2024
*By:	/S/ MATTHEW J. MALETTA Matthew J. Maletta	Attorney-in-fact pursuant to a Power of Attorney filed with this Report as Exhibit 24.1	March 6, 2024

INDEX TO FINANCIAL STATEMENTS

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Endo International plc is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as amended. Endo International plc's internal control over financial reporting was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

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

Endo International plc's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (2013)*. Based on management's assessment, as of December 31, 2023, the Company's internal control over financial reporting is effective based on those criteria.

/S/ BLAISE COLEMAN

Blaise Coleman
President and Chief Executive Officer
(Principal Executive Officer)

/S/ MARK T. BRADLEY

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

March 6, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Endo International plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Endo International plc (Debtor-in-Possession) and its subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations, of comprehensive loss, of shareholders' deficit and of cash flows for each of the three years in the period ended December 31, 2023, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2023 appearing under Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Notes 1 and 2 to the consolidated financial statements, the Company, together with certain of its direct and indirect subsidiaries, has filed voluntary petitions for relief under the bankruptcy code, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to this matter are also described in Notes 1 and 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. This matter is also discussed below as a critical audit matter.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

Sales Deduction Reserves

As described in Note 3 to the consolidated financial statements, the amount of revenue recognized by the Company is equal to the fixed amount of the transaction price, adjusted for management's estimates of a number of significant variable components including, but not limited to, estimates for chargebacks, rebates, sales incentives and allowances, DSA and other fees for services, returns and allowances, which management collectively refer to as sales deductions. As of December 31, 2023, reserves for sales deductions totaled $434.0 million. These amounts relate primarily to management's estimates of unsettled obligations for returns and allowances, rebates and chargebacks. The most significant sales deduction reserves relate to returns, wholesaler chargebacks and rebates for the Sterile Injectables and Generic Pharmaceuticals segments. Management estimates the reserves for sales deductions based on factors such as direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, specific known market events and estimated future trends, current contractual and statutory requirements, industry data, estimated customer inventory levels, current contract sales terms with direct and indirect customers and other competitive factors.

The principal considerations for our determination that performing procedures relating to sales deduction reserves is a critical audit matter are (i) the significant judgment by management in developing these reserves; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's reserves, as the reserves are based on direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, estimated future trends, estimated customer inventory levels, and current contract sales terms with direct and indirect customers.

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

Goodwill Impairment Assessment - Sterile Injectables Reporting Unit

As described in Notes 3 and 11 to the consolidated financial statements, the Company's goodwill balance for the Sterile Injectables reporting unit was $523 million as of December 31, 2023. An impairment assessment is conducted as of October 1, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. Management performs the goodwill impairment test by estimating the fair value of the reporting units using an income approach that utilizes a discounted cash flow model or, where appropriate, a market approach. The discounted cash flow models are dependent upon management's estimates of future cash flows and other factors including estimates of (i) future operating performance, including future sales, long-term growth rates, gross margins, operating expenses, discount rate and the probability of achieving the estimated cash flows and (ii) future economic conditions.

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

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) testing management's process for developing the fair value estimate of the Sterile Injectables reporting unit; (ii) evaluating the appropriateness of the discounted cash flow model used by management; (iii) testing the completeness and accuracy of underlying data used by management in the discounted cash flow model; (iv) evaluating management's assignment of assets and liabilities to the Sterile Injectables reporting unit; and (v) evaluating the reasonableness of the significant assumptions used by management related to future sales, long-term growth rates, gross margins, operating expenses, discount rate and the probability of achieving the estimated cash flows and future economic conditions. Evaluating management's assumptions related to future sales, long-term growth rates, gross margins, operating expenses, discount rate and the probability of achieving the estimated cash flows and future economic conditions involved evaluating whether the assumptions used were reasonable considering (i) historical performance of the reporting unit; (ii) the consistency with industry and economic forecasts; and (iii) whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating (i) the appropriateness of the discounted cash flow model and (ii) the reasonableness of the discount rate assumption.

Bankruptcy Proceedings

As described above and in Notes 2 and 16 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 plc, together with certain of its direct and indirect subsidiaries (the Debtors), filed voluntary petitions for relief under the bankruptcy code. As a result of the bankruptcy proceedings, management has applied generally accepted accounting principles 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. Pre-petition unsecured and undersecured claims related to the Debtors that may be impacted by the bankruptcy reorganization process in the amount of $11,096 million have been classified as liabilities subject to compromise in the consolidated balance sheet as of December 31, 2023. Additionally, certain expenses, gains and losses resulting from and recognized during the bankruptcy proceedings in the amount of $1,170 million are recorded in reorganization items, net in the consolidated statements of operations for the year ended December 31, 2023. On August 16, 2022 the Company entered into a Restructuring Support Agreement (RSA) with an ad hoc group of certain creditors (the Purchaser). During December 2023, the Company filed a proposed chapter 11 plan of reorganization (the Plan), as amended, and an amended version of the RSA, which reflects the terms of the Company's proposed Plan. The Plan provides for the establishment by the Debtors of opioid trusts, and other forms of funding, 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 February 2024, resolution was reached with the Department of Justice (DOJ), acting on behalf of itself and certain other agencies of the U.S. federal government, including with respect to claims filed in the chapter 11 cases by various agencies of the United States of America (collectively, the U.S. Government). The resolution provides that the U.S. Government will have in connection with its criminal, civil and tax-related claims: (i) an allowed, general unsecured claim in the amount of $1,086 million in connection with a criminal fine arising from a plea agreement entered into by Endo Health Solutions Inc. (EHSI); (ii) an allowed, general unsecured claim in the amount of approximately $476 million in connection with a civil settlement agreement entered into by EHSI; and (iii) in part, an allowed, unsubordinated priority claim and, in part, an allowed, unsubordinated general unsecured claim, each in such amount equal to the settlement amounts to be received by the IRS as allocated by the U.S. Government. The Company recorded an additional net charge of approximately $1,557 million in the fourth quarter of 2023 to increase the aggregate opioid liability to approximately $2,178 million as of December 31, 2023. The liabilities recorded by the Company represent management's best estimate of the allowed claims related to the claims against the Company and its subsidiaries.

The principal considerations for our determination that performing procedures relating to the bankruptcy proceedings is a critical audit matter are (i) the significant judgment by management when developing the estimate for allowed claims and assessing the accounting and disclosures related to the bankruptcy proceedings; (ii) a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence relating to management's significant judgments and estimate for allowed claims; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included among others, (i) reading the restructuring support agreement and related amendments, disclosure statement and subsequent updates, plan of reorganization and subsequent amendments and settlement agreements entered into during the year and; (ii) testing management's process for developing the estimate of the allowed claims related to the opioid and tax claims; (iii) evaluating, on a sample basis, management's accounting for claims submitted to the bankruptcy court; (iv) testing, for a sample of transactions, the completeness and accuracy of the classification of transactions as liabilities subject to compromise or reorganization items, net; and (v) obtaining and evaluating letters of audit inquiry with internal and external legal counsel related to opioid litigation and the bankruptcy proceedings. Professionals with specialized skill and knowledge were used to assist in evaluating (i) the application of generally accepted accounting principles applicable to reorganizations; and (ii) the completeness and accuracy of amounts classified as liabilities subject to compromise and reorganization items, net. These procedures also included evaluating the accuracy of the Company's disclosures with respect to the bankruptcy proceedings.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
March 6, 2024

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

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2023 AND 2022
(Dollars in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 777,919	$ 1,018,883
Restricted cash and cash equivalents	167,702	145,358
Accounts receivable, net	386,919	493,988
Inventories, net	246,017	274,499
Prepaid expenses and other current assets	82,163	136,923
Income taxes receivable	7,781	7,117
Total current assets	$ 1,668,501	$ 2,076,768
PROPERTY, PLANT AND EQUIPMENT, NET	476,240	438,314
OPERATING LEASE ASSETS	23,033	28,070
GOODWILL	1,352,011	1,352,011
OTHER INTANGIBLES, NET	1,477,883	1,732,935
OTHER ASSETS	139,626	129,839
TOTAL ASSETS	$ 5,137,294	$ 5,757,937
LIABILITIES AND SHAREHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 537,736	$ 687,183
Current portion of operating lease liabilities	956	903
Income taxes payable	102	1,541
Total current liabilities	$ 538,794	$ 689,627
DEFERRED INCOME TAXES	16,248	13,825
OPERATING LEASE LIABILITIES, LESS CURRENT PORTION	4,132	5,129
OTHER LIABILITIES	79,812	42,746
LIABILITIES SUBJECT TO COMPROMISE	11,095,868	9,168,782
COMMITMENTS AND CONTINGENCIES (NOTE 16)		
SHAREHOLDERS' DEFICIT:		
Euro deferred shares, $0.01 par value; 4,000,000 shares authorized and issued at both December 31, 2023 and December 31, 2022	44	43
Ordinary shares, $0.0001 par value; 1,000,000,000 shares authorized; 235,219,612 and 235,208,039 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	24	24
Additional paid-in capital	8,980,561	8,969,322
Accumulated deficit	(15,354,427)	(12,904,620)
Accumulated other comprehensive loss	(223,762)	(226,941)
Total shareholders' deficit	$ (6,597,560)	$ (4,162,172)
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	$ 5,137,294	$ 5,757,937

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021
(Dollars and shares in thousands, except per share data)

	2023	2022	2021
TOTAL REVENUES, NET	$ 2,011,518	$ 2,318,875	$ 2,993,206
COSTS AND EXPENSES:			
Cost of revenues	946,415	1,092,499	1,221,064
Selling, general and administrative	567,727	777,169	861,760
Research and development	115,462	128,033	123,440
Acquired in-process research and development	—	68,700	25,120
Litigation-related and other contingencies, net	1,611,090	478,722	345,495
Asset impairment charges	503	2,142,746	414,977
Acquisition-related and integration items, net	1,972	408	(8,379)
Interest expense, net	—	349,776	562,353
Loss on extinguishment of debt	—	—	13,753
Reorganization items, net	1,169,961	202,978	—
Other income, net	(9,688)	(34,054)	(19,774)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX	$ (2,391,924)	$ (2,888,102)	$ (546,603)
INCOME TAX EXPENSE	55,862	21,516	22,478
LOSS FROM CONTINUING OPERATIONS	$ (2,447,786)	$ (2,909,618)	$ (569,081)
DISCONTINUED OPERATIONS, NET OF TAX (NOTE 4)	(2,021)	(13,487)	(44,164)
NET LOSS	$ (2,449,807)	$ (2,923,105)	$ (613,245)
NET LOSS PER SHARE—BASIC:			
Continuing operations	$ (10.41)	$ (12.39)	$ (2.44)
Discontinued operations	(0.01)	(0.06)	(0.19)
Basic	$ (10.42)	$ (12.45)	$ (2.63)
NET LOSS PER SHARE—DILUTED:			
Continuing operations	$ (10.41)	$ (12.39)	$ (2.44)
Discontinued operations	(0.01)	(0.06)	(0.19)
Diluted	$ (10.42)	$ (12.45)	$ (2.63)
WEIGHTED AVERAGE SHARES:			
Basic	235,219	234,840	232,785
Diluted	235,219	234,840	232,785

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021
(Dollars in thousands)

	2023	2022	2021
NET LOSS	$ (2,449,807)	$ (2,923,105)	$ (613,245)
OTHER COMPREHENSIVE INCOME (LOSS):			
Net unrealized gain (loss) on foreign currency	$ 3,179	$ (10,496)	$ 1,308
Total other comprehensive income (loss)	$ 3,179	$ (10,496)	$ 1,308
COMPREHENSIVE LOSS	$ (2,446,628)	$ (2,933,601)	$ (611,937)

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021
(Dollars in thousands, except share data)

	Ordinary Shares		Euro Deferred Shares					
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Deficit
BALANCE, DECEMBER 31, 2020	230,315,768	$ 23	4,000,000	$ 49	$ 8,938,012	$ (9,368,270)	$ (217,753)	$ (647,939)
Net loss	—	—	—	—	—	(613,245)	—	(613,245)
Other comprehensive income	—	—	—	—	—	—	1,308	1,308
Compensation related to share-based awards	—	—	—	—	30,046	—	—	30,046
Exercise of options	82,331	—	—	—	622	—	—	622
Ordinary shares issued	3,292,717	—	—	—	—	—	—	—
Tax withholding for restricted shares	—	—	—	—	(14,774)	—	—	(14,774)
Other	—	—	—	(4)	—	—	—	(4)
BALANCE, DECEMBER 31, 2021	233,690,816	$ 23	4,000,000	$ 45	$ 8,953,906	$ (9,981,515)	$ (216,445)	$ (1,243,986)
Net loss	—	—	—	—	—	(2,923,105)	—	(2,923,105)
Other comprehensive loss	—	—	—	—	—	—	(10,496)	(10,496)
Compensation related to share-based awards	—	—	—	—	17,314	—	—	17,314
Ordinary shares issued	1,517,223	1	—	—	(1)	—	—	—
Tax withholding for restricted shares	—	—	—	—	(1,898)	—	—	(1,898)
Other	—	—	—	(2)	1	—	—	(1)
BALANCE, DECEMBER 31, 2022	235,208,039	$ 24	4,000,000	$ 43	$ 8,969,322	$ (12,904,620)	$ (226,941)	$ (4,162,172)
Net loss	—	—	—	—	—	(2,449,807)	—	(2,449,807)
Other comprehensive income	—	—	—	—	—	—	3,179	3,179
Compensation related to share-based awards	—	—	—	—	11,240	—	—	11,240
Ordinary shares issued	11,573	—	—	—	—	—	—	—
Other	—	—	—	1	(1)	—	—	—
BALANCE, DECEMBER 31, 2023	235,219,612	$ 24	4,000,000	$ 44	$ 8,980,561	$ (15,354,427)	$ (223,762)	$ (6,597,560)

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021
(Dollars in thousands)

	2023	2022	2021
OPERATING ACTIVITIES:			
Net loss	$ (2,449,807)	$ (2,923,105)	$ (613,245)
Adjustments to reconcile Net loss to Net cash provided by operating activities:			
Depreciation and amortization	306,448	391,629	457,098
Share-based compensation	11,240	17,314	30,046
Amortization of debt issuance costs and discount	—	9,406	14,437
Deferred income taxes	4,702	(7,303)	(3,157)
Change in fair value of contingent consideration	1,972	408	(8,793)
Loss on extinguishment of debt	—	—	13,753
Acquired in-process research and development charges	—	68,700	25,120
Asset impairment charges	503	2,142,746	414,977
Non-cash reorganization items, net	905,868	89,197	—
Gain on sale of business and other assets	(10,392)	(26,183)	(4,516)
Other	(222)	2,776	—
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	106,506	105,912	(82,052)
Inventories	22,195	(4,359)	48,978
Prepaid and other assets	38,006	80,350	(34,002)
Accounts payable, accrued expenses and other liabilities	1,500,094	321,055	84,391
Income taxes payable/receivable, net	(2,015)	650	68,015
Net cash provided by operating activities	$ 435,098	$ 269,193	$ 411,050
INVESTING ACTIVITIES:			
Capital expenditures, excluding capitalized interest	(94,325)	(99,722)	(77,929)
Capitalized interest payments	—	(3,140)	(2,721)
Proceeds from the U.S. Government Cooperative Agreement	39,397	18,635	—
Acquisitions, including in-process research and development, net of cash and restricted cash acquired	—	(90,320)	(5,000)
Product acquisition costs and license fees	—	—	(4,177)
Proceeds from sale of business and other assets	5,134	41,400	30,283
Net cash used in investing activities	$ (49,794)	$ (133,147)	$ (59,544)

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021
(Dollars in thousands)

	2023	2022	2021
FINANCING ACTIVITIES:			
Proceeds from issuance of notes, net	—	—	1,279,978
Proceeds from issuance of term loans, net	—	—	1,980,000
Repayments of notes	—	(180,342)	—
Repayments of term loans	—	(10,000)	(3,310,475)
Repayments of revolving debt	—	—	(22,800)
Adequate protection payments	(592,759)	(313,109)	—
Repayments of other indebtedness	(6,733)	(6,062)	(5,448)
Payments for debt issuance and extinguishment costs	—	—	(8,574)
Payments for contingent consideration	(5,136)	(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	$ (604,628)	$ (513,873)	$ (105,481)
Effect of foreign exchange rate	704	(4,242)	285
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS	$ (218,620)	$ (382,069)	$ 246,310
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, BEGINNING OF PERIOD	1,249,241	1,631,310	1,385,000
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, END OF PERIOD	$ 1,030,621	$ 1,249,241	$ 1,631,310
SUPPLEMENTAL INFORMATION:			
Cash paid for interest, excluding capitalized interest and adequate protection payments	$ —	$ 289,664	$ 538,424
Cash paid for income taxes, gross	$ 10,465	$ 14,101	$ 10,019
Cash refunds from income taxes, gross	$ 1,776	$ 3,092	$ 57,801
SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:			
Acquisitions, including in-process research and development, accrued in the period but not yet paid	$ —	$ —	$ 20,120

See accompanying Notes to Consolidated Financial Statements.

ENDO INTERNATIONAL PLC
(DEBTOR-IN-POSSESSION)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021

NOTE 1. DESCRIPTION OF BUSINESS

Background and Basis of Presentation

Endo International plc is an Ireland-domiciled specialty pharmaceutical company that conducts business through its operating subsidiaries. Unless otherwise indicated or required by the context, references throughout to "Endo," the "Company," "we," "our" or "us" refer to Endo International plc and its subsidiaries. The accompanying Consolidated Financial Statements of Endo International plc and its subsidiaries have been prepared in accordance with U.S. GAAP.

Going Concern

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 and, as further described in the Second-Quarter 2022 Form 10-Q, we previously concluded that the related conditions and events gave rise to substantial doubt about our ability to continue as a going concern.

Subsequent to the filing of the Second-Quarter 2022 Form 10-Q, beginning 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 15. Debt for additional information. 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 these Consolidated Financial Statements. 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.

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 15. Debt for additional information.

Restructuring Support Agreement and Marketing Process

On August 16, 2022, we entered into a Restructuring Support Agreement (as amended, 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 Purchaser) agreed to serve as stalking horse bidder in connection with the proposed sale of all or substantially all of our assets pursuant to section 363 of the Bankruptcy Code (the Sale).

As described in the RSA, the Purchaser's bid (the Stalking Horse Bid), which was subject to higher or otherwise better bids from other parties, included 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 Purchaser agreed to make offers of employment to all of our active employees. The proposed purchase and sale agreement with respect to the Stalking Horse Bid was filed with the Bankruptcy Court on November 23, 2022, and amended versions were subsequently filed with the Bankruptcy Court several times, including most recently on August 3, 2023.

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 Purchaser) 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), were supported by the Debtors. 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, which established deadlines by which claimants must file proofs of claims with the Bankruptcy Court.

As part of the Bidding Procedures Order, the Bankruptcy Court also approved certain internal restructuring transactions under Irish law that would 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 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, naming the Purchaser 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. The hearing to approve the Sale was subsequently adjourned several times as negotiations continued with our stakeholders and we explored alternative restructuring transactions.

On December 28, 2023, we filed an amended version of the RSA. The amended RSA reflects the terms of our proposed Plan (as defined and discussed in more detail below) while preserving our rights and the rights of the Ad Hoc First Lien Group to toggle back to a standalone sale under section 363 of the Bankruptcy Code.

Pursuant to the amended 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 amended 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 amended 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 16. Commitments and Contingencies.

The amended 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 amended 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 amended RSA. These milestones, (which may be further modified from time to time) include: (i) not later than 11:59 p.m. prevailing Eastern Time on January 17, 2024, the Bankruptcy Court shall have entered an order conditionally approving our disclosure statement and related solicitation materials; (ii) not later than 11:59 p.m. prevailing Eastern Time on March 22, 2024, the Bankruptcy Court shall have entered one or more orders confirming our Plan and approving the backstop commitment agreements and related subscription materials; and (iii) not later than 11:59 p.m. prevailing Eastern Time on April 22, 2024, the Plan shall have gone effective. The amended RSA also includes certain milestones that would apply if we toggle back to a standalone sale under section 363 of the Bankruptcy Code. As of the date of this report, milestone (i) referenced above has been satisfied. Each of the parties to the amended RSA may terminate the agreement (and thereby their support for the Plan) under certain limited circumstances, including for material breaches and materially untrue representations and warranties by their counterparties, if a governmental agency enjoins the Plan or if the purchase and sale agreement with respect to the sale contemplated by the Plan is terminated under certain circumstances.

The transactions contemplated by the amended 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.

On January 12, 2024, the Bankruptcy Court entered an order conditionally approving our disclosure statement which authorized us to solicit votes on our Plan. The Bankruptcy Court also scheduled a combined hearing for: (i) final approval of the disclosure statement as containing "adequate information" as required by the Bankruptcy Code; and (ii) confirmation of the Plan for March 19, 2024.

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 15. Debt of this 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.

Claims Reconciliation Process

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 February 28, 2024, approximately 907,100 claims, totaling approximately $979 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 21. Income Taxes. As claims are filed, they are being evaluated for validity and compared to amounts recorded in our accounting records. Due to the voluminous number of claims received, Endo is continuing to review the proofs of claims filed in the Chapter 11 Cases to identify which, if any, additional claims constitute unresolved claims not previously known. 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 Consolidated Financial Statements.

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 Purchaser) 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 Purchaser and the Future Claimants' Representative (the FCR). In August 2023, a resolution was reached between the Purchaser and an ad hoc group of public school district creditors (the Public School District Creditors). In September 2023, a resolution was reached between the Purchaser and certain Canadian governmental entities that had previously filed an objection to the Sale (the Canadian Provinces). In February 2024, the Debtors announced an agreed resolution with the DOJ, acting on behalf of itself and certain other agencies of the U.S. federal government. The DOJ resolution formalized the terms of the economic agreement in principle announced by the Ad Hoc First Lien Group in November 2023 and set forth certain non-economic terms mutually agreed upon by the parties. The foregoing resolutions, which are set forth in greater detail in the solicitation version of the disclosure statement filed with the Bankruptcy Court on January 16, 2024, and, in the case of the DOJ resolution, in the notice filed with the Bankruptcy Court on February 29, 2024, are supported by the Debtors.

The resolution reached with the UCC provides that, on or prior to the effective date of the Plan, the Debtors will establish 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) up to 4.02% of equity in the Purchaser (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 and subject to a maximum recovery available under 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 Purchaser. The resolution also contemplated a fee cap of $15 million for the UCC professionals for any work done between April 1, 2023 and October 31, 2023.

The resolution reached with the OCC provides that, on or prior to the effective date of the Plan, the Purchaser 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, $119.2 million of gross cash consideration payable in three installments (subject to the Purchaser's exercise of certain prepayment options and triggers) to be distributed to eligible private present opioid claimants. An additional $0.5 million will be funded to the trust by certain third parties, for a total of $119.7 million in aggregate consideration being funded to the trust. As set forth in the amended RSA, the Purchaser has agreed, on or prior to the effective date of the Plan, 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 contemplated a fee cap of $8.5 million for opioid claimants' committee hourly professionals for work done between April 1, 2023 and October 31, 2023. From November 1, 2023 through the effective date of the Plan, the OCC fees are subject to a monthly cap of $0.5 million subject to certain carve-outs and limitations pursuant to the OCC resolution.

The resolution reached with the FCR provides that, on or prior to the effective date of the Plan, the Purchaser will create personal injury trusts (the Future PI Trust) for the benefit of certain private opioid and mesh claimants whose first injury did not arise until after the applicable bar date. As consideration, the Future PI Trust will receive, among other things, $11.9 million of gross cash consideration payable in installments to be distributed to eligible private future opioid and mesh claimants.

The resolution reached with the Public School District Creditors provides that, on or prior to the effective date of the Plan, the Purchaser will fund an opioid school district recovery trust for the benefit of public school districts that elect to participate. As consideration, the trust will receive up to $3 million of gross cash consideration payable in installments to provide grants and other funding to participating school districts for the purpose of funding opioid abuse/misuse abatement or remediation programs.

The resolution reached with the Canadian Provinces provides that, on the effective date of the Plan, the Debtors will establish a trust for the benefit of the Canadian Provinces. As consideration, the trust will receive $7.3 million of gross cash consideration payable in installments expected to be used for government programs and services aimed at assisting Canadians who suffer from opioid misuse or addiction disorder.

The resolution reached with the Ad Hoc First Lien Group and the DOJ with respect to claims filed in the Chapter 11 Cases by the United States of America, acting through the United States Attorney's Office for the Southern District of New York, for and on behalf of: (i) the United States Department of Justice Civil Division's Consumer Protection Branch; (ii) the United States Attorney's Office for the Southern District of Florida; (iii) the United States Department of Justice Civil Division's Fraud Section, acting on behalf of the Office of Inspector General of the Department of Health and Human Services, the Defense Health Agency, as administrator of the TRICARE program, the Office of Personnel Management, as administrator of the Federal Employees Health Benefits program, and the VA; (iv) the IRS; (v) HHS, CMS and Indian Health Service; and (vi) the VA (collectively, the U.S. Government), including criminal, civil and tax-related claims provides for payment by Endo of $364.9 million over 10 years, or $200 million if the obligation is paid in full on the Plan effective date, plus contingent consideration of $25 million in each of 2024 through 2028 (up to $100 million in aggregate) if our Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) sufficiently exceeds defined baselines (U.S. Government Economic Settlement). The resolution further contemplates that Endo's subsidiary, EHSI, will enter into a plea agreement and civil settlement agreement in resolution of the DOJ's criminal and civil investigations of the Debtors. The plea agreement contemplates that EHSI will plead guilty to a single misdemeanor violation of the Food, Drug, and Cosmetic Act, contrary to Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1). Pursuant to the plea agreement, EHSI will be subject to a criminal fine of $1,086 million, which will be treated as an allowed, general unsecured claim in the Chapter 11 Cases, and a criminal forfeiture judgment in the amount of $450 million. Pursuant to the civil settlement agreement, the Debtors agree that the U.S. Government shall have an allowed, general unsecured claim in the Chapter 11 Cases in the amount of approximately $476 million. The claims brought against the Debtors by the IRS will be deemed to be, in part, an allowed, unsubordinated priority claim and, in part, an allowed, unsubordinated general unsecured claim, each in such amount equal to the settlement amounts to be received by the IRS as allocated by the U.S. Government. The criminal fine, civil settlement agreement amount and the IRS claims will be satisfied in full by the payments made pursuant to the U.S. Government Economic Settlement. The criminal forfeiture judgment will be deemed satisfied in full by payments made to state opioid claimants pursuant to the Plan.

In connection with the resolutions, the UCC, the OCC, the FCR, the Public School District Creditors, the Canadian Provinces, the ad hoc groups of debtholders party thereto and the DOJ have agreed to support the Plan.

Chapter 11 Plan of Reorganization

On December 19, 2023, we filed a proposed chapter 11 plan of reorganization (as amended, including on January 5, 2024 and January 9, 2024, and including any future amendments, exhibits and supplements filed with respect thereto, the Plan) and related disclosure statement with the Bankruptcy Court. The Plan contemplates a sale of substantially all of our assets on substantially similar terms to the proposed 363 sale to the Purchaser, including the assumption of certain liabilities, and offers of employment to all of our active team members, and reflects the resolutions described above.

Under the Plan, our first lien creditors would receive 96.3% of equity in a new entity formed to acquire our assets and an opportunity to participate in a rights offering, and second lien creditors and unsecured noteholders would receive the remaining 3.7% of the equity (both subject to dilution). Second lien creditors and unsecured noteholders would also receive $23.3 million in cash, certain proceeds of litigation claims and insurance rights, and the opportunity to participate in a $160 million rights offering (which was subscribed in July 2023). Other general unsecured creditors would receive up to $2 million in cash and a small percentage of the proceeds of trust litigation claims and insurance rights, subject to certain qualifications. Opioid claimants would receive distributions from certain trusts and sub-trusts, including pursuant to the resolutions described above, as follows: $460 million in installments for state opioid claimants (subject to certain prepayment rights), $119.7 million in installments for several subclasses of private opioid claimants (subject to certain prepayment rights), up to $15 million for tribal opioid claimants and up to approximately $11.4 million for future opioid claimants. The Plan also provides for the treatment of opioid claims held by other claimants, including public school districts, Canadian provinces and foreign holders of claims against certain foreign entities who file proofs of claim against us by a date certain (but after the general bar date). The Plan contemplates that we will use the, among other things, net proceeds from a potential exit financing facility (to the extent implemented), net proceeds from proposed rights offerings, cash on hand and certain litigation consideration to fund Plan distributions.

In addition to the previously reached settlements, the Plan also incorporates the recently announced economic settlement in principle with the DOJ, described above.

The Plan also sets forth a post-reorganization governance structure and includes releases for us and certain other parties. It is subject to certain conditions precedent and confirmation by the Bankruptcy Court. We currently anticipate seeking Bankruptcy Court confirmation of our proposed Plan on March 19, 2024.

To protect our Irish entities and assets from the risk of value-destructive litigation and enforcement efforts not enjoined by the Plan, we are also proposing an Irish scheme of arrangement in parallel with the Plan to implement certain terms of the Plan as a matter of Irish law. If the scheme of arrangement is approved by the required creditors and sanctioned by the High Court of Ireland, all claims against us covered by the scheme will be completely released and discharged as a matter of Irish law.

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, 2023 and 2022, information about the amounts presented as Liabilities subject to compromise in our Consolidated Balance Sheets (in thousands):

	December 31, 2023	December 31, 2022
Accounts payable	$ 32,281	$ 30,317
Accrued interest	160,617	160,617
Debt	8,147,826	7,834,717
Litigation accruals	2,431,455	820,805
Uncertain tax positions	259,611	235,176
Other (1)	64,078	87,150
Total	$ 11,095,868	$ 9,168,782

(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 the Plan is confirmed 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 years ended December 31, 2023 and 2022, information about the amounts presented as Reorganization items, net in our Consolidated Statements of Operations (in thousands):

	2023	2022
Professional fees	$ 264,093	$ 113,781
Debt valuation adjustments	905,868	89,197
Total	$ 1,169,961	$ 202,978

During the years ended December 31, 2023 and 2022, our operating cash flows included net cash outflows of $261.3 million and $53.7 million, respectively, 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 the non-cash debt valuation adjustments reflected in Reorganization items, net, as well as 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.

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

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 revenue recognition, including sales deductions, long-lived assets, goodwill, other intangible assets, income taxes, contingencies, financial instruments, share-based compensation, estimated allowed claim amounts, liabilities subject to compromise and reorganization items, net, among others. Some of these estimates can be subjective and complex. Uncertainties related to the magnitude and duration of potential public health crises, like the recent COVID-19 pandemic, and epidemics, the extent to which it may impact our estimated future financial results, worldwide macroeconomic conditions including interest rates, employment rates, consumer spending and health insurance coverage, among others, 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 our anticipated sale process in connection with the Plan 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 revenues from direct customers that accounted for 10% or more of our total consolidated net revenues during the years ended December 31, 2023, 2022 and 2021 are as follows:

	2023	2022	2021
Cencora, Inc. (1)	29 %	35 %	36 %
McKesson Corporation	25 %	26 %	32 %
Cardinal Health, Inc.	17 %	20 %	22 %
CVS Health Corporation (1)	16 %	4 %	— %

(1) During the second quarter of 2022, CVS Health Corporation finalized the acquisition of US Bioservices from Cencora, Inc. (known as AmerisourceBergen Corporation at the time).

Net revenues from these customers are generally included within each of our segments.

XIAFLEX® accounted for 24%, 19% and 14% of our 2023, 2022 and 2021 net revenues, respectively. Varenicline tablets (our generic version of Pfizer Inc.'s Chantix®) accounted for 13% of our 2022 net revenues. VASOSTRICT® accounted for 11% and 30% of our 2022 and 2021 net revenues, respectively. No other products accounted for 10% or more of our net revenues during any of the years ended December 31, 2023, 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 16. Commitments and Contingencies for information on any material manufacturing, supply and other service agreements.

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

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

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

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

At December 31, 2023 and 2022, our reserves for sales deductions totaled $434.0 million and $600.2 million, respectively. These amounts relate primarily to our estimates of unsettled obligations for returns and allowances, rebates and chargebacks. The most significant sales deduction reserves relate to returns, wholesaler chargebacks and rebates for the Sterile Injectables and Generic Pharmaceuticals segments. Our estimates are based on factors such as our direct and indirect customers' buying patterns and the estimated resulting contractual deduction rates, historical experience, specific known market events and estimated future trends, current contractual and statutory requirements, industry data, estimated customer inventory levels, current contract sales terms with our direct and indirect customers and other competitive factors. Significant judgment and estimation is required in developing the foregoing and other relevant assumptions. The most significant sales deductions are further described below.

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

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

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

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

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

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

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

Contract Assets and Contract Liabilities. Contract assets represent 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 Statements of Operations. 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. Property, plant and equipment that are acquired or constructed for R&D activities and that have alternate future uses are capitalized and depreciated over their estimated useful lives on a straight-line basis. 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 and Cash Equivalents. The Company considers all highly liquid money market instruments with an original maturities of three months or less when purchased to be cash equivalents. At December 31, 2023 and 2022, cash equivalents were deposited in financial institutions and consisted almost entirely of immediately available fund balances. The Company maintains its cash deposits and cash equivalents with financial institutions it believes to be well-known and stable.

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

Accounts Receivable. 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 81% and 83% of our gross trade accounts receivable balances represent amounts due from three customers (Cardinal Health, Inc., McKesson Corporation and Cencora, Inc.) at December 31, 2023 and December 31, 2022, respectively. We perform ongoing credit evaluations of these and our other customers based on information available to us. We consider these and other factors, including changes in the composition and aging of our accounts receivable, in developing our allowance for expected credit losses. The estimated allowance was not material to the Company's Consolidated Financial Statements at December 31, 2023 or December 31, 2022, 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, the extent of which cannot be fully predicted.

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

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

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

Property, Plant and Equipment. Property, plant and equipment is generally stated at cost less accumulated depreciation. Major improvements are capitalized, while routine maintenance and repairs are expensed as incurred. Costs incurred during the construction or development of property, plant and equipment are capitalized as assets under construction. Once an asset has been placed into service, depreciation expense is taken on a straight-line basis over the estimated useful life of the related assets or, in the case of leasehold improvements and finance lease assets, over the shorter of the estimated useful life and the lease term. As of December 31, 2023, the useful lives of our property, plant and equipment range from 1 year to up to 30 years for buildings, 15 years for machinery and equipment, 10 years for computer equipment and software and 10 years for furniture and fixtures. Depreciation expense is not recorded on assets held for sale. Gains and losses on disposals are included in Other income, net in the Consolidated Statements of Operations. As further described below under the heading "Long-Lived Asset Impairment Testing," our property plant and equipment assets are also subject to impairment reviews.

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

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

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

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

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

The present value of lease payments is calculated based on:

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

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

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

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

Cloud Computing Arrangements. The Company may from time to time incur costs in connection with hosting arrangements that are service contracts. The Company capitalizes any such implementation costs, expenses them over the terms of the respective hosting arrangements and subjects them to impairment testing consistent with other long-lived assets.

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

To the extent an intangible asset is deemed to have a finite life 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 income and net income per share to decrease. Amortization expense is not recorded on assets held for sale.

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

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

In the case of long-lived assets to be disposed of by sale or otherwise, including assets held for sale, the assets and the associated liabilities to be disposed of together as a group in a single transaction (the disposal group) are measured at the lower of their carrying amount or fair value less cost to sell. 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.

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

Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our estimates of the probability and amount of any such liabilities involve significant judgment regarding future events.

The Company records receivables from its insurance carriers only when the realization of the potential claim for recovery is considered probable.

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

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

Advertising Costs. Advertising costs are expensed as incurred and included in Selling, general and administrative expenses in the Consolidated Statements of Operations. Advertising costs amounted to $98.2 million, $130.4 million and $136.8 million for the years ended December 31, 2023, 2022 and 2021, respectively.

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

Restructuring. Restructuring charges related to nonretirement postemployment benefits that fall under *Accounting Standards Codification Topic 712, Compensation—Nonretirement Postemployment Benefits* 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 Company granted share-based compensation awards to certain employees and non-employee directors. Generally, the grant-date fair value of each award was recognized as expense over the requisite service period. However, expense recognition differed in the case of certain performance share units (PSUs) where the ultimate payout was performance-based. For these awards, at each reporting period, the Company generally estimated the ultimate payout and adjusted the cumulative expense based on its estimate and the percent of the requisite service period that elapsed. Share-based compensation expense was reduced for estimated future forfeitures. These estimates were revised in future periods if actual forfeitures differed from the estimates. Changes in forfeiture estimates impacted compensation expense in the period in which the change in estimate occurs. New ordinary shares are generally issued upon the exercise of stock options or vesting of stock awards by employees and non-employee directors. Refer to Note 19. Share-based Compensation for additional discussion.

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

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

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

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

The Company records unrecognized income tax positions (UTPs) on the basis of a two-step process whereby the Company first determines whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position and then measures those tax positions that meet the more-likely-than-not recognition threshold. The Company recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the tax authority. The Company generally recognizes changes in UTPs, interest and penalties in the Income tax expense line in the Consolidated Statements of Operations. Refer to Note 21. 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 company's shareholders. Other comprehensive income or loss refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to shareholders' equity.

Government Assistance Transactions. We are party to the U.S. Government Cooperative Agreement (as defined and discussed in more detail below). Under the terms of the U.S. Government Cooperative 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 Company has concluded that reimbursements it receives pursuant to the U.S. Government Cooperative 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 Cooperative 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 (IAS) 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. Under IAS 20, government grants related to assets are presented in the Consolidated Balance Sheets either by presenting the grant as deferred income or by deducting the grant in arriving at the carrying amount of the asset. Either of these two methods of presentation of grants related to assets in the Consolidated Balance Sheets are regarded as acceptable alternatives under IAS 20. Reimbursements received prior to the asset being placed into service are recognized 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. When the constructed capital assets are placed into service we deduct the grant reimbursement from Property, plant and equipment and the grant income is recognized over the useful life of the asset as a reduction to depreciation expense.

Refer to Note 16. Commitments and Contingencies for additional discussion of this agreement.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted at December 31, 2023

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (ASU 2023-07) to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 14, 2024, on a retrospective basis. Early adoption is permitted. The Company is currently evaluating the impact of this accounting standards update on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvement to Income Tax Disclosures* (ASU 2023-09) to enhance the transparency and decision usefulness of income tax disclosures, primarily related to standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 on a prospective basis. Early adoption is permitted. The Company is currently evaluating the impact of this accounting standards update on its consolidated financial statements and related disclosures.

NOTE 4. DISCONTINUED OPERATIONS AND ASSET SALES

Astora

The operating results of the Company's Astora business, which the Board resolved to wind down in 2016, are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. The following table provides the operating results of Astora Discontinued operations, net of tax, for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Litigation-related and other contingencies, net	$ 495	$ —	$ 25,000
Loss from discontinued operations before income taxes	$ (2,329)	$ (15,543)	$ (49,594)
Income tax benefit	$ (308)	$ (2,056)	$ (5,430)
Discontinued operations, net of tax	$ (2,021)	$ (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 $2.0 million, $13.5 million and $44.2 million for the years ended December 31, 2023, 2022 and 2021, respectively, and the impact of cash activity related to vaginal mesh cases. During the periods presented above, there were no material net cash flows related to Astora discontinued investing activities and there was no depreciation or amortization expense related to Astora.

Refer to Note 16. Commitments and Contingencies for amounts and additional information relating to vaginal mesh-related matters.

Certain Assets and Liabilities of Endo's Retail Generics Business

In November 2020, we announced the initiation of several strategic actions to further optimize the Company's operations and increase overall efficiency (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. 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 inventory. 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 Statements of Operations, 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 property, plant and equipment. 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 Statements of Operations.

The assets described in this section, which primarily related to the Company'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 Statements of Operations are included in the quantitative disclosures of the 2020 Restructuring Initiative included in Note 5. Restructuring.

NOTE 5. RESTRUCTURING

2020 Restructuring Initiative

As noted above, in November 2020, the Company announced the initiation of several strategic actions to optimize the Company'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 Company's key strategic priority to expand and enhance its product portfolio. These actions included the following:

- Optimizing the Company'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 Company's commercial, operations and research and development functions, respectively, to support the Company's key strategic priorities.

As a result of the 2020 Restructuring Initiative, the Company's global workforce was reduced by approximately 300 net full-time positions. Future costs associated with the 2020 Restructuring Initiative are not expected to be material.

There have been no material charges or cash payments associated with the 2020 Restructuring Initiative in 2023.

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

	2022	2021
Net restructuring charges (charge reversals) related to:		
Accelerated depreciation	$ 3,773	$ 24,718
Asset impairments	—	42,155
Inventory 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 included charges related to accelerated depreciation of $51.0 million, asset impairments related to certain identifiable intangible assets, operating lease assets and disposal groups totaling $49.5 million, inventory adjustments of $11.6 million, employee separation, continuity and other benefit-related costs, net of $53.9 million and certain other restructuring costs of $3.5 million. Of these amounts, $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 Company's Consolidated Statements of Operations during the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Net restructuring charges (charge reversals) related to:		
Cost of revenues	$ 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, 2023, 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 December 31, 2020	$ 58,338	$ 664	$ 59,002
Net (charge reversals) charges	(7,384)	3,711	(3,673)
Cash payments	(39,975)	(4,170)	(44,145)
Liability balance as of December 31, 2021	$ 10,979	$ 205	$ 11,184
Net charges	1,216	796	2,012
Cash payments	(11,926)	(1,001)	(12,927)
Liability balance as of December 31, 2022	$ 269	$ —	$ 269
Net (charge reversals) charges	(198)	—	(198)
Cash payments	(71)	—	(71)
Liability balance as of December 31, 2023	$ —	$ —	$ —

2022 Restructuring Initiative

In April 2022, the Company communicated the initiation of actions to streamline and simplify certain functions, including its commercial organization, to increase its overall organizational effectiveness and better align with current and future needs. In December 2022, the Company 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 Company's key strategic priority to expand and enhance its product portfolio. In December 2022, the Bankruptcy Court approved an order authorizing the Company to cease the production and commercialization of QWO® and granting related relief.

As a result of the 2022 Restructuring Initiative, the Company's global workforce was reduced by approximately 175 net full-time positions. Future costs associated with the 2022 Restructuring Initiative are not expected to be material.

There have been no material charges associated with the 2022 Restructuring Initiative in 2023.

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

	2022
Net restructuring charges related to:	
Asset impairments	$ 180,248
Inventory 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.

As of December 31, 2022, cumulative amounts incurred to date included charges related to asset impairments related to certain identifiable intangible assets of $180.2 million, inventory adjustments of $34.9 million, employee separation, continuity and other benefit-related costs, net of $28.3 million and certain other restructuring costs of $8.7 million. Of these amounts, $238.6 million was attributable to the Branded Pharmaceuticals segment, with the remaining amounts related to our Generic Pharmaceuticals segment and certain corporate unallocated costs.

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

	2022
Net restructuring charges included in:	
Cost of revenues	$ 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 years ended December 31, 2023 and 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
Net charge reversals	(248)	—	(248)
Cash payments	(13,376)	—	(13,376)
Liability balance as of December 31, 2023	$ 1,373	$ —	$ 1,373

The liability at December 31, 2023 is classified as current and is included in Accounts payable and accrued expenses in the Consolidated Balance Sheets.

NOTE 6. SEGMENT RESULTS

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

We evaluate segment performance based on Segment adjusted income from continuing operations before income tax, which we define as Loss from continuing operations before income tax and before 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 Company are not directly attributable to any specific segment. Accordingly, these costs are not allocated to any of the Company's segments and are included in the results below as "Corporate unallocated costs." Interest income and expense are also considered corporate items and not allocated to any of the Company's segments. The Company's Total segment adjusted income from continuing operations before income tax is equal to the combined results of each of its segments.

Branded Pharmaceuticals

Our Branded Pharmaceuticals segment includes a variety of branded products in the areas of urology, orthopedics, endocrinology 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 ADRENALIN®, VASOSTRICT® and APLISOL®, among others, and certain generic sterile injectable products.

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 Company's reportable segments for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Net revenues from external customers:			
Branded Pharmaceuticals	$ 859,087	$ 851,142	$ 893,617
Sterile Injectables	429,563	589,633	1,266,097
Generic Pharmaceuticals	650,352	795,457	740,586
International Pharmaceuticals (1)	72,516	82,643	92,906
Total net revenues from external customers	$ 2,011,518	$ 2,318,875	$ 2,993,206
Segment adjusted income from continuing operations before income tax:			
Branded Pharmaceuticals	$ 459,309	$ 366,554	$ 384,186
Sterile Injectables	157,179	349,424	998,453
Generic Pharmaceuticals	237,870	336,133	160,046
International Pharmaceuticals	16,733	19,920	30,325
Total segment adjusted income from continuing operations before income tax	$ 871,091	$ 1,072,031	$ 1,573,010

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

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

The table below provides reconciliations of our Total consolidated loss from continuing operations before income tax, which is determined in accordance with U.S. GAAP, to our Total segment adjusted income from continuing operations before income tax for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Total consolidated loss from continuing operations before income tax	$ (2,391,924)	$ (2,888,102)	$ (546,603)
Interest expense, net	—	349,776	562,353
Corporate unallocated costs (1)	158,717	182,335	180,866
Amortization of intangible assets	255,933	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)	44,098	198,381	90,912
Certain litigation-related and other contingencies, net (3)	1,611,090	478,722	345,495
Certain legal costs (4)	7,256	31,756	136,148
Asset impairment charges (5)	503	2,142,746	414,977
Acquisition-related and integration items, net (6)	1,972	408	(8,379)
Loss on extinguishment of debt	—	—	13,753
Foreign currency impact related to the remeasurement of intercompany debt instruments	2,159	(5,328)	797
Reorganization items, net (7)	1,169,961	202,978	—
Other, net (8)	11,326	(27,652)	(15,336)
Total segment adjusted income from continuing operations before income tax	$ 871,091	$ 1,072,031	$ 1,573,010

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

(2) Amounts in 2023 include net employee separation, continuity and other benefit-related charges of $43.7 million and other net charges of $0.4 million. Amounts in 2022 include net employee separation, continuity and other benefit-related charges of $85.6 million, accelerated depreciation charges of $3.8 million, inventory charges related to restructurings of $36.4 million and other net charges, including those related to 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 16. 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, property, plant and equipment, 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 10. Property, Plant and Equipment 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 income 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 2023 primarily relates to a charge of approximately $9.2 million associated with the rejection of certain equity award agreements, which was approved by the Bankruptcy Court in March 2023. Amounts in 2021 include gains of $15.5 million associated with the termination of certain contracts, partially offset by $3.9 million of third-party fees incurred in connection with the March 2021 Refinancing Transactions, which were accounted for as debt modification costs as further discussed in Note 15. Debt. Other amounts in this row relate to gains and losses on sales of business and other assets and certain other items.

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

During the years ended December 31, 2023, 2022 and 2021, the Company disaggregated its revenue from contracts with customers into the categories included in the table below (in thousands). The Company believes these categories depict how the nature, timing and uncertainty of revenue and cash flows are affected by economic factors.

	2023	2022	2021
Branded Pharmaceuticals:			
Specialty Products:			
XIAFLEX®	$ 475,014	$ 438,680	$ 432,344
SUPPRELIN® LA	96,849	113,011	114,374
Other Specialty (1)	73,797	70,009	86,432
Total Specialty Products	$ 645,660	$ 621,700	$ 633,150
Established Products:			
PERCOCET®	$ 106,375	$ 103,943	$ 103,788
TESTOPEL®	42,464	38,727	43,636
Other Established (2)	64,588	86,772	113,043
Total Established Products	$ 213,427	$ 229,442	$ 260,467
Total Branded Pharmaceuticals (3)	$ 859,087	$ 851,142	$ 893,617
Sterile Injectables:			
ADRENALIN®	$ 99,910	$ 114,304	$ 124,630
VASOSTRICT®	93,180	253,696	901,735
Other Sterile Injectables (4)	236,473	221,633	239,732
Total Sterile Injectables (3)	$ 429,563	$ 589,633	$ 1,266,097
Total Generic Pharmaceuticals (5)	$ 650,352	$ 795,457	$ 740,586
Total International Pharmaceuticals (6)	$ 72,516	$ 82,643	$ 92,906
Total revenues, net	$ 2,011,518	$ 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, 2023 and/or any product having revenues in excess of $25 million during any completed quarterly period in 2023 or 2022.
(4) Products included within Other Sterile Injectables include, but are not limited to, APLISOL®. No individual product within Other Sterile Injectables has exceeded 5% of consolidated total revenues for the periods presented.
(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. Varenicline tablets (Endo's generic version of Pfizer Inc.'s Chantix®), which launched in September 2021, made up 8% and 13% for the years ended December 31, 2023 and 2022, respectively, of consolidated total revenues. Dexlansoprazole delayed release capsules (Endo's generic version of Takeda Pharmaceuticals USA, Inc.'s Dexilant®), which launched in November 2022, made up 6% for the year ended December 31, 2023 of consolidated total revenues. No other individual product within this segment has exceeded 5% of consolidated total revenues for the periods presented.
(6) The International Pharmaceuticals segment, which accounted for less than 5% of consolidated total revenues for each of the periods presented, includes a variety of specialty pharmaceutical products sold outside the U.S., primarily in Canada through Endo's operating company Paladin.

The following represents depreciation expense for our reportable segments for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Branded Pharmaceuticals	$ 9,252	$ 9,862	$ 10,632
Sterile Injectables	22,652	20,224	17,796
Generic Pharmaceuticals	11,829	16,952	47,343
International Pharmaceuticals	3,561	3,638	4,242
Corporate unallocated	3,221	3,642	4,178
Total depreciation expense	$ 50,515	$ 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 and cash equivalents, restricted cash and cash equivalents, accounts receivable, accounts payable and accrued expenses, acquisition-related contingent consideration and debt obligations. Included in cash and cash equivalents and restricted cash and cash equivalents are money market funds representing a type of mutual fund required by law to invest in low-risk securities (for example, U.S. government bonds, U.S. Treasury Bills and commercial paper). Money market funds pay dividends that generally reflect short-term interest rates. Due to their initial maturities, the carrying amounts of non-restricted and restricted cash and cash equivalents (including money market funds), accounts receivable, accounts payable and accrued expenses approximate their fair values.

Restricted Cash and Cash Equivalents

The following table presents current and noncurrent restricted cash and cash equivalent balances at December 31, 2023 and December 31, 2022 (in thousands):

	Balance Sheet Line Items	December 31, 2023	December 31, 2022
Restricted cash and cash equivalents—current (1)	Restricted cash and cash equivalents	$ 167,702	$ 145,358
Restricted cash and cash equivalents—noncurrent (2)	Other assets	85,000	85,000
Total restricted cash and cash equivalents		$ 252,702	$ 230,358

(1) Amounts at December 31, 2023 and December 31, 2022 include: (i) restricted cash and cash equivalents associated with litigation-related matters, including $49.8 million and $50.7 million, respectively, held in Qualified Settlement Funds (QSFs) for mesh and/or opioid-related matters, and (ii) approximately $85.9 million and $86.0 million, respectively, of restricted cash and cash equivalents related to certain self-insurance related matters. These balances are classified as current assets in the Consolidated Balance Sheets as the potential for, and timing of, future claims is unknown and could result in distributions within the next twelve months. See Note 16. Commitments and Contingencies for further information about litigation-related matters.

(2) The amounts at December 31, 2023 and December 31, 2022 relate to the TLC Agreement. This balance, which may be used to fund certain future contractual obligations or returned to us upon satisfaction of certain conditions, is classified as a noncurrent asset in the Consolidated Balance Sheets. See Note 12. License, Collaboration and Asset Acquisition Agreements for further information.

Acquisition-Related Contingent Consideration

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

Recurring Fair Value Measurements

The Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2023 and December 31, 2022 were as follows (in thousands):

	Fair Value Measurements at December 31, 2023 using:			
	Level 1 Inputs	Level 2 Inputs	Level 3 Inputs	Total
Assets:				
Money market funds (1)	$ 7,123	$ —	$ —	$ 7,123
Liabilities:				
Acquisition-related contingent consideration (2)	$ —	$ —	$ 12,447	$ 12,447

	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

(1) At December 31, 2023 and December 31, 2022, money market funds include $7.1 million and $12.2 million, respectively, in QSFs. Amounts in QSFs are considered restricted cash equivalents. See Note 16. Commitments and Contingencies for further discussion of our litigation. At December 31, 2023 and December 31, 2022, 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, 2023 and December 31, 2022, the balances of the Company's liability for acquisition-related contingent consideration, which are governed by executory contracts and recorded at the expected amount of the total allowed claim, are classified within Liabilities subject to compromise in the Consolidated Balance Sheets.

Fair Value Measurements Using Significant Unobservable Inputs

The following table presents changes to the Company's liability for acquisition-related contingent consideration, which is measured at fair value on a recurring basis using significant unobservable inputs (Level 3), for the years ended December 31, 2023 and 2022 (in thousands):

	2023	2022
Beginning of period	$ 16,571	$ 20,076
Amounts settled	(6,177)	(3,127)
Changes in fair value recorded in earnings	1,972	408
Effect of currency translation	81	(786)
End of period	$ 12,447	$ 16,571

At December 31, 2023, 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 10.4%, weighted based on relative fair value). Changes in fair value recorded in earnings related to acquisition-related contingent consideration are included in our Consolidated Statements of Operations as Acquisition-related and integration items, net.

The following table presents changes to the Company's liability for acquisition-related contingent consideration during the year ended December 31, 2023 by acquisition (in thousands):

	Balance as of December 31, 2022 (1)	Changes in Fair Value Recorded in Earnings	Amounts Settled and Other	Balance as of December 31, 2023 (1)
Auxilium acquisition	$ 10,618	$ 1,041	$ (2,165)	$ 9,494
Lehigh Valley Technologies, Inc. acquisitions	2,300	(91)	(1,209)	1,000
Other	3,653	1,022	(2,722)	1,953
Total	$ 16,571	$ 1,972	$ (6,096)	$ 12,447

(1) At December 31, 2023 and December 31, 2022, the balances of the Company's liability for acquisition-related contingent consideration, which are governed by executory contracts and recorded at the expected amount of the total allowed claim, are classified within Liabilities subject to compromise in the Consolidated Balance Sheets.

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

	Balance as of December 31, 2021	Changes in Fair Value Recorded in Earnings	Amounts Settled and Other	Balance as of 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 Company'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.

Nonrecurring Fair Value Measurements

Long-lived assets, goodwill and other intangible assets may be subject to nonrecurring fair value measurement for the evaluation of potential impairment. During the year ended December 31, 2023, nonrecurring fair value measurements, which related primarily to certain property, plant and equipment, were not material.

The Company's financial assets and liabilities measured at fair value on a nonrecurring basis during the year ended December 31, 2022 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 property, plant and equipment	—	—	—	(9,045)
Total	$ —	$ —	$ 67,082	$ (297,746)

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

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

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

NOTE 8. INVENTORIES

Inventories consisted of the following at December 31, 2023 and December 31, 2022 (in thousands):

	December 31, 2023	December 31, 2022
Raw materials (1)	$ 103,336	$ 105,975
Work-in-process (1)	29,827	43,057
Finished goods (1)	112,854	125,467
Total	$ 246,017	$ 274,499

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

Inventory in excess of the amount expected to be sold within one year is classified as noncurrent inventory and is not included in the table above. At December 31, 2023 and December 31, 2022, $29.7 million and $23.0 million, respectively, of noncurrent inventory was included in Other assets in the Consolidated Balance Sheets. As of December 31, 2023 and December 31, 2022, the Company's Consolidated Balance Sheets included approximately $2.7 million and $5.8 million, respectively, of capitalized pre-launch inventories related to products that were not yet available to be sold.

NOTE 9. LEASES

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

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

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

Our most significant lease is for our Malvern, Pennsylvania location. The term of the lease is through 2024.

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 through a sublease arrangement ending in 2024, with certain limited early termination options.

The following table presents information about the Company's right-of-use assets and lease liabilities at December 31, 2023 and December 31, 2022 (in thousands):

	Balance Sheet Line Items	December 31, 2023	December 31, 2022
Right-of-use assets:			
Operating lease right-of-use assets	Operating lease assets	$ 23,033	$ 28,070
Finance lease right-of-use assets	Property, plant and equipment, net	18,668	26,761
Total right-of-use assets		$ 41,701	$ 54,831
Operating lease liabilities, excluding amounts classified as Liabilities subject to compromise:			
Current operating lease liabilities	Current portion of operating lease liabilities	$ 956	$ 903
Noncurrent operating lease liabilities	Operating lease liabilities, less current portion	4,132	5,129
Total operating lease liabilities		$ 5,088	$ 6,032
Finance lease liabilities, excluding amounts classified as Liabilities subject to compromise:			
Noncurrent finance lease liabilities	Other liabilities	$ 1,386	$ 1,392
Total finance lease liabilities		$ 1,386	$ 1,392
Operating and finance leases, amounts classified as Liabilities subject to compromise:			
Operating lease liabilities	Liabilities subject to compromise	$ 20,635	$ 28,387
Finance lease liabilities	Liabilities subject to compromise	9,981	17,078
Total operating and finance leases classified as Liabilities subject to compromise		$ 30,616	$ 45,465

The following table presents information about lease costs and expenses and sublease income for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	Statement of Operations Line Items	2023	2022	2021
Operating lease cost	Various (1)	$ 6,811	$ 10,959	$ 13,892
Finance lease cost:				
Amortization of right-of-use assets	Various (1)	$ 8,096	$ 8,479	$ 9,244
Interest on lease liabilities	Interest expense, net	$ 781	$ 1,127	$ 1,480
Other lease costs and income:				
Variable lease costs (2)	Various (1)	$ 10,913	$ 11,707	$ 13,202
Finance lease right-of-use asset impairment charges	Asset impairment charges	$ —	$ 3,063	$ —
Sublease income	Various (1)	$ (5,616)	$ (6,436)	$ (3,793)

(1) Amounts are included in the Consolidated Statements of Operations based on the function that the underlying leased asset supports. The following table presents the components of such aggregate amounts for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Cost of revenues	$ 6,150	$ 6,189	$ 11,316
Selling, general and administrative	$ 13,952	$ 18,305	$ 21,013
Research and development	$ 102	$ 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, 2023 for each of the five years subsequent to December 31, 2023 and thereafter, as well as a reconciliation of such undiscounted cash flows to our lease liabilities at December 31, 2023 (in thousands):

	Operating Leases	Finance Leases
2024	$ 6,136	$ 8,037
2025	6,747	896
2026	5,496	895
2027	5,380	895
2028	3,412	299
Thereafter	1,214	8,921
Total future lease payments	$ 28,385	$ 19,943
Less: amounts representing interest	2,662	8,576
Present value of future lease payments (lease liabilities, including amounts classified as Liabilities subject to compromise)	$ 25,723	$ 11,367
Less: amounts classified as Liabilities subject to compromise	20,635	9,981
Lease liabilities, excluding amounts classified as Liabilities subject to compromise	$ 5,088	$ 1,386

The following table provides the weighted average remaining lease term and weighted average discount rates for our leases as of December 31, 2023 and December 31, 2022:

	December 31, 2023	December 31, 2022
Weighted average remaining lease term (years), weighted based on lease liability balances:		
Operating leases	4.7 years	4.9 years
Finance leases	13.4 years	9.9 years
Weighted average discount rate (percentages), weighted based on the remaining balance of lease payments:		
Operating leases	6.2 %	6.1 %
Finance leases	7.3 %	7.5 %

The following table provides certain cash flow and supplemental noncash information related to our lease liabilities for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash payments for operating leases	$ 10,476	$ 13,152	$ 14,478
Operating cash payments for finance leases	$ 1,148	$ 1,673	$ 2,256
Financing cash payments for finance leases	$ 6,733	$ 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. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net consists of the following at December 31, 2023 and December 31, 2022 (in thousands):

	December 31, 2023	December 31, 2022
Land and buildings	$ 243,679	$ 239,207
Machinery and equipment	251,895	241,930
Leasehold improvements	41,074	54,388
Computer equipment and software	97,782	92,566
Furniture and fixtures	8,595	9,129
Assets under construction	197,670	142,560
Total property, plant and equipment, gross	$ 840,695	$ 779,780
Less: accumulated depreciation	(364,455)	(341,466)
Total property, plant and equipment, net	$ 476,240	$ 438,314

Depreciation expense was $50.5 million, $54.3 million and $84.2 million for the years ended December 31, 2023, 2022 and 2021, respectively. During the years ended December 31, 2023, 2022 and 2021, the Company recorded property, plant and equipment impairment charges totaling $0.5 million, $9.0 million and $2.0 million, respectively. These charges are included in the Asset impairment charges line item in our Consolidated Statements of Operations and primarily reflect the write-off of certain property, plant and equipment.

At December 31, 2023 and December 31, 2022, $226.0 million and $205.2 million of the Company's Property, plant and equipment, net, representing net book amounts, were located in India. At December 31, 2023 and December 31, 2022, there were no other material tangible long-lived assets located outside of the U.S., individually or in the aggregate.

NOTE 11. GOODWILL AND OTHER INTANGIBLES

Goodwill

Changes in the carrying amounts of our goodwill for the years ended December 31, 2023 and December 31, 2022 were as follows (in thousands):

	Branded Pharmaceuticals	Sterile Injectables	Generic Pharmaceuticals	International Pharmaceuticals	Total
Goodwill as of December 31, 2021	$ 828,818	$ 2,368,193	$ —	$ —	$ 3,197,011
Goodwill impairment charges	—	(1,845,000)	—	—	(1,845,000)
Goodwill as of December 31, 2022	$ 828,818	$ 523,193	$ —	$ —	$ 1,352,011
Goodwill as of December 31, 2023	$ 828,818	$ 523,193	$ —	$ —	$ 1,352,011

The carrying amounts of goodwill at December 31, 2023 and December 31, 2022 are net of the following accumulated impairments (in thousands):

	Branded Pharmaceuticals	Sterile Injectables	Generic Pharmaceuticals	International Pharmaceuticals	Total
Accumulated impairment losses as of December 31, 2022	$ 855,810	$ 2,208,000	$ 3,142,657	$ 513,211	$ 6,719,678
Accumulated impairment losses as of December 31, 2023	$ 855,810	$ 2,208,000	$ 3,142,657	$ 525,244	$ 6,731,711

Other Intangible Assets

Changes in the amounts of other intangible assets for the year ended December 31, 2023 are set forth in the table below (in thousands).

Cost basis:	Balance as of December 31, 2022	Acquisitions	Other (1)	Effect of Currency Translation	Balance as of December 31, 2023
Licenses (weighted average life of 14 years)	$ 442,107	$ —	$ (10,000)	$ —	$ 432,107
Tradenames	6,409	—	—	—	6,409
Developed technology (weighted average life of 12 years)	5,920,021	—	—	5,641	5,925,662
Total other intangibles (weighted average life of 12 years)	$ 6,368,537	$ —	$ (10,000)	$ 5,641	$ 6,364,178

Accumulated amortization:	Balance as of December 31, 2022	Amortization	Other (1)	Effect of Currency Translation	Balance as of December 31, 2023
Licenses	$ (424,508)	$ (4,576)	$ 10,000	$ —	$ (419,084)
Tradenames	(6,409)	—	—	—	(6,409)
Developed technology	(4,204,685)	(251,357)	—	(4,760)	(4,460,802)
Total other intangibles	$ (4,635,602)	$ (255,933)	$ 10,000	$ (4,760)	$ (4,886,295)
Net other intangibles	$ 1,732,935				$ 1,477,883

(1) Other adjustments relate to the removal of certain fully amortized intangible assets.

Amortization expense for the years ended December 31, 2023, 2022 and 2021 totaled $255.9 million, $337.3 million and $372.9 million, respectively. Amortization expense is included in Cost of revenues in the Consolidated Statements of Operations. For intangible assets subject to amortization, estimated amortization expense for the five fiscal years subsequent to December 31, 2023 is as follows (in thousands):

2024	$ 246,050
2025	$ 232,930
2026	$ 209,784
2027	$ 134,322
2028	$ 112,476

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 Statements of Operations.

Annual Goodwill Impairment Tests

The Company performed its annual goodwill impairment tests as of October 1, 2023, 2022 and 2021. For the purposes of these annual tests, the Company 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 14.5%, 15.0% and 14.5%, respectively, and the discount rates used for the Sterile Injectables reporting units in these annual tests were 14.5%, 19.5% and 11.0%, respectively.

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

We did not record any other goodwill impairment charges as a result of our October 1, 2023, 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 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 anticipated 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 Company 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 Company's projected future cash flows resulting from: (i) the discontinuation of QWO®; (ii) the disruption to XIAFLEX® revenues 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 Company'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 Company'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 most recent 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 did not record an asset impairment charge during the year ended December 31, 2023. 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 AGREEMENTS

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.

Nevakar Agreements

In May 2022, we announced that we 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 Statements of Operations.

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 Company will control all remaining development, regulatory, manufacturing and commercialization activities for the acquired product candidates.

In August 2022, within the ongoing bankruptcy proceedings, the Company 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 the Company. In December 2022, the Company 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 (the Nevakar Amendment) of the 2018 Nevakar Agreement to revoke the Company's license of two products covered by the 2018 Nevakar Agreement, modify the Company's license to the remaining three products covered by the 2018 Nevakar Agreement to reduce the royalty owed to Nevakar, terminate any obligations of the Company to make payments to Nevakar upon achievement of contingent milestones and eliminate Nevakar's ability to terminate the remaining licenses for the Company's breach or material breach. The Nevakar Settlement also provided that the Company 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 Consolidated Financial Statements for the year ended December 31, 2023.

TLC Agreement

In June 2022, we announced that we had entered into an agreement with TLC to commercialize TLC599 (the TLC Agreement). We are accounting for the agreement as an asset acquisition. 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 Statements of Operations. On October 13, 2023, we commenced an adversary proceeding against TLC in the Bankruptcy Court. Due to the commercially sensitive nature of the dispute, the complaint initiating such proceeding has been filed under seal and is not publicly available. In February 2024, the parties to the adversary proceeding have informed the Bankruptcy Court that they are finalizing a settlement and expect to file a motion related to that settlement in the near future. As of the date of this report no motion has been filed.

NOTE 13. CONTRACT ASSETS AND LIABILITIES

Our revenue consists almost entirely of sales of our products to customers, whereby we ship products to a customer pursuant to a purchase order. Revenue contracts such as these do not generally give rise to contract assets or contract liabilities because: (i) the underlying contracts generally have only a single performance obligation and (ii) we do not generally receive consideration until the performance obligation is fully satisfied. At December 31, 2023, the unfulfilled performance obligations for these types of contracts relate to ordered but undelivered products. We generally expect to fulfill the performance obligations and recognize revenue within one week of entering into the underlying contract. Based on the short-term initial contract duration, additional disclosure about the remaining performance obligations is not required.

Certain of our other 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, 2023	December 31, 2022	$ Change	% Change
Contract assets (1)	$ 11,387	$ 8,193	$ 3,194	39 %
Contract liabilities (2)	$ 3,534	$ 4,099	$ (565)	(14)%

(1) At December 31, 2023 and December 31, 2022, approximately $2.1 million and $1.5 million, respectively, of these contract asset amounts are classified as current and are included in Prepaid expenses and other current assets in the Company's Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other assets.

(2) At both December 31, 2023 and December 31, 2022, approximately $0.6 million of these contract liability amounts are classified as current and are included in Accounts payable and accrued expenses in the Company's Consolidated Balance Sheets. The remaining amounts are classified as noncurrent and are included in Other liabilities. During the year ended December 31, 2023, approximately $0.6 million of revenue was recognized that was included in the contract liability balance at December 31, 2022.

During the year ended December 31, 2023, we recognized revenue of $20.3 million relating to performance obligations satisfied, or partially satisfied, in prior periods. Such revenue generally relates to changes in estimates with respect to our variable consideration.

NOTE 14. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses included the following at December 31, 2023 and December 31, 2022 (in thousands):

	December 31, 2023	December 31, 2022
Trade accounts payable	$ 94,735	$ 109,033
Returns and allowances	119,577	160,619
Rebates	105,428	167,516
Other sales deductions	3,212	7,116
Accrued payroll and related benefits	81,145	95,666
Accrued royalties and other distribution partner payables	35,856	24,072
Other (1)	97,783	123,161
Total	$ 537,736	$ 687,183

(1) Amounts include a wide variety of accrued expenses, the most significant of which relate to accrued legal and other professional fees.

The decrease in the Returns and allowances, Rebates and Other sales deductions accruals are primarily due to changes in gross sales and customer mix, as well as other factors. The decrease in the Other accrued expense category, inclusive of accrued legal and other professional fee accruals, is primarily a result of timing of payments. Refer to Note 2. Bankruptcy Proceedings for additional information about certain professional fees recognized during our bankruptcy proceedings.

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.

NOTE 15. DEBT

The following table presents information about the Company's total indebtedness at December 31, 2023 and December 31, 2022 (dollars in thousands):

	December 31, 2023			December 31, 2022		
	Effective Interest Rate (1)	Principal Amount (2)	Carrying Amount (2)	Effective Interest Rate (1)	Principal Amount (2)	Carrying Amount (2)
5.375% Senior Notes due 2023	5.38 %	$ 6,127	$ 6,127	5.38 %	$ 6,127	$ 6,127
6.00% Senior Notes due 2023	6.00 %	56,436	56,436	6.00 %	56,436	56,436
5.875% Senior Secured Notes due 2024	6.88 %	300,000	300,000	6.88 %	300,000	286,375
6.00% Senior Notes due 2025	6.00 %	21,578	21,578	6.00 %	21,578	21,578
7.50% Senior Secured Notes due 2027	8.50 %	2,015,479	2,015,479	8.50 %	2,015,479	1,894,774
9.50% Senior Secured Second Lien Notes due 2027	9.50 %	940,590	940,590	9.50 %	940,590	940,590
6.00% Senior Notes due 2028	6.00 %	1,260,416	1,260,416	6.00 %	1,260,416	1,260,416
6.125% Senior Secured Notes due 2029	7.13 %	1,295,000	1,295,000	7.13 %	1,295,000	1,230,799
Term Loan Facility	14.50 %	1,975,000	1,975,000	13.50 %	1,975,000	1,871,894
Revolving Credit Facility	12.00 %	277,200	277,200	11.00 %	277,200	265,728
Total (3)		$ 8,147,826	$ 8,147,826		$ 8,147,826	$ 7,834,717

(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, 2023 and December 31, 2022 "effective interest rates" included in the table above represent the rates in effect on such dates 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, if applicable.

(2) The December 31, 2023 and 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 Statements of Operations) $89.2 million of previously deferred and unamortized costs associated with these instruments. The December 31, 2023 carrying amounts of our First Lien Debt Instruments are further discussed below. The December 31, 2022 carrying amounts of our First Lien Debt Instruments reflect reductions for certain adequate protection payments made since the Petition Date.

(3) As of December 31, 2023 and 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.

General Information

The Company and its subsidiaries, with certain customary exceptions, guarantee or serve as issuers or borrowers of the debt instruments representing substantially all of the Company's indebtedness at December 31, 2023. 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 Company's long-term debt, which was determined based on Level 2 quoted market price inputs for the same or similar debt issuances, was $4.1 billion and $4.9 billion at December 31, 2023 and December 31, 2022, respectively.

Credit Facilities

The Company and certain of its subsidiaries are party to the Credit Agreement (as amended from time to time, the Credit Agreement), which provides 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, 2023 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 Company's borrowings under the Revolving Credit Facility outstanding at December 31, 2023, $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 Company's Total Net Leverage Ratio plus the Adjusted LIBO Rate (as defined in the Credit Agreement) or (ii) an applicable margin between 0.50% and 2.00% depending on the Company's Total Net Leverage Ratio plus the Alternate Base Rate (as defined in the Credit Agreement). In addition, borrowings under our Term Loan Facility bear interest, at the borrower's election, at a rate per annum equal to: (i) 5.00% plus the Adjusted LIBO Rate, subject to a 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 Credit Agreement includes provisions for a transition to an alternative benchmark rate other than LIBOR, which would have been effective upon notification from the applicable administrative agent. As a result of the ongoing Chapter 11 Cases, discussed in more detail below, the Company is not currently making scheduled interest payments under the Credit Agreement and therefore no notification was received, or required, from the administrative agent regarding the shift of the benchmark rate.

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 terms of the various senior notes and senior secured notes outstanding as of December 31, 2023 include maturities 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 amended 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 Company 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, 2023 and December 31, 2022, and we ceased the recognition of interest expense related to these instruments as of the Petition Date. During the years ended December 31, 2023 and 2022, we did not recognize approximately $638 million and $231 million, respectively, 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 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.

Pursuant to the Cash Collateral Order that is further discussed in Note 2. Bankruptcy Proceedings, we are, among other things, 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, 2023, we made the following adequate protection payments pursuant to the Cash Collateral Order:

- $43.5 million with respect to the Revolving Credit Facility;
- $379.7 million with respect to the Term Loan Facility; and
- $482.7 million with respect to the applicable senior secured notes.

Adequate protection payments have generally been 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 which creates uncertainties surrounding the holders of First Lien Debt Instruments ability to recover, in full, the amount of outstanding principal associated with those instruments. Accordingly, from the Petition Date and through the third quarter of 2023, the carrying amounts of the respective First Lien Debt Instruments were reduced by the amount of adequate protection payments made. In December 2023, the Plan and related disclosure statement were filed with the Bankruptcy Court, which included for the first time, among other things, the estimated allowed claims with respect to outstanding debt obligations. As a result, we adjusted the carrying amount of all unsecured and potentially undersecured debt obligations at December 31, 2023 to equal the expected amount of the allowed claim as detailed in the Plan, resulting in an adjustment of approximately $905.9 million to Liabilities subject to compromise and a corresponding expense recognized within Reorganization items, net in the Consolidated Statements of Operations. As further discussed in Note 2. Bankruptcy Proceedings, on January 12, 2024, the Bankruptcy Court entered an order conditionally approving our disclosure statement. Certain of the adequate protection payments may later be characterized 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, 2023, 2022 and 2021.

March 2021 Refinancing

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

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

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

The $2,000.0 million portion of the Term Loan Refinancing associated with the new term loan was accounted for as a debt modification, while the $1,295.0 million portion associated with the new notes issued was accounted for as an extinguishment. During the first quarter of 2021, in connection with the Term Loan Refinancing, $7.8 million of deferred and unamortized costs associated with the Existing Term Loans, representing the portion associated with the extinguishment, was charged to expense and is included in the Loss on extinguishment of debt line item in the Consolidated Statements of Operations. The Company also incurred an additional $56.7 million of new costs and fees, of which: (i) $29.2 million and $17.6 million 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 Statements of Operations; and (iii) $3.9 million was considered debt modification costs and was charged to expense in the first quarter of 2021 and is included in the Selling, general and administrative expense line item in the Consolidated Statements of Operations. 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 Statements of Operations.

During the first quarter of 2021, the Company also incurred $2.1 million of new costs and fees associated with the extension of the Revolving Credit Facility, which were initially deferred to be amortized as interest expense over the new term of the Revolving Credit Facility. 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 Statements of Operations.

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

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

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, 2023, for each of the five fiscal years subsequent to December 31, 2023, the stated maturities on our long-term debt that would have been applicable if not for such acceleration (in thousands):

	Maturities (1)
2024 (2)	$ 394,600
2025	$ 41,578
2026 (2)	$ 222,600
2027	$ 2,976,069
2028	$ 3,125,416

(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 Company's borrowings under the Revolving Credit Facility that were outstanding at December 31, 2023, $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 $30.0 million of principal outstanding on our Term Loan Facility that, pursuant to the terms of the Credit Agreement, matured on or before December 31, 2023 but has not yet been paid as a result of the Chapter 11 Cases. Additionally, the table above excludes $62.6 million of principal outstanding on our 5.375% Senior Notes due 2023 and 6.00% Senior Notes due 2023 that matured on or before December 31, 2023 but has not yet been paid as a result of the Chapter 11 Cases.

NOTE 16. COMMITMENTS AND CONTINGENCIES

Manufacturing, Supply and Other Service Agreements

Our subsidiaries contract with various third-party manufacturers, suppliers and service providers to provide raw materials used in our subsidiaries' products and semi-finished and finished goods, as well as certain packaging, labeling services, customer service support, warehouse and distribution services. If, for any reason, we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products or services needed to conduct our business, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition to the manufacturing and supply agreements described above, we have agreements with various companies for clinical development and certain other services. Although we have no reason to believe that the parties to these agreements will not meet their obligations, failure by any of these third parties to honor their contractual obligations may have a material adverse effect on our business, financial condition, results of operations and cash flows.

U.S. Government Cooperative Agreement

In November 2021, we entered into a cooperative agreement with the U.S. Department of Defense (DoD), pursuant to an interagency agreement with the U.S. Department of Health and Human Service (HHS) whereby the DoD provided contracting support to HHS during the COVID-19 pandemic. The cooperative agreement with the DoD concluded in the third quarter of 2023 and a new

cooperative agreement with HHS, containing substantially the same terms, was simultaneously executed. The purpose of the original cooperative agreement with the DoD, and subsequently the cooperative agreement with HHS, is 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 Cooperative Agreement). The U.S. Government Cooperative 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 Cooperative 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 Company 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 years ended December 31, 2023 and December 31, 2022, we incurred costs of approximately $52.9 million and $39.0 million, respectively, associated with the U.S. Government Cooperative Agreement. The following table summarizes certain information about the activity under the U.S. Government Cooperative Agreement at December 31, 2023 and December 31, 2022 (dollars in thousands):

	Year Ended December 31,	
	2023	2022
Cumulative grant proceeds received to reimburse asset construction	$ 58,032	$ 18,635
Capex reimbursement receivable, included in Accounts receivable, net	5,514	7,856
Cumulative amounts applied against assets placed in service (1)	(18,922)	—
Total deferred grant income (2)	$ 44,624	$ 26,491
Assets under construction, gross	$ 58,359	$ 34,950
Assets placed in service, gross	24,898	—
Endo's portion of costs included in Property, plant and equipment, net	(19,711)	(8,459)
Cumulative amounts applied against assets placed in service (1)	(18,922)	—
Total deferred grant income (2)	$ 44,624	$ 26,491

(1) During 2023, a portion of the facility constructed under the U.S. Government Cooperative Agreement was placed into service. Consistent with our policy election, discussed in Note 3. Summary of Significant Accounting Policies, we have deducted the corresponding grant reimbursement from Property, plant and equipment, net when the asset was placed in service.

(2) At December 31, 2023 and 2022, this amount, representing the reimbursable portion of costs included in assets under construction is included in Other liabilities in our Consolidated Balance Sheets.

Approximately $1.3 million and $1.0 million has been charged to expense, including depreciation for assets placed into service, during the years ended December 31, 2023 and 2022, respectively, with the majority of such expense included within Selling, general and administrative expenses and Cost of revenues in our Consolidated Statements of Operations. During the years ended December 31, 2023 and 2022, these amounts are net of approximately $4.1 million and $3.1 million, respectively, 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 estimate that approximately three-quarters 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, 2023. We 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 Cooperative 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 Cooperative 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 Cooperative 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 with the UCC.

As of December 31, 2023, our accrual for loss contingencies totaled $2,431.5 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, 2023, our entire accrual for loss contingencies is classified as Liabilities subject to compromise in the Consolidated Balance Sheets and recorded at the expected allowed claim amount, even if they may ultimately be settled for different amounts. 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 surgical mesh products, 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 POP and SUI. We have not sold such products since March 2016. Plaintiffs claim a variety of personal injuries, including chronic pain, incontinence, inability to control bowel function and permanent deformities, and seek compensatory and punitive damages, where available.

At various times from June 2013 through the Petition Date, the Company 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, 2023 (in thousands):

	Mesh Qualified Settlement Funds	Mesh Liability Accrual (1)
Balance as of December 31, 2022	$ 50,339	$ 222,972
Additional charges	—	495
Cash distributions to settle disputes from Qualified Settlement Funds	(2,279)	(2,279)
Other (2)	1,404	1,404
Balance as of December 31, 2023	$ 49,464	$ 222,592

(1) As of December 31, 2023 and December 31, 2022, the entire accrual is classified as Liabilities subject to compromise in the Consolidated Balance Sheets.

(2) 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.

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

As of December 31, 2023, the Company has made total cumulative mesh liability payments of approximately $3.6 billion, $49.5 million of which remains in the QSFs as of December 31, 2023. 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 and cash equivalents.

In June 2023, the Company 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). In July 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 Company does not have a reversionary interest, as scheduled in the QSF Motion, and authorizing the Company to request the return of the QSF funds for the mesh claimants who did not object to the QSF Motion. Objecting mesh claimants have until March 14, 2024 to file a formal objection to the QSF Motion, unless otherwise agreed by the Company and such claimants and approved by the Bankruptcy Court. Any such objections are currently scheduled to be heard by the Bankruptcy Court on March 21, 2024.

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 with the UCC contemplates the creation and funding 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 mesh claimants. Additionally, on April 13, 2023, the Purchaser and the FCR filed a resolution with the Bankruptcy Court that contemplates that the Future PI Trust will allocate an aggregate amount of $0.5 million to eligible 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 Plan is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed sale transaction to the Purchaser contemplated by the Plan, or the establishment and funding of the trusts contemplated under the Plan, 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 Company 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 EHSI, EPI, PPI, PPCI, Endo Generics Holdings, Inc. (EGHI), Vintage Pharmaceuticals, LLC, Generics Bidco I, LLC, DAVA Pharmaceuticals, LLC, PSP LLC and in Canada, Paladin and 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 February 28, 2024, 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 Company 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 August 2023, the Bankruptcy Court extended the preliminary injunction by a further 180 days. 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 Company'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 Company 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 Plan provides for the establishment by the Debtors of opioid trusts, and other forms of funding, 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 be funded over a period of ten years (subject to prepayment mechanics), with up to a total of approximately $613 million to be distributed to eligible claimants, and the opioid school district recovery trust would be funded, over a period of two years, with up to $3 million to be distributed to public school districts that elect to participate in such initiative. 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. As previously noted, the Plan is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed transactions contemplated by the Plan to the Purchaser, and the funding of the opioid trusts and the opioid school district recovery trust (including the trusts for certain future opioid claimants), will actually occur.

Although the proposed opioid trusts and opioid school district recovery trust were initially contemplated to be funded by the Purchaser in connection with the standalone Sale, and not by the Company or any of its subsidiaries, we previously concluded that these proposed funding amounts, which are now reflected in the Plan, represent the Company's best estimate of the allowed claims related to the contingencies associated with various opioid claims against the Company 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 Purchaser) 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 on Form 10-K for the year ended December 31, 2022; 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 Report on Form 10-K for the year ended December 31, 2022. 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. On July 13, 2023, the Purchaser 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 in the second quarter of 2023 to increase our aggregate opioid liability to approximately $611 million. In August 2023, the Purchaser and the Public School District Creditors filed with the Bankruptcy Court a term sheet for a proposed resolution among such parties. 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 an opioid school district recovery trust up to $3 million for the purpose of funding opioid abuse/misuse abatement or remediation programs to be implemented by the Public School District Creditors. In September 2023, the Purchaser and the Canadian Provinces filed with the Bankruptcy Court a term sheet for a proposed resolution among such parties. 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 voluntary trust of approximately $7 million to be established for the benefit of the Canadian Provinces. Accordingly, we recorded an additional charge of approximately $10 million in the third quarter of 2023 to increase our aggregate opioid liability to approximately $621 million. In December 2023, in connection with the Plan, state opioid claimants agreed to decrease the gross amount of the initial public opioid trust settlement by approximately $5 million in exchange for certain prepayment rights. In February 2024, the resolutions reached with the DOJ with respect to claims filed in the Chapter 11 Cases by the U.S. Government provides that the U.S. Government will have in connection with its opioid-related criminal and civil investigations of certain of the Debtors: (i) an allowed, general unsecured claim in the amount of $1,086 million in connection with a criminal fine arising from a plea agreement entered into by EHSI and; (ii) an allowed, general unsecured claim in the amount of approximately $476 million in connection with a civil settlement agreement entered into by EHSI. Accordingly, we recorded an additional charge of approximately $1,557 million in the fourth quarter of 2023 to increase our aggregate opioid liability to approximately $2,178 million. These liabilities represent the Company's best estimate of the allowed claims related to the contingencies associated with various opioid claims against the Company and its subsidiaries.

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

- Various state attorneys general have served subpoenas and/or CIDs on EHSI and/or EPI. Some of these state attorneys general subsequently filed lawsuits against the Company 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 (S.D. Florida) seeking documents and information related to OPANA® ER, other oxymorphone products and marketing of opioid medications. S.D. Florida's investigation is contemplated to be resolved in accordance with Endo's resolution with the DOJ.

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

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

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.

In May 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. To facilitate entry of these final judgments notwithstanding the automatic stay applicable to PPI, the MDL court entered orders severing PPI in thousands of pending cases on September 26, 2023.

At various times, certain MDL plaintiffs appealed the MDL court's various orders and judgments. These appeals generally remain pending with briefing expected in 2024, although PPI has been dismissed from certain of them and the Eleventh Circuit has stayed any appeals as to PPI due to the PPI bankruptcy.

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 with the UCC contemplates the creation and funding 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 Plan is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed transactions contemplated by the Plan, 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 Company, Generics Bidco I, LLC, DAVA Pharmaceuticals, LLC, DAVA International, LLC, EPI, EHSI and/or PPCI, as well as other pharmaceutical manufacturers and, in some instances, other corporate and/or individual defendants, alleging price-fixing and other anticompetitive conduct with respect to generic pharmaceutical products. These cases, which include proposed class actions filed on behalf of direct purchasers, end-payers and indirect purchaser resellers, as well as non-class action suits, have generally been consolidated and/or coordinated for pretrial proceedings in a federal MDL pending in the U.S. District Court for the Eastern District of Pennsylvania; 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 Company 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 an FCA 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 with the UCC contemplates the creation and funding 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 Plan is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed transactions contemplated by the Plan, 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 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 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 USA Inc., 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 Pharmaceuticals USA Inc. 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 named PPI as a defendant. In September 2023, the court entered an order dismissing the case.

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 dismissal was affirmed on appeal in September 2023.

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 with UCC contemplates the creation and funding 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 Plan is subject to the approval of the Bankruptcy Court and therefore there is no guarantee that the proposed sale transaction to the Purchaser contemplated by the Plan, 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 Company, 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 Company 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

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 FFDCA 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. On October 4, 2023, PSP LLC, PPI and EPIC filed a motion for a preliminary injunction/temporary restraining order after the FDA approved Baxter's NDA in late September 2023. The preliminary injunction hearing was held on October 27, 2023. On November 3, 2023, the magistrate judge issued a report and recommendation recommending the court: (i) deny the motion for preliminary injunction/temporary restraining order; and (ii) deny Baxter's motion for judgment on the pleadings. The District Court has not yet entered its final order.

In September 2023, PSP LLC, PPI and EPIC received a notice letter from Long Grove Pharmaceuticals, LLC (Long Grove) pursuant to 505(b)(3)(B)-(D) of the FFDCA of its NDA submitted under 21 U.S.C. §355(b)(2) seeking FDA approval for vasopressin injection products in 20 units/100 ml, 40 units/100 ml, and 50 units/50ml strengths. In December 2023, PSP LLC, PPI and EPIC filed a complaint against Long Grove in the U.S. District Court for the District of Delaware asserting infringement of two patents. These patents are not listed in the Orange Book; therefore, the patent infringement suit does not trigger a 30-month stay on FDA approval of Long Grove's NDA.

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 17. OTHER COMPREHENSIVE INCOME (LOSS)

During the years ended December 31, 2023, 2022 and 2021 and 2022, there were no tax effects allocated to any component of Other comprehensive income (loss) and there were no reclassifications out of Accumulated other comprehensive loss. Substantially all of the Company's Accumulated other comprehensive loss balances at December 31, 2023 and December 31, 2022 consist of Foreign currency translation loss.

NOTE 18. SHAREHOLDERS' DEFICIT

The Company has issued 4,000,000 euro deferred shares of $0.01 each at par. The euro deferred shares are held by nominees in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro and to have at least seven registered shareholders. The euro deferred shares carry no voting rights and are not entitled to receive any dividend or distribution.

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 19. SHARE-BASED COMPENSATION

Stock Incentive Plans

In June 2015, the Company's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan), which has subsequently been amended, as approved by the Company's shareholders, on multiple occasions. 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.

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.

In March 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.

At December 31, 2023, approximately 21.3 million ordinary shares were reserved for future grants under the 2015 Plan. As of December 31, 2023, 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.

Generally, the grant-date fair value of each award was recognized as expense over the requisite service period. However, expense recognition differed in the case of certain PSUs where the ultimate payout was performance-based. For these awards, at each reporting period, the Company generally estimated the ultimate payout and adjusted the cumulative expense based on its estimate and the percent of the requisite service period that elapsed.

Presented below are the components of total share-based compensation as recorded in our Consolidated Statements of Operations for the years ended December 31, 2023, 2022 and 2021 (in thousands).

	2023	2022	2021
Selling, general and administrative expenses	$ 10,593	$ 16,019	$ 23,400
Research and development expenses	107	1,059	1,378
Cost of revenues	540	1,136	5,268
Total share-based compensation expense	$ 11,240	$ 18,214	$ 30,046

As of December 31, 2023, there is no unrecognized compensation cost related to non-vested share-based compensation awards for which a grant date has been established as of December 31, 2023.

Stock Options

From time to time, the Company granted stock options to its employees as part of their annual share compensation awards and, in certain circumstances, on an ad hoc basis or upon their commencement of service with the Company.

Although we have not granted employee stock options since 2018, previous grants have generally vested ratably, in equal amounts, over a three or four-year service period. As of December 31, 2023, there are no remaining stock options outstanding.

We estimated the fair value of stock option grants at the date of grant using the Black-Scholes option-pricing model. This model utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model were based mainly on the historical volatility of the Company's share price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate was derived from the U.S. Treasury yield curve in effect at the time of grant. We estimated 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, 2023, 2022 and 2021 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	6,916,586	$ 18.11		
Exercised	(82,331)	$ 7.55		
Forfeited	(11,887)	$ 13.19		
Expired	(438,454)	$ 40.76		
Outstanding as of December 31, 2021	6,383,914	$ 16.70		
Expired	(1,304,602)	$ 20.04		
Outstanding as of December 31, 2022	5,079,312	$ 15.84		
Forfeited (1)	(2,854,056)	$ 14.73		
Expired	(2,225,256)	$ 17.27		
Outstanding as of December 31, 2023 (1)	—	$ —	—	$ —
Vested and expected to vest as of December 31, 2023 (1)	—	$ —	—	$ —
Exercisable as of December 31, 2023 (1)	—	$ —	—	$ —

(1) In March 2023, the Bankruptcy Court entered orders authorizing the Company to reject outstanding stock option agreements, restricted stock award agreements and performance award agreements.

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 Company granted RSUs and PSUs to its employees as part of their annual share compensation awards and, in certain circumstances, on an ad hoc basis or upon their commencement of service with the Company.

As of December 31, 2023, there are no unvested RSUs or PSUs. Previous 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 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 2023 or 2022. PSUs awarded in 2021 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 were valued based on the closing price of Endo's ordinary shares on the date of grant. PSUs with TSR conditions were valued using a Monte-Carlo variant valuation model, while those with FCF conditions were 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, 2023, 2022 and 2021 is presented below:

	Number of Shares	Aggregate Intrinsic Value
Non-vested as of December 31, 2020	10,340,279	
Granted	4,483,385	
Forfeited	(1,302,292)	
Vested	(5,380,262)	
Non-vested as of December 31, 2021	8,141,110	
Granted	280,373	
Forfeited	(1,116,960)	
Vested	(2,324,696)	
Non-vested as of December 31, 2022	4,979,827	
Forfeited (1)	(4,960,249)	
Vested	(19,578)	
Non-vested as of December 31, 2023 (1)	—	$ —
Vested and expected to vest as of December 31, 2023 (1)	—	$ —

(1) In March 2023, the Bankruptcy Court entered orders authorizing the Company to reject outstanding stock option agreements, restricted stock award agreements and performance award agreements. In connection with the rejection of these agreements, the Company recognized the remaining unrecognized compensation cost associated with these agreements in 2023.

As of December 31, 2023, there was no weighted average remaining requisite service period of the units presented in the table above or remaining unrecognized compensation costs.

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 20. OTHER INCOME, NET

The components of Other income, net for the years ended December 31, 2023, 2022 and 2021 are as follows (in thousands):

	2023	2022	2021
Net gain on sale of business and other assets (1)	$ (10,392)	$ (26,183)	$ (4,516)
Foreign currency loss (gain), net (2)	1,779	(2,087)	1,253
Net (gain) loss from our investments in the equity of other companies (3)	(199)	378	453
Other miscellaneous, net (4)	(876)	(6,162)	(16,964)
Other income, net	$ (9,688)	$ (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 Company's foreign currency denominated assets and liabilities.
(3) Amounts relate to the income statement impacts of our investments in the equity of other companies, including investments accounted for under the equity method.
(4) Amounts in 2021 include gains of $15.5 million associated with the termination of certain contracts.

NOTE 21. INCOME TAXES

Loss from Continuing Operations before Income Tax

Our operations are conducted through our various subsidiaries in numerous jurisdictions throughout the world. We have provided for income taxes based upon the tax laws and rates in the jurisdictions in which our operations are conducted.

The components of our Loss from continuing operations before income tax by geography for the years ended December 31, 2023, 2022 and 2021 are as follows (in thousands):

	2023	2022	2021
U.S.	$ (1,609,064)	$ (2,429,315)	$ 4,792,852
International	(782,860)	(458,787)	(5,339,455)
Total loss from continuing operations before income tax	$ (2,391,924)	$ (2,888,102)	$ (546,603)

Income tax from continuing operations consists of the following for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Current:			
U.S. Federal	$ 44,304	$ 21,057	$ 13,649
U.S. State	2,900	1,731	1,491
International	3,956	6,031	10,495
Total current income tax	$ 51,160	$ 28,819	$ 25,635
Deferred:			
U.S. Federal	$ 5,126	$ (622)	$ 118
U.S. State	451	1,065	(564)
International	(875)	(7,746)	(2,711)
Total deferred income tax	$ 4,702	$ (7,303)	$ (3,157)
Total income tax	$ 55,862	$ 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, 2023, 2022 and 2021 is as follows (in thousands):

	2023	2022	2021
Notional U.S. federal income tax provision at the statutory rate	$ (502,304)	$ (606,502)	$ (114,787)
State income tax, net of federal benefit	3,283	(9,517)	6,750
Uncertain tax positions	32,191	21,930	42,415
Residual tax on non-U.S. net earnings	(610,200)	(32,257)	(181,739)
Non-deductible goodwill impairment	—	385,459	76,230
Change in valuation allowance	6,449,891	306,497	495,565
Non-deductible expenses	109,629	47,221	25,679
Executive compensation limitation	7,254	5,580	6,215
Equity based compensation	4,522	3,247	2,695
Financing activities (1)	(3,035,598)	73,629	(287,012)
Investment activities (2)	(2,681,806)	(178,018)	(68,943)
Non-deductible legal settlement	279,216	—	14,112
Other	(216)	4,247	5,298
Income tax	$ 55,862	$ 21,516	$ 22,478

(1) The amount in 2023 primarily relates to tax deductible losses associated with receivables in consolidated subsidiaries. The tax benefit is fully offset by an increase to the valuation allowance. The 2022 amount primarily relates to nondeductible foreign currency gains and losses on intercompany debt.

(2) The amounts in 2023 and 2022 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 2023 compared to 2022, and the change in 2022 income tax expense compared to 2021, primarily relates to an increase in accrued interest on uncertain tax positions and changes in the geographic mix of pre-tax earnings.

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, 2023 and 2022 are as follows (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Accrued expenses and reserves	$ 274,424	$ 220,415
Deferred interest deduction	492,394	421,552
Fixed assets, intangible assets and deferred amortization	549,715	560,257
Loss on capital assets	4,755	23,511
Net operating loss carryforward	15,478,840	9,214,688
Other	59,145	49,943
Research and development and other tax credit carryforwards	7,402	7,777
Total gross deferred income tax assets	$ 16,866,675	$ 10,498,143
Deferred tax liabilities:		
Other	$ (9,148)	$ (3,156)
Investments	(136)	(107)
Intercompany notes	—	(72,286)
Total gross deferred income tax liabilities	$ (9,284)	$ (75,549)
Valuation allowance	(16,873,639)	(10,436,419)
Net deferred income tax liability	$ (16,248)	$ (13,825)

As of December 31, 2023, the Company had significant deferred tax assets for tax credits, net operating and capital loss carryforwards, net of unrecognized tax positions, as presented below (in thousands):

Jurisdiction	Amount	Begin to Expire
Ireland	$ 85,816	Indefinite
Luxembourg	$ 15,201,302	2034
U.S.:		
Federal-ordinary losses	$ 21,132	2037
Federal-capital losses	$ 4,010	2024
Federal-tax credits	$ 9,768	2024
State-ordinary losses	$ 210,249	2024
State-capital losses	$ 392	2024
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 Company assesses the available positive and negative evidence to estimate whether the existing deferred tax assets will be realized.

The Company has recorded a valuation allowance against certain jurisdictional NOL carryforwards and other tax attributes. As of December 31, 2023 and 2022, the total valuation allowance was $16,873.6 million and $10,436.4 million, respectively. During the years ended December 31, 2023 and 2022, the Company increased its valuation allowance by $6.4 billion and $267.1 million, respectively, which was primarily driven by taxable losses in Luxembourg related to investments and financing activities in consolidated subsidiaries. As previously disclosed, the Company 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 Company 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 Company's net deferred tax assets was recorded in various jurisdictions during the second quarter of 2022.

As of December 31, 2023, the Company had the following significant valuation allowances (in thousands):

Jurisdiction	December 31, 2023
Ireland	$ 330,465
Luxembourg	$ 15,201,530
U.S.	$ 1,328,840

The Company 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, 2023. It is possible that in the future 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, 2023. 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 Company and its subsidiaries are subject to income taxes in the U.S., various states and numerous foreign jurisdictions with varying statutes as to which tax years are subject to examination by the tax authorities. The Company has taken positions on its tax returns that may be challenged by various tax authorities. The Company believes it has appropriately established reserves for tax-related uncertainties. The Company endeavors to resolve matters with a tax authority at the examination level and could reach agreement with a tax authority at any time. The accruals for tax-related uncertainties are based on the Company's best estimate of the potential tax exposures. When particular matters arise, a number of years may elapse before such matters are audited and finally resolved. The final outcome with a tax authority may result in a tax liability that is more or less than that reflected in our financial statements. Favorable resolution of such matters could be recognized as a reduction of the Company's effective tax rate in the year of resolution, while a resolution that is not favorable could increase the effective tax rate and may require the use of cash. Uncertain tax positions are reviewed quarterly and adjusted as necessary when events occur that affect potential tax liabilities, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, identification of new issues and issuance of new legislation, regulations or case law.

As of December 31, 2023, the Company had total UTPs, including accrued interest and penalties, of $680.2 million. If recognized in future years, $295.9 million of such amounts would impact the income tax provision and effective tax rate. As of December 31, 2022, the Company had total UTPs, including accrued interest and penalties, of $646.4 million. If recognized in future years, $251.4 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, 2023, 2022 and 2021 (in thousands):

	Unrecognized Tax Positions Federal, State and Foreign Tax
UTP Balance at December 31, 2020	$ 529,775
Gross additions for current year positions	36,662
Gross reductions for prior period positions	(702)
Gross additions for prior period positions	1,203
Decrease due to lapse of statute of limitations	(475)
Currency translation adjustment	(24)
UTP Balance at December 31, 2021	$ 566,439
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
Gross additions for current year positions	12,457
Decrease due to lapse of statute of limitations	(186)
Currency translation adjustment	(199)
UTP Balance at December 31, 2023	$ 591,702
Accrued interest and penalties	88,463
Total UTP balance including accrued interest and penalties	$ 680,165

The Company records accrued interest and penalties, where applicable, related to uncertain tax positions as part of the provision for income taxes. The cumulative accrued interest and penalties related to uncertain tax positions were $88.5 million and $66.7 million as of December 31, 2023 and 2022, respectively.

During the year ended December 31, 2023, the Company recognized net expense of $43.8 million associated with UTPs, primarily related to interest. During the year ended December 31, 2022, the Company recognized net expense of $16.2 million associated with UTPs, primarily related to interest and penalties. During the year ended December 31, 2021, the Company recognized net expense of $10.6 million associated with UTPs, primarily related to interest and penalties. At December 31, 2023 and 2022, the Company'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.

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.

As a result of the U.S. Government Economic Settlement, it is expected that the amount of UTPs will change during the next 12 months, which is expected to have a material impact on our results of operations and 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, 2023, we may be subject to examination in the following major tax jurisdictions:

Jurisdiction	Open Years
Canada	2016 through 2023
India	2012 through 2023
Ireland	2016 through 2023
Luxembourg	2015 through 2023
U.S. - federal, state and local	2006 through 2023

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 asserted 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. The IRS amended its proof of claims on May 30, 2023 and increased the total amount of approximately $20 billion. A number of the amended 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 $4 billion (the IRS's initial net claim amount was approximately $2.6 billion). In general, 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 amended claims and, if necessary, intend to contest any additional tax determined to be owed with respect to the claims.

The IRS's claims and uncertain tax positions related to historical federal income tax positions not specifically challenged by the IRS, as well as certain federal income tax-related claims anticipated to arise during the Chapter 11 Cases and as a result of the consummation of the Plan which is subject to Bankruptcy Court approval, will be resolved in accordance with the U.S. Government Economic Settlement. The claims brought against the Debtors by the IRS will be deemed to be, in part, an allowed, unsubordinated priority claim and, in part, an allowed, unsubordinated general unsecured claim, each in such amount equal to the settlement amounts to be received by the IRS as allocated by the U.S. Government.

NOTE 22. NET LOSS PER SHARE

The following is a reconciliation of the numerator and denominator of basic and diluted net loss per share for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	2023	2022	2021
Numerator:			
Loss from continuing operations	$ (2,447,786)	$ (2,909,618)	$ (569,081)
(Loss) income from discontinued operations, net of tax	(2,021)	(13,487)	(44,164)
Net loss	$ (2,449,807)	$ (2,923,105)	$ (613,245)
Denominator:			
For basic per share data—weighted average shares	235,219	234,840	232,785
Dilutive effect of ordinary share equivalents	—	—	—
For diluted per share data—weighted average shares	235,219	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 income from continuing operations during the period, the dilutive effect of ordinary share equivalents outstanding during the period.

The dilutive effect of ordinary share equivalents, if any, is measured using the treasury stock method.

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 because to do so would have been antidilutive (in thousands):

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

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.

NOTE 23. CONDENSED COMBINED DEBTOR-IN-POSSESSION FINANCIAL INFORMATION

The financial statements included in this Note represent the Condensed Combined Financial Statements of the Debtors only, which include Endo International plc and most of its wholly-owned subsidiaries, except for its Indian subsidiaries and certain subsidiaries associated with the Company's former Astora business. These statements reflect the results of operations, financial position and cash flows of the combined Debtors, including certain amounts and activities between Debtors and Non-Debtor Affiliates of the Company that are eliminated in the Consolidated Financial Statements.

CONDENSED COMBINED BALANCE SHEETS
(Dollars in thousands)

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 735,927	$ 991,901
Restricted cash and cash equivalents	81,806	59,358
Accounts receivable, net	375,613	478,889
Inventories, net	219,230	241,349
Prepaid expenses and other current assets	68,245	111,807
Income taxes receivable	7,715	7,038
Receivables from Non-Debtor Affiliates	100,829	94,608
Total current assets	$ 1,589,365	$ 1,984,950
PROPERTY, PLANT AND EQUIPMENT, NET	250,286	233,114
OPERATING LEASE ASSETS	19,002	23,200
GOODWILL	1,352,011	1,352,011
OTHER INTANGIBLES, NET	1,477,883	1,732,935
INVESTMENTS IN NON-DEBTOR AFFILIATES	48,253	50,001
RECEIVABLES FROM NON-DEBTOR AFFILIATES	258,445	240,002
OTHER ASSETS	134,224	126,494
TOTAL ASSETS	$ 5,129,469	$ 5,742,707
LIABILITIES AND DEFICIT		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 510,697	$ 654,414
Current portion of operating lease liabilities	248	230
Income taxes payable	181	10
Payables to Non-Debtor Affiliates	14,419	20,162
Total current liabilities	$ 525,545	$ 674,816
DEFERRED INCOME TAXES	16,248	13,479
OPERATING LEASE LIABILITIES, LESS CURRENT PORTION	750	994
OTHER LIABILITIES	74,223	37,367
LIABILITIES SUBJECT TO COMPROMISE	11,095,868	9,168,782
TOTAL DEFICIT	(6,583,165)	(4,152,731)
TOTAL LIABILITIES AND DEFICIT	$ 5,129,469	$ 5,742,707

CONDENSED COMBINED STATEMENTS OF OPERATIONS
(Dollars in thousands)

	2023	2022
TOTAL REVENUES, NET	$ 2,011,565	$ 2,321,426
COSTS AND EXPENSES:		
Cost of revenues	954,349	1,106,855
Selling, general and administrative	558,183	764,768
Research and development	124,987	137,851
Acquired in-process research and development	—	68,700
Litigation-related and other contingencies, net	1,611,090	478,722
Asset impairment charges	503	2,137,107
Acquisition-related and integration items, net	1,972	408
Interest (income) expense, net	(11,660)	345,593
Reorganization items, net	1,169,961	202,978
Other income, net	(9,330)	(13,409)
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX	$ (2,388,490)	$ (2,908,147)
INCOME TAX EXPENSE	52,521	17,721
LOSS FROM CONTINUING OPERATIONS	$ (2,441,011)	$ (2,925,868)
DISCONTINUED OPERATIONS, NET OF TAX	(2,021)	(13,468)
NET LOSS ATTRIBUTABLE TO DEBTOR ENTITIES	$ (2,443,032)	$ (2,939,336)
EQUITY IN LOSS OF NON-DEBTOR AFFILIATES, NET OF TAX	(1,822)	22,671
NET LOSS	$ (2,444,854)	$ (2,916,665)

CONDENSED COMBINED STATEMENTS OF COMPREHENSIVE LOSS
(Dollars in thousands)

	2023	2022
NET LOSS	$ (2,444,854)	$ (2,916,665)
OTHER COMPREHENSIVE INCOME (LOSS):		
Net unrealized gain (loss) on foreign currency	$ 3,179	$ (10,496)
Total other comprehensive income (loss)	$ 3,179	$ (10,496)
COMPREHENSIVE LOSS	$ (2,441,675)	$ (2,927,161)

CONDENSED COMBINED STATEMENTS OF CASH FLOWS
(Dollars in thousands)

	2023	2022
OPERATING ACTIVITIES:		
Net cash provided by operating activities (1)	$ 416,541	$ 209,523
INVESTING ACTIVITIES:		
Capital expenditures, excluding capitalized interest	(67,149)	(43,743)
Capitalized interest payments	—	(3,140)
Proceeds from the U.S. Government Cooperative Agreement	39,397	18,635
Acquisitions, including in-process research and development, net of cash and restricted cash acquired	—	(90,320)
Proceeds from sale of business and other assets	5,134	41,400
Proceeds from loans made to Non-Debtor Affiliates	1,572	2,355
Disbursements for loans made to Non-Debtor Affiliates	(25,243)	(51,486)
Net cash used in investing activities	$ (46,289)	$ (126,299)
FINANCING ACTIVITIES:		
Repayments of notes	—	(180,342)
Repayments of term loans	—	(10,000)
Adequate protection payments	(592,759)	(313,109)
Repayments of other indebtedness	(6,733)	(6,062)
Payments for contingent consideration	(5,136)	(2,462)
Payments of tax withholding for restricted shares	—	(1,898)
Net cash used in financing activities	$ (604,628)	$ (513,873)
Effect of foreign exchange rate	850	(1,790)
NET DECREASE IN CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS	$ (233,526)	$ (432,439)
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, BEGINNING OF PERIOD	1,136,259	1,568,698
CASH, CASH EQUIVALENTS, RESTRICTED CASH AND RESTRICTED CASH EQUIVALENTS, END OF PERIOD	$ 902,733	$ 1,136,259

(1) The difference between the amount of Net cash provided by operating activities included in the table above and the amount of Net cash provided by operating activities included in the Consolidated Statements of Cash Flows for the same period primarily relates to the fact that the table above: (i) excludes the operating cash flows of our Non-Debtor Affiliates, which are included in the Consolidated Statements of Cash Flows, and (ii) includes the effects of the operating cash flows of the Debtors with the Non-Debtor Affiliates, which are eliminated in the Consolidated Statements of Cash Flows.

NOTE 24. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS

Savings and Investment Plan

The Company maintains a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all U.S.-based eligible employees. The Company matches 100% of the first 3% of eligible cash compensation that a participant contributes to the Endo 401(k) Plan plus 50% of the next 2% for a total of up to 4%, subject to statutory limitations. The Company's matching contributions generally vest ratably over a two-year period.

Costs incurred for contributions made by the Company to the Endo 401(k) Plan amounted to $5.7 million, $6.5 million and $7.6 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Exhibit 10.38

Execution Version

SETTLEMENT AGREEMENT

This SETTLEMENT AGREEMENT ("***Agreement***"), dated February 28, 2024, is entered into by and among (a) the United States of America, acting through the United States Attorney's Office for the Southern District of New York, for and on behalf of (i) the United States Department of Justice Civil Division's Consumer Protection Branch ("***DOJ-CPB***"); (ii) the United States Attorney's Office for the Southern District of Florida ("***SDFL***"); (iii) the United States Department of Justice Civil Division's Fraud Section ("***DOJ-Civil Fraud***"), acting on behalf of the Office of Inspector General of the Department of Health and Human Services ("***OIG-HHS***"), the Defense Health Agency ("***DHA***"), as administrator of the TRICARE program ("***TRICARE***"), the Office of Personnel Management ("***OPM***"), as administrator of the Federal Employees Health Benefits program ("***FEHBP***"), and the United States Department of Veterans Affairs (the "***VA***"); (iv) the Internal Revenue Service ("***IRS***"); (v) the United States Department of Health and Human Services' ("***HHS***") Centers for Medicare and Medicaid Services ("***CMS***") and Indian Health Service ("***IHS***"); and (vi) the VA (collectively, the "***United States***"); (b) Endo, Inc. ("***Purchaser Parent***"); and (c) Endo International plc ("***Endo***" and, together with the United States and Purchaser Parent, the "***Parties***"), as debtor and debtor-in-possession, acting on behalf of itself and its debtor affiliates, including but not limited to all of its U.S. taxpayer entity affiliates, in each case through their authorized representatives.

RECITALS

WHEREAS, Endo is a public limited company organized under the laws of the Republic of Ireland with corporate offices in Malvern, Pennsylvania.

WHEREAS, beginning on August 16, 2022 (such date, the "***Petition Date***"), Endo and certain of its affiliates and subsidiaries (collectively, the "***Debtors***") each commenced voluntary chapter 11 cases (the "***Chapter 11 Cases***") by filing a petition for relief under chapter 11 of title 11 of the United States Code (the "***Bankruptcy Code***") in the United States Bankruptcy Court for the Southern District of New York (the "***Bankruptcy Court***" or, the "***Court***"), Case No. 22-22549 (JLG).

WHEREAS, immediately prior to the commencement of the Chapter 11 Cases, on August 16, 2022, Endo, together with each of its affiliates and subsidiaries, entered into the RSA,[1] pursuant to which the Debtors and the Consenting First Lien Creditors agreed to undertake and support a financial restructuring of the existing claims against, and interests in, the Debtors (the "***Restructuring***").

WHEREAS, on November 23, 2022, the Debtors filed the *Debtors' Motion for an Order (I) Establishing Bidding, Noticing, and Assumption and Assignment Procedures, (II) Approving Certain Transaction Steps, (III) Approving the Sale of Substantially all of the Debtors' Assets and (IV) Granting Related Relief* [Docket No. 728] (the "***Bidding Procedures and Sale Motion***") pursuant to which the Debtors sought Court authority to engage in a comprehensive sale and marketing process (the "***Sale Process***") for substantially all of the assets of the Debtors and their Non-Debtor Affiliates (the "***Sale***"). Consistent with the RSA, the Consenting First Lien Creditors, through a separate entity, agreed to cause such entity to serve as the stalking horse bidder in connection with the Sale Process (the "***Stalking Horse Bidder***").

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[1] Capitalized terms have the meaning ascribed to them in Article I below or in the Approved Plan (defined below), as applicable.

WHEREAS, on April 3, 2023, the Bankruptcy Court entered the *Order (I) Establishing Bidding, Noticing, and Assumption and Assignment Procedures, (II) Approving Certain Transaction Steps, and (III) Granting Related Relief* [Docket No. 1765] (as may be amended from time to time and as entered by the Bankruptcy Court, the "***Bidding Procedures Order***" and, the bidding procedures set forth therein, the "***Bidding Procedures***"), whereby the Sale Process was authorized to commence in accordance with the Bidding Procedures.

WHEREAS, on June 20, 2023, the Debtors filed the *Notice of (I) Debtors' Termination of the Sale and Marketing Process, (II) Naming the Stalking Horse Bidder as the Successful Bidder, and (III) Scheduling of the Accelerated Sale Hearing* [Docket No. 2240] naming the Stalking Horse Bidder as the sole Successful Bidder (as defined in the Bidding Procedures Order) and setting the Sale Objection Deadline (as defined in the Bidding Procedures Order).

WHEREAS, on July 18, 2023, the Sale Objection Deadline, the United States filed the *Objection of the United States of America to the Debtors' Motion for an Order (I) Establishing Bidding, Noticing, and Assumption and Assignment Procedures, (II) Approving Certain Transaction Steps, (III) Approving the Sale of Substantially All of the Debtors' Assets and (IV) Granting Related Relief – and – Memorandum of Law in Support of Motion to Appoint Chapter 11 Trustee* [Docket No. 2460] (the "***USG Objection***") and the Office of the United States Trustee (the "***U.S. Trustee***") filed the *Amended Objection of the United States Trustee to Order Approving the Sale of Substantially All of the Debtors' Assets* [Docket No. 2464] (the "***UST Objection***"), each objecting to the proposed Sale to the Stalking Horse Bidder.

WHEREAS, before the Petition Date, the DOJ-CPB and SDFL commenced a criminal investigation of certain of the Debtors in connection with their marketing, promotion, sale, and manufacturing of Opana ER (the "***Alleged Conduct***"). DOJ-CPB filed proof of claim number 3056 in the Chapter 11 Cases in connection with this investigation (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "***DOJ Criminal Claim***").

WHEREAS, in order to resolve the DOJ Criminal Claim, Debtor Endo Health Solutions Inc. ("***EHSI***"), the DOJ-CPB, and SDFL, on behalf of the United States, have agreed to the form of plea agreement (the "***DOJ Criminal Plea Agreement***") attached hereto as **Exhibit A**, whereby (i) EHSI will agree to plead guilty to a criminal misdemeanor in the United States District Court for the Eastern District of Michigan (the "***Criminal Court***") pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure on the terms and conditions set forth in the DOJ Criminal Plea Agreement; (ii) EHSI will agree to a sentence that includes a criminal fine in the amount of $1,086,000,000.00, for which the United States will receive an Allowed general unsecured Claim in the Chapter 11 Cases, which Claim, for the avoidance of doubt, shall be Allowed (and not subject to reconsideration or subordination) under the Approved Plan and be fully satisfied and released by the Settlement Consideration pursuant to this Agreement, the Approved Plan, and the DOJ Criminal Plea Agreement (the "***Criminal Fine***"); and (iii) EHSI will agree to a sentence that includes a criminal forfeiture judgment on the terms and conditions set forth in the DOJ Criminal Plea Agreement and which shall be satisfied solely in accordance with the terms and conditions set forth in the DOJ Criminal Plea Agreement (the "***Forfeiture***").

WHEREAS, the DOJ-Civil Fraud and SDFL commenced a civil investigation of certain of the Debtors in connection with the Alleged Conduct. DOJ-Civil Fraud filed proof of claim number 3157 on behalf of (a) HHS and its component agency CMS, which administers the Medicare program ("***Medicare***") and is responsible for overseeing the Medicaid program ("***Medicaid***"), (b) OPM, which administers the FEHBP, (c) the DHA, which administers TRICARE, and (d) the VA, in connection with such investigation (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "***DOJ Civil Claim***").

WHEREAS, in order to resolve the DOJ Civil Claim, EHSI, DOJ-Civil Fraud, HHS, OPM, the DHA, and the VA have agreed to the form of a civil settlement agreement (the "***DOJ Civil Settlement Agreement***") attached hereto as **Exhibit B**, whereby the United States will have an Allowed general unsecured Claim in the Chapter 11 Cases in the amount of $475,600,000.00, which Claim, for the avoidance of doubt, shall be Allowed (and not subject to reconsideration or subordination) under the Approved Plan and be fully satisfied and released by the Settlement Consideration pursuant to this Agreement, the Approved Plan, and the DOJ Civil Settlement Agreement.

WHEREAS, (x) HHS filed (i) proof of claim number 2350 on behalf of CMS for claims related to opioid-related items and services provided to Medicare beneficiaries for which certain Debtors are alleged to be responsible under the Medicare Secondary Payer ("***MSP***") statute, 42 U.S.C. § 1395y(b) *et seq.*, and (ii) proof of claim number 3636 on behalf of IHS, pursuant to the Federal Medical Care Recovery Act ("***MCRA***"), 42 U.S.C. § 2651 *et seq.*, to recover charges associated with treating IHS beneficiaries whose medical care is alleged to be a direct result of conduct of certain Debtors, and (y) the VA filed proof of claim number 4186 (amending proof of claim number 707) pursuant to MCRA to recover the reasonable value of medical care and treatment provided to veterans and other VA beneficiaries that are alleged to be a direct result of certain of the Debtors' conduct (collectively and as each may be amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "***Healthcare Agencies Opioid Claims***").

WHEREAS, HHS has also asserted Claims on behalf of CMS under the MSP statute against certain of the Debtors for items and services provided to Medicare beneficiaries related to the transvaginal mesh ("***TVM***") and ranitidine products manufactured and/or sold by such Debtors, their predecessors, or their affiliates. Proof of claim number 2211 was filed in connection with such Claims (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "***HHS TVM Claim***" and, together with the Healthcare Agencies Opioid Claims, the "***Healthcare Agencies Claims***").

WHEREAS, CMS has also asserted claim numbers 2026, 2029, 2045, and 2073 representing (i) potential overpayments under agreements between certain Debtors and CMS to make certain quarterly payments based on rebates for the Medicare Coverage Gap Discount Program and (ii) potential group health plan and workers' compensation plan overpayments under the MSP statute (collectively, the "***Protective CMS Claims***"). The Protective CMS Claims will be addressed elsewhere and are therefore not addressed by this Agreement.

WHEREAS, the IRS has asserted Claims against certain of the Debtors with respect to certain tax returns and federal income taxes related to or allegedly payable in respect of the period before the Petition Date, which Claims relate to ongoing IRS audits of certain Debtors. The proofs of claim listed on the schedule attached hereto as **Exhibit C** were filed in connection with such Claims (collectively with any other proofs of claim filed by or on behalf of the IRS, as each may be amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "***IRS Prepetition Claims***"). On June 14, 2023, the Debtors docketed a *Notice of Filing of Information Relating to Proofs of Claim Filed by the Internal Revenue Service* [Docket No. 2223] (the "***IRS Claims Information Notice***"), which describes the issues that are the subject of the IRS audits (the "***IRS Prepetition Tax Issues***"). In addition, the IRS anticipates that it may have an Administrative Expense Claim against the Debtors that would arise from any federal income taxes that become due between the Petition Date and the Plan Effective Date (including, for the avoidance of doubt, any federal income taxes arising out of or attributable to the consummation of the Approved Plan) (the "***IRS Administrative Expense Claim***" and, together with the IRS Prepetition Claims, the "***IRS Claims***").

WHEREAS, this Agreement refers to the IRS Claims, the DOJ Criminal Claim, the DOJ Civil Claim, and the Healthcare Agencies Claims, collectively—but not the Protective CMS Claims—as the "***USG Claims***."

WHEREAS, the IRS Claims and the Healthcare Agencies Claims are fully and finally satisfied and released by the Settlement Consideration pursuant to this Agreement and the Approved Plan.

WHEREAS, the DOJ Criminal Claim is resolved pursuant to this Agreement and the DOJ Criminal Plea Agreement.

WHEREAS, the DOJ Civil Claim is resolved pursuant to this Agreement and the DOJ Civil Settlement Agreement.

WHEREAS, on January 27, 2023, the Court entered that certain *Stipulation and Order (A) Granting Mediation and (B) Referring Matters to Mediation* [Docket No. 1257] (as amended, restated, amended and restated, supplemented, extended, or otherwise modified from time to time, the "***Mediation Order***"). Pursuant to the Mediation Order, Judge Shelley C. Chapman (Ret.) (the "***Mediator***") facilitated discussions between the Ad Hoc First Lien Group and the United States regarding a potential resolution of the USG Claims and the USG Objection.

WHEREAS, on September 19, 2023, the Ad Hoc First Lien Group and the United States came to a preliminary understanding as to the potential economic resolution of all USG Claims, which was expressly subject to further approvals by the United States that had not yet been obtained, the terms of which were attached to the *Notice of Filing of Term Sheet* [Docket No. 3118] (the "***USG Resolution Term Sheet***"), a copy of which is attached hereto as **Exhibit D**.

WHEREAS, in conjunction with the potential economic resolutions set forth in the USG Resolution Term Sheet, the Debtors decided, with the assent of the United States, to seek to implement the Restructuring through a plan of reorganization; *provided* that the Debtors retained the right to seek to implement the Restructuring through the Debtors' pending Sale on a standalone basis, and the United States retained the right to object to such a Sale.

WHEREAS, on December 19, 2023, the Debtors filed the *Joint Plan of Reorganization of Endo International plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code* [Docket No. 3355] (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, in each case, consistent in all material respects with this Agreement, the "***Approved Plan***"), which plan is subject to confirmation by the Bankruptcy Court (such order confirming the Approved Plan, as amended, restated, amended and restated, supplemented or otherwise modified from time to time, in each case, consistent in all material respects with this Agreement and as entered by the Bankruptcy Court, the "***Confirmation Order***").

WHEREAS, the Parties agreed to enter into this Agreement to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation in connection with the USG Claims and the USG Objection.

WHEREAS, this Agreement is neither an admission of liability for the USG Claims by Endo or any of its affiliates (with the exception of the admissions made by EHSI in connection with the DOJ Criminal Plea Agreement) nor a concession by the United States that the USG Claims are not well founded.

WHEREFORE, the Parties have negotiated this Agreement in good faith and at arm's length and intend for it to be consummated on the Plan Effective Date.

NOW, THEREFORE, in consideration of the mutual promises and obligations of this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree and covenant as follows:

ARTICLE I.
DEFINED TERMS

1.01 Certain Defined Terms. For purposes of this Agreement:

(a) "***Ad Hoc First Lien Group***" has the meaning ascribed to it in the Approved Plan.

(b) "***Administrative Expense Claim***" means any and all Claims for costs and expenses of administration of the Debtors' Estates pursuant to sections 503(b), 507(a)(2), 507(b), or 1114(e)(2) of the Bankruptcy Code, including: (a) the actual and necessary costs and expenses, incurred on or after the Petition Date through and including the Effective Date, of preserving the Estates and operating the business of the Debtors; (b) Allowed Fee Claims; (c) all Allowed requests for compensation or expense reimbursement for making a substantial contribution in the Chapter 11 Cases pursuant to sections 503(b)(3), (4), and (5) of the Bankruptcy Code; (d) fees and charges assessed against the Estates pursuant to 28 U.S.C. § 1930; and (e) all other Claims entitled to administrative claim status.

(c) "***Applicable Amount***" means the amount equal to the product of (1) (x) in the case of a sale of Purchaser Equity under clause (A) of Section 2.02(e)(ii), the amount raised in the applicable Stock Sale Liquidity Event divided by the total equity value implied by the price per each Share sold in such Stock Sale Liquidity Event or (y) in the case of a series of sales of Purchaser Equity under clause (B) of Section 2.02(e)(ii), the aggregate amount raised in the applicable sales of Purchaser Equity comprising such Stock Sale Liquidity Event divided by the average equity value implied by the price per each Share sold in the sales of Purchaser Equity comprising such Stock Sale Liquidity Event and (2) the Contingent Payment Balance immediately before the Liquidity Event Trigger Date in respect of such Stock Sale Liquidity Event.

(d) "***Audited Financial Statements***" means the consolidated balance sheet of Purchaser Parent and its subsidiaries as of the end of Purchaser Parent's fiscal year, and the related consolidated statement of income or operations, consolidated statement of changes in shareholders' or members' equity, and cash flows for such fiscal year, setting forth, in each case and in comparative form, the figures for the previous fiscal year, all in reasonable detail and prepared in accordance with generally accepted accounting principles (GAAP); such consolidated statements to be audited and accompanied by a report and opinion of Purchaser Parent's nationally recognized, independent certified public accountant, which report and opinion shall be prepared in accordance with generally accepted auditing standards.

(e) "***Bankruptcy Rules***" means the Federal Rules of Bankruptcy Procedure and any corresponding local rules of the Bankruptcy Court.

(f) "***Business Day***" means any day other than a Saturday, Sunday, or "Legal Holiday" as defined in Bankruptcy Rule 9006(a).

(g) "***Cause of Action***" has the meaning ascribed to it in the Approved Plan.

(h) "***Claim***" has the meaning ascribed to it in the Approved Plan.

(i) "***Consenting First Lien Creditors***" has the meaning ascribed to it in the Approved Plan.

(j) "***Contingent Payment Balance***" means, at the time of measurement, the Maximum Contingent Payment Amount less the sum of any Contingent Payments and any Applicable Amounts paid by Purchaser Parent hereunder through such measurement date.

(k) "***EBITDA***" means net income (loss) as reported on Purchaser Parent's consolidated audited annual financial statements before interest expense (net), income tax expense, depreciation, and amortization, each prepared in accordance with generally accepted accounting principles (GAAP).

(l) "***EBITDA Outperformance Percentage***" means, with respect to the applicable Reporting Calendar Year, the percentage set forth below under the column "EBITDA Outperformance Percentage" for such calendar year:

Year	EBITDA Outperformance Percentage
2024	135%
2025	120%
2026	120%
2027	120%
2028	120%

(m) "***EBITDA Outperformance Target***" means, with respect to the applicable Reporting Calendar Year, the Projected EBITDA for such Reporting Calendar Year multiplied by the EBITDA Outperformance Percentage for such Reporting Calendar Year.

Year	Current EBITDA Outperformance Targets[2]
2024	$627,000,000 multiplied by 135% = $846,450,000
2025	$738,000,000 multiplied by 120% = $885,600,000
2026	$833,000,000 multiplied by 120% = $999,600,000
2027	$889,000,000 multiplied by 120% = $1,066,800,000
2028	$949,000,000 multiplied by 120% = $1,138,800,000

(n) "***Final Order***" has the meaning ascribed to it in the Approved Plan.

(o) "***First Lien Backstop Commitment Parties***" has the meaning ascribed to it in the Approved Plan.

(p) "***First Lien Claims***" has the meaning ascribed to it in the Approved Plan.

(q) "***GUC Backstop Commitment Parties***" has the meaning ascribed to it in the Approved Plan.

[2] Subject to change in accordance with any adjustment of Projected EBITDA pursuant to Section 2.02(c).

(r) "***GUC Trust***" has the meaning ascribed to in the Approved Plan.

(s) "***Historic Filing Positions***" means the Debtors' historic filing positions with respect to the IRS Prepetition Tax Issues, which historic filing positions are reflected in the Debtors' U.S. federal income tax returns filed with respect to taxable periods ending on or before the Petition Date, as discussed in the IRS Claims Information Notice.

(t) "***Interim Period***" means the period beginning with the day following the Petition Date and ending with the Plan Effective Date.

(u) "***Interim Period Tax Returns***" means any U.S. federal income tax returns filed or required to be filed with respect to the Interim Period (or portion thereof).

(v) "***Liquidity Event***" means any of the transactions described in Section 2.02(e)(i) and any Stock Sale Liquidity Event. For the avoidance of doubt, neither (x) the listing by Purchaser Parent of Purchaser Equity on a stock exchange on or after the Plan Effective Date nor (y) an individual shareholder of Purchaser Parent's sale of its Purchaser Equity (whether in a block trade or multiple trades) is a Liquidity Event.

(w) "***Liquidity Event Trigger Date***" means, as applicable, (1) in the case of a Liquidity Event described in clause (A) of Section 2.02(e)(i), the closing date of such Liquidity Event, (2) in the case of a series of sales that constitute a Qualifying Series Liquidity Event described in clause (B) of Section 2.02(e)(i), the final closing date in such series of sales, (3) in the case of a sale of Purchaser Equity comprising a Stock Sale Liquidity Event under clause (A) of Section 2.02(e)(ii), the closing date of such sale of Purchaser Equity, or (4) in the case of a series of sales of Purchaser Equity comprising a Stock Sale Liquidity Event under clause (B) of Section 2.02(e)(ii), the final closing date in such series of sales of Purchaser Equity.

(x) "***Non-Debtor Affiliates***" has the meaning ascribed to it in the Approved Plan.

(y) "***Person***" means an individual, a partnership, a joint venture, a limited liability company, a corporation, a trust, a government entity, an unincorporated organization, a group, or any legal entity or association.

(z) "***Plan Buyer***" means any Purchaser Entity or other Person that is treated as acquiring assets or equity of the Debtors or their Non-Debtor Affiliates pursuant to the Approved Plan for U.S. federal income tax purposes.

(aa) "***Plan Effective Date***" has the meaning ascribed to the term "Effective Date" in the Approved Plan.

(bb) "***Post-Emergence Entities***" has the meaning ascribed to it in the Approved Plan.

(cc) "***Prepetition Secured Parties***" has the meaning ascribed to it in the Approved Plan.

(dd) "***Projected EBITDA***" means, with respect to the applicable Reporting Calendar Year, the amount set forth below under the column "Projected EBITDA" for such calendar year:

Year	Projected EBITDA
2024	$627,000,000
2025	$738,000,000
2026	$833,000,000
2027	$889,000,000
2028	$949,000,000

(ee) "***Purchaser Entity***" has the meaning ascribed to it in the Approved Plan.

(ff) "***Purchaser Equity***" has the meaning ascribed to it in the Approved Plan.

(gg) "***Purchaser Parent Board***" has the meaning ascribed to it in the Approved Plan.

(hh) "***Remaining Reporting Calendar Years***" means the Reporting Calendar Year(s) that have not yet ended as of the applicable date of adjustment pursuant to Section 2.02(c).

(ii) "***Reporting Calendar Year***" means, as applicable, each of the calendar years 2024, 2025, 2026, 2027, and 2028.

(jj) "***Representatives***" means, with respect to any Person, such Person's current and former officers, directors (including any Persons in any analogous roles under applicable law), employees, contractors, principals, members, equityholders, managers, partners, agents, advisory board members, financial advisors, attorneys, accountants, investment bankers, consultants, representatives, experts, and other professionals.

(kk) "***Required Consenting Global First Lien Creditors***" has the meaning ascribed to it in the RSA.

(ll) "***RSA***" has the meaning ascribed to it the Approved Plan.

(mm) "***Taxable Asset Sale***" means a transaction to which neither 26 U.S.C. §§ 351 nor 368 applies.

(nn) "***Threshold Enterprise Value***" means the amount set forth below with respect to the applicable Reporting Calendar Year in which a Liquidity Event Trigger Date occurs, subject to adjustment in accordance with Section 2.02, below:

($ in millions)					
Reporting Calendar Year	2024	2025	2026	2027	2028
Threshold Enterprise Value	$6,772	$7,085	$7,997	$8,534	$9,110

(oo) "***Total Enterprise Value***" means (1) the market capitalization of Purchaser Parent plus the book value of the outstanding interest-bearing indebtedness of the Purchaser Entities, in each case, on the Liquidity Event Trigger Date minus (2) the consolidated cash of Purchaser Parent as of the most recent calendar month-end before the Liquidity Event Trigger Date.

(pp) "***Trusts***" means any and all trusts or sub-trusts established or that are contemplated to receive a distribution pursuant to the Approved Plan, including the PPOC Trust, each PPOC Sub-Trust, the GUC Trust, each Distribution Sub Trust, the Future PI Trust, the Public Opioid Trust, the Tribal Opioid Trust, the Canadian Provinces Trust, the Other Opioid Claims Trust, the EFBD Claims Trust, and the Opioid School District Recovery Trust.

1.02 Table of Definitions. The following terms have the meanings set forth in the Sections referenced below:

Advisor Notice Parties 5.07
Agreement Preamble
Agreement Effective Date 3.01
Alleged Conduct Recitals
Approved Plan Recitals
Bankruptcy Code Recitals
Bankruptcy Court Recitals
Bidding Procedures Recitals
Bidding Procedures and Sale Motion Recitals
Bidding Procedures Order Recitals
Chapter 11 Cases Recitals
CMS Preamble
Conference 5.09(a)
Confirmation Order Recitals
Contingent Consideration 2.02(b)
Contingent Note Payment 2.02(a)
Contingent Note Payment Amount 2.02(a)
Court Recitals
Criminal Court Recitals
Criminal Fine Recitals
Debtors Recitals
DHA Preamble
Dispute 5.09(a)
Dispute Notice 5.09(a)
DOJ Civil Claim Recitals
DOJ Civil Settlement Agreement Recitals
DOJ Criminal Claim Recitals
DOJ Criminal Plea Agreement Recitals
DOJ-Civil Fraud Preamble
DOJ-CPB Preamble
EHSI Recitals
Endo Preamble
Endo Group 3.05(a)
Event of Default 4.01
FEHBP Preamble
Fixed Consideration 2.01(a)
Fixed Consideration Amount 2.01(a)
Forfeiture Recitals

VA Preamble

ARTICLE II.
ECONOMIC TERMS AND CONDITIONS

2.01 Fixed Consideration.

In full and final satisfaction of all USG Claims, Purchaser Parent (or any other Purchaser Entity at the direction of Purchaser Parent) shall pay the United States as follows in this Article II:

(a) Fixed Consideration Amount. Subject to the terms and conditions of this Agreement, Purchaser Parent shall pay to the United States an aggregate amount equal to $364,900,000.00 (such aggregate amount, the "***Fixed Consideration Amount***" and, such consideration, the "***Fixed Consideration***"), payable in ten equal annual installments of $36,490,000.00, commencing on the first anniversary of the Plan Effective Date and concluding on the tenth anniversary of the Plan Effective Date.

(b) Prepayment Right. Purchaser Parent shall have the right to prepay the entire balance of the Fixed Consideration Amount or any portion thereof (any such amount subject to prepayment, a "***Prepayment Amount***"), at any time without premium or penalty, in an amount equal to the net present value of the Prepayment Amount, discounted at a rate of 12.75%, as determined on the date of such prepayment (such right, the "***Obligor Fixed Consideration Prepayment Right***"). An illustrative schedule of Prepayment Amounts (assuming the full discounted prepaid balance of the Fixed Consideration Amount is paid on the Plan Effective Date or any successive month thereafter) is attached hereto as **Exhibit E** (the "***Illustrative Fixed Consideration Prepayment Schedule***").

(c) Call Right. No later than fourteen (14) days after the date on which the Bankruptcy Court enters the Confirmation Order, the United States may elect, by delivery of written notice of such election to Purchaser Parent in accordance with Section 5.07, that Purchaser Parent prepay in full on the Plan Effective Date the Fixed Consideration Amount, in the amount of $200,000,000.00 (such right, the "***USG Call Right***"). This payment will be made on the Plan Effective Date.

(d) In lieu of direct payment by Purchaser Parent, Purchaser Parent shall have the right to direct EHSI (or any of its affiliates) to make any payment to the United States under this Section 2.01 that is scheduled for payment on the Plan Effective Date.

2.02 Contingent Consideration.

(a) Contingent Note Payment Amount. Subject to the terms and conditions of this Agreement, Purchaser Parent shall pay to the United States an amount equal to $25,000,000, subject to adjustment in accordance with Section 2.02(e)(ii) (the "***Contingent Note Payment Amount***" and, any such payment, a "***Contingent Note Payment***") as follows:

(i) Purchaser Parent shall deliver its Audited Financial Statements for each Reporting Calendar Year to the United States on the 30th day after the date Purchaser Parent files such Audited Financial Statements with the Securities and Exchange Commission (or, in the event Purchaser Parent does not have public reporting obligations for that Reporting Calendar Year, as soon as possible, but no later than 90 days after the end of such fiscal year);

(ii) Concurrently with the delivery of such Audited Financial Statements, Purchaser Parent shall deliver to the United States a certificate signed by a responsible officer providing the calculation of EBITDA based on such Audited Financial Statements and, for the purpose of determining whether the EBITDA Outperformance Target has been achieved, the calculation of the EBITDA as a percentage relative to the EBITDA Outperformance Target;

(iii) if the EBITDA for that Reporting Calendar Year (as reported in the aforementioned Audited Financial Statements and certified in the officer's certificate) exceeds the applicable EBITDA Outperformance Target for such Reporting Calendar Year then, concurrently with the delivery of such officer's certificate, Purchaser Parent shall remit the Contingent Note Payment to the United States in accordance with the remittance instructions provided by the United States in writing; and

(iv) if the EBITDA for that Reporting Calendar Year (as reported in the aforementioned Audited Financial Statements and certified in the officer's certificate) is equal to or less than the applicable EBITDA Outperformance Target for such Reporting Calendar Year, then Purchaser Parent shall have no obligation to make any Contingent Note Payment to the United States in respect of such Reporting Calendar Year.

(b) Purchaser Parent's obligation to make a Contingent Note Payment in any given Reporting Calendar Year is determined according to the aforementioned criteria and is calculated independently of, and in addition to, Purchaser Parent's obligation to make a Contingent Note Payment in any other Reporting Calendar Year. Notwithstanding anything else in this Agreement, the sum of any and all (i) Contingent Note Payments and (ii) Applicable Amounts paid to the United States (collectively, the "***Contingent Consideration***") under this Agreement shall not exceed $100,000,000.00 in the aggregate (such amount, the "***Maximum Contingent Payment Amount***"). The Contingent Consideration shall be a senior unsecured obligation of Purchaser Parent, and shall not be made structurally junior to any of the obligations outstanding under any other settlement incorporated into the Approved Plan. The Contingent Consideration and the Fixed Consideration are together defined as the "***Settlement Consideration***."

(c) Asset Acquisitions and Sales. For any Remaining Reporting Calendar Year in which the Purchaser Entities acquire or sell assets, as well as for any subsequent Remaining Reporting Calendar Years, the Projected EBITDA for such year(s) shall be adjusted upward or downward dollar for dollar in an amount equal to the EBITDA contribution of such acquired or sold assets, respectively, in each case, calculated as of the closing date of each such asset acquisition or sale; *provided* that any single sale or series of sale transactions, within a twelve-month period, of assets that contributed more than 66.7% of the actual EBITDA of the four calendar quarters preceding the last such sale shall constitute a Liquidity Event (such a series of sales within a twelve-month period, a "***Qualifying Series Liquidity Event***"). The Threshold Enterprise Value for each Remaining Reporting Calendar Year shall be adjusted upward or downward dollar for dollar in an amount equal to the purchase or sale price of any assets purchased or sold during any Remaining Reporting Calendar Year. For the avoidance of doubt, each adjustment of Projected EBITDA and Threshold Enterprise Value made pursuant to this Section 2.02(c) shall account for the timing of the applicable asset acquisition or sale.

(d) Restated Financials. Contingent Payments shall not be subject to avoidance or clawback on account of the subsequent restatement by Purchaser Parent of any annual financial statements for any of the Reporting Calendar Years.

(e) Liquidity Event Accelerator.

(i) Upon the occurrence of (A) a single transaction that, in form or substance, effects a sale of Purchaser Parent and closes during any Reporting Calendar Year at an implied

Total Enterprise Value that exceeds the applicable Threshold Enterprise Value for such Reporting Calendar Year or (B) a Qualifying Series Liquidity Event, the final sale of which closes during any Reporting Calendar Year, whereby (1) the sum of (w) the total purchase price paid or payable for each such sale on the Liquidity Event Trigger Date, (x) the book value of the outstanding interest-bearing indebtedness of Purchaser Parent on the Liquidity Event Trigger Date, and (y) the average daily closing market capitalization of Purchaser Parent's publicly traded equity for the 30 consecutive trading days following the applicable Liquidity Event Trigger Date, *minus* (z) the consolidated cash of Purchaser Parent as of the most recent calendar month-end before the Liquidity Event Trigger Date, exceeds (2) the applicable Threshold Enterprise Value for the Reporting Calendar Year in which such Liquidity Event Trigger Date occurs, then, in the case of either (A) or (B), the Contingent Payment Balance shall become fully due and payable on the applicable Liquidity Event Trigger Date. In the event that Purchaser Parent's equity is not publicly listed on and after the Liquidity Event Trigger Date, such equity value shall be determined by a nationally recognized investment banking or valuation firm selected and retained by Purchaser Parent with the United States' approval, which approval is not to be unreasonably withheld, conditioned, or delayed.

(ii) Upon the occurrence of (A) any single sale or (B) multiple sales, in the case of either (A) or (B), of Purchaser Equity with an aggregate value of $500,000,000.00 or more that is or are consummated by two or more unaffiliated shareholders of Purchaser Parent acting in concert (but not including Purchaser Parent or any of its subsidiaries or the GUC Trust) and that is (1) organized and managed by an investment bank or broker-dealer that is engaged by the selling shareholder(s) and not an open market sale or (2) a secondary registered offering of such Purchaser Equity that is underwritten by an underwriter, which, in each case, closes during any Reporting Calendar Year at an implied Total Enterprise Value exceeding the Threshold Enterprise Value for the Reporting Calendar Year in which the applicable Liquidity Event Trigger Date occurs (each of the transactions described in this Section 2.02(e)(ii), a "***Stock Sale Liquidity Event***"), then Purchaser Parent shall pay the Applicable Amount on the applicable Liquidity Event Trigger Date. Any payment of an Applicable Amount shall reduce the Maximum Contingent Payment Amount hereunder on a dollar-for-dollar basis. Following the payment of any Applicable Amount, the maximum Contingent Note Payment Amount payable in any subsequent Reporting Calendar Year shall be equal to the product of (1) the Contingent Note Payment Amount prior to the payment of such Applicable Amount and (2) one (1) minus the result of (a) the amount raised in the applicable Stock Sale Liquidity Event divided by (b) either (x) in the case of a Stock Sale Liquidity Event described in subclause (A) of this clause (ii), the total equity value implied by the price per each Share sold in such Stock Sale Liquidity Event or (y) in the case of a Stock Sale Liquidity Event described in subclause (B) of this clause (ii), the average equity value implied by the price per each Share sold in the sales comprising such Stock Sale Liquidity Event.

(f) Evidence of Obligations. The obligations under this Section 2.02 shall be evidenced by this Agreement. In addition, the United States may request that Purchaser Parent further evidence such obligations in the form of a promissory note, in which event, Purchaser Parent shall prepare, execute, and deliver to the United States a promissory note payable to the United States incorporating the applicable terms hereunder.

ARTICLE III.
IMPLEMENTATION

3.01 Conditions to Effectiveness.

The following are conditions precedent to the effectiveness of this Agreement that must be satisfied or waived by the Parties with the consent of the Required Consenting Global First Lien Creditors (the date on which such conditions are met, the "***Agreement Effective Date***"):

(a) The Bankruptcy Court or another court of competent jurisdiction shall have entered the Confirmation Order, and such order shall not have been stayed pending any appeal therefrom.

(b) (i) The Endo Group and the Plan Buyers shall have structured the sale transaction in the Approved Plan in a manner that is intended to be treated as a Taxable Asset Sale, as required by Section 3.05(a) hereof, and (ii) the IRS shall not have raised any objection or request for modification under Section 3.05(a) hereof that has not been addressed by the Endo Group and the Plan Buyers to the satisfaction of the IRS.

(c) The Bankruptcy Court shall have authorized the Debtors' entry into and performance under the DOJ Civil Settlement Agreement, which authorization may be provided in the Confirmation Order.

(d) The Bankruptcy Court shall have authorized the Debtors' entry into and performance under the DOJ Criminal Plea Agreement, which authorization may be provided in the Confirmation Order.

(e) EHSI and the United States shall have executed the DOJ Civil Settlement Agreement.

(f) EHSI and the United States shall have executed the DOJ Criminal Plea Agreement.

(g) The Plan Effective Date shall have occurred or be deemed to have occurred concurrent with the Agreement Effective Date.

(h) The Criminal Court shall have accepted the DOJ Criminal Plea Agreement and shall have imposed criminal penalties consistent with, and in an amount no greater than, the terms set forth in the DOJ Criminal Plea Agreement and this Agreement.

(i) OIG-HHS shall not have exercised any available authority, or confirmed in writing its intent to exercise, any available authority to exclude any of EHSI's parent companies or any of their respective affiliates, divisions, or subsidiaries (other than EHSI), or its or their successors or assigns, including any Purchaser Entity, from participation in Federal healthcare programs.

(j) Any agency of the Federal Government shall not have exercised any available authority, or expressed in writing its intent to exercise any available authority, to exclude render ineligible, suspend, propose for debarment, or debar any of EHSI's parent companies or any of their respective affiliates, divisions, or subsidiaries (other than EHSI), or its or their successors or assigns, including any Purchaser Entity from participation in Federal Government procurement or non-procurement programs on account of the Alleged Conduct underlying the DOJ Criminal Claim or the DOJ Civil Claim or the resolutions thereof.

(k) Each of the Parties shall have delivered counterpart signatures to this Agreement.

3.02 Allocation of Settlement Consideration.

The United States may, in its sole discretion, allocate and apportion the Settlement Consideration as between the respective claimants that have asserted the USG Claims; *provided* that Purchaser Parent (or EHSI (or any of its affiliates), as applicable) shall be entitled to make all payments required under this Agreement to a single payee and in accordance with remittance instructions provided by the United States in writing. Within thirty (30) days following the Plan

Effective Date, the United States shall provide the Debtors and the Purchaser Entities with a statement setting forth the United States' allocation and apportionment of the Settlement Consideration as between the IRS Claims, on the one hand, and the other USG Claims.

3.03 Effect of Plan Effective Date.

On the Plan Effective Date, in accordance with the Approved Plan, the USG Claims shall be fully and finally satisfied and released. For the avoidance of doubt, on and after the Plan Effective Date (a) the Approved Plan shall fully and finally resolve all USG Claims; (b) the Approved Plan shall effect a sale and/or transfer of the Debtors' assets to the Purchaser Entities free and clear of all USG Claims; and (c) the obligations to provide the Settlement Consideration shall be the only monetary obligations owed to the United States related to the USG Claims (the "***Settlement Monetary Obligations***"), including pursuant to the DOJ Criminal Plea Agreement (provided that the Forfeiture shall be satisfied in full in accordance with the terms of the DOJ Criminal Plea Agreement) and the DOJ Civil Settlement Agreement, and the only recourse of the United States with respect to the Settlement Monetary Obligations shall be to Purchaser Parent, as set forth in this Agreement. For the avoidance of doubt, nothing in this Agreement shall absolve any party from any non-monetary obligation in the DOJ Criminal Plea Agreement or the DOJ Civil Settlement Agreement.

3.04 Treatment of Settlement Monetary Obligations.

To the extent that Purchaser Parent (or any affiliate filing a consolidated U.S. income tax return therewith) commences voluntary chapter 11 cases prior to the repayment in full of the Settlement Consideration (and prior to the expiration of the last Reporting Calendar Year, if applicable) (a "***Future Bankruptcy Proceeding***"), the Parties hereby consent and agree that any unpaid balance of the Settlement Consideration comprises an assumption of liability and a compromise of taxes payable by the applicable U.S. taxpayer Purchaser Entity and shall, accordingly, receive priority status under Bankruptcy Code section 507(a)(8) in a Future Bankruptcy Proceeding. For the avoidance of doubt, the applicable time periods shall be tolled, pursuant to the flush language at the end of Bankruptcy Code section 507(a)(8), from the Petition Date until the date of the Uncured Payment Default, plus ninety days.

3.05 Tax Matters.

(a) The Approved Plan shall be implemented through a Taxable Asset Sale by Endo and one or more of Endo's controlled subsidiaries (together with Endo, the "***Endo Group***") to one or more of the Plan Buyers for U.S. federal income tax purposes. In connection with any acquisition of equity interests in a member of the Endo Group by a Plan Buyer, the applicable Plan Buyer and/or member of the Endo Group shall make all elections permitted under applicable law to treat, or otherwise report on any applicable U.S. federal income tax return, such acquisition as a taxable purchase of assets for U.S. federal income tax purposes. By no later than February 23, 2024, the Endo Group and the Plan Buyers will provide to the IRS a summary of the proposed transaction, including a description of why the transaction qualifies as a Taxable Asset Sale. If the IRS does not agree that the proposed transaction will result in a Taxable Asset Sale, the Endo Group and Plan Buyers will modify the proposed transaction so as to satisfy the IRS in this regard. The IRS will provide its response no later than March 4, 2024.

(b) No Plan Buyer or Purchaser Entity shall succeed to any U.S. federal income net operating losses, tax credits or other U.S. federal income tax attributes of any member of the Endo Group.

(c) The Approved Plan shall provide that all IRS Claims shall be fully satisfied solely by the portion of the Settlement Consideration allocated to the IRS Claims pursuant to

Section 3.02 of this Agreement. On the Plan Effective Date, the IRS Claims shall be deemed, in part, an allowed, unsubordinated priority claim and, in part, an allowed, unsubordinated general unsecured claim, each in such amount equal to the settlement amounts to be received by the IRS as allocated by the United States. For the avoidance of doubt, the United States shall make no Claim against the Debtors, the Endo Group, or any Purchaser Entities (or their respective affiliates) with respect to any IRS Claims and none of the Debtors, the Endo Group, or any Purchaser Entities (or their respective affiliates) shall have any liability for any IRS Claims (notwithstanding that any tax returns filed with respect to taxes that are IRS Claims may reflect liability for taxes). Furthermore, the Debtors, the Endo Group, and the Purchaser Entities may not claim a refund of U.S. federal income taxes for any tax period covered by the IRS Claims.

(d) The Plan Buyers' aggregate U.S. federal income tax basis (the "***Stipulated Basis***") in all of the assets acquired from the Endo Group on the Plan Effective Date shall equal the fair market value of these assets as of the Plan Effective Date as determined by a valuation conducted after the Plan Effective Date by Deloitte LLP or another nationally recognized firm selected by the Purchaser Parent Board and retained by the Purchaser Parent and/or the applicable Plan Buyer (as applicable) (the "***Independent Valuation***"); *provided* that the Plan Buyers' Stipulated Basis as of the end of the Plan Effective Date shall not be less than $3,500,000,000.00 and, to the extent the Independent Valuation exceeds $4,650,000,000.00, the Stipulated Basis shall be $4,650,000,000.00. In the event that the Independent Valuation is lower than $4,650,000,000.00, the Plan Buyers may add any costs and expenses incurred by any Purchaser Entity (on its own behalf) in connection with or arising from the Approved Plan or the Chapter 11 Cases to their basis so long as their total basis in the acquired assets does not exceed the maximum Stipulated Basis amount of $4,650,000,000.00. For the avoidance of doubt, this limitation on Stipulated Basis does not preclude the Plan Buyers from making post-acquisition expenditures or other payments after the Effective Date that increase their basis in the assets at issue in accordance with applicable federal tax law; *provided* that none of the payments made pursuant to the Approved Plan to any creditor or administrative claimant of the Debtors or to the Trusts shall be added to the Plan Buyers' basis in the acquired assets based on the Independent Valuation of their fair market value. In addition, no part of the Settlement Consideration or payments made pursuant to the Approved Plan to any creditor or administrative claimant of the Debtors or to the Trusts shall be deductible for U.S. federal income tax purposes on any return filed by or on behalf of the Purchaser Entities.

(e) The Debtors and the Plan Buyers reserve the right to determine, in accordance with applicable law, that the respective and separate taxable year of each of the Debtors and the Plan Buyers shall end as of the end of the Plan Effective Date and a new and separate taxable year of each of the Debtors and the Plan Buyers shall begin as of immediately following the Plan Effective Date.

(f) For the avoidance of doubt, nothing in this Agreement absolves the Debtors, the Endo Group, the Purchaser Entities, or any other Person from filing any tax returns that are otherwise required to be filed for any tax period, including for the tax period covered by the IRS Administrative Expense Claim. The Parties agree that, in connection with the preparation and filing of any Interim Period Tax Returns, the Debtors shall prepare and file such Interim Period Tax Returns in accordance with the Historic Filing Positions. For the avoidance of doubt, the United States shall make no claim, demand, or take any action against the Debtors, the Endo Group, or any Purchaser Entities (or their respective affiliates) with respect to any Historic Filing Positions reflected on any Interim Period Tax Return. For the further avoidance of doubt, the IRS reserves the right to challenge any tax position taken by the Purchaser Entities after the Plan Effective Date, including any tax position that is consistent with or relies on the Debtors' Historic Filing Positions but excluding any positions expressly agreed to by the Parties in this Agreement (including, without limitation, the Stipulated Basis described in Section 3.05(d)). Moreover, any decision by the IRS not to challenge any of the Debtors' tax returns based on the

Historic Filing Positions pursuant to this Agreement shall not constitute evidence of the IRS's acceptance of these Historical Filing Positions with respect to any return filed by or on behalf of the Purchaser Entities.

3.06 Releases.

(a) With respect to the IRS Claims and the Healthcare Agencies Claims, the United States fully and finally releases the Debtors, the Purchaser Entities, the Ad Hoc First Lien Group, the Prepetition Secured Parties, the Consenting First Lien Creditors, the GUC Backstop Commitment Parties, the First Lien Backstop Commitment Parties, and any of their respective Representatives from any liability to pay any part of the liabilities reflected in or arising out of such Claims; *provided* that Purchaser Parent is not released from its obligation to pay the Settlement Consideration pursuant to this Agreement.

(b) In addition, the United States waives and shall not assert claims under the MSP statute or MCRA against or seek payment based upon, related to, or arising from any of the Healthcare Agencies Claims from (1) any person or entity (as well as a beneficiary, parent, sponsor, attorney or legally responsible individual of such person or entity), that receives payment or proceeds from or on behalf of any Debtor, including those parties receiving payments or proceeds from the Trusts, with respect to such payments or proceeds, or (2) any entity (including, without limitation, a creditor of a Debtor) making payment on behalf of any Debtor to the Trusts, with respect to such payments.

(c) With respect to the DOJ Criminal Claim and the DOJ Civil Claim, respectively, the United States provides those releases as set forth in the DOJ Civil Settlement Agreement and the DOJ Criminal Plea Agreement, respectively. In addition, the United States fully and finally releases the Purchaser Entities, the Ad Hoc First Lien Group, the Prepetition Secured Parties, the Consenting First Lien Creditors, the GUC Backstop Commitment Parties, the First Lien Backstop Commitment Parties, and all of their respective Representatives from any liability to pay any part of the monetary liabilities reflected in or arising out of those Claims, except the Purchaser Parent's obligation to satisfy the obligations hereunder.

(d) For the avoidance of doubt, with respect to the United States, nothing in the Approved Plan or this Agreement shall limit or expand the meaning or effect of section 1141(c) of the Bankruptcy Code with respect to the asset transfers set forth in the Approved Plan, or in any agreement, instrument, or other document incorporated in the Approved Plan (including the PSA). Nor, with respect to the United States, does anything in the Approved Plan or this Agreement limit or expand the scope of discharge, release or injunction to which the Debtors or Post-Emergence Entities are entitled to under the Bankruptcy Code, if any; *provided* that nothing in this Section 3.06(d) shall serve to limit the scope of the releases granted pursuant to this Agreement.

(e) Notwithstanding the releases given in Section 3.03 and this Section 3.06, or any other terms of this Agreement, the following Claims of the United States are specifically reserved and are not released:

(i) except as otherwise provided in this Agreement, the DOJ Criminal Plea Agreement or DOJ Civil Settlement Agreement, any injunctive or regulatory enforcement right of the United States (including any agency thereof), in either case, that is not a "claim" as defined under 11 U.S.C. § 101(5);

(ii) any non-monetary obligations set forth in the DOJ Criminal Plea Agreement or DOJ Civil Settlement Agreement;

(iii) any liability based upon obligations created by this Agreement; and

(iv) any liability of Persons other than the Persons described in this Section 3.06.

(f) Each of the Debtors, the Purchaser Entities, and, pursuant to the Confirmation Order, the Ad Hoc First Lien Group, the Prepetition Secured Parties, the Consenting First Lien Creditors, the GUC Backstop Commitment Parties, and the First Lien Backstop Commitment Parties, in each case, together with all of their respective Representatives, fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that the Debtors or Purchaser Entities have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the USG Claims or the United States' investigation or prosecution thereof. Notwithstanding the foregoing: (1) nothing herein shall prevent Endo (including any of its affiliates, divisions, or subsidiaries, or its successors, or assigns) or the Purchaser Entities from challenging in an administrative proceeding, legal proceeding, or otherwise an exclusion, ineligibility or non-responsibility determination, termination, or proposed or actual suspension or debarment from or in connection with participation by Endo (including any of its affiliates, divisions, or subsidiaries, or its successors, or assigns, in each case, other than EHSI) or any Purchaser Entity in any Federal Government procurement, non-procurement, or healthcare program or agreement; and (2) all claims of the Debtors and/or the Purchaser Entities with respect to any liability based upon obligations created by this Agreement are specifically reserved and are not released.

ARTICLE IV.
EVENTS OF DEFAULT; TERMINATION OF AGREEMENT

4.01 Events of Default.

Each of the following, upon (and subject to) delivery of written notice thereof by the non-defaulting Party to the defaulting Party in accordance with Section 5.07, shall constitute a breach of, and an event of default under, this Agreement (each, an "***Event of Default***"):

(a) On or after the Plan Effective Date, the failure of Purchaser Parent to pay any portion of the Settlement Consideration as provided herein (any such occurrence, a "***Payment Default***");

(b) On or after the Plan Effective Date, (i) the filing of a motion or pleading by the Post-Emergence Entities or the United States, as applicable, seeking to withdraw, amend or modify the Approved Plan, the Confirmation Order, or any motion to assume or approve this Agreement, which withdrawal, amendment, modification or filing is not consistent with this Agreement in any material respect or (ii) the filing of a motion or pleading by the Post-Emergence Entities or the United States, as applicable, that is not consistent with this Agreement in any material respect and, in the case of each of (i) or (ii), such motion or pleading has not been withdrawn prior to the earlier of (x) three (3) Business Days after the moving Party receives written notice in accordance with Section 5.07 from the non-moving Party that such motion or pleading is inconsistent with this Agreement, and (y) the entry of an order of a court approving such motion or pleading; and

(c) On or after the Plan Effective Date, the violation of any term of this Agreement, including, without limitation, the violation of any of the terms set forth in Section 3.03, Section 3.04, Section 3.05, or Section 3.06.

4.02 Effect of Event of Default.

(a) Payment Default. Upon the occurrence of a Payment Default, the United States shall provide a written "Notice of Payment Default" to Purchaser Parent (with copies, not constituting notice, to the Advisor Notice Parties) in accordance with Section 5.07 and Purchaser Parent shall have an opportunity to cure or dispute such Payment Default within twenty (20) Business Days from the date of its receipt of the Notice of Payment Default by either (1) making the payment due under this Agreement or (2) sending a Dispute Notice to the United States in accordance with Section 5.07. If Purchaser Parent, following receipt of a Notice of Payment Default, fails to timely cure or Dispute the Payment Default in accordance with the terms of this Agreement, absent an agreement otherwise with the United States, the Payment Default shall be deemed an "***Uncured Payment Default***" and the remaining unpaid balance of the Fixed Consideration and any due and owing Contingent Consideration, calculated in accordance with this Agreement, shall become immediately due and payable by Purchaser Parent and any affiliated entities that file a consolidated U.S. federal income tax return therewith. For the avoidance of doubt, the occurrence of an Uncured Payment Default does not relieve Purchaser Parent or its consolidated U.S. income tax return affiliates of any future obligation to make Contingent Consideration payments.

(b) Other Defaults. Upon the occurrence of an Event of Default that is not a Payment Default or an Uncured Payment Default, the defaulting Party shall have sixty (60) days to cure the default, following which time period (to the extent the default has not been cured) the non-defaulting Party shall be entitled to avail itself of the Dispute Resolution procedures set forth in Section 5.09 to obtain appropriate equitable, monetary, injunctive, or other relief, as applicable, in accordance with Section 5.10.

4.03 Provisions Governing Approved Plan's Failure to Be Confirmed or Become Effective.

(a) Failure to Achieve Confirmation or Effectiveness of Approved Plan. The following events constitute a "***Non-Effectiveness Event***": (x) failure to achieve confirmation of the Approved Plan by September 30, 2024; (y) the Plan Effective Date does not occur by February 1, 2025; or (y) the Debtors inform the Bankruptcy Court that they are abandoning the Approved Plan or are no longer seeking to have the Approved Plan become effective.

(b) Unless each of the Parties consents (in its sole discretion) to waive or delay the effect of this paragraph, then, upon occurrence of a Non-Effectiveness Event, and notwithstanding Section 5.09 below: (x) this Agreement shall be void, and all USG Claims shall be restored to their status prior to this Agreement, with all parties to retain their rights and defenses regarding such Claims as they existed on the day before this Agreement was executed; and (y) any applicable deadline for the United States to object to the dischargeability of any USG Claims shall be set to the date that is 90 days from the date of the occurrence of the Non-Effectiveness Event. For the avoidance of doubt, nothing in this paragraph or in the Agreement restricts the ability of the United States to object to any other plan of reorganization.

4.04 Termination of Agreement.

(a) If the Parties agree to terminate this Agreement prior to the payment in full of the Settlement Consideration, the Parties shall contemporaneously decide what, if any, obligations of this Agreement, including any releases set forth in Section 3.06, may survive such termination, and reduce to writing their new agreement in that respect.

(b) If either the Bankruptcy Court or any other court of competent jurisdiction terminates or declares unenforceable this Agreement or any provision thereof, the parties will

attempt to come to agreement on which, if any of the terms of this Agreement, including any releases set forth in Section 3.06, survive such a judicial determination, and if they are not able to do so, will seek clarification from the court whose decision they are implementing.

(c) For the avoidance of doubt, the termination of the DOJ Criminal Plea Agreement and DOJ Civil Settlement Agreement shall be in accordance with their own terms.

4.05 Inconsistency with Approved Plan.

In the event of an inconsistency between this Agreement and the Approved Plan, this Agreement shall govern, and any Party may request that the Bankruptcy Court amend the Approved Plan to conform to this Agreement.

ARTICLE V.
MISCELLANEOUS

5.01 Third-Party Beneficiaries.

This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other Person, except to the extent provided for in Section 3.06. Each of the releasees set forth in Section 3.06 who is not a Party hereto shall be an express third-party beneficiary of such release.

5.02 Contemporaneous Exchange.

In evaluating whether to execute this Agreement, the Parties warrant that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Purchaser Parent, within the meaning of Bankruptcy Code section 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Purchaser Parent was or became indebted to on or after the date of this transfer, within the meaning of Bankruptcy Code section 548(a)(1).

5.03 No Solicitation.

This Agreement is not and shall not be deemed to be a solicitation for consents to any chapter 11 plan.

5.04 No Other Claims

The Parties have each reviewed the Claims Register and are not aware of any proofs of claim by federal agencies in the Chapter 11 Cases other than the USG Claims and the Protective CMS Claims, as of February 28, 2024.

5.05 Representation by Counsel.

Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion. Each Party further acknowledges that it, or its advisors, has had an opportunity to receive information from the other Parties and that it has been represented by counsel in connection with this Agreement and the transactions contemplated hereby. Accordingly, any rule of law or any legal decision that would provide any Party with a defense to the enforcement of the terms of this Agreement

against such Party based upon lack of legal counsel shall have no application and is expressly waived. In addition, each party hereby waives the application of any law, regulation, holding, or rule of construction providing that ambiguities in an agreement or other document shall be construed against the party drafting such agreement or document.

5.06 Costs.

Each Party shall bear, or seek reimbursement through entitlements set forth in existing orders of the Bankruptcy Court, contracts, or otherwise, its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

5.07 Notice.

All notices hereunder shall be deemed given if in writing and delivered, if contemporaneously sent by electronic mail, courier or by registered or certified mail (return receipt requested) to the following addresses or such other addresses of which notice is given pursuant hereto:

if to Endo, to:

Endo International plc
1400 Atwater Drive
Malvern, PA 19355
Attn: Chief Legal Officer

with copies (which shall not constitute notice) to the following advisors:

Skadden, Arps, Slate, Meagher & Flom LLP
One Manhattan West
New York, NY 10001
Attention: Paul Leake, Lisa Laukitis, Shana Elberg, and Evan Hill
E-mail: paul.leake@skadden.com, lisa.laukitis@skadden.com,
shana.elberg@skadden.com, evan.hill@skadden.com

– and –

if to Purchaser Parent, to:

Endo, Inc.
1400 Atwater Drive
Malvern, PA 19355
Attn: Chief Legal Officer

with copies (which shall not constitute notice) to the following advisors (together with the foregoing advisors, the "***Advisor Notice Parties***"):

Gibson, Dunn & Crutcher LLP
200 Park Ave
New York, New York 10166
Attention: Scott Greenberg, Michael J. Cohen, Joshua K. Brody, and Christina Brown
E-mail: SGreenberg@gibsondunn.com, MCohen@gibsondunn.com, JBrody@gibsondunn.com, christina.brown@gibsondunn.com, EndoTrusts@gibsondunn.com

if to United States, to:

United States Attorney's Office
Southern District of New York
86 Chambers Street, 3rd Floor
New York, New York 10007
Attention: Assistant U.S. Attorneys Jean-David Barnea, Peter Aronoff, and Tara Schwartz
E-mail: Jean-David.Barnea@usdoj.gov, Peter.Aronoff@usdoj.gov, Tara.Schwartz@usdoj.gov

5.08 Governing Law.

This Agreement is governed by the laws of the United States. Subject to Section 5.09 below, the Parties will bring any dispute relating to this Agreement (other than a dispute arising out of the DOJ Civil Settlement Agreement, the DOJ Criminal Plea Agreement, or the determination of any tax liability of the Purchaser Entities or any other non-Debtor) in the Bankruptcy Court, to the extent that the Bankruptcy Court has jurisdiction over such a dispute. For the avoidance of doubt, the Parties agree that the Bankruptcy Court shall not have jurisdiction over the determination of the tax liabilities of any Persons other than the Debtors. For the further avoidance of doubt, nothing in this Agreement or the Approved Plan shall confer jurisdiction on the Bankruptcy Court over any criminal proceeding.

5.09 Dispute Resolution.

(a) In the event of a dispute concerning this Agreement (other than a dispute arising out of the DOJ Civil Settlement Agreement, the DOJ Criminal Plea Agreement, or the determination of any tax liability of the Purchaser Entities or other non-Debtors) (a "***Dispute***") while this Agreement is in effect, including any such Dispute regarding whether an Event of Default has occurred, the Parties will bring such Dispute in the Bankruptcy Court, unless the Bankruptcy Court lacks jurisdiction or the Parties otherwise agree. Any Party to this Agreement may contact chambers to arrange a telephonic conference (a "***Conference***") with the Bankruptcy Court for purposes of resolving a Dispute. The Party requesting a Conference (the "***Requesting Party***") shall provide a written notice (a "***Dispute Notice***") to the other Party describing the Disputes (the "***Identified Disputes***") concerning which the Requesting Party seeks the Bankruptcy Court's guidance in sufficient detail for the other Party to frame its response. The Requesting Party shall provide such Dispute Notice to the other Party at least three (3) Business Days before any Conference is convened (unless exigent circumstances do not afford time for such notice, in which case the Requesting Party shall provide as much notice as reasonably possible). If the Identified Disputes are not resolved during the Conference, and written submissions are requested or authorized by the Bankruptcy Court, unless the Bankruptcy Court directs otherwise at the Conference, the Requesting Party may brief any remaining Identified Disputes by submitting a letter to the Bankruptcy Court, not to exceed five (5) single-spaced pages, within three (3) Business Days after the Conference. The opposing Party may respond

within seven (7) Business Days of the Requesting Party's letter with a letter not to exceed five (5) single-spaced pages. Any further hearing concerning any remaining Identified Disputes shall be convened promptly, subject to the Bankruptcy Court's availability.

(b) Nothing in this Agreement precludes any Party from seeking to withdraw the reference to the Bankruptcy Court pursuant to 28 U.S.C. § 157(d) or to oppose or object to any such attempt to withdraw the reference. Nor shall anything in this Agreement confer any jurisdiction on the Bankruptcy Court or limit or modify the jurisdiction of any other court.

5.10 Specific Performance; Limitation of Remedies.

It is understood and agreed by the Parties that money damages would be an insufficient remedy for any breach of this Agreement of any non-monetary obligations by any Party and each non-breaching Party shall be entitled to specific performance and injunctive or other equitable relief (including attorneys' fees and costs) as a remedy of any such breach, without the necessity of proving the inadequacy of money damages as a remedy. Unless otherwise expressly stated in this Agreement, no right or remedy described or provided in this Agreement is intended to be exclusive or to preclude a Party from pursuing other rights and remedies to the extent available under this Agreement, at law, or in equity. The Parties hereby waive any requirement for the security or posting of any bond in connection with such remedies. Notwithstanding anything to the contrary in this Agreement, none of the Parties will be liable for, and none of the Parties shall claim or seek to recover on the basis of anything in this Agreement, any punitive, special, indirect, or consequential damages or damages for lost profits, in each case against any other Party to this Agreement.

5.11 No Admission.

Each of the Parties does not concede any infirmity in the claims and defenses which it has asserted or could assert with regard to the USG Claims, and this Agreement shall not be considered such a concession.

5.12 Complete Agreement.

This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by a Party from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

5.13 Business Day Convention.

When a period of days under this agreement ends on a Saturday, Sunday, or any legal holiday as defined in Bankruptcy Rule 9006(a), then such period shall be extended to the specified hour of the next Business Day.

5.14 Authorization.

The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the Persons indicated below.

5.15 Prior Negotiations; Entire Agreement.

This Agreement, including the exhibits and schedules hereto, constitutes the entire agreement of the Parties, and supersedes all other prior negotiations regarding the subject matters hereof and thereof, except that the Parties acknowledge that the Approved Plan, Confirmation

Order, DOJ Criminal Plea Agreement, and DOJ Civil Settlement Agreement shall continue in full force and effect.

5.16 Counterparts.

This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement. Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

5.17 Successors and Assigns; Severability.

This Agreement is intended to bind and inure to the benefit of the Parties and their respective successors, permitted assigns, heirs, executors, administrators, and representatives. If any provision of this Agreement, or the application of any such provision to any Person or circumstance, shall be held invalid or unenforceable, in whole or in part, such invalidity or unenforceability shall attach only to such provision or part thereof and the remaining part of such provision hereof and this Agreement shall continue in full force and effect. Upon any such determination of invalidity, the Parties shall negotiate in good faith to modify this Agreement so as to effectuate the original intent of the Parties as closely as possible in a reasonably acceptable manner so that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

5.18 Disclosure.

All Parties consent to the disclosure of this Agreement, and information about this Agreement, by any of the Parties, to the public.

THE UNITED STATES OF AMERICA

DATED: February 28, 2024

DAMIAN WILLIAMS
United States Attorney
Southern District of New York

By: /s/ Jean-David Barnea

Jean-David Barnea
Peter Aronoff
Tara Schwartz
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, NY 10007

Endo International plc

DATED: 2/28/2024 BY: /s/ Matthew J. Maletta
Matthew J. Maletta
Executive Vice President, Chief Legal Officer
and Company Secretary

Endo, Inc.

DATED: 2/28/2024 BY: /s/ Matthew J. Maletta
Matthew J. Maletta
Executive Vice President, Chief Legal Officer
and Company Secretary

Exhibit A

DOJ Criminal Plea Agreement

Exhibit B

DOJ Civil Settlement Agreement

Exhibit C

IRS Proofs of Claim

Debtor	POC #	Date Filed	Amends Previous POC (POC #)	Tax Periods	Priority Tax Amount	Priority Interest Amount	Total Priority Amount	GUC Penalty Amount	GUC Other Amount	Total GUC Amount
Actient Pharmaceuticals LLC	489	1/19/2023		2013	$0.00	$0.00	$0.00	$2,670.00	$819.50	$3,489.50
Endo International plc	728	4/26/2023	490	2021	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Generics International (US), Inc.	492	1/19/2023		2013 2016	$0.00	$0.00	$0.00	$4,220.00	$747.58	$4,967.58
Actient Therapeutics LLC	493	1/19/2023		2013	$0.00	$0.00	$0.00	$2,430.00	$745.82	$3,175.82

Generics Bidco I, LLC	495	1/19/2023		2013-2012	$0.00	$0.00	$0.00	$306,576.07	$794,422.35	$1,100,998.42
Endo U.S. Inc.	3289	5/30/2023	494, 507	2006-2013 2016-2018 2020-2021	$2,739,783,109.00	$755,759,160.77	$3,495,542,269.77	$516,700,716.00	$0.00	$516,700,716.00
Endo Pharmaceutical Solutions Inc.	510	1/27/2023	491	2016-2018 2020-2021	$822,550,876.00	$274,701,019.08	$1,097,251,895.08	$241,966,097.00	$267.68	$241,966,364.68
Endo Pharmaceuticals Valera Inc.	511	1/27/2023	496	2016-2018 2020-2021	$822,550,876.00	$274,701,019.08	$1,097,251,895.08	$241,966,577.00	$414.34	$241,966,991.34
DAVA Pharmaceuticals, LLC	512	1/27/2023		2020-2021	$103,348,234.00	$4,527,373.81	$107,875,607.81	$79,928,770.00	$0.00	$79,928,770.00
JHP Group Holdings, LLC	513	1/30/2023		2013 2016-2018 2020-2021	$826,801,533.00	$276,319,570.11	$1,103,121,103.11	$242,008,963.20	$123.48	$242,009,086.68
Endo Health Solutions Inc.	515	1/30/2023		2006-2013 2016-2018 2020-2021	$1,610,550,060.00	$525,270,868.51	$2,135,820,928.51	$241,965,227.00	$0.00	$241,965,227.00
Endo Innovation Valera, LLC	516	1/30/2023		2018 2020-2021	$134,010,579.00	$11,247,827.51	$145,258,406.51	$100,551,118.00	$0.00	$100,551,118.00
Par, LLC	517	1/30/2023		2016	$0.00	$0.00	$0.00	$137,020.00	$14,719.28	$151,739.28

Endo Pharmaceuticals Finance LLC	518	1/30/2023		2017-2018 2020-2021	$221,385,643.00	$38,450,631.34	$259,836,274.34	$148,895,804.00	$0.00	$148,895,804.00
Endo Pharmaceuticals Inc.	519	1/30/2023		2016-2018 2020-2021	$822,550,876.00	$274,701,019.08	$1,097,251,895.08	$241,965,227.00	$0.00	$241,965,227.00
Auxilium International Holdings, LLC	520	1/30/2023		2016	$601,165,233.00	$236,250,387.74	$837,415,620.74	$93,099,423.00	$0.00	$93,099,423.00
Generics International (US) 2, Inc.	521	1/30/2023		2016-2018 2020-2021	$822,550,876.00	$274,701,019.08	$1,097,251,895.08	$241,965,227.00	$0.00	$241,965,227.00
Kali Laboratories 2, Inc.	522	1/30/2023		2016-2018 2020-2021	$822,550,876.00	$274,701,019.08	$1,097,251,895.08	$241,965,227.00	$0.00	$241,965,227.00
Endo Aesthetics LLC	523	1/30/2023		2020-2022	$103,357,485.67	$4,527,373.81	$107,884,859.48	$70,928,770.00	$0.00	$70,928,770.00
Branded Operations Holdings, Inc.	524	1/30/2023		2020-2021	$103,348,234.00	$4,527,373.81	$107,875,607.81	$70,928,770.00	$0.00	$70,928,770.00
Endo Generics Holdings, Inc.	525	1/30/2023		2016-2018 2020-2021	$822,550,876.00	$274,701,019.08	$1,097,251,895.08	$241,965,227.00	$0.00	$241,965,227.00
Slate Pharmaceuticals, LLC	526	1/30/2023		2016	$601,165,233.00	$236,250,387.74	$837,415,620.74	$93,099,423.00	$0.00	$93,099,423.00

Par Pharmaceutical 2, Inc.	527	1/30/2023		2016-2018 2020-2021	$822,550,876.00	$274,701,019.08	$1,097,251,895.08	$241,965,227.00	$0.00	$241,965,227.00
Endo Global Finance LLC	769	4/26/2023		2021	$5,297.00	$78.80	$5,375.80	$0.00	$0.00	$0.00

Exhibit D

USG Resolution Term Sheet

Exhibit E

Illustrative Fixed Consideration Prepayment Schedule

Exhibit 10.39

U.S. Department of Justice

Consumer Protection Branch

450 5th St NW
Washington, DC 20001

February 27, 2024

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Re: Plea Agreement with Endo Health Solutions Inc.

Dear Counsel:

This letter sets forth the plea agreement ("Agreement") between the United States Department of Justice, Civil Division, Consumer Protection Branch ("United States") and your client, Endo Health Solutions Inc. ("EHSI").

Charge

Conditioned on the understandings specified below, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the United States will accept a guilty plea from EHSI to a one-count Information (the "Information"), to be filed in the U.S. District Court for the Eastern District of Michigan (the "Court"), which charges EHSI with a misdemeanor violation of the Food, Drug, and Cosmetic Act ("FDCA"), contrary to Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in that EHSI caused the introduction and delivery for introduction into interstate commerce of Opana ER, a drug that was misbranded in that the drug's labeling lacked adequate directions for use.

Agreement Not to Prosecute

If EHSI enters a guilty plea and a judgment of conviction is entered that is consistent with the terms of the agreed disposition included in this Agreement, and if EHSI otherwise fully

complies with all of the terms of this Agreement, the United States agrees that, other than the charge in the Information in this case, it will not bring any other criminal charges or criminal forfeiture actions against EHSI, Endo International plc, or their present or former companies, affiliates, divisions, or subsidiaries, or their predecessors, successors, or assigns (including, for the avoidance of doubt, any purchaser of the assets of the foregoing entities in the jointly administered bankruptcy cases of *In re Endo International plc*, Bankr. S.D.N.Y. Case No. 22-22549 (the "Endo Bankruptcy")) (collectively, the "Released Parties") for conduct which (1) is covered by the Information; (2) falls within the scope of the investigations conducted by the United States Attorney's Office for the Southern District of Florida and the Consumer Protection Branch of the Department of Justice, or (3) was known to the United States Attorney's Office for the Southern District of Florida or the Consumer Protection Branch of the Department of Justice as of the date of the execution of this Agreement and which relates to the Released Parties' production, sale, marketing, promotion or distribution of Opana ER between 2006 and the present.

The non-prosecution provisions of this sub-section are binding on the Consumer Protection Branch, Civil Division, of the Department of Justice, the United States Attorney's Offices for each of the 94 judicial districts of the United States, and the Criminal Division of the United States Department of Justice, with the exception that it does not prohibit any component of the United States Department of Justice from bringing charges against any culpable individual as a result of such investigation. An investigation and prosecution of any culpable individual, if any, is specifically excluded from the release in this paragraph. EHSI understands that this Agreement does not bind any other government agency, or any component of the Department of Justice, except as specified in this Agreement.

Sentencing Guidelines

The violation of 21 U.S.C. §331(a) and 333(a)(1) to which EHSI is agreeing to plead guilty carries a statutory maximum fine equal to the greatest of: (1) $200,000; (2) twice the gross amount of any pecuniary gain that any persons derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. *See* 18 U.S.C. § 3571(c)(5), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

While the fine provisions of the United States Sentencing Guidelines do not apply to organizational defendants for misdemeanor violations of the FDCA, *see* U.S.S.G. § 8C2.1, the parties stipulate that the Guidelines have been used as a reference to determine the appropriate multiplier for criminal actions brought against organizations under that provision consistent with previous corporate FDCA misdemeanor cases.

Using these fine provisions, EHSI's culpability score of 5 is calculated as follows:

1. 5 points base, *see* U.S.S.G. § 8C2.5(a);

2. 2 points added because EHSI had more than 50 employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offense, *see id*. § 8C2.5(b)(4);

3. with 2 points subtracted because EHSI accepts responsibility for its criminal conduct, *see id*. § 8C2.5(g).

4. Under U.S.S.G. § 8C2.6, a culpability score of 5 results in a 1.0-2.0 multiplier for any criminal fine.

The pecuniary gain earned by EHSI as a result of the sales of misbranded Reformulated Opana ER was approximately $543,000,000. Therefore, the advisory Guidelines Fine Range would be $543,000,000 to $1,086,000,000.

The statutory maximum fine is $1,086,000,000.

In addition to imposing a fine on EHSI, the sentencing judge will order EHSI to pay an assessment of $125, pursuant to Title 18, United States Code, Section 3013, which assessment must be paid by the date of sentencing.

Agreed Disposition

The United States and EHSI agree to recommend and advocate to the Court that, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the appropriate disposition of this case is as follows (the "Agreed Disposition"):

1. FINE: The sentence imposed shall include a criminal fine in the amount of $1,086,000,000;

2. FORFEITURE: Subject to the terms of this Agreement, the sentence shall include criminal forfeiture in the amount of $450,000,000 to be satisfied as discussed below;

3. RESTITUTION: No restitution shall be entered because restitution to other persons is not administratively feasible in this case, and attempting to fashion an order to provide restitution to any such possible persons would result in complication and prolongation of the sentencing process that would outweigh the need to provide restitution to any such possible persons under 18 U.S.C. § 3663(a)(1)(B)(ii); and

4. PROBATION: EHSI shall not be subject to a term of probation.

The Agreed Disposition takes into account, among other things, EHSI's status as a debtor in the Endo Bankruptcy, and EHSI's agreement to an allowed, general unsecured claim not subject to reconsideration or subordination in the amount of $475,600,000, which shall be deemed satisfied as a result of the consummation of the U.S. Government Settlement Agreement (as defined below), to resolve its civil liability arising from the Department of Justice's civil investigation relating to similar conduct (attached as **Exhibit B**) (the "Civil Settlement Agreement").

Criminal Fine

The parties agree that the criminal fine imposed by the Court as part of the Agreed Disposition shall be treated as an allowed, general unsecured claim not subject to reconsideration or subordination in the Endo Bankruptcy, to be paid in accordance with the terms of a separate agreement (the "U.S. Government Settlement Agreement") by and among EHSI, the United States and other relevant parties, providing for the terms of resolving such claim and other federal government claims in the Endo Bankruptcy.

Procedural Matters

The parties agree that, within 3 business days after the expiration of the stay under Fed. R. Bankr. P. 3020(e) following the United States Bankruptcy Court for the Southern District of New York's (the "Bankruptcy Court") confirmation under 11 U.S.C. § 1129 of the chapter 11 plan of reorganization first filed by EHSI and its debtor affiliates in the Endo Bankruptcy on December 19, 2023 at docket number 3355 (as may be amended, modified, or supplemented from time to time, the "Plan of Reorganization"), the parties will jointly request a plea hearing before the Court pursuant to Rule 11 of the Federal Rules of Criminal Procedure. The parties will further request that the plea hearing occur on the earliest possible date available to the Court.

Pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the United States and EHSI agree to make a joint recommendation and advocate to the Court that the Agreed Disposition is the appropriate disposition of this case. The parties agree to request that the Court's acceptance of EHSI's plea and the Plea Agreement, pursuant to Rule 11(c)(3)(A), be deferred until the date of the sentencing hearing (the "Sentencing Hearing Date").

The parties further agree to request that the Sentencing Hearing Date take place no earlier than the date on which the order entered by the Bankruptcy Court confirming the Plan of Reorganization becomes final and non-appealable, but in any event prior to the Plan of Reorganization becoming effective. The parties may jointly agree to request a Sentencing Hearing Date prior to the order confirming the plan becoming final and non-appealable. The Plan of Reorganization shall be amended to provide (or the order confirming the Plan of Reorganization shall provide) that the Court's acceptance of this Agreement and imposition of a sentence consistent with the Agreed Disposition is a condition precedent to the effectiveness of the Plan of Reorganization.

In the event the Endo Bankruptcy is converted from a chapter 11 case to a chapter 7 case, or the Endo Bankruptcy is dismissed, subject to EHSI's right to withdraw from its plea of guilty and from this Agreement upon the occurrence of a Plea Withdrawal Triggering Event, as defined below, the parties agree to jointly request that a plea hearing before the Court pursuant to Rule 11 of the Federal Rules of Criminal Procedure and the Sentencing Hearing Date take place within fourteen days of such event, to the extent a plea hearing and/or sentencing hearing has not yet occurred.

Pursuant to Rule 11(c)(1)(C), if the Court accepts this Agreement on the Sentencing Hearing Date, the Court will be bound to impose a sentence consistent with the Agreed Disposition. If, however, the sentencing judge rejects this Agreement and the Agreed Disposition, pursuant to Rule 11(c)(5), EHSI will have the opportunity to withdraw its plea of guilty and withdraw from the Plea Agreement, and the United States may also withdraw from the Plea Agreement.

Additionally, prior to the Sentencing Hearing Date, EHSI may withdraw its plea of guilty and from this Agreement if the following "Condition Precedent to Agreement Effectiveness" is not satisfied or any of the following "Plea Withdrawal Triggering Events" occurs:

Condition Precedent to Agreement Effectiveness

(1) the Bankruptcy Court shall have approved EHSI's entry into and performance under this Agreement.

Plea Withdrawal Triggering Events

(1) The Bankruptcy Court rejects, or otherwise declines to approve, EHSI's and its debtor affiliates' entry into and performance under the Civil Settlement Agreement;

(2) the Bankruptcy Court rejects, or otherwise declines to approve, EHSI's and its debtor affiliates' entry into and performance under the U.S. Government Settlement Agreement;

(3) the Bankruptcy Court converts the Endo Bankruptcy from a chapter 11 case to a chapter 7 case, or the Bankruptcy Court dismisses the Endo Bankruptcy;

(4) the Bankruptcy Court denies confirmation of, or otherwise declines to confirm, the Plan of Reorganization which contemplates this Plea Agreement;

(5) if, upon the exercise of its fiduciary duties, EHSI concludes that one or more of the conditions precedent to emergence from bankruptcy as contemplated in the Plan of Reorganization cannot reasonably be satisfied and therefore provides notice on the public docket of the Endo Bankruptcy that it is withdrawing or abandoning the Plan of Reorganization; or

(5) the Department of Health and Human Services Office of Inspector General ("HHS-OIG") exercises, or confirms its intent to exercise such authority in writing, any available authority to exclude any of EHSI's parent companies or any of their respective affiliates, divisions, or subsidiaries (other than EHSI), or its or their successors or assigns (including, for the avoidance of doubt, any purchaser of the assets of the foregoing entities in the Endo Bankruptcy), from participation in Federal health care programs based, in any part, on the production, sale, marketing, promotion or distribution of Opana ER between 2006 and the present, including the conduct described in **Schedule A**, the Information filed at the time of the plea hearing, or the Civil Settlement Agreement.

If a Plea Withdrawal Triggering Event occurs, EHSI shall determine whether to withdraw its plea of guilty, and shall notify the United States of its decision, within 14 days. If EHSI elects to withdraw its plea of guilty, EHSI may also elect to withdraw from the Agreement. If a Plea Withdrawal Triggering Event has occurred and EHSI elects to withdraw its plea of guilty after the Court has accepted EHSI's plea, the United States agrees that EHSI will have met the conditions set forth in Rule 11(d)(2)(B). If EHSI elects not to withdraw its plea of guilty within 14 days of a Plea Withdrawal Triggering Event, EHSI will have waived its right to withdraw its plea based on that Plea Withdrawal Triggering Event, except under the circumstances set forth in Rule 11(c)(5). EHSI's decision not to withdraw its plea based on a Plea Withdrawal Triggering Event does not waive its right to withdraw its plea based on another Plea Withdrawal Triggering Event. If a Plea Withdrawal Triggering Event does not occur, EHSI shall not be permitted to withdraw its plea of guilty, except under the circumstances set forth in Rule 11(c)(5). EHSI and the United States may jointly to agree the extend the 14-day period referenced herein.

In the event that EHSI withdraws its guilty plea, the Information filed at the time of the plea hearing shall remain pending and EHSI will waive defenses based on the Speedy Trial Act and the relevant statute of limitations with respect to the offense conduct set forth in the

Information for a period of 180 days from the date of withdrawal. Nothing in this Agreement shall be deemed a waiver by EHSI of the provisions of Federal Rule of Evidence 410.

Rights Regarding Sentencing

Except as otherwise provided in this Agreement, the parties reserve their rights to correct any misstatements relating to the sentencing proceedings and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, the parties may inform the sentencing judge and the United States Probation Office of: (1) this Agreement; and (2) the full nature and extent of EHSI's activities and relevant conduct with respect to this case.

Stipulations

The United States and EHSI stipulate and agree to the statements set forth in the attached **Schedule A**, which hereby are made a part of this Agreement. To the extent that the parties do not stipulate to a particular fact or legal conclusion, each reserves the right to argue the existence of and the effect of any such fact or conclusion upon the sentence. Moreover, this agreement to stipulate on the part of the United States is based on the information and evidence that the United States possesses as of the date of this agreement. Thus, if the United States obtains or receives additional evidence or information prior to sentencing that it determines to be credible and to be materially in conflict with any stipulation in the attached **Schedule A**, the United States shall not be bound by any such stipulation. These stipulations do not restrict the parties' right to respond to questions from the Court and to correct misinformation that may be provided to the Court. Accordingly, the parties agree that they will not challenge at any time, using any means, the District Court's acceptance of those stipulated facts.

Waiver of Appeal and Post-Sentencing Rights

The United States and EHSI agree that, provided that the District Court imposes a sentence in accordance with this Rule 11(c)(1)(C) Agreement, neither party will appeal that sentence. EHSI further agrees that, in exchange for the concessions the United States made in entering into this Rule 11(c)(1)(C) Agreement, and provided that this Agreement remains in full force and effect it will not challenge its conviction for any reason by any means, other than ineffective assistance of counsel, and it will not challenge or seek to modify any component of its sentence for any reason by any means, other than ineffective assistance of counsel. The term "any means" includes, but is not limited to, a direct appeal under 18 U.S.C. § 3742 or 28 U.S.C. § 1291, a motion to vacate the sentence under 28 U.S.C. § 2255, or any other motion, however captioned, that seeks to attack or modify any component of the judgment of conviction or sentence.

Forfeiture

Subject to the proviso at the end of this paragraph, as part of its acceptance of responsibility for its violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), and pursuant to 18 U.S.C. §982(a)(7) and 18 U.S.C. § 24(a)(2), EHSI agrees to forfeit to the United States all of its right, title, and interest in all property EHSI obtained that constituted and was derived, directly and indirectly, from gross proceeds traceable to misbranded Opana ER that was introduced or delivered for the introduction into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). EHSI further agrees that the aggregate value of such property was $450,000,000; that one or more of the conditions set forth in 21 U.S.C. § 853(p) exists; and that the United States is therefore entitled to forfeit substitute assets in an amount not to exceed $450,000,000 (the "Forfeiture Judgment"); *provided* that if EHSI withdraws, for any reason, from the Agreement or its plea of guilty, the United States shall not be entitled to the

Forfeiture Judgment and any statements contained herein relating thereto shall be deemed null and void.

In order to avoid the unnecessary imposition of duplicative fines, penalties, and/or forfeiture for the same or similar misconduct, the United States agrees to credit against the Forfeiture Judgment the aggregate nominal amount allocated in settlement of claims asserted by state, tribal, or local government entities (the "Public and Tribal Opioid Claims") under the Plan of Reorganization up to the total amount of the Forfeiture Judgment (the "Public and Tribal Opioid Credit"). The Plan of Reorganization contemplates that the Public and Tribal Opioid Claims may be satisfied either by (i) a series of installment payments in an aggregate nominal amount in excess of $450,000,000, or (ii) a lump-sum discounted prepayment intended to equal the present value of the aforementioned installment payments. Irrespective of which payment option is utilized, the United States agrees that the effectiveness of the Plan of Reorganization will result in a Public and Tribal Opioid Credit in excess of $450,000,000 and will fully, finally, and permanently satisfy the Forfeiture Judgment no later than one business day after the effective date of the Plan of Reorganization.

The parties agree that no earlier than the Sentencing Hearing Date, upon the Court's acceptance of this Plea Agreement, the Court will enter an agreed order of forfeiture (the "Forfeiture Order") implementing the Forfeiture Judgment and providing that the Forfeiture Judgment shall not become final or effective until one business day after the effective date of the Plan of Reorganization and that until such time the Forfeiture Judgment shall not be incorporated into the criminal judgment. The parties further agree that the Forfeiture Order shall provide that the Forfeiture Judgment will be fully, finally, and permanently satisfied by the Public and Tribal Opioid Credit no later than one business day after the effective date of the Plan of Reorganization.

If, however, by the Sentencing Hearing Date, the Endo Bankruptcy is converted from a chapter 11 case to a chapter 7 case, the Endo Bankruptcy is dismissed, or EHSI provides notice on the public docket of the Endo Bankruptcy that it is withdrawing or abandoning the Plan of Reorganization, subject to EHSI's right to withdraw from its plea of guilty and from this Agreement upon the occurrence of a Plea Withdrawal Triggering Event, then the Forfeiture Order by the Court shall become effective as of the Sentencing Hearing Date and be incorporated into the criminal judgment.

In the event that the Public and Tribal Opioid Credit does not occur, and subject in all respects to EHSI's right to withdraw its plea of guilty and withdraw from this Agreement upon the occurrence of a Plea Withdrawal Triggering event, EHSI agrees to the following:

(a) EHSI will tender to the United States Marshals a payment in satisfaction of the Forfeiture Judgment within 60 business days following entry of the judgment of conviction. If this payment is not paid by close of business of the 60th day following the entry of the judgment of conviction: (1) interest shall accrue on any unpaid portion thereof at the judgment rate of interest from that date; and (2) the United States shall be authorized to conduct any discovery needed to identify, locate, or dispose of property sufficient to pay the Forfeiture Judgment in full or in connection with any petitions filed with regard to proceeds or substitute assets, including depositions, interrogatories, and requests for production of documents, and the issuance of subpoenas.

(b) EHSI will not file, or cause any other person or entity to file, or assist any other person or entity in filing, any claim to the Forfeiture Judgment, or in any other way interfere with or delay the forfeiture of the Forfeiture Judgment.

(c) EHSI will not file a claim or a petition for remission or mitigation in any proceeding involving the Forfeiture Judgment and will not cause or assist anyone else in doing so.

(d) Upon reasonable request from the United States, EHSI will agree to reasonably cooperate with the United States in connection with responding to any claims asserted against the Forfeiture Judgment.

(e) EHSI will waive the requirements of Rules 32.2 and 43(a) of the Federal Rules of Criminal Procedure regarding notice of the forfeiture in the charging instrument, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. EHSI understands that criminal forfeiture is part of the sentence that may be imposed in this case and waives any failure by the court to advise it of this pursuant to Rule 11(b)(1)(J) of the Federal Rules of Criminal Procedure when the plea is entered. EHSI will waive any and all constitutional, statutory, and other challenges to the forfeiture on any and all grounds, including that the forfeiture constitutes an excessive fine or punishment under the Eighth Amendment.

Cooperation

EHSI shall continue to cooperate with the United States' ongoing investigation, if any, and any resulting prosecutions, if any, pertaining to investigations by the Consumer Protection Branch and United States Attorney's Office for the Southern District of Florida in connection with matters relating to the production, sale, marketing, promotion or distribution of Opana ER until 180 days after the effective date of the Plan of Reorganization. As reflected by Sections 9.28.700 through 9.28.750 in the Justice Manual, EHSI's cooperation will include: (1) upon request, making disclosures of all relevant facts about any individuals who were involved in the misconduct that falls within the scope of the investigation conducted by the Consumer Protection Branch of the Department of Justice and the United States Attorney's Office for the Southern District of Florida (including, but not limited to, the conduct that forms the basis for this Agreement, including conduct described in **Schedule A** and the Information); (2) to the extent possible, making witnesses available for interview and providing the United States relevant documentary evidence; and (3) voluntary disclosure of other wrongdoing identified by EHSI.

Notwithstanding any provision of this Agreement, EHSI is not required to: (1) request of its current or former directors, officers, agents, or employees that they forgo seeking the advice of an attorney or that they act contrary to that advice; (2) take any action against its directors, officers, agents, or employees for following their attorney's advice; and (3) waive any privilege or claim of work product protection.

Other Provisions

No provision of this Agreement shall preclude EHSI from pursuing in an appropriate forum, when permitted by law, an appeal, collateral attack, writ, or motion claiming that EHSI received constitutionally ineffective assistance of counsel.

Corporate Authorization

EHSI agrees that, subject to obtaining approval from the Bankruptcy Court, it is authorized to enter into this Agreement, that it has authorized the undersigned corporate representative, to take this action, and that all corporate formalities for such authorization have been observed.

EHSI has provided to the United States a certified copy of a resolution of the governing body of EHSI, affirming that it has authority to enter into this Agreement and has (1) reviewed this Plea Agreement in this case; (2) consulted with outside legal counsel in this matter; (3) authorized execution of this Agreement; (4) authorized EHSI to enter a conditional plea of guilty if authorized in the Endo Bankruptcy; and (5) authorized the undersigned corporate representative to execute this Agreement and all other documents necessary to carry out the provisions of this Agreement. A copy of this resolution attached hereto as **Exhibit A**.

No Other Promises

This Agreement and the Exhibits hereto constitute the plea agreement between EHSI and the United States and together their terms supersede any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.

Sincerely,

AMANDA LISKAMM
DIRECTOR

/s/ Gabriel H. Scannapieco
Gabriel H. Scannapieco
Assistant Director

Tara M. Shinnick
Ben Cornfeld
Trial Attorneys
Consumer Protection Branch
Civil Division
Department of Justice

COMPANY REPRESENTATIVE'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Endo Health Solutions Inc. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Outside counsel and I discussed all of the Agreement's provisions, including those addressing the charges, sentencing, stipulations, and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this Agreement. Counsel fully advised me of the rights of the Company, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Executive Vice President, Chief Legal Officer and Secretary of the Company and that I have been duly authorized by the Board of Directors of the Company to execute this Agreement on behalf of the Company. My ability to bind the Company remains subject to approval by the United States Bankruptcy Court for the Southern District of New York.

Date: February 28, 2024 Endo Health Solutions Inc.

By: /s/ Matthew J. Maletta

Matthew J. Maletta
Executive Vice President,
Chief Legal Officer & Secretary

CERTIFICATE OF COUNSEL

I am counsel for Endo Health Solutions Inc. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined the relevant Company documents and have discussed the terms of this Agreement, including those addressing the charges, sentencing, stipulations, and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this Agreement, with the Company's Board of Directors. Based on our review of the foregoing materials and discussion, I am of the opinion that, subject to approval of the United States Bankruptcy Court for the Southern District of New York, the representative of the Company has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of the Agreement with the Board of Directors, the Chief Executive Officer, and the [ ] of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: February 28, 2024 Endo Health Solutions Inc.

By: /s/ Carole S. Rendon

Carole S. Rendon
Baker & Hostetler LLP
Counsel for Endo Health Solutions Inc.

Schedule A

Endo Health Solutions Inc. admits that it is responsible for the acts of its employees and agents, described below, and admits the following facts:

1. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. At all times relevant to the Information, defendant Endo Health Solutions Inc. (hereinafter "ENDO"), was either a direct or indirect parent company of Endo Pharmaceuticals Inc. and was a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

2. ENDO was engaged in the pharmaceutical business throughout the United States, including in the Eastern District of Michigan. ENDO's business included the marketing, promotion, and sales of extended-release opioid drugs containing oxymorphone under the brand names Opana ER and reformulated Opana ER with INTAC (hereinafter "reformulated Opana ER").

3. Between 2006 and December 2016, ENDO marketed Opana ER, and then reformulated Opana ER, to prescribers and healthcare providers throughout the United States. Between 2006 and July 2017, ENDO sold Opana ER and then reformulated Opana ER throughout the United States.

4. Opana ER and reformulated Opana ER were Schedule II drugs under the Controlled Substances Act. The DEA defines Schedule II drugs as those drugs "with a high potential for abuse, with use potentially leading to severe psychological or physical dependence." The labels for Opana ER and reformulated Opana ER contained "black box" warnings of serious risks from taking the opioid medication, such as addiction and respiratory depression, which can lead to death.

5. The U.S. Food and Drug Administration (FDA) first approved Opana ER in 2006 for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. In July 2010, ENDO submitted a new drug application (NDA) to FDA for a reformulated version of Opana ER. In that NDA, ENDO asked FDA to approve a product label that stated: "[reformulated Opana ER] is formulated as a hard tablet to withstand crushing forces in excess of 800 Newtons. In standardized . . . studies, [reformulated Opana ER] demonstrated resistance to crushing, breaking, pulverization or powdering; however, the clinical significance of these properties and the impact on abuse liability has not been established."

6. In January 2011, FDA, after receiving the clinical data submitted by ENDO, recommended that reformulated Opana ER's "product label should not include language asserting that [it] provides resistance to crushing, because it may provide a false sense of security since the product may be chewed and ground for subsequent abuse."

7. In December 2011, FDA approved reformulated Opana ER, which ENDO called Opana ER with INTAC, which was bioequivalent to Opana ER. FDA did not, however, approve labeling for reformulated Opana ER describing crush resistance, tamper resistance, or abuse-deterrent properties, because FDA concluded that the available data was inadequate to support such labeling.

8. In February 2012, ENDO submitted proposed promotion materials for reformulated Opana ER to FDA for advisory review. In April 2012, FDA sent ENDO a marketing claims review letter stating that claims and representations in the proposed promotion materials suggesting that reformulated Opana ER offered any therapeutic advantage over the

original formulation—including claims of "mechanical stability," "mechanical strength," and "obstacle[s]" or "resistance to crushing by tools"—"ha[ve] not been demonstrated by substantial evidence or clinical experience" and "misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation . . . confers some form of abuse deterrence properties when this has not been demonstrated by substantial evidence." The FDA concluded:

> We are especially concerned from a public health perspective because the presence of this information in the detail aid could result in health care practitioners or patients thinking that the new formulation is safer than the old formulation, when this is not the case.

Following FDA's recommendation, ENDO removed the proposed claims identified in FDA's claims review letter and did not include them in ENDO's marketing and promotional materials for reformulated Opana ER.

9. In February 2013, ENDO submitted an NDA supplement to FDA, proposing new labeling regarding abuse deterrence for reformulated Opana ER. In May 2013, FDA denied ENDO's request for the addition of abuse deterrent language on reformulated Opana ER's label, noting that the drug could still be abused by being ground into powder or cut into small pieces, the data submitted was insufficient, and that the "ease with which the product can be manipulated . . . [is] not consistent with a formulation that would provide a reduction in oral, intranasal or intravenous abuse of OPANA ER."

10. ENDO hired hundreds of sales representatives to conduct in-person marketing of Opana ER and reformulated Opana ER (known in the industry as "detailing") of healthcare providers. ENDO's analyses showed that its detailing of healthcare providers was effective at increasing the drug's sales, which is a finding generally consistent with the effect of detailing efforts for branded pharmaceuticals in the industry.

11. Despite FDA's guidance to ENDO, from April 2012 through May 2013, certain ENDO sales representatives marketed reformulated Opana ER to prescribers by touting Opana ER's purported abuse deterrence, crush resistance and/or tamper resistance. Moreover, certain ENDO sales managers were aware that certain sales representatives were making claims regarding reformulated Opana ER's purported abuse deterrence, crush resistance, and/or tamper resistance during sales calls.

12. In January 2013, ENDO supplied its sales representatives with demonstration cards that contained sample rods of the INTAC technology used in reformulated Opana ER. Some ENDO sales representatives improperly hit the demonstration rods with hammers and conducted other demonstrations with sample rods to attempt to convey the message that reformulated Opana ER was, in fact, crush proof, tamper resistant, and/or abuse deterrent until May 2013.

13. In December 2016, ENDO voluntarily stopped the detailing of reformulated Opana ER by sales representatives to healthcare providers.

14. ENDO continued to sell reformulated Opana ER until July 2017. ENDO voluntarily withdrew the product from the market after FDA requested that ENDO do so due to concerns related to intravenous abuse of the product.

15. The FDA-approved labeling for reformulated Opana ER did not provide adequate information for healthcare providers to safely prescribe reformulated Opana ER for use as an opioid that is abuse deterrent. For example, the FDA approved labeling for reformulated Opana ER did not reflect reformulated Opana ER's purported abuse-deterrent, crush resistant, and/or

tamper resistant properties that certain sales representatives conveyed to healthcare providers when marketing reformulated Opana ER (as described in paragraphs 11 and 12 above).

16. As a result of the conduct described above, ENDO is responsible for the misbranding of reformulated Opana ER by marketing the drug in a manner designed to convey abuse deterrence, but with a label that failed to include adequate directions for use for its claimed abuse deterrence, in violation of the Federal Food, Drug, and Cosmetic Act.

Exhibit 10.40

SETTLEMENT AGREEMENT

This Settlement Agreement (this "Agreement") is entered into among (a) the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Defense Health Agency (DHA), acting on behalf of the TRICARE Program; the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP); and the United States Department of Veterans Affairs (VA) (collectively, the "United States"); (b) Endo Health Solutions Inc. ("Endo"); and (c) relator Loretta Reed ("Relator"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

A. At all relevant times, Endo, a Delaware corporation, manufactured, marketed, and sold pharmaceutical products in the United States, including long-acting opioid analgesics Opana ER and Opana ER with INTAC (collectively, "Opana ER"). Opana ER is an opioid drug whose label contained "black box" warnings of serious risks from taking the drug, such as addiction and respiratory depression, which can lead to death.

B. On April 29, 2019, Relator filed a *qui tam* action against Endo and others in the United States District Court for the Southern District of Florida captioned *United States ex rel. Reed v. Endo International PLC, et al.*, No. 9:19-cv-80574 (S.D. Fla.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) and the analogous provisions of a number of state and local false claims acts (the "Civil Action").

C. On August 16, 2022 (the "Petition Date"), Endo and seventy-five affiliated entities (collectively, the "Initial Debtors") each filed a voluntary petition under Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code") in the United States Bankruptcy Court for the Southern District of New York (the "S.D.N.Y. Bankruptcy Court"). On May 25, 2023 and May 31, 2023, a total of four additional entities (together with the Initial Debtors, the "Debtors") filed voluntary petitions under Chapter 11 of the Bankruptcy Code. The Debtors are operating their businesses and managing their properties as debtors in possession pursuant to Bankruptcy Code §§ 1107(a) and 1108. On August 17, 2022, the S.D.N.Y. Bankruptcy Court entered an order authorizing the joint administration and procedural consolidation of the Debtors' chapter 11 cases pursuant to Federal Rule of Bankruptcy Procedure 1015(b) under the case captioned *In re Endo International PLC, et al.*, No. 22-22549 (Bankr. S.D.N.Y.) (the "Chapter 11 Cases") (Jointly Administered). The Debtors in the Chapter 11 Cases are listed in **Exhibit A** hereto along with the last four digits of each Debtor's registration number in the applicable jurisdiction.

D. On May 30, 2023, the United States Department of Justice, Civil Division, Fraud Section ("Fraud Section") filed Claim No. 3157 on behalf of HHS, DHA, OPM, and VA against Endo in the Chapter 11 Cases, alleging that from 2011 to 2017 Endo knowingly caused the submission of false and fraudulent claims to federal healthcare programs for prescriptions of Opana ER without a medically accepted indication.

E. On such date as may be determined by the Court, Endo will plead guilty pursuant to Fed. R. Crim. P. l l(c)(l)(C) (the "Plea Agreement") to an Information to be filed in *United States v. Endo Health Solutions Inc.*, Criminal Action No. [to be assigned] (E.D. Mich.) (the "Criminal Action") that will allege a single misdemeanor violation of Title 21, United States

Code, Sections 331(a), 333(a)(1) and 352(f)(1), namely, the introduction into interstate commerce of a misbranded drug, Opana ER.

F. The United States contends that Endo caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (Medicaid); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (TRICARE); the FEHBP, 5 U.S.C. §§ 8901-8914; and the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17 (VA) (collectively, the "Federal Healthcare Programs").

G. The United States contends that it has certain civil claims against Endo arising from Endo's marketing, promotion and sale, and manufacturing of Opana ER from 2011 to 2017, as alleged in the Addendum to the Fraud Section's Claim No. 3157 filed in the Chapter 11 Cases, attached hereto in **Exhibit B**. The conduct set forth in this Paragraph G is referred to below as the "Covered Conduct."

H. On December 19, 2023, the Debtors filed an amended chapter 11 plan of reorganization in the S.D.N.Y. Bankruptcy Court, which will incorporate the terms of this Agreement and the transactions contemplated hereunder. Pursuant to the chapter 11 plan, substantially all of the Debtors' assets will be directly or indirectly acquired by an entity (including its ultimate parent, the "Buyer") which will be owned on the effective date of such plan by certain of the Debtors' creditors.

I. This Agreement is neither an admission of wrongdoing or liability by Endo or by the Debtors nor a concession by the United States that its claims are not well founded. Endo and the Debtors deny all allegations in Claim No. 3157 and deny that they engaged in the Covered Conduct.

J. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the United States' claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. The Debtors agree that the United States shall have an allowed, not subject to reconsideration or subordination, general unsecured claim in the Chapter 11 Cases in the amount of Four Hundred Seventy-Five Million Six Hundred Thousand Dollars ($475,600,000) ("Civil Settlement Claim Amount"). The Civil Settlement Claim Amount shall be deemed satisfied as provided for in the U.S. Government Settlement Agreement as defined in Paragraph 2 below.

2. The chapter 11 plan and supporting documents, including the U.S. Government Settlement Agreement (defined below) and this Agreement, shall provide for the allowance and treatment of Claim No. 3157 and any other potential claims associated with the Covered Conduct to the extent set forth in this Agreement. The satisfaction in full of the Civil Settlement Claim Amount shall be provided for in a separate agreement (the "U.S. Government Settlement Agreement") consistent with the DOJ Economic Term Sheet[1] and otherwise in form and substance satisfactory to the Debtors, the United States, and the Buyer, to be docketed in the Chapter 11 Cases, and subject to the approval of the S.D.N.Y. Bankruptcy Court as set forth herein. Only the amount(s) up to Two Hundred Thirty-Two Million Dollars ($232,000,000.00) paid to the United States in satisfaction of the Civil Settlement Claim Amount shall constitute restitution to the United States.

[1] "DOJ Economic Term Sheet" means that term sheet appended as Exhibit A to the *Notice of Filing of Term Sheet* filed at docket no. 3118 on the docket of the Chapter 11 Cases.

3. Conditioned upon either (a) the United States exercising its Call Right and receiving the Prepayment Amount as specified in the U.S. Government Settlement Agreement, (b) the Purchaser Parent exercising its right to pay the Prepayment Amount as specified in the U.S. Government Settlement Agreement, or (c) the United States receiving an installment payment as specified in the U.S. Government Settlement Agreement, and as soon as feasible after receipt, the United States shall pay to the Relator a fifteen (15) percent share of the actual amount that the United States receives in satisfaction of the Civil Settlement Claim Amount by electronic funds transfer (the "Relator's Share"). If the United States receives payment in installment payments, the Relator shall receive a fifteen (15) percent share of each installment payment in satisfaction of the Civil Settlement Claim Amount. For avoidance of doubt, other than as specified in this Agreement, Relator has no entitlement to a share of any other claim by the United States against Endo, whether civil, criminal, or administrative.

4. Endo agrees to pay Relator's reasonable expenses, attorneys' fees and costs on the effective date of the chapter 11 plan of reorganization, as contemplated by 31 U.S.C. § 3730(d) and comparable provisions of any applicable state statutes, in the amount of $75,000, and will do so in accordance with written instructions to be provided by Relator's counsel, in full and complete satisfaction of Relator's claims for attorneys' fees, expenses, and costs. No additional attorneys' fees, expenses, or costs, whether related to 31 U.S.C. § 3730(d)(1) or otherwise, shall be paid to or claimed by Relator or her counsel.

5. Subject to the exceptions in Paragraph 8 (concerning reserved claims) below, and conditioned on Paragraphs 1 and 2 above and Paragraph 11 (concerning treatment of claims in the Chapter 11 Cases) below and the United States' receipt of any payment as specified in the U.S. Government Settlement Agreement, the United States releases Endo together with its

current and former parent corporations; direct or indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (collectively, the "Released Entities") from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; or the common law theories of payment by mistake, unjust enrichment, nuisance, and fraud.

6. Endo understands and acknowledges that as a result of the guilty plea described in Paragraph E of the Preamble above, it will be excluded pursuant to 42 U.S.C. § 1320a-7(a)(1) from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). Such exclusion shall have national effect and shall be effective after Endo has been convicted, as defined in 42 U.S.C. § 1320a-7(i), and after notice has been provided in accordance with 42 U.S.C. § 1320a-7(c) and 42 C.F.R. §§ 1001.2001–1001.2002. After Endo is excluded, Federal health care programs shall not pay anyone for items or services, including administrative and management services furnished, ordered, or prescribed by Endo in any capacity.

7. Conditioned upon either (a) the United States' exercising its Call Right and receiving the Prepayment Amount as specified in the U.S. Government Settlement Agreement, (b) the Purchaser Parent exercising its right to pay the Prepayment Amount and the United States receiving the Prepayment Amount as specified in the U.S. Government Settlement Agreement, or (c) the United States receiving an installment payment as specified in the U.S. Government Settlement Agreement, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases the Released Entities together with their current or former owners, officers, directors, employees, agents, shareholders, and attorneys; and the heirs, representatives, family

members, successors and assigns of any of them) from claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages, costs and expenses of any kind, whether known or unknown as of the Effective Date that Relator has, may have, could have asserted, or may assert in the future against the Released Entities on her behalf, on behalf of the United States, on behalf of any state or local government or sovereign, or on behalf of any other person or entity, including but not limited to any claim relating to in any way the Covered Conduct, the allegations in the *qui tam* complaint, the investigation and prosecution of this matter, or the negotiation of the Agreement, any claims for attorneys' fees, costs, or expenses, including under 31 U.S.C. § 3730(d) or any other state or local law that is similar, comparable, or equivalent to 31 U.S.C. § 3730(d) (including, without limitation, the law governing each claim set forth in the *qui tam* complaint), including all liability, claims, demands, actions or causes of action existing as of the Effective Date, fixed or contingent, in law or in equity, in contract or in tort, or under any federal or state statute, regulation, or common law; ***provided however***, that Relator's release of her state false claims act claims shall not become effective until the earlier of: (a) the adjudication by the United States District Court for the Southern District of Florida of the majority of Relator's claim(s) to a relator's share under any state law that is similar, comparable, or equivalent to 31 U.S.C. § 3730(d); (b) the settlement or resolution of the majority of such claim(s); or (c) two (2) calendar years after the effective date of the plan of reorganization in the chapter 11 cases. Notwithstanding anything to the contrary herein, Relator's state false claims act claim(s) shall not impose any liability or obligation on the Released Entities after the Effective Date of this Agreement. Relator represents and warrants that she has not assigned or transferred any of her claims to any person, entity, or thing.

8. Notwithstanding the releases given in Paragraph 5 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released under this Agreement:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal Healthcare Programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability of corporate entities other than the Released Entities;

h. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

i. Any liability for failure to deliver goods or services due; and

j. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

9. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns fully and

finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement, the U.S. Government Settlement Agreement, the Civil Action, the Criminal Action, and/or any recovery by the United States relating to Endo.

10. Subject to the exceptions in Paragraph 7, Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases the Released Entities, and their officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) or any other state or local law that is similar, comparable, or equivalent to 31 U.S.C. § 3730(d) (including, without limitation, the law governing each claim set forth in the qui tam complaint) for expenses or attorneys' fees and costs.

11. In connection with the Chapter 11 Cases, the United States and Endo and the Debtors agree:

a. The Debtors shall file a motion or other appropriate request (an "Approval Motion") seeking approval to enter into and perform this Agreement, which may include seeking such approval as part of the Debtors' seeking confirmation of a chapter 11 plan. Before filing such Approval Motion, the Debtors shall obtain the United States' consent as to form of such Approval Motion or the applicable provisions of a chapter 11 plan related to approval of this Agreement (not to be unreasonably withheld).

b. The proposed order approving the Debtors' performance hereunder shall provide that, upon the Effective Date, the Civil Settlement Claim Amount shall not be subordinated, disallowed, or reconsidered in these Chapter 11 Cases, including based on 11

U.S.C. §§ 510, 726(a)(4) or for any other reason, and shall be fully satisfied through the approval of, and the Buyer's entry into, the U.S. Government Settlement Agreement.

c. The Debtors will not propose a sale, chapter 11 plan of reorganization, or liquidation that is materially inconsistent with this Agreement unless this Agreement is rescinded.

d. Endo and the United States each have the option to rescind this Agreement in all respects in the event of any of the following:

(1) If the S.D.N.Y. Bankruptcy Court does not grant the Approval Motion.

(2) If the S.D.N.Y. Bankruptcy Court does not grant the Debtors' motion or other appropriate request seeking approval to enter into and perform under the Plea Agreement.

(3) If the S.D.N.Y. Bankruptcy Court does not grant the Debtors' motion or other appropriate request seeking approval to enter into and perform under the U.S. Government Settlement Agreement.

(4) If the S.D.N.Y. Bankruptcy Court does not confirm a chapter 11 plan of reorganization submitted by the Debtors that contemplates the Debtors' entry into this Agreement (a "Plan").

(5) If, upon the exercise of their fiduciary duties, the Debtors withdraw or abandon any Plan.

e. Nothing in this Agreement shall affect the United States' right to object to any proposed chapter 11 plan of reorganization or liquidation for any reason not covered by this Agreement.

12. Nothing in this Agreement exempts the United States or Relator from or otherwise grants any relief under the bar date order, to the extent applicable, entered in the Chapter 11 Cases on April 3, 2023, as amended on June 23, 2023 and July 14, 2023 with respect to the Debtors.

13. If Endo defaults on any material obligation under this Agreement; if there is a dismissal or conversion of the Chapter 11 Cases, voluntary or otherwise; or if the Debtors' obligations under this Agreement are voided for any reason, the United States in its sole discretion may elect to rescind the releases in this Agreement and pursue the Civil Action or bring any civil and/or administrative claims, actions, or proceedings against Endo for the Covered Conduct. In the event of a rescission, the United States fully reserves any and all setoff and recoupment rights, claims, and defenses as to the Debtors that the United States may have, and the United States may pursue its claims in the Chapter 11 Cases as well as in any other case, action, or proceeding, in each case, subject to applicable law. In the event of a rescission, the Debtors fully reserve all rights, claims, privileges, and defenses with respect to the United States or Relator and any claims that the United States or Relator may assert, including any claim, case, action or proceeding in connection with the Covered Conduct.

14. If Endo or the Debtors exercise the option of recission pursuant to Paragraph 11 of this Agreement or if the United States exercises the option of rescission pursuant to any Paragraph of this Agreement, the Agreement will be rescinded except for Paragraphs 11, 13, 14, and 27. If this Agreement is rescinded for any reason, the Debtors will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims, actions or proceedings that are brought by the United States within sixty (60) calendar days of written notification that the releases have

been rescinded, except to the extent such defenses were available on the last date that this Agreement is executed by any Party.

15. The satisfaction of the Civil Settlement Claim Amount, as provided for in the U.S. Government Settlement Agreement, represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct and such other claims that are resolved in connection with the U.S. Government Settlement Agreement due solely to the Debtors' financial condition.

16. Endo waives and shall not assert any defenses Endo may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

17. Endo fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Endo has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct, the United States' investigation or prosecution thereof, or the Civil Action other than any liability based upon obligations created by this Agreement; *provided* that the releases described in this paragraph shall be withdrawn and rescinded without need for further action by Endo if the United States' releases described in Paragraph 5 of this Agreement are rescinded for any reason, including pursuant to Paragraph 13 of this Agreement.

18. Conditioned on the effectiveness of the releases in Paragraphs 5 and 7 of this Agreement and subject to the reservation at the end of this Paragraph, Endo fully and finally

releases Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Endo has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct, Relator's investigation or prosecution thereof, or the Civil Action other than any liability based upon obligations created by this Agreement. Endo specifically reserves and does not release its right to contest on any basis any claim by Relator to an award of expenses, attorneys' fees, and costs.

19. The Civil Settlement Claim Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, or carrier), TRICARE, FEHBP, or any state payer, related to the Covered Conduct; and Endo agrees not to resubmit to any Medicare contractor, TRICARE, FEHBP, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

20. Endo agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Endo, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement and any related plea agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) Endo's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement, the U.S. Government Settlement Agreement, and any related plea agreement; and

(5) the payment the United States receives pursuant to this Agreement and the U.S. Government Settlement Agreement and any payments that Relator might receive, including costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare, Medicaid, TRICARE, and FEHBP Programs (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Endo, and Endo shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Endo or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Endo further agrees that within ninety (90) days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid fiscal agents and FEHBP carriers and/or contractors, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost

statements, information reports, or payment requests already submitted by Endo or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Endo agrees that the United States, at a minimum, shall be entitled to recoup from Endo any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Endo or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Endo or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Endo's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

21. Endo agrees to reasonably cooperate fully and truthfully with the United States' investigation relating to the Covered Conduct of individuals and entities not released in this Agreement. Upon reasonable notice, Endo shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its reasonable best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Unless already produced or publicly available, Endo further agrees to furnish to the United States, upon

reasonable request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf. Notwithstanding any provision of this Agreement, (1) Endo is not required to request of their current or former officers, agents, or employees that they forgo seeking the advice of an attorney or that they act contrary to that advice; (2) Endo is not required to take any action against their officers, agents, or employees for following their attorney's advice; and (3) Endo is not required to waive or furnish to the United States any materials subject to any privilege or claim of work product protection. Endo's obligations as set forth in this paragraph will terminate one hundred eighty (180) calendar days after the Effective Date.

22. This Agreement is intended to be for the benefit of the Parties, entities and individuals referenced herein only. The Parties do not release any claims against any other person or entity, except to the extent provided for herein and in Paragraph 23 (waiver for beneficiaries paragraph) below.

23. Endo agrees that it waives and shall not seek payment for any of the healthcare billings covered by this Agreement from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

24. Within five (5) business days of the Agreement Effective Date in the U.S. Government Settlement Agreement, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1).

25. Except as provided in Paragraph 4 above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

26. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

27. This Agreement is governed by the laws of the United States. The venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Florida, provided that disputes regarding any provisions of this Agreement related to the Chapter 11 Cases may also be heard by the S.D.N.Y. Bankruptcy Court, including but not limited to Paragraphs 1, 2, 5, 7, 8, 11, 12, 13, 14, 15, 27, 31, and 34. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

28. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

29. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

30. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

31. This Agreement is binding on Endo's and the Debtors' successors, transferees, heirs, and assigns, including any reorganized debtor, in any and all forms, or trustee appointed in these Chapter 11 Cases or under a confirmed plan.

32. This Agreement is binding on Relator's successors, transferees, heirs, assigns, agents, and representatives.

33. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

34. This Agreement is effective on the day that the last of the following events has occurred (the "Effective Date"): (1) the date that the S.D.N.Y. Bankruptcy Court approves Endo's performance hereunder and (2) the effective date of any confirmed Plan. Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[Signature Page(s) Follow]

THE UNITED STATES OF AMERICA

DATED: 2/28/2024 BY: /s/ Natalie A. Waites
NATALIE A. WAITES
CHRISTOPHER TERRANOVA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 2/28/2024 BY: /s/ Matthew J. Feeley
MATTHEW J. FEELEY
Assistant United States Attorney
United States Attorney's Office
Southern District of Florida

DATED: 2024.02.26 BY: /s/ Susan Gillin
SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 02/26/2024 BY: Digitally signed by BLEY.PAUL.NICHOLAS
SALVATORE M. MAIDA
for General Counsel
United States Department of Defense

DATED: 2024.02.28 BY: /s/ Edward Deharde
EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: 2024.02.27 BY: /s/ Paul St. Hillaire
PAUL ST. HILLAIRE
Assistant Inspector General for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

ENDO

DATED: 2/28/2024 BY: /s/ Matthew Maletta
MATTHEW MALETTA
Executive Vice President, Chief Legal Officer and Secretary
Endo Health Solutions Inc.

DATED: 2/28/2024 BY: /s/ Carole S. Rendon
CAROLE S. RENDON
Baker Hostetler LLP
Counsel for Endo Health Solutions Inc.

RELATOR LORETTA REED

DATED: 2/23/24 BY: /s/ Loretta Reed
LORETTA REED

DATED: 2-23-2024 BY: /s/ Eric L. Young
ERIC L. YOUNG
Young Law Group
Counsel for Loretta Reed

EXHIBIT A – LIST OF DEBTORS

1. 70 Maple Avenue, LLC (1491);
2. Actient Pharmaceuticals LLC (7232);
3. Actient Therapeutics LLC (2019);
4. Anchen Incorporated (8760);
5. Anchen Pharmaceuticals, Inc. (9179);
6. Astora Women's Health Ireland Limited (5829);
7. Astora Women's Health, LLC (0427);
8. Auxilium International Holdings, LLC (9643);
9. Auxilium Pharmaceuticals, LLC (6883);
10. Auxilium US Holdings, LLC (8967);
11. Bermuda Acquisition Management Limited (N/A);
12. BioSpecifics Technologies LLC (4851);
13. Branded Operations Holdings, Inc. (6945);
14. DAVA International, LLC (9945);
15. DAVA Pharmaceuticals, LLC (7354);
16. Endo Aesthetics LLC (0218);
17. Endo Bermuda Finance Limited (4093);
18. Endo Designated Activity Company (7135);
19. Endo Eurofin Unlimited Company (2009);
20. Endo Finance IV Unlimited Company (2779);
21. Endo Finance LLC (6481);
22. Endo Finance Operations LLC (6355);
23. Endo Finco Inc. (5794);
24. Endo Generics Holdings, Inc. (4834);
25. Endo Global Aesthetics Limited (2898);
26. Endo Global Biologics Limited (2735);
27. Endo Global Development Limited (4785);
28. Endo Global Finance LLC (7754);
29. Endo Global Ventures (4244);
30. Endo Health Solutions Inc. (2871);
31. Endo Innovation Valera, LLC (3622);
32. Endo International plc (3755);
33. Endo Ireland Finance II Limited (0535);
34. Endo LLC (6640);
35. Endo Luxembourg Finance Company I S.à r.l. (3863);
36. Endo Luxembourg Holding Company S.à.r.l. (7168);
37. Endo Luxembourg International Financing S.à.r.l. (2905);
38. Endo Management Limited (4866);
39. Endo Par Innovation Company, LLC (2435);
40. Endo Pharmaceuticals Finance LLC (5768);
41. Endo Pharmaceuticals Inc. (5829);
42. Endo Pharmaceuticals Solutions Inc. (7911);
43. Endo Pharmaceuticals Valera Inc. (9931);
44. Endo Procurement Operations Limited (7840);
45. Endo TopFin Limited (8086);
46. Endo U.S. Inc. (0786);
47. Endo US Holdings Luxembourg I S.à.r.l. (7910);
48. Endo Ventures Aesthetics Limited (9967);
49. Endo Ventures Bermuda Limited (0688);
50. Endo Ventures Cyprus Limited (1544);
51. Endo Ventures Limited (6029);
52. Generics Bidco I, LLC (6905);

53. Generics International (US) 2, Inc. (5075);
54. Generics International (US), Inc. (6489);
55. Generics International Ventures Enterprises LLC (4685);
56. Hawk Acquisition Ireland Limited (4776);
57. Innoteq, Inc. (3381);
58. JHP Acquisition, LLC (7861);
59. JHP Group Holdings, LLC (7688);
60. Kali Laboratories 2, Inc. (6751);
61. Kali Laboratories, LLC (4898);
62. Luxembourg Endo Specialty Pharmaceuticals Holding I S.à r.l. (0601);
63. Moores Mill Properties L.L.C. (9523);
64. Operand Pharmaceuticals Holdco II Limited (0648);
65. Operand Pharmaceuticals Holdco III Limited (0649);
66. Operand Pharmaceuticals II Limited (1365);
67. Operand Pharmaceuticals III Limited (1366);
68. Paladin Labs Canadian Holding Inc. (N/A);
69. Paladin Labs Inc. (1410);
70. Par Laboratories Europe, Ltd. (9597);
71. Par Pharmaceutical 2, Inc. (4895);
72. Par Pharmaceutical Companies, Inc. (8301);
73. Par Pharmaceutical Holdings, Inc. (3135);
74. Par Pharmaceutical, Inc. (8342);
75. Par Sterile Products, LLC (0105);
76. Par, LLC (1286);
77. Quartz Specialty Pharmaceuticals, LLC (5368);
78. Slate Pharmaceuticals, LLC (6201);
79. Timm Medical Holdings, LLC (8744); and
80. Vintage Pharmaceuticals, LLC (7882).

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

The following is a list of the subsidiaries of the Company as of December 31, 2023.

Subsidiary	Jurisdiction of Incorporation or Organization	Ownership by Endo International plc
70 Maple Avenue, LLC	Delaware	Indirect
Actient Pharmaceuticals LLC	Delaware	Indirect
Actient Therapeutics, LLC	Delaware	Indirect
Anchen Incorporated	New York	Indirect
Anchen Pharmaceuticals, Inc.	Delaware	Indirect
Astora Women's Health Bermuda ULC	Bermuda	Indirect
Astora Women's Health Ireland Limited	Ireland	Indirect
Astora Women's Health Technologies	Ireland	Indirect
Astora Women's Health, LLC	Delaware	Indirect
Auxilium International Holdings, LLC	Delaware	Indirect
Auxilium Pharmaceuticals, LLC	Delaware	Indirect
Auxilium US Holdings, LLC	Delaware	Indirect
Bermuda Acquisition Management Limited	Bermuda	Indirect
BioSpecifics Technologies LLC	Delaware	Indirect
Branded Operations Holdings, Inc.	Delaware	Indirect
CPEC LLC	Delaware	Indirect
DAVA International, LLC	Delaware	Indirect
DAVA Pharmaceuticals, LLC	Delaware	Indirect
Endo Aesthetics LLC	Delaware	Indirect
Endo Bermuda Finance Limited	Bermuda	Indirect
Endo Designated Activity Company	Ireland	Direct
Endo Eurofin Unlimited Company	Ireland	Indirect
Endo Finance IV Unlimited Company	Ireland	Indirect
Endo Finance LLC	Delaware	Indirect
Endo Finance Operations LLC	Delaware	Indirect
Endo Finco Inc.	Delaware	Indirect
Endo Generics Holdings, Inc.	Delaware	Indirect
Endo Global Aesthetics Limited	Ireland	Indirect
Endo Global Biologics Unlimited Company	Ireland	Indirect
Endo Global Development Limited	Ireland	Indirect
Endo Global Finance LLC	Delaware	Indirect
Endo Global Ventures	Bermuda	Indirect
Endo Health Solutions Inc.	Delaware	Indirect
Endo India Holdings, LLC	Delaware	Indirect
Endo Innovation Valera, LLC	New York	Indirect
Endo Ireland Finance II Limited	Ireland	Indirect
Endo LLC	Delaware	Indirect
Endo Luxembourg Finance Company I S.a r.l.	Luxembourg	Indirect
Endo Luxembourg Holding Company S.a r.l.	Luxembourg	Indirect
Endo Luxembourg International Financing S.a r.l.	Luxembourg	Indirect
Endo Management Limited	Ireland	Indirect
Endo Par Innovation Company, LLC	Delaware	Indirect
Endo Pharmaceuticals Finance LLC	Delaware	Indirect
Endo Pharmaceuticals Inc.	Delaware	Indirect
Endo Pharmaceuticals Solutions Inc.	Delaware	Indirect
Endo Pharmaceuticals Valera Inc.	Delaware	Indirect
Endo Procurement Operations Limited	Ireland	Indirect
Endo TopFin Limited	Ireland	Indirect
Endo U.S. Inc.	Delaware	Indirect
Endo US Holdings Luxembourg I S.a r.l.	Luxembourg	Indirect
Endo Ventures Aesthetics Limited	Ireland	Indirect
Endo Ventures Bermuda Limited	Bermuda	Indirect

Subsidiary	Jurisdiction of Incorporation or Organization	Ownership by Endo International plc
Endo Ventures Cyprus Limited	Cyprus	Indirect
Endo Ventures Unlimited Company	Ireland	Indirect
Generics Bidco I, LLC	Delaware	Indirect
Generics International (US) 2, Inc.	Delaware	Indirect
Generics International (US), Inc.	New York	Indirect
Generics International Ventures Enterprises LLC	Pennsylvania	Indirect
Hawk Acquisition Ireland Limited	Ireland	Indirect
Innoteq, Inc.	Delaware	Indirect
JHP Acquisition, LLC	Delaware	Indirect
JHP Group Holdings, LLC	Delaware	Indirect
Kali Laboratories 2, Inc.	Delaware	Indirect
Kali Laboratories, LLC	New Jersey	Indirect
Luxembourg Endo Specialty Pharmaceuticals Holding I S.a r.l.	Luxembourg	Indirect
Moores Mill Properties L.L.C.	Delaware	Indirect
Operand Pharmaceuticals Holdco I Limited	Ireland	Indirect
Operand Pharmaceuticals Holdco II Limited	Ireland	Indirect
Operand Pharmaceuticals Holdco III Limited	Ireland	Indirect
Operand Pharmaceuticals II Limited	Ireland	Indirect
Operand Pharmaceuticals III Limited	Ireland	Indirect
Paladin Labs Canadian Holding Inc.	Canada	Indirect
Paladin Labs Inc.	Canada	Indirect
Par Active Technologies Private Limited	India	Indirect
Par Biosciences Private Limited	India	Indirect
Par Formulations Private Limited	India	Indirect
Par Laboratories Europe, Ltd.	England and Wales	Indirect
Par Pharmaceutical 2, Inc.	Delaware	Indirect
Par Pharmaceutical Companies, Inc.	Delaware	Indirect
Par Pharmaceutical Holdings, Inc.	Delaware	Indirect
Par Pharmaceutical, Inc.	New York	Indirect
Par Sterile Products, LLC	Delaware	Indirect
Par, LLC	Delaware	Indirect
Quartz Specialty Pharmaceuticals, LLC	Delaware	Indirect
Slate Pharmaceuticals, LLC	Delaware	Indirect
Timm Medical Holdings, LLC	Delaware	Indirect
Vintage Pharmaceuticals, LLC	Delaware	Indirect

Exhibit 24.1

POWER OF ATTORNEY

Each of the undersigned, hereby constitutes and appoints each of Blaise Coleman, Mark T. Bradley, Matthew J. Maletta and Brian Morrissey to be his or her true and lawful attorneys-in-fact and agents, with full power of each to act alone, and to sign for the undersigned and in each of their respective names in any and all capacities stated below, this Annual Report on Form 10-K (and any amendments hereto) and to file the same, with exhibits hereto and thereto and other documents in connection herewith and therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Power of Attorney has been signed by the following persons in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Mark G. Barberio Mark G. Barberio	Chairman and Director	February 21, 2024
/s/ Jennifer M. Chao Jennifer M. Chao	Director	February 21, 2024
/s/ Shane M. Cooke Shane M. Cooke	Director	February 21, 2024
/s/ Nancy J. Hutson, Ph.D. Nancy J. Hutson, Ph.D.	Director	February 21, 2024
/s/ Michael Hyatt Michael Hyatt	Director	February 21, 2024
/s/ William P. Montague William P. Montague	Director	February 21, 2024
/s/ M. Christine Smith, Ph.D. M. Christine Smith, Ph.D.	Director	February 21, 2024

Exhibit 31.1

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

I, Blaise Coleman, certify that:

1. I have reviewed this annual report on Form 10-K of Endo International plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ BLAISE COLEMAN

Blaise Coleman
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 6, 2024

Exhibit 31.2

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

I, Mark T. Bradley, certify that:

1. I have reviewed this annual report on Form 10-K of Endo International plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ MARK T. BRADLEY

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

Date: March 6, 2024

Exhibit 32.1

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

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

(1) The Annual Report on Form 10-K of the Company for the annual period ended December 31, 2023 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

/S/ BLAISE COLEMAN
Name: Blaise Coleman
Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: March 6, 2024

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

Exhibit 32.2

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

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

(1) The Annual Report on Form 10-K of the Company for the annual period ended December 31, 2023 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

/S/ MARK T. BRADLEY

Name: Mark T. Bradley

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

Date: March 6, 2024

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