UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 30, 2022

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number : 001-35803

Mallinckrodt plc

(Exact name of registrant as specified in its charter)

Ireland	**98-1088325**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

College Business & Technology Park, Cruiserath,
Blanchardstown, Dublin 15, Ireland
(Address of principal executive offices) (Zip Code)
Telephone: +353 1 696 0000
(Registrant's telephone number, including area code)

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

(Title of each class)	(Trading Symbol(s))	(Name of each exchange on which registered)
Ordinary shares, par value $0.01 per share	MNK	NYSE American LLC

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. Yes ☒ No ☐

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 Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant as of July 1, 2022, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $317.4 million (based upon the closing price of $24.40 per share as reported by the Pink Open Market on that date).

The number of shares of the registrant's common stock outstanding as of February 24, 2023 was 13,170,932.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its annual meeting of shareholders, to be filed with the Securities and Exchange Commission within 120 days after December 30, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

MALLINCKRODT PLC
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Presentation of Information

Unless the context requires otherwise, references to "Mallinckrodt plc," "Mallinckrodt," "we," "us," "our" and "the Company" refer to Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries. References to "dollars" or "$" refer to United States dollars.

Trademarks and Trade Names

Mallinckrodt owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this Annual Report on Form 10-K (this "Annual Report") is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the United States and other jurisdictions. Solely for convenience, the Company only uses the ™ or ® symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks and trade names. Each trademark or trade name of any other company appearing in this Annual Report is, to the Company's knowledge, owned by such other company.

Forward-Looking Statements

The Company has made forward-looking statements in this Annual Report that are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include, but are not limited to, information concerning the Company's possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "plan," "intend," "project," "anticipate," "estimate," "predict," "potential," "continue," "may," "will," "should" or the negative of these terms or similar expressions.

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

The risk factors included in Item 1A. Risk Factors of this Annual Report could cause the Company's results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that the Company is unable to predict at this time or that the Company currently does not expect to have a material adverse effect on its business.

These forward-looking statements are made as of the filing date of this Annual Report. The Company expressly disclaims any obligation to update these forward-looking statements other than as required by law.

Summary of Selected Risk Factors

Our business is subject to numerous material and other risks and uncertainties that you should be aware of. These risks and uncertainties are described more fully in "Item 1A. Risk Factors" in this Annual Report, and include, but are not limited to, the following:

Risks Related to Our Emergence from Bankruptcy

- We recently emerged from bankruptcy, which could adversely affect our business and relationships.
- Our actual financial results after emergence from bankruptcy may not be comparable to our projections filed with the Bankruptcy Court or otherwise made public in the course of the Chapter 11 Cases (as defined below).
- Our historical financial statements are not comparable to those produced after the application of fresh-start accounting.
- Upon our emergence from bankruptcy, our Board of Directors was changed and may implement changes in our business strategy that could affect the scope and results of our operations.
- We have contractual and court-ordered compliance obligations that if violated could result in exclusion from participation in federal healthcare programs and monetary, injunctive and/or other sanctions.

Risks Related to Our Business

- Governmental investigations, inquiries, and regulatory actions and lawsuits brought against us with respect to our historical commercialization of opioids could adversely affect, among other things, our business and results of operations.
- The healthcare industry has been under increasing scrutiny and changes to, or non-compliance with, relevant policies, laws, regulations or government guidance may result in actions that could adversely affect our business.
- We face significant competition and may not be able to compete effectively.
- We may experience pricing pressure on certain of our products, which could reduce our future revenue and profitability.

- Sales of our products are affected by the reimbursement practices of governmental health administration authorities, private health coverage insurers and other third-party payers. Reimbursement criteria and the use of tender systems outside the United States could reduce prices for our products.
- Any determination of failure to comply with the reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, could have a material adverse effect on our business.
- Cost-containment efforts of our customers and other parties could materially adversely affect our business.
- Any failure to comply with the extensive laws and regulations governing our industry may materially adversely affect us.
- Our approved products and investigational products may cause undesirable side effects.
- We may be unable to successfully commercialize or launch new products or expand opportunities for existing products.
- We may not be successful in our efforts to identify or discover additional products or product candidates beyond our existing products and product candidates at the rate we expect.
- We may not achieve the anticipated benefits of price increases enacted on our pharmaceutical products.
- Our customer and product concentration may materially adversely affect our business.
- We may be unable to protect our intellectual property rights or subject to intellectual property rights infringement claims.
- Clinical trials demonstrating the efficacy of Acthar® Gel are limited, which could cause physicians not to prescribe Acthar Gel, or payers not to reimburse the drug, which could negatively impact our business.
- Clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain and regulatory approval may be delayed or become unobtainable.
- We may incur litigation liability, including product liability losses.
- Our operations expose us to the risk of liability of violations of health, safety and environmental laws and regulations.
- If our business development activities are unsuccessful, it may adversely affect us.
- If we are unable to attract and retain key scientific, technical, regulatory and commercial personnel, we may be unable to maintain or expand our business.
- Without continued effectiveness and availability of information technology infrastructure, our operations could be harmed.
- Some of our products are regulated as controlled substances, the making, use, sale, importation, exportation, and distribution of which are subject to significant regulation by the United States Drug Enforcement Administration and other regulatory agencies.
- The United States Drug Enforcement Agency regulates the availability of controlled substances, including active pharmaceutical ingredients. At times, the procurement and manufacturing quotas granted by the United States Drug Enforcement Agency may be insufficient to meet our needs.
- The manufacture of our products is complex, and our business could suffer due to manufacturing or supply problems.
- Our global operations expose us to risks and challenges associated with conducting business internationally.
- We have significant levels of intangible assets which utilize our future projections of cash flows in impairment testing. If we experience unfavorable variances from these projections these assets may have an increased risk of future impairment.
- We are subject to labor and employment laws and regulations, which could increase our costs and restrict our operations.

Risks Related to Our Indebtedness and Settlement Obligations

- Our substantial indebtedness and settlement obligations could adversely affect our financial condition and prevent us from fulfilling our obligations and could further adversely affect our ability to make ongoing payments in respect of the Plan (as defined below).
- We may not be able to generate sufficient cash to service all of our indebtedness and other commitments.
- The terms of the agreements that govern our indebtedness and settlement obligations restrict our current and future operations.
- Our debt and settlement obligation levels may materially adversely affect our ability to issue debt on acceptable terms and future access to capital.
- Borrowing capacity under our receivables-based financing facility may decrease, may not be extended upon maturity, or the maturity date may be accelerated.
- Our variable-rate indebtedness exposes us to interest rate risk, which could cause our debt service obligations to increase significantly.
- Despite current and anticipated indebtedness and settlement obligation levels, we may still be able to incur more debt.
- Future financing may not be available on favorable terms when needed and may be dilutive to existing shareholders.
- The phase out of London Interbank Offered Rate, or the replacement of London Interbank Offered Rate with a different reference rate, may adversely affect interest rates associated with our debt.

Risks Related to Tax Matters

- The United States could treat Mallinckrodt plc (parent corporation) as a United States taxpayer under Internal Revenue Code Section 7874.
- The Internal Revenue Service may interpret Internal Revenue Code Section 382 limitation and cancellation of debt income attribution rules differently.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

- A loss of a major tax dispute or a challenge to our operating structure or intercompany pricing policies could result in a higher tax rate on our worldwide earnings.
- Our status as a foreign corporation for United States federal tax purposes could be affected by a change in law.
- Future changes to United States and foreign tax laws could adversely affect us.
- We may not be able to maintain a competitive worldwide effective corporate tax rate.
- A change in our tax residency could have a negative effect on our future profitability and taxes on dividends.

Risks Related to Our Jurisdiction of Incorporation

- Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.
- Irish law imposes restrictions on certain aspects of capital management.

Risks Related to Our Ordinary Shares

- An active trading market of our ordinary shares may not develop and the price and trading volume may fluctuate significantly.

PART I

Item 1. Business.

Overview

Mallinckrodt plc is a global business of multiple wholly owned subsidiaries (collectively, "Mallinckrodt" or "the Company") that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products.

We operate our business in two reportable segments, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and active pharmaceutical ingredients ("API(s)").

We continue to pursue our ongoing transformation to become an innovation-driven biopharmaceutical company focused on improving outcomes for underserved patients with severe and critical conditions. For further information on our products, refer to "Our Businesses and Products" within this Item 1. Business.

Our principal executive offices are located at College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland, where our Specialty Brands global external manufacturing operations are also located. In addition, we have other locations in the United States ("U.S."), most notably our corporate shared services office in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bridgewater, New Jersey (formerly Hampton, New Jersey), and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

Emergence from Voluntary Reorganization

On October 12, 2020 ("Petition Date"), we voluntarily initiated Chapter 11 proceedings ("Chapter 11 Cases") under chapter 11 of title 11 ("Chapter 11") of the United States Code ("Bankruptcy Code") in the U.S. Bankruptcy Court for the District of Delaware ("Bankruptcy Court"). On March 2, 2022, the U.S. Bankruptcy Court for the District of Delaware ("Bankruptcy Court") entered an order confirming the fourth amended plan of reorganization (with technical modifications ("Plan"). Subsequent to the filing of the Chapter 11 Cases, Chapter 11 proceedings commenced by a limited subset of the debtors were recognized and given effect in Canada, and separately the High Court of Ireland made an order confirming a scheme of arrangement on April 27, 2022, which is based on and consistent in all respects with the Plan ("Scheme of Arrangement"). The Plan and Scheme of Arrangement became effective on June 16, 2022, ("Effective Date"), and on such date we emerged from the Chapter 11 and Irish examinership proceedings. Refer to Note 2 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report for further information on the Plan and emergence from Chapter 11.

Upon emergence from Chapter 11, we adopted fresh-start accounting in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 852 - *Reorganizations* ("ASC 852"), and became a new entity for financial reporting purposes as of the Effective Date. References to "Successor" relate to the financial position as of June 16, 2022 and results of operations of the reorganized Company subsequent to June 16, 2022, while references to "Predecessor" relate to the financial position prior to June 16, 2022 and results of operations of the Company prior to, and including, June 16, 2022. All emergence-related transactions of the Predecessor were recorded as of June 16, 2022. Accordingly, the consolidated financial statements for the Successor are not comparable to the consolidated financial statements for the Predecessor. Refer to Note 3 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report for further information.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. The period June 17, 2022 through December 30, 2022 reflects the Successor period, while the period January 1, 2022 through, and including, June 16, 2022 reflects the Predecessor period. Fiscal year ended December 31, 2021 (Predecessor) ("fiscal 2021") consisted of 53 weeks, while the combined periods of January 1, 2022 through June 16, 2022 and June 17, 2022 through December 30, 2022 ("fiscal 2022") and fiscal year ended December 25, 2020 (Predecessor) ("fiscal 2020") consisted of 52 weeks.

Our Businesses and Products

We manage our business in two reportable segments: Specialty Brands and Specialty Generics. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion.

Specialty Brands

Our business markets branded pharmaceutical products for autoimmune and rare diseases in the specialty areas of neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products. Our diversified, in-line portfolio of both marketed and development products is focused on patients with significant unmet medical needs.

Our long-term strategy is to:

- increase patient access and appropriate utilization of our existing products;
- develop innovative new therapies and next-generation devices for our products; and
- selectively acquire or license products that are strategically aligned with our product portfolio to expand the size and profitability of our Specialty Brands segment.

We promote our branded products directly to physicians in their offices, hospitals and ambulatory surgical centers (including neurologists, rheumatologists, hepatologists, nephrologists, pulmonologists, ophthalmologists, oncologists, neonatologists, surgeons and pharmacy directors) with our own direct sales force of almost 300 sales representatives as of December 30, 2022 (Successor). These products are purchased by independent wholesale drug distributors, specialty pharmaceutical distributors, retail pharmacy chains and hospital procurement departments, among others, and are eventually dispensed by prescription to patients. We also contract directly with payer organizations to ensure reimbursement for our products to patients that are prescribed our products by their physicians.

The following is a description of select products in our product portfolio:

- *Acthar® Gel (repository corticotropin injection) ("Acthar Gel")* is a complex mixture of peptides approved by the U.S. Food and Drug Administration ("FDA") for use in 19 indications. The product currently generates substantially all of its net sales from 11 of the on-label indications, including adjunctive therapy for short-term administration for an acute episode or exacerbation in rheumatoid arthritis ("RA"), including juvenile RA; monotherapy for the treatment of infantile spasms in infants and children under two years of age; treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus; treatment of acute exacerbations of multiple sclerosis ("MS") in adults; including a diuresis or a remission of proteinuria in nephrotic syndrome ("NS") without uremia of the idiopathic type or that due to lupus; treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis); treatment of symptomatic sarcoidosis; and treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa including keratitis and uveitis. The currently approved indications of Acthar Gel are not subject to patent or other exclusivity.

  There is significant clinical data generated to support the effectiveness of Acthar Gel. This data is the result of company-sponsored controlled clinical trials, as well as previously completed and largely independent clinical case series and smaller trials that have expanded the product's evidence base and strengthened its clinical profile. We continue our data generation efforts through pre-clinical studies and additional independent research, as well as our efforts to extend the value of the product through product enhancements including the ongoing development of the Acthar Gel self-injection device, which we believe will create an easier and more patient-friendly application for single unit dosage indications.

- *INOmax® (nitric oxide) gas, for inhalation ("INOmax")* is a vasodilator that, in conjunction with ventilatory support and other appropriate agents, is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure ("HRF") associated with clinical or echocardiographic evidence of pulmonary hypertension. INOmax is also approved in Australia for the treatment of perioperative pulmonary hypertension in adults in conjunction with cardiovascular surgery. Additionally, our Phase 4 registry assessing INOmax for treatment of pulmonary hypertension in premature (27 to 34 weeks) and term and near-term neonates was completed early in February 2020 due to achievement of the pre-specified primary outcome measure of non-inferiority. The decision to end the study early was made following the second planned interim analysis at 75% enrollment. The interim analysis assessed 54 premature and 84 term and near-term neonates and reflected that the trial achieved the significance level for non-inferiority. Evaluation of significant improvement for each neonate is based on at least a 25% decrease in oxygenation index or surrogate oxygenation index during the INOmax treatment period.

INOmax is marketed as part of the INOmax Total Care package, which includes the drug product, proprietary drug-delivery systems, technical and clinical assistance, 24/7/365 customer service, emergency supply and delivery and on-site training. The development and subsequent FDA submission of a 510(k) premarket notification application was completed in September 2022 for an investigational inhaled nitric oxide delivery system for INOmax gas, for inhalation. If cleared, this next generation inhaled nitric oxide delivery system will offer a compact, portable design that we believe will further enhance the safety of the product, as well as the simplicity and flexibility of use in a number of settings.

- *Therakos® photopheresis ("Therakos")* is focused on providing innovative immunotherapy treatment platforms that enhance the ability of a patient's immune system to fight disease. We believe Therakos is a global leader in autologous immunotherapy delivered through extracorporeal photopheresis ("ECP") and provides the only integrated ECP system in the world. ECP involves drawing blood from the patient, separating white blood cells from plasma and red blood cells that are returned to the patient, and treating the white blood cells with an Ultraviolet-A ("UVA") light activated drug. The treated white blood cells are immediately re-administered back into the patient. ECP is approved by the FDA for use in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma ("CTCL") that is unresponsive to other forms of treatment. Outside the U.S., ECP is approved to treat several other serious diseases that arise from immune system imbalances. Therakos' product suite, which is sold to hospitals, clinics, academic centers and blood banks, includes an installed system, a disposable procedural kit used for each treatment and a drug, UVADEX® (methoxsalen) Sterile Solution ("UVADEX"), as well as instrument accessories and instrument maintenance and repair services.

- *StrataGraft® (allogenic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat) ("StrataGraft")* regenerative skin tissue is an allogeneic cellularized scaffold product derived from keratinocytes grown on gelled collagen containing dermal fibroblasts indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns). StrataGraft is designed to deliver viable cells to support the body's own ability to heal. StrataGraft contains metabolically active cells that produce and secrete a variety of growth factors and cytokines. Growth factors and cytokines are known to be involved in wound repair and regeneration. The product is designed with both dermal and epidermal layers composed of well-characterized human cells. StrataGraft is intended to be applied in appropriate aseptic conditions, such as the operating room, and can be sutured, stapled or secured with a tissue adhesive.

  During the first quarter of fiscal 2022, we released our first commercial shipment of StrataGraft. The FDA granted StrataGraft orphan drug designation, and it was among the first products designated by the FDA as a Regenerative Medicine Advanced Therapy (RMAT) under the provisions of the 21st Century Cures Act. At the time of approval, the FDA awarded us a Priority Review Voucher ("PRV"), which has been sold pursuant to an asset purchase agreement dated June 30, 2022. In June 2021, the FDA had approved the StrataGraft biologics license application ("BLA") for deep partial-thickness. We are currently conducting a StrataGraft continued access clinical trial under an expanded access program. The trial sites involved in the pivotal Phase 3 trial have the opportunity to participate in this multicenter, open-label study. Overall, 52 patients were enrolled. There were no unexpected wound or StrataGraft-related events. The safety results were consistent with prescribing information and patients treated achieved durable wound closure without autografting and thus showed expected clinical benefit in this population. We are currently conducting a Phase 2 trial to evaluate StrataGraft for the treatment of adults with full-thickness burns (also referred to as third-degree burns) and a pediatric study evaluating StrataGraft in the treatment of pediatric populations.

  The Biomedical Advanced Research and Development Authority ("BARDA") expressed interest in StrataGraft as a medical countermeasure in response to large-scale burn incidents, and provided funding and technical support for the continued development of StrataGraft. These efforts are part of BARDA's strategy to build emergency preparedness in response to mass casualty events involving trauma and thermal burns by developing novel medical countermeasures for adult and at-risk populations. In the case of a mass casualty thermal burn event, the Government Accountability Office estimates that more than 10,000 patients might require thermal burn care. The limited number of specialized burn centers and related medical infrastructure in the U.S. creates a public health need for therapies that could be deployed quickly for use in these and other care sites.

- *Terlivaz® (terlipressin) ("Terlivaz")* is the first and only FDA-approved product indicated to improve kidney function in adults with hepatorenal syndrome ("HRS") type 1 (collectively "HRS-1") with rapid reduction in kidney function, an acute and life-threatening condition requiring hospitalization. The FDA granted Terlivaz orphan drug designation. Terlivaz is one of the most studied pharmacological agents in HRS-1 with more than 70 published manuscripts and presented abstracts on clinical data to date. The FDA approval was based, in part, on results from the Phase 3 CONFIRM trial, the largest-ever prospective study (n=300) conducted to assess the safety and efficacy of Terlivaz in patients with HRS-1 in the U.S. and Canada. The CONFIRM trial met its primary endpoint of Verified HRS Reversal, defined as renal function improvement, avoidance of dialysis and short-term survival. It has been approved outside the U.S. for more than 30 years and is available on five continents for its indications in the countries where it is approved. Terlivaz is

recommended for line use by both the American Association for the Study of Liver Diseases and the American College of Gastroenterology guidelines. On September 14, 2022, we announced the FDA had approved Terlivaz for injection and during the fourth quarter of fiscal 2022, we released our first commercial shipment of the product.

- *Amitiza® (lubiprostone) ("Amitiza")* is approved by the FDA for treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women 18 years of age and older, and opioid-induced constipation in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation. Amitiza is a chloride channel type-two activator that increases fluid secretion and motility of the intestine, facilitating passage of stool. We believe Amitiza is a leading global product in the branded constipation market. Of the branded products currently marketed, only Amitiza is approved for three constipation indications in the U.S.

Specialty Generics

Our Specialty Generics segment is focused on providing our customers high-quality specialty generic drugs and APIs. Specialty Generics include a variety of product formulations containing hydrocodone-containing tablets, oxycodone-containing tablets and several other controlled substances for the treatment of pain. Other controlled substances products include medicines used to treat attention-deficit/hyperactivity disorder ("ADHD") and addiction treatment medications. Our near-term pipeline in this segment includes the expected launch of several new products in the next few years, with additional products in development long-term. Within this segment, we provide bulk API products, including acetaminophen, mixed amphetamine salts, opioids and stearates, to a wide variety of pharmaceutical companies, many of which are direct competitors of our Specialty Generics finished dosage business. In addition, we use our APIs for internal manufacturing of our finished dosage products.

We are among the world's largest manufacturers of bulk acetaminophen and the only producer of acetaminophen in the North American and European regions with manufacturing facilities exclusively in the U.S. We manufacture controlled substances under the U.S. Drug Enforcement Administration ("DEA") quota restrictions, and in calendar 2022, we estimated that we received approximately 36.4% of the total DEA quota provided to the U.S. market for the controlled substances we manufacture. We believe that our market position in the API business and allocation of quota-governed controlled substance materials from the DEA is a competitive advantage for our API business and, in turn, for our Specialty Generics segment. The strategy for our API business is based on manufacturing large volumes of high-quality product and customized product offerings, responsive technical services and timely delivery to our customers.

We market these products principally through independent channels, including drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, food store chains with pharmacies, pharmaceutical benefit managers that have mail order pharmacies and hospital buying groups.

Research and Development

Specialty Brands. Our research and development ("R&D") resources are primarily devoted to our branded products. Our R&D investments center on supporting our current late-stage product development, maximizing new product launches and accelerating additional lifecycle management opportunities, inclusive of new product enhancements, line extensions and geo-expansions that provide value to patients, physicians and payers. Our strategy focuses on growth, including pipeline opportunities related to late-stage development products to meet the needs of underserved patient populations, where we execute on the development process and perform clinical trials to support regulatory approval of new products.

Data generation is an important strategic driver for our products, as they extend evidence in approved uses, label enhancements and new indications. Our data strategy is realized through investments in both clinical and health economic activities. We are committed to supporting research that helps advance the understanding and treatment of a variety of different disease states that will further the understanding and development of our currently marketed products, including Acthar Gel, INOmax, Therakos, StrataGraft and Terlivaz.

Specialty Generics. The R&D efforts in this segment are focused on hard-to-manufacture pharmaceuticals with difficult-to-replicate pharmacokinetic profiles and products that would benefit from our vertically integrated manufacturing capabilities. Our Specialty Generics pipeline consists of a number of products in various stages of development. We currently perform most of our development work at our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

We are developing a number of complex generic pharmaceutical products that take advantage of our API and drug product manufacturing capabilities as well as our experience in working with API and contract manufacturing organizations. We currently have five Abbreviated New Drug Applications ("ANDA(s)") at various stages of review with the FDA and a diverse portfolio of oral, solid and parenteral formulations under development. Our pipeline is focused on applying our capabilities to develop difficult formulations, utilizing our expertise in working with controlled substances to develop potent products, and expanding both our

therapeutic and technology platforms into areas with less competitive pressure. We utilize our proven abilities to design around competitor patents to advance both our API and drug product development opportunities and to create our own intellectual property.

To facilitate our development efforts, we have a multipurpose commercial production facility and pilot plant in St. Louis, Missouri, where we test and scale our manufacturing processes for new products. This also allows us to more rapidly and economically develop certain drug product submissions, all under one roof at our pilot plant, with a limited amount of API or drug product. This facility was converted to dual purpose for both pilot and commercial manufacturing in 2018, and the first product from this facility was approved and launched in 2020.

Competition

Specialty Brands. Certain of our Specialty Brands products do not face direct competition from similar products, but instead compete against alternative forms of treatment that a prescriber may utilize. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our branded products offer not only superior health outcomes but also cost and service advantages, as compared with other forms of care. For example, while there is no therapeutically substitutable generic alternative for Acthar Gel, it faces significant competition from earlier-line treatment alternatives including high-dose steroids, and is generally prescribed when earlier-line treatments have failed to provide positive outcomes or are not well tolerated by the patient. Competition intensified with the commercial launch of a purified cortrophin gel product in 2022, which is a distinct product from Acthar Gel; however, it is in a similar drug class. We experienced pressure from their launch in 2022 and we anticipate that this pressure will continue. We continue to differentiate Acthar Gel through pre-clinical studies and through product enhancements including the ongoing development of the Acthar Gel self-injection device, which is designed to create an easier and more patient-friendly application for single unit dosage indications.

Certain of our Specialty Brands products now do have direct competition in the U.S. market. For example, there is now direct competition in the U.S. market for INOmax. However, we believe INOmax's highly differentiated service offering and the next generation delivery system, if approved, will help to differentiate the product and mitigate the impact of competition longer-term.

The highly competitive environment of our Specialty Brands segment requires us to continually seek out new products to treat diseases and conditions in areas of high unmet medical need, to create technological innovations and to market our products effectively. Most new products that we introduce must compete with other products already on the market, as well as other products that are subsequently developed by competitors. For our branded products, we may be granted market exclusivity either through the FDA, the U.S. Patent Office or similar agencies internationally. Regulatory exclusivity is granted by the FDA for new innovations, such as new clinical data, a new chemical entity or orphan drugs, and patents are issued for inventions, such as composition of matter or method of use. While patents offer a longer period of exclusivity, there are more bases to challenge patent-conferred exclusivity than with regulatory exclusivity. Generally, once market exclusivity expires on our branded products, competition will likely intensify as generic forms of the product are launched. Products that do not benefit from regulatory or patent exclusivity must rely on other competitive advantages, such as confidentiality agreements or product formulation trade secrets for difficult to replicate products.

Manufacturers of generic pharmaceuticals typically invest far less in R&D than research-based pharmaceutical companies, allowing generic versions to typically be significantly less expensive than the related branded products. The generic form of a drug may also enjoy a preferred position relative to the branded version under third-party reimbursement programs, or be routinely dispensed in substitution for the branded form by pharmacies. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions, decreased sales volume or both. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our branded products offer not only superior health outcomes but also cost advantages, as compared with other forms of care. Certain of our Specialty Brands products are targeted for niche patient populations with unmet medical needs, for example Acthar Gel, that may not be prescribed unless a clear benefit in efficacy or safety is demonstrated or until alternatives have failed to provide positive patient outcomes or are not well tolerated by the patient.

As it relates to our Amitiza product, many patients are currently treated for chronic idiopathic constipation ("CIC"), irritable bowel syndrome with constipation ("IBS-C") or opioid-induced constipation ("OIC") with a variety of medications. Over-the-counter medications are available and are generally intended to provide relief for occasional constipation. Prescription products are also available and are generally intended to provide relief for chronic constipation. As such, the U.S. constipation market is expansive and diverse with a multitude of products intended to treat a large heterogeneous patient population. The prescription chronic constipation market can generally be bifurcated into two categories: 1) generic laxatives and 2) branded products. Generic laxatives make up roughly 80%-90% of the total prescription volume while branded prescriptions have grown to represent 10%-20% of the prescription market. At this time, Amitiza is the only branded product with chloride channel type-two activator mechanism of action. Amitiza is also the only branded product on the market today in three separate indications for CIC, IBS-C and OIC.

Prior to our acquisition of Amitiza in February 2018, the previous owner had entered into agreements to license certain rights to Amitiza to third parties in exchange for royalties on net sales of the product. Historically, we received a double-digit royalty based on a percentage of the gross profits of the licensed products sold during the term of the agreement, which was reduced to

zero for the agreement with Par Pharmaceuticals, Inc. et al. (collectively "Par") upon the entrance of two or more generics in addition to Par in fiscal 2023.

Specialty Generics. Our Specialty Generics products compete with products manufactured by many other companies in highly competitive markets, primarily throughout the U.S. Our competitors vary depending upon therapeutic and product categories. Major competitors of our Specialty Generics products include Rhodes Pharmaceuticals LP, Teva Pharmaceutical Industries Ltd., Aurobindo Pharma Ltd., Amneal Pharmaceutical Ltd., Noramco, Inc. and Johnson Matthey plc, among others. We believe our secure sources of opioid raw materials, vertically integrated manufacturing capabilities, broad offerings of API controlled substances and acetaminophen, comprehensive generic controlled substances product line and established relationships with national and regional distributors of generic drugs in the U.S. enable us to compete with larger generic manufacturers. In addition, we believe that our experience with the FDA, DEA and Risk Evaluation and Mitigation Strategies ("REMS") provides us the knowledge to operate efficiently and effectively in this highly regulated, competitive environment.

The Specialty Generics segment faces intense competition from other generic drug manufacturers, brand-name pharmaceutical companies marketing authorized generics, existing branded equivalents and manufacturers of therapeutically similar drugs. The competition varies depending upon the specific product category and dosage strength. Among the large generic controlled substance providers, we are one of the only generic manufacturers that has its own controlled substance API manufacturing capability, and we believe that we offer more vertically integrated generic controlled substance products than any other U.S. manufacturer. New drugs and future developments in improved or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages when compared to the products we sell. The maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and timely launch new generic products, as well as our ability to manufacture such new products in a cost efficient, high-quality manner and implement and drive market volume.

As a result of consolidation among wholesale distributors and rapid growth of large retail drug store chains, a small number of large wholesale distributors and retail drug store chains control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. This has resulted in customers gaining more purchasing power. Consequently, there is heightened competition among generic drug producers for the business of this smaller and more selective customer base.

In our API business, we believe that our competitive advantages include our manufacturing capabilities in controlled substances that enable high-speed, high-volume tableting, packaging and distribution. Additionally, we believe we offer customers reliability of supply and broad-based technical customer service.

The competitive landscape in the acquisition and in-licensing of pharmaceutical products has intensified in recent years, reflecting both a reduction in the number of compounds available and an increase in the number of companies and the collective resources bidding on available assets. The ability to effectively compete in product development, acquisitions and in-licensing is important to our long-term growth strategy. In addition to product development and acquisitions, other competitive factors in the pharmaceutical industry include product efficacy, safety, ease of use, price, demonstrated cost-effectiveness, third-party reimbursement, marketing effectiveness, customer service, reliability of supply, reputation and technical capabilities.

Intellectual Property

We own or license a number of patents in the U.S. and other countries covering certain products and have also developed brand names and trademarks for those and other products. Generally, our Specialty Brands business relies upon patent protection to protect our products, related inventions, and product innovations that are important to our business.

In a broad sense, patents provide the innovator companies with the right to exclude others from practicing an invention related to a product. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

In the U.S. branded pharmaceutical industry, an innovator product’s market exclusivity is generally determined by two forms of intellectual property: (i) patent rights held by the innovator company and listed in the FDA’s Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") and (ii) any regulatory forms of exclusivity to which the innovator is entitled. In addition, commercial durability may also partially depend upon product-related trade secrets, confidentiality agreements and trademark and copyright laws. These additional items may not prevent competitors from independently developing similar technology or a bioequivalent product.

Many developed countries provide certain non-patent incentives for the development of pharmaceuticals. Regulatory exclusivity is independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory exclusivity on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

The patents and patent applications that relate to our major marketed products include:

- *Acthar Gel*. We have four U.S. patents that relate to Acthar Gel. These patents expire from 2031 to 2034. The Acthar Gel is protected primarily by trade secrets. In addition, we continue our efforts to pursue product enhancements, including the ongoing development of the Acthar Gel self-injection device, for which we have additional pending patent applications in the U.S.
- *INOmax.* We have a portfolio of U.S. and non-U.S. patents and patent applications for INOmax and related technologies. These include over 100 issued patents, expiring between 2023 to 2039, and numerous pending patent applications in the U.S., and over 700 issued patents, expiring between 2026 to 2037, and numerous pending patent applications in other countries.
- *Therakos.* We currently have 23 issued patents and two pending patent applications relating to Therakos in the U.S. These issued patents expire from 2023 to 2037. We also have 235 issued patents, expiring from 2023 to 2036, relating to Therakos in other countries. We have filed additional patent applications for this product.
- *StrataGraft.* Our patent portfolio relating to StrataGraft includes 30 issued patents, expiring from 2022 to 2034, and numerous pending patent applications in the U.S. StrataGraft is protected by a mix of patents and trade secrets.
- *Terlivaz.* We currently have one issued patent, expiring in 2037, and a number of pending patent applications in the U.S. that relate to Terlivaz.
- *Amitiza.* We have four patents listed in the Orange Book that will expire from 2025 to 2027. We also obtained patent protection in Japan that will expire from 2023 to 2027.

In addition, we have rights to a number of trademarks and service marks, and pending trademark and service mark applications, in the U.S. and elsewhere in the world to further protect the proprietary position of our products.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of our branded products because of the complex interaction between patent and regulatory forms of exclusivity, the relative success or lack thereof by potential competitors' experience in product development and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

We consider the overall protection of our patents, trademarks and license rights to be of material value and act to protect these rights from infringement. For a discussion of the challenges we face in obtaining or maintaining patent and/or trade secret protection, see the risk factor captioned "*We may be unable to protect our intellectual property rights, intellectual property rights may be limited or we may be subject to claims that we infringe on the intellectual property rights of others"* included within Item 1A. Risk Factors of this Annual Report.

Regulatory Matters

Quality Assurance and Current Good Manufacturing Practice Requirements

The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging and holding of drugs, biologics, and medical devices conform to current good manufacturing practice ("cGMP"). The cGMP regulations that the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, and are designed to ensure that the finished products meet all the required identity, strength, quality and purity characteristics. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The cGMP regulations for devices, called the Quality System Regulations, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the U.S. Federal Food, Drug and Cosmetic Act ("FFDCA"). Other regulatory authorities have their own cGMP rules. Ensuring compliance requires a continuous commitment of time, money and effort in all operational areas.

United States

In general, drug and device manufacturers operate in a highly regulated environment. In the U.S., we must comply with laws, regulations, guidance documents and standards promulgated by the FDA, the Department of Health and Human Services ("HHS"), the DEA, the Environmental Protection Agency ("EPA"), the Customs Service and state boards of pharmacy.

The FFDCA provides several distinct pathways for the approval of new drugs. A new drug application ("NDA") under Section 505(b)(1) of the FFDCA is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure the identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA generally contains results of the full set of pre-clinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate. Section 505(b)(2) of the FFDCA provides an alternate regulatory pathway to obtain FDA approval; it permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference drug, and submit its own product-specific data - which may include data from pre-clinical studies or clinical trials conducted by or on behalf of the applicant - to address differences between the product candidate and the reference drug. Drug manufacturers may also submit an ANDA under section 505(j) of the FFDCA to market a generic version of an approved branded drug product. The ANDA must show that the generic version is "therapeutically equivalent," or expected to have the same clinical effect and safety profile as the branded drug product when administered to patients under the conditions specified in the labeling.

The FFDCA and Public Health Service Act ("PHSA") also provide pathways for the approvals of biological products. A company can submit a BLA to the FDA so that the agency can assess, among other things, whether the biological product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The PHSA also permits an abbreviated approval pathway to encourage the development of biosimilars, which are defined as biologics that are "highly similar" to an already approved biologic ("reference product"), notwithstanding minor differences in clinically inactive components and that have no clinically meaningful differences from the reference product in terms of safety, purity and potency.

The FDA typically uses different approval pathways for medical devices. To market and sell a new medical device in the U.S., the manufacturer generally must follow one of two paths. First, a manufacturer could follow what is known as pre-market notification or the 510(k) process. This process requires the manufacturer to demonstrate that the medical device is substantially equivalent to a legally marketed medical device. The second process, pre-market approval, is a more stringent time-consuming process. This requires that the medical device is independently proven to be safe and effective for its intended use.

For all pharmaceuticals (including both drugs and biologics) sold in the U.S., the FDA and other federal regulatory agencies also closely regulate the marketing and promotion of pharmaceutical products through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A pharmaceutical product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses—that is, uses not approved by the FDA and therefore not described in the drug's labeling—because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. In general, a manufacturer may not promote a drug for off-label use, but may engage in non-promotional, balanced communication regarding off-label use under specified conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the United States Department of Justice ("DOJ") or the Office of the Inspector General ("OIG") of the HHS, as well as state authorities. Enforcement action could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal penalties and agreements that materially restrict the manner in which a company promotes or distributes drug products.

In addition, the manufacture, marketing and selling of certain drug products that are controlled substances may be limited by quota grants and other requirements or restrictions enforced by the DEA. Refer to "Drug Enforcement Administration" within this Item 1. Business for further information.

The path leading to FDA approval of a marketing application (NDA for a drug, BLA for a biological product) for a new pharmaceutical product begins when the product is merely a chemical formulation in the laboratory. In general, the process involves the following steps:

- Completion of formulation and laboratory testing in accordance with good laboratory practice that fully characterizes the drug product from a pre-clinical perspective and provides preliminary evidence that the drug product is safe to test in human beings;
- Filing an investigational new drug ("IND") application with the FDA, which must become effective before the conduct of clinical trials (testing in human beings under adequate and well-controlled conditions);
- Approval by an independent institutional review board ("IRB") or ethics committee representing each clinical trial site before each trial may be initiated;

- Designing and conducting adequate and well-controlled human clinical trials to show the safety and efficacy of the product candidate for the proposed indication in accordance with the applicable IND and other clinical trial-related regulations, sometimes collectively referred to as good clinical practice ("GCP");
- Submitting the marketing application for FDA review, which provides a complete characterization of the product;
- Determination by the FDA within 60 days of its receipt of a marketing application to accept and file the application for review;
- Satisfactory completion of potential FDA pre-approval inspections of the designated facility or facilities where the product is produced to assess compliance with cGMP requirements;
- Potential FDA audit of the non-clinical and/or clinical trial sites that generated the data in support of the marketing application;
- Payment of applicable user fees;
- If applicable, satisfactory completion of an FDA Advisory Committee meeting in which the FDA requests views from outside experts in evaluating the application;
- FDA approval of the application, including prescribing information, labeling and packaging of the drug product; and
- Implementation of a REMS program, if applicable, and conduct of any required Phase 4 studies, and compliance with post-approval requirements, including ongoing monitoring and reporting of adverse events related to the product.

Clinical Trials. Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:

- *Phase 1.* Phase 1 includes the initial introduction of an investigational product candidate into humans. Phase 1 trials generally are conducted in healthy volunteers but in some cases are conducted in patients with the target disease or condition. These trials are designed to evaluate the safety, metabolism, pharmacokinetic properties and pharmacologic actions of the investigational product candidate in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 trials, sufficient information about the investigational product candidate's pharmacokinetic properties and pharmacological effects may be obtained to permit the design of Phase 2 trials. The total number of participants included in Phase 1 trials varies, but is generally in the range of 20 to 80.
- *Phase 2.* Phase 2 includes the controlled clinical trials conducted in patients with the target disease or condition, to determine dosage tolerance and optimal dosage, to identify possible adverse side effects and safety risks associated with the product candidate, and to obtain initial evidence of the effectiveness of the investigational product candidate for a particular indication. Phase 2 trials are typically well-controlled, closely monitored, and conducted in a limited subject population, usually involving no more than several hundred participants.
- *Phase 3.* Phase 3 trials are controlled clinical trials conducted in an expanded subject population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product candidate has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate, and to provide an adequate basis for drug approval. Phase 3 trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 trials to demonstrate the efficacy and safety of the drug; however, the FDA may find a single Phase 2 or Phase 3 trial with other confirmatory evidence to be sufficient in rare instances, particularly in an area of significant unmet medical need and if the trial design provides a well-controlled and reliable assessment of clinical benefit.
- *Phase 4*. In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the product. Such post-approval trials are typically referred to as Phase 4 clinical trials.

Clinical trials may not be completed successfully within a specified period of time, if at all. The decision to terminate development of an investigational product candidate may be made by a health authority (such as the FDA), an IRB/ethics committee, or by a company for various reasons. At any time, the FDA may order the temporary or permanent discontinuation of a clinical trial, which is referred to as a clinical hold, or impose other sanctions, if the agency believes the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or subjects are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of product candidates on public registries and the disclosure of certain clinical trial results and other trial information after completion.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product candidate information is submitted to the FDA in the form of a marketing application to request market approval for the product in specified indications.

New Drug Applications and Biologics License Applications. In order to obtain approval to market a drug in the United States, a marketing application (NDA for drug product candidates and BLA for biological product candidates) must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The application includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product candidate to the satisfaction of the FDA.

Under the Prescription Drug User Fee Act ("PDUFA"), the FDA has the authority to collect fees from drug manufacturers who submit pharmaceutical marketing applications for review and approval, although there may be some instances in which the user fee is waived. These user fees help the FDA fund the drug approval process. For calendar 2023, the user fee rate has been set at $3,242,030 for a marketing application requiring clinical data (which could be a 505(b)(1) or 505(b)(2) NDA), and $1,621,010 for an application not requiring a clinical data. No user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan-designated indication. We expense these fees as they are incurred.

The FDA will initially review the pharmaceutical marketing application (NDA or BLA) for completeness before it accepts the application for filing. The FDA has 60 days from its receipt of an application to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the application submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of applications. Applications for standard review product candidates are reviewed within ten months of FDA's acceptance for filing. An accelerated six-month review can be given to applications that meet certain criteria. The FDA can extend the review period by three months, or potentially longer, to consider certain late-submitted information or information intended to clarify information provided in the initial submission. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. FDA Advisory Committee meetings are often held for New Chemical Entities, novel indications, or for applications that otherwise present scientific, technical, or policy questions on which the agency believes it would benefit from the perspectives of outside experts. An advisory committee meeting includes a panel of independent experts, including clinicians and other scientific experts, who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an application, the FDA often will inspect the facilities at which the product is manufactured for cGMP compliance, and may inspect one or more clinical sites to assure compliance with GCP. After it evaluates the application and the results of inspections, the FDA issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If those deficiencies are addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory requirements is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, may require submission and prior FDA approval of a supplemental application (or in some cases a new application) before the change can be implemented. A supplemental application for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing original marketing applications.

Expedited Programs. The FDA maintains certain expedited programs to facilitate the development and review processes for certain qualifying pharmaceutical product candidates, including fast track designation, breakthrough therapy designation, priority review, accelerated approval, and regenerative medicine advanced therapy ("RMAT") designation. A pharmaceutical product

candidate may be granted fast track designation if it is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such condition. With fast track designation, the sponsor may be eligible for more frequent opportunities to obtain the FDA's feedback, and the FDA may initiate review of sections of an application before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the remaining information. Even if a product receives fast track designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

The FDA may designate a product candidate as a breakthrough therapy if it finds that the product candidate is intended, alone or in combination with one or more other product candidates or approved products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates designated as breakthrough therapies, more frequent interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Product candidates designated as breakthrough therapies by the FDA may also be eligible for priority review. Even if a product receives Breakthrough Therapy designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

Accelerated approval under FDA regulations allows a product designed to treat a serious or life-threatening disease or condition that provides a meaningful therapeutic advantage over available therapies to be approved on the basis of either an intermediate clinical endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit. Approvals of this kind typically include requirements for confirmatory clinical trials to be conducted with due diligence to validate the surrogate endpoint or otherwise confirm clinical benefit and for all promotional materials to be submitted to the FDA for review prior to dissemination.

The FDA may also grant priority review designation to a product candidate, which sets the target date for FDA action on the application at six months from FDA filing, or eight months from the sponsor's submission. Priority review may be granted where a product is intended to treat a serious or life-threatening disease or condition and, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in safety or efficacy compared to available therapy. If criteria are not met for priority review, the standard FDA review period is ten months from FDA filing or 12 months from sponsor submission. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

RMAT designation may be granted to regenerative medicine therapies, defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, that are intended to treat, modify, reverse, or cure a serious condition, and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. Advantages of the RMAT designation include all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with FDA. The FDA granted StrataGraft RMAT designation in July 2017.

Orphan Drug Designation. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug product intended to treat a "rare disease or condition," which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S., but for which there is no reasonable expectation that the cost of developing and making a drug product available in the U.S. for this type of disease or condition will be recovered from sales of the product. If orphan product designation is sought, it must be requested before submitting an NDA for the drug for the proposed rare disease or condition. If the FDA grants orphan drug designation, the common name of the therapeutic agent and its designated orphan use are disclosed publicly by the FDA. Orphan product designation does not, by itself, convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which the FDA has interpreted to preclude approving for seven years any other sponsor's application to market the same drug for the same use for which the drug has been granted orphan drug designation, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Orphan exclusivity operates independently from other regulatory exclusivities and other protection against generic competition, including patents that we hold for our products. A sponsor of a product application that has received an orphan drug designation may also be granted tax incentives for clinical research undertaken to support the application.

Generally, orphan drug exclusivity does not block approval of competing products intended for the orphan-protected indication but containing a different active moiety, or containing the same moiety but intended for a different use. Orphan product exclusivity that could block a competitor to one of our products also could block the approval of one of our products for seven years if a competitor obtains approval of a product containing the same moiety for the same orphan disease or condition.

Marketing Exclusivity. Upon NDA approval of a new chemical entity, which is a drug substance that contains no active moiety that has previously been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot accept for review any ANDA or 505(b)(2) NDA for which a new chemical entity is a reference product (an application that contains a challenge to a patent associated with the reference product may be submitted at four years after reference

product approval). There are provisions that operate to preclude approval of the application for an additional period of time. Certain changes to a drug, such as the approval of a new indication, may qualify for a three-year period of exclusivity during which the FDA cannot approve an ANDA or 505(b)(2) NDA for a drug that includes the change.

Under the PHSA, the FDA must wait four years after approval of a biological product under a BLA before accepting a filing for a biosimilar version of the reference product, and the FDA cannot approve a biosimilar version of the reference product until 12 years after the reference product was approved under a BLA. The PHSA also provides for limited regulatory exclusivity for the first FDA-approved interchangeable biologic with respect to each reference product. This means that the FDA will defer approval of additional interchangeable biologics to the same reference product for defined periods of one year or more.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an application is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the application, plus the time between the date of submission of the application and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term restoration.

Post-Approval Regulation. After regulatory approval of a drug is obtained, a sponsor is required to comply with a number of post-approval requirements. For example, as a condition of approval of an application, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, as a holder of an approved NDA, a sponsor is required to report adverse reactions and production problems to the FDA, provide updated safety and efficacy information, submit annual reports and comply with advertising and promotional labeling requirements. Manufacturing must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, as discussed in *Quality Assurance and Current Good Manufacturing Practice Requirements* above**.**

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings, contraindications, or limitations of use, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

ANDA Process. The path leading to FDA approval of generic drug product under an ANDA is different from that of an NDA, a BLA or even a biosimilar. Generally, a generic drug product is one that is the same as an approved "brand" or "innovator" drug product (the reference listed drug or "RLD") in active ingredient, dosage form, strength, and route of administration, bioequivalent to the RLD, and labeled the same as the RLD, Generic drug applications are termed "abbreviated" because they are not required to include data to establish safety and effectiveness, instead relying on demonstrating the sameness to the RLD, which FDA has already found to be safe and effective.

The FDA has the authority to collect, user fees from generic drug manufacturers who submit ANDAs for review and approval, and the fees collected help the FDA fund the drug approval process. The fiscal 2023 user fee rate is set at $240,580 for an ANDA. These fees are expensed as incurred. The FDA has set a target of approving 90% of standard ANDA submissions within ten months of submission for submissions made in 2023, and 90% of priority ANDA submissions within eight months of submission.

Medical Devices. There are two primary pathways to receive authorization to distribute a new device in the U.S. The first pathway is premarket notification or the 510(k) process. Under this pathway, the applicant must demonstrate to the FDA that the new device is as safe and effective or substantially equivalent to a legally marketed device. The applicant can demonstrate this by submitting data. This data may be from human clinical trials. The FDA will make a determination as to whether the new device is substantially equivalent before commercial distribution occurs. Changes that do not significantly affect the safety or efficacy of a legally marketed device may generally be made without additional 510(k) premarket notifications.

The second primary pathway is a premarket approval application ("PMA"). This pathway is generally more complex, time-consuming and expensive than the 510(k) process. Under the PMA pathway, the applicant must demonstrate that the device is safe and effective for its intended use. This generally requires data from clinical trials to show the safety and efficacy of the device. These trials must be performed in accordance with the applicable Investigational Device Exemption regulations. The FDA will approve the application if it finds that the evidence is scientifically valid to demonstrate that the device is safe and effective for its intended use.

Patent and Non-Patent Exclusivity Periods. 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 the Orange Book. Any person that files a Section 505(b)(2) NDA, the type of NDA that relies upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of a previous drug, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless the generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for

the RLD of the bases upon which the patents are challenged, and the holder of the RLD does not sue the later applicant for patent infringement within 45 days of receipt of notice. If an infringement suit is filed, the FDA may not approve the later application until the earliest of: (a) 30 months after receipt of the notice by the holder of the NDA for the RLD; (b) entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; (c) such time as the court may order; or (d) the expiration of the patent.

One of the key motivators for challenging patents is the 180-day market exclusivity period ("generic exclusivity") granted to the developer of a generic version of a product that is the first to file an ANDA containing a Paragraph IV certification and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s) or is not sued or enters into a settlement agreement with the manufacturer of the branded product. For a variety of reasons, there are situations in which a company may not be able to take advantage of an award of generic exclusivity. The determination of when generic exclusivity begins and ends is very complicated as it depends on several different factors.

The holder of the NDA for the RLD may also be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b)(2) NDA product. Generally, if the RLD is a new chemical entity, the FDA may not accept for filing any application that references the innovator's NDA for five years from the approval of the innovator's NDA. However, this five-year period is shortened to four years where a filer's ANDA includes a Paragraph IV certification. In other cases, where the innovator has provided certain clinical study information, the FDA may accept for filing, but may not approve, an application that references the innovator's NDA for a period of three years from the approval of the innovator's NDA.

Certain additional periods of exclusivity may be available if the RLD is indicated for use in a rare disease or condition or is studied for pediatric indications.

Risk Evaluation and Mitigation Strategies. The FDA has the authority to require a pharmaceutical manufacturer to provide a REMS that is intended to ensure that the benefits of a drug or biological product or class of products outweigh the risks of harm. The goal of these programs is to mitigate the risk of abuse, misuse, overdose and accidental exposure as well as educating prescribers, pharmacists, healthcare providers and patients about the safe use of the drug product or class of drug products and the treatment and monitoring of patients. The FDA has the authority to impose civil penalties on or take other enforcement action against any drug manufacturer who fails to properly implement an approved REMS program. We participate in the Transmucosal Immediate Release Fentanyl REMS Program, Opioid Analgesic REMS, Buprenorphine Transmucosal Products for Opioid Dependence REMS, Vigabatrin REMS and other such REMS programs.

Drug Enforcement Administration. The DEA is the U.S. federal agency responsible for domestic enforcement of the federal Controlled Substances Act of 1970 ("CSA"). Compounds that have a potential for dependence and abuse are scheduled as controlled substances under the CSA and similar state and foreign laws. Drugs that are scheduled as controlled substances are subject to stringent regulatory requirements, including requirements for registering manufacturing and distribution facilities, security controls and employee screening, recordkeeping, reporting, product labeling and packaging, import and export. There are five federal schedules for controlled substances, known as Schedule I, II, III, IV and V. The CSA classifies drugs and other substances based on identified potential for abuse. The regulatory requirements that apply to a drug vary depending on the particular controlled substance schedule into which a drug is placed, based on consideration of a number of factors, including its potential for dependence and abuse. Schedules I and II contain the most stringent restrictions and requirements, and Schedule V the least. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Opioids, such as oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are Schedule II controlled substances. Consequently, the manufacture, storage, distribution and sale of these substances are highly regulated. For all controlled substances, there are potential criminal and civil penalties that apply for the failure to meet applicable legal requirements, and healthcare professionals must have a DEA license in order to handle, prescribe, or dispense controlled substances.

The DEA regulates the availability of substances that are classified as Schedule I or II controlled substances by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products for our products that are classified as Schedule II controlled substances. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our commercial and R&D needs. In calendar year 2022, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements. In December 2022, the DEA continued to further reduce, as it has done over the past several years, the manufacturing quota for the top misused Schedule II opioids that may be manufactured in the U.S. in calendar year 2023. This includes oxycodone, hydrocodone, oxymorphone, hydromorphone and fentanyl. The DEA has complete discretion to adjust or leave unchanged these quotas from time to time during the calendar year and to allocate manufacturing and procurement quota to manufacturers.

DEA regulations include certain restrictions for a manufacturer in the U.S. to import finished dosage forms of controlled substances manufactured outside the U.S. These rules reflect a broader enforcement approach by the DEA to regulate the manufacture, distribution and dispensing of legally produced controlled substances. Accordingly, drug manufacturers who market and sell finished dosage forms of controlled substances in the U.S. typically manufacture or have them manufactured in the U.S.

The DEA also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior

to distribution of the controlled substance order. A compliant suspicious order monitoring ("SOM") system includes well-defined due diligence, "know your customer" efforts and order monitoring. One of our Specialty Generics subsidiaries utilizes all available transaction information to identify suspicious orders of any Mallinckrodt controlled substance product and reports such suspicious orders to the DEA when it concludes that chargeback data or other information indicates that a downstream registrant poses a risk of diversion.

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 and accounting mechanisms required by the DEA to prevent loss and diversion.

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.

We and, to our knowledge, our third-party API suppliers, dosage form manufacturers, distributors and researchers have all necessary registrations, and we believe all registrants operate in conformity with applicable registration requirements, under controlled substance laws.

Government Benefit Programs. Statutory and regulatory requirements for Medicaid, Medicare, Tricare and other government healthcare programs govern provider reimbursement levels, as well as require that each pharmaceutical manufacturer that participates in the Medicaid Drug Rebate Program pay rebates to individual states based on a percentage of their net sales arising from Medicaid program-reimbursed products. The federal and state governments may continue to enact measures in the future aimed at containing or reducing payment levels for, or increasing rebates on, prescription pharmaceuticals paid for in whole or in part with government funds. We cannot predict the nature of such measures, which could have material adverse consequences for the pharmaceutical industry as a whole and, consequently, also for us. However, we believe we have provided for our best estimate of potential refunds based on current information available.

From time to time, legislative changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 created a prescription drug coverage program for people with Medicare through a system of government-regulated private market drug benefit plans. This law provides a prescription drug benefit to seniors and individuals with disabilities in the Medicare program ("Medicare Part D"). Congress continues to examine various Medicare policy proposals that may result in pressure on the prices of prescription drugs in the Medicare program.

The Centers for Medicare & Medicaid Services ("CMS"), the agency that administers the Medicare and Medicaid programs, may implement or revise reimbursement or coverage restrictions under those programs, and a state may do likewise under the Medicaid program. Any reduction in reimbursement or restriction of coverage under Medicare, Medicaid or other government programs may result in a similar reduction in payments or restriction of coverage by private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

In addition, the Patient Protection and Affordable Care Act of 2010, as amended ("Affordable Care Act") provided for major changes to the U.S. healthcare system, which impacted the delivery and payment for healthcare services in the U.S. Our business has been impacted by, among other things, changes to the rebates under the Medicaid Fee-For-Service Program and new rebates on Medicaid Managed Care utilization and the imposition of an annual fee on branded prescription pharmaceutical manufacturers. Medicaid provisions reduced net sales by $70.7 million, $65.2 million, $106.5 million and $665.3 million for the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), respectively. The fiscal 2021 (Predecessor) decrease in provision for Medicaid payments was due to the $536.0 million retrospective one-time charge related to the Medicaid lawsuit in fiscal 2020 (Predecessor). Our business was also impacted by the annual fee on branded prescription pharmaceutical manufacturers, which is reflected within selling, general and administrative expenses ("SG&A"). During the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor), and fiscal 2020 (Predecessor), we recorded an expense of $2.0 million, $3.8 million and $11.6 million, respectively. Comparatively, in fiscal 2021 (Predecessor), we recorded a gain of $1.0 million driven primarily by favorable adjustments by the Internal Revenue Service ("IRS") for prior periods primarily related to the Medicaid lawsuit ruling.

The Affordable Care Act also established a Medicare Part D coverage gap discount program, under which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during the coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. These discounts were increased to 70% of negotiated costs pursuant to the Bipartisan Budget Act of 2018, which as effective beginning in 2019.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("Inflation Reduction Act") which, among other things, establishes Medicare Part B and Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug or the average manufacture price of a Part D drug increases faster than the pace of inflation. Failure to timely pay an inflation rebate is subject to a civil monetary penalty. The Inflation Reduction Act also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologics

without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price, starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. The Inflation Reduction Act further makes changes to the Medicare Part D benefit, including sunsetting the existing coverage gap discount program and replacing it with a new manufacturer discount program in 2025. Failure to offer discounts under this program could be subject to civil monetary penalties. Under the Inflation Reduction Act, certain drug products may be eligible for a small biotech exemption based on specified thresholds around Medicare program spending. Products with this designation are exempt from the drug price negotiation program in 2026, 2027, and 2028; and will be phased into the manufacturer liability for Medicare Part D benefit redesign over a number of years. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs in the government health benefit programs. The Inflation Reduction Act or other legislative changes could impact the market conditions for our product candidates.

Pharmaceutical Pricing and Reimbursement. Certain of our affiliates that are manufacturers participate in the Medicaid Drug Rebate Program and other governmental programs. Each manufacturer that participates in the Medicaid Drug Rebate Program is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program, as a condition of having federal funds available for that manufacturer's drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data the manufacturer reports on a monthly and quarterly basis to CMS, the federal agency that administers the Medicare and Medicaid programs. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug, which best price, in general, represents the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. Where the average manufacturer price of a drug increases faster than the pace of inflation, the drug may be subject to an additional rebate paid by its manufacturer in the amount that the average manufacturer price has exceeded the pace of inflation. Currently, the Medicaid rebate is capped at 100 percent of the average manufacturer price, but, effective January 1, 2024, this cap on the rebate will be removed, the rebate liability could increase significantly for certain products. On December 31, 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); and provide definitions for "line extension," "new formulation," and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula (beginning in 2022). A manufacturer's failure to comply with these price reporting and rebate payment requirements, as well as forthcoming statutory changes to such requirements, could negatively impact its financial results.

Federal law requires that each manufacturer that participates in the Medicaid Drug Rebate Program also participate in the 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients, certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The Affordable Care Act exempts "orphan drugs" from the ceiling price requirements for certain hospital covered entities. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program, and, in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Where a drug is subject to an additional rebate, as noted previously, or a low best price, the 340B ceiling price may calculate as low as, but not lower than, $0.01 per unit. Changes to the Medicaid Drug Rebate amount also could affect a manufacturer's 340B ceiling price calculations and negatively impact results of operations.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that are found to have knowingly and intentionally overcharged covered entities, which became effective on January 1, 2019. It is unclear how the government will apply its enforcement authority under the regulation. Manufacturers also are required to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes them to covered entities. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution ("ADR"), process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject a manufacturer to onerous procedural requirements and result in additional liability.

For calendar quarters beginning January 1, 2022, manufacturers are required to report the average sales price for certain Medicare Part B-covered products under the Medicare program, whereas they previously were only required to do so if they participated in the Medicaid Drug Rebate Program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologics, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages, for units of discarded drug reimbursed by Medicare Part B in excess of ten percent of total allowed charges under Medicare Part B for that drug.

Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount. In addition, as noted previously, a manufacturer may be liable for Part B inflation rebates for utilization in quarters starting with the first quarter of 2023. Manufacturers may be liable for civil monetary penalties for violations of this program.

Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for approved products and the resulting Medicare payment rate, and could negatively impact results of operations. Also, the Medicare Part B drug payment methodology is subject to change based on legislation enacted by Congress.

Congress also could enact additional changes that affect overall rebate liability and the information manufacturers report to the government as part of price reporting calculations, which could impact the market conditions for our products. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies, and are seeing an increase in state interest in price reporting, transparency, and other policies to address drug pricing concerns. For additional information about the risk associated with these programs, please see "*Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our business"* included within Item 1A. Risk Factors of this Annual Report.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs ("VA"), Department of Defense ("DoD"), Public Health Service, and Coast Guard (collectively, the Big Four agencies) and certain federal grantees, we are required to participate in the VA Federal Supply Schedule ("FSS") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make our "covered" drugs (*i.e.*, innovator drugs and biologics) available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. The FSS program also allows us (but does not require us) to list certain non-covered drugs on an FSS contract at negotiated pricing, not capped at the FCP. The FCP is derived from a calculated price point called the "non-federal average manufacturer price" ("non-FAMP"), which we are required to calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements. In addition, Section 703 of the National Defense Authorization Act for FY 2008, requires us to pay quarterly rebates to DoD on utilization of covered drugs that are dispensed through DoD's Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual non-FAMP and FCP for the calendar year that the product was dispensed. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, we will be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act ("FCA") and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Healthcare Fraud and Abuse Laws

We are subject to various laws targeting fraud and abuse in the healthcare industry. For example, in the U.S., there are federal and state anti-kickback, false claims, and other related laws that apply to healthcare products and services that are ultimately paid for by government health care programs. These laws include the following:

- The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving anything of value to induce (or in return for) the referral of business, including the purchase, recommendation or prescription of a particular drug reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and patients, prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exemptions and safe harbors are drawn narrowly and are subject to regulatory revision or changes in interpretation by the DOJ and OIG. Practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Violations of the federal Anti-Kickback Statute may be established without providing specific intent to violate the statute.
- The federal civil FCA prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false statement material to a false claim. A claim resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of themselves and federal government alleging violations of the statute and to share in any monetary recovery.

- The healthcare fraud provisions under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which extend to non-government health benefit programs and which impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third party payors, or falsifying or covering up a material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

Violations of these laws can lead to civil and criminal penalties, fines (including mandatory penalties on a per claim or statement basis for violations of the FCA), damages, imprisonment and exclusion from participation in federal healthcare programs. These laws apply to hospitals, physicians and other potential purchasers of our products and are applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs. In addition, some states in the U.S. have enacted compliance and reporting requirements aimed at drug manufacturers. Many states also have statutes or regulations similar to the federal anti-kickback law and the FCA and which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Other states restrict whether and when pharmaceutical companies may provide meals to health care professionals or engage in other marketing-related activities, and certain states and cities require identification or licensing of sales representatives.

We are also subject to the Foreign Corrupt Practices Act of 1977 ("FCPA") and similar worldwide anti-bribery laws in non-U.S. jurisdictions, such as the United Kingdom ("U.K.") Bribery Act of 2010, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents.

Sunshine Act and Transparency Laws

The U.S. Physician Payment Sunshine Act ("Sunshine Act") requires tracking of payments and transfers of value to physicians and teaching hospitals and ownership interests held by physicians and their families, and reporting to the federal government and public disclosure of these data. As of last year, manufacturers must also report transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. Certain states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report transfers of value made to healthcare providers in the applicable state.

Data Protection and Privacy

We are also subject to laws and regulations governing the privacy and security of health related and other personal data we collect and maintain (e.g., European Union's ("E.U.") General Data Protection Regulation ("GDPR"), Section 5 of the Federal Trade Commission Act ("FTC Act"), HIPAA, and the California Consumer Privacy Act ("CCPA"), as amended by the California Privacy Rights Act ("CPRA").

In Europe, the GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data breaches to the competent national data processing authorities, requires having lawful bases on which personal data can be processed. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our annual global turnover) and confers the right for data subjects to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

The Federal Trade Commission ("FTC") sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates" – certain persons or covered entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In California, the CCPA establishes certain requirements for data use and sharing transparency and creates new data privacy rights for California residents. The CCPA and its implementing regulations have already been amended multiple times since their enactment, including by the CPRA. The CPRA introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA went into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Other states, including Virginia, Colorado, Utah, and Connecticut have enacted similar privacy laws that impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislation, on our business as additional information and guidance becomes available. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business.

Compliance with these laws and regulations may require significant additional cost expenditures or changes in products or our business that increase competition or reduce revenue. Noncompliance could result in the imposition of fines, penalties, or orders to stop noncompliant activities, or withdrawal of non-compliant products from a market.

Compliance Programs

In order to systematically and comprehensively mitigate the risks of non-compliance with legal and regulatory requirements described within this Item 1. Business, we have developed what we believe to be robust compliance programs based on the April 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the U.S. DOJ Guidance on the Evaluation of Corporate Compliance Programs, the U.S. Federal Sentencing Guidelines, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, the Code of Ethics of the Advanced Medical Technology Association, the U.K. Anti-Bribery guidance, and other relevant guidance from government and national or regional industry codes of behavior. As further described below, we also operate under a corporate integrity agreement ("CIA") and an Operating Injunction (as defined below). We conduct ongoing compliance training programs for all employees and maintain a 24-hour integrity and compliance reporting hotline with a strict policy of non-retaliation. Our compliance programs are implemented and facilitated by our Chief Compliance Officer ("CCO"), who reports to the Chief Executive Officer ("CEO") and the Governance and Compliance Committee of our Board of Directors. The Compliance function is independent of the manufacturing and commercial operations functions.

As part of our compliance program, we have implemented internal cross-functional processes to review and approve product-specific promotional materials, presentations and external communications to address the risk of misbranding, mislabeling or making false or misleading claims about our products through our promotional efforts. In addition, we monitor business activities through our compliance monitoring program including: sales representative expenses, promotional speaker activities and a "ride along" program for compliance to observe field sales and medical representatives interacting with healthcare professionals and organizations. We have also implemented a comprehensive controlled substances compliance program, including SOM and anti-diversion efforts and we regularly assist federal, state and local law enforcement and prosecutors in the U.S. by providing information and testimony on our products and placebos for use by the DEA and other law enforcement agencies in investigations and at trial. As part of this program, we also work with some of our customers to help develop and implement what we believe are best practices for SOM and other anti-diversion activities.

We believe our compliance program's design addresses our FDA, healthcare anti-kickback, anti-fraud, and anti-bribery-related risks. We believe we have complied with reporting obligations of the Sunshine Act and relevant state disclosure laws and have implemented a program across the Company to track and report data per CMS guidance and state disclosure requirements.

Corporate Integrity Agreement

In concert with the Plan, the Company entered into a CIA with the OIG within the HHS in March 2022. The CIA has a five-year term and requires, among other things, enhancements to our compliance program, fulfillment of self-reporting, monitoring and training obligations, management certifications and resolutions from the Mallinckrodt Board of Directors. In addition, we are required to retain an independent review organization to conduct annual reviews of certain Company systems and transactions related to Specialty Brands government pricing and patient assistance activities. We continue to comply with our CIA obligations.

Operating Injunction

In connection with the Plan, we agreed to be bound by an injunction enjoining those entities from engaging in certain conduct related to the manner in which they operate their opioid business ("Operating Injunction"). The Operating Injunction prohibits, among other things, certain promotional activities related to opioid products and pain treatment, financial and in-kind support for third parties involved with opioids or pain treatment, and certain lobbying activities and communications related to opioids and pain treatment. The Operating Injunction also contains requirements for controlled substances SOM and reporting. The Operating Injunction further requires Mallinckrodt to make available certain clinical data through a third-party data archive and publicly disclose certain produced documents related to the opioid litigation. We implemented an Opioid Product Operating Injunction compliance program as a result of the Operating Injunction. The Operating Injunction provides that Mallinckrodt must retain an independent monitor to evaluate and audit compliance with the Operating Injunction for a term of five to seven years. On February 8, 2021, the Bankruptcy Court entered an order appointing R. Gil Kerlikowske to serve as monitor.

The monitor has issued seven compliance reports describing his work and making certain recommendations regarding potential enhancements to the Company's processes that the Company has worked to implement. The Company has, among other actions, retained a consulting firm with expertise in data analytics to consult regarding the Company's SOM program; enhanced the Company's internal system for customer inquiries and concerns to encourage further collaboration across business units; and implemented a plan to audit state and federal lobbying activity to monitor compliance with the Operating Injunction.

Outside the United States

Outside the U.S., we must comply with laws, guidelines and standards promulgated by other regulatory authorities that regulate the development, testing, manufacturing, distribution, marketing and selling of medicinal products and medical devices, including, but not limited to, Health Canada, the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the U.K., the European Medicines Agency ("EMA"), the European Commission and member states of the E.U. and their competent authorities such as the Irish Medicines Board, the Therapeutic Goods Administration in Australia, the Ministry of Health and Welfare in Japan, the European Pharmacopoeia of the Council of Europe and the International Conference on Harmonization. Although international harmonization efforts continue, many laws, guidelines and standards differ by region or country. We currently market our products in Canada, in various countries in the E.U., and in the Latin American, Middle Eastern, African and Asia-Pacific regions. The approval requirements and process vary by country, and the time required to obtain a marketing authorization may vary from that required for FDA approval. Certain drug products and variations in drug product lines also must meet country-specific and other local regulatory requirements. The following discussion highlights some of the differences in the approval process in other regions or countries outside the U.S.

European Union. Marketing authorizations for medicinal products are obtained pursuant to a centralized, decentralized or mutual recognition procedure. Irrespective of the procedure, an authorization may only be granted to an applicant established in the E.U.

The centralized procedure, which provides for a single marketing authorization valid for all E.U. member states as well as three of the four European Free Trade Association countries (Iceland, Liechtenstein and Norway), is mandatory for the approval of certain medicinal products including orphan medicinal products and biotechnology-derived medicinal products and is optional for others such as novel drug products that are in the interest of patient health. Under the centralized procedure, a single marketing authorization application is submitted for review to the Committee for Medicinal Products for Human Use established at the EMA, which makes a recommendation on the application to the European Commission, who determines whether or not to approve the application. The decentralized procedure allows companies to file identical applications to several E.U. member states simultaneously for product candidates that have not yet been authorized in any E.U. member state. The maximum timeframe for completion of the procedure is in principle 210 days.

A mutual recognition procedure allows companies that have a product already authorized in one E.U. member state to apply for that authorization to be recognized by the competent authorities in other E.U. member states..

Biosimilars can only be authorized once the period of data exclusivity on our candidate, as 'reference' biological medicinal product, has expired. In general, this means that the biological reference medicine must have been authorized for at least eight years before another company can apply for approval of a similar biological product and further two years until the biosimilar can be marketed.

Medical Devices. In the E.U., medical devices must currently comply with the General Safety and Performance Requirements laid down in Annex I to the E.U. Medical Devices Regulation ("MDR"). Compliance with these requirements is a prerequisite to be able to affix the CE mark on products, without which they cannot be marketed or sold in the E.U. To demonstrate compliance with the General Safety and Performance Requirements of the E.U. MDR and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile and not reusable), in relation to which the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the General Safety and Performance Requirements, a conformity assessment procedure requires the intervention of a notified body, which is an organization designated by a Competent Authority of an E.U. member state to conduct conformity

assessments. Depending on the relevant conformity assessment procedure, the notified body would audit and examine the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the General Safety and Performance Requirements. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. Notified bodies must be accredited by the E.U. member states' accreditation bodies to conduct assessment procedures for medical devices in accordance with the E.U. MDR. There are currently a relatively small number of notified bodies that have been accredited to conduct these assessments. This may delay conformity assessment procedures in the future in the E.U.

The E.U. has also adopted directives and other laws that govern the labeling, marketing, advertising, supply, distribution of medicinal products and medical devices. Such directives set regulatory standards throughout the E.U. and permit member states to supplement such standards with additional requirements.

Country-specific regulation of the E.U. member states remains essential also regarding pricing and reimbursement. European governments also regulate medicinal products prices through the control of national healthcare systems that fund a large part of such costs to patients. Many regulate the pricing of a new medicinal product at launch through direct price controls or reference pricing and, recently, some have also imposed additional cost-containment measures on drug products. Such differences in national pricing regimes may create price differentials between E.U. member states. Many European governments also advocate generic substitution by requiring or permitting prescribers or pharmacists to substitute a different company's generic version of a branded medicinal product that was prescribed, and patients are unlikely to take a drug product that is not reimbursed by their government.

The regulatory regime for the U.K. is different which may cause additional administrative burdens. The U.K., comprising Great Britain and Northern Ireland, left the E.U. on January 31, 2020, following which existing E.U. medicinal product legislation continued to apply in the U.K. during the transition period until December 31, 2020 under the terms of the E.U.-U.K. Withdrawal Agreement. During this period, the U.K. and the E.U. negotiated a Trade and Cooperation Agreement ("TCA"), for their future relationship that became effective on January 1, 2021.

Great Britain (England, Scotland and Wales) is now treated as a "third country," a country that is not a member of the E.U. whereas, as a result of the Northern Ireland Protocol, Northern Ireland continues to follow the E.U. regulatory regime. The MHRA is responsible for both Great Britain and Northern Ireland. Following the effectiveness of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 on January 31, 2020, the U.K. regulatory regime for clinical trials, marketing authorizations, importing, exporting and pharmacovigilance largely mirrors that of the E.U. As part of the TCA, the E.U. and the U.K. will recognize Good manufacturing practice ("GMP") inspections carried out by the other party and accept official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The U.K. has unilaterally agreed to accept E.U. batch testing and batch release for a period of at least 2 years which terminated on January 1, 2023. However, the E.U. continues to apply E.U. laws that require batch testing and batch release to take place in the E.U. territory. This means that medicinal products that are tested and released in the U.K. must be retested and re-released when entering the E.U. market for commercial use. As it relates to marketing authorizations, Great Britain has introduced a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland, however, continues to be covered by the marketing authorizations granted by the European Commission. The U.K. regulatory regime for medical devices is largely aligned with previous E.U. directives and will soon be subject to changes that will probably bring it closer to the current E.U. regulations.

Emerging Markets. Many emerging markets continue to evolve their regulatory review and oversight processes. At present, such countries typically require prior regulatory approval or marketing authorization from large, developed markets (such as the U.S.) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorization. Many emerging markets continue to implement measures to control drug product prices, such as implementing direct price controls or advocating the prescribing and use of generic drugs.

Environmental

Our operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, we are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations. We cannot provide assurance that we have been or will be in full compliance with environmental, health and safety laws and regulations at all times. Certain environmental laws assess strict, (i.e., can be imposed regardless of fault) joint and several liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. We have, from time to time, received notification from the EPA and from state environmental agencies in the U.S. that conditions at a number of sites where the disposal of hazardous substances has taken place requires investigation, cleanup and other possible remedial actions. These agencies may require that we reimburse the

government for costs incurred at these sites or otherwise pay for the cost of investigation and cleanup of these sites including compensation for damage to natural resources. Primarily due to past operations, operations of predecessor companies or past disposal practices, we have projects underway at a number of current and former manufacturing facilities as well as former disposal sites to investigate and remediate environmental contamination resulting from past operations, as further described in Note 19 to the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

We continue to be dedicated to environmental sustainability programs to minimize the use of natural resources and reduce the utilization and generation of hazardous materials from our manufacturing process and to remediate identified environmental concerns. Environmental laws are complex and generally have become more stringent over time. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations, and have planned for future capital and operating expenditures to comply with these laws and to address liabilities arising from past or future releases of, or exposures to, hazardous substances.

Raw Materials

We contract with various third-party manufacturers and suppliers, most notably related to our Specialty Brands products, to provide us with raw materials used in our products, finished goods and certain services. If, for any reason, we are unable to obtain sufficient quantities of any of the raw materials, finished goods, services or components required for our products, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The active ingredients in the majority of our current Specialty Generics products and certain products in development, including oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are listed by the DEA as Schedule II substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation and the DEA limits the availability of narcotic raw materials and the production of APIs and generic Schedule II substances through manufacturing and procurement quotas that we must apply for annually in order to obtain and produce these substances.

Sales, Marketing and Customers

Sales and Marketing

We market our branded products to physicians (including neurologists, rheumatologists, hepatologists, nephrologists, pulmonologists, ophthalmologists, oncologists, neonatologists and surgeons), other health care providers including respiratory therapists, pharmacists, pharmacy buyers, hospital procurement departments, ambulatory surgical centers and specialty pharmacies. We distribute our branded and generic products through independent channels, including wholesale drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, hospital networks, ambulatory surgical centers and governmental agencies. In addition, we contract with group purchasing organizations ("GPO(s)") and managed care organizations to improve access to our products. We sell and distribute API directly or through distributors to other pharmaceutical companies.

For further information on our sales and marketing strategies, refer to "Our Businesses and Product Strategies" above.

Customers

Net sales to distributors that accounted for more than 10.0% of our total net sales in the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor) were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
FFF Enterprise, Inc.	26.1 %	11.8 %	*%	*%
CuraScript, Inc.	*	15.6 %	26.1 %	27.4 %

* Net sales to this distributor were less than 10.0% of total net sales during the respective periods presented above.

No other customer accounted for 10.0% or more of our net sales in the above periods presented.

Manufacturing and Distribution

As of December 30, 2022 (Successor), we had 11 manufacturing sites, including eight located in the U.S., as well as sites in Ireland and Japan, which handle production, assembly, quality assurance testing, packaging and sterilization of our products.

Approximately 93.9%, 4.0% and 2.1% of our manufacturing production (as measured by cost of production) was performed within the U.S., Ireland and Japan, respectively, in fiscal 2022.

As of December 30, 2022 (Successor), we maintained distribution centers in ten countries. In addition, in certain countries outside the U.S. we utilize third-party distribution centers. Products generally are delivered to these distribution centers from our manufacturing facilities and then subsequently delivered to the customer. In some instances, product is delivered directly from our manufacturing facility to the customer. We contract with a wide range of transport providers to deliver our products by road, rail, sea and air.

We utilize contract manufacturing organizations ("CMOs") to manufacture certain of our finished goods that are available for resale. We most frequently utilize CMOs in the manufacture of certain of our Specialty Brands products, including Acthar Gel (for finish and filling of the product) and Therakos products.

Seasonality

We have historically experienced fluctuations in our business resulting from seasonality. For example, Acthar Gel has typically experienced lower net sales during the first calendar quarter compared to other calendar quarters, which we believe is partially attributable to effects of annual insurance deductibles and the lack of warm temperatures that may exacerbate certain medical conditions. DEA quotas for raw materials and final dosage products are allocated in each calendar year to companies and may impact our sales until the DEA grants additional quotas, if any. Impacts from quota limitations are most commonly experienced during the third and fourth calendar quarters, and we have typically experienced lower net sales in DEA controlled products during the fourth calendar quarter. While we have experienced these fluctuations in the past, they may not be indicative of what we will experience in the future.

Human Capital

At Mallinckrodt, we value our employees as our most important asset. We aim to create a culture and a work environment that is inclusive and that welcomes diverse experiences and perspectives. We work hard to identify, retain and attract a diverse workforce that shares our corporate vision to improve the lives of underserved patients with severe and critical conditions. We believe that in doing this, it will make us stronger and more innovative. We invest in human resources programs designed to develop capabilities to deliver on our critical business priorities. We do this by offering competitive pay and benefit programs, investing in our employees' growth and development and creating a safe and healthy work environment. We embrace diversity and empower each individual employee to bring their whole, authentic self to work. Further, we encourage and support our employees to be active members of their communities.

As of December 30, 2022 (Successor), we employed a multi-national workforce of approximately 2,700 people. Our products are developed by a workforce with specialized degrees in science, engineering and technology. Our manufacturing and distribution sites located across the U.S., Ireland and Japan made up 60% of our workforce and 18% were field-based working across multiple countries engaging with healthcare professionals and facilities. The remaining 22% of our employees worked within our corporate services locations of Hampton, New Jersey; Hazelwood, Missouri; Webster Groves, Missouri; Washington, District of Columbia ("D.C."), Staines, U.K. and Dublin, Ireland. Of our total workforce, 99% were full time.

Employee Benefits and Well-being

We believe in providing comprehensive and competitive benefits our employees value, designed to be equitable and meet their diverse and unique needs. We are intentional about building inclusivity into our benefits strategy.

In the U.S., Mallinckrodt provides:

- Up to four weeks of paid caregiver leave to help eligible employees deal with family responsibilities;
- Medications at zero employee cost to promote medication adherence for certain chronic medical conditions; and
- Fertility benefits that provide equitable benefits to same-sex couples.

Mallinckrodt also offers a variety of advocacy support resources for employees and their families, including:

- Clinical support for infertility, maternity, oncology, inpatient care, musculoskeletal conditions, congenital heart disease and transplant situation;
- Second opinion services for new or existing medical issues by board-certified, elite specialists at zero cost to employees; and
- Behavioral Health Advocacy to assist employees and their families with complex behavioral health concerns.

Additionally we leverage our well-being platform by collaborating with our diversity focused Business Resource Groups ("BRGs") to provide resources and activities to support their specific goals.

Talent Development and Employee Engagement

We are committed to a culture of continuous learning, aimed at advancing our workforce through personal and professional development. Our talent strategies are aligned to business priorities creating opportunities for our employees to grow and develop. We offer a wide range of leadership and individual development offerings, inclusive of but not limited to, tuition reimbursement, leadership development training, individual development planning, a robust library of on-demand e-learning content, workshops and seminars, networking and professional coaching. We partner with external organizations and invest in programs specifically aimed at advancing diverse talent. We have established processes to identify and align individual employee aspirations with business needs so that development and succession planning can occur. These processes have yielded positive results in the advancement of high potential and diverse talent. We create opportunities to advance our talent through development assignments, on-the-job training and career advancement. Our learning platforms are designed to provide flexibility to meet the needs, interests and aspirations of all employees.

At Mallinckrodt, we value employee feedback. We are intentional about creating a culture where employees can speak freely and are empowered to ask questions. We create opportunities to solicit feedback from employees through one-on-one sessions, focus groups and employee surveys. These forums have and will continue to provide us the opportunity to ensure our employees are engaged and supported both personally and professionally.

Diversity, Equity and Inclusion

We strive to foster inclusive and equitable work environment and a diverse workforce that reflects the customers and patients we serve. We believe the unique and diverse perspectives of our employees enable us to better understand and respond to patients' needs.

Our workforce is built on the foundation of equal opportunity and fair treatment. As a multi-national company, we celebrate the diversity of our workforce. Our employee-led Diversity, Equity and Inclusion ("DEI") Council and BRGs play key roles in cultivating and inspiring a more inclusive culture. These groups are open to anyone and are typically centered on shared interests, identities and affiliations. Our BRGs provide resources for professional development, personal growth, community engagement, well-being and networking, all while fostering connectivity and enhancing our unique culture.

Our BRGs frequently host company-wide educational events to help foster a culture of diversity, equity and inclusion. Examples from 2022 include:

- African American BRG hosted its third annual Summit, titled Beyond Equity: A Call to Action that included leadership and guest speakers discussing how Mallinckrodt can play a role in bringing equity to underrepresented groups.
- Women in Business BRG hosted quarterly "Climb the Ladder" skill-building workshops, as well as a roundtable discussion with members of our Executive Committee on the topics of gender diversity and allyship.
- Namaste Asia BRG hosted an educational webinar that explored the misconceptions about Asian Americans that create impediments to leadership and collaboration, and what they can do achieve equality.
- LGBTQ+ BRG hosted a roundtable discussion around transgender and nonbinary inclusion and ally-ship.

Our approach to DEI continues to receive national recognition. Mallinckrodt has been recognized as a "Best Places to Work for LGBTQ Equality" from the Human Rights Campaign Foundation's Corporate Equity Index.

Social Impact

Mallinckrodt is committed to being a force for good. Our social impact strategy focuses on improving the health and well-being of patients, building stronger communities, and empowering our employees to dedicate their time and resources to the causes they care about most. We provide grants to nonprofits worldwide and support employees with their own philanthropy through volunteerism and giving programs.

Corporate Charitable Giving Program

Mallinckrodt provides patient-related and philanthropic support to nonprofit organizations that are aligned with our mission to address unmet needs with innovative solutions. Our patient-centric charitable contributions support initiatives and programs that have broad public benefit and advance medical care and/or patient care within the Company's therapeutic areas of focus. Our community-

based investments are centered in three strategic areas: (i) improving health and wellness; (ii) advancing science, technology, engineering and mathematics ("STEM") education; and (iii) stimulating jobs and economic growth in life sciences.

Mallinckrodt continues to focus efforts on advancing health equity and improving outcomes for underrepresented communities. We collaborate with patient advocacy organizations to improve engagement with these communities and promote greater awareness of health disparities in our key therapeutic areas of focus. For example, Mallinckrodt supported:

- *NephCure Kidney International's* Health Equity and Diversity Initiative aimed at creating more equitable access to research and care for underrepresented individuals living with, or are at high risk of developing, chronic kidney diseases.
- *The Myositis Association's* Affinity Groups program to amplify patient voices, equity and access, and create safe spaces for communities that share more in common than their myositis.
- *The American Liver Foundation's* Think Liver Think Life national public health campaign that focuses on awareness and screening of liver disease.

We supported STEM education helping to expanded opportunities for female and minority students, further closing the gap in access for these underrepresented groups. Examples of 2022 grant support include:

- *Students 2 Science*, a New Jersey-based nonprofit that inspires and educates students in underserved communities to pursue STEM careers.
- *Maydm, Inc.*, a nonprofit in Madison, Wisconsin that provides girls and youth of color in grades 6-12 with skill-based training in STEM fields.
- *Millbrook Robotics "GearCats" Booster Club* that provides invaluable hands-on STEM education and experience for the students at Millbrook High School, one of North Carolina's largest and most diverse public high schools.

Employee Giving and Volunteerism

We believe that our employees are the cornerstone of our corporate citizenship efforts, and we provide opportunities for them to embrace their passions and amplify their philanthropic impact. Our volunteerism program provides eight hours of extra paid time off to eligible employees annually for qualified volunteer activities, in addition to time off to participate in our global month of service that's held every October. To encourage charitable giving, Mallinckrodt matches U.S. employee donations to eligible nonprofit organizations - up to $2,500 per employee, per calendar year. We also activate special matching opportunities during times of disaster or crisis.

Information About Our Executive Officers

Set forth below are the names, ages as of February 2, 2023, and current positions of our executive officers.

Name	Age	Title
Sigurdur O. Olafsson	54	President, Chief Executive Officer and Director
Bryan M. Reasons	55	Executive Vice President and Chief Financial Officer
Henriette Nielsen	57	Executive Vice President and Chief Transformation Officer
Mark Tyndall	47	Executive Vice President and Chief Legal Officer and Company Secretary
Kassie Harrold	43	Executive Vice President and Chief Compliance Officer
Lisa French	54	Executive Vice President and Chief Commercial Officer
Peter Richardson	63	Executive Vice President and Chief Scientific Officer
Stephen Welch	45	Executive Vice President and Head of Specialty Generics
Jason Goodson	42	Executive Vice President and Head of Corporate Development

Set forth below is a brief description of the position and business experience of each of our executive officers.

Sigurdur O. Olafsson has been President, CEO and a board director since June 2022. Mr. Olafsson has almost 30 years of diverse pharmaceutical experience across branded and generic drugs. Before joining Mallinckrodt, Mr. Olafsson served as CEO of Hikma Pharmaceuticals plc ("Hikma") from February 2018 to June 2022. Prior to Hikma, Mr. Olafsson served as president and CEO of the Global Generic Medicines Group of Teva Pharmaceuticals ("Teva"), from July 2014 to January 2017. Before that, he served in various senior executive roles at Actavis plc (Watson) from September 2010 to June 2014 and the Actavis Group from October 2003 to August 2010, which develop, manufacture and distribute branded, generic and biosimilar products. Mr. Olafsson has also held a number of leadership positions in Pfizer's Global R&D organization in the U.K. and U.S., focused on branded drug development, and served as head of drug development for Omega Farma in Iceland. Mr. Olafsson has previously served as a director on the boards of Hikma from 2018 to 2022 and Pfenex Inc. from 2017 to 2019. Mr. Olafsson holds a Master of Science in Pharmacy (Cand Pharm) from the University of Iceland, Reykjavik.

Bryan M. Reasons is our Executive Vice President ("EVP") and Chief Financial Officer ("CFO"). He has executive responsibility for the global finance function. Prior to joining Mallinckrodt in March 2019, Mr. Reasons served as Senior Vice President ("SVP") and CFO of Amneal Pharmaceuticals, Inc. from May 2018 until January 2019 and as SVP, Finance and CFO of Impax Laboratories, Inc. from December 2012 until Amneal and Impax completed their business combination to form Amneal in May 2018. Mr. Reasons previously served as Impax's Acting CFO from June 2012 to December 2012 and as Impax's Vice President ("VP"), Finance from January 2012 to June 2012. Prior to joining Impax in January 2012, he held various finance management positions at Cephalon, Inc. from 2005 to 2012 and at E. I. Du Pont De Nemours and Company from 2003 to 2005 and was at PricewaterhouseCoopers LLP ("PwC") from 1993 to 2003, last serving as senior manager. Mr. Reasons also serves as an independent board director and audit committee chair for both Aclaris Therapeutics, Inc. and Recro Pharma, Inc.

Henriette Nielsen is our EVP and Chief Transformation Officer ("CTO"), a role she assumed in August 2022. Ms. Nielsen has executive responsibility for all human resources, communications and people-related matters, as well as a focus on further building out our Environment, Social and Governance program. Ms. Nielsen brings significant experience from a range of corporate functions and an impressive track record of enhancing operations at pharmaceutical companies. Previously, Ms. Nielsen served at Hikma as EVP, Business Operations, a role she held from 2018 to 2022. Before that, Ms. Nielsen served at Teva as SVP, CTO, Global Marketing and Portfolio from 2015 to 2018, and SVP, CTO, Global Generics Medicine from 2014 to 2015. Before that, she was the founder of System Matters APS, a healthcare and impact investing consultancy from 2011 to 2014 and the general counsel and an executive vice president at Actavis Group from 2006 to 2011. Ms. Nielsen began her career as a commercial lawyer in Denmark at Kromann Reumert. She presently serves as Vice Chair of Think Equal USA, a not-for-profit providing and advocating for early-age social emotional learning, and an advisor to EIR, which promotes women's sports in Denmark. From 2017 to 2018 she served as a board member and observer at PGT Healthcare, a joint venture between Teva and Procter & Gamble Company. Ms. Nielsen was a candidate of law at the University of Copenhagen, received her Master of Laws at the University of Edinburgh, and completed the Leading Sustainable Corporation Program at the University of Oxford.

Mark Tyndall is our EVP, Chief Legal Officer, and Corporate Secretary, roles he assumed in August 2022. Mr. Tyndall has executive responsibility for all legal functions and serves as the primary liaison to the Board of Directors. He also has responsibility for Mallinckrodt's Government Affairs and Patient Advocacy functions. Previously, from February 2021 to August 2022, Mr. Tyndall served as Mallinckrodt's SVP and U.S. General Counsel, where he had responsibility for the U.S. and international commercial legal teams, corporate litigation and investigations, legal operations, and the corporate privacy function, and oversaw the Government Affairs team. Before that, Mr. Tyndall held the roles of SVP of Government Affairs and Chief Counsel of Litigation from February 2019 to February 2021, and VP of Government Affairs, Policy and Patient Advocacy from June 2014 to February 2019. Prior to Mallinckrodt, Mr. Tyndall served as Head of Global Policy and Public Affairs at Bayer Healthcare's consumer health division, a role he served in from January 2013 to June 2014. Prior to joining Bayer, Mr. Tyndall practiced healthcare and political law in the Washington, D.C. office of Sidley Austin LLP, where he focused on healthcare regulatory issues, fraud and abuse matters and legislative and policy issues. He is also a former professional staff member of the U.S. Senate Committee on Agriculture, Nutrition and Forestry. Mr. Tyndall holds a Juris Doctor ("J.D.") from George Washington University Law School, a Master of Public Policy from the College of William and Mary, and a Bachelor of Arts ("B.A.") degree in Economics from Christopher Newport University. He also completed the International Human Rights Law Summer Program at the University of Oxford, New College.

Kassie Harrold is our EVP and CCO, a role she assumed in August 2022. Ms. Harrold has executive responsibility for overseeing Mallinckrodt's global integrity and compliance program. Previously, Ms. Harrold served as our SVP and CCO, with responsibility for global ethics and the compliance program, including risk assessment and mitigation, hotline reporting and investigations, program monitoring and governance. Ms. Harrold has more than 15 years of compliance experience in the pharmaceutical and specialty chemical industries, and has assessed, implemented and managed compliance programs in a broad range of subject matter areas. Ms. Harrold has held roles of increasing responsibility since joining Mallinckrodt in 2013, including leading the trade compliance and business support functions and advising senior management on a broad range of business matters as the Senior Staff Liaison to the President and CEO. Previously, Ms. Harrold held several positions, including global compliance, litigation and employment counsel and government affairs, with Solutia Inc., the specialty chemicals spin-off of Monsanto. Ms. Harrold is a member of the Healthcare Businesswomen's Association ("HBA"), previously serving on the St. Louis chapter board. She also participates in the Pharmaceutical Compliance Forum as a member of the CCO Roundtable. She earned her Bachelor of Science ("B.S.") and J.D. degrees from Duquesne University in Pittsburgh, Pennsylvania.

Lisa French is our EVP and Chief Commercial Officer, a role she assumed in October 2022. She has executive responsibility for all commercial and market-access activities for the Company's Specialty Brands products, as well as new product launch execution for assets in Mallinckrodt's near-term development portfolio. Ms. French has more than 30 years of experience in U.S. go-to-market commercialization strategy development and operating experience across the therapeutics lifecycle. Prior to joining the Company, she served as U.S. Business Unit Lead of Organon & Co.'s, a global healthcare company, Women's Health Franchise, where she led the commercial team. Prior to that, she held various positions of increasing responsibility at Merck, where she ultimately led all aspects of a multi-billion dollar brand, executed commercial innovation initiatives and oversaw multiple sales teams. Her roles included:

Associate Vice President, U.S. Marketing Lead – HPV Franchise; Vice President of U.S. Strategy and Commercial Model Innovation; Executive Director of U.S. Federal Policy; National Executive Director of Commercial Operations – Women's Health; National

Director of Commercial Operations – HIV; Regional Director of Commercial Operations – Chronic Care; and Regional Director of Commercial Operations – Cardiovascular Care, among other roles. Ms. French earned her B.S. in Biology from West Chester University and completed Harvard Business School's Emerging Leaders and Leadership & Strategy executive programs.

Dr. Peter Richardson, MRCP, is our EVP and Chief Scientific Officer, a role he assumed in January 2023. He has executive responsibility for Mallinckrodt's branded research and development, medical affairs, safety, portfolio and project management, and regulatory affairs functions. Dr. Richardson is a pharmaceutical executive with more than 30 years of experience in research and development leadership, including building and supporting product development pipelines and clinical program management. Prior to joining the Company, Dr. Richardson served as EVP and Chief Medical Officer at Antares Pharmaceuticals, Inc. leading the organization's research and development activities. Prior to Antares Pharmaceuticals, Inc. he held senior leadership positions in research and development at several pharmaceutical companies, including Novartis, MannKind Corporation and Adare Pharmaceuticals. Dr. Richardson earned his Bachelor of Medical Sciences from the University of Nottingham and his Bachelor of Medicine and Bachelor of Surgery from the University of Nottingham Medical School. He completed Stanford University Graduate School of Business' executive program and is a member of the Royal College of Physicians in the United Kingdom.

Stephen Welch is our EVP and Head of Specialty Generics, a role he assumed in August 2022. He has executive responsibility for the Company's Specialty Generics segment, directly managing all aspects of the segment's business. Before that, from January 2022 to August 2022, Mr. Welch served as our SVP and General Manager, Specialty Generics. He previously served as the segment's CFO from December 2020 to January 2022 and CTO for Mallinckrodt from August 2019 to June 2022, including during the Company's Chapter 11 process, and regularly represented the Company in those proceedings. He joined Mallinckrodt in 2012 and during his time with the Company has held a number of increasingly strategic roles, including Chief of Staff to the President and CEO and Vice President of Corporate Strategy. He began his time at Mallinckrodt in the tax department, focused primarily on mergers and acquisitions transactions and business integrations. Prior to joining Mallinckrodt, Mr. Welch led the tax functions at Human Genome Sciences and PharMerica. He began his career at PwC. Mr. Welch holds a J.D. from the Georgetown University Law Center and a Bachelor's degree in Political Science from California State University, Bakersfield.

Jason Goodson is our EVP and Head of Corporate Development, a role he assumed in August 2022. Mr. Goodson has executive responsibility for overseeing corporate strategy, business development and business intelligence. He is a seasoned executive leader with a track record of navigating complex business issues and delivering results against corporate strategy. Mr. Goodson previously served as our VP of Business Operations, where he had responsibility for corporate strategy, business development and business intelligence and analytics. Mr. Goodson has also served as Chief of Staff to the President and CEO supporting various strategic initiatives including key workstreams within the Chapter 11 process. Mr. Goodson has over 18 years of experience in various finance leadership, strategy and mergers and acquisitions transaction focused roles. He began his career at Mallinckrodt as Assistant Controller, within the finance organization focused on mergers and acquisitions transactions, integration and transformation projects. Prior to joining Mallinckrodt, Mr. Goodson was with SunEdison Inc, in various finance leadership roles including responsibility for finance transformation initiatives and various business development transactions. Prior to his time at SunEdison, Inc, he was with PricewaterhouseCoopers as a manager in the audit practice. Mr. Goodson holds Masters and Bachelor's degrees from the University of Missouri – Columbia in Accounting. He is a Certified Public Accountant in the state of Missouri.

Available Information

Our website address is mallinckrodt.com. We are not including the information contained on our website as part of, or incorporating it by reference into, this filing. We make available to the public on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 ("Exchange Act") as soon as reasonably practicable after such material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission ("SEC"). Our reports filed with, or furnished to, the SEC are available on the SEC's website at sec.gov.

We use our website at mallinckrodt.com as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. We also use our website to expedite public access to time-critical information regarding our company in advance of or in lieu of distributing a press release or a filing with the SEC disclosing the same information. Therefore, investors should look to the Investor Relations page of our website for important and time-critical information. Visitors to our website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of our website.

Item 1A. Risk Factors.

You should carefully consider the risks described below in addition to all other information provided to you in this Annual Report. Our competitive position, business, financial condition, results of operations and cash flows could be affected by the factors set forth below, any one of which could cause our actual results to vary materially from recent results or from our anticipated future results. The risks and uncertainties described below are those that we currently believe may materially affect our company.

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks and others are discussed elsewhere in this Annual Report. These and other risks could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Risks Related to Our Emergence from Bankruptcy

We recently emerged from bankruptcy, which could adversely affect our business and relationships.

Our having filed for bankruptcy, notwithstanding our recent emergence from the resulting bankruptcy proceedings, could adversely affect our business and relationships with customers, vendors, contractors, employees or suppliers. Due to uncertainties, many risks associated with the bankruptcy exist, including the following:

- the ability to attract, motivate, and/or retain key executives and employees may be adversely affected;
- employees may be more easily attracted to other employment opportunities;
- competitors may take business away from us, and our ability to retain customers may be negatively impacted;
- suppliers may not be willing to do business with us at all or on acceptable terms; and
- appeals from orders of the bankruptcy court increase our liabilities.

The occurrence of one or more of these events could have a material and adverse effect on our operations, financial condition and reputation and we cannot assure you that having been subject to bankruptcy proceedings will not adversely affect our operations in the future.

Our actual financial results after emergence from bankruptcy may not be comparable to our projections filed with the Bankruptcy Court or otherwise made public in the course of the Chapter 11 Cases.

In connection with the disclosure statement we filed with the Bankruptcy Court and the hearing to consider confirmation of our Plan (as well as in certain other filings), we prepared projected financial information for various reasons, including to demonstrate to the Bankruptcy Court the feasibility of the Plan and our ability to continue operations upon our emergence from Chapter 11. Those projections were prepared solely for the purposes stated therein and have not been, and will not be, updated on an ongoing basis and should not be relied upon by investors. At the time they were prepared, the projections reflected numerous assumptions concerning our anticipated future performance with respect to then prevailing and anticipated market and economic conditions that were and remain beyond our control and that may not materialize. Projections are inherently subject to substantial and numerous uncertainties and to a wide variety of significant business, economic and competitive risks and the assumptions underlying the projections or valuation estimates may prove to be wrong in material respects. Actual results may vary significantly from those contemplated by the projections. As a result, investors should not rely on those projections.

Our historical financial statements are not comparable to the information contained in our financial statements after the application of fresh-start accounting.

Upon emergence from bankruptcy, we qualified for and adopted fresh-start accounting in accordance with Financial Accounting Standards Board ASC 852, Reorganizations, which on the Effective Date resulted in a new entity, the Successor, for financial reporting purposes, with no beginning retained earnings or deficit as of the fresh-start reporting date. Fresh-start accounting requires that new fair values be established for our assets, liabilities, and equity as of the Effective Date. The Effective Date fair values of the Successor's assets and liabilities differ materially from their recorded values as reflected on the historical balance sheets of the Predecessor. In addition, as a result of the application of fresh-start accounting and the effects of the implementation of the Plan, the financial statements for the period after June 16, 2022 are not comparable with the financial statements prior to and including June 16, 2022. Our consolidated financial statements after the Effective Date are not comparable with the consolidated financial statements on or before that date and may be different from historical trends. This will make it difficult for shareholders to assess our performance in relation to prior periods. See Note 3 to the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Upon our emergence from bankruptcy, our Board of Directors was changed and may implement changes in our business strategy that could affect the scope and results of our operations.

Our corporate business strategy is subject to continued development, evaluation and implementation by our management and Board of Directors. Pursuant to the Plan, the composition of our Board of Directors changed significantly following our emergence

from bankruptcy. Our Board of Directors is now made up of nine directors, with a new non-executive Chairman of the Board, all of whom have not previously served on our Board of Directors prior to our emergence from bankruptcy. The new directors have different backgrounds, experiences and perspectives from those individuals who previously served on the Board of Directors of the Company prior to our emergence from bankruptcy and, thus, may have different views on the issues that will determine our future, including our strategic plans and priorities. The Board of Directors may determine, from time to time, to implement changes in our business strategy which may affect our operations and the future strategy and plans of the Company and differ materially from those of the past. There is, however, no guarantee that the strategic initiatives and plans, whether current or future, of the Board of Directors will be implemented in a timely manner or at all and, consequently, there is no guarantee that the operational and financial objectives of the Board of Directors will be achieved in a timely manner or at all.

We have contractual and court-ordered compliance obligations that if violated could result in exclusion from participation in federal healthcare programs and monetary, injunctive or other sanctions.

In March 2022, we entered into a CIA with the OIG-HHS. The CIA has a five-year term and requires, among other things, enhancements to our compliance program, fulfillment of self-reporting, monitoring and training obligations, management certifications and resolutions from the Mallinckrodt Board of Directors. In addition, we are required to retain an independent review organization to conduct annual reviews of certain Company systems and transactions related to Specialty Brands government pricing and patient assistance activities. Complying with the CIA requires the expenditure of significant resources and management time. If we fail to comply with the terms of the CIA, we may be subject to significant stipulated monetary penalties and/or exclusion from participation in federal health care programs, including Medicare.

Additionally, a failure to meet the requirements or terms of the Operating Injunction entered by the Bankruptcy Court which places obligations on us with respect to the operation of our opioid business could lead to adverse action by the Bankruptcy Court, one or more state Attorneys General, or other enforcement authorities. Such actions may result in monetary, injunctive or other sanctions, as well as increased legal fees and costs associated with such actions. Such actions and associated violations may also increase the Company’s risk for future lawsuits or other actions by third parties related to the opioid business.

Risks Related to Our Business

Governmental investigations, inquiries, and regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our historical commercialization of opioids could adversely affect our reputation, business, financial condition, results of operations and cash flows.

As a result of greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers by state and federal agencies. As a company that first began processing opioids in the 1890s, we understand the utility of these products and that they are safe and effective when taken as appropriately prescribed. We are deeply committed to diversion control efforts, have sophisticated systems in place to identify suspicious orders and engage in significant due diligence and ongoing monitoring of customers. However, we, along with other opioid manufacturers, have been the subject of federal and state government investigations and enforcement actions, focused on the misuse and abuse of opioid medications in the U.S. Similar investigations may be initiated in the future.

In addition, a significant number of lawsuits have been filed against us, other opioid manufacturers, distributors and others in the supply chain by cities, counties, state Attorneys General and private persons seeking to hold us and others accountable for opioid misuse and abuse. As a result of the Company's emergence from bankruptcy, all opioid claims against us were deemed to have been settled, discharged, waived, released and extinguished in full on the Effective Date. We may face new opioid claims in the future, which could have a material adverse effect on our competitive position, business, financial condition and results of operations.

In connection with the bankruptcy, we have implemented steps to comply with an Operating Injunction enjoining certain Mallinckrodt entities from engaging in certain conduct related to the manner in which they operate their opioid business. The Operating Injunction prohibits, among other things, certain promotional activities related to opioid products and pain treatment, financial and in-kind support for third parties involved with opioids or pain treatment, and certain lobbying activities and communications related to opioids and pain treatment. The Operating Injunction also contains requirements for controlled substances suspicious order monitoring and reporting. The Operating Injunction further requires Mallinckrodt to make available certain clinical data through a third-party data archive and publicly disclose certain produced documents related to the opioid litigation. The Operating Injunction provides that Mallinckrodt must retain a monitor to evaluate and monitor compliance with the Operating Injunction for a term of five to seven years. On February 8, 2021, the Bankruptcy Court entered an order appointing R. Gil Kerlikowske to serve as monitor. The obligations imposed by the Operating Injunction would apply to the operation of Mallinckrodt's opioid business by any subsequent purchaser. The Operating Injunction imposes material limitations on Mallinckrodt's business in addition to those imposed by otherwise applicable law. Those limitations may have an adverse financial impact on Mallinckrodt's opioid business, including but

not limited to by increasing overhead costs or reducing product sales. A violation of the Operating Injunction may also subject the company to adverse action by the Bankruptcy Court, state and territory Attorneys General, or other enforcement authorities, as well as increased legal fees and costs associated with such actions.

In addition, legislative, regulatory or industry measures to address the misuse of prescription opioid medications may also affect our business in ways that we are not able to predict. For example, the State of New York enacted the Opioid Stewardship Act ("OSA"), which went into effect on July 1, 2018 and established an aggregate $100.0 million annual assessment on sales of certain opioid medications in New York. The OSA was challenged, and on December 19, 2018, the U.S. District Court for the Southern District of New York ruled that the OSA was unconstitutional and enjoined its enforcement. On January 17, 2019, the State of New York appealed this ruling. On September 14, 2020, a panel of the U.S. Court of Appeals for the Second Circuit reversed in part the lower court's judgment, finding that the lower court should have dismissed our (and other parties') challenges to the OSA for lack of subject matter jurisdiction. Together with the other plaintiffs, we filed a petition for rehearing en banc to challenge the panel's decision, which was denied on December 18, 2020. On February 12, 2021, the Second Circuit granted the parties' request to stay the mandate. The parties filed a petition for certiorari with the Supreme Court, which was denied. On October 21, 2021, the District Court vacated its December 19, 2018 order, except for its invalidation of the "pass through prohibition" on the basis it violates the Commerce Clause. Some states have enacted opioid taxes or enacted increased licensure and registration fees. For example, New York, effective July 1, 2019, imposed an excise tax on certain opioids. Other states may consider similar legislation that could require entities to pay an assessment or tax on the sale or distribution of opioid medications in those states and may vary in the assessment or tax amounts and the means of calculation from the OSA. If additional state or local jurisdictions successfully enact such legislation and we are not able to mitigate the impact on our business through price increases, operational changes or commercial arrangements, such legislation in the aggregate may have a material adverse effect on our business, financial condition, results of operations and cash flows. See the risk factor captioned "*Extensive laws and regulations govern the industry in which we operate, and any failure to comply with such laws and regulations, including any changes to those laws and regulations may materially adversely affect us.*" for more information.

Furthermore, in the current climate, stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are frequently in the media. Unfavorable publicity regarding the use or misuse of opioid drugs, the limitations of abuse-deterrent formulations, the ability of drug abusers to discover previously unknown ways to abuse our products, public inquiries and investigations into prescription drug abuse, litigation, or regulatory activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation, leading to parties being unwilling to engage with us from a business perspective, and could have a material impact on the results of litigation.

Finally, various government entities, including Congress, state legislatures or other policy-making bodies have in the past and may in the future hold hearings, conduct investigations and/or issue reports calling attention to the opioid crisis, and may mention or criticize the perceived role of manufacturers, including us, in the opioid crisis. Similarly, press organizations have and likely will continue to report on these issues, and such reporting may result in adverse publicity for us, resulting in reputational harm.

The healthcare industry has been under increasing scrutiny from governments, legislative bodies and enforcement agencies related to sales, marketing and pricing practices, and changes to, or non-compliance with, relevant policies, laws, regulations or government guidance may result in actions that could adversely affect our business.

In the U.S. over the past several years, a significant number of pharmaceutical and biotechnology companies have been subject to inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales, marketing and pricing practices, including the DOJ and various other agencies including the OIG within the HHS, the FDA, the FTC and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FFDCA, the FCA, the Prescription Drug Marketing Act, anti-kickback laws, data and patient privacy laws, export and import laws, consumer protection laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. These laws are described in greater detail in Item 1. Business. The DOJ and the SEC have also increased their focus on the enforcement of the FCPA, particularly as it relates to the conduct of pharmaceutical companies.

Many companies have faced government investigations or lawsuits by whistleblowers who bring a “qui tam” action under the FCA on behalf of themselves and the government for a variety of alleged improper promotional and marketing activities, including providing free product to customers expecting that the customers would bill the federal programs for the product; providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company’s products; providing assistance to patients with their insurance co-insurance obligations and providing donations to third-party charities that provide patients with such assistance; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued FCA cases against pharmaceutical companies for causing false claims to be submitted as a result of the promotion and marketing of their products for unapproved uses or violations of the federal Anti-Kickback Statute. If we become the subject of a FCA or other government

investigation or whistleblower suit, we could incur substantial legal costs (including settlement costs) and business disruption responding to such investigation or suit, regardless of the outcome.

If we are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and/or civil sanctions, including significant fines, damages, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, actions against executives overseeing our business, consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations and/or burdensome remediation measures. Any such fines, awards, other sanctions or required remediation could have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We face significant competition and may not be able to compete effectively.

The industries in which we operate are highly competitive. Competition takes many forms, such as price reductions on products that are comparable to our own, development of new products with different mechanisms that obviate the need for our treatments, acquisition or in-licensing of new products that may be more cost-effective than or have performance superior to our products, the introduction of generic versions when our proprietary products lose their patent protection or market exclusivity, and technologies that are similar to our devices but may operate either more effectively or less expensively. This competition may limit the effectiveness of any price increases we initiate. Following any price increase by us, competitors may elect to maintain a lower price point that may result in a decline in our sales volume. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

As to competition for our specific products:

- Acthar Gel—Given the approval by the FDA of a competitor's purified cortrophin gel product for the treatment of certain chronic autoimmune disorders (including acute exacerbations of multiple sclerosis and rheumatoid arthritis as well as excess urinary protein due to nephrotic syndrome), we anticipate that competition will likely continue to intensify, which could have an adverse effect on our financial condition, results of operations and cash flows.
- INOmax—We have seen increased competition following the launch of a competitive nitric oxide product before the expiration of the last of the listed patents on May 3, 2026 (November 3, 2026 including pediatric exclusivity), which has had an adverse effect on our ability to successfully maximize the value of INOmax, and if it continues, could have an adverse effect on our financial condition, results of operations and cash flows.

In addition, manufacturers of generic pharmaceuticals typically invest far less in R&D than research-based pharmaceutical companies, allowing generic versions to typically be significantly less expensive than the related branded products. The generic form of a drug may also enjoy a preferred position relative to the branded version under third-party reimbursement programs, or be routinely dispensed in substitution for the branded form by pharmacies. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions, decreased sales volume or both.

For further discussion on the competitive nature of our business, as well as the intellectual property rights and market exclusivity that play a key role in our business, refer to Item 1. Business included within this Annual Report. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may experience pricing pressure on certain of our products due to competitor's product entries, legal changes or changes in insurers' reimbursement practices resulting from increased public scrutiny of healthcare and pharmaceutical costs, which could reduce our future revenue and profitability.

Public and governmental scrutiny of the cost of healthcare generally and pharmaceuticals in particular, especially in connection with price increases of certain products, could affect our ability to maintain or increase the prices of one or more of our products, which could negatively impact our future revenue and profitability. Certain press reports and other commentary have criticized the increases in the price of Acthar Gel over time, including related to the period prior to our acquisition of the product. Acthar Gel represented 28.3% and 25.4% of our net sales for period of June 17, 2022 through December 30, 2022 (Successor) and January 1, 2022 through June 16, 2022 (Predecessor), respectively. In addition, U.S. federal prosecutors have issued subpoenas to certain pharmaceutical companies seeking information about their drug pricing practices, among other issues, and in October 2020, the U.S. House of Representatives Committee on Oversight and Reform held hearings relating to drug pricing at which our former CEO testified along with executives from other major pharmaceutical companies. On December 10, 2021, the committee issued its final majority report detailing findings from the investigation. We cannot predict whether any particular legislative or regulatory changes or changes in insurers' reimbursement practices may result from any such public scrutiny, what the nature of any such changes might be or what impact they may have on us. If legislative or regulatory action were taken or insurers changed their reimbursement practices in

a manner that limits our ability to maintain or increase the prices of our products, our financial condition, results of operations and cash flows could be negatively affected.

Sales of our products are affected by, and we may be negatively impacted by any changes to, the reimbursement practices of governmental health administration authorities, private health coverage insurers and other third-party payers. In addition, reimbursement criteria or policies and the use of tender systems outside the U.S. could reduce prices for our products or reduce our market opportunities.

Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities, private health coverage insurers and other third-party payers. The ability of patients to obtain appropriate reimbursement for products and services from these third-party payers affects the selection of products they purchase and the prices they are willing to pay. In the U.S., there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that third-party payers may pay to reimburse the cost of drugs, including with respect to Acthar Gel. We believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the usage and reimbursement of Acthar Gel. 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. Furthermore, demand for new products may be limited unless we obtain reimbursement approval from governmental and private third-party payers prior to introduction. Reimbursement criteria, which vary by country, are becoming increasingly stringent and require management expertise and significant attention to obtain and maintain qualification for reimbursement.

For any marketed drug products which are covered in the U.S. by the federal or state healthcare programs, such as the Medicare and Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require medicines be offered at substantial rebates and/or discounts to the government and certain private purchasers including "covered entities" purchasing under the 340B Drug Discount Program. Some of these programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear or precise. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties. One component of the rebate and discount calculations under the Medicaid and 340B programs, respectively, is the "additional rebate," a complex calculation which is based, in part, on the extent that a branded drug's price increases over time more than the rate of inflation (based on the Consumer Price Index for All Urban Consumers). This "additional rebate" calculation can result in Medicaid rebates up to 100% of a drug's "average manufacturer price" and 340B prices of one penny. With respect to Acthar Gel, the "additional rebate" scheme of the 340B pricing rules, as applied to the historical pricing of Acthar Gel both before and after we acquired the medicine, have resulted in a 340B ceiling price of one penny, which has negatively impacted and is expected to continue to negatively impact our net sales of Acthar Gel.

In the E.U., each E.U. member state can restrict the range of medicinal products for which its national health insurance system provides reimbursement and can control the prices of medicinal products for human use marketed on its territory. In many countries in the E.U., procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing authorization. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the E.U. member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some E.U. member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment ("HTA"), of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some E.U. member states, including those representing the larger markets. The HTA process, which is currently governed by national laws in each E.U. member state, is the procedure to assess the therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual E.U. member state. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between E.U. member states. The E.U. HTA Regulation (EU) 2021/2282, which was adopted in December 2021 and entered into force in January 2022, aims to harmonize the clinical benefit assessment of HTA across the E.U. and will apply from January 12, 2025. It provides for common HTA tools, methodologies and procedures and complements Directive 2011/24/EU on the application of patients' rights in cross-border healthcare under which a voluntary network of national authorities or bodies responsible for HTA in the individual E.U. member states was established.

If we are unable to obtain, then maintain favorable pricing and reimbursement status in E.U. member states that represent significant markets, our anticipated revenue from and growth prospects for our products in the E.U. could be negatively affected. Due

to persisting effects of the novel coronavirus ("COVID-19") pandemic, we may still anticipate delays by certain European regulatory authorities in their pricing and reimbursement reviews. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement decisions, including as a result of regulatory review delays due to the COVID-19 pandemic, planned launches in the affected E.U. member states would be delayed, which could negatively impact anticipated revenue from and growth prospects for any product candidate.

With regard to private payers, reimbursement of highly-specialized products, such as Acthar Gel, is typically reviewed and approved or denied on a patient-by-patient, case-by-case basis, after careful review of details regarding a patient's health and treatment history that is provided to the insurance carriers through a prior authorization submission, and appeal submission, if applicable. During this case-by-case review, the reviewer may refer to coverage guidelines issued by that carrier. These coverage guidelines are subject to on-going review by insurance carriers. Because of the large number of insurance carriers, there are a large number of guideline updates issued each year.

In addition, a number of markets outside the U.S. in which we operate have implemented or may implement tender systems in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for products. The company that wins the tender receives preferential reimbursement for a period of time. Accordingly, the tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Certain other countries may consider implementation of a tender system. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions. Failing to win tenders, or the implementation of similar systems in other markets leading to price declines, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We are unable to predict what additional legislation or regulation or changes in third-party coverage and reimbursement policies may be enacted or issued in the future or what effect such legislation, regulation and policy changes would have on our business.

Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our business.

The regulations regarding reporting and payment obligations with respect to Medicare and Medicaid reimbursement programs, and rebates and other governmental programs, are complex. Because our processes for these calculations and the judgments used in making these calculations involve subjective decisions and complex methodologies, these accruals may have a higher inherent risk for material changes in estimates. In addition, they are subject to review and challenge by the applicable governmental agencies and it is possible that such reviews could result in material adjustments to amounts previously paid. See the risk factor captioned "*Sales of our products are affected by, and we may be negatively impacted by any changes to, the reimbursement practices of governmental health administration authorities, private health coverage insurers and other third-party payers. In addition, reimbursement criteria or policies and the use of tender systems outside the U.S. could reduce prices for our products or reduce our market opportunities.*"

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount will be computed each quarter based on each manufacturer's submission to CMS of its current average manufacturer prices and, in the case of innovator products, best prices for the quarter. If a manufacturer becomes aware that its Medicaid reporting for a prior period was incorrect, or has changed as a result of recalculation of the pricing data, the manufacturer is obligated to resubmit the corrected data. Such restatements and recalculations could increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to its rebate calculations could result in an overage or underage in a manufacturer's rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which a manufacturer is required to offer its products to covered entities under the 340B program, and may require us to issue refunds to 340B covered entities, which can be costly and burdensome. It is unclear how these restatements will impact a manufacturer's liability with respect to the Part B and Part D inflation rebates, passed as part of the Inflation Reduction Act.

Each manufacturer that participates in the Medicaid Drug Rebate Program could be held liable for errors associated with affiliates' submission of or failure to submit pricing data. Civil monetary penalties can be applied if a manufacturer is found to have made a misrepresentation in the reporting of its average sales price for each misrepresentation and for each day in which the misrepresentation was applied, or if the manufacturer is found to have charged 340B covered entities more than the statutorily mandated ceiling price. In addition to retroactive rebates and the potential for 340B program refunds, if a manufacturer is found to have knowingly submitted false average manufacturer price or best price information to the government, or to have misrepresented that information, the manufacturer may be liable for significant civil monetary penalties per item of false information. A manufacturer's failure to submit monthly/quarterly average manufacturer price and best price data on a timely basis could result in a significant civil monetary penalty per day for each day the information is late beyond the due date. Such failures also could be grounds for CMS to terminate the manufacturer's Medicaid drug rebate agreement, pursuant to which it participates in the Medicaid program, or, if the manufacturer fails to comply with 340B program requirements, HRSA could decide to terminate its 340B program participation agreement. In the event that CMS terminates a manufacturer's rebate agreement or HRSA terminates its 340B program participation agreement, no federal payments would be available under Medicaid or Medicare Part B for the manufacturer's covered

outpatient drugs. Finally, manufacturers that fail to offer discounts under the Medicare Part D coverage gap discount program may be liable for additional civil monetary penalties.

CMS and the OIG have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. Manufacturers cannot guarantee that a submissions will not be found by CMS to be incomplete or incorrect.

Further, the Inflation Reduction Act, as noted in the Healthcare Reform section, establishes Medicare Part B and Part D inflation rebate schemes (the first Part B inflation rebate period is the first quarter of 2023; the first Part D inflation rebate period is the fourth quarter of 2022 through the third quarter of 2023) and a drug price negotiation program (with the first negotiated prices to take effect in 2026). It also makes changes to the Medicare Part D benefit, including the creation of a new manufacturer discount program in place of the current coverage gap discount program (beginning in 2025). Manufacturers may be subject to civil monetary penalties for certain violations of the negotiation and inflation rebate provisions and an excise tax during a noncompliance period under the negotiation program. Drug manufacturers may be subject to civil monetary penalties with respect to their compliance with the new Part D manufacturer drug discount program. Manufacturers thus could be subject to additional liability with respect to these programs as well.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Big Four agencies and certain federal grantees, we are required to participate in the FSS pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make our "covered" drugs (*i.e.*, innovator drugs and biologics) available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the FCP, which is a price calculated pursuant to a statutory formula. The FSS program also allows us (but does not require us) to list certain non-covered drugs on an FSS contract at negotiated pricing, not capped at the FCP. The FCP is derived from a calculated price point called the non-FAMP, which we are required to calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements. In addition, Section 703 of the National Defense Authorization Act for Fiscal Year 2008, requires us to pay quarterly rebates to DoD on utilization of covered drugs that are dispensed through DoD's Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual non-FAMP and FCP for the calendar year that the product was dispensed. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, we will be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Any governmental agencies that have commenced, or may commence, an investigation of us relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal healthcare programs including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments, and even in the absence of any such ambiguity, a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. For example, in May 2019, CMS issued a final decision directing the Company to revert to the original base date average manufacturer price ("AMP") used to calculate Medicaid drug rebates for Acthar Gel despite having granted Questcor Pharmaceuticals, Inc. ("Questcor") written authorizations to reset the base date AMP in 2012. In addition, from time to time, state attorneys general have brought cases against us that allege generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and generally seek monetary damages and attorneys' fees. Any such penalties or sanctions that we might become subject to in this or other actions could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Cost-containment efforts of our customers, purchasing groups, third-party payers and governmental organizations could materially adversely affect our business.

In an effort to reduce cost, many existing and potential customers for our products within the U.S. are members of GPOs and integrated delivery networks ("IDNs"). GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple manufacturers with the intention of driving down pricing. Due to the highly competitive nature of the GPO and IDN contracting processes, there is no assurance that we will be able to obtain or maintain contracts with major GPOs and IDNs across our product portfolio. Furthermore,

the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability. While having a contract with a GPO or IDN for a given product can facilitate sales to members of that GPO or IDN, having a contract is no assurance that sales volume of those products will be maintained. GPOs and IDNs increasingly are awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days prior notice. Accordingly, our net sales and results of operations may be negatively affected by the loss of a contract with a GPO or IDN. In addition, although we have contracts with many major GPOs and IDNs, the members of such groups may choose to purchase from our competitors, which could result in a decline in our net sales. Distributors of our products are also forming strategic alliances and negotiating terms of sale more aggressively in an effort to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms of sale could cause us to lose market share to our competitors or result in lower pricing on volume we retain, both of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Outside the U.S., we have experienced pricing pressure due to the concentration of purchasing power in centralized governmental healthcare authorities and increased efforts by such authorities to lower healthcare costs. We frequently are required to engage in competitive bidding for the sale of our products to governmental purchasing agents. Our failure to maintain volume and pricing with historical or anticipated levels could materially adversely affect our business, financial condition, results of operations and cash flows.

Extensive laws and regulations govern the industry in which we operate and any failure to comply with such laws and regulations, including any changes to those laws and regulations may materially adversely affect us.

The testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, import, export, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulations that govern and influence the development, testing, manufacturing, processing, packaging, holding, record keeping, safety, efficacy, approval, advertising, promotion, sale, distribution and import/export of our products.

Under these laws and regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and similar authorities within and outside the U.S., which conduct periodic inspections to confirm that we are in compliance with all applicable requirements. We are also required to monitor, track and (periodically) report adverse events and product quality problems associated with our products to the FDA and other regulatory authorities including the competent authorities of the E.U. member states on behalf of the EMA and the competent authorities of other European countries. Failure to comply with the requirements of FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, or any other unexpected or serious health or safety concerns associated with our products, including our opioid pain products and Acthar Gel, could result in adverse inspection reports, warning letters, product recalls or seizures, product liability claims, labeling changes, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. For instance, in the E.U. the EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that the authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended or revoked. Any of these actions could cause a loss of customer confidence in our products, which could adversely affect our sales, or otherwise have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. In addition, the requirements of regulatory authorities, including interpretative guidance, are subject to change and compliance with additional or changing requirements or interpretative guidance may subject us to further review, result in product delays or otherwise increase our costs, and thus have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Furthermore, the FDA and various foreign regulatory authorities approve drugs and medical devices for the treatment of specific indications, and products may only be promoted or marketed for the indications for which they have been approved. For example, applicable laws in the E.U. require that promotional materials and advertising in relation to medicinal products comply with the product’s Summary of Product Characteristics ("SmPC") as approved by the competent authorities in connection with a marketing authorization approval. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the E.U. However, in the U.S. the FDA does not attempt to regulate physicians' use of approved products, and physicians are free to prescribe most approved products for purposes outside the indication for which they have been approved. This practice is sometimes referred to as "off-label" use. While physicians are free to prescribe approved products for unapproved uses, it is unlawful for drug and device manufacturers to market or promote a product for an unapproved use. The laws and regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other governmental agencies. Promotion of a product for unapproved use is prohibited; however, certain activities that we and others in the pharmaceutical industry engage in are permitted by the FDA. We have compliance programs in place, including policies, training and various forms of monitoring, designed to address these risks. Nonetheless, these programs and policies may not always protect us from conduct by individual employees that violate these laws. If the FDA or any other governmental agency initiates an enforcement action against us and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses in connection with past or future activities, we could

be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions could have an adverse effect on our business, financial condition, results of operations and cash flows.

Our approved products and investigational products, if successfully developed and approved, may cause undesirable side effects that limit their commercial profile; delay or prevent further development or regulatory approval; cause regulatory authorities to require labeling statements, such as boxed warnings or a REMS; or result in other negative consequences.

We may observe undesirable side effects or other potential safety issues in nonclinical studies, in clinical trials at any stage of development of our product candidates, as part of an expanded access program or in commercial use or post-approval studies of any approved product. Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, certain side effects of our product candidates, if successfully developed and approved, may only be uncovered with a larger number of patients exposed to the product. Those side effects could be serious or life-threatening. If we or others identify undesirable side effects caused by our products:

- regulatory authorities may withdraw or limit their approval of such products;
- the FDA or regulatory authorities outside the U.S. may impose a clinical hold or partial clinical hold prior to the initiation of development or during development of our product candidates which could cause us or our collaborators to have to stop, delay or restrict further development; or we or our collaborators may, even without a clinical hold, decide to interrupt, delay or halt existing non-clinical studies and clinical trials or stop development;
- we may have difficulty enrolling patients in our clinical trials and completing such trials on the timelines we expect or at all, or we may have to conduct additional non-clinical studies or clinical trials as part of a development program;
- we may not be able ultimately to demonstrate, to the satisfaction of the FDA or other regulatory authorities, that our product candidates are safe and that the benefits outweigh the safety risks, and the FDA or applicable foreign regulatory authorities may not approve the product candidate;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or additions to an existing boxed warning, or a contraindication, including as a result of inclusion in a class of drugs for a particular disease, or may require a REMS, or modifications to an existing REMS;
- we may be required to change the way such products are distributed or administered, conduct post-approval studies or change the labeling of the products;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our products or product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected products, could substantially increase the risks and costs of developing our product candidates or commercializing our products, and could significantly adversely impact our ability to successfully develop, gain regulatory approval for, and commercialize our current product candidates or future products and generate revenues.

We may be unable to successfully develop, commercialize or launch new products or expand commercial opportunities for existing products or adapt to a changing technology and, as a result, our business may suffer.

Our future results of operations will depend, to a significant extent, upon our ability to successfully develop, commercialize and launch new products or expand commercial opportunities for existing products in a timely manner. There are numerous difficulties in developing, commercializing and launching new products or expanding commercial opportunities for existing products, including:

- developing, testing and manufacturing products in compliance with regulatory and quality standards in a timely manner;
- our ability to successfully engage with the FDA or other regulatory authorities as part of the development and approval process and to receive requisite regulatory approvals for such products in a timely manner, or at all;
- agreement on acceptable terms with prospective clinical research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and trial sites;

- the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients for our products;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable trial patients to participate in a trial;
- clinical sites and investigators deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for competing product candidates with the same indication;
- failure of our third-party clinical trial sites to satisfy their contractual duties or meet expected deadlines;
- ambiguous or negative interim results or results that are inconsistent with earlier results;
- feedback from the FDA or a comparable regulatory authority outside the United States, IRBs, or data safety monitoring boards, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for the trial;
- decision by the FDA or a comparable regulatory authority outside the United States, an IRB or us, or a recommendation by a data safety monitoring board to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects or adverse reactions associated with a product candidate;
- failure of a product candidate to demonstrate any or enough of a benefit;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials or commercial use that meet internal and regulatory standards
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs and other third parties;
- developing, commercializing and launching a new product is time-consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development, commercialization and/or launch of new products;
- multiple product launches in a short period of time may be challenging, particularly for an organization that has not launched a new product in many years, and may result in strained resources that could lead to launch delays and cost;
- other unanticipated costs;
- payment of prescription drug user fees to the FDA to defray the costs of review and approval of marketing applications for branded and generic drugs;
- experiencing delays as a result of limited resources at the FDA or other regulatory authorities;
- changing review and approval policies and standards at the FDA or other regulatory authorities;
- changing standards of care;
- potential delays in the commercialization of generic products by up to 30 months resulting from the listing of patents with the FDA;
- effective execution of the product launches in a manner that is consistent with expected timelines and anticipated costs;

- identifying appropriate partners for distribution of our products, including any future over-the-counter commercialization opportunities, and negotiating contractual arrangements in a timely manner with commercially reasonable terms; and
- changes in governmental regulations or administrative actions.

As a result of these and other difficulties, products currently in development by us may or may not receive timely regulatory approvals, or approvals at all. This risk is heightened with respect to the development of proprietary branded products due to the uncertainties, higher costs and length of time associated with R&D of such products and the inherent unproven market acceptance of such products. Moreover, the FDA regulates the facilities, processes and procedures used to manufacture and market pharmaceutical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with cGMP regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. Prior to approval of any product, the FDA inspects both our facilities and procedures to ensure compliance with regulatory standards, and those inspections are also conducted periodically once a product is approved. The FDA may also 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, 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 competitive position, business, financial condition, results of operations and cash flows. If we or the manufacturing facilities for our products fail to comply with applicable regulatory requirements, a regulatory authority may, among other things:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit or preclude our ability to commercialize our products and generate revenue.

Advertising and promotion of our products is heavily scrutinized by, among others, the FDA, the DOJ, the OIG within the HHS, state attorneys general, members of Congress and the public. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action, including enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies.

Furthermore, the market perception and reputation of our products are important to our business and the continued acceptance of our products. Any negative press reports or other commentary about our products, whether accurate or not, could have a material adverse effect on our business, reputation, financial condition, results of operation or cash flows or could cause the market value of our common shares and/or debt securities to decline.

With respect to generic products for which we are the first developer to have its application accepted for filing by the FDA, and which filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (known as a "Paragraph IV certification"), our ability to obtain and realize the full benefits of 180-days of market exclusivity is dependent upon a number of factors, including, being the first to file, the status of any litigation that might be brought against us as a result of our filing or our not meeting regulatory, manufacturing or quality requirements or standards. If any of our products are not approved timely, or if we are unable to obtain and realize the full benefits of the respective market exclusivity period for our products, or if our products cannot be successfully manufactured or commercialized timely, our results of operations could be materially adversely affected. In addition, we cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products. Finally, once developed and approved, new products may fail to achieve commercial acceptance due to the price of the product, third-party reimbursement of the product and the effectiveness of sales, marketing and distribution efforts to support the product.

We may not be successful in our efforts to identify or discover additional products or product candidates beyond our existing products and product candidates at the rate we expect, or we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

The success of our business depends upon our ability to successfully develop, gain approval of and commercialize our products and on our ability to identify compounds for development and commercialization in the future and to successfully complete the non-clinical work necessary to file INDs to pursue clinical development of such new compounds. Our programs may fail to identify or generate new compounds that meet our standards for development and commercialization, and, even if we are successful in generating or identifying such compounds, we may not be able to produce the data necessary to support a regulatory approval.

Because we have limited financial and management resources, we focus on a limited number of commercial and R&D programs. As a result, we may forego or delay pursuit of opportunities with other products or product candidates that later prove to have greater commercial potential. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful and may not yield any commercially viable products. Our resource allocation decisions may cause us to fail to capitalize on other viable opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain such sole development and commercialization rights. If any of these events occur, it may have a material adverse effect on our business.

We may not achieve the anticipated benefits of price increases enacted on our pharmaceutical products, which may adversely affect our business.

From time to time, we may initiate price increases on certain of our pharmaceutical products. There is no guarantee that our customers will be receptive to these price increases and continue to purchase the products at historical quantities. In addition, it is unclear how market participants will react to price increases, particularly in light of the scrutiny being paid to drug pricing in the U.S. If customers do not maintain or increase existing sales volumes, we may be unable to replace lost sales with orders from other customers, and it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Our customer concentration may materially adversely affect our business.

We sell a significant amount of our products to a limited number of independent wholesale drug distributors, large pharmacy chains and specialty pharmaceutical distributors. In turn, these wholesale drug distributors, large pharmacy chains and specialty pharmaceutical distributors supply products to pharmacies, hospitals, governmental agencies and physicians. Sales to one of our distributors that supplies our products to many end user customers accounted for 10.0% or more of our total net sales, FFF Enterprises, Inc. for the period April 2, 2022 (Predecessor) through December 30, 2022 (Successor) and previously CuraScript, Inc. from fiscal 2020 through April 1, 2022 (Predecessor), respectively. If we were to lose the business of this distributor, if this distributor failed to fulfill their obligations, if this distributor was to experience difficulty in paying us on a timely basis, or if this distributor negotiates lower pricing terms, the occurrence of one or more of these factors could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Our product concentration may materially adversely affect our business.

We sell a wide variety of products including specialty branded and specialty generic pharmaceuticals, as well as API. However, a small number of relatively significant products, most notably Acthar Gel, INOmax and Therakos, represent a significant percentage of our net sales. Our ability to maintain and increase net sales from these products depends on several factors, including:

- our ability to increase market demand for products through our own marketing and support of our sales force;
- our ability to implement and maintain pricing and continue to maintain or increase market demand for these products;
- our ability to achieve hospital and other third-party payer formulary acceptance, and maintain reimbursement levels by third-party payers;
- our ability to maintain confidentiality of the proprietary know-how and trade secrets relating to Acthar Gel;
- our ability to continue to procure raw materials or finished goods, as applicable, for Acthar Gel, INOmax and Therakos from internal and third-party manufacturers in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;

- our ability to maintain fees and discounts payable to the wholesalers and distributors and GPOs, at commercially reasonable levels;
- whether the DOJ or other third parties seek to challenge and are successful in challenging patents or patent-related settlement agreements or our sales and marketing practices;
- warnings or limitations that may be required to be added to FDA-approved labeling; and
- the occurrence of adverse side effects related to or emergence of new information related to the therapeutic efficacy of these products, and any resulting product liability claims or product recalls.

Moreover, net sales of Acthar Gel may also be materially impacted by the decrease in the relatively small number of prescriptions written for Acthar Gel as compared to other products in our portfolio, given Acthar Gel's use in treating rare diseases. Any disruption in our ability to generate net sales from Acthar Gel could have an adverse impact on our business, financial condition, results of operations and cash flows.

We may be unable to protect our intellectual property rights, intellectual property rights may be limited or we may be subject to claims that we infringe on the intellectual property rights of others.

We rely on a combination of patents, trademarks, trade secrets, proprietary know-how, market exclusivity gained from the regulatory approval process and other intellectual property to support our business strategy. However, our efforts to protect our intellectual property rights may not be sufficient. If we do not obtain sufficient protection for our intellectual property, or if we are unable to effectively enforce our intellectual property rights, or if there is a change in the way courts and regulators interpret the laws, rules and regulations applicable to our intellectual property, our competitiveness could be impacted, which could adversely affect our competitive position, business, financial condition, results of operations and cash flows.

Our pending patent applications may not result in the issuance of patents, or the patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors. Existing patents may be found to be invalid or insufficiently broad to preclude our competitors from using methods or making or selling products similar or identical to those covered by our patents and patent applications. Regulatory agencies may refuse to grant us the market exclusivity that we were anticipating, or may unexpectedly grant market exclusivity rights to other parties. In addition, our ability to obtain and enforce intellectual property rights is limited by the unique laws of each country. In some countries, it may be particularly difficult to adequately obtain or enforce intellectual property rights, which could make it easier for competitors to capture market share in such countries by utilizing technologies and product features that are similar or identical to those developed or licensed by us. Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our patents, including by coupling separate technologies to replicate what our products accomplish through a single system. Competitors may diminish the value of our trade secrets by reverse engineering or by independent invention. Additionally, current or former employees may improperly disclose such trade secrets to competitors or other third parties. We may not become aware of any such improper disclosure, and, in the event we do become aware, we may not have an adequate remedy available to us.

We operate in an industry characterized by extensive patent litigation, and we may from time to time be a party to such litigation.

The pursuit of or defense against patent infringement is costly and time-consuming and we may not know the outcomes of such litigation for protracted periods of time. We may be unsuccessful in our efforts to enforce our patent or other intellectual property rights. In addition, patent litigation can result in significant damage awards, including the possibility of treble damages and injunctions. Additionally, we could be forced to stop manufacturing and selling certain products, or we may need to enter into license agreements that require us to make significant royalty or up-front payments in order to continue selling the affected products. Given the nature of our industry, we are likely to face additional claims of patent infringement in the future. A successful claim of patent or other intellectual property infringement against us could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Specifically, we believe that the following risks could impact our existing product portfolio:

- Acthar Gel – The composition patent for Acthar Gel has expired and we have no patent-based market exclusivity with respect to any indication or condition we might target. We rely on trade secrets and proprietary know-how to protect the commercial viability and value of Acthar Gel. We currently obtain such protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for proprietary technology in the event of unauthorized use or disclosure of confidential and proprietary information. The parties may not comply with or may breach these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, competitors.
- INOmax – Certain patents related to the use of therapeutic nitric oxide for treating or preventing bronchoconstriction or reversible pulmonary vasoconstriction expired in 2013. Prior to their expiration, we depended, in part, upon these patents to provide us with exclusive marketing rights for our product for some period of time. Since then, we have obtained

additional patents, which expire at various dates through 2036, including patents on methods of identifying patients at risk of serious adverse events when nitric oxide is administered to patients with particular heart conditions. Such methods have been approved by the FDA for inclusion in the Warnings and Precautions sections of the INOmax label. Other patents are on inhaled nitric oxide gas delivery systems as well as methods of using such systems, and on use of nitric oxide gas sensors. The Paragraph IV patent litigation trial against Praxair Distribution, Inc. and Praxair, Inc. to prevent the marketing of its potential infringing nitric oxide drug product delivery system prior to the expiration of the patents covering INOmax was held in March 2017 and a decision was rendered in September 2017 that ruled five patents invalid and six patents not infringed. We appealed the decision all the way up to the U.S. Supreme Court but were unsuccessful in those efforts. As a result, a broader-scale launch of competitive nitric oxide products has taken place in the market which has adversely impacted our business and may continue to adversely affect our ability to successfully maximize the value of INOmax and could have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

- Therakos – Our Therakos products provide extracorporeal photopheresis, which is an autologous immune cell therapy that is indicated in the U.S. for skin manifestations of CTCL and is available for several additional indications in markets outside the U.S. In the ECP process, blood is drawn from the patient, separating white blood cells from plasma and red blood cells (which are immediately returned to the patient). The separated white blood cells are treated with a UVA light activated drug, UVADEX, followed by UVA radiation in the photopheresis instrument, prior to being returned to the patient. Patents related to the methoxsalen composition have expired. Therakos historically manufactured two photopheresis systems, the CELLEX® Photopheresis System ("CELLEX"), which is the only FDA-approved closed ECP system, and the UVAR XTS® Photopheresis System. Patents related to the CELLEX system, disposable kit and overall photopheresis method expire in 2023. We continue to pursue additional patentable enhancements to the Therakos ECP system. Recently granted patents relating to improvements to the CELLEX system, processing of blood, disposable kit and overall photopheresis method may offer additional patent protection through approximately 2037.

Clinical trials demonstrating the efficacy of Acthar Gel are limited, which could cause physicians not to prescribe Acthar Gel, or payers not to reimburse the drug, which could negatively impact our business.

Our net sales of Acthar Gel, which comprise a significant portion of our overall product portfolio, could be negatively impacted by the level of clinical data available on the product. Acthar Gel was originally approved by the FDA in 1952, prior to the enactment of the 1962 Kefauver Harris Amendment, or the "Drug Efficacy Amendment," to the FFDCA. This amendment introduced the requirement that drug manufacturers provide proof of the effectiveness (in addition to the previously required proof of safety) of their drugs in order to obtain FDA approval. As such, the FDA's original approval in 1952 was based on safety data as clinical trials evaluating efficacy were not then required. In the 1970s, the FDA reviewed the safety and efficacy of Acthar Gel during its approval of Acthar Gel for the treatment of acute exacerbations in multiple sclerosis and evaluated all other previous indications on the label through the Drug Efficacy Study Implementation ("DESI") process. In this process, the medical and scientific merits of the label and each indication on the label were evaluated based on publications, information from sponsors, and the judgment of the FDA. The label obtained after the DESI review and the addition of the multiple sclerosis indication is the Acthar Gel label that was used until the changes in 2010.

In 2010, in connection with its review of a supplemental NDA for use of Acthar Gel in treatment of IS, the FDA again reviewed evidence of safety and efficacy of Acthar Gel, and added the IS indication to the label of approved indications while maintaining approval of Acthar Gel for treatment of acute exacerbations in multiple sclerosis and 17 other indications. In conjunction with its decision to retain these 19 indications on a modernized Acthar Gel label, the FDA eliminated approximately 30 other indications from the label. The FDA review included a medical and scientific review of Acthar Gel and each indication and an evaluation of available clinical and non-clinical literature as of the date of the review. The FDA did not require additional clinical trials for Acthar Gel.

Accordingly, evidence of efficacy is largely based on physician's clinical experience with Acthar Gel and does not include clinical trials except for the MS and IS indications. We conducted several Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of Acthar Gel. The completion of future clinical trials to provide further evidence on the efficacy of Acthar Gel in the treatment of its approved indications could take several years to complete and will require the expenditure of significant time and financial and management resources. Such clinical trials may not result in data that supports the use of Acthar Gel to treat any of its approved indications. In addition, a clinical trial to evaluate the use of Acthar Gel to treat indications not on the current Acthar Gel label may not provide a basis to pursue adding such indications to the current Acthar Gel label. Furthermore, even if prescribed by a physician, third-party payers may implement restrictions on reimbursement of Acthar Gel due, in part, to the limited clinical data of efficacy, which may negatively impact our business, financial condition, results of operations and cash flows.

Clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

We must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. For example, INOmax is approved for sale in the U.S. only for the treatment of HRF associated with pulmonary hypertension in term and near-term infants, and the Therakos systems are approved for sale in the U.S. only for the palliative treatment of the skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. In order to market these products in the U.S. for any other indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials, and obtain regulatory approval for such proposed indications. Conducting such studies is a lengthy, time-consuming, and expensive process and obtaining regulatory approval is uncertain. Even well conducted studies of effective drugs will sometimes appear to be negative in either safety or efficacy results, or otherwise may not achieve approval. The regulatory review and approval process to obtain marketing approval for a new indication can take many years, often requires multiple clinical trials and requires the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product candidate involved. Success in early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results.

These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to other products or product candidates), difficulty in enrolling and maintaining subjects in a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GLPs or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. The FDA and other regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that any data submitted is insufficient for approval and require additional studies or clinical trials or varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of product candidate or a new indication for a product candidate.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), which would have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may incur litigation liability, including product liability losses.

We are or may become involved in various legal proceedings and government inquiries and investigations, including with respect to, but not limited to, patent infringement, product liability, personal injury, antitrust matters, securities class action lawsuits, disclosure matters, breach of contract, Medicare and Medicaid reimbursement claims, opioid related matters, promotional practices, compliance with laws relating to the manufacture and sale of controlled substances, and matters relating to the Chapter 11 Cases (including appeals of orders issued in the Chapter 11 Cases). Such proceedings, inquiries and investigations may involve claims for, or the possibility of, fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties, changes in business practices and exclusion from participation in various government healthcare-related programs. Some of our existing legal proceedings, inquiries and investigations and related matters are described in Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report. If existing or future legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Even if one or more of these matters do not result in a direct adverse outcome, they could lead to distraction of management, the incurrence of additional costs and damage to our reputation, among other potential results that could have a material adverse effect on our business.

With respect to product liability and clinical trial risks, in the ordinary course of business we are subject to liability claims and lawsuits, including potential class actions, alleging that our marketed products or products in development have caused, or could cause, serious adverse events or other injury. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairment or even death. This could result in product liability claims against us and/or recalls of one or more of our products. In many countries, including in E.U. member states, national laws provide for strict (no-fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party. Any such claim brought against us, with or without merit, could be costly to defend and could result in an increase in our insurance premiums. We retain liability for $10.0 million per claim of the first $50.0 million of a loss in our primary liability policies and purchase an additional $60.0 million using a combination of umbrella/excess

liability policies with respect to any such claims. We believe this coverage level is adequate to address our current risk exposure related to product liability claims and lawsuits. However, some claims, such as those brought against us related to our sale of opioids, might not be covered by our insurance policies. Moreover, where the claim is covered by our insurance, if our insurance coverage is inadequate, we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our operations expose us to the risk of violations of applicable health, safety and environmental laws and regulations and related liabilities and litigation.

We are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations governing, among other things:

- the generation, storage, use and transportation of hazardous materials;
- emissions or discharges of substances into the environment;
- investigation and remediation of hazardous substances or materials at various sites;
- chemical constituents in products and end-of-life disposal, mandatory recycling and take-back programs; and
- the health and safety of our employees.

We may not have been, or we may not at all times be, in full compliance with environmental and health and safety laws and regulations. In the event a regulatory authority concludes that we are not in full compliance with these laws, we could be fined, criminally charged or otherwise sanctioned. Environmental laws are becoming more stringent, including outside the U.S., resulting in increased costs and compliance burdens.

Certain environmental laws assess liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. Liability for investigative, removal and remediation costs under certain federal and state laws is retroactive, strict (i.e., can be imposed regardless of fault) and joint and several. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury or other claims due to the presence of, or exposure to, hazardous substances. We have received notification from the EPA and similar state environmental agencies that conditions at a number of sites where the disposal of hazardous substances has taken place requires investigation, cleanup and other possible remedial action. These agencies may require that we reimburse the government for its costs incurred at these sites or otherwise pay for the costs of investigation and cleanup of these sites, including by providing compensation for natural resource damage claims arising from such sites.

In the ordinary course of our business planning process, we take into account our known environmental matters as we plan for our future capital requirements and operating expenditures. The ultimate cost of site cleanup and timing of future cash outflows is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations, and alternative cleanup methods.

We concluded that, as of December 30, 2022 (Successor), it was probable that we would incur remediation costs in the range of $18.4 million to $48.5 million. We also concluded that, as of December 30, 2022 (Successor), the best estimate within this range was $36.9 million. For further information on our environmental obligations, refer to Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report. Based upon information known to date, we believe our current capital and operating plans are adequate to address costs associated with the investigation, cleanup and potential remedial action for our known environmental matters.

While we have planned for future capital and operating expenditures to comply with environmental laws, our costs of complying with current or future environmental protection and health and safety laws and regulations, or our liabilities arising from past or future releases of, or exposures to, hazardous substances may exceed our estimates or could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. We may also be subject to additional environmental claims for personal injury or cost recovery actions for remediation of facilities in the future based on our past, present or future business activities.

If our business development activities are unsuccessful, it may adversely affect us.

One of our business strategies includes evaluating potential business development opportunities to potentially grow the business through merger, acquisition, licensing agreements or other strategic transactions. The process to evaluate potential opportunities may be complex, time-consuming and expensive. Once a potential opportunity is identified, we may not be able to conclude negotiations of

a potential transaction on terms that are satisfactory to us, which could result in a significant diversion of management and other employee time, as well as substantial out-of-pocket costs. In addition, there are a number of risks and uncertainties relating to our ability to close a potential transaction.

Once an acquisition or licensing transaction is consummated, there are further potential risks related to integration activities, including with regard to operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions in the expected time frame, we may not obtain the advantages and synergies that such acquisitions were intended to create, which may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

In addition, we intend to continue to explore opportunities to enter into strategic collaborations with other parties, which may include other pharmaceutical companies, academic and research institutions, government agencies and other public and private research organizations. These third-party collaborators are often directly responsible for certain obligations under these types of arrangements, and we may not have the same level of decision-making capabilities for the prioritization and management of development-related activities as we would for our internal research and development activities. Failures by these partners to meet their contractual, regulatory, or other obligations to us, or any disruption in the relationships with these partners, could have a material adverse effect on our pipeline and business. In addition, these collaborative relationships for research and development could extend for many years and may give rise to disputes regarding the relative rights, obligations and revenues of us versus our partners, including the ownership of intellectual property and associated rights and obligations. These could result in the loss of intellectual property rights or other intellectual property protections, delay the development and sale of potential products, and lead to lengthy and expensive litigation or arbitration.

Furthermore, the due diligence that we conduct in conjunction with an acquisition or other strategic collaboration may not sufficiently discover risks and contingent liabilities associated with the other party and, consequently, we may consummate an acquisition or otherwise enter into a strategic collaboration for which the risks and contingent liabilities are greater than were projected. In addition, in connection with acquisitions or other strategic collaborations, we could experience disruption in our business, technology and information systems, and our customers, licensors, suppliers and employees and may face difficulties in managing the expanded operations of a larger and more complex company. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire or otherwise collaborate on may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies which we acquire or enter into strategic collaborations with that may create conflicts in relationships or other commitments detrimental to the integrated businesses or impacted products. Additionally, the time between our expenditures to acquire new products, technologies or businesses and the subsequent generation of revenues from those acquired products, technologies or businesses, or the timing of revenue recognition related to licensing agreements and/or strategic collaborations, could cause fluctuations in our financial performance from period to period. Finally, if we are unable to successfully integrate products, technologies, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences. Many of these factors are outside of our control and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact our business, financial condition, results of operations and cash flows.

If we are unable to attract and retain key scientific, technical, regulatory and commercial personnel, 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, regulatory and commercial personnel. The loss of key scientific, technical, regulatory and commercial personnel, or the failure to recruit additional key scientific, technical, regulatory and commercial personnel, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. There is intense competition for qualified personnel in our industry, and we may not be able to continue to attract and retain the qualified personnel necessary for the development or operation of our business.

Our business depends on the continued effectiveness and availability of our information technology infrastructure, and failures of this infrastructure could harm our operations.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. To remain competitive in our industry, we must employ information technologies to support manufacturing processes, quality processes, distribution, financial reporting, as well as R&D and regulatory applications that capture, manage and analyze the large streams of data generated in our clinical trials, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also rely extensively on technology to allow concurrent work sharing around the world. As with all information technology, our systems are vulnerable to potential damage or interruptions from fires, blackouts, telecommunications failures and other unexpected events, as well as physical and electronic break-ins, sabotage, piracy or intentional

acts of vandalism. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, financial condition, results of operations and cash flows.

We also have outsourced significant elements of our operations to third parties, some of which are outside the U.S., including significant elements of our information technology infrastructure, and as a result we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions. The size and complexity of our and our vendors' systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. We and our vendors could be susceptible to third-party attacks on our information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, "hackers" and others.

Maintaining the secrecy of all of our confidential, proprietary, and/or trade secret information is important to our competitive business position. However, such information can be difficult to protect. While we have taken steps to protect such information and invested heavily in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information, including those caused by our own employees or others to whom we have granted access to our systems, that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A 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, hacking, human error, sabotage, industrial espionage, fraud, trickery or other forms of deception, or for 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 information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Some of our products are regulated as controlled substances, the making, use, sale, importation, exportation, and distribution of which are subject to significant regulation by the DEA and other regulatory agencies.

Some of our products are considered controlled substances under the federal CSA. The manufacturing, shipping, distribution, import, export, packaging, storing, prescribing, dispensing, selling and use of controlled substances are subject to additional regulations, including under the CSA and DEA regulations. These regulations increase the personnel needs and the expense associated with commercialization of products. Because of their restrictive nature, these laws and regulations could also limit commercialization of our controlled substance products. Failure to comply with these laws and regulations could also result in loss of DEA registrations, disruption in manufacturing and distribution activities, consent decrees, criminal and civil penalties and state actions, among other consequences.

Various states also independently regulate controlled substances. Though state-controlled substances laws often mirror federal law, because states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be a rulemaking or a legislative action. Many states require separate state registrations in order to be able to obtain, manufacture, handle, distribute and dispense controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

The DEA regulates the availability of controlled substances, including API, drug products under development and marketed drug products. At times, the procurement and manufacturing quotas granted by the DEA may be insufficient to meet our needs.

The DEA is the U.S. federal agency responsible for domestic enforcement of the CSA. The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Schedule II controlled substances include molecules such as oxycodone, oxymorphone, morphine, fentanyl and hydrocodone. The manufacture, storage, distribution and sale of these controlled substances are permitted, but highly regulated. The DEA regulates the availability of API, products under development and marketed drug products that are in the Schedule II category by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our needs. In 2022, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. Over the past several years and into 2023, the DEA has steadily reduced the amount of opioid medication that may be manufactured in the U.S. as a response to the opioid crisis. These quota reductions have included oxycodone, hydrocodone, oxymorphone, hydromorphone, and fentanyl. The DEA could take similar actions in the future. Future delay or refusal by the DEA to grant, in whole or in part, our quota requests could delay or result in stopping the manufacture

of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials. Such delay or refusal also could require us to allocate marketed drug products among our customers. These factors, along with any delay or refusal by the DEA to provide customers who purchase API from us with sufficient quota, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. In addition, the DEA conducts periodic inspections of registered establishments that handle controlled substances and has stringent regulations on those establishments to prevent loss and diversion. Failure to maintain compliance with these regulations, particularly as manifested in loss or diversion, can result in regulatory action that could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

The manufacture of our products is highly exacting and complex, and our business could suffer if we, or our suppliers, encounter manufacturing or supply problems.

The manufacture of our products is highly exacting and complex, due in part to strict regulatory and manufacturing requirements, as well as due to the biologic nature of some of our products, which are inherently more difficult to manufacture than chemical-based products. Problems may arise during manufacturing for a variety of reasons including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors. If a batch of finished product fails to meet quality standards during a production run, then that entire batch of product may have to be discarded. These problems could lead to launch delays, product shortages, backorders, increased costs (including contractual damages for failure to meet supply requirements), lost revenue, damage to our reputation and customer relationships, time and expense spent investigating, correcting and preventing the root causes and, depending on the root causes, similar losses with respect to other products. If manufacturing problems are not discovered before the product is released to the market, we also could incur product recall and product liability costs. If we incur a product recall or product liability costs involving one of our products, such product could receive reduced market acceptance and thus reduced product demand and could harm our reputation and our ability to market our products in the future. Significant manufacturing problems could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We rely on third-party manufacturers to manufacture certain components of our products and certain of our finished products. In the event that these third-party manufacturers cease to manufacture sufficient quantities of our products or components in a timely manner and on terms acceptable to us, we could be forced to locate alternate third-party manufacturers. Additionally, if our third-party manufacturers determine to no longer partner with us, experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fail to meet regulatory or quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative third-party manufacturer. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes for our investigational product candidates, including any failure to deliver sufficient quantities of our investigational product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our investigational products. In addition, such failure, or failures by our third-party manufacturers to comply with cGMP in manufacturing our approved products, could be the basis for the FDA or other regulatory authorities to issue a warning letter, withdraw approvals, or take other regulatory or legal action, including recall or seizure of outside supplies of our products, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties. Several of our products are manufactured at a single manufacturing facility or stored at a single storage site. Loss or damage to a manufacturing facility or storage site due to a natural disaster or otherwise could adversely affect our ability to manufacture sufficient quantities of key products or otherwise deliver products to meet customer demand or contractual requirements which may result in a loss of revenue and other adverse business consequences. Furthermore, while we work closely with our suppliers to ensure the continuity of supply and to diversify our sources of components and materials, in certain instances we do acquire components and materials from a sole supplier. Although we do carry strategic inventory and maintain insurance to mitigate the potential risk related to any related supply disruption, there can be no assurance that such measures will be effective. Because of the time required to obtain regulatory approval and licensing of a manufacturing facility, an alternate third-party manufacturer may not be available on a timely basis to replace production capacity in the event we lose manufacturing capacity, experience supply challenges, or products are otherwise not available due to natural disaster, regulatory action or otherwise.

Significant manufacturing problems could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Our global operations expose us to risks and challenges associated with conducting business internationally.

We operate globally with offices or activities in Europe, Africa, Asia, South America, Australia and North America. We face several risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to our international operations. These laws and regulations include data privacy requirements, labor relations laws, tax laws, anti-competition regulations, import and trade restrictions, export requirements, U.S. anti-bribery laws such as the FCPA and similar

local laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct, which also prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws, there is a risk that some provisions may be violated, inadvertently or through fraudulent or negligent behavior of individual employees, or through our failure to comply with certain formal documentation requirements or otherwise. Violations of these laws and regulations could result in fines or criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our international expansion efforts and our ability to attract and retain employees.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

- potentially longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain non-U.S. legal systems;
- potential inability to sell products into certain countries given the delay of foreign governments in responding to changes in our U.S. business licensing;
- political and economic instability, including the impact of U.K.'s exit from the E.U. (commonly known as Brexit) and the related uncertainties;
- the unpredictability of U.S. trade policy, including Section 301 tariffs and U.S. trade relations with other countries, that may increase raw material cost or impact our ability to obtain the raw materials we need to manufacture our products and impact our ability to sell our products outside of the U.S.;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and trade barriers;
- difficulties and costs of staffing and managing our non-U.S. operations;
- exposure to global economic conditions;
- exposure to potentially unfavorable movements in foreign currency exchange rates associated with international net sales and operating expense and intercompany debt financings; and
- potential negative impact of public health epidemics on employees, our supply chain and the global economy.

These or other factors or any combination of them may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We have significant levels of intangible assets which utilize our future projections of cash flows in impairment testing. Should we experience unfavorable variances from these projections these assets may have an increased risk of future impairment.

Our intangible assets were $2,843.8 million as of December 30, 2022 (Successor). At least annually, we review the carrying value of our non-amortizing intangible assets, and for amortizing intangible assets when indicators of impairment are present. Conditions that could indicate impairment and necessitate an evaluation of intangible assets include, but are not limited to, a significant adverse change in the business climate or the legal or regulatory environment.

In performing our impairment tests, we utilize our future projections of cash flows. Projections of future cash flows are inherently subjective and reflect assumptions that may or may not ultimately be realized. Significant assumptions utilized in our projections include, but are not limited to, our evaluation of the market opportunity for our products, the current and future competitive landscape and resulting impacts to product pricing, future legislative and regulatory actions or the lack thereof, planned strategic initiatives, the ability to achieve cost synergies from acquisitions, the realization of benefits associated with our existing and anticipated patents and regulatory approvals. Given the inherent subjectivity and uncertainty in projections, we could experience significant unfavorable variances in future periods or revise our projections downward. This would result in an increased risk that our intangible assets may be impaired. If an impairment were recognized, this could have a material impact to our financial condition and results of operations.

We are subject to labor and employment laws and regulations, which could increase our costs and restrict our operations in the future.

As of December 30, 2022, we employed approximately 2,700 employees worldwide. Some of our employees are represented by labor organizations and national works councils. Our management believes that our employee relations are satisfactory. However, further organizing activities or collective bargaining may increase our employment-related costs and we may be subject to work stoppages and other labor disruptions. Moreover, if we are subject to employment-related claims, such as individual and class actions relating to alleged employment discrimination, wage-hour and labor standards issues, and such actions are successful in whole or in

part, this may affect our ability to compete or have a material adverse effect on our business, financial condition, results of operations and cash flows.

Risks Related to Our Indebtedness and Settlement Obligations

Our substantial indebtedness could adversely affect our financial condition and prevent us from fulfilling our obligations and could further adversely affect our ability to make ongoing payments in respect of the Plan.

We have substantial indebtedness and settlement obligations. As of December 30, 2022 (Successor), total debt principal was $3,534.1 million, of which $44.1 million was classified as current. Our substantial indebtedness could adversely affect our ability to fulfill our financial obligations (including our ability to service our indebtedness and our settlement obligations of the remaining $1,275.0 million and $245.0 million for our Opioid-Related Litigation Settlement and Acthar Gel-Related Litigation Settlement, respectively (as defined within Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report) and have a negative impact on our financing options and liquidity positions.

Our degree of debt leverage and our significant settlement obligations have significant consequences, including the following:

- making it more difficult for us to satisfy our obligations with respect to our debt and our ongoing obligations in respect of the Opioid-Related Litigation Settlement and Acthar Gel-Related Litigation Settlement;
- limiting our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions or other corporate requirements;
- requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, acquisitions, other general corporate purposes, and research and development;
- limiting our ability to refinance our indebtedness or make prepayments of our ongoing obligations in respect of the Opioid-Related Litigation Settlement and Acthar Gel-Related Litigation Settlement on terms acceptable to us or at all;
- placing us at a competitive disadvantage to other less leveraged competitors;
- making us more vulnerable to economic downturns and limiting our ability to withstand competitive pressures;
- limiting our flexibility in planning for and reacting to changes, opportunities, and challenges in our business, including changes in the industry in which we compete, changes in our business and strategic opportunities, and adverse developments in our operations; and
- increasing our costs of borrowing.

We may not be able to generate sufficient cash to service all of our indebtedness and settlement obligations and may be forced to take other actions to satisfy our obligations under our indebtedness and settlement obligations, which may not be successful.

Our ability to make scheduled payments on or to refinance our debt obligations and settlement obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to fund our day-to-day operations or to pay the principal, premium, if any, and interest on our indebtedness and satisfy our settlement obligations.

If our cash flows and capital resources are insufficient to fund our debt service obligations and other cash requirements (including our settlement obligations), we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures or to sell assets or operations, seek additional capital or restructure or refinance our indebtedness and our settlement obligations. We may not be able to effect any such alternative measures, if necessary, on commercially reasonable terms or at all and, even if successful, such alternative actions may not allow us to meet our scheduled debt service obligations and settlement obligations. The agreements governing our existing indebtedness and settlement obligations (a) have terms and conditions that restrict our ability to dispose of assets and the use of proceeds from any such dispositions and (b) restrict our ability to raise debt capital to be used to repay our indebtedness when it becomes due. We may not be able to consummate those dispositions or to obtain proceeds in an amount sufficient to meet any debt service obligations or settlement obligations then due.

Our inability to generate sufficient cash flows to satisfy our debt obligations and settlement obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our financial position and results of operations.

Certain of our secured indebtedness has near-term maturity dates, most notably our First Lien Senior Secured Notes due 2025 and our Second Lien Senior Secured Notes due 2025. Adequate funds may not be available to us, or, depending on market conditions, we may be unable to refinance or fund the repayment of our debt maturities as they come due, resulting in an event of default under the applicable indentures, permitting our creditors to exercise various remedies. A refinancing, depending upon market conditions, could increase borrowing costs and add restrictive covenants which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and cash flows.

If we cannot make scheduled payments on our debt, Opioid-Related Litigation Settlement, or the Acthar Gel-Related Litigation Settlement, we will be in default and, as a result, lenders under any of our then-outstanding indebtedness could declare essentially all outstanding principal and interest to be due and payable, beneficiaries of our then-outstanding settlement obligations could declare such obligations to be due and payable, our secured lenders could foreclose against the assets securing such borrowings and we could be forced to return to bankruptcy or into liquidation.

The terms of the agreements that govern our indebtedness and settlement obligations restrict our current and future operations, particularly our ability to respond to changes or to pursue our business strategies.

The agreements that govern the terms of our existing indebtedness and settlement obligations contain a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest, including limitations or restrictions on our ability to:

- incur, assume or guarantee additional indebtedness;
- declare or pay dividends, make other distributions with respect to equity interests, or purchase or otherwise acquire or retire equity interests;
- make any principal payment on, or redeem or repurchase, subordinated, junior secured or unsecured debt and, with respect to certain of our indebtedness, the Opioid-Related Litigation Settlement and the Acthar Gel-Related Litigation Settlement;
- make loans, advances or other investments;
- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- incur liens;
- enter into transactions with affiliates;
- enter into sale and lease-back transactions;
- permit the occurrence of certain change of control transactions;
- consolidate or merge with or into or sell all or substantially all of our assets to, another person or entity; and
- draw the full amount otherwise available of our receivables-based financing lending facility.

A breach of the covenants under the agreements that govern the terms of any of our indebtedness or settlement obligations could result in an event of default under the applicable indebtedness or settlement obligations. Such default may allow the creditors to accelerate the related debt or settlement obligations and may result in the acceleration of any other debt or settlement obligations to which a cross-acceleration or cross-default provision applies. In addition, an event of default under the credit agreement that governs our receivables-based financing facility would permit the lenders under such facilities to terminate all commitments to extend further credit thereunder. Furthermore, if we are unable to repay the amounts due and payable under our secured indebtedness, those creditors will be able to proceed against the collateral granted to them to secure that secured indebtedness. Additionally, if a change in control transaction were to occur, such a transaction may accelerate the maturity dates on our indebtedness and opioid-related litigation settlement. If the holders of our debt or settlement obligations accelerate the repayment of our borrowings or the payment of our settlement obligations for the above reasons, or any other, we may not have sufficient assets to repay such indebtedness or settlement obligations.

As a result of these restrictions, coupled with operating limitations imposed by the Plan and related arrangements, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns;
- unable to respond to changing circumstances or to pursue our business strategies; or
- unable to compete effectively, execute our growth strategy or take advantage of new business opportunities.

These restrictions may affect our ability to operate in accordance with our plans.

Our debt levels and challenges in the commercial and credit environment may materially adversely affect our ability to issue debt on acceptable terms and our future access to capital.

Our ability to issue debt or enter into other financing arrangements on acceptable terms could be materially adversely affected by our debt levels or if there is a material decline in the demand for our products or in the solvency of our customers or suppliers or other significantly unfavorable changes in economic conditions occur. In addition, volatility in the world financial markets could increase borrowing costs or affect our ability to access the capital markets, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Borrowing capacity under our receivables-based financing facility may decrease, may not be extended upon maturity, or the maturity date may be accelerated.

The borrowing capacity under our receivables-based financing facility is dependent upon the level of accounts receivable securing the borrowing capacity as well as certain financial covenants. The amount of accounts receivable may decrease due to various factors such as normal business variations, business contractions, or asset divestitures, any of which may result in a decrease of the associated borrowing capacity. Failure to comply with the financial covenants may decrease our ability to borrow up to the full borrowing capacity. Further, the issuance of additional debt having a maturity date that precedes the facility's current maturity date may result in the acceleration of the existing maturity date, or, separately, we may be unable to extend the date of existing maturity date to have continued access to such borrowing capacity beyond the current maturity date. These could have a material adverse effect on our competitive position, business, financial condition, results of operations, and cash flows.

Our variable-rate indebtedness exposes us to interest rate risk, which could cause our debt service obligations to increase significantly.

Certain of our secured indebtedness, including borrowings under our existing senior secured credit facilities, is or is expected to be, as applicable, subject to variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable-rate indebtedness would increase and our net loss would increase, even though the amount borrowed under the facility remained the same. As of December 30, 2022 (Successor), we had $1,738.9 million outstanding variable-rate debt on our senior secured term loans. An unfavorable movement in interest rates, primarily London Interbank Offered Rate ("LIBOR") and Secured Overnight Financing Rate ("SOFR"), could result in higher interest expense and cash payments for us. Although we may enter into interest rate hedges, involving the partial or full (i) exchange of floating for fixed-rate interest payments or (ii) obtaining an interest rate cap, to reduce interest rate volatility, we cannot provide assurance that we will enter into such arrangements or that they will successfully mitigate such interest rate volatility.

Despite current and anticipated indebtedness levels, we may still be able to incur more debt. This could further exacerbate the risks described above.

We may be able to incur substantial additional indebtedness in the future. Although agreements governing our existing indebtedness and settlement obligations restrict the incurrence of additional indebtedness, these restrictions are and will be subject to a number of qualifications and exceptions and the additional indebtedness incurred in compliance with these restrictions could be substantial. If new debt is added to our current debt levels, the related risks that we now face could intensify.

We may need additional financing in the future to meet our capital needs or to make acquisitions, and such financing may not be available on favorable or acceptable terms, and may be dilutive to existing shareholders.

We may need to seek additional financing for general corporate purposes. For example, we may need to increase our investment in R&D activities or need funds to make acquisitions. We may be unable to obtain any desired additional financing on terms that are favorable or acceptable to us. Depending on market conditions, adequate funds may not be available to us on acceptable terms and we may be unable to fund our expansion, successfully develop or enhance products, or respond to competitive pressures, any of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. If we raise additional funds through the issuance of equity securities, our shareholders will experience dilution of their ownership interest.

The phase out of LIBOR, or the replacement of LIBOR with a different reference rate, may adversely affect interest rates associated with our debt.

In July 2017, the Financial Conduct Authority (the authority that regulates LIBOR) announced that it would phase out LIBOR by the end of 2021. The Financial Conduct Authority also announced that certain of the commonly used LIBOR tenors will continue to be published until June 30, 2023; however, the Federal Reserve, Federal Deposit Insurance Corporation and the Office of the Comptroller of Currency (and certain other government agencies) in the U.S. as well as the Financial Conduct Authority announced that all market participants should stop using LIBOR in new contracts after December 31, 2021, subject to limited exemptions. Accordingly, new contracts entered into after December 31, 2021, generally must utilize an alternative reference rate. Certain of our existing indebtedness, including our senior secured credit facilities, bears interest at rates that are currently indexed to LIBOR and expected to convert to SOFR in June 2023. Changes in the method of calculating LIBOR, SOFR, or the replacement of LIBOR or SOFR with an alternative rate or benchmark, may adversely affect interest rates on our current or future indebtedness and result in higher borrowing costs. This could materially and adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the potential changes to LIBOR, SOFR, or the establishment and use of alternative rates or benchmarks.

Risks Related to Tax Matters

The United States could treat Mallinckrodt plc (parent corporation) as a U.S. taxpayer under Internal Revenue Code Section 7874.

Following the emergence from bankruptcy, Mallinckrodt plc continues to be an Irish tax resident. The IRS may, however, assert that Mallinckrodt plc should be treated as a U.S. corporation for U.S. federal income tax purposes pursuant to Internal Revenue Code ("IRC") Section 7874. For U.S. federal income tax purposes, a corporation is generally considered to be tax resident in the jurisdiction of its organization or incorporation. Because Mallinckrodt plc is an Irish incorporated entity, it would generally be classified as a foreign corporation under these rules. IRC Section 7874 provides an exception to this general rule under which a foreign corporation may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes if the following requirements are met: (i) the foreign corporation completes the direct or indirect acquisition of substantially all of the assets held directly or indirectly by a U.S. corporation (including the indirect acquisition of assets of the U.S. corporation by acquiring the outstanding shares of the U.S. corporation), (ii) the former shareholders of the acquired U.S. corporation hold at least 80% (or 60% in certain circumstances) of the shares of the foreign acquiring corporation, and (iii) the foreign corporation's "expanded affiliated group" does not have substantial business activities in the foreign corporation's country of organization or incorporation compared to the expanded affiliated group's worldwide activities. Although it is not free from doubt, we believe that after implementation of the Plan, Mallinckrodt plc should not be treated as acquiring directly or indirectly substantially all of the properties of a U.S. corporation and, as a result, Mallinckrodt plc is not expected to be treated as a U.S. corporation or otherwise subject to the adverse tax consequences of IRC Section 7874. The law and the Treasury Regulations promulgated under IRC Section 7874 are, however, unclear and there can be no assurance that the IRS will agree with this conclusion. If it is determined that IRC Section 7874 is applicable, Mallinckrodt plc would be treated as a U.S. corporation for U.S. federal income tax purposes which could result in additional adverse tax consequences. In addition, although Mallinckrodt plc would be treated as a U.S. corporation for U.S. federal income tax purposes, it would also be considered an Irish tax resident for Irish tax and other non-U.S. tax purposes.

The IRS may interpret IRC Section 382 limitation and cancellation of debt income attribution rules differently.

In general, IRC Section 382, provides an annual limitation with respect to the ability of a corporation to utilize its tax attributes, as well as certain built-in-losses ("BILs"), against future taxable income in the event of a change in ownership. Emergence from Chapter 11 bankruptcy proceedings resulted in a change in ownership for purposes of IRC Section 382. Any discharge of our external or internal debt obligations as a result of the Chapter 11 filing for an amount less than the adjusted issue price may give rise to cancellation of debt income, which must either be included in our taxable income or result in a reduction to our tax attributes. U.S. tax attributes subject to reduction include: (i) net operating loss ("NOL(s)") and NOL carryforwards; (ii) credit carryforwards (iii) capital losses and capital loss carryforwards; and (iv) the tax basis of our depreciable, amortizable and other assets. The amount of our post-ownership change annual U.S. taxable income that can be offset by the pre-ownership change U.S. NOLs and BILs generally cannot exceed an amount equal to the product of (a) the applicable federal long-term tax exempt rate in effect on the date of the ownership change and (b) the value of our U.S. affiliate stock immediately prior to implementation of the Plan ("Annual Limitation"). The Annual Limitation may also be increased or decreased during the first five years post-ownership change for certain realized built-in-gains or realized BILs, respectively. Our interpretation of the impact of the IRC's limitations on the utilization of tax attributes after the ownership change caused by the emergence from bankruptcy may differ from the IRS's interpretation. Any additional limitations on our ability to prospectively use these tax attributes may have an adverse effect on our prospective cash flow.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under IRC Sections 382 and 383, if a corporation undergoes an "ownership change", generally defined as a greater than 50 percent change, determined by value in its equity ownership by certain stockholders over a rolling three-year period, the corporation's ability to use its pre-ownership change NOLs and other pre-ownership change tax attributes to offset its post-ownership change taxable income or tax liability may be limited. We may experience ownership changes in the future due to shifts in our stock ownership, some of which is outside of our control. Additionally, similar laws at the state level may apply.

A loss of a major tax dispute or a challenge to our operating structure or intercompany pricing policies could result in a higher tax rate on our worldwide earnings, which could result in a material adverse effect on our financial condition, results of operations and cash flows.

Income tax returns that we file are subject to review and examination. We recognize the benefit of income tax positions we believe are more likely than not to be sustained upon challenge by a tax authority. If any tax authority successfully challenges our operational structure, intercompany pricing or financing policies; if the terms of certain income tax treaties are interpreted in a manner that is adverse to our structure; or if we lose a material tax dispute in any country; our effective tax rate on our worldwide earnings could increase substantially and result in a material adverse effect on our financial condition.

Our status as a foreign corporation for U.S. federal tax purposes could be affected by a change in law.

We believe that, under current law, we are treated as a foreign corporation for U.S. federal tax purposes. However, changes in tax law, such as additional changes to the rules under IRC Section 7874 or the U.S. Treasury Regulations promulgated thereunder or other IRS guidance, could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such changes could have prospective or retroactive application to us and our shareholders and affiliates. In addition, legislative proposals issued by the U.S. Department of the Treasury and Congress have aimed to expand the scope of U.S. corporate tax residence, and such proposals, if passed, could have an adverse effect on us. Although the proposals would generally apply to prospective transactions, no assurance can be given that such proposals will not be changed to apply retroactively.

Future changes to U.S. and foreign tax laws could adversely affect us.

The European Commission, U.S. Congress and Treasury Department, the Organization for Economic Co-operation and Development ("the OECD"), and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations, particularly payments made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the U.K., Ireland, E.U., Switzerland, Japan, U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us and our affiliates.

Recent examples include the European Commission's Anti-Tax Avoidance Directives (ATAD I and ATAD II), the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting (Multilateral Instrument) and the new corporate alternative minimum tax created in the U.S. by the Inflation Reduction Act.

Additionally, on December 20, 2021, the OECD released the Global Anti-Base Erosion ("GloBE") Model Rules ("Pillar Two") providing a legislative framework for the Income Inclusion Rule and the Under-Taxed Payment Rule ("UTPR"). Pillar Two is designed to ensure that large multinational enterprise groups pay a minimum level of tax on the income arising in each of the jurisdictions where they operate, principally creating a 15% minimum global effective tax rate. On December 15, 2022, the E.U. member states unanimously adopted a directive implementing the Pillar Two global minimum tax rules. E.U. member states have until December 31, 2023 to transpose the directive into national legislation with the rules to be applicable for fiscal years beginning on or after December 31, 2023, with the exception of the UTPR which is to be applicable for fiscal years beginning on or after December 31, 2024. On December 20, 2022, the OECD released three guidance documents related to Pillar Two. These documents included guidance on safe harbors and penalty relief and consultation papers on the GloBE Information Return and Tax Certainty for the GloBE rules. The latter two releases were open for public consultation until February 3, 2023.

These rules could adversely affect us and our affiliates by increasing our effective tax rate and cash tax obligations, which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and cash flows.

We may not be able to maintain a competitive worldwide effective corporate tax rate.

We cannot give any assurance as to what our effective tax rate will be in the future, because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we operate. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of Ireland and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate.

A change in our tax residency could have a negative effect on our future profitability and taxes on dividends.

Under current Irish legislation, a company is regarded as resident in Ireland for tax purposes if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. Under current U.K. legislation, a company is regarded as resident in the U.K. for tax purposes if it is centrally managed and controlled in the U.K. Where a company is treated as tax resident under the domestic laws of both the U.K. and Ireland then the provisions of article 4(3) of the Double Taxation Convention between Ireland and the U.K. provide that such company shall be treated as resident only in the jurisdiction in which its place of effective management is situated. From May 21, 2015 until July 15, 2020, we managed the affairs of Mallinckrodt plc so that it was effectively managed and controlled in the U.K. and therefore treated as resident only in the U.K. for tax purposes, by operation of the Double Taxation Convention. However, if subject to any review by applicable tax authorities, we cannot provide assurance that Mallinckrodt plc will be treated as a resident only in the U.K. for tax purposes during this period. As of July 15, 2020, the activities of the Company's principal executive offices were relocated from the U.K. to Ireland, which resulted in a change in the Company's tax residence to Ireland. It is possible that in the future, whether as a result of a change in law or a change in the practice or conduct of the affairs of any relevant tax authority, Mallinckrodt plc could become, or be regarded as having become resident in a jurisdiction other than Ireland. If Mallinckrodt plc were considered to be a tax resident of a jurisdiction other than Ireland, in addition to any Irish consequences, it could become liable for corporate tax in that jurisdiction and any dividends paid by it could be subject to dividend withholding tax in that jurisdiction.

Risks Related to Our Jurisdiction of Incorporation

Irish law differs from the laws in effect in the U.S. and may afford less protection to holders of our securities.

It may not be possible to enforce court judgments obtained in the U.S. against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

A judgment obtained against us will be enforced by the courts of Ireland if the following general requirements are met: (i) U.S. courts must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule) and (ii) the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it. A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. Where however the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that in the meantime the judgment may not be actionable in Ireland. It remains to be determined whether final judgment given in default of appearance is final and conclusive. However, Irish courts may refuse to enforce a judgment of the U.S. courts which meets the above requirements for one of the following reasons: (i) if the judgment is not for a definite sum of money; (ii) if the judgment was obtained by fraud; (iii) the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice; (iv) the judgment is contrary to Irish public policy or involves certain U.S. laws which will not be enforced in Ireland; or (v) jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Ireland Superior Courts Rules.

As an Irish company, we are governed by the Irish Companies Act 2014, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the U.S.

Irish law imposes restrictions on certain aspects of capital management.

Irish law allows our shareholders to pre-authorize shares to be issued by our Board of Directors without further shareholder approval for up to a maximum of five years. Additionally, subject to specified exceptions, including as opt-out approved by a shareholder vote, Irish law grants statutory pre-emptive rights to existing shareholders to subscribe for new issuances of shares for cash. The Company's current Memorandum and Articles of Association, adopted on June 16, 2022, contains that a five-year pre-authorization of the Board of Directors to issue shares and opt-out of pre-emption rights. We cannot guarantee that renewal of the pre-authorization or opt-out from pre-emptive rights will always be sought or approved. We cannot provide assurance that these Irish legal restrictions will not interfere with our capital management.

Risks Related to Our Ordinary Shares

Although our ordinary shares recently began to trade on the NYSE American stock exchange, an active trading market may not develop and the price and trading volume of our ordinary shares may fluctuate significantly.

Our ordinary shares were previously delisted from the New York Stock Exchange ("NYSE"), and the subsequent cancellation of our ordinary shares and issuance of new ordinary shares in connection with our emergence from bankruptcy resulted in reduced liquidity for investors seeking to buy or sell our ordinary shares. Our ordinary shares were quoted on the Pink Open Market (formerly known as the OTC Pink Marketplace) after our emergence from bankruptcy. On October 27, 2022, our ordinary shares began to trade on the New York Stock Exchange American LLC ("NYSE American"), and trading on the Pink Open Market ceased concurrent with the NYSE American listing. To maintain listing on this market, we must meet certain listing requirements, including requirements for a minimum stockholders' equity, minimum market capitalization or total assets and revenue, minimum public float, minimum market value of public float, minimum number of round lot shareholders, and continued business operations. If our ordinary shares are delisted for any reason, it could reduce the value of our ordinary shares and liquidity.

We cannot predict the extent to which investor interest in us will lead to the development of an active trading market or how liquid that market might become, and there can be no assurance that there will be an active trading market for our ordinary shares, either now or in the future. If an active trading market does not develop, holders of our shares may have difficulty selling any of our ordinary shares that may now be owned or may be purchased later. In addition, the number of investors willing to hold or acquire our ordinary shares may be reduced, the trading price of our ordinary shares may be depressed, we may receive decreased news and analyst coverage and we may be limited in our ability to issue additional securities or obtain additional financing in the future on terms acceptable to us, or at all.

Even if an active trading market develops for our ordinary shares, the market price of our ordinary shares may be highly volatile and could be subject to wide fluctuations. In addition, the trading volume of our ordinary shares may fluctuate and cause significant price variations to occur. Volatility in the market price or trading volume of our ordinary shares may prevent investors from being able to sell shares at or above the price they paid to acquire their ordinary shares, or at all.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices and Specialty Brands global external manufacturing operations are located in Dublin, Ireland. In addition, we have other locations in the U.S., most notably our corporate shared services facility in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bridgewater, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri. As of December 30, 2022 (Successor), we owned a total of ten facilities in the U.S., Ireland and Japan. Our owned facilities consist of approximately 2.1 million square feet, and our leased facilities consist of approximately 0.5 million square feet. We have 11 manufacturing sites: one in Ireland; two in Japan; and eight in the U.S. We believe all of these facilities are well-maintained and suitable for the operations conducted in them.

Item 3. Legal Proceedings.

We are subject to various legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and other legal proceedings, in the ordinary course of business. Although it is not feasible to predict the outcome of these matters, we believe, unless otherwise indicated, given the information currently available, that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

For further information, refer to Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report, which is incorporated by reference into this Part I, Item 3.

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

Prior to our filing for Chapter 11, our ordinary shares were traded on the NYSE under the ticker symbol "MNK." On October 13, 2020, the NYSE filed a Form 25 with the SEC to delist our ordinary shares from the NYSE. The delisting became effective October 26, 2020. The deregistration of the ordinary shares under Section 12(b) of the Exchange Act became effective on January 11, 2021, at which point the ordinary shares were deemed registered under Section 12(g) of the Exchange Act. Our ordinary shares began trading on the Pink Open Market (formerly known as the OTC Pink Marketplace) on October 13, 2020, under the symbol "MNKKQ." On October 24, 2022, we received approval to list our ordinary shares on the NYSE American. Our ordinary shares were listed on NYSE American and began trading on October 27, 2022, under the ticker symbol "MNK". At such time, trading of our ordinary shares on the OTC Pink Current Market ceased, concurrent with the NYSE American listing.

There was one shareholder of record of our ordinary shares as of February 24, 2023. However, there are substantially more shareholders who own their shares beneficially or in "street name," whose shares are held by banks, brokers and other financial institutions.

Dividends and Issuer Purchase of Equity Securities

Under Irish law, we can only pay dividends and repurchase shares out of distributable reserves. We did not declare or pay any dividends and we do not currently intend to pay dividends in the foreseeable future. We made no repurchases of our ordinary shares during fiscal 2022.

On the Effective Date, we issued 3,290,675 warrants with a strike price of $103.40 to opioid claimants that are exercisable at any time on or prior to the sixth anniversary of the Effective Date ("Opioid Warrants"); and subsequently, we repurchased all of our outstanding Opioid Warrants during the fourth quarter of 2022. For additional information, refer to Note 2 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Performance Graph

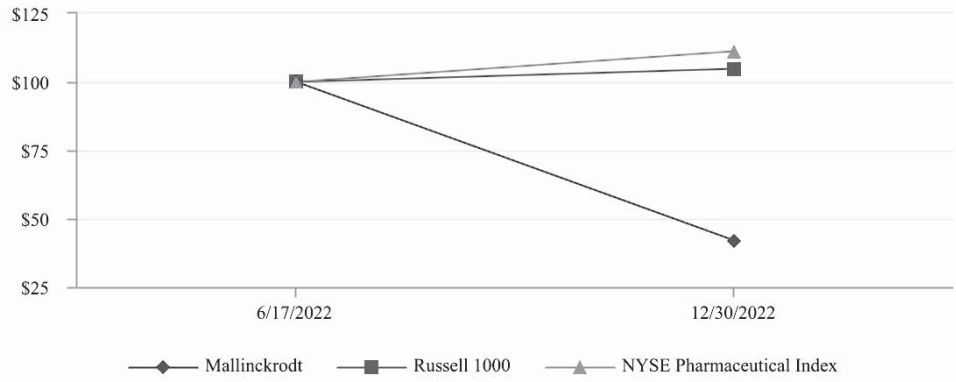
The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

Pursuant to the Plan, on the Effective Date, all of our ordinary shares issued and outstanding before the Effective Date were cancelled and we issued 13,770,932 ordinary shares to holders of our former unsecured notes. Therefore, the following graph does not reflect the total value of an investment in our ordinary shares prior to the Effective Date, as such shares were cancelled. The increase in value of the ordinary shares shown in the graph represents a hypothetical $100 investment in new ordinary shares issued in the bankruptcy on the Effective Date. The following graph compares the changes, for the period indicated, in the cumulative total value of $100 hypothetically invested on the Effective Date, which is the date the Plan became effective and the date on which we emerged from the Chapter 11 and Irish examinership proceedings, in each of (a) Mallinckrodt ordinary shares, (b) the Russell 1000 index and (c) the NYSE Pharmaceutical Index.

Comparison of Cumulative Total Return

Among Mallinckrodt plc, the Russell 1000 Index and NYSE Pharmaceutical Index

The following graph covers the period from June 17, 2022 (Successor) through December 30, 2022 (Successor):



The share price performance included in this graph is not necessarily indicative of future share price performance.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes included within this Annual Report. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs and involve risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Item 1A. Risk Factors and "Forward-Looking Statements" included within this Annual Report.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. The period June 17, 2022 through December 30, 2022 reflects the Successor period, while the period January 1, 2022 through, and including, June 16, 2022 reflects the Predecessor period. Fiscal 2021 (Predecessor) consisted of 53 weeks, while fiscal 2022 and fiscal 2020 (Predecessor) consisted of 52 weeks.

Overview

We are a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products.

We operate our business in two reportable segments, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and API(s).

For further information on our business and products, refer to Item 1. Business included within this Annual Report.

Significant Events

INOmax

On September 28, 2022, we submitted a 510(k) premarket notification to the FDA for an investigational inhaled nitric oxide delivery system for INOmax (nitric oxide) gas, for inhalation, which has been previously approved by the FDA for treating hypoxic respiratory failure in newborns. The safety and efficacy of the inhaled nitric oxide delivery system has not been evaluated by the FDA and is subject to the pending 510(k) premarket notification. The delivery system combines automation, integration and interaction into one device, and if the 510(k) premarket notification is cleared, would be the latest in a long line of dual channel delivery systems implemented with the objective of building on our dedication to meeting clinicians' evolving needs.

Terlivaz

On September 14, 2022, we announced that the FDA had approved Terlivaz for injection and during the fourth quarter of fiscal 2022, we released our first commercial shipment of the product. The FDA approval gave rise to a $17.5 million milestone payment. A corresponding intangible asset was recorded and began amortizing over the useful life of the related asset beginning with the first commercial shipment of the product, which occurred in October 2022.

StrataGraft

During the three months ended April 1, 2022 (Predecessor), we released our first commercial shipment of StrataGraft. Net sales of this product have been and are expected to continue to be uneven as a result of contracting with hospitals and the government procurement schedule associated with sales to the BARDA for placement in the Strategic National Stockpile.

On June 30, 2022, we completed the sale for $100.0 million of the PRV we were awarded under an FDA program intended to encourage the development of certain product applications for therapies used to treat or prevent material threat medical countermeasures. We received the PRV upon FDA approval of StrataGraft for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns). We received from the buyer $65.0 million and the buyer remitted $35.0 million to the General Unsecured Claims Trustee pursuant to the terms of (i) the Plan, and (ii) the General Unsecured Claims Trust Agreement entered into in connection with the Plan.

Emergence from Voluntary Reorganization

On the Petition Date, we voluntarily initiated the Chapter 11 Cases under Chapter 11 of the Bankruptcy Code in the Bankruptcy Court. On March 2, 2022, the Bankruptcy Court entered an order confirming the Plan. Subsequent to the filing of the Chapter 11 Cases, Chapter 11 proceedings commenced by a limited subset of the debtors were recognized and given effect in Canada, and separately the High Court of Ireland made an order confirming the Scheme of Arrangement on April 27, 2022. The Plan and Scheme of Arrangement became effective on the Effective Date, and on such date we emerged from the Chapter 11 and Irish examinership proceedings.

On the Effective Date, pursuant to the Plan and Scheme of Arrangement, among other things:

- We issued 13,170,932 ordinary shares to holders of the former unsecured notes;
- All opioid claims against us were deemed to have been settled, discharged, waived, released and extinguished in full in exchange for $1,725.0 million in deferred payments over the next eight years ("Opioid-Related Litigation Settlement");
- We issued 3,290,675 Opioid Warrants;
- We adopted a management incentive plan providing for the issuance to management, key employees and directors of the Company of equity awards with respect to up to an aggregate of 1,829,068 shares;
- All claims of the DOJ and other governmental parties relating to Acthar Gel were deemed to have been settled, discharged, waived, released and extinguished in full in exchange for $260.0 million of deferred payments over the next seven years ("Acthar Gel-Related Settlement");
- All shares of our stock issued and outstanding immediately prior to the Effective Date were canceled;
- Principal debt outstanding was reduced by more than $1.3 billion; and
- General unsecured claims were satisfied in an aggregate settlement of $135.0 million in cash plus other potential consideration, including but not limited to 35.0% of the proceeds of the sale of the StrataGraft PRV and $20.0 million payable upon the achievement of (i) FDA approval of Terlivaz and (ii) cumulative net sales of $100.0 million of Terlivaz.

For further details of the Plan and the subsequent repurchase of the Opioid Warrants, refer to Note 2 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of the Annual Report.

New Financing

In connection with emergence from bankruptcy, we issued $650.0 million in aggregate principal amount of new first lien senior secured notes. The net proceeds of the issuance of such notes were applied to repay in part our former senior secured revolving credit facility. We also entered into a $200.0 million accounts receivable financing facility, which was undrawn as of December 30, 2022 (Successor).

Pursuant to the Plan and Scheme of Arrangement, as of the Effective Date, we reinstated $495.0 million in aggregate principal amount of our existing first lien senior secured notes and issued $1,762.6 million in aggregate principal amount of new first lien senior secured term loans to the holders of our existing term loans in satisfaction thereof, issued $322.9 million in aggregate principal amount of new second lien senior secured notes to the holders of our existing second lien senior secured notes in satisfaction thereof and issued $375.0 million in aggregate principal amount of new second lien senior secured notes to the holders of certain of our existing unsecured senior notes in partial satisfaction thereof.

Fresh-Start Accounting

We adopted fresh-start accounting as of the Effective Date. As a result of the application of fresh-start accounting, our financial statements for periods prior to the Effective Date are not comparable to those for periods subsequent to the Effective Date. References in this Annual Report to "Successor" refer to the results of operations of the Company after the Effective Date. References to "Predecessor" refer to the results of operations of the Company on or prior to the Effective Date. Operating results for the Successor and Predecessor periods are not necessarily indicative of the results to be expected for a full fiscal year. References such as the "Company," "we," "our," and "us" refer to Mallinckrodt and its consolidated subsidiaries, whether Predecessor and/or Successor, as appropriate.

Our results of operations as reported in our Consolidated Financial Statements for the Successor and Predecessor periods are in accordance with generally accepted accounting principles in the U.S. ("GAAP"). The presentation of the combined financial information of the Predecessor and Successor for fiscal 2022 is not in accordance with GAAP. However, we believe that for purposes of discussion and analysis in this Annual Report the combined financial information is useful for management and investors to assess our ongoing financial and operational performance and trends.

For further information, refer to Note 3 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Reorganization items, net

During the period January 1, 2022 through June 16, 2022 (Predecessor), we incurred expenses of $630.9 million from reorganization items, net. These expenses were primarily driven by the loss on application of fresh-start accounting of $1,354.6 million and professional and lender fees, partially offset by a $943.7 million gain on settlement of liabilities subject to compromise ("LSTC") in accordance with the Plan. During the period from June 17, 2022 through December 30, 2022 (Successor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), we incurred expenses of $23.2 million, $428.2 million and $61.4 million from reorganization items, net, respectively. The Successor expenses represent amounts incurred after the Effective Date that directly resulted from Chapter 11 and were entirely comprised of professional fees associated with the implementation of the Plan. The amounts incurred in fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor) were primarily professional fees and adjustments to reflect the carrying value of LSTC at their estimated allowed claim amounts.

Business Factors Influencing the Results of Operations

We cannot adequately benchmark certain operating results of fiscal 2022 against fiscal 2021 (Predecessor) as the comparison would include the twelve months ended December 30, 2022 combined Successor and Predecessor periods against the fiscal 2021 Predecessor period, which would be considered to not be in accordance with GAAP. We do not believe that reviewing the results of these Successor periods in isolation would be useful in identifying trends in or reaching conclusions regarding our overall operating performance. Management believes that our key performance metrics such as net sales and segment results of operations for the Successor Period combined with the current Predecessor year-to-date period for fiscal 2022, provide more meaningful comparisons to prior Predecessor periods and are more useful in identifying current business trends. Accordingly, in addition to presenting our results of operations as reported in our consolidated financial statements in accordance with GAAP, in certain circumstances the discussion in "Results of Operations" and "Segment Results" below utilizes the combined results for fiscal 2022.

Specialty Brands

Net sales of INOmax for the period June 17, 2022 through December 30, 2022 (Successor) were $173.9 million. Net sales of INOmax for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $165.8 million and $448.5 million, respectively. Non-GAAP combined net sales for fiscal 2022 were $339.7 million. Net sales decreased $108.8 million, or 24.3%, driven primarily by continued competition from alternative nitric oxide products, which could continue to adversely affect our ability to successfully maximize the value of INOmax and have an adverse effect on our financial condition, results of operations and cash flows. We continue to develop and pursue patent protection of next generation nitric oxide delivery systems and additional uses of nitric oxide through our submission of a 510(k) premarket notification to the FDA for our next generation nitric oxide delivery system, as discussed above. We further intend to vigorously enforce our intellectual property rights relating to our nitric oxide products against any additional parties that may seek to market an alternative version of our INOmax product and/or next generation delivery systems.

Net sales of Acthar Gel for the period June 17, 2022 through December 30, 2022 (Successor) were $294.1 million. Net sales of Acthar Gel for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $221.9 million and $593.6 million, respectively. Non-GAAP combined net sales for fiscal 2022 were $516.0 million. Net sales decreased $77.6 million, or 13.1%, driven primarily by continued scrutiny on overall specialty pharmaceutical spending and the entrance of new competition in fiscal 2022. Competition intensified with the commercial launch of a purified cortrophin gel product in 2022 and this competitive pressure is expected to continue to negatively impact sales of Acthar Gel in 2023. The ongoing competition is expected to continue to have an adverse effect on our financial condition, results of operations and cash flows. We continue to differentiate Acthar Gel through pre-clinical studies and through product enhancements, including the development of the Acthar Gel self-injection device, which was has been completed, but we do not anticipate a launch in 2023. We continue to work toward the resolution of a regulatory matter involving one of our partners and not specific to our device. If approved, this product is expected to create an easier and more patient-friendly application for single unit dosage indications.

Net sales of Amitiza for the period June 17, 2022 through December 30, 2022 (Successor) were $77.1 million. Net sales of Amitiza for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $81.5 million and $196.9 million, respectively. Non-GAAP combined net sales for fiscal 2022 were $158.6 million. Net sales decreased $38.3 million, or 19.5%, driven primarily by a decline in royalties associated with loss of exclusivity in the U.S. Additional generic competitors have entered the market in 2023, resulting in the reduction of the Par U.S. royalties to zero going forward.

Net sales of Therakos for the period June 17, 2022 through December 30, 2022 (Successor) were $130.5 million. Net sales of Therakos for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $109.6 million and $266.5 million, respectively. Non-GAAP combined net sales for fiscal 2022 were $240.1 million. Net sales decreased $26.4 million, or 9.9%, driven primarily by the lagging effect of the COVID-19 pandemic that contributed to a reduction in use of the platform for treatment of graft-versus-host disease ("GvHD"), which is a non-promoted use in the U.S. market, and to a lesser extent the impact of competitive oral therapies for GvHD.

Specialty Generics

Net sales of the Specialty Generics segment for the period June 17, 2022 through December 30, 2022 (Successor) were $357.3 million. Net sales of the Specialty Generics segment for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $287.5 million and $661.8 million, respectively. Non-GAAP combined net sales for fiscal 2022 were $644.8 million. Net sales decreased $17.0 million, or 2.6%, driven primarily by a decrease in API net sales of $15.4 million and a decrease in generics net sales of $1.6 million.

Results of Operations

This Annual Report contains certain financial measures, including net sales, gross profit, gross profit margin, SG&A expenses as a percentage of net sales and R&D expenses as a percentage of net sales, which exclude the one-time charge related to the Medicaid lawsuit that is included as a component of net sales for fiscal 2020 (Predecessor).

We have provided these measures because they are used by management to evaluate our operating performance. In addition, we believe that they will be used by investors to measure Mallinckrodt's operating results. Management believes that presenting these measures provides useful information about our performance across reporting periods on a consistent basis by excluding items that we do not believe are indicative of our core operating performance. These measures should be considered supplemental to and not a substitute for financial information prepared in accordance with GAAP.

Because these measures exclude the effect of items that will increase or decrease our reported results of operations, management strongly encourages investors to review our consolidated financial statements and this Annual Report in its entirety. A reconciliation of certain of these financial measures to the most directly comparable GAAP financial measures is included herein.

Period from June 17, 2022 through December 30, 2022 (Successor) and Period from January 1, 2022 through June 16, 2022 (Predecessor) Compared with Fiscal Year Ended December 31, 2021 (Predecessor)

Net Sales

Net sales by geographic area are as follows (dollars in millions):

	Successor	Predecessor	Non-GAAP	Predecessor	Non-GAAP
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Combined Fiscal Year Ended December 30, 2022	Fiscal Year Ended December 31, 2021	Percentage Change
U.S.	$ 928.3	$ 784.2	$ 1,712.5	$ 1,991.8	(14.0)%
Europe, Middle East and Africa	100.4	73.6	174.0	181.8	(4.3)
Other	11.0	16.8	27.8	35.2	(21.0)
Net sales	$ 1,039.7	$ 874.6	$ 1,914.3	$ 2,208.8	(13.3)%

Net sales for the period June 17, 2022 through December 30, 2022 (Successor) were $1,039.7 million. Net sales for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $874.6 million and $2,208.8 million, respectively. Net sales decreased $294.5 million, or 13.3%, for the non-GAAP combined fiscal 2022, compared to fiscal 2021 (Predecessor). This decrease was primarily driven by a decrease in our Specialty Brands segment including a decrease in net sales of INOmax, Acthar Gel, Amitiza, and Therakos, as previously discussed. For further information on changes in our net sales, refer to "Business Segment Results" within this Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Loss

Gross profit. Gross profit for the period June 17, 2022 through December 30, 2022 (Successor) was $48.7 million. Gross profit for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) was $292.6 million and $891.7 million, respectively. Gross profit margin was 4.7% for the period June 17, 2022 through December 30, 2022 (Successor), 33.5% for the period January 1, 2022 through June 16, 2022 (Predecessor) and 40.4% for fiscal 2021 (Predecessor). The decrease during the period June 17, 2022 through December 30, 2022 (Successor) was primarily driven by a decrease in net sales and a change in product mix, coupled with $268.7 million of inventory step-up amortization expense and $30.0 million in fresh-start inventory-related expenses. The decrease during the period January 1, 2022 through June 16, 2022 (Predecessor) was primarily driven by a $13.6 million increase in amortization expense for the Amitiza intangible asset resulting from a change in amortization method as discussed further in Note 13 of the Notes to the Consolidated Financial Statements.

Selling, general and administrative expenses. SG&A expenses for the period June 17, 2022 through December 30, 2022 (Successor) were $290.1 million. SG&A expenses for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $275.3 million and $581.8 million, respectively. As a percentage of net sales, SG&A expenses were 27.9% for the period June 17, 2022 through December 30, 2022 (Successor), 31.5% for the period January 1, 2022 through June 16, 2022 (Predecessor) and 26.3% for fiscal 2021 (Predecessor). The decrease in SG&A expense for the period June 17, 2022 through December 30, 2022 (Successor) and the period January 1, 2022 through June 16, 2022 (Predecessor) as compared to fiscal 2021 (Predecessor) was primarily driven by continued cost containment initiatives coupled with an $11.1 million increase to certain of our environmental liabilities during the period January 1, 2022 through June 16, 2022 (Predecessor), compared to the $35.0 million increase to our environmental liabilities during fiscal 2021 (Predecessor). The decrease was partially offset by $21.2 million and $9.0

million of separation costs incurred during the period June 17, 2022 through December 30, 2022 (Successor) and the period January 1, 2022 through June 16, 2022 (Predecessor), respectively, related to the severance for the former CEO and certain former executives of the Predecessor, expense associated with the Predecessor directors' and officers' insurance policies and professional fees and costs incurred as we explore potential sales of non-core assets to enable further deleveraging post-emergence, respectively, compared to $1.2 million during fiscal 2021 (Predecessor). Also included in the offset was $6.4 million of bad debt expense attributable to a customer bankruptcy during the period June 17, 2022 through December 30, 2022 (Successor).

Research and development expenses. R&D expenses for the period June 17, 2022 through December 30, 2022 (Successor) were $64.2 million. R&D expenses for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $65.5 million and $205.2 million, respectively. As a percentage of net sales, R&D expenses were 6.2% for the period June 17, 2022 through December 30, 2022 (Successor), 7.5% for the period January 1, 2022 through June 16, 2022 (Predecessor) and 9.3% for fiscal 2021 (Predecessor). These decreases were driven by cost containment initiatives coupled with the completion of certain development programs. We continue to focus current R&D activities on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic activities and patient outcomes.

Restructuring and related charges, net. During the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor), we incurred $12.1 million, $9.6 million and $29.0 million of restructuring charges and related charges, net, respectively. Included in these charges was $0.8 million and $0.2 million of accelerated depreciation in cost of sales and SG&A, respectively, related to restructuring charges incurred during the period June 17, 2022 through December 30, 2022 (Successor), and $2.1 million of accelerated depreciation in SG&A related to restructuring charges incurred during fiscal 2021. The remaining charges primarily related to employee severance and benefits.

Non-restructuring impairment charges. Non-restructuring impairment charges were $154.9 million for fiscal 2021 (Predecessor) resulting from a partial impairment of $90.4 million related to the Amitiza intangible asset and a full impairment of $64.5 million related to the MNK-6105 and MNK-6106 in-process research & development ("IPR&D") asset.

Non-Operating Items

Interest expense and interest income. During the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor), net interest expense was $320.4 million, $108.0 million and $220.7 million, respectively. During the period June 17, 2022 through December 30, 2022 (Successor), interest expense included $87.5 million and $51.7 million of accretion expense associated with our settlement obligations and debt, respectively. The period June 17, 2022 through December 30, 2022 (Successor) and the period January 1, 2022 through June 16, 2022 (Predecessor) reflected increased interest rates on our variable interest rate debt as compared to fiscal 2021 (Predecessor). Interest expense during the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) included $28.8 million and $63.1 million, respectively, in expense related to cash adequate protection payments on certain of our predecessor senior secured debt instruments. Fiscal 2021 (Predecessor) also included the recognition of a $15.8 million benefit to interest expense due to a lapse of certain statute of limitations.

Other income (expense), net. During the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor), we recorded other income of $10.0 million, other expense of $14.6 million and other income of $22.0 million, respectively. We recognized a $9.2 million unrealized gain, a $22.2 million unrealized loss, and a $4.7 million unrealized gain on our equity investments for the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor), respectively. The period from January 1, 2022 through June 16, 2022 (Predecessor) also included $5.8 million of miscellaneous credits. Additionally, there were one-time milestone receivables of $9.0 million as well as a one-time Japanese consumption tax credit of $6.8 million in fiscal 2021 (Predecessor).

Reorganization items, net. During the period June 17, 2022 through December 30, 2022 (Successor), we recorded a loss of $23.2 million in reorganization items, net entirely driven by professional fees related to the implementation of the Plan. During the period January 1, 2022 through June 16, 2022 (Predecessor), we recorded a loss of $630.9 million in reorganization items, net driven primarily by the loss on fresh-start adjustments of $1,678.8 million and professional fees and lender fees of $205.4 million, partially offset by a gain on adjustments to LSTC of $1,253.3 million. During fiscal 2021 (Predecessor), we recorded a loss of $428.2 million in reorganization items, net, driven primarily by professional fees of $405.6 million and $23.1 million of deferred financing fee write-offs related to the predecessor term loans.

(Benefit) expense from income taxes. We recognized an income tax benefit of $52.0 million on a loss from continuing operations before income taxes of $650.3 million for the period from June 17, 2022 through December 30, 2022 (Successor). This resulted in an effective tax rate of 8.0%. The income tax benefit was comprised of $27.1 million of current tax benefit and $24.9 million of deferred tax benefit.

Our effective tax rate for the period from June 17, 2022 through December 30, 2022 (Successor) was impacted by $52.1 million tax benefit associated with $268.7 million of inventory step-up amortization expense, $44.0 million tax benefit associated with $318.7 million of intangible asset amortization expense, $19.1 million of tax benefit associated with $87.5 million of accretion expense

related to our settlement obligations, and $2.4 million of tax benefit associated with $51.7 million of accretion expense related to our debt offset by $4.7 million withholding tax expense associated with a Swiss distribution. The remaining $60.9 million of tax expense is predominately associated with pretax earnings in various jurisdictions and valuation allowances.

We recognized an income tax benefit of $497.3 million on a loss from continuing operations before income taxes of $811.3 million for the period from January 1, 2022 through June 16, 2022 (Predecessor). This resulted in an effective tax rate of 61.3%. The income tax benefit was comprised of $23.9 million of current tax benefit and $473.4 million of deferred tax benefit.

Our effective tax rate for the period from January 1, 2022 through June 16, 2022 (Predecessor) was impacted by $600.8 million of tax benefit associated with valuation allowance and $31.6 million of tax benefit associated with emergence further detailed in Note 8 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report. Additional impacts include $80.9 million of tax benefit associated with the $1,678.8 million loss on fresh-start adjustments, $29.1 million of tax benefit associated with $205.4 million of professional and lender fees, and $14.7 million of tax benefit predominately associated with pretax earnings in various jurisdictions offset with $259.8 million of tax expense associated with $1,253.0 million of gain on adjustments to LSTC.

During fiscal 2021 (Predecessor), we recognized an income tax benefit of $106.3 million on a loss from continuing operations before income taxes of $829.8 million. The fiscal 2021 (Predecessor) income tax benefit was comprised of $46.4 million of current tax benefit and $59.9 million of deferred tax benefit. The current tax benefit was primarily the result of an increase to prepaid taxes and a decrease to uncertain tax positions. The deferred tax benefit was predominately related to intangible asset amortization, partially offset by utilization of loss carryforwards in non-valuation allowance jurisdictions.

Our effective tax rate was 12.8% for fiscal 2021 (Predecessor). Our effective tax rate for fiscal 2021 (Predecessor) was most significantly impacted by the tax benefit of $286.3 million predominately related to changes in the jurisdictional mix of operating loss resulting from the fiscal 2020 (Predecessor) reorganization of the Company's intercompany financing and associated asset and legal entity ownership and a $9.7 million tax benefit associated with accrued income tax liabilities and uncertain tax positions, partially offset with $189.7 million of tax expense associated with valuation allowances recorded against our net deferred tax assets in applicable tax jurisdictions. Additional impacts to the fiscal 2021 (Predecessor) effective tax rate include a tax benefit of $49.9 million associated with $428.2 million of reorganization items, net, $34.8 million of tax benefit associated with an impairment charge of $154.9 million, and $21.1 million of tax benefit associated with the $125.0 million opioid-related litigation settlement charge. These additional impacts are significantly offset with the above referenced valuation allowance, thus resulting in a tax benefit of $15.0 million included within our jurisdictional mix of operating loss.

Income from discontinued operations, net of income taxes. We recorded income from discontinued operations of $0.2 million, $0.9 million and $6.1 million for the period June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor), respectively. The income during fiscal 2021 (Predecessor) primarily related to the recognition of a tax benefit related to the releases of tax and interest on unrecognized tax benefits due to lapses of certain statute of limitations related to the Nuclear Imaging business that we divested in 2017. The remaining activity in both periods related to various post-sale adjustments associated with our previous divestitures.

Fiscal Year Ended December 31, 2021 (Predecessor) Compared with Fiscal Year Ended December 25, 2020 (Predecessor)

Net Sales

Net sales by geographic area are as follows (dollars in millions):

	Fiscal Year		
	2021	2020	Percentage Change
U.S.	$ 1,991.8	$ 2,465.5	(19.2)%
Europe, Middle East and Africa	181.8	227.5	(20.1)
Other	35.2	56.4	(37.6)
Geographic area net sales	2,208.8	2,749.4	(19.7)
Medicaid lawsuit	—	(536.0)	*
Net sales	$ 2,208.8	$ 2,213.4	(0.2)%

*Not meaningful

Net sales in fiscal 2021 (Predecessor) were $2,208.8 million, which was relatively flat when compared with $2,213.4 million in fiscal 2020 (Predecessor).

Net sales in fiscal 2021 (Predecessor) decreased $540.6 million, or 19.7%, to $2,208.8 million, compared with $2,749.4 million in fiscal 2020 (Predecessor) (excluding the one-time charge related to the Medicaid lawsuit). This decrease was primarily driven by a

decrease in our Specialty Brands segment including a significant decrease in net sales of Ofirmev, Acthar Gel and INOmax. For further information on changes in our net sales, refer to "Business Segment Results" within this Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Loss

Gross profit. Gross profit for fiscal 2021 (Predecessor) increased $222.3 million, or 33.2%, to $891.7 million, compared with $669.4 million in fiscal 2020 (Predecessor). This increase was primarily driven by the retrospective one-time charge of $536.0 million reflected as a component of net sales related to the Medicaid lawsuit in fiscal 2020 (Predecessor).

Gross profit in fiscal 2021 (Predecessor) decreased $313.7 million, or 26.0%, to $891.7 million, compared with $1,205.4 million in fiscal 2020 (Predecessor) (excluding the one-time charge related to the Medicaid lawsuit). Gross profit margin was 40.4% for fiscal 2021 (Predecessor), compared with 43.8% in fiscal 2020 (Predecessor). The decrease in gross profit and gross profit margin was primarily attributable to the $540.6 million decrease in net sales, as discussed above, as well as a change in product mix.

Selling, general and administrative expenses. SG&A expenses for fiscal 2021 (Predecessor) were $581.8 million, compared with $884.1 million for fiscal 2020 (Predecessor), a decrease of $302.3 million, or 34.2%. As a percentage of net sales, SG&A expenses were 26.3% for fiscal 2021 (Predecessor), compared to 39.9%, or 32.2% when excluding the one-time charge related to the Medicaid lawsuit, for fiscal 2020 (Predecessor). These decreases were primarily driven by the bankruptcy-related professional fees being classified as reorganization items, net, subsequent to the Petition Date. Comparatively, during fiscal 2020 (Predecessor), we incurred $93.4 million and $55.7 million in separation costs and opioid defense costs, respectively, that were reflected in SG&A. These decreases were also driven by cost containment initiatives and lower employee compensation costs, coupled with a $7.4 million decrease in the fair value of our former contingent consideration liabilities during fiscal 2021 (Predecessor), compared to a $9.9 million increase during fiscal 2020 (Predecessor). The decrease was partially offset by a $35.0 million increase to our environmental liabilities during fiscal 2021 (Predecessor).

Research and development expenses. R&D expenses decreased $85.6 million, or 29.4%, to $205.2 million in fiscal 2021 (Predecessor), compared with $290.8 million in fiscal 2020 (Predecessor). This decrease was driven by the completion of certain development programs coupled with the abandonment of the MNK-6105 and MNK-6106 asset in fiscal 2021 (Predecessor). The Company continues to focus current R&D activities on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic activities and patient outcomes. As a percentage of our net sales, R&D expenses were 9.3% for fiscal 2021 (Predecessor) compared to 13.1%, or 10.6% when excluding the one-time charge related to the Medicaid lawsuit, for fiscal 2020 (Predecessor), respectively.

Restructuring and related charges, net. During fiscal 2021 (Predecessor), we recognized $29.0 million of restructuring and related charges, net, of which $2.1 million related to accelerated depreciation and was included in SG&A. The remaining $26.9 million primarily related to employee severance and benefits. The fiscal 2020 (Predecessor) charge of $49.8 million, which included $12.3 million related to accelerated depreciation, primarily related to the exiting of our Bedminster, New Jersey facility as we moved our Specialty Brands commercial headquarters from Bedminster to Hampton, New Jersey, as well as employee severance and benefits.

Non-restructuring impairment charges. Non-restructuring impairment charges were $154.9 million for fiscal 2021 (Predecessor) resulting from a partial impairment of $90.4 million related to the Amitiza intangible asset and a full impairment of $64.5 million related to the MNK-6105 and MNK-6106 IPR&D asset. Non-restructuring impairment charges were $63.5 million for fiscal 2020 (Predecessor) primarily related to the partial impairment related to the Ofirmev intangible asset.

Losses (gains) on divestiture. During fiscal 2021 (Predecessor) and 2020 (Predecessor), we incurred a loss on divestiture of $0.8 million and a gain of $16.6 million, respectively. Fiscal 2020 (Predecessor) included a gain of $16.5 million, related to the achievement of milestones affiliated with the sale of a portion of our Hemostasis business in fiscal 2018 to Baxter International, Inc.

Opioid-related litigation settlement loss (gain). During fiscal 2021 (Predecessor), we recorded a charge of $125.0 million as a result of an additional payment expected to be made on the eighth anniversary of the effective date of the Opioid-Related Litigation Settlement, in accordance with the agreement in principle reached on September 2, 2021. For further information, refer to Note 2 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report. For fiscal 2020 (Predecessor), we recorded a gain of $43.4 million due to the decrease in the fair value of the settlement warrants, which were determined to have no value given we could not reasonably estimate the equity value at emergence.

Medicaid lawsuit. During fiscal 2020 (Predecessor), we incurred a retrospective one-time charge of $105.1 million, which represents a pre-acquisition contingency related to the portion of the liability that arose from sales of Acthar Gel prior to our acquisition of Questcor in August 2014.

Non-Operating Items

Interest expense and interest income. During fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), net interest expense was $220.7 million and $255.2 million, respectively. The $38.5 million decrease in interest expense was primarily attributable to a $72.5 million decrease resulting from the cessation of interest accruals as of the Petition Date on outstanding unsecured pre-petition debt classified as LSTC in connection with the Chapter 11 Cases, coupled with a lower average outstanding debt balance and a $7.6 million decrease in the amortization of discount and debt issuance costs. This decrease was partially offset by a $51.4 million increase in

expense related to adequate protection payments in fiscal 2021 (Predecessor) as compared to fiscal 2020 (Predecessor). Additionally, fiscal 2021 (Predecessor) and 2020 (Predecessor) included the recognition of a $15.8 million and $19.2 million benefit to interest expense, respectively, due to lapses of certain statutes of limitations. Interest income decreased $4.0 million to $1.9 million during fiscal 2021 (Predecessor), compared to $5.9 million during fiscal 2020 (Predecessor), primarily driven by interest earned on our preferred equity certificates that were received as contingent consideration related to the sale of the Nuclear Imaging business during fiscal 2020 (Predecessor) and lower interest rates during fiscal 2021 (Predecessor).

Other income, net. During fiscal 2021 (Predecessor) and 2020 (Predecessor), we recorded other income, net, of $22.0 million and $7.4 million, respectively. This increase was primarily driven by $9.0 million of one-time milestone receivables in fiscal 2021 (Predecessor), coupled with a $6.8 million one-time Japanese consumption tax credit. The remaining activity in both periods represented unrealized gains on our equity investment in Silence Therapeutics plc, non-service pension expense and other items, including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Reorganization items, net. During fiscal 2021 (Predecessor) and 2020 (Predecessor), we recorded $428.2 million and $61.4 million of reorganization items, net in conjunction with our Chapter 11 proceedings, respectively. The fiscal 2021 (Predecessor) charges included $405.6 million of advisor and legal fees directly related to the Chapter 11 Cases and $23.1 million of deferred financing fee write-offs related to the senior secured term loan due September 2024, senior secured term loan due February 2025 and second lien senior notes in order to reflect the carrying value of the notes within LSTC on the consolidated balance sheet as of December 31, 2021, at their estimated allowed claim amounts. The fiscal 2020 (Predecessor) charges included $51.1 million of advisor and legal fees directly related to the Chapter 11 Cases and $10.2 million of deferred financing fee write-offs related to the unsecured notes.

(Benefit) expense from income taxes. During fiscal 2021 (Predecessor), we recognized an income tax benefit of $106.3 million on a loss from continuing operations before income taxes of $829.8 million. The fiscal 2021 (Predecessor) income tax benefit was comprised of $46.4 million of current tax benefit and $59.9 million of deferred tax benefit. The current tax benefit was primarily the result of an increase to prepaid taxes and a decrease to uncertain tax positions. The deferred tax benefit was predominately related to intangible asset amortization, partially offset by utilization of loss carryforwards in non-valuation allowance jurisdictions. During fiscal 2020 (Predecessor), we recognized an income tax expense of $8.9 million on a loss from continuing operations before income taxes of $960.8 million. The fiscal 2020 (Predecessor) income tax expense was comprised of $375.3 million of current tax benefit and $384.2 million of deferred tax expense. The current tax benefit was primarily the result of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act and unrecognized tax benefits, partially offset by the fiscal 2020 (Predecessor) reorganization of our intercompany financing and associated asset and legal entity ownership. The deferred tax expense was predominately related to the valuation allowance recorded against our net deferred tax assets, and the fiscal 2020 (Predecessor) reorganization of our intercompany financing and associated asset and legal entity ownership.

Our effective tax rate was 12.8% and negative 0.9% for fiscal 2021 (Predecessor) and 2020 (Predecessor), respectively. Our effective tax rate for fiscal 2021 (Predecessor) was most significantly impacted by the tax benefit of $286.3 million predominately related to changes in the jurisdictional mix of operating loss resulting from the fiscal 2020 (Predecessor) reorganization of the Company's intercompany financing and associated asset and legal entity ownership and a $9.7 million tax benefit associated with accrued income tax liabilities and uncertain tax positions, partially offset with $189.7 million of tax expense associated with valuation allowances recorded against our net deferred tax assets in applicable tax jurisdictions. Additional impacts to the fiscal 2021 (Predecessor) effective tax rate include a tax benefit of $49.9 million associated with $428.2 million of reorganization items, net, $34.8 million of tax benefit associated with an impairment charge of $154.9 million, and $21.1 million of tax benefit associated with the $125.0 million opioid-related litigation settlement charge. These additional impacts are significantly offset with the above referenced valuation allowance, thus resulting in a tax benefit of $15.0 million included within our jurisdictional mix of operating loss. Our effective tax rate for fiscal 2020 (Predecessor) was most significantly impacted by $618.2 million of tax expense associated with valuation allowances and an $82.0 million tax expense associated with the reorganization of our intercompany financing and associated asset and legal entity ownership, partially offset by a $281.5 million tax benefit associated with the CARES Act and $11.9 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions. Additional impacts to the fiscal 2020 (Predecessor) effective tax rate included a tax benefit of $11.8 million associated with $93.4 million of separation costs, $5.4 million of tax benefit associated with $61.4 million of reorganization items, net, $0.5 million of tax benefit associated with $25.3 million of share-based compensation, and no tax expense associated with a gain of $43.4 million due to the decrease in the fair value of the New Opioid Warrants. All of these additional impacts are offset with the above referenced valuation allowance, thus resulting in no net impact on tax expense or benefit.

Income from discontinued operations, net of income taxes. We recorded income of $6.1 million and $25.1 million on discontinued operations, net of income taxes, during fiscal 2021 (Predecessor) and 2020 (Predecessor), respectively. Fiscal 2021 (Predecessor) and 2020 (Predecessor) both included the recognition of a tax benefit related to a release of tax and interest on unrecognized tax benefits due to lapses of certain statutes of limitations related to the Nuclear Imaging business. The remaining income during fiscal 2020 (Predecessor) primarily related to the receipt of contingent consideration associated with the sale of the Nuclear Imaging business, partially offset by various post-sale adjustments associated with our previous divestitures.

Business Segment Results

Management measures and evaluates our operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment net sales and operating income because management and the chief operating decision maker evaluate the operating results of the segments excluding such items. These items include, but are not limited to, depreciation and amortization, share-based compensation, net restructuring charges, non-restructuring impairment charges, separation costs, R&D upfront payments, changes related to the Opioid-Related Litigation Settlement and the Medicaid lawsuit. Although these amounts are excluded from segment net sales and segment operating income, as applicable, they are included in reported consolidated net sales and operating loss and in the reconciliations presented below. Selected information by business segment is as follows:

Period from June 17, 2022 through December 30, 2022 (Successor) and Period from January 1, 2022 through June 16, 2022 (Predecessor) Compared with Fiscal Year Ended December 31, 2021 (Predecessor)

Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Successor	Predecessor	Non-GAAP	Predecessor	Non-GAAP
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Combined Fiscal Year Ended December 30, 2022	Fiscal Year Ended December 31, 2021	Percentage Change
Specialty Brands	$ 682.4	$ 587.1	$ 1,269.5	$ 1,547.0	(17.9)%
Specialty Generics	357.3	287.5	644.8	661.8	(2.6)
Net sales	$ 1,039.7	$ 874.6	$ 1,914.3	$ 2,208.8	(13.3)%

Specialty Brands. Net sales for the period June 17, 2022 through December 30, 2022 (Successor) were $682.4 million. Net sales for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $587.1 million and $1,547.0 million, respectively. Net sales decreased $277.5 million, or 17.9%, for the non-GAAP combined fiscal 2022, compared to fiscal 2021 (Predecessor). The decrease in combined net sales was primarily driven by a decrease of $108.8 million, or 24.3% in INOmax, a decrease of $77.6 million, or 13.1%, in Acthar Gel, a decrease of $38.3 million, or 19.5%, in Amitiza, and a decrease of $26.4 million, or 9.9%, in Therakos.

Net sales for Specialty Brands by geography are as follows (dollars in millions):

	Successor	Predecessor	Non-GAAP	Predecessor	Non-GAAP
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Combined Fiscal Year Ended December 30, 2022	Fiscal Year Ended December 31, 2021	Percentage Change
U.S.	$ 642.1	$ 547.1	$ 1,189.2	$ 1,450.5	(18.0)%
Europe, Middle East and Africa	33.9	29.2	63.1	75.3	(16.2)
Other	6.4	10.8	17.2	21.2	(18.9)
Net sales	$ 682.4	$ 587.1	$ 1,269.5	$ 1,547.0	(17.9)%

Net sales for Specialty Brands by key products are as follows (dollars in millions):

	Successor	Predecessor	Non-GAAP	Predecessor	Non-GAAP
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Combined Fiscal Year Ended December 30, 2022	Fiscal Year Ended December 31, 2021	Percentage Change
Acthar Gel	$ 294.1	$ 221.9	$ 516.0	$ 593.6	(13.1)%
INOmax	173.9	165.8	339.7	448.5	(24.3)
Ofirmev	(0.3)	2.5	2.2	28.9	(92.4)
Therakos	130.5	109.6	240.1	266.5	(9.9)
Amitiza	77.1	81.5	158.6	196.9	(19.5)
Other	7.1	5.8	12.9	12.6	2.4
Specialty Brands	$ 682.4	$ 587.1	$ 1,269.5	$ 1,547.0	(17.9)%

Specialty Generics. Net sales for the period June 17, 2022 through December 30, 2022 (Successor) were $357.3 million. Net sales for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) were $287.5 million and $661.8 million, respectively. Net sales decreased $17.0 million, or 2.6%, for the non-GAAP combined fiscal 2022, compared to fiscal 2021 (Predecessor). The decrease in combined net sales was primarily driven by a decrease in API of $15.4 million, or 4.7%, and a decrease in generics of $1.6 million, or 0.5%.

Net sales for Specialty Generics by geography are as follows (dollars in millions):

	Successor	Predecessor	Non-GAAP	Predecessor	Non-GAAP
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Combined Fiscal Year Ended December 30, 2022	Fiscal Year Ended December 31, 2021	Percentage Change
U.S.	$ 286.2	$ 237.1	$ 523.3	$ 541.3	(3.3)%
Europe, Middle East and Africa	66.5	44.4	110.9	106.5	4.1
Other	4.6	6.0	10.6	14.0	(24.3)
Net sales	$ 357.3	$ 287.5	$ 644.8	$ 661.8	(2.6)%

Net sales for Specialty Generics by key products are as follows (dollars in millions):

	Successor	Predecessor	Non-GAAP	Predecessor	Non-GAAP
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Combined Fiscal Year Ended December 30, 2022	Fiscal Year Ended December 31, 2021	Percentage Change
Opioids	$ 117.9	$ 88.8	$ 206.7	$ 213.2	(3.0)%
ADHD	28.4	17.5	45.9	37.4	22.7
Addiction treatment	35.0	30.0	65.0	68.3	(4.8)
Other	6.8	4.9	11.7	12.0	(2.5)
Generics	188.1	141.2	329.3	330.9	(0.5)
Controlled substances	47.0	37.6	84.6	93.4	(9.4)
APAP	111.4	96.5	207.9	215.9	(3.7)
Other	10.8	12.2	23.0	21.6	6.5
API	169.2	146.3	315.5	330.9	(4.7)
Specialty Generics	$ 357.3	$ 287.5	$ 644.8	$ 661.8	(2.6)%

Operating Loss

Operating income by segment and as a percentage of segment net sales for the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) is shown in the following table (dollars in millions):

	Successor		Predecessor		Non-GAAP		Predecessor	
	Period from June 17, 2022 through December 30, 2022		Period from January 1, 2022 through June 16, 2022		Combined Fiscal Year Ended December 30, 2022		Fiscal Year Ended December 31, 2021	
Specialty Brands [1]	$ 113.8	16.7 %	$ 267.2	45.5 %	$ 381.0	30.0 %	$ 812.8	52.5 %
Specialty Generics [2]	(3.6)	(1.0)	65.3	22.7	61.7	9.6	107.9	16.3
Segment operating income	110.2	10.6 %	332.5	38.0 %	442.7	23.1 %	920.7	41.7 %
Unallocated amounts:								
Corporate and unallocated expenses [3]	(39.3)		(48.2)		(87.5)		(129.6)	
Depreciation and amortization	(347.5)		(321.8)		(669.3)		(675.8)	
Share-based compensation	(1.4)		(1.7)		(3.1)		(10.2)	
Restructuring charges, net	(11.1)		(9.6)		(20.7)		(26.9)	
Non-restructuring impairment charges	—		—		—		(154.9)	
Separation costs [4]	(21.2)		(9.0)		(30.2)		(1.2)	
Opioid-related litigation settlement loss	—		—		—		(125.0)	
Bad debt expense - customer bankruptcy	(6.4)		—		(6.4)		—	
Total operating loss	$ (316.7)		$ (57.8)		$ (374.5)		$ (202.9)	

(1) Includes $241.7 million of inventory fair-value step-up expense during the period from June 17, 2022 through December 30, 2022 (Successor).

(2) Includes $30.0 million of fresh-start inventory-related expense primarily driven by the Company's change in accounting estimate as disclosed in Note 1 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report and $27.0 million of inventory fair-value step-up expense during the period from June 17, 2022 through December 30, 2022 (Successor).

(3) Includes administration expenses and certain compensation, legal, environmental and other costs not charged to our reportable segments.

(4) Represents costs included in SG&A, primarily related to expenses incurred related to severance for the former CEO and certain former executives of the Predecessor and the Predecessor directors' and officers' insurance policies, in addition to professional fees and costs incurred as we explore potential sales of non-core assets to enable further deleveraging post-emergence from bankruptcy.

Specialty Brands. Operating income for the period June 17, 2022 through December 30, 2022 (Successor) was $113.8 million. Operating income for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) was $267.2 million and $812.8 million, respectively. Operating income decreased $431.8 million, or 53.1%, for the non-GAAP combined fiscal 2022 when compared to fiscal 2021 (Predecessor). Operating margin decreased to 30.0% for the non-GAAP combined fiscal 2022 from 52.5% for fiscal 2021 (Predecessor). These decreases in operating income and margin were primarily driven by the $277.5 million, or 17.9%, decrease in combined net sales and a change in product mix over the same period, coupled with $241.7 million of inventory fair-value step-up expense during the period June 17, 2022 through December 30, 2022 (Successor), which resulted in a $489.2 million decrease in combined gross profit. Partially offsetting the decrease in operating income and serving to increase operating margin was a $56.6 million, or 35.5%, decrease in combined R&D expenses driven by continued cost containment initiatives.

Specialty Generics. Operating loss for the period June 17, 2022 through December 30, 2022 (Successor) was $3.6 million. Operating income for the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor) was $65.3 million and $107.9 million, respectively. Operating income decreased $46.2 million, or 42.8%, for the non-GAAP combined fiscal 2022 when compared to fiscal 2021 (Predecessor). Operating margin increased to 9.6% for the non-GAAP combined fiscal 2022, compared with 16.3% for fiscal 2021 (Predecessor). The decrease in combined operating income and operating margin was primarily attributable to $30.0 million of fresh-start inventory-related expense primarily driven by the Company's change in accounting estimate and $27.0 million of inventory fair-value step-up expense during the period from June 17, 2022 through December 30, 2022 (Successor), coupled with a $17.0 million decrease to combined net sales resulting in a decrease in combined gross profit of $57.2 million, or 26.1%. The decrease in combined operating income and operating margin was also partially offset by a $13.7 million, or 37.0%, decrease in combined R&D expense driven by continued cost containment initiatives.

Corporate and unallocated expenses. Corporate and unallocated expenses were $39.3 million, $48.2 million and $129.6 million for the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor), respectively. Corporate and unallocated expenses decreased by $42.1 million for the non-GAAP combined fiscal 2022 compared to fiscal 2021 (Predecessor). The combined decrease in corporate and unallocated expenses was predominately driven by continued cost containment initiatives, coupled with an $11.1 million increase to certain of our environmental liabilities during the period January 1, 2022 through June 16, 2022 (Predecessor) compared to the $34.3 million increase during fiscal 2021 (Predecessor). These decreases were partially offset by a $7.4 million gain related to the change in the fair value of our

contingent consideration liabilities during fiscal 2021 compared to a $0.5 million loss during the period June 17, 2022 through December 30, 2022 (Successor).

Fiscal Year Ended December 31, 2021 (Predecessor) Compared with Fiscal Year Ended December 25, 2020 (Predecessor)

Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Predecessor		
	Fiscal Year Ended December 31, 2021	Fiscal Year Ended December 25, 2020	Percentage Change
Specialty Brands	$ 1,547.0	$ 2,059.6	(24.9)%
Specialty Generics	661.8	689.8	(4.1)
Net sales	2,208.8	2,749.4	(19.7)
Medicaid lawsuit	—	(536.0)	*
Net sales	$ 2,208.8	$ 2,213.4	(0.2)%

*Not meaningful

Specialty Brands. Net sales for fiscal 2021 (Predecessor) decreased $512.6 million, or 24.9%, to $1,547.0 million, compared with $2,059.6 million for fiscal 2020 (Predecessor). This decrease was primarily driven by a $247.6 million, or 89.5%, decrease in Ofirmev driven by the loss of exclusivity at the end of fiscal 2020 (Predecessor) and the entrance of generic competition during fiscal 2021 (Predecessor). The decrease in net sales was also impacted by a $174.3 million, or 22.7%, decrease in Acthar Gel net sales driven primarily by the marketplace impact of the COVID-19 pandemic and continued payer scrutiny on overall specialty pharmaceutical spending and a $125.6 million, or 21.9%, decrease in INOmax due to increased competition. These decreases were partially offset by a $27.9 million, or 11.7%, increase in Therakos net sales driven by increased demand as the product begun to see a recovery from the impact of the COVID-19 pandemic during the first half of fiscal 2021 (Predecessor) and an $8.1 million, or 4.3%, increase in Amitiza, primarily as a result of the royalty from Par beginning in fiscal 2021 (Predecessor).

Net sales for Specialty Brands by geography are as follows (dollars in millions):

	Predecessor		
	Fiscal Year Ended December 31, 2021	Fiscal Year Ended December 25, 2020	Percentage Change
U.S.	$ 1,450.5	$ 1,901.0	(23.7)%
Europe, Middle East and Africa	75.3	116.7	(35.5)
Other	21.2	41.9	(49.4)
Net sales	$ 1,547.0	$ 2,059.6	(24.9)%

Net sales for Specialty Brands by key products are as follows (dollars in millions):

	Predecessor		
	Fiscal Year Ended December 31, 2021	Fiscal Year Ended December 25, 2020	Percentage Change
Acthar Gel	$ 593.6	$ 767.9	(22.7)%
INOmax	448.5	574.1	(21.9)
Ofirmev	28.9	276.5	(89.5)
Therakos	266.5	238.6	11.7
Amitiza	196.9	188.8	4.3
Other	12.6	13.7	(8.0)
Specialty Brands	$ 1,547.0	$ 2,059.6	(24.9)%

Specialty Generics. Net sales for fiscal 2021 (Predecessor) decreased $28.0 million, or 4.1%, to $661.8 million, compared to $689.8 million for fiscal 2020 (Predecessor). The decrease in net sales was primarily driven by a $27.5 million, or 7.7%, decrease in generics net sales, driven by an increased competitive environment.

Net sales for Specialty Generics by geography are as follows (dollars in millions):

	Predecessor		
	Fiscal Year Ended December 31, 2021	Fiscal Year Ended December 25, 2020	Percentage Change
U.S.	$ 541.3	$ 564.5	(4.1)%
Europe, Middle East and Africa	106.5	110.8	(3.9)
Other	14.0	14.5	(3.4)
Net sales	$ 661.8	$ 689.8	(4.1)%

Net sales for Specialty Generics by key products are as follows (dollars in millions):

	Predecessor		
	Fiscal Year Ended December 31, 2021	Fiscal Year Ended December 25, 2020	Percentage Change
Opioids	$ 213.2	$ 233.9	(8.8)%
ADHD	37.4	48.3	(22.6)
Addiction treatment	68.3	68.9	(0.9)
Other	12.0	7.3	64.4
Generics	330.9	358.4	(7.7)
Controlled substances	93.4	98.3	(5.0)
APAP	215.9	213.0	1.4
Other	21.6	20.1	7.5
API	330.9	331.4	(0.2)
Specialty Generics	$ 661.8	$ 689.8	(4.1)%

Operating Loss

Operating income by segment and as a percentage of segment net sales for fiscal 2021 (Predecessor) and 2020 (Predecessor) is shown in the following table (dollars in millions):

	Predecessor			
	Fiscal Year Ended December 31, 2021		Fiscal Year Ended December 25, 2020	
Specialty Brands	$ 812.8	52.5 %	$ 1,015.7	49.3 %
Specialty Generics	107.9	16.3	206.4	29.9
Segment operating income	920.7	41.7	1,222.1	44.4
Unallocated amounts:				
Corporate and unallocated expenses [1]	(129.6)		(166.1)	
Depreciation and amortization	(675.8)		(885.2)	
Share-based compensation	(10.2)		(25.3)	
Restructuring charges, net	(26.9)		(37.5)	
Non-restructuring impairment charges	(154.9)		(63.5)	
Separation costs [2]	(1.2)		(93.4)	
R&D upfront payment [3]	—		(5.0)	
Opioid-related litigation settlement (loss) gain	(125.0)		43.4	
Medicaid lawsuit	—		(641.1)	
Total operating loss	$ (202.9)		$ (651.6)	

(1) Includes administration expenses and certain compensation, legal, environmental and other costs not charged to our reportable segments.

(2) Represents costs included in SG&A expenses, primarily related to professional fees and costs incurred in preparation for the Chapter 11 proceedings. As of the Petition Date, professional fees directly related to the Chapter 11 proceedings that were previously reflected as separation costs were classified on a go-forward basis as reorganization items, net.

(3) Represents R&D expense incurred related to an upfront payment made to acquire product rights in Japan for terlipressin in fiscal 2020 (Predecessor).

Specialty Brands. Operating income for fiscal 2021 (Predecessor) decreased $202.9 million to $812.8 million, compared with $1,015.7 million for fiscal 2020 (Predecessor). Operating margin increased to 52.5% for fiscal 2021 (Predecessor), compared with 49.3% for fiscal 2020 (Predecessor). The decrease in operating income is primarily driven by the $512.6 million, or 24.9%, decrease

in net sales over the same period, which resulted in a $410.0 million decrease in gross profit. Partially offsetting the decrease in operating income and serving to increase operating margin was a $125.9 million, or 26.2%, decrease in SG&A expenses primarily driven by cost containment initiatives in addition to bankruptcy-related legal fees being classified as reorganization items, net, subsequent to the Petition Date, and an $81.3 million, or 33.7%, decrease in R&D expenses driven by the completion of certain development programs during fiscal 2020 (Predecessor), coupled with the decision to no longer pursue further development of the MNK-6105 and MNK-6106 asset in fiscal 2021 (Predecessor).

Specialty Generics. Operating income for fiscal 2021 (Predecessor) decreased $98.5 million to $107.9 million, compared with $206.4 million for fiscal 2020. Operating margin decreased to 16.3% for fiscal 2021 (Predecessor), compared with 29.9% for fiscal 2020. The decrease in operating income and operating margin was primarily attributable to a $97.1 million decrease in gross profit, primarily driven by an increased competitive environment with respect to other controlled substances and hydrocodone-related products.

Corporate and unallocated expenses. Corporate and unallocated expenses were $129.6 million and $166.1 million for fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), respectively. This decrease was primarily driven by the bankruptcy-related professional fees being classified as reorganization items, net, subsequent to the Petition Date, in addition to cost containment initiatives and lower employee compensation costs. Comparatively, during fiscal 2020 (Predecessor), we incurred $55.7 million of opioid defense costs that were reflected in SG&A. The decrease also included changes in the fair value of our former contingent consideration liabilities with a $7.4 million gain during fiscal 2021 (Predecessor) compared to a $9.9 million charge during fiscal 2020 (Predecessor). The decrease was partially offset by a $35.0 million increase to our environmental remediation liabilities during fiscal 2021 (Predecessor).

Liquidity and Capital Resources

Significant factors driving our liquidity position include cash flows generated from operating activities, financing transactions (inclusive of interest on our variable-rate debt instruments), capital expenditures, cash paid in connection with legal settlements (refer to Note 2 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report), acquisitions and licensing agreements and cash received as a result of our divestitures. We have historically generated and expect to continue to generate positive cash flows from operations, and we believe that our sources of liquidity are adequate to fund our operations for the next twelve months and the foreseeable future. Our ability to fund our capital needs is impacted by our ongoing ability to generate cash from operations and access to capital markets.

As market conditions warrant, we may from time to time repurchase debt securities issued by us, in the open market, in privately negotiated transactions, by tender offer or otherwise. Such repurchases, if any, will depend on prevailing market conditions, our liquidity requirements and other factors. In September 2022 (Successor), our Board of Directors authorized us to utilize certain cash to reduce our outstanding debt at a discount through the end of fiscal 2022. During the period June 17, 2022 through December 30, 2022 (Successor), we repurchased debt that aggregated to a principal amount of $46.7 million and $1.0 million related to our 10.00% second lien senior secured notes due 2029 and 10.00% second lien senior secured notes due 2025, respectively.

Cash Requirements and Sources From Existing Contractual Arrangements

Our material cash requirements from known contractual obligations include debt obligations, legal settlements, lease obligations, purchase obligations and other liabilities reflected on our balance sheet, as presented and discussed below.

The following table summarizes our contractual obligations as of December 30, 2022 (Successor) (dollars in millions):

	Payments Due By Period				
	Total	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Long-term debt obligations [1]	$ 3,534.1	$ 44.1	$ 894.0	$ 1,617.7	$ 978.3
Interest on long-term debt obligations [2]	1,663.0	365.7	672.9	500.4	124.0
Opioid-Related Litigation Settlement [3]	1,275.0	200.0	350.0	300.0	425.0
Acthar Gel-Related Litigation Settlement [3]	252.6	16.5	42.7	67.2	126.2
Operating lease obligations [4]	62.4	16.0	19.9	8.2	18.3
Purchase obligations [5]	21.8	8.9	10.6	2.3	—
Total contractual obligations	$ 6,808.9	$ 651.2	$ 1,990.1	$ 2,495.8	$ 1,671.8

(1) For further details on our debt obligations, refer to Note 14 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

(2) Interest on long-term debt obligations are projected for future periods using interest rates in effect as of December 30, 2022 (Successor). Contractual obligations under the long-term debt agreements have been shown in the table above. Certain of these projected interest payments may differ in the future based on changes in market interest rates.

For further information regarding the fixed and variable rates of our debt obligations, refer to Note 14 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

(3) Acthar Gel-Related Litigation Settlement includes interest of $1.5 million, $2.7 million, $2.2 million and $1.2 million for obligations due within one year, one to three years, three to five years and more than five years, respectively. For further details on these litigation settlements, refer to Note 2 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

(4) Includes obligations for leases with an initial term of 12 months or less and not recorded on the consolidated balance sheet. Refer to Note 12 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report for further information on our lease liabilities.

(5) Purchase obligations consist of commitments for purchases of goods and services made in the ordinary course of business to meet operational requirements.

Non-current income taxes payable, primarily related to unrecognized tax benefits, is included within other income tax liabilities on the consolidated balance sheet and, as of December 30, 2022 (Successor), was $18.2 million. Payment of these liabilities is uncertain and, even if payments are determined to be necessary, they are subject to the timing of rulings by the taxing authorities related to tax positions we take. Additionally, we expect to receive CARES Act income tax refunds totaling $135.9 million, excluding related interest, within the next twelve months, of which $112.1 million, plus interest, was received on February 28, 2023. The remaining refund is expected to be received during fiscal 2023. For further information on income tax related matters and the partial receipt of the CARES Act income tax refunds, refer to Notes 8 and 22 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report, respectively.

We are obligated to pay royalties under certain agreements with third parties. During the period of June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), we made payments under these arrangements of $0.5 million, $0.8 million, $14.1 million and $81.9 million, respectively. The timing and amounts to be paid in future periods are uncertain as they are dependent upon net sales generated in future periods. The decrease in royalties paid during fiscal 2022 and 2021 (Predecessor) was primarily driven by loss of exclusivity and entrance of competition for our Ofirmev product, which caused a large decline in net sales coupled with the cessation of Acthar Gel royalty payments as a result of the Chapter 11 process.

As of December 30, 2022 (Successor), we had net unfunded pension and postretirement benefit obligations of $18.7 million and $26.8 million, respectively. The timing and amounts of long-term funding requirements for pension and postretirement obligations are uncertain. We do not anticipate making material involuntary contributions in fiscal 2023, but may elect to make voluntary contributions to our defined pension plans or our postretirement benefit plans during fiscal 2023. For further information regarding pension and postretirement benefit obligations, refer to Note 15 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites. The ultimate cost of cleanup and timing of future cash outlays is difficult to predict given uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. As of December 30, 2022 (Successor), we believe that it is probable that we will incur investigation and remediation costs of approximately $36.9 million, of which $1.1 million was included in accrued and other current liabilities and the remaining $35.8 million was included in environmental liabilities on the consolidated balance sheet as of December 30, 2022 (Successor). Refer to Notes 2 and 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information regarding environmental matters, respectively.

In general, we intend to fund capital expenditures with cash generated from operations. As of December 30, 2022 (Successor), we had no capital expenditure commitments.

Our remaining cash requirements are obligations that arise from the normal course of our business.

A summary of our cash flows from operating, investing and financing activities is provided in the following table (dollars in millions):

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Net cash from:				
Operating activities	$ 47.1	$ (642.3)	$ 455.4	$ 498.9
Investing activities	27.5	(33.0)	(37.8)	(11.2)
Financing activities	(54.1)	(278.7)	(137.5)	(185.6)
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	(1.1)	(3.9)	(1.9)	2.3
Net increase in cash, cash equivalents and restricted cash	$ 19.4	$ (957.9)	$ 278.2	$ 304.4

Operating Activities

Net cash provided by operating activities of $47.1 million for the period June 17, 2022 through December 30, 2022 (Successor) was attributable to a net loss of $598.1 million, adjusted for non-cash items of $480.0 million, driven by depreciation and amortization of $347.5 million and accretion on our settlement obligations and debt of $139.2 million, partially offset by $165.2 million of cash inflow from net changes in working capital. The change in working capital was primarily driven by a $267.9 million decrease in inventory primarily driven by the fair-value step-up expense of $268.7 million and an $8.1 million net cash inflow related to an increase in accounts payable coupled with a $28.1 million net cash inflow in other working capital driven by an increase in our accrued rebates, partially offset by a $90.7 million net cash outflow related to a decrease in accrued consulting driven by payment of professional fees related to emergence from Chapter 11, a $30.1 million change in income taxes, primarily driven by an increase in prepaid income taxes and an $18.1 million increase in accounts receivable, net.

Net cash used in operating activities of $642.3 million for the period January 1, 2022 through June 16, 2022 (Predecessor) was attributable to a net loss of $313.1 million, adjusted for non-cash items of $311.2 million, driven by non-cash reorganization items of $425.4 million and depreciation and amortization of $321.8 million, partially offset by a $473.0 million change in net deferred tax assets coupled with cash used in working capital of $640.4 million. The change in working capital was primarily driven by a $629.0 million cash outflow related to the payment of claims as a result of the Plan coupled with a $2.5 million net cash outflow related to a decrease in other working capital, a $26.9 million change in income taxes, primarily driven by a decrease in income taxes payable and a $33.2 million increase in inventory, partially offset by a $49.8 million decrease in accounts receivable primarily due to lower net sales.

Net cash provided by operating activities of $455.4 million for fiscal 2021 (Predecessor) included a loss of $717.4 million, adjusted for non-cash items of $802.7 million driven by depreciation and amortization of $675.8 million and a $154.9 million non-cash impairment charge related to the Amitiza asset and the MNK-6105 and MNK-6106 asset, partially offset by a $59.9 million reduction in our deferred income tax liabilities. The net loss was also offset by cash provided from net investment in working capital of $370.1 million, which was primarily driven by an increase to the opioid-related litigation settlement liability of $125.0 million, a $108.5 million decrease in net tax receivables driven by the receipt of CARES Act income tax refunds, partially offset by an increase in prepaid income taxes and a $98.2 million decrease in accounts receivable. These inflows were partially offset by a $14.0 million increase in inventory.

Net cash provided by operating activities of $498.9 million for fiscal 2020 (Predecessor) included a loss of $944.6 million, adjusted for non-cash items of $1,331.2 million driven by depreciation and amortization of $885.2 million, a $385.3 million reduction in our deferred income tax assets, and a $63.5 million non-cash impairment charge related to the Ofirmev intangible asset. The net loss was also offset by cash provided from net investment in working capital of $112.3 million, primarily driven by the $638.9 million Medicaid lawsuit liability. Also included within this change in working capital was a $37.9 million decrease in accounts receivable, and a $15.7 million increase in accounts payable, net of transfers to LSTC. These items were offset by a $433.8 million increase in net receivables related to income taxes that was driven by tax benefits from the CARES Act and changes in uncertain tax positions, a $95.3 million net cash outflow related to other assets and liabilities primarily driven by decreases in accrued payroll and accrued restructuring, net of transfers to LSTC, and a $51.1 million increase in inventory.

Investing Activities

Net cash provided by investing activities was $27.5 million for the period June 17, 2022 through December 30, 2022 (Successor) primarily driven primarily by the sale of our PRV for $100.0 million in which we received from the buyer $65.0 million and the buyer remitted $35.0 million to the General Unsecured Claims Trustee pursuant to the terms of (i) the Plan, and (ii) the General Unsecured Claims Trust Agreement entered into in connection with the Plan as previously discussed, partially offset by capital expenditures of $28.8 million and a $17.5 million milestone payment related to the FDA approval of Terlivaz, as previously discussed.

Net cash used in investing activities was $33.0 million for the period January 1, 2022 through June 16, 2022 (Predecessor), primarily driven by $33.4 million in capital expenditures.

Net cash used in investing activities of $37.8 million for fiscal 2021 (Predecessor) was primarily attributable to capital expenditures of $55.3 million, partially offset by cash proceeds of $16.5 million related to the sale of a portion of our Hemostasis business in fiscal 2018.

Net cash used in investing activities of $11.2 million for fiscal 2020 (Predecessor) was primarily attributable to capital expenditures of $47.7 million, partially offset by cash proceeds of $29.8 million for the redemption of 100% of the outstanding preferred equity certificates received as part of contingent earn-out payments related to the sale of the Nuclear Imaging business, as previously discussed. The remaining activity primarily relates to post-sale adjustments from various divestitures.

Under our term loan credit agreement and our notes, the proceeds from the sale of assets and businesses must be either reinvested into capital expenditures or business development activities within one year of the respective transaction or we are required to make prepayments on our term loans and offer to repurchase certain of our notes.

Financing Activities

Net cash used in financing activities was $54.1 million for the period June 17, 2022 through December 30, 2022 (Successor) driven primarily by debt repayments of $50.1 million on our variable-rate term loans and open market debt repurchases at a discount that aggregated to a total principal amount of $47.7 million coupled with the repurchase of the Opioid Warrants for $4.0 million.

Net cash used in financing activities was $278.7 million for the period January 1, 2022 through June 16, 2022 (Predecessor) which was inclusive of debt repayments of $904.6 million primarily driven by the repayment of our predecessor revolving credit facility of $900.0 million, as well as $24.1 million of debt issuance costs, partially offset by $650.0 million in proceeds from the issuance of the 11.50% first lien senior secured notes due December 2028.

Net cash used in financing activities was $137.5 million for fiscal 2021 (Predecessor), compared with $185.6 million for fiscal 2020 (Predecessor). This decrease was primarily attributable to payments of contingent considerations related to the acquisition of Questcor and Stratatech Corporation during fiscal 2020 (Predecessor) of $25.0 million and $20.0 million, respectively, $9.4 million in debt issuance costs incurred in fiscal 2020 (Predecessor) and a $2.0 million decrease in debt repayments. Our fiscal 2021 (Predecessor) debt repayments included $137.5 million in aggregate payments on our variable-rate term loans. Our fiscal 2020 (Predecessor) debt repayments included a $119.8 million payment on the remaining principal amount of the 4.875% senior unsecured notes that had a maturity date of April 15, 2020, and $19.7 million in aggregate payments on our variable-rate senior secured term loans.

Concentration of Credit and Other Risks

Financial instruments that potentially subject us to concentrations of credit risk primarily consist of accounts receivable. We generally do not require collateral from customers. A portion of our accounts receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries' national economies.

Capitalization

Shareholders' equity was $1,613.7 million as of December 30, 2022 (Successor) compared with $313.4 million as of December 31, 2021 (Predecessor). The increase in shareholders' equity is primarily attributed to the cancellation of the Predecessor equity and issuance of Successor common stock of approximately $2.2 billion as a result of the emergence from Chapter 11 and application of fresh-start accounting. The remaining activity is primarily attributable to the net loss of $313.1 million and $598.1 million during the period from January 1, 2022 through June 16, 2022 (Predecessor) and the period from June 17, 2022 through December 30, 2022 (Successor).

The Company issued 3,290,675 Opioid Warrants as part of the effectuation of the Plan with a value of $13.9 million. In December 2022, the Company repurchased and cancelled all outstanding Opioid Warrants for $4.0 million. For further information, refer to Note 2 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Dividends

Historically, we have not made any cash dividend payments and we do not currently intend to pay dividends in the foreseeable future.

Commitments and Contingencies

Legal Proceedings

We are subject to various legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and all other legal proceedings, all in the ordinary course of business. Although it is not feasible to predict the outcome of these matters, we believe, unless otherwise indicated, given the information currently available, that their ultimate resolution will not have a material adverse effect on our business, financial condition, results of operations and cash flows.

For further information, refer to Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report, which are incorporated by reference into this Part II, Item 7.

Guarantees

In disposing of assets or businesses, we have from time to time provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. We assess the probability of potential liabilities related to such representations, warranties and indemnities and adjust potential liabilities as a result of changes in facts and circumstances. We believe, given the information currently available, that the ultimate resolutions will not have a material adverse effect on our financial condition, results of operations and cash flows. These representations, warranties and indemnities are discussed in Note 18 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Off-Balance Sheet Arrangements

As of December 30, 2022 (Successor), we had various other letters of credit, guarantees and surety bonds totaling $30.1 million and restricted cash of $37.9 million held in segregated accounts primarily to collateralize surety bonds for our environmental liabilities.

Critical Accounting Estimates

The consolidated financial statements have been prepared in U.S. dollars and in accordance with GAAP. The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. The following critical accounting estimates are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. Management's estimates are based on the relevant information available at the end of each period.

Revenue Recognition

Product Sales Revenue

We sell products through independent channels, including direct to retail pharmacies, end user customers and through distributors who resell our products to retail pharmacies, institutions and end user customers, while certain products are sold and distributed directly to hospitals. We also enter into arrangements with indirect customers, such as health care providers and payers, wholesalers, government agencies, institutions, managed care organizations and GPOs to establish contract pricing for certain products that provide for government-mandated and/or privately-negotiated rebates, sales incentives, chargebacks, distribution service agreement fees, fees for services and administration fees and discounts with respect to the purchase of our products.

Reserve for Variable Considerations

Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves result from estimated chargebacks, rebates, product returns and other sales deductions that are offered within contracts between us and our customers, health care providers and payers relating to the sale of our products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of our products and other competitive factors. Overall, these reserves reflect our best estimate of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained (reduced), and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We adjust reserves for chargebacks, rebates, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of net sales recognized in the period of adjustment.

The following table reflects activity in our sales reserve accounts (dollars in millions):

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
Balance as of December 27, 2019 (Predecessor)	$ 295.8	$ 28.4	$ 13.2	$ 337.4
Provisions	2,065.9	28.9	59.5	2,154.3
Provision for Medicaid lawsuit [1]	536.0	—	—	536.0
Payments or credits	(2,701.2)	(30.7)	(60.4)	(2,792.3)
Balance as of December 25, 2020 (Predecessor)	196.5	26.6	12.3	235.4
Provisions	2,087.1	23.7	55.2	2,166.0
Payments or credits	(2,041.8)	(28.8)	(58.0)	(2,128.6)
Balance as of December 31, 2021 (Predecessor)	241.8	21.5	9.5	272.8
Provisions	693.4	5.2	17.1	715.7
Payments or credits	(684.6)	(8.1)	(18.9)	(711.6)
Balance as of June 16, 2022 (Predecessor)	$ 250.6	$ 18.6	$ 7.7	$ 276.9
Balance as of June 17, 2022 (Successor)	$ 250.6	$ 18.6	$ 7.7	$ 276.9
Provisions	804.4	7.0	36.7	848.1
Payments or credits	(789.7)	(9.6)	(31.7)	(831.0)
Balance as of December 30, 2022 (Successor)	$ 265.3	$ 16.0	$ 12.7	$ 294.0

(1) Excludes the $105.1 million that is reflected as a component of operating expenses as it represents a pre-acquisition contingency related to the portion of the liability that arose from sales of Acthar Gel prior to the Company's acquisition of Questcor in August 2014.

Provisions presented in the table above are recorded as reductions to net sales. As of December 30, 2022 (Predecessor), a five percent change in our sales reserve accounts would have led to an approximately $14.7 million impact on our loss from continuing operations before income taxes. For our presentation of net sales by product family, refer to Note 21 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Total provisions for the period June 17, 2022 through December 30, 2022 (Successor) were $848.1 million and the total provisions for the period from January 1, 2022 through June 16, 2022 (Predecessor) were $715.7 million for a non-GAAP combined $1,563.8 million for fiscal 2022, compared to $2,166.0 million for fiscal 2021 (Predecessor). The decrease of $602.2 million was driven primarily by a decrease in rebates and chargebacks within the Specialty Generics segment of $504.6 million as a result of price reductions, coupled with a $71.8 million decrease in rebates and chargebacks in Specialty Brands primarily driven by the decrease in net sales and loss of exclusivity for Ofirmev during fiscal 2021 (Predecessor). Provisions for returns decreased $11.5 million driven by the Specialty Generics segment, and other sales deductions decreased by $1.4 million from the non-GAAP combined fiscal 2022 to fiscal 2021 (Predecessor).

Total provisions for fiscal 2021 (Predecessor) decreased $524.3 million compared with fiscal 2020 (Predecessor), which was inclusive of the $536.0 million provision for the Medicaid lawsuit incurred in fiscal 2020 (Predecessor). Excluding the impact of the Medicaid lawsuit, the increase in rebates and chargebacks of $21.2 million primarily related to an increase of $32.7 million in the Specialty Generics segment as result of pricing pressure on our business, partially offset by an $11.5 million decrease in Specialty Brands. Provisions for returns decreased $5.2 million driven by the Specialty Generics segment, and other sales deductions decreased by $4.3 million from fiscal 2020 (Predecessor) to fiscal 2021 (Predecessor).

Product sales are recognized when the customer obtains control of our product. Control is transferred either at a point in time, generally upon delivery to the customer site, or in the case of certain of our products, over the period in which the customer has access to the product and related services. Revenue recognized over time is based upon either consumption of the product or passage of time based upon our determination of the measure that best aligns with how the obligation is satisfied. Our considerations of why such measures provide a faithful depiction of the transfer of our products are as follows:

- For those contracts whereby revenue is recognized over time based upon consumption of the product, we either have:
    1. the right to invoice the customer in an amount that directly corresponds with the value to the customer of our performance to date, for which the practical expedient to recognize in proportion to the amount it has the right to invoice has been applied, or
    2. the remaining goods and services to which the customer is entitled is diminished upon consumption.
- For those contracts whereby revenue is recognized over time based upon the passage of time, the benefit that the customer receives from unlimited access to our product does not vary, regardless of consumption. As a result, our obligation diminishes with the passage of time; therefore, ratable recognition of the transaction price over the contract period is the measure that best aligns with how the obligation is satisfied.

For additional information, refer to Note 4 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Intangible Assets

Intangible assets include completed technology and IPR&D. Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost. Intangible assets with finite useful lives are amortized according to the pattern in which the economic benefit of the asset is used up over their estimated useful lives. We assess the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset, or the asset group they are a part of, to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets, or asset group, with their carrying value. The fair value of the intangible asset, or asset group, is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, or asset group, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the fair value of the asset. We annually test the indefinite-lived intangible assets for impairment, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable by either a qualitative or income approach. We compare the fair value of the assets with their carrying value and record an impairment when the carrying value exceeds the fair value. Changes in economic and operating conditions impacting these assumptions could result in intangible asset impairment in future periods.

For more information on our intangible impairment analyses and the results thereof, refer to Notes 13 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Acquisitions

For acquisitions that meet the criteria for business combination accounting, the amounts paid are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. We then allocate the purchase price in excess of net tangible assets acquired to identifiable intangible assets, including purchased research and development. The fair value of identifiable intangible assets is based on detailed valuations. These valuations rely on a number of factors including operating results, business plans, economic projections, anticipated future cash flows, transactions and market place data. There are inherent uncertainties related to these factors and judgment in applying them to estimate the fair value of individual assets acquired in a business combination. Due to these inherent uncertainties, there is risk that the carrying value of our recorded intangible assets may be overstated, which may result in an increased risk of impairment in future periods. We perform our intangible asset valuations using an income approach based on the present value of future cash flows. This approach incorporates many assumptions including future growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in impairment in future periods.

Our purchased research and development represents the estimated fair value as of the acquisition date of in-process projects that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval.

The fair value of IPR&D is determined using the discounted cash flow method. In determining the fair value of IPR&D, we consider, among other factors, appraisals, the stage of completion of the projects, the technological feasibility of the projects, whether the projects have an alternative future use and the estimated residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used includes a rate of return that accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized.

The fair value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested annually for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset is charged to expense.

Certain asset acquisitions or license agreements may not meet the criteria for a business combination. We account for these transactions as an asset acquisition and recognize the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquired entity. Any initial up-front payments incurred in connection with the acquisition or licensing of IPR&D product candidates that do not meet the definition of a business are treated as research and development expense.

Contingent Consideration

As part of certain acquisitions, we are subject to contractual arrangements to pay contingent consideration to former owners of these businesses. The payment of obligations under these arrangements are uncertain, and even if payments are expected to be made the timing of these payments may be uncertain as well. These contingent consideration obligations are required to be recorded at fair value within the consolidated balance sheet and adjusted at each respective balance sheet date, with changes in the fair value being recognized in the consolidated statement of operations. The determination of fair value is dependent upon a number of factors, which include projections of future revenues, the probability of successfully achieving certain regulatory milestones, competitive entrants into the marketplace, the timing associated with the aforementioned criteria and market place data (e.g., interest rates). Several of these assumptions require projections several years into the future. Due to these inherent uncertainties, there is risk that the contingent consideration liabilities may be overstated or understated. Changes in economic and operating conditions impacting these assumptions are expected to impact future operating results, with the magnitude of the impact tied to the significance in the change in assumptions. For additional information, refer to Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

Contingencies

We are involved, either as a plaintiff or a defendant, in various legal proceedings that arise in the ordinary course of business, including, without limitation, government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and other legal proceedings, as further discussed in Note 19 of Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report. Accruals recorded for various contingencies, including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provisions are recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

Income Taxes

In determining income for financial statement purposes, we must make certain estimates and judgments. These estimates and judgments affect the calculation of certain tax liabilities and the determination of the recoverability of certain of the deferred tax assets, which arise from temporary differences between the tax and financial statement recognition of revenue and expense.

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of cumulative losses in the most recent years and our forecast of future taxable income. In estimating future taxable income, we develop assumptions including the amount of future state, federal and international pre-tax operating income, the reversal of temporary differences, and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates we use to manage the underlying businesses.

We determine whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50.0% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not realized on the uncertain tax position, an income tax liability or a reduction to a deferred tax asset ("contra-DTA"), is established. We adjust these liabilities and contra-DTAs as a result of changing facts and circumstances; however, due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across our global operations. Changes in tax laws and rates could affect recorded deferred tax assets and liabilities in the future. Management is not aware of any such changes, however, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Refer to Note 8 of Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report for further information.

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

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of December 30, 2022 (Successor), our outstanding debt included $1,738.9 million variable-rate debt on our senior secured term loans. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, annual interest expense for fiscal 2023 would increase by approximately $17.4 million.

The remaining outstanding debt as of December 30, 2022 (Successor) is fixed-rate debt. Changes in market interest rates generally affect the fair value of fixed-rate debt, but do not impact earnings or cash flows.

Currency Risk

Certain net sales and costs of our international operations are denominated in the local currency of the respective countries. As such, profits from these subsidiaries may be impacted by fluctuations in the value of these local currencies relative to the U.S. dollar. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain operational and intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations.

The consolidated statement of operations is exposed to currency risk from intercompany financing arrangements, which primarily consist of intercompany debt and intercompany cash pooling, where the denominated currency of the transaction differs from the functional currency of one or more of our subsidiaries. The aggregate potential unfavorable impact from a hypothetical 10.0% adverse change in foreign exchange rates was $2.1 million as of December 30, 2022 (Successor), with all other variables held constant. This hypothetical loss does not reflect any hypothetical benefits that would be derived from hedging activities, including cash holdings in similar foreign currencies, that we have historically utilized to mitigate our exposure to movements in foreign exchange rates.

Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Mallinckrodt plc (the "Company") as of December 30, 2022 (Successor Company balance sheet) and December 31, 2021 (Predecessor Company balance sheet), the related consolidated statements of operations, comprehensive operations, changes in shareholders' equity, and cash flows for the period from June 17, 2022 through December 30, 2022 (Successor Company operations), for the period from January 1, 2022 through June 16, 2022 (Predecessor Company operations), and the fiscal years ended December 31, 2021 (Predecessor Company operations) and December 25, 2020 (Predecessor Company operations), and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the Successor Company financial statements present fairly, in all material respects, the financial position of the Company as of December 30, 2022, and the results of its operations and its cash flows for the period from June 17, 2022 through December 30, 2022, in conformity with accounting principles generally accepted in the United States of America. Further, in our opinion, the Predecessor Company financial statements present fairly, in all material respects, the financial position of the Predecessor Company as of December 31, 2021, and the results of its operations and its cash flows for the period from January 1, 2022 through June 16, 2022, and the fiscal years ended December 31, 2021 and December 25, 2020, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 30, 2022, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 3, 2023, expressed an unqualified opinion on the Company's internal control over financial reporting.

Fresh-Start Accounting

As discussed in Note 1 to the financial statements, on March 2, 2022, and April 27, 2022, the United States Bankruptcy Court for the District of Delaware and the High Court of Ireland, respectively, entered an order confirming the fourth amended plan of reorganization and the scheme of arrangement, respectively, which became effective after the close of business on June 16, 2022. Accordingly, the accompanying financial statements have been prepared in conformity with FASB Accounting Standard Codification 852, *Reorganizations*, for the Successor Company as a new entity with assets, liabilities, and a capital structure having carrying values not comparable with prior periods as described in Note 3 to the financial statements. Fresh start accounting is also communicated as a critical audit matter below.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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 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 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 financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the 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.

Fresh-start Accounting - Refer to Note 3 to the financial statements (also see fresh-start accounting explanatory paragraph above)

Critical Audit Matter Description

On March 2, 2022, and April 27, 2022, the United States Bankruptcy Court for the District of Delaware and the High Court of Ireland, respectively, entered an order confirming the fourth amended plan of reorganization and the scheme of arrangement, respectively, which became effective on June 16, 2022 (the "Effective Date") and the Company emerged from chapter 11 of title 11 of the United States Code. In connection with its emergence and in accordance with ASC 852, *Reorganizations*, the Company qualified for and adopted fresh-start accounting which resulted in a new basis of accounting and the Company becoming a new entity for financial reporting purposes. Management derived a reorganization value from the Company's enterprise value which was estimated to be $5,223.0 million. Under fresh-start accounting, reorganization value represents the fair value of the Successor Company's total assets and is intended to approximate the amount a willing buyer would pay for the assets immediately after restructuring. Upon the application of fresh-start accounting, the Company allocated the reorganization value to its individual assets based on their estimated fair values in accordance with Accounting Standards Codification Topic 805 - *Business Combinations*. The Company engaged a third-party valuation advisor to assist with the determination of the fair value of certain assets, liabilities, and equity.

Auditing the adoption of fresh-start accounting was complex due to the significant estimation uncertainty in determining the fair value of the Company's assets and liabilities and required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists. The identified intangible assets of $3,152.2 million, which principally consisted of completed technology and in-process research and development, were subject to significant estimation uncertainty primarily due to the sensitivity of the respective fair values to underlying assumptions in the discounted cash flow models used to measure the intangible assets. Significant assumptions included projected cash flows and discount rates. The Successor Company equity value of $2,203.6 million, was subject to significant estimation uncertainty primarily due to the adjustments made by management to the estimated enterprise value as a result of changes to certain cash flow projections.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to management's significant assumptions related to the application of fresh-start accounting, specifically the fair value of intangibles assets, included the following, among others:

- We tested the operating effectiveness of internal controls related to the Company's projected financial information and discount rates.
- We evaluated the reasonableness of management's projected financial information by performing the following:
  - Compared the projected financial information to historical results by product, evaluated certain assumptions that form the basis of the projected financial information, such as revenue growth rates and margins, which may be affected by future economic and market conditions.
  - Inspected internal communications from members of management to (1) other members of management and (2) the Board of Directors.
- With the assistance of our fair value specialists, we assessed the discount rates.
- We evaluated the Company's third-party valuation advisor's experience and qualifications.
- We obtained an understanding and evaluated the methodologies used by the Company's third-party valuation advisor for the development of the fair values of the intangible assets.
- We obtained an understanding of the methodology used by the Company's third-party valuation advisor for determining the significant assumptions related to the discount rates, tax rates, and contributory asset charges.
  - We evaluated the methods and significant assumptions used by management for the development of the fair values of the intangible assets.
  - We evaluated the completeness and accuracy of the underlying data supporting the significant assumptions and estimates used by management for the development of the fair values of the intangible assets.

Our audit procedures related to management's significant assumptions related to the application of fresh-start accounting, specifically the determination of Successor Company equity value, included the following, among others:

- We tested the operating effectiveness of internal controls related to the Company's determination of Successor Company equity value.
- We evaluated the Company's third-party valuation advisor's experience and qualifications.
- We evaluated the estimated enterprise value of the Successor Company, which was estimated with the assistance of a third-party valuation advisor using various valuation methods.

- We evaluated the adjustments made by management to the estimated enterprise value to determine the implied fair value of the Successor Company's equity value.

Income Taxes - Income Tax Impacts from Emergence from Voluntary Reorganization - Refer to Notes 2, 3, 4 and 8 to the financial statements

Critical Audit Matter Description

On March 2, 2022, and April 27, 2022, the United States Bankruptcy Court for the District of Delaware and the High Court of Ireland, respectively, entered an order confirming the fourth amended plan of reorganization and the scheme of arrangement, respectively, which became effective on June 16, 2022, and the Company emerged from chapter 11 of title 11 of the United States Code. Evaluating the associated income tax impacts involved the interpretation of multi-jurisdictional tax laws and regulations, supported by third-party tax opinions. Interpretation of tax laws can be inherently uncertain as tax law is complex and often subject to varied interpretations. Accordingly, tax law interpretations can be subject to potential challenges by the relevant tax authorities and the ultimate outcome with respect to taxes the Company may owe may differ from the amounts recognized, which the Company considered in assessing the need for reserves for uncertain tax positions. We identified the income taxes associated with emergence from chapter 11 bankruptcy as a critical audit matter because of the significant judgments made by management and the complex nature of identifying, measuring, and interpreting the tax implications, particularly related to the interpretation of multi-jurisdictional tax laws and regulations. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our tax specialists with specialized skills and knowledge when performing audit procedures to evaluate the Company's interpretation of, and compliance with multi-jurisdictional tax laws.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the income taxes associated with the restructuring transactions and emergence from voluntary reorganization included the following, among others:

- We tested the operating effectiveness of the internal control related to the Company's income taxes for the restructuring transactions, emergence from voluntary reorganization, the realizability of deferred tax assets, and the interpretation of tax laws and regulations.
- With the assistance of our tax specialists, we evaluated the income taxes associated with the restructuring transactions and emergence from voluntary reorganization by performing the following:
  - Obtained an understanding of the Company's restructuring transactions.
  - Obtained and evaluated management and third-party tax specialist memoranda regarding the analysis of relevant tax laws and regulations.
  - Evaluated the Company's third-party tax specialists' experience and qualifications.
  - Evaluated the appropriateness of management's judgments and conclusions with respect to reserves for uncertain tax positions, including the technical merits and reasonableness of probabilities applied to uncertain tax positions.
  - Evaluated the completeness and accuracy of the underlying data, calculations, and allocations supporting the amount of current and deferred income tax benefit recorded.
  - Tested significant assumptions and key inputs to assess the Company's recognition and measurement of current and deferred income tax benefit.

/s/ Deloitte & Touche LLP

St. Louis, Missouri
March 3, 2023

We have served as the Company's auditor since 2011.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions, except per share data)

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Net sales (includes retrospective one-time charge of $536.0 related to the Medicaid lawsuit for fiscal 2020)	$ 1,039.7	$ 874.6	$ 2,208.8	$ 2,213.4
Cost of sales	991.0	582.0	1,317.1	1,544.0
Gross profit	48.7	292.6	891.7	669.4
Selling, general and administrative expenses	290.1	275.3	581.8	884.1
Research and development expenses	64.2	65.5	205.2	290.8
Restructuring charges, net	11.1	9.6	26.9	37.5
Non-restructuring impairment charges	—	—	154.9	63.5
Losses (gains) on divestiture	—	—	0.8	(16.6)
Opioid-related litigation settlement loss (gain)	—	—	125.0	(43.4)
Medicaid lawsuit	—	—	—	105.1
Operating loss	(316.7)	(57.8)	(202.9)	(651.6)
Interest expense	(324.3)	(108.6)	(222.6)	(261.1)
Interest income	3.9	0.6	1.9	5.9
Other income (expense), net	10.0	(14.6)	22.0	7.4
Reorganization items, net	(23.2)	(630.9)	(428.2)	(61.4)
Loss from continuing operations before income taxes	(650.3)	(811.3)	(829.8)	(960.8)
(Benefit) expense from income taxes	(52.0)	(497.3)	(106.3)	8.9
Loss from continuing operations	(598.3)	(314.0)	(723.5)	(969.7)
Income from discontinued operations, net of tax benefit of $—, $—, $(5.0) and $(16.2)	0.2	0.9	6.1	25.1
Net loss	$ (598.1)	$ (313.1)	$ (717.4)	$ (944.6)
Basic loss per share (Note 9):				
Loss from continuing operations	$ (45.43)	$ (3.70)	$ (8.54)	$ (11.48)
Income from discontinued operations	0.02	0.01	0.07	0.30
Net loss	$ (45.41)	$ (3.69)	$ (8.47)	$ (11.18)
Basic weighted-average shares outstanding	13.2	84.8	84.7	84.5
Diluted loss per share (Note 9):				
Loss from continuing operations	$ (45.43)	$ (3.70)	$ (8.54)	$ (11.48)
Income from discontinued operations	0.02	0.01	0.07	0.30
Net loss	$ (45.41)	$ (3.69)	$ (8.47)	$ (11.18)
Diluted weighted-average shares outstanding	13.2	84.8	84.7	84.5

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS
(in millions)

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Net loss	$ (598.1)	$ (313.1)	$ (717.4)	$ (944.6)
Other comprehensive income (loss), net of tax				
Currency translation adjustments	2.1	(1.5)	(0.5)	2.1
Unrecognized gain on derivatives	—	—	—	0.4
Unrecognized gain (loss) on benefit plans	8.7	—	1.8	(4.2)
Total other comprehensive income (loss), net of tax	10.8	(1.5)	1.3	(1.7)
Comprehensive loss	$ (587.3)	$ (314.6)	$ (716.1)	$ (946.3)

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED BALANCE SHEETS
(in millions, except share data)

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 409.5	$ 1,345.0
Accounts receivable, less allowance for doubtful accounts of $4.4 and $4.7	405.3	439.1
Inventories	947.6	347.2
Prepaid expenses and other current assets	273.4	178.3
Total current assets	2,035.8	2,309.6
Property, plant and equipment, net	457.6	776.0
Intangible assets, net	2,843.8	5,448.4
Deferred income taxes	475.5	—
Other assets	201.1	382.3
Total Assets	$ 6,013.8	$ 8,916.3
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 44.1	$ 1,388.9
Accounts payable	114.0	123.0
Accrued payroll and payroll-related costs	49.5	84.6
Accrued interest	29.0	17.0
Acthar Gel-Related Settlement liability	16.5	—
Opioid-Related Litigation Settlement liability	200.0	—
Accrued and other current liabilities	290.7	328.7
Total current liabilities	743.8	1,942.2
Long-term debt	3,027.7	—
Acthar Gel-Related Settlement liability	75.0	—
Opioid-Related Litigation Settlement liability	379.9	—
Pension and postretirement benefits	41.0	30.1
Environmental liabilities	35.8	43.0
Deferred income taxes	0.3	20.9
Other income tax liabilities	18.2	83.2
Other liabilities	78.4	85.8
Liabilities subject to compromise	—	6,397.7
Total Liabilities	4,400.1	8,602.9
Shareholders' Equity:		
Predecessor preferred shares, $0.20 par value, 500,000,000 authorized; none issued or outstanding	—	—
Successor preferred shares, $0.01 par value, 500,000,000 authorized; none issued or outstanding	—	—
Predecessor ordinary A shares, €1.00 par value, 40,000 authorized; none issued or outstanding	—	—
Successor ordinary A shares, €1.00 par value, 40,000 authorized; none issued or outstanding	—	—
Predecessor ordinary shares, $0.20 par value, 500,000,000 authorized; 94,296,235 issued; 84,726,590 outstanding	—	18.9
Successor ordinary shares, $0.01 par value, 500,000,000 authorized; 13,170,932 issued and outstanding	0.1	—
Ordinary shares held in treasury at cost, none and 9,569,645	—	(1,616.1)
Additional paid-in capital	2,191.0	5,597.8
Retained deficit	(588.2)	(3,678.9)
Accumulated other comprehensive income (loss)	10.8	(8.3)
Total Shareholders' Equity	1,613.7	313.4
Total Liabilities and Shareholders' Equity	$ 6,013.8	$ 8,916.3

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Cash Flows From Operating Activities:				
Net loss	$ (598.1)	$ (313.1)	$ (717.4)	$ (944.6)
Adjustments to reconcile net cash provided by operating activities:				
Depreciation and amortization	347.5	321.8	675.8	885.2
Share-based compensation	1.4	1.7	10.2	25.3
Deferred income taxes	(24.9)	(473.0)	(59.9)	385.3
Non-cash impairment charges	—	—	154.9	63.5
Losses (gains) on divestiture	—	—	0.8	(16.6)
Reorganization items, net	—	425.4	22.5	10.2
Non-cash accretion expense	139.2	—	—	—
Other non-cash items	16.8	35.3	(1.6)	(21.7)
Changes in assets and liabilities, net of the effects of acquisitions:				
Accounts receivable, net	(18.1)	49.8	98.2	37.9
Inventories	267.9	(33.2)	(14.0)	(51.1)
Accounts payable	8.1	(3.6)	(1.1)	15.7
Accrued consulting	(90.7)	0.1	14.3	38.1
Income taxes	(30.1)	(26.9)	108.5	(433.8)
Opioid-related litigation settlement liability	—	—	125.0	—
Medicaid lawsuit	—	—	(4.2)	638.9
Payment of claims	—	(629.0)	—	—
Other	28.1	2.4	43.4	(133.4)
Net cash from operating activities	47.1	(642.3)	455.4	498.9
Cash Flows From Investing Activities:				
Capital expenditures	(28.8)	(33.4)	(55.3)	(47.7)
Proceeds (payments) related to divestiture, net of cash	70.0	—	15.7	(0.7)
Other	(13.7)	0.4	1.8	37.2
Net cash from investing activities	27.5	(33.0)	(37.8)	(11.2)
Cash Flows From Financing Activities:				
Issuance of external debt	—	650.0	—	—
Repayment of external debt	(50.1)	(904.6)	(137.5)	(139.5)
Debt financing costs	—	(24.1)	—	(9.4)
Other	(4.0)	—	—	(36.7)
Net cash from financing activities	(54.1)	(278.7)	(137.5)	(185.6)
Effect of currency rate changes on cash	(1.1)	(3.9)	(1.9)	2.3
Net change in cash, cash equivalents and restricted cash	19.4	(957.9)	278.2	304.4
Cash, cash equivalents and restricted cash at beginning of period	447.3	1,405.2	1,127.0	822.6
Cash, cash equivalents and restricted cash at end of period	$ 466.7	$ 447.3	$ 1,405.2	$ 1,127.0
Cash and cash equivalents at end of period	$ 409.5	$ 297.9	$ 1,345.0	$ 1,070.6
Restricted cash included in prepaid expenses and other assets at end of period	20.6	113.0	24.0	20.2
Restricted cash included in other long-term assets at end of period	36.6	36.4	36.2	36.2
Cash, cash equivalents and restricted cash at end of period	$ 466.7	$ 447.3	$ 1,405.2	$ 1,127.0
Supplemental Disclosures of Cash Flow Information:				
Cash paid for interest	$ 164.1	$ 111.5	$ 243.2	$ 256.1
Cash paid (received) for income taxes, net	3.0	3.0	(160.0)	39.9

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
(in millions)

	Ordinary Shares		Treasury Shares				Accumulated Other Comprehensive (Loss) Income	Total Shareholders' Equity
	Number	Par Value	Number	Amount	Additional Paid-In Capital	Retained Deficit		
Balance as of December 27, 2019 (Predecessor)	93.5	$ 18.7	9.4	$ (1,615.7)	$ 5,562.5	$ (2,016.9)	$ (7.9)	$ 1,940.7
Net loss	—	—	—	—	—	(944.6)	—	(944.6)
Other comprehensive loss	—	—	—	—	—	—	(1.7)	(1.7)
Vesting of restricted shares	0.6	0.1	0.1	(0.4)	(0.2)	—	—	(0.5)
Share-based compensation	—	—	—	—	25.3	—	—	25.3
Balance as of December 25, 2020 (Predecessor)	94.1	$ 18.8	9.5	$ (1,616.1)	$ 5,587.6	$ (2,961.5)	$ (9.6)	$ 1,019.2
Net loss	—	—	—	—	—	(717.4)	—	(717.4)
Other comprehensive loss	—	—	—	—	—	—	1.3	1.3
Vesting of restricted shares	0.2	0.1	0.1	—	—	—	—	0.1
Share-based compensation	—	—	—	—	10.2	—	—	10.2
Balance as of December 31, 2021 (Predecessor)	94.3	$ 18.9	9.6	$ (1,616.1)	$ 5,597.8	$ (3,678.9)	$ (8.3)	$ 313.4
Net loss	—	—	—	—	—	(313.1)	—	(313.1)
Other comprehensive loss	—	—	—	—	—	—	(1.5)	(1.5)
Share-based compensation	—	—	—	—	1.7	—	—	1.7
Cancellation of Predecessor equity	(94.3)	(18.9)	(9.6)	1,616.1	(5,599.5)	3,992.0	9.8	(0.5)
Issuance of Successor common stock	13.2	0.1	—	—	2,189.6	—	—	2,189.7
Issuance of Successor Opioid Warrants	—	—	—	—	13.9	—	—	13.9
Balance as of June 16, 2022 (Successor)	13.2	0.1	—	—	2,203.5	—	—	2,203.6
Net loss	—	—	—	—	—	(598.1)	—	(598.1)
Other comprehensive income	—	—	—	—	—	—	10.8	10.8
Share-based compensation	—	—	—	—	1.4	—	—	1.4
Repurchase of Successor Opioid Warrants	—	—	—	—	(13.9)	9.9	—	(4.0)
Balance as of December 30, 2022 (Successor)	13.2	$ 0.1	—	$ —	$ 2,191.0	$ (588.2)	$ 10.8	$ 1,613.7

See Notes to Consolidated Financial Statements.

1. Background and Basis of Presentation

Background

Mallinckrodt plc is a global business of multiple wholly owned subsidiaries (collectively, "Mallinckrodt" or "the Company") that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products.

The Company operates in two reportable segments, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and active pharmaceutical ingredients ("API(s)").

The Company is incorporated and maintains its principal executive offices in Ireland. The Company continues to be subject to United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements.

Basis of Presentation

On October 12, 2020 ("Petition Date"), Mallinckrodt plc and substantially all of its U.S. subsidiaries, including certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business ("Specialty Generics Subsidiaries") and the Specialty Brands business ("Specialty Brands Subsidiaries"), and certain of the Company's international subsidiaries (together with the Company, Specialty Generics Subsidiaries and Specialty Brands Subsidiaries, the "Debtors") voluntarily initiated proceedings ("Chapter 11 Cases") under chapter 11 of title 11 ("Chapter 11") of the United States Code ("Bankruptcy Code"). On March 2, 2022, the U.S. Bankruptcy Court for the District of Delaware ("Bankruptcy Court") entered an order confirming the fourth amended plan of reorganization (with technical modifications) ("Plan"). Subsequent to the filing of the Chapter 11 Cases, Chapter 11 proceedings commenced by a limited subset of the Debtors were recognized and given effect in Canada, and separately the High Court of Ireland made an order confirming a scheme of arrangement on April 27, 2022, which is based on and consistent in all respects with the Plan ("Scheme of Arrangement"). On June 8, 2022, the Bankruptcy Court entered an order approving a minor modification to the Plan. The Plan became effective on June 16, 2022 ("Effective Date"), and on such date the Company emerged from the Chapter 11 and the Scheme of Arrangement became effective concurrently.

See Note 2 for further information on the Plan and emergence from Chapter 11.

Upon emergence from Chapter 11, the Company adopted fresh-start accounting in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification ("ASC") Topic 852 - *Reorganizations* ("ASC 852"), and became a new entity for financial reporting purposes as of the Effective Date. References to "Successor" relate to the financial position as of June 16, 2022 and results of operations of the reorganized Company subsequent to June 16, 2022, while references to "Predecessor" relate to the financial position prior to June 16, 2022 and results of operations of the Company prior to, and including, June 16, 2022. All emergence-related transactions of the Predecessor were recorded as of June 16, 2022. Accordingly, the consolidated financial statements for the Successor are not comparable to the consolidated financial statements for the Predecessor. See Note 3 for further information.

The Company's significant accounting policies are described within Note 4. In connection with the adoption of fresh-start accounting, the Company elected to make an accounting policy change as described below:

Predecessor Contingencies — Legal fees pertaining to asbestos-related matters were estimated and accrued as part of the Company's projected asbestos liability.

Successor Contingencies — Legal fees pertaining to asbestos matters are expensed as incurred.

This change in accounting policy resulted in a $22.8 million fresh-start adjustment to the asbestos-related liability and a $20.3 million adjustment to the corresponding indemnification receivable as of the Effective Date.

Also in connection with the adoption of fresh-start accounting, the Company made a change in estimate related to the Specialty Generics segment inventory turn calculation. This prospective change is expected to result in the discrete amortization of $20.5 million of capitalized variances through the first quarter of fiscal 2023. The amount recognized for the period June 17, 2022 through December 30, 2022 (Successor) was $19.9 million.

The Company also reassessed and updated its product line net sales presentation for its Specialty Generics segment. Beginning with the Quarterly Report on Form 10-Q for the quarterly period ended July 1, 2022 (Successor), the Company's consolidated financial

statements reflect the updated product line net sales structure for its Specialty Generics segment. Prior year amounts have been recast to conform to current presentation.

The consolidated financial statements have been prepared in U.S. dollars and in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. Actual results may differ from those estimates. The consolidated financial statements include the accounts of the Company, its wholly owned subsidiaries and entities in which they own or control more than 50.0% of the voting shares, or have the ability to control through similar rights. All intercompany balances and transactions have been eliminated in consolidation and all normal recurring adjustments necessary for a fair presentation have been included in the results reported.

The results of entities disposed of are included in the consolidated financial statements up to the date of disposal and, where appropriate, these operations have been reported in discontinued operations. Divestitures of product lines and businesses not meeting the criteria for discontinued operations have been reflected in operating loss.

Certain prior-period amounts on the consolidated financial statements have been reclassified to conform to current-period presentation.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. The period June 17, 2022 through December 30, 2022 reflects the Successor period, while the period January 1, 2022 through, and including, June 16, 2022 reflects the Predecessor period. Fiscal year ended December 31, 2021 (Predecessor) ("fiscal 2021") consisted of 53 weeks, while the combined periods of January 1, 2022 through June 16, 2022 and June 17, 2022 through December 30, 2022 ("fiscal 2022") and fiscal year ended December 25, 2020 (Predecessor) ("fiscal 2020") consisted of 52 weeks.

2. Emergence from Voluntary Reorganization

During the pendency of the Chapter 11 Cases, the Debtors operated their businesses as debtors-in-possession under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and orders of the Bankruptcy Court. As debtors-in-possession, the Debtors were authorized to continue to operate as ongoing businesses, and were allowed to pay all debts and honor all obligations arising in the ordinary course of their businesses after the Petition Date. However, the Debtors were not allowed to 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 Company as of the Petition Date, were subject to an automatic stay. See *Plan of Reorganization* section below for the distributions to creditors and interest holders.

Plan of Reorganization

In accordance with the effectuated Plan, the following significant transactions occurred upon the Company's emergence from bankruptcy on the Effective Date:

Resolution of Opioid-Related Claims.

Pursuant to the Plan and the Scheme of Arrangement, on the Effective Date all opioid claims against the Company and its subsidiaries were deemed to have been settled, discharged, waived, released and extinguished in full against the Company and its subsidiaries, and the Company and its subsidiaries ceased to have any liability or obligation with respect to such claims, which were treated in accordance with the Plan as follows:

- Opioid claims were channeled to certain trusts, which will receive $1,725.0 million in deferred payments from the Company and certain of its subsidiaries ("Opioid-Related Litigation Settlement") consisting of (i) a $450.0 million payment upon the Effective Date (of which $2.6 million was prefunded); (ii) a $200.0 million payment upon each of the first and second anniversaries of the Effective Date; (iii) a $150.0 million payment upon each of the third through seventh anniversaries of the Effective Date; and (iv) a $125.0 million payment upon the eighth anniversary of Effective Date (collectively, the "Opioid Deferred Payments") with the Company retaining an eighteen-month option to prepay outstanding Opioid Deferred Payments (other than the initial Effective Date payment) at a discount (and to prepay the Opioid Deferred Payments at their undiscounted value even after the expiration of such eighteen-month period). The Opioid Deferred Payments are unsecured and are guaranteed by Mallinckrodt and its subsidiaries that are borrowers, issuers or guarantors under the Takeback Term

Loans and the New 1L Notes, Existing 1L Notes, New 2L Notes and Takeback 2L Notes (such notes collectively, the "Effective Date Notes") (except for the Effective Date Notes), and certain future indebtedness (subject to certain exceptions). The Opioid Deferred Cash Payments Agreement contains affirmative and negative covenants (including an obligation to offer to pay the Opioid Deferred Payments without discount upon the occurrence of certain change of control triggering events) and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the Opioid Deferred Cash Payments Agreement could result in the required repayment of all outstanding Opioid Deferred Payments and could cause a cross-default that could result in the acceleration of certain indebtedness of Mallinckrodt and its subsidiaries.

- Opioid claimants also received, in addition to other potential consideration, 3,290,675 warrants for approximately 19.99% of the reorganized Company's new outstanding shares, with a nominal value $0.01 per share ("Ordinary Share(s)"), after giving effect to the exercise of the warrants, but subject to dilution from equity reserved under the management incentive plan, exercisable at any time on or prior to the sixth anniversary of the Effective Date, at a strike price of $103.40 per Ordinary Share ("Opioid Warrant(s)").
- Pursuant to the Plan, certain subsidiaries of the Company will remain subject to an agreed-upon operating injunction with respect to the operation of their opioid business.

Governmental Acthar Gel Settlement

Pursuant to the Plan and the Scheme of Arrangement, on the Effective Date, all claims of the U.S. Department of Justice ("DOJ") and other governmental parties relating to Acthar® Gel (repository corticotropin injection) ("Acthar Gel") against the Company were deemed to have been settled, discharged, waived, released and extinguished in full against the Company, and the Company ceased to have any liability or obligation with respect to such claims, which were treated in accordance with the Plan and the terms of the settlement that is summarized below:

- The Company entered into an agreement with the DOJ and other governmental parties to settle a range of litigation matters and disputes relating to Acthar Gel ("Acthar Gel-Related Settlement") including a Medicaid lawsuit with the Centers for Medicare and Medicaid Services ("CMS"), a related False Claims Act ("FCA") lawsuit in Boston, and an Eastern District of Pennsylvania ("EDPA") FCA lawsuit principally relating to interactions of Acthar Gel's previous owner (Questcor Pharmaceuticals Inc. ("Questcor")) with an independent charitable foundation. To implement the Acthar Gel-Related Settlement, the Company entered into two settlement agreements with the U.S. and certain relators. Under the Acthar Gel-Related Settlement, which was conditioned upon the Company commencing its Chapter 11 proceeding and provided for the distributions the applicable claimants received under the Plan, the Company will pay $260.0 million to the DOJ and other parties over seven years and reset Acthar Gel's Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. The $260.0 million in payments consists of (i) a $15.0 million payment upon the Effective Date; (ii) a $15.0 million payment upon the first anniversary of the Effective Date; (iii) a $20.0 million payment upon each of the second and third anniversaries of the Effective Date; (iv) a $32.5 million payment upon each of the fourth and fifth anniversaries of the Effective Date; and (v) a $62.5 million payment upon the sixth and seventh anniversaries of Effective Date. Also in connection with the Acthar Gel-Related Settlement, the Company entered into (a) separate settlement agreements with certain states, the Commonwealth of Puerto Rico, the District of Columbia and the above-noted relators, which further implement the Acthar Gel-Related Settlement, and (b) a five-year corporate integrity agreement ("CIA") with the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS") in March 2022. As a result of these agreements, upon effectiveness of the Acthar Gel-Related Settlement in connection with the effectiveness of the Plan, the U.S. Government has dropped its demand for approximately $640 million in retrospective Medicaid rebates for Acthar Gel and agreed to dismiss the FCA lawsuit in Boston and the EDPA FCA lawsuit. Similarly, state and territory Attorneys General have also dropped related lawsuits. In turn, the Company has dismissed its appeal of the U.S. District Court for the District of Columbia's ("D.C. District Court") adverse decision in the Medicaid lawsuit, which was filed in the U.S. Court of Appeals for the District of Columbia Circuit ("D.C. Circuit").
- Mallinckrodt has entered into the Acthar Gel-Related Settlement with the DOJ and other governmental parties solely to move past these litigation matters and disputes and does not make any admission of liability or wrongdoing.
- In accordance with the effectuated Acthar Gel-Related Settlement, on June 28, 2022, the Bankruptcy Court entered an order dismissing the federal government's FCA lawsuit with prejudice, and further ordered the related state lawsuits dismissed without prejudice.
- In accordance with the effectuated Acthar Gel-Related Settlement, on July 20, 2022, the court entered an order dismissing the EDPA FCA lawsuit with prejudice.

Satisfaction of Existing Term Loans and Repayment of Existing Revolver

On the Effective Date and pursuant to the Plan, Mallinckrodt International Finance S.A. ("MIFSA") and Mallinckrodt CB LLC ("MCB" and together with MIFSA, the "Issuers"), each of which is a subsidiary of the Company, entered into a senior secured term

loan facility with an aggregate principal amount of $1,392.9 million ("2017 Replacement Term Loans") and a senior secured term loan facility with an aggregate principal amount of $369.7 million ("2018 Replacement Term Loans", and together with the 2017 Replacement Term Loan, the "Takeback Term Loans"). Pursuant to the Plan and Scheme of Arrangement, on the Effective Date, lenders holding allowed claims in respect of the existing senior secured term loans due September 2024 ("2024 Term Loans") and senior secured term loans due February 2025 ("2025 Term Loans" and, together with the 2024 Term Loans, the "Existing Term Loans") incurred by the Issuers received their pro rata share of the 2017 Replacement Term Loans (in the case of the 2024 Term Loans) or the 2018 Replacement Term Loans (in the case of the 2025 Term Loans) and payment in cash of an exit fee equal to 1.00% of the remaining principal amount of Existing Term Loans held by such lenders in satisfaction thereof.

Pursuant to the Plan and Scheme of Arrangement, on the Effective Date, lenders' allowed claims in respect of the existing $900.0 million senior secured revolving credit facility ("Existing Revolver") incurred by the Issuers and certain of their respective subsidiaries were paid in full in cash.

Reinstatement of Existing 10.00% First Lien Senior Secured Notes due 2025

On the Effective Date and pursuant to the Plan and the Scheme of Arrangement, the Issuers' existing 10.00% First Lien Senior Secured Notes due 2025 ("Existing 1L Notes") in an aggregate principal amount of $495.0 million and the note documents relating thereto were reinstated. In addition, pursuant to the terms of the indenture governing the Existing 1L Notes, the Issuers, Mallinckrodt plc and the subsidiary guarantors of the Existing 1L Notes entered into a supplemental indenture, dated of the Effective Date ("Existing 1L Notes Indenture"), pursuant to which certain additional assets were added to the collateral securing the Existing 1L Notes and the guarantees thereof.

Satisfaction of 10.00% Second Lien Senior Secured Notes due 2025

Pursuant to the Plan and Scheme of Arrangement, on the Effective Date, lenders holding allowed claims in respect of the Issuers' existing 10.00% second lien senior secured notes due 2025 ("Existing 2L Notes") in an aggregate principal amount of $322.9 million received their pro rata share of a like aggregate principal amount of new 10.00% second lien senior secured notes due 2025 ("New 2L Notes") in satisfaction thereof.

Discharge of Mallinckrodt's Guaranteed Unsecured Notes

Pursuant to the Plan and Scheme of Arrangement, on the Effective Date, holders of allowed claims in respect of the Issuers' 5.75% Senior Notes due 2022, the 5.625% Senior Notes due 2023 and the 5.50% Senior Notes due 2025 ("Guaranteed Unsecured Notes") received their pro rata share of $375.0 million aggregate principal amount of new 10.00% second lien senior secured notes due 2029 ("Takeback 2L Notes") and 100% of the new 13,170,932 Ordinary Shares issued, subject to dilution by the Opioid Warrants described above and the management incentive plan. Otherwise, pursuant to the Plan and the Scheme of Arrangement, all claims in respect of the Guaranteed Unsecured Notes and the indentures governing them were settled, discharged, waived, released and extinguished in full.

Resolution of Other Remaining Claims

Pursuant to the Plan and Scheme of Arrangement, on the Effective Date, certain trade claims and other general unsecured claims, including the claims of holders of the 4.75% senior notes due April 2023, against the Debtors were deemed to have been settled, discharged, waived, released and extinguished in full, and Mallinckrodt ceased to have any liability or obligation with respect to such claims, which were then treated in accordance with the Plan and Scheme of Arrangement, which provided for the holders of such claims to share in $135.0 million in cash, plus other potential consideration, including but not limited to 35.0% of the proceeds of the sale of the StrataGraft® (allogenic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat) ("StrataGraft") Priority Review Voucher ("PRV") and $20.0 million payable upon the achievement of (1) U.S. Food and Drug Administration ("FDA") approval of Terlivaz® (terlipressin) ("Terlivaz") and (2) cumulative net sales of $100.0 million of Terlivaz.

On June 30, 2022, subsequent to the Effective Date, the Company completed the sale of its PRV for $100.0 million and received net proceeds of $65.0 million as the buyer remitted the remaining $35.0 million to the General Unsecured Claims Trustee pursuant to the terms of (i) the Plan, and (ii) that certain General Unsecured Claims Trust Agreement entered into in connection with the Plan.

New Warrant Agreement

On the Effective Date and pursuant to the Plan, Mallinckrodt entered into a warrant agreement and issued 3,290,675 Opioid Warrants to purchase the Ordinary Shares to MNK Opioid Abatement Fund, LLC ("Initial Holder"), a wholly owned subsidiary of the Opioid Master Disbursement Trust II, a master disbursement trust established in accordance with the Plan. Each Opioid Warrant was initially exercisable for one Ordinary Share at an initial exercise price of $103.40 per Ordinary Share ("Exercise Price"), subject to the cashless exercise provisions contained in the warrant agreement. The Opioid Warrants were exercisable from the date of issuance until the sixth anniversary of the Effective Date. The warrant agreement governing the Opioid Warrants contained customary anti-dilution adjustments in the event of any share dividends, share splits, distributions, issuance of additional shares or options, or certain other dilutive events.

Warrant Termination Agreement

On December 8, 2022, the Company, the Initial Holder and Opioid Master Disbursement Trust II entered into an agreement to accelerate the expiration date of the Opioid Warrants and to terminate the warrant agreement in exchange for a payment by the Company of $4.0 million to the Initial Holder ("Warrant Termination Agreement"). At the closing of the transactions contemplated by the Warrant Termination Agreement, which also occurred on December 8, 2022, the Company and the warrant agent entered into an amendment to the warrant agreement that accelerated the expiration of the Opioid Warrants to such date. As a result of such expiration, the Opioid Warrants were cancelled and each of the warrant agreement and the registration rights agreement that were entered into on the Effective date terminated in accordance with its terms.

Exit Financing

On the Effective Date, the Company issued $650.0 million aggregate principal amount of new 11.50% First Lien Senior Secured Notes due 2028 ("New 1L Notes") and entered into a receivables financing facility based on a borrowing base with a maximum draw of up to $200.0 million. See Note 14 for further information on these debt instruments.

Financing

Predecessor Chapter 11 Financing

The Company obtained an order of the Bankruptcy Court in the Chapter 11 Cases (in a form agreed with, among others, the agent under the predecessor senior secured credit facilities, lenders under the Existing Revolver and the Existing Term Loans and holders of the Existing 1L Notes and the Existing 2L Notes) permitting the use of cash collateral to finance the Chapter 11 Cases.

Such order required that the Company make cash adequate protection payments on the Existing Revolver and Existing Term Loans for, among other things, unpaid pre-petition and post-petition fees, unpaid pre-petition interest (at the specified contract rate) and post-petition interest (at a rate equal to (1) the adjusted London Interbank Offered Rate ("LIBOR"), plus (2) the contract-specified applicable margin, and plus (3) an incremental 200 basis points), quarterly amortization payments on the Existing Term Loans and reimbursement of certain costs. Such order further required that the Company make cash adequate protection payments on the Existing 1L Notes and Existing 2L Notes for, among other things, unpaid pre-petition and post-petition interest (at the specified non-default interest rate) and reimbursement of certain costs. On April 13, 2021, the Debtors received Bankruptcy Court approval of their motion to amend the final cash collateral order as of March 22, 2021 to pay post-petition interest on the senior secured term loans at a rate equal to (1) the adjusted LIBOR, plus (2) the contract-specified applicable margin, and plus (3) an incremental 250 basis points for its Existing Term Loans. The cash collateral order expired on June 16, 2022.

Interest expense incurred and paid with respect to the incremental adequate protection payments of 200 basis points and 250 basis points on the Existing Revolver and Existing Term Loans, respectively, were as follows:

	Predecessor		
	Period from January 1, 2022 through June 16. 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Interest expense incurred for adequate protection payments	$ 28.8	$ 63.1	$ 11.7
Cash paid for adequate protection payments	28.8	66.7	7.8

Contractual interest

While the Chapter 11 Cases were pending, the Company was not accruing interest on its unsecured debt instruments as of the Petition Date on a go-forward basis as the Debtors did not anticipate making interest payments due under their respective unsecured debt instruments; however, the Debtors expect to pay all interest payments in full as they come due under their respective senior secured debt instruments. The total aggregate amount of interest payments contractually due under the Company's unsecured debt instruments, which the Company did not pay as the obligation was extinguished pursuant to the Plan, was $46.5 million, $93.0 million and $28.8 million for the period January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), respectively.

3. Fresh-start Accounting

The Company qualified for and adopted fresh-start accounting as of the Effective Date in accordance with ASC 852 as (i) the reorganization value of the assets of the Company immediately prior to the date of effectuation of the Plan was less than the post-petition liabilities and allowed claims and (ii) the holders of the voting shares of the Predecessor immediately before effectuation of the Plan received less than 50% of the voting shares of the Successor.

Reorganization Value

Reorganization value represents the fair value of the Successor Company's total assets and is intended to approximate the amount a willing buyer would pay for the assets immediately after restructuring. Upon the application of fresh-start accounting, the Company allocated the reorganization value to its individual assets based on their estimated fair values in accordance with ASC Topic 805 - *Business Combinations*. Deferred income tax amounts were determined in accordance with ASC Topic 740 - *Income Taxes*.

As set forth in the disclosure statement approved by the Bankruptcy Court, the estimated enterprise value of the Successor was estimated to be between $5,200.0 million and $5,700.0 million, with a midpoint of $5,450.0 million, which was estimated with the assistance of third-party valuation advisors using various valuation methods, including (i) discounted cash flow analysis, a calculation of the present value of the future cash flows to be generated by the business based on its projection, and (ii) comparable public company analysis, a method to estimate the value of a company relative to other publicly traded companies with similar operation and financial characteristics. The estimated enterprise value per the disclosure statement included estimated equity value in a range between $563.0 million and $1,063.0 million, with a midpoint of $813.0 million. Subsequent to the filing of the disclosure statement, the Company made revisions to certain of the cash flow projections due to declines in projected operating performance. Based upon a reevaluation of relevant factors used in determining the range of enterprise value and updated expected cash flow projections, the Company concluded the enterprise value, or fair value, was $5,223.0 million.

The basis of the discounted cash flow analysis used in developing the enterprise value was based on Company prepared projections that included a variety of estimates and assumptions. While the Company considers such estimates and assumptions reasonable, they are inherently subject to significant business, economic and competitive uncertainties, many of which are beyond the Company’s control and, therefore, may not be realized. Changes in these estimates and assumptions may have had a significant effect on the determination of the Company’s enterprise value.

The following table reconciles the enterprise value to the implied fair value of the Successor's equity as of the Effective Date:

Enterprise value	$	5,223.0
Plus: Enterprise value adjustments [(1)]		197.0
Adjusted enterprise value		5,420.0
Plus: Cash and cash equivalents		297.9
Plus: Non-operating assets, net [(2)]		178.7
Less: Fair value of debt		(3,067.2)
Less: Fair value of Opioid-Related Litigation Settlement, Acthar Gel-Related Settlement, StrataGraft PRV proceeds and Terlivaz contingent value rights		(625.8)
Successor equity value	$	2,203.6

(1) Represents incremental tax benefits not contemplated in the projections utilized in the disclosure statement.

(2) Represents non-operating assets and liabilities which were excluded from the enterprise value as put forth in the disclosure statement as there were no cash projections associated with these net assets.

Upon the application of fresh-start accounting, the Company allocated the reorganization value to its individual assets based on their estimated fair values. Reorganization value represents the fair value of the Successor’s assets before considering liabilities.

The following table reconciles the Company's enterprise value to its reorganization value as of the Effective Date:

Adjusted enterprise value	$	5,420.0
Plus: Cash and cash equivalents		297.9
Plus: Non-operating assets, net		178.7
Plus: Current liabilities (excluding debt or debt-like items)		522.5
Plus: Other non-current liabilities (excluding debt or debt-like items)		183.2
Reorganization value of Successor assets	$	6,602.3

Consolidated Balance Sheet

The four-column consolidated balance sheet as of the Effective Date included herein, applies effects of the Plan (reflected in the column "Reorganization Adjustments") and fresh-start accounting (reflected in the column "Fresh-Start Adjustments") to the carrying values and classifications of assets or liabilities. Upon adoption of fresh-start accounting, the recorded amounts of assets and liabilities were adjusted to reflect their estimated fair values. Accordingly, the reported historical financial statements of the Predecessor prior to the adoption of fresh-start accounting for periods ended on or prior to the Effective Date are not comparable to those of the Successor. The explanatory notes highlight methods used to determine fair values or other amounts of the assets and liabilities as well as significant assumptions.

The four-column consolidated balance sheet as of June 16, 2022 is as follows:

	Predecessor	Reorganization Adjustments	Fresh-Start Adjustments	Successor
Assets				
Current Assets:				
Cash and cash equivalents	$ 1,392.6	$ (1,094.7) (a)	$ —	$ 297.9
Accounts receivable, less allowance for doubtful accounts	387.4	—	—	387.4
Inventories	375.2	—	851.8 (q)	1,227.0
Prepaid expenses and other current assets	322.6	75.3 (b)	(58.3) (r)	339.6
Current asset held for sale	—	—	100.0 (j)	100.0
Total current assets	2,477.8	(1,019.4)	893.5	2,351.9
Property, plant and equipment, net	748.6	—	(299.2) (s)	449.4
Intangible assets, net	5,166.6	—	(2,014.4) (t)	3,152.2
Deferred income taxes	—	—	453.4 (l)	453.4
Other assets	222.8	(3.9) (c)	(23.5) (u)	195.4
Total Assets	$ 8,615.8	$ (1,023.3)	$ (990.2)	$ 6,602.3
Liabilities and Shareholders' Equity				
Current Liabilities:				
Current maturities of long-term debt	$ 1,389.9	$ (1,355.2) (d)	$ —	$ 34.7
Accounts payable	156.4	(53.8) (e)	—	102.6
Accrued payroll and payroll-related costs	71.4	—	—	71.4
Accrued interest	20.8	(13.0) (f)	—	7.8
Acthar Gel-Related Settlement	—	16.5 (g)	—	16.5
Opioid-Related Litigation Settlement	—	200.0 (h)	—	200.0
Accrued and other current liabilities	296.1	50.8 (i)	(6.1) (v)	340.8
Current liability held for sale	—	35.0 (j)	—	35.0
Total current liabilities	1,934.6	(1,119.7)	(6.1)	808.8
Long-term debt	—	3,050.9 (d)	(18.4) (w)	3,032.5
Acthar Gel-Related Settlement	—	63.2 (g)	—	63.2
Opioid-Related Litigation Settlement liability	—	304.3 (h)	—	304.3
Pension and postretirement benefits	27.6	27.2 (k)	—	54.8
Environmental liabilities	37.1	—	—	37.1
Deferred income taxes	20.4	102.7 (l)	(121.7) (l)	1.4
Other income tax liabilities	75.9	—	(61.9) (x)	14.0
Other liabilities	68.6	23.6 (m)	(9.6) (v)	82.6
Liabilities subject to compromise	6,402.7	(6,402.7) (n)	—	—
Total Liabilities	8,566.9	(3,950.5)	(217.7)	4,398.7
Shareholders' Equity:				
Predecessor preferred shares	—	—	—	—
Predecessor ordinary A shares	—	—	—	—
Predecessor ordinary shares	18.9	(18.9) (o)	—	—
Successor ordinary shares	—	0.1 (o)	—	0.1
Predecessor ordinary shares held in treasury	(1,616.1)	1,616.1 (o)	—	—
Predecessor additional paid-in capital	5,599.5	(5,599.5) (o)	—	—
Successor additional paid-in capital	—	2,203.5 (o)	—	2,203.5
Predecessor accumulated other comprehensive loss	(9.9)	—	9.9 (y)	—
Retained (deficit) earnings	(3,943.5)	4,725.9 (p)	(782.4) (z)	—
Total Shareholders' Equity	48.9	2,927.2	(772.5)	2,203.6
Total Liabilities and Shareholders' Equity	$ 8,615.8	$ (1,023.3)	$ (990.2)	$ 6,602.3

Reorganization Adjustments

(a) The table below reflects the sources and uses of cash on the Effective Date:

Sources:		
Proceeds from New 1L Notes	$	637.0
Total Sources		637.0
Uses:		
Payment of Predecessor revolving credit facility		(900.0)
Upfront payment of the Opioid-Related Litigation Settlement		(447.4)
Upfront payment of the Acthar Gel-Related Settlement, inclusive of settlement interest		(17.8)
Payment of secured, administrative, priority and trade claims		(26.2)
Payment of professional fees		(43.5)
Payment to fund professional fees escrow (prepaid and other current assets restricted cash)		(89.0)
Payment of general unsecured claims		(135.0)
Payment of noteholder consent fees		(19.3)
Payment of costs, fees and expenses related to exit-financing activities, an exit fee associated with senior secured loans and accrued and unpaid interest on certain pre-emergence debt		(53.5)
Total Uses		(1,731.7)
Net Uses of Cash	$	(1,094.7)

(b) Represents the transfer of funds to a restricted cash account for purposes of funding the $89.0 million professional fee reserve offset by the release of a $10.9 million prepaid success fee as a result of emergence from bankruptcy and the write off of prepaid expenses related to premiums for the Predecessor Company's directors' and officers' insurance policy.

(c) Debt issuance costs of $2.6 million related to entering into a receivables financing facility. These costs were capitalized as other non-current assets as the facility was undrawn as of June 16, 2022. Refer to Note 14 for further information on the receivables financing facility. Also reflects a write-off of $6.5 million of prepaid expenses related to premiums for the Predecessor Company's directors' and officers' insurance policy.

(d) Impacts to long-term debt, net of current maturities, pursuant to the Plan, include the following:

- Repayment of the $900.0 million Existing Revolver;
- Issuance of the 2017 and 2018 Replacement Term Loans of $1,392.9 million and $369.7 million, respectively, of which $34.7 million was current;
- Issuance of the New 2L Notes of $322.9 million;
- Issuance of the Takeback 2L Notes of $375.0 million;
- Reinstatement of the Existing 1L Notes of $495.0 million principal, net of $5.1 million deferred financing fees; and
- Issuance of $650.0 million New IL Notes, net of a $13.0 million original issuance discount and $9.7 million of deferred debt issuance costs.

Fair value adjustments to the carrying value of debt instruments impacted by the Plan as determined by the Black-Derman-Toy model as follows:

2017 Replacement Term Loan	$	(169.4)
2018 Replacement Term Loan		(42.2)
New 2L Notes		(95.7)
Takeback 2L Notes		(184.8)
Total fair value adjustment to debt instruments	$	(492.1)

Predecessor debt for certain of these instruments described above were classified in liabilities subject to compromise ("LSTC") as of the Effective Date.

(e) Represents $43.5 million of professional fees paid to the Company’s restructuring advisors upon the Company's emergence from Chapter 11 bankruptcy and $25.2 million of secured, administrative and priority payments, partially offset by $14.6 million of professional advisor success fees incurred on the Effective Date plus reinstatement of LSTC.

(f) Represents payments of accrued interest on the Company's Existing Revolver, Existing Term Loans and Existing 2L Notes in accordance with the cash collateral order on the Effective Date.

(g) Pursuant to the Plan, the Company agreed to pay $260.0 million to the DOJ and other parties over seven years to settle the Acthar Gel-related matters. The Company reduced its estimated allowed claim amount related to these matters to the settlement amount of $260.0 million and reclassified it from LSTC to other non-current liabilities. On the Effective Date, the Company made an upfront payment of $17.8 million, inclusive of settlement interest. The remaining deferred cash payments of $245.0 million and related settlement interest were recorded at fair value utilizing a discounted cash flow model with an average credit-adjusted discount rate of 27.8%. The fair value of the liability was $16.5 million and $63.2 million, respectively, reflected within current and other non-current liabilities in the above table.

(h) Pursuant to the Plan, the Company agreed to pay $1,725.0 million into certain trusts to resolve all opioid claims, and made an upfront payment of $447.4 million on the Effective Date. The remaining deferred cash payments of $1,275.0 million were recorded at fair value utilizing the Black-Derman-Toy model, which incorporates the option to prepay as well as other inputs such as an average credit-adjusted discount rate of 27.8%. The fair value of the liability was $200.0 million and $304.3 million, respectively, reflected within current and other non-current liabilities in the above table.

(i) The following table reconciles reorganization adjustments to accrued and other current liabilities:

Severance - Exiting Chief Executive Officer ("CEO")	$	5.7
Reinstatement of various successor obligations from LSTC		15.4
Success fees for professionals incurred on Effective Date		29.7
	$	50.8

(j) As part of fresh-start accounting, the Company recorded a $100.0 million intangible asset in relation to the Company's PRV that was awarded under an FDA program intended to encourage the development of certain product applications for therapies used to treat or prevent material threat medical countermeasures. It also recorded a $35.0 million liability related to the proceeds from a sale of the PRV which is due to the general unsecured claims trustee pursuant to the term of the Plan and the general unsecured claims trust agreement entered into with the Plan. As of the Effective Date, this asset and liability were classified as held-for-sale. Refer to Note 13 for further information on the subsequent sale of the PRV.

(k) Reinstatement of certain long-term pension and other postretirement plans from LSTC to other liabilities.

(l) Reflects reorganization adjustments consisting of (1) the reduction in federal and state net operating loss ("NOL") carryforwards from cancellation of debt income ("CODI") realized upon emergence from bankruptcy and limitations under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986 ("IRC"); (2) the net decrease in deferred tax assets resulting from reorganization adjustments; (3) the reduction in the valuation allowance on the Company's deferred tax assets and fresh-start adjustments consisting of (4) the net decrease in deferred tax liabilities resulting from fresh-start adjustments; and (5) the release of uncertain tax positions that are no longer required upon emergence from bankruptcy.

(m) Reinstatement of the Company's $16.8 million asbestos-related defense costs from LSTC to other liabilities and establishment of a liability for the contingent value right ("CVR") associated with Terlivaz in accordance with the Plan and Scheme of Arrangement. The CVR is based upon the achievement of a cumulative net sales milestone. The Company will assess the likelihood of and timing of making such payment at each balance sheet date. The fair value of the contingent payment was measured based on the net present value of a probability-weighted assessment estimated using a Monte Carlo simulation. The Company determined the fair value of the CVR to be $6.8 million as of the Effective Date.

(n) LSTC were settled as follows in accordance with the Plan *(in millions)*:

Liabilities subject to compromise		
Accounts payable	$	17.7
Accrued interest		35.2
Debt		3,746.2
Environmental liabilities		67.2
Acthar Gel-Related Settlement liability		630.0
Opioid-Related Litigation Settlement liability		1,722.4
Other current and non-current liabilities		151.6
Pension and postretirement benefits		32.4
Total liabilities subject to compromise	$	6,402.7
To be reinstated on the Effective Date:		
Accounts payable	$	(0.1)
Other current and non-current liabilities		(27.3)
Pension and postretirement benefits		(32.4)
Total liabilities reinstated	$	(59.8)
Consideration provided to settle amounts per the Plan		
Issuance of Successor common stock	$	(2,189.7)
Issuance of Opioid Warrants		(13.9)
Issuance of Takeback Term Loans and New 2L Notes		(1,778.3)
Acthar Gel-Related Settlement liability		(79.7)
Opioid-Related Litigation Settlement liability		(504.3)
Issuance of Takeback 2L Notes to holders of the Guaranteed Unsecured Notes		(190.2)
Contingent liabilities for proceeds of sale of StrataGraft PRV and Terlivaz CVR		(41.8)
Cash payment		(601.3)
Total consideration provided to settle amounts per the Plan	$	(5,399.2)
Gain on settlement of liabilities subject to compromise	$	943.7

(o) Pursuant to the Plan, as of the Effective Date, all Predecessor's preferred and ordinary shares were cancelled without any distribution. The following table reconciles reorganization adjustments made to Successor common stock, Opioid Warrants and additional paid in capital:

Par value of 13,170,932 shares of Successor Common Stock issued to former holders of the Guaranteed Unsecured Notes (par valued at $0.01 dollars per share)	$	0.1
Fair value of Opioid Warrants issued to holders of the Guaranteed Unsecured Notes [(1)]		13.9
Additional paid in capital - Successor Common Stock		2,189.6
Successor equity	$	2,203.6

(1) The fair value of the Opioid Warrants was estimated using a Black-Scholes model with the following assumptions: $18.50 stock price of the Successor Company; exercise price per share of $103.40; expected volatility of 62.28%; risk free interest rate of 3.34%, continuously compounded; and a holding period of six years. The expected volatility assumption is based on the historical and implied volatility of the Company's peer group with similar business models.

(p) Retained deficit - The cumulative effect of the consummation of the Plan on the Predecessor's retained deficit is as follows:

Gain on settlement of LSTC	$	943.7
Professional, success and exit fees		(91.6)
Release of prepaid success fee		(10.9)
Release of prepaid insurance [(1)]		(9.2)
Accrual of severance for former CEO		(5.7)
Income tax expense on plan adjustments		(102.7)
Cancellation of Predecessor equity		4,002.3
Net impact on retained deficit	$	4,725.9

(1) Write off of prepaid expenses related to premiums for the Predecessor Company's directors' and officers' insurance policy.

Fresh-Start Adjustments

(q) Reflects the fair value adjustment related to the Company's inventory. Both the bottom-up and top-down approach were used. The bottom-up approach considers the inventory value that had been created by the Company including the costs incurred, profit realized, and tangible and intangible assets used pre-Effective Date. The top-down approach measures the incremental inventory value created by the market participant buyer as part of its selling effort to an end customer and considers the costs that will be incurred, the profit that will be realized, and the tangible and intangible assets that will be used post-Effective Date.

(r) Reflects the reduction of $54.0 million in prepaid income taxes due to remeasurement as a result of fresh-start accounting. Also reflects a write-off of $4.3 million of asbestos indemnification receivable affiliated with asbestos-related defense costs in line with the Company's accounting policy change as outlined in Note 1.

(s) Reflects the fair value adjustment related to the Company's property, plant and equipment. Both the market and cost approaches were utilized to fair value land and buildings. The cost approach was utilized to fair value capitalized software and machinery and equipment. Construction in process was reported at its cost less adjustments for economic obsolescence.

(t) Reflects the fair value adjustment related to the Company's intangible assets. The fair value of the completed technology and in-process research and development ("IPR&D") intangible assets were determined using the income approach. The cash flows were discounted commensurate with the level of risk associated with each asset or its projected cash flows. The valuation used discount rates ranging from 13.0% through 15.0%, depending on the asset. The IPR&D discount rate was developed after assigning a probability of success to achieving the projected cash flows based on the current stages of development, inherent uncertainty in the FDA approval process and risks associated with commercialization of a new product. See Note 13 for further information on intangible assets.

(u) Reflects the write-off of (i) $16.0 million of asbestos indemnification receivable affiliated with asbestos-related defense costs in line with the Company's accounting policy change as outlined in Note 1; (ii) $3.9 million of spare parts that did not meet the Company's capitalization threshold; and (iii) $1.1 million of third party debt issuance costs. Also reflects a decrease of $0.9 million to income tax receivables associated with a change in uncertain tax positions as a result of fresh-start accounting.

In addition, the Company’s lease obligations were revalued using the incremental borrowing rate applicable to the Company upon emergence from the Chapter 11 proceedings and commensurate with its new capital structure. The incremental borrowing rate used in the revaluation of the lease obligations increased from 8.85% in the Predecessor period to 11.83% in the Successor period. The revaluation of lease obligations includes the adjustment for contract-based off-market intangibles for favorable or unfavorable terms to the right-of-use assets as well as the removal of right-of-use assets (and affiliated lease liabilities) associated with the Company’s leases with a remaining contract term of less than one year as of the Effective Date. The revaluation resulted in a reduction in the right-of-use asset of $1.6 million.

(v) Reflects the write-off of (i) $6.1 million and $16.7 million of current and non-current asbestos-related defense costs, respectively, in line with the Company's accounting policy change as outlined in Note 1; and (ii) an adjustment of $6.9 million to increase the Company's total lease liabilities as a result of the revaluation of the lease obligations as described in footnote (t) above.

(w) Reflects the write-off of $5.1 million of unamortized debt issuance costs and a $23.5 million fair value adjustment to debt principal as determined by the Black-Derman-Toy model related to the reinstated Existing 1L Notes.

(x) Reflects the reduction of liabilities for unrecognized tax benefits that are no longer required upon emergence from bankruptcy.

(y) Reflects the fair value adjustment to eliminate the accumulated other comprehensive income of $8.1 million related to pension benefits and $2.1 million of currency translation adjustment, partially offset by the elimination of $0.3 million of income tax effects, which resulted in income tax benefit of $0.3 million.

(z) The cumulative effect of the fresh-start accounting on the Successor's retained deficit is as follows:

Fresh-start adjustment:		
Inventories	$	851.8
Property, plant and equipment, net		(299.2)
Intangible assets, net		(2,014.4)
Current asset held for sale		100.0
Debt		18.4
Other assets and liabilities		(11.2)
Total fresh-start adjustments impacting reorganization items, net		(1,354.6)
Fresh-start adjustments to accumulated other comprehensive income, net of $0.3 million of tax benefit		(9.9)
Total fresh-start adjustments recorded to income tax benefit		582.1
Net fresh-start impact to accumulated deficit	$	(782.4)

Reorganization items, net

Reorganization items, net, for the Predecessor represent amounts incurred after the Petition Date but prior to emergence from bankruptcy as a direct result of the Chapter 11 Cases and were comprised of gains and losses associated with the reorganization, primarily the loss on fresh-start adjustments, gain on settlement of LSTC, bankruptcy-related professional fees, debt financing fees and write-off of debt issuance costs and related unamortized premiums and discounts. Successor reorganization items, net represent amounts incurred after the Effective Date that directly resulted from Chapter 11 and were entirely comprised of professional fees associated with the implementation of the Plan. Cash paid for reorganization items, net for the period from June 17, 2022 through December 30, 2022 (Successor), January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor) were $18.4 million, $304.1 million, $333.1 million, and $8.7 million, respectively. Reorganization items, net, were comprised of the following:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Gain on settlements of LSTC	$ —	$ (943.7)	$ —	$ —
Loss on fresh-start adjustments	—	1,354.6	—	—
Professional and other service provider fees	23.2	161.1	405.6	51.1
Success fees for professional service providers	—	44.3	—	—
Write off of prepaid premium for directors and officers' insurance policies	—	9.2	—	—
Debt valuation adjustments	—	—	23.1	10.2
Adjustments of other claims	—	5.4	(0.5)	0.1
Total reorganization items, net	$ 23.2	$ 630.9	$ 428.2	$ 61.4

4. Summary of Significant Accounting Policies

Revenue Recognition

Product Sales Revenue

The Company sells its products through independent channels, including direct to retail pharmacies, end user customers and through distributors who resell the products to retail pharmacies, institutions and end user customers, while certain products are sold and distributed directly to hospitals. The Company also enters into arrangements with indirect customers, such as health care providers and payers, wholesalers, government agencies, institutions, managed care organizations and group purchasing organizations to establish contract pricing for certain products that provide for government-mandated and/or privately-negotiated rebates, sales incentives, chargebacks, distribution service agreements fees, fees for services and administration fees and discounts with respect to the purchase of the Company's products.

Reserve for Variable Considerations

Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves result from estimated chargebacks, rebates, product returns and other sales deductions that are offered within contracts between the Company and its customers, health care providers and payers relating to the sale of the Company's products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as the Company's historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of the Company's products and other competitive factors. Overall, these reserves reflect the Company's best estimate of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained (reduced) and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company adjusts reserves for chargebacks, rebates, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of net sales recognized in the period of adjustment.

Product sales are recognized when the customer obtains control of the Company's product. Control is transferred either at a point in time, generally upon delivery to the customer site, or in the case of certain of the Company's products, over the period in which the customer has access to the product and related services. Revenue recognized over time is based upon either consumption of the product or passage of time based upon the Company's determination of the measure that best aligns with how the obligation is satisfied. The Company's considerations of why such measures provide a faithful depiction of the transfer of its products are as follows:

- For those contracts whereby revenue is recognized over time based upon consumption of the product, the Company either has:
    1. the right to invoice the customer in an amount that directly corresponds with the value to the customer of the Company's performance to date, for which the practical expedient to recognize in proportion to the amount it has the right to invoice has been applied, or
    2. the remaining goods and services to which the customer is entitled is diminished upon consumption.
- For those contracts whereby revenue is recognized over time based upon the passage of time, the benefit that the customer receives from unlimited access to the Company's product does not vary, regardless of consumption. As a result, the Company's obligation diminishes with the passage of time; therefore, ratable recognition of the transaction price over the contract period is the measure that best aligns with how the obligation is satisfied.

Transaction price allocated to the remaining performance obligations

The majority of the Company's contracts have a term of less than one year; and the amount of transaction price allocated to the performance obligations that are unsatisfied at period end is generally expected to be satisfied within one year.

Cost to obtain a contract

As the majority of the Company's contracts are short-term in nature, sales commissions are generally expensed when incurred as the amortization period would have been less than one year. These costs are recorded within selling, general and administrative expense ("SG&A") in the consolidated statements of operations. For contracts that extend beyond one year, the incremental expense recognition matches the recognition of related revenue.

Costs to fulfill a contract

The Company capitalizes the costs associated with the devices used in the Company's portfolio of drug-device combination products, which are used in satisfaction of future performance obligations. Capital expenditures for these devices represent cash outflows for the Company's cost to produce the asset, which is classified in property, plant and equipment, net on the consolidated balance sheets and expensed to cost of sales over the useful life of the equipment.

Product Royalty Revenues

The Company licensed certain rights to Amitiza® (lubiprostone) ("Amitiza") to third parties in exchange for royalties on net sales of the product. The Company recognized such royalty revenue as the related sales occurred.

Contract Balances

Accounts receivable are recorded when the right to consideration becomes unconditional. Payments received from customers are typically based upon payment terms of 30 days. The Company does not maintain contract asset balances aside from the accounts receivable balance as presented on the consolidated balance sheets as costs to obtain a contract are expensed when incurred as the amortization period would have been less than one year. These costs are recorded within SG&A on the consolidated statements of

operations. Contract liabilities are recorded when cash payments are received in advance of the Company's performance, including amounts that are refundable.

Taxes collected from customers relating to product sales and remitted to governmental authorities are accounted for on a net basis. Accordingly, such taxes are excluded from both net sales and expenses.

Shipping and Handling Costs

Shipping costs, which are costs incurred to physically move product from the Company's premises to the customer's premises, are classified as SG&A. Handling costs, which are costs incurred to store, move and prepare product for shipment, are classified as cost of sales. Shipping costs included in SG&A expenses in continuing operations were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Shipping costs	$ 13.9	$ 12.8	$ 23.6	$ 20.1

Research and Development

Internal research and development costs are expensed as incurred. Research and development ("R&D") expenses include salary and benefits, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services, medical affairs and other costs.

From time to time, the Company has entered into licensing or collaborative agreements with third parties to develop a new drug candidate or intellectual property asset. These agreements may include R&D, marketing, promotion and selling activities to be performed by one or all parties involved. These collaborations generally include upfront, milestone and royalty or profit sharing payments contingent upon future events tied to the developmental and commercial success of the asset. In general, upfront and milestone payments made to third parties under these agreements are expensed as incurred up to the point of regulatory approval of the product. Milestone payments made to third parties upon regulatory approval are capitalized as an intangible asset and amortized to cost of sales over the estimated useful life of the related product.

Currency Translation

For the Company's non-U.S. subsidiaries that transact in a functional currency other than U.S. dollars, assets and liabilities are translated into U.S. dollars using fiscal year-end exchange rates. Revenues and expenses are translated at the average exchange rates in effect during the related month. The net effect of these translation adjustments is shown in the consolidated financial statements as a component of accumulated other comprehensive income (loss). From time to time, the Company has entered into derivative instruments to mitigate the exposure of movements in certain of these foreign currency transactions. Gains and losses resulting from foreign currency transactions are included in net loss.

Cash and Cash Equivalents

The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Company of three months or less, as cash and cash equivalents.

Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are presented net of an allowance for doubtful accounts. The allowance for doubtful accounts reflects an estimate of losses inherent in the Company's accounts receivable portfolio determined on the basis of historical experience, current facts and circumstances, reasonable and supportable forecasts and other available evidence. Accounts receivable are written off when management determines they are uncollectible. Trade accounts receivable are also presented net of reserves related to chargebacks and rebates payable to customers with whom the Company has trade accounts receivable and the right of offset exists.

Inventories

Inventories are recorded at the lower of cost or net realizable value, primarily using the first-in, first-out convention. The Company reduces the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation and impairment. Major renewals and improvements are capitalized, while routine maintenance and repairs are expensed as incurred. Depreciation for property, plant and equipment, other than land and construction in process, is generally based upon the following estimated useful lives, using the straight-line method:

Buildings	10	to	45 years
Leasehold improvements	1	to	20 years
Capitalized software	1	to	10 years
Machinery and equipment	1	to	20 years

The Company capitalizes certain computer software and development costs incurred in connection with developing or obtaining software for internal use.

Upon retirement or other disposal of property, plant and equipment, the cost and related amount of accumulated depreciation are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds is included in net loss.

The Company assesses the recoverability of assets or asset groups using undiscounted cash flows whenever events or circumstances indicate that the carrying value of an asset or asset group may not be recoverable. If an asset or asset group is found to be impaired, the amount recognized for impairment is equal to the difference between the carrying value of the asset or asset group and its fair value.

Leases

The Company assesses all contracts at inception to determine whether a lease exists. The Company leases office space, manufacturing and warehousing facilities, equipment and vehicles, which are generally operating leases. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are accounted for separately. The Company's lease agreements generally do not contain variable lease payments or any material residual value guarantees.

Lease assets and liabilities are recognized based on the present value of the future minimum lease payments over the lease term as of the commencement date. As the Company's leases do not generally provide an implicit rate, the Company utilizes its incremental borrowing rate based on the information available at commencement date in determining the present value of future lease payments. Most leases include one or more options to terminate or renew, with renewal terms that can extend the lease term from one to five years. The exercise of lease renewal options is at the Company's sole discretion. Termination and renewal options are included within the lease assets and liabilities only to the extent they are reasonably certain.

Acquisitions

Amounts paid for acquisitions that meet the criteria for business combination accounting are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The Company then allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets, including purchased R&D. The fair value of identifiable intangible assets is based on detailed valuations. The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

The Company's purchased R&D represents the estimated fair value as of the acquisition date of in-process projects that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval.

The fair value of in-process research and development ("IPR&D") is determined using the discounted cash flow method. In determining the fair value of IPR&D, the Company considers, among other factors, appraisals, the stage of completion of the projects, the technological feasibility of the projects, whether the projects have an alternative future use and the estimated residual cash flows

that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used includes a rate of return that accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized.

The fair value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested annually for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset is charged to expense.

Certain asset acquisitions or license agreements may not meet the criteria for a business combination. The Company accounts for these transactions as asset acquisitions and recognizes the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquired entity. Any initial up-front payments incurred in connection with the acquisition or licensing of IPR&D product candidates that do not meet the definition of a business are treated as R&D expense.

Intangible Assets

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost. Intangible assets with finite useful lives are amortized according to the pattern in which the economic benefit of the asset is used up over their estimated useful lives, as shown below. The estimated useful lives of the Company's intangible assets as of December 30, 2022 (Successor) were the following:

Completed technology	3	to	20 years

Amortization expense related to completed technology and certain other intangible assets is included in cost of sales.

When a triggering event occurs, the Company evaluates potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset, or the asset group they are part of, to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets, or asset group, with their carrying value. The fair value of the intangible asset, or asset group, is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, or asset group, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the fair value of the asset. The Company assesses the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. The Company annually tests the indefinite-lived intangible assets for impairment, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable by either a qualitative or income approach. The Company will compare the fair value of the assets with their carrying value and record an impairment when the carrying value exceeds the fair value.

Contingencies

The Company is subject to various legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and all other legal proceedings, all in the ordinary course of business as further discussed in Note 19. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company discounts environmental liabilities using a risk-free rate of return when the obligation is fixed or reasonably determinable. The impact of the discount in the consolidated balance sheets was not material in any period presented. Legal fees, other than those pertaining to environmental matters, are expensed as incurred. Insurance recoveries related to potential claims are recognized up to the amount of the recorded liability when coverage is confirmed and the estimated recoveries are probable of payment. Assets and liabilities are not netted for financial statement presentation.

Liabilities Subject to Compromise

As a result of the commencement of the Chapter 11 Cases, the payment of pre-petition liabilities was subject to compromise or other treatment pursuant to a plan of reorganization. The determination of how liabilities would ultimately be settled or treated could not be made until the confirmed Chapter 11 plan of reorganization became effective. Accordingly, the ultimate amount of such liabilities was not determinable prior to the Effective Date. Pre-petition liabilities that were subject to compromise were reported at the amounts that were expected to be allowed by the Bankruptcy Court, even if they may be settled for different amounts. The amounts classified as LSTC prior to the Effective Date were preliminary and were subject to future adjustments dependent upon Bankruptcy Court actions, further developments with respect to disputed claims, determinations of the secured status of certain claims, the values of any collateral securing such claims, rejection of executory contracts, continued reconciliation or other events.

Share-Based Compensation

The Company recognizes the cost of employee services received in exchange for awards of equity or liability-based instruments based on the grant-date fair value of those awards. That cost is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (generally the vesting period). The cost for liability-based instruments is remeasured accordingly each reporting period throughout the requisite service period.

Restructuring

The Company recognizes charges associated with the Company's Board of Directors approved restructuring programs designed to transform its business and improve its cost structure. Restructuring charges can include severance costs, infrastructure charges, distributor contract cancellations and other items. The Company accrues for costs when they are probable and reasonably estimable.

Income Taxes

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been reflected in the consolidated financial statements. Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and operating loss carryforwards, using tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided to reduce net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50.0% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not realized on the uncertain tax position, an income tax liability or a reduction to a deferred tax asset ("contra-DTA(s)") is established. Interest and penalties on income tax obligations, associated with uncertain tax positions, are included in the provision for income taxes.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across the Company's global operations. The Company adjusts these liabilities and contra-DTAs as a result of changing facts and circumstances; however, due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from current estimates of the tax liabilities. If the Company's estimate of tax liabilities proves to be less than the ultimate assessment, an additional charge to expense would result. If payment of these amounts ultimately proves to be less than the recorded amounts, the reversal of the liabilities may result in income tax benefits being recognized in the period when it is determined that the liabilities are no longer necessary. Refer to Note 8 for further information regarding the classification of such amounts in the consolidated balance sheets.

5. Revenue from Contracts with Customers

Product Sales Revenue

See Note 21 for presentation of the Company's net sales by product family.

Reserves for variable consideration

The following table reflects activity in the Company's sales reserve accounts:

	Rebates and Chargebacks [1]	Product Returns	Other Sales Deductions	Total
Balance as of December 27, 2019 (Predecessor)	$ 295.8	$ 28.4	$ 13.2	$ 337.4
Provisions	2,065.9	28.9	59.5	2,154.3
Provision for Medicaid lawsuit [2]	536.0	—	—	536.0
Payments or credits	(2,701.2)	(30.7)	(60.4)	(2,792.3)
Balance as of December 25, 2020 (Predecessor)	196.5	26.6	12.3	235.4
Provisions	2,087.1	23.7	55.2	2,166.0
Payments or credits	(2,041.8)	(28.8)	(58.0)	(2,128.6)
Balance as of December 31, 2021 (Predecessor)	241.8	21.5	9.5	272.8
Provisions	693.4	5.2	17.1	715.7
Payments or credits	(684.6)	(8.1)	(18.9)	(711.6)
Balance as of June 16, 2022 (Predecessor)	$ 250.6	$ 18.6	$ 7.7	$ 276.9
Balance as of June 17, 2022 (Successor)	$ 250.6	$ 18.6	$ 7.7	$ 276.9
Provisions	804.4	7.0	36.7	848.1
Payments or credits	(789.7)	(9.6)	(31.7)	(831.0)
Balance as of December 30, 2022 (Successor)	$ 265.3	$ 16.0	$ 12.7	$ 294.0

(1) Includes $89.3 million and $49.6 million of accrued Medicaid and $55.3 million and $30.4 million of accrued rebates as of December 30, 2022 and December 31, 2021, respectively, included within accrued and other current liabilities in the consolidated balance sheets.

(2) Excludes the $105.1 million that is reflected as a component of operating expenses as it represents a pre-acquisition contingency related to the portion of the liability that arose from sales of Acthar Gel prior to the Company's acquisition of Questcor in August 2014.

Product sales transferred to customers at a point in time and over time were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Product sales transferred at a point in time	83.0 %	80.8 %	79.4 %	78.9 %
Product sales transferred over time	17.0	19.2	20.6	21.1

Transaction price allocated to the remaining performance obligations

The following table includes estimated revenue from contracts extending greater than one year for certain of the Company's hospital products that are expected to be recognized in the future related to performance obligations that were unsatisfied or partially unsatisfied as of December 30, 2022 (Successor):

Fiscal 2023	$ 115.4
Fiscal 2024	23.5
Thereafter	2.7

Costs to fulfill a contract

As of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), the total net book value of the devices used in the Company's portfolio of drug-device combination products, which are used in satisfying future performance obligations and reflected in property, plant and equipment, net, on the consolidated balance sheets was $10.3 million and $25.8 million, respectively. The associated depreciation expense recognized during the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor) was $1.0 million, $2.9 million, $6.1 million and $5.5 million, respectively.

Product Royalty Revenues

The Company licensed certain rights to Amitiza to third parties in exchange for royalties on net sales of the product. The Company received a double-digit royalty based on a percentage of the gross profits of the licensed products sold during the term of the agreements. The Company recognized such royalty revenue as the related sales occurred. The associated royalty revenue recognized was as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Royalty revenue	$ 36.2	$ 34.9	$ 102.4	$ 70.3

6. Discontinued Operations and Divestitures

Discontinued Operations

Nuclear Imaging: The Company received a total of $9.0 million in contingent consideration in fiscal 2020 (Predecessor) related to the 2017 sale of the Nuclear Imaging business, consisting primarily of the issuance of $9.0 million par value non-voting preferred equity certificates. The preferred equity certificates accrued interest at a rate of 10.0% per annum and were redeemable on the retirement date of July 27, 2025, or earlier if elected by the issuer, for cash at a price equal to the par value and any accrued but unpaid interest. Interest was able to be paid on an annual basis in additional preferred equity certificates. The receipt of the preferred equity certificates are presented as a non-cash investing activity on the consolidated statements of cash flows for fiscal 2020 (Predecessor). In December 2020, the issuer elected to redeem 100% of the outstanding preferred equity certificates, and the Company received a cash payment of $32.5 million, which included $29.8 million for the outstanding preferred equity certificates and $2.7 million for accrued interest receivable through the redemption date. In addition, during fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), a tax benefit of $5.1 million and $18.1 million, respectively, comprised of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business, was recognized due to a lapse of statutes of limitations.

Divestitures

The below businesses did not meet the criteria for discontinued operations classification and accordingly were included in continuing operations for all periods presented.

PreveLeak/Recothrom: In March 2018, the Company completed the sale of a portion of its Hemostasis business, inclusive of its PreveLeak™ Surgical Sealant and RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") products to Baxter International Inc. During fiscal 2020 (Predecessor), the Company recorded a $16.5 million gain on divestiture related to certain commercial milestones for the Recothrom product.

7. Restructuring and Related Charges

During fiscal 2021 (Predecessor), fiscal 2018 (Predecessor) and fiscal 2016 (Predecessor), the Company launched restructuring programs designed to improve its cost structure, neither of which has a specified time period. Charges of $50.0 million to $100.0 million were provided for under the 2021 program and $100.0 million to $125.0 million were provided for under the 2018 and 2016 programs. The 2021 program will commence upon substantial completion of the 2018 program, and has not commenced as of December 30, 2022 (Successor). In addition to the aforementioned restructuring programs, the Company has taken restructuring actions to generate synergies from its acquisitions.

Net restructuring and related charges by segment were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Specialty Brands	$ —	$ —	$ 0.1	$ 0.1
Specialty Generics	0.8	3.5	4.9	0.1
Corporate	11.3	6.1	24.0	49.6
Restructuring and related charges, net	12.1	9.6	29.0	49.8
Less: accelerated depreciation	(1.0)	—	(2.1)	(12.3)
Restructuring charges, net	$ 11.1	$ 9.6	$ 26.9	$ 37.5

Net restructuring and related charges by program from continuing operations were comprised of the following:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
2018 Program	$ 12.1	$ 9.6	$ 29.0	$ 52.0
2016 Program	—	—	—	(0.3)
Acquisition programs	—	—	—	(1.9)
Total programs	12.1	9.6	29.0	49.8
Less: non-cash charges, including accelerated depreciation	(2.2)	(3.6)	(6.3)	(23.8)
Total charges expected to be settled in cash	$ 9.9	$ 6.0	$ 22.7	$ 26.0

The following table summarizes cash activity for restructuring reserves, substantially all of which related to contract termination costs, employee severance and benefits and exiting of certain facilities:

	2018 Program	2016 Program	Acquisition Programs	Total
Balance as of December 27, 2019 (Predecessor)	$ 2.7	$ 31.3	$ 0.2	$ 34.2
Charges from continuing operations	28.6	0.1	—	28.7
Changes in estimate from continuing operations	(0.4)	(0.4)	(1.9)	(2.7)
Cash payments	(20.1)	(30.7)	(0.2)	(51.0)
Reclassifications [1]	(10.0)	—	—	(10.0)
Currency translation and other	0.2	(0.3)	1.9	1.8
Balance as of December 25, 2020 (Predecessor)	1.0	—	—	1.0
Charges from continuing operations	23.7	—	—	23.7
Changes in estimate from continuing operations	(1.0)	—	—	(1.0)
Cash payments	(12.8)	—	—	(12.8)
Balance as of December 31, 2021 (Predecessor)	10.9	—	—	10.9
Charges from continuing operations	7.1	—	—	7.1
Changes in estimate from continuing operations	(1.1)	—	—	(1.1)
Cash payments	(15.9)	—	—	(15.9)
Balance as of June 16, 2022 (Predecessor)	$ 1.0	$ —	$ —	$ 1.0
Balance as of June 17, 2022 (Successor)	$ 1.0	$ —	$ —	$ 1.0
Charges from continuing operations	12.7	—	—	12.7
Changes in estimate from continuing operations	(2.8)	—	—	(2.8)
Cash payments	(6.3)	—	—	(6.3)
Balance as of December 30, 2022 (Successor)	$ 4.6	$ —	$ —	$ 4.6

(1) Represents the reclassification of certain restructuring reserve balances to LSTC as a result of the Company rejecting certain of its executory contracts.

As of December 30, 2022 (Successor), net restructuring and related charges incurred cumulative to date for the 2018 Program were as follows:

	Successor	Predecessor
Specialty Brands	$ —	$ 3.1
Specialty Generics	0.8	18.5
Corporate	11.3	84.0
	$ 12.1	$ 105.6

All of the restructuring reserves were included in accrued and other current liabilities on the Company's consolidated balance sheets. Amounts paid in the future may differ from the amount currently recorded.

8. Income Taxes

The domestic and international components [1] of loss from continuing operations before income taxes were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Domestic	$ (359.4)	$ (2,883.3)	$ (512.2)	$ (656.9)
International	(290.9)	2,072.0	(317.6)	(303.9)
Total	$ (650.3)	$ (811.3)	$ (829.8)	$ (960.8)

(1) Domestic reflects Ireland.

Significant components [1] of income taxes related to continuing operations are as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Current:				
Domestic	$ (32.8)	$ 33.7	$ (33.7)	$ 0.1
International	5.7	(57.6)	(12.7)	(375.4)
Current income tax (benefit) provision	(27.1)	(23.9)	(46.4)	(375.3)
Deferred:				
Domestic	(44.6)	(82.3)	(59.5)	102.2
International	19.7	(391.1)	(0.4)	282.0
Deferred income tax (benefit) provision	(24.9)	(473.4)	(59.9)	384.2
Total	$ (52.0)	$ (497.3)	$ (106.3)	$ 8.9

(1) Domestic reflects Ireland.

The domestic current income tax provision reflects a tax benefit of $7.9 million, $4.1 million, $2.2 million, and $0.2 million from using NOL carryforwards for the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor), and fiscal 2020 (Predecessor), respectively. The international current income tax provision reflects a tax benefit of $61.0 million, $0.1 million, $1.2 million, and $33.4 million from using NOL carryforwards for the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor), and fiscal 2020 (Predecessor), respectively. The fiscal 2020 (Predecessor) international current income tax provision also included a tax benefit of $1.0 million related to refundable credits and a tax benefit of $281.5 million related to carryback claims. The international credit utilization is comprised of credit carryforwards.

During the period from June 17, 2022 through December 30, 2022 (Successor) and the period from January 1, 2022 through June 16, 2022 (Predecessor), net cash payments for income taxes were $3.0 million and $3.0 million, respectively. During fiscal 2021 (Predecessor) net cash refunds for income taxes were $160.0 million and fiscal 2020 (Predecessor) net cash payments for income taxes were $39.9 million. Included within the net cash refunds of $160.0 million were refunds of $178.8 million received as a result of the provisions in the Coronavirus Aid, Relief and Economic Security ("CARES") Act and net payments of $18.8 million related to operational activity.

The reconciliation between domestic income taxes at the statutory rate and the Company's provision for income taxes on continuing operations is as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Benefit for income taxes at domestic statutory income tax rate [1]	$ (81.3)	$ (101.4)	$ (103.7)	$ (120.1)
Adjustments to reconcile to income tax provision:				
Rate difference between domestic and international jurisdictions	(4.7)	226.5	(224.9)	(315.3)
Adjustments to accrued income tax liabilities and uncertain tax positions [2]	—	—	(9.7)	16.7
Credits, principally research and orphan drug	—	(0.9)	(4.7)	(11.2)
Permanently nondeductible and nontaxable items [3]	3.1	(1.7)	9.8	2.8
Emergence	—	(31.6)	—	—
Withholding tax on Swiss distribution	4.7	—	—	—
U.S. Tax Reform [4]	—	—	—	(281.5)
Legal entity reorganization [5]	—	—	—	82.0
Separation costs	—	—	—	8.4
Reorganization items, net	1.7	15.7	36.9	8.8
Other	(1.4)	(3.1)	0.3	0.1
Valuation allowances [6]	25.9	(600.8)	189.7	618.2
(Benefit) provision for income taxes	$ (52.0)	$ (497.3)	$ (106.3)	$ 8.9

(1) The statutory tax rate reflects the Irish statutory tax rate of 12.5%.

(2) Includes interest and penalties on accrued income tax liabilities and uncertain tax positions.

(3) For fiscal 2021 (Predecessor), the permanently nondeductible and nontaxable item were primarily driven by the opioid-related litigation settlement loss.

(4) For fiscal 2020 (Predecessor), the Company recognized a tax benefit as a result of the CARES Act. Associated unrecognized tax benefit and valuation allowance are netted within this line.

(5) Associated unrecognized tax benefit and valuation allowance are netted within this line.

(6) Fiscal 2020 (Predecessor) includes a tax expense of $204.9 million for an increase to the valuation allowance on certain net deferred tax assets that were no longer more likely than not realizable due to the Company's former substantial doubt about its ability to continue as a going concern. Additional valuation allowance impacts are netted within other line items, as referenced in the associated footnotes.

The Successor Company’s rate difference between domestic and international jurisdictions was $4.7 million of tax benefit for the period from June 17, 2022 through December 30, 2022 (Successor). The rate difference between domestic and international jurisdictions was primarily related to $19.7 million of tax benefit attributable to inventory step-up amortization expense, $8.9 million of tax benefit attributable to accretion expense associated with our settlement liabilities and $6.3 million of tax benefit attributable to accretion expense associated with our debt offset by $30.2 million of tax expense predominately attributable to the pretax earnings in various jurisdictions.

The Predecessor Company’s rate difference between domestic and international jurisdictions was $226.5 million of tax expense for the period from January 1, 2022, through June 16, 2022 (Predecessor). The rate difference between domestic and international jurisdictions was primarily related to $128.9 million of tax expense related to fresh-start adjustments, $103.4 million of tax expense attributable to gain on adjustments to LSTC and $12.8 million of tax expense predominately related to the pretax earnings in various jurisdictions offset by $18.6 million of tax benefit related to professional and lender fees.

As a result of the Plan, the Company recognized CODI on its indebtedness, resulting in the utilization of, and reduction to, certain of its tax losses and tax credits in the U.S. and Luxembourg. The emergence from Chapter 11 bankruptcy proceedings resulted in a change in ownership for purposes of IRC Section 382, causing the remaining U.S. tax losses and credits to be limited under IRC Sections 382 and 383. The Company also recognized a U.S. capital loss as a result of the Plan, which may be carried forward to offset capital gains recognized by the Company in the next five years, to the extent it is not reduced by CODI or limited under IRC section 382 or 383. The deferred tax asset associated with the capital loss carryforward is offset by a valuation allowance due to significant uncertainty regarding the Company’s ability to utilize the carryforward prior to its expiration. The portion of deferred tax assets associated with the tax losses and credits that are limited under IRC Section 382 or 383, and that have a remote possibility of being utilized, have been written off. The Plan's tax effect, and impacts on the Company's tax losses and credits, is expected to be finalized when the associated U.S. Federal income tax return is filed in 2023. Refer to Note 4 for further information regarding the Company's income tax accounting policies.

During the period from January 1, 2022 through June 16, 2022 (Predecessor), the Company recognized a tax benefit of $31.6 million upon emergence from Chapter 11 bankruptcy. These impacts of emergence consist of a $1,202.0 million tax benefit related to the revaluation of net deferred tax assets as a result of fresh-start accounting and a $285.3 million tax benefit related to the release of uncertain tax positions, offset by $1,209.8 million of tax expense for the reduction in federal and state NOL carryforwards

from the CODI realized upon emergence from bankruptcy and limitations under IRC Sections 382 and 383, $191.9 million of tax expense related to permanently nondeductible impacts on fair value adjustments, and $54.0 million of tax expense related to prepaid income taxes.

During the period from January 1, 2022 through June 16, 2022 (Predecessor), the Company recognized a tax benefit of $600.8 million related to valuation allowances, consisting of $512.1 million of tax benefit for the reduction in the valuation allowance on the Company's deferred tax assets due to the alleviation of the previous substantial doubt about the Company's ability to continue as a going concern and $88.7 million of tax benefit which mainly offsets impacts included within the benefit for income taxes at the domestic statutory income tax rate and the rate difference between domestic and international jurisdictions.

The rate difference between domestic and international jurisdictions changed to $224.9 million of tax benefit for fiscal 2021 (Predecessor) from $315.3 million of tax benefit for fiscal 2020 (Predecessor). Of the $90.4 million decrease in the tax benefit, $48.9 million of the decrease is attributable to the Medicaid lawsuit and $92.9 million of decrease is predominately attributable to changes in the jurisdictional mix of operating loss resulting from the fiscal 2020 (Predecessor) reorganization of the Company's intercompany financing and associated asset and legal entity ownership, partially offset by $27.6 million of an increase attributable to reorganization items, $13.2 million of an increase attributable to non-restructuring impairment charges and $10.6 million of an increase attributable to the opioid-related litigation settlement loss.

The Company's valuation allowance tax expense was $189.7 million for fiscal 2021 (Predecessor), compared to $618.2 million for fiscal 2020 (Predecessor). Of the $428.5 million decrease in tax expense, $288.9 million of decrease was attributable to operational activity in applicable tax jurisdictions that are fully offset by a valuation allowance and $204.9 million of decrease was attributable to the discrete valuation allowance recorded in fiscal 2020 (Predecessor) on certain beginning-of-the-year net deferred tax assets, partially offset by a $65.3 million increase attributable to deferred remeasurement as a result of tax rate changes. The valuation allowance tax expense mainly offsets impacts included within the benefit for income taxes at the domestic statutory income tax rate and the rate difference between domestic and international jurisdictions.

The following table summarizes the activity related to the Company's unrecognized tax benefits, excluding interest:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Balance at beginning of period	$ 24.8	$ 333.5	$ 349.0	$ 398.6
Additions related to current year tax positions	—	—	—	71.1
Additions related to prior period tax positions	—	—	9.3	9.8
Reductions related to prior period tax positions	—	(306.1)	(2.8)	(14.2)
Settlements	—	(2.6)	(0.2)	(80.3)
Lapse of statutes of limitations	—	—	(21.8)	(36.0)
Balance at end of period	$ 24.8	$ 24.8	$ 333.5	$ 349.0

Unrecognized tax benefits, excluding interest, were reported in the following consolidated balance sheet captions in the amounts shown:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Other assets [1]	$ —	$ 255.7
Deferred income tax asset	9.4	—
Other income tax liabilities	15.4	64.1
Deferred income tax liability	—	13.7
	$ 24.8	$ 333.5

(1) Included as a reduction to deferred tax assets.

Total unrecognized tax benefits ("UTB(s)") of $24.8 million as of both December 30, 2022 (Successor) and June 16, 2022 (Predecessor), if favorably settled, would benefit the effective tax rate. Total UTBs of $77.0 million and $85.9 million as of December 31, 2021 (Predecessor) and December 25, 2020 (Predecessor), respectively, if favorably settled, would benefit the effective tax rate with the remaining reflected as a write-off of related other tax assets. During the period January 1, 2022 through June 16, 2022 (Predecessor), the decrease of $306.1 million primarily resulted from fresh-start adjustments. During fiscal 2021 (Predecessor) and 2020 (Predecessor), due to a lapse of statutes of limitations, $5.1 million and $18.1 million of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business were eliminated, and a benefit of $5.1 million and $18.1 million was recorded in discontinued operations within the consolidated statement of operations, respectively. The Company recorded an increase to accrued

interest and penalties of $0.6 million during the period from June 17, 2022 through December 30, 2022 (Successor) and a net decrease of $16.7 million during the period from January 1, 2022 through June 16, 2022 (Predecessor). Interest and penalties activity during fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), was a net increase of $2.2 million and a net decrease of $16.2 million, respectively. The total amount of accrued interest and penalties related to uncertain tax positions was $2.8 million and $18.9 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively.

Within the next twelve months, the unrecognized tax benefits and the related interest and penalties are not expected to significantly increase or decrease.

Certain of the Company's subsidiaries continue to be subject to examination by taxing authorities. The earliest open years subject to examination for the U.S. federal, U.S. state and other jurisdictions, including Ireland, Japan, Luxembourg, Switzerland and the U.K. is 2013.

Income taxes payable, including uncertain tax positions and related interest accruals, was reported in the following consolidated balance sheet captions in the amounts shown:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Accrued and other current liabilities	$ 3.6	$ 1.7
Other income tax liabilities	18.2	83.2
	$ 21.8	$ 84.9

Tax receivables were included in the following consolidated balance sheet captions in the amounts shown:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Other assets	$ —	$ 141.3
Prepaid expenses and other current assets	179.5	36.5
	$ 179.5	$ 177.8

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The components of the net deferred tax asset (liability) at the end of each fiscal year were as follows:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Deferred tax assets:		
Tax loss and credit carryforward	$ 3,646.0	$ 4,147.5
Capital tax loss carryforward and related assets	1,412.6	1,605.0
Intangible assets	278.4	—
Opioid-Related Litigation Settlement liability	111.7	294.7
Excess interest	84.0	159.5
Other	159.8	292.2
	5,692.5	6,498.9
Deferred tax liabilities:		
Intangible assets	—	(108.5)
Investment in partnership	(67.4)	(67.1)
Other	(157.0)	—
	(224.4)	(175.6)
Net deferred tax asset before valuation allowances	5,468.1	6,323.3
Valuation allowances	(4,992.9)	(6,344.2)
Net deferred tax asset (liability)	$ 475.2	$ (20.9)

The net deferred tax asset before valuation allowances was $5,468.1 million as of December 30, 2022 (Successor), compared to $6,323.3 million as of December 31, 2021 (Predecessor). This decrease consists of $904.5 million of a decrease related to fresh-start activity and $72.8 million of a net decrease associated with payments and accretion on the opioid-related litigation settlement offset by a $61.5 million increase associated with amortization on intangible assets and a $60.6 million increase predominately related to tax loss and other operational activity. The $904.5 million decrease related to fresh-start activity consists of (i) CODI realized upon emergence from bankruptcy and limitations under IRC Sections 382 and 383 which resulted in reductions to tax loss and credit carryforward, capital tax loss carryforward, and excess interest deferred tax assets; (ii) fair value adjustments which resulted in

reductions to the opioid-related litigation settlement liability deferred tax assets and intangible asset deferred tax liabilities, and increases to other deferred tax liabilities and (iii) increases to certain deferred tax assets due to the release of uncertain tax positions.

The deferred tax asset valuation allowances were $4,992.9 million and $6,344.2 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively. The valuation allowance as of December 30, 2022 (Successor) relates primarily to the uncertainty of the utilization of certain deferred tax assets, driven by domestic and international net operating and capital losses, credits, and intangible assets. As of December 30, 2022 (Successor), due to the alleviation of the previous substantial doubt about the Company's ability to continue as a going concern, the associated valuation allowances were released through fresh-start accounting at emergence. The valuation allowance as of December 31, 2021 (Predecessor) was related to the Company's substantial doubt about its ability to continue as a going concern, as well as the uncertainty of the utilization of certain deferred tax assets, driven by domestic and international net operating and capital losses, credits, intangible assets and the opioid-related litigation settlement liability.

Deferred taxes were included in the following consolidated balance sheet captions in the amounts shown:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Deferred income tax asset	$ 475.5	$ —
Deferred income tax liability	(0.3)	(20.9)
Net deferred tax asset (liability)	$ 475.2	$ (20.9)

As of December 30, 2022 (Successor), the Company had approximately $3,600.6 million of NOL carryforwards in certain international jurisdictions measured at the applicable statutory rates, of which $1,532.4 million have no expiration and the remaining $2,068.2 million will expire in future years through 2043. As of December 30, 2022 (Successor), the Company had $43.5 million of domestic NOL carryforwards measured at the applicable statutory rates, which have no expiration date.

As of December 30, 2022 (Successor), the Company had $8.7 million of capital loss carryforwards in certain international jurisdictions measured at the applicable statutory rates, which will expire in 2027. As of December 30, 2022 (Successor), the Company had approximately $969.5 million of domestic capital loss carryforwards measured at the applicable statutory rates, which have no expiration date.

As of December 30, 2022 (Successor), the Company had $1.9 million of tax credits available to reduce future income taxes payable, in international jurisdictions, which will expire in future years through 2043.

As of December 30, 2022 (Successor), the Company's taxable financial reporting basis in subsidiaries exceeded its corresponding tax basis by $3.1 million. Such excess amount is indefinitely reinvested and it is not practicable to determine the associated potential tax liability due to the complexity of the Company's legal entity structure as well as the timing, extent, and nature of any hypothetical realization.

9. Loss per Share

Loss per share is computed by dividing net loss by the number of weighted-average shares outstanding during the period. Dilutive securities, including participating securities, have not been included in the computation of loss per share as the Company reported a net loss from continuing operations during all periods presented below and therefore, the impact would have been anti-dilutive.

The weighted-average number of shares outstanding used in the computations of both basic and diluted loss per share were as follows (*in millions*):

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Basic	13.2	84.8	84.7	84.5

The computation of diluted weighted-average shares outstanding for the periods June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor) excluded approximately zero, 0.5 million, 5.2 million and 5.6 million, respectively, shares of equity awards because the effect would have been anti-dilutive.

10. Inventories

Inventories were comprised of the following at the end of each period:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Raw materials	$ 80.2	$ 59.8
Work in process	552.1	196.4
Finished goods	315.3	91.0
Inventories	$ 947.6	$ 347.2

11. Property, Plant and Equipment

The gross carrying amount and accumulated depreciation of property, plant and equipment were comprised of the following at the end of each period:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Land	$ 51.0	$ 43.5
Buildings	127.2	387.8
Capitalized software	17.5	121.1
Machinery and equipment	216.8	1,254.1
Construction in process	72.5	80.1
	485.0	1,886.6
Less: accumulated depreciation	(27.4)	(1,110.6)
Property, plant and equipment, net	$ 457.6	$ 776.0

Depreciation expense was as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Depreciation expense	$ 28.8	$ 40.0	$ 94.7	$ 114.0

12. Leases

Lease assets and liabilities related to the Company's operating leases are reported in the following consolidated balance sheet captions:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Other assets	$ 38.1	$ 35.0
Accrued and other current liabilities	$ 10.3	$ 11.1
Other liabilities	30.4	20.0
Other current and non-current liabilities subject to compromise	—	0.4
Total lease liabilities	$ 40.7	$ 31.5

Dependent on the nature of the leased asset, lease expense is included within cost of sales or SG&A. The primary components of lease expense were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Lease cost:				
Operating lease cost	$ 7.9	$ 8.7	$ 19.6	$ 21.2
Short-term lease cost	1.6	0.4	1.1	1.1
Variable lease cost	1.5	1.2	2.4	3.1
Total lease cost	$ 11.0	$ 10.3	$ 23.1	$ 25.4

Lease terms and discount rates were as follows:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Weighted-average remaining lease term (in years) - operating lease	6.7	5.7
Weighted-average discount rate - operating leases	11.9 %	4.4 %

Contractual maturities of operating lease liabilities as of December 30, 2022 (Successor) were as follows:

Fiscal 2023	$ 14.9
Fiscal 2024	12.0
Fiscal 2025	7.9
Fiscal 2026	5.0
Fiscal 2027	3.2
Thereafter	18.3
Total lease payments	61.3
Less: Interest	(20.6)
Present value of lease liabilities	$ 40.7

Other supplemental cash flow information related to leases were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 9.2	$ 9.4	$ 20.4	$ 23.1
Lease assets obtained in exchange for lease obligations:				
Operating leases	7.1	13.4	2.6	6.9

13. Intangible Assets

Intangible Assets

The gross carrying amount and accumulated amortization of intangible assets were comprised of the following at the end of each period:

	Successor		Predecessor	
	December 30, 2022		December 31, 2021	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 3,041.2	$ 318.7	$ 10,404.0	$ 5,160.4
License agreements	—	—	120.1	82.1
Trademarks	—	—	77.7	26.9
Total	$ 3,041.2	$ 318.7	$ 10,601.8	$ 5,269.4
Non-Amortizable:				
Trademarks	$ —		$ 35.0	
In-process research and development	121.3		81.0	
Total	$ 121.3		$ 116.0	

The Company recorded impairment charges related to its Specialty Brands segment totaling $154.9 million and $63.5 million during fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), respectively. The valuation method used to approximate fair value in each of these periods was based on the estimated discounted cash flows for the respective asset. The fiscal 2021 (Predecessor) impairment charge included a partial impairment of $90.4 million related to Amitiza as the undiscounted cash flows were less than its net book value, and a full impairment of $64.5 million related to MNK-6105 and MNK-6106 as the Company decided it would no longer pursue further development of this IPR&D asset. The fiscal 2020 impairment charge was related to the Ofirmev product and was primarily driven by a change in the estimate of the asset's useful life resulting in its undiscounted cash flow being less than its net book value.

As part of fresh-start accounting, as of the Effective Date, the Company wrote-off the existing intangible assets and accumulated amortization of the Predecessor and recorded $3,152.2 million to reflect the fair value of intangible assets of the Successor (see also Note 3). Such adjustment included $100.0 million in relation to the Company's PRV that was awarded under an FDA program intended to encourage the development of certain product applications for therapies used to treat or prevent material threat medical countermeasures. On June 30, 2022, subsequent to the Effective Date, the Company completed the sale of its PRV for $100.0 million and received net proceeds of $65.0 million as the buyer remitted the remaining $35.0 million to the General Unsecured Claims Trustee pursuant to the terms of (i) the Plan, and (ii) that certain General Unsecured Claims Trust Agreement entered into in connection with the Plan.

Intangible assets of the Successor as of the Effective Date consisted of the following:

	Carrying Amount	Amortization Method	Amortization Period *(in years)*	Discount Rate	Segment
Amortizable completed technology:					
Acthar Gel	$ 1,069.0	Sum of the years digits	13.5	14.2%	Specialty Brands
Therakos	913.8	Sum of the years digits	10.0	14.0	Specialty Brands
Amitiza	84.5	Sum of the years digits	3.0	14.0	Specialty Brands
INOmax	652.9	Sum of the years digits	9.0	14.0	Specialty Brands
StrataGraft	56.8	Straight-line	11.0	14.0	Specialty Brands
Generics	71.4	Straight-line	5.0	13.3	Specialty Generics
APAP	70.5	Straight-line	20.5	13.0	Specialty Generics
	2,918.9				
Non-Amortizable in-process research and development:					
Terlivaz [(1)]	104.8	Straight-line	7.0	15.0	Specialty Brands
Generics IPR&D	128.5	Not applicable	Not applicable	14.0	Specialty Generics
	233.3				
	$ 3,152.2				

(1) Subsequent to the Effective Date, Terlivaz was approved by the FDA and was transferred to amortizable, finite-lived completed technology. See further discussion below.

Amitiza

Beginning January 1, 2022 (Predecessor), the Company changed its amortization method used for the Amitiza intangible asset from the straight-line method to the sum of the years digits method, an accelerated method of amortization, to more accurately reflect the consumption of economic benefits over the remaining useful life of the asset. This change in amortization method resulted in additional amortization expense of $21.7 million, which impacted basic loss per share by $0.26 for the period January 1, 2022 through June 16, 2022 (Predecessor).

Terlivaz

On September 14, 2022, the Company announced that the FDA had approved Terlivaz for injection. Upon FDA approval, the Company transferred the total $104.8 million of asset value from non-amortizable indefinite-lived acquired IPR&D rights to amortizable, finite-lived completed technology and began amortization of the asset in tandem with the first commercial shipment of the product during the fourth quarter of fiscal 2022. The FDA approval gave rise to a $17.5 million milestone payable and a corresponding intangible asset was recorded, which is amortized over the useful life of the related asset that began with the first commercial shipment of the product during the fourth quarter of fiscal 2022.

Intangible asset amortization expense

Intangible asset amortization expense was as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Amortization expense	$ 318.7	$ 281.8	$ 581.1	$ 771.2

The estimated aggregate amortization expense on intangible assets owned by the Company and being amortized as of December 30, 2022 (Successor), is expected to be as follows:

Fiscal 2023	$ 509.3
Fiscal 2024	446.1
Fiscal 2025	385.1
Fiscal 2026	337.5
Fiscal 2027	284.4

14. Debt

Debt was comprised of the following at the end of each period:

	Successor			Predecessor	
	December 30, 2022			December 31, 2021	
	Principal	Carrying Value [1]	Unamortized Discount and Debt Issuance Costs [1]	Principal	Unamortized Discount and Debt Issuance Costs
10.00% first lien senior secured notes due April 2025	$ 495.0	$ 475.9	$ —	$ 495.0	$ 5.9
10.00% second lien senior secured notes due April 2025	321.9	242.2	—	—	—
2017 Replacement Term loan due September 2027	1,374.1	1,222.1	—	—	—
2018 Replacement Term loan due September 2027	364.8	326.9	—	—	—
11.50% first lien senior secured notes due December 2028	650.0	650.0	20.8	—	—
10.00% second lien senior secured notes due June 2029	328.3	175.5	—	—	—
Revolving credit facility due February 2022	—	—	—	900.0	0.2
9.50% debentures due May 2022	—	—	—	10.4	—
5.75% senior notes due August 2022	—	—	—	610.3	—
8.00% debentures due March 2023	—	—	—	4.4	—
4.75% senior notes due April 2023	—	—	—	133.7	—
5.625% senior notes due October 2023	—	—	—	514.7	—
Term loan due September 2024	—	—	—	1,396.5	—
Term loan due February 2025	—	—	—	370.7	—
10.00% second lien senior notes due April 2025	—	—	—	322.9	—
5.50% senior notes due April 2025	—	—	—	387.2	—
Total debt	3,534.1	3,092.6	20.8	5,145.8	6.1
Less: Current portion	(44.1)	(44.1)	—	(1,395.0)	(6.1)
Less: Amounts reclassified to liabilities subject to compromise	—	—	—	(3,750.8)	—
Total long-term debt, net of current portion	$ 3,490.0	$ 3,048.5	$ 20.8	$ —	$ —

(1) Upon adoption of fresh-start accounting, the Company recorded its debt instruments at fair value utilizing the Black-Derman-Toy model, which takes into consideration prepayment options and a credit-adjusted discount rate. Subsequent to the Effective Date, the Company accounted for its debt instruments utilizing the amortized cost method and accretes the instruments up from their fair value to the principal amount over the term of the respective instruments. Such accretion expense is reflected as interest expense on the consolidated statement of operations for the successor period.

The commencement of the Chapter 11 Cases constituted an event of default under certain of the Company's predecessor debt agreements. As a result of the Chapter 11 Cases, the principal and interest due under these debt instruments became immediately due and payable. However, any efforts to enforce payment was automatically stayed in accordance with the applicable provisions of the Bankruptcy Code.

On the Effective Date, the principal balance outstanding under the Existing Term Loans of $1,762.6 million, Existing 2L Notes of $322.9 million, Guaranteed Unsecured Notes of $1,512.2 million, 9.50% debentures of $10.4 million, 8.00% debentures of $4.4 million and 4.75% senior notes due April 2023 of $133.7 million were canceled and the Company entered into new Takeback Term Loans, New 2L Notes, and Takeback 2L Notes (all further described in Note 2). The Existing 1L Notes were reinstated and the Existing Revolver was paid in full in cash. Additionally, the Company issued New 1L Notes and entered into a receivables financing facility (discussed further below).

Successor Company Indebtedness

Takeback Term Loans

On the Effective Date and pursuant to the Plan, the Issuers entered into the Takeback Term Loans, each pursuant to a Credit Agreement, dated as of the Effective Date ("Credit Agreement"), among Mallinckrodt plc, the Issuers, the lenders party thereto from time to time, Acquiom Agency Services LLC and Seaport Loan Products LLC, as co-administrative agents, and Deutsche Bank AG New York Branch, as collateral agent. The Takeback Term Loans were issued to the holders of the existing senior secured term loans incurred by the Issuers in satisfaction thereof. All obligations under the Takeback Term Loans are unconditionally guaranteed by Mallinckrodt plc, certain of its direct or indirect wholly owned U.S. subsidiaries, each of its direct or indirect wholly owned subsidiaries that owns directly or indirectly any such wholly owned U.S. subsidiary, and certain other subsidiaries, subject to certain exceptions (collectively, the "Guarantors") and are secured by a security interest in certain assets of the Issuers and the Guarantors.

The 2017 Replacement Term Loans bear interest at a rate equal to, at the option of the borrowers thereunder, adjusted LIBOR, subject to a floor of 0.75%, plus a spread equal to 5.25% or an alternate base rate, subject to a floor of 1.75%, plus a spread equal to 4.25%. The 2018 Replacement Term Loans bear interest at a rate equal to, at the option of the borrowers thereunder, adjusted LIBOR, subject to a floor of 0.75%, plus a spread equal to 5.50% or an alternate base rate, subject to a floor of 1.75%, plus a spread equal to 4.50%. The LIBOR reference rate under the Takeback Term Loans will be replaced with the Secured Overnight Financing Rate ("SOFR") plus a spread of (i) 0.11448% for an available tenor of one-month's duration, (ii) 0.26161% for an available tenor of three months' duration, or (iii) 0.42826% for an available tenor of six-months' duration and is currently anticipated to occur on or about June 30, 2023. Interest on the Takeback Term Loans is payable at the end of each applicable interest period, but in no event less frequently than quarterly. The Takeback Term Loans mature on September 30, 2027. Amounts outstanding under the Takeback Term Loans may be prepaid at any time, subject, under certain circumstances, to a 1.00% prepayment premium on prepayments made within the first nine months of the Effective Date. The Issuers may be obligated to prepay the Takeback Term Loans with the net proceeds of certain asset sales and recovery events, subject to certain qualifications and exceptions. The Issuers may also be obligated to prepay the Term Loans with a specified percentage of excess cash flow, subject to certain qualifications and exceptions.

The Credit Agreement contains certain customary affirmative and negative covenants, representations and warranties and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the Credit Agreement could result in the acceleration of all outstanding borrowings under the Takeback Term Loans and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries.

11.50% First Lien Senior Secured Notes due 2028

On June 15, 2022, the Issuers and Mallinckrodt plc entered into a purchase agreement ("Note Purchase Agreement") with certain Purchasers (as defined in the Note Purchase Agreement) with respect to the issuance and sale of $650.0 million aggregate principal amount of New 1L Notes. The Note Purchase Agreement contains customary representations, warranties and covenants and includes the terms and conditions for the sale of the New 1L Notes, and other terms and conditions customary in agreements of this type. The net proceeds of the issuance of the New 1L Notes were applied to repay in part the existing senior secured revolving credit facility incurred by the Issuers and certain of their respective subsidiaries. The issuance of the New 1L Notes was exempt from registration under the Securities Act.

The New 1L Notes were issued by the Issuers on the Effective Date pursuant to an indenture, dated as of the Effective Date ("New 1L Notes Indenture") among the Issuers, Mallinckrodt plc, the Subsidiary Note Guarantors (as defined below), Wilmington Savings Fund Society, FSB, as first lien trustee, and Deutsche Bank AG New York Branch, as first lien collateral agent. The New 1L Notes mature on December 15, 2028.

Interest on the New 1L Notes, at a rate of 11.50% per annum, is payable semi-annually in cash on June 15 and December 15 of each year, which commenced on December 15, 2022.

The Issuers may redeem some or all of the New 1L Notes prior to June 15, 2027 by paying a "make-whole" premium, plus accrued and unpaid interest, if any. The Issuers may redeem some or all of the New 1L Notes on or after June 15, 2027 at par, plus accrued and unpaid interest, if any. The Issuers may also redeem all, but not less than all, of the New 1L Notes at any time at a price of 100% of their principal amount, plus accrued and unpaid interest, if any, in the event the Issuers become obligated to pay additional amounts as a result of changes affecting certain withholding tax laws applicable to payments on the New 1L Notes. The Issuers are obligated to offer to repurchase the New 1L Notes (a) at a price of 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) at a price of 100% of their principal amount plus accrued and unpaid interest, if any, with the net proceeds of certain asset sales. These obligations are subject to certain qualifications and exceptions.

The New 1L Notes Indenture contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the New 1L Notes Indenture could result in the acceleration of the New 1L Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. The New 1L Notes are jointly and severally guaranteed on a secured, unsubordinated basis by Mallinckrodt plc and each of its subsidiaries (other than the Issuers) that guarantees the obligations under the Takeback Term Loans ("Subsidiary Note Guarantors"). The New 1L Notes and the guarantees thereof are secured by liens on the same assets of the Issuers, Mallinckrodt plc and the Subsidiary Note Guarantors that are subject to liens securing the Takeback Term Loans, subject to certain exceptions.

Existing 10.00% First Lien Senior Secured Notes due 2025

The Existing 1L Notes were initially issued by the Issuers on April 7, 2020 pursuant to an indenture, dated as of April 7, 2020 among the Issuers, Mallinckrodt plc, the Subsidiary Note Guarantors, Wilmington Savings Fund Society, FSB, as first lien trustee, and Deutsche Bank AG New York Branch, as first lien collateral agent. The Existing 1L Notes mature on April 15, 2025. On the Effective Date and pursuant to the Plan and the Scheme of Arrangement, the Issuers' Existing 1L Notes in an aggregate principal amount of $495.0 million and the note documents relating thereto were reinstated.

In addition, pursuant to the terms of the Existing 1L Notes Indenture, the Issuers, Mallinckrodt plc, the Subsidiary Note Guarantors, Wilmington Savings Fund Society, FSB, as first lien trustee, and Deutsche Bank AG New York Branch, as first lien

collateral agent, entered into the Existing 1L Notes Indenture, dated as of the Effective Date, pursuant to which certain additional assets were added to the collateral securing the Existing 1L Notes and the guarantees thereof.

Interest on the Existing 1L Notes, at a rate of 10.00% per annum, is payable semi-annually in cash on April 15 and October 15 of each year, which commenced on October 15, 2020.

The Issuers may redeem some or all of the Existing 1L Notes prior to April 15, 2024 at specified redemption prices, plus accrued and unpaid interest, if any. The Issuers may redeem some or all of the Existing 1L Notes on or after April 15, 2024 at par, plus accrued and unpaid interest, if any. The Issuers may also redeem all, but not less than all, of the Existing 1L Notes at any time at a price of 100% of their principal amount, plus accrued and unpaid interest, if any, in the event the Issuers become obligated to pay additional amounts as a result of changes affecting certain withholding tax laws applicable to payments on the Existing 1L Notes. The Issuers are obligated to offer to repurchase the Existing 1L Notes (a) at a price of 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) at a price of 100% of their principal amount plus accrued and unpaid interest, if any, with the net proceeds of certain asset sales. These obligations are subject to certain qualifications and exceptions.

The Existing 1L Notes Indenture contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the Existing 1L Notes could result in the acceleration of all outstanding borrowings under the Existing 1L Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. The Existing 1L Notes are jointly and severally guaranteed on a secured, unsubordinated basis by Mallinckrodt plc and the Subsidiary Note Guarantors. The Existing 1L Notes and the guarantees thereof are secured by liens on the same assets of the Issuers, Mallinckrodt plc and the Subsidiary Note Guarantors that are subject to liens securing the Takeback Term Loans, subject to certain exceptions.

10.00% Second Lien Senior Secured Notes due 2025

On the Effective Date, pursuant to the Plan and the Scheme of Arrangement, the Issuers issued New 2L Notes in an aggregate principal amount of $322.9 million to the holders of the Issuers' Existing 2L Notes in satisfaction thereof. The New 2L Notes were issued pursuant to an Indenture, dated as of the Effective Date ("New 2L Notes Indenture"), among the Issuers, Mallinckrodt plc, the Subsidiary Note Guarantors and Wilmington Savings Fund Society, FSB, as second lien trustee and second lien collateral agent. The New 2L Notes mature on April 15, 2025. The issuance of the New 2L Notes was exempt from registration under the Securities Act.

Interest on the New 2L Notes, at a rate of 10.00% per annum, is payable semi-annually in cash on April 15 and October 15 of each year, which commenced on October 15, 2022.

The Issuers may redeem some or all of the New 2L Notes prior to April 15, 2024 at specified redemption prices, plus accrued and unpaid interest, if any. The Issuers may redeem some or all of the New 2L Notes on or after April 15, 2024 at par, plus accrued and unpaid interest, if any. The Issuers may also redeem all, but not less than all, of the New 2L Notes at any time at a price of 100% of their principal amount, plus accrued and unpaid interest, if any, in the event the Issuers become obligated to pay additional amounts as a result of changes affecting certain withholding tax laws applicable to payments on the New 2L Notes. The Issuers are obligated to offer to repurchase the New 2L Notes (a) at a price of 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) at a price of 100% of their principal amount plus accrued and unpaid interest, if any, with the net proceeds of certain asset sales. These obligations are subject to certain qualifications and exceptions.

The New 2L Notes Indenture contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the New 2L Notes Indenture could result in the acceleration of the New 2L Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. The New 2L Notes are jointly and severally guaranteed, subject to certain exceptions, on a secured, unsubordinated basis by Mallinckrodt plc and the Subsidiary Note Guarantors. The New 2L Notes and the guarantees thereof are secured by liens on the same assets of the Issuers, Mallinckrodt plc and the Subsidiary Note Guarantors that are subject to liens securing the Takeback Term Loans, subject to certain exceptions.

10.00% Second Lien Senior Secured Notes due 2029

On the Effective Date, pursuant to the Plan and the Scheme of Arrangement, the Issuers issued Takeback 2L Notes in an aggregate principal amount of $375.0 million to the holders of the Issuers' Guaranteed Unsecured Notes in partial satisfaction thereof. The Takeback 2L Notes were issued pursuant to an indenture, dated as of the Effective Date ("Takeback 2L Notes Indenture"), among the Issuers, Mallinckrodt plc, the Subsidiary Note Guarantors and Wilmington Savings Fund Society, FSB, as second lien trustee and second lien collateral agent. The Takeback 2L Notes mature on June 15, 2029. The issuance of the Takeback 2L Notes was exempt from registration under the Securities Act.

Interest on the Takeback 2L Notes, at a rate of 10.00% per annum, is payable semi-annually in cash on June 15 and December 15 of each year, which commenced on December 15, 2022.

The Issuers may redeem some or all of the Takeback 2L Notes prior to June 15, 2026 by paying a "make-whole" premium, plus accrued and unpaid interest, if any. The Issuers may redeem some or all of the Takeback 2L Notes on or after June 15, 2026 but prior

to June 15, 2028 at specified redemption prices, plus accrued and unpaid interest, if any. The Issuers may redeem some or all of the Takeback 2L Notes on or after June 15, 2028 at par, plus accrued and unpaid interest, if any. In addition, prior to June 15, 2026, the Issuers may redeem up to 40% of the aggregate principal amount of the Takeback 2L Notes with the net proceeds of certain equity offerings. The Issuers may also redeem all, but not less than all, of the Takeback 2L Notes at any time at a price of 100% of their principal amount, plus accrued and unpaid interest, if any, in the event the Issuers become obligated to pay additional amounts as a result of changes affecting certain withholding tax laws applicable to payments on the Takeback 2L Notes. The Issuers are obligated to offer to repurchase the Takeback 2L Notes (a) at a price of 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) at a price of 100% of their principal amount plus accrued and unpaid interest, if any, with the net proceeds of certain asset sales. These obligations are subject to certain qualifications and exceptions.

The Takeback 2L Notes Indenture contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the Takeback 2L Notes Indenture could result in the acceleration of the Takeback 2L Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. The Takeback 2L Notes are jointly and severally guaranteed, subject to certain exceptions, on a secured, unsubordinated basis by Mallinckrodt plc and the Subsidiary Note Guarantors. The Takeback 2L Notes and the guarantees thereof are secured by liens on the same assets of the Issuers, Mallinckrodt plc and the Subsidiary Note Guarantors that are subject to liens securing the Takeback Term Loans, subject to certain exceptions.

Accounts Receivable Financing Facility

On the Effective Date, MEH, Inc. ("MEH"), as servicer, ST US AR Finance LLC, a direct wholly owned subsidiary of MEH ("ST US AR"), as borrower, the lenders party thereto, and the letter of credit issuers party thereto entered into a receivables financing facility ("Receivables Financing Facility") pursuant to an ABL Credit Agreement ("Receivables Financing Credit Agreement") and a Purchase and Sale Agreement ("Purchase and Sale Agreement"). Under the Receivables Financing Facility, ST US AR may borrow money up to an amount based on a borrowing base with a maximum draw of up to $200.0 million, which may vary depending on the underlying receivables amount. Borrowings are secured by a first-lien security interest under the Receivables Financing Facility on existing and future accounts receivables and related assets that have been sold from certain subsidiaries of MEH to ST US AR. The Receivables Financing Facility includes customary affirmative and negative covenants for transactions of this type. From the closing date until the last day of the first fiscal quarter after the closing date, borrowings bear interest at a rate of (a) either (i) the alternate base rate or (ii) SOFR, and (b) an applicable margin. On the first day of each fiscal quarter thereafter, the applicable margins shall be determined from a pricing grid based upon the historical excess availability for the most recent fiscal quarter ended immediately prior. The Receivables Financing Facility matures on the earlier of June 16, 2026 and a date that is 91 days prior to the maturity date of other material debt or any other material indebtedness that is incurred after the closing date. ST US AR may borrow, pay or prepay and reborrow under the Receivables Financing Facility at any time. So long as there is not an overadvance under the Receivables Financing Facility, and subject to certain other conditions, ST US AR can elect to repay borrowings or use cash to make distributions to MEH and certain subsidiaries of MEH that have contributed receivables to ST US AR. The obligations under the Receivables Financing Facility are not guaranteed by MEH or any of its restricted subsidiaries. The Receivables Financing Facility is subject to customary events of defaults for transactions of this type. As of December 30, 2022 (Successor), the Company had no outstanding borrowings on its Receivables Financing Facility.

Applicable interest rate

As of December 30, 2022 (Successor), the applicable interest rate and outstanding principal on the Company's debt instruments were as follows:

	Applicable interest rate	Outstanding principal
Fixed-rate instruments	10.54 %	$ 1,795.2
2017 Replacement Term Loan due September 2027	9.99	1,374.1
2018 Replacement Term Loan due September 2027	10.24	364.8

The Company's stated long-term debt principal maturity amounts as of December 30, 2022 are as follows:

Fiscal 2023	$ 44.1
Fiscal 2024	33.0
Fiscal 2025	861.0
Fiscal 2026	44.0
Fiscal 2027	1,573.7

15. Retirement Plans

Defined Benefit Plans

The Company sponsors a number of defined benefit retirement plans covering certain of its U.S. employees and non-U.S. employees. As of December 30, 2022 (Successor), U.S. plans represented 33.9% of the Company's remaining projected benefit obligation. The Company generally does not provide postretirement benefits other than retirement plan benefits for its employees; however, certain of the Company's U.S. employees participate in postretirement benefit plans that provide medical benefits. These plans are unfunded.

The benefit obligation recognized on the consolidated balance sheets were $18.7 million and $27.3 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively, for pension benefits and $26.8 million and $37.3 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively, for postretirement benefits. The weighted-average discount rate to determine benefit obligations for the Company's pension and postretirement benefit plans ranged from 1.0% to 5.5%. For the Company's unfunded U.S. plans, the discount rate is based on the market rate for a broad population of AA-rated (Moody's Investor Services, Inc. or Standard & Poor's Corporation) corporate bonds over $250.0 million.

Defined Contribution Retirement Plans

The Company maintains one active tax-qualified 401(k) retirement plan and one active non-qualified deferred compensation plan in the U.S. The 401(k) retirement plan provides for an automatic Company contribution of 3% of an eligible employee's pay, with an additional Company matching contribution generally equal to 50.0% of each employee's elective contribution to the plan up to 8% of the employee's eligible pay. The deferred compensation plan permitted eligible employees to defer a portion of their compensation. The deferred compensation plan is currently frozen for employee deferrals. Total defined contribution expense was $7.8 million, $9.6 million, $22.2 million and $26.0 million for the period June 17, 2022 through December 30, 2022 (Successor), January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), respectively.

Rabbi Trusts and Other Investments

The Company maintains several rabbi trusts, the assets of which are used to pay retirement benefits. The rabbi trust assets are subject to the claims of the Company's creditors in the event of the Company's insolvency. Plan participants are general creditors of the Company with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in other assets on the consolidated balance sheets. Note 20 provides additional information regarding the debt and equity securities. The carrying value of the 55 and 57 life insurance contracts held by these trusts was $39.5 million and $43.4 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively. These contracts had a total death benefit of $81.0 million and $86.4 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively. However, there are outstanding loans against the policies amounting to $21.6 million and $20.8 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively.

The Company has insurance contracts that serve as collateral for certain of the Company's non-U.S. pension plan benefits. These insurance contracts totaled $7.3 million and $7.9 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively. These amounts were included in other assets on the consolidated balance sheets.

16. Equity

Preferred Shares

Mallinckrodt is authorized to issue 500,000,000 preferred shares, par value of $0.01 per share, none of which were issued or outstanding as of December 30, 2022 (Successor). Rights as to dividends, return of capital, redemption, conversion, voting and otherwise with respect to these shares may be determined by Mallinckrodt's Board of Directors on or before the time of issuance. In the event of the liquidation of the Company, the holders of any preferred shares then outstanding would, if issued on such terms that they carry a preferential distribution entitlement on liquidation, be entitled to payment to them of the amount for which the preferred shares were subscribed and any unpaid dividends prior to any payment to the ordinary shareholders.

Share Repurchases

The Predecessor's Board of Directors previously authorized share repurchase programs. Under the March 2017 Repurchase Program, $1,000.0 million was authorized for share repurchase. No shares were repurchased during the period from January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021(Predecessor) and fiscal 2020 (Predecessor). The March 2017 Repurchase Program

was terminated upon the emergence from bankruptcy.

On September 29, 2022, during the 2022 Annual General Meeting of Shareholders, the Company's shareholders approved that the Company may make market purchases or overseas market purchases of a maximum of 1,317,093 Ordinary Shares of the Company. The maximum price to be paid for any Ordinary Share shall be an amount equal to 110% of the closing price on the relevant stock exchange on which the Ordinary Shares are listed (such as the New York Stock Exchange American LLC) for the Ordinary Shares on the trading day preceding the day on which the relevant share is purchased by the Company or the relevant subsidiary of the Company, and the minimum price to be paid for any Ordinary Share shall be the nominal value of such share. This repurchase program will expire at the close of business on March 29, 2024 unless renewed at the Annual General Meeting of Shareholders in 2023. No shares were repurchased during the period from June 17, 2022 through December 30, 2022 (Successor).

The Company also repurchases shares from certain employees in order to satisfy employee tax withholding requirements in connection with the vesting of restricted shares. In addition, the Company repurchases shares to settle certain option exercises. The Company spent zero for each of the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022 through June 16, 2022 (Predecessor) and fiscal 2021 (Predecessor), respectively, and $0.4 million during and fiscal 2020 (Predecessor) to acquire shares in connection with equity-based awards.

17. Share Plans

Total share-based compensation cost was $1.4 million, $1.7 million, $10.2 million and $25.3 million for the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor), respectively. These amounts are generally included within SG&A expenses in the consolidated statements of operations. The Company recognized a related tax benefit associated with this expense of zero for the period June 17, 2022 through December 30, 2022 (Successor), the period January 1, 2022 through June 16, 2022 (Predecessor), fiscal 2021 (Predecessor) and fiscal 2020 (Predecessor).

Stock Compensation Plans

On the Effective Date, all outstanding equity-based awards under the Mallinckrodt Pharmaceuticals Stock and Incentive Plan, as amended and restated effective February 23, 2022, were automatically cancelled without consideration.

A new Mallinckrodt Pharmaceuticals Stock and Incentive Plan became effective on the Effective Date, which provides for the award of share options, share appreciation rights, annual performance bonuses, long-term performance awards, restricted units, restricted shares, deferred share units, promissory shares and other share-based awards (collectively, "Awards"). The maximum number of common shares to be issued as Awards, subject to adjustment as provided under the terms of the plan was 1.8 million shares.

Share options. Share options are granted to purchase the Company's ordinary shares at prices that are equal to the fair market value of the shares on the date the share option is granted. Share options generally vest in equal annual installments over a period of four years and expire ten years after the date of grant. The grant-date fair value of share options, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are estimated based on historical experience.

Share option activity and information was as follows:

	Share Options	Weighted-Average Exercise Price
Outstanding as of December 27, 2019 (Predecessor)	6,890,700	36.39
Expired/Forfeited	(820,988)	39.65
Outstanding as of December 25, 2020 (Predecessor)	6,069,712	35.95
Expired/Forfeited	(516,193)	45.63
Outstanding as of December 31, 2021 (Predecessor)	5,553,519	35.05
Expired/Forfeited	(5,553,519)	35.05
Outstanding as of June 16, 2022 (Predecessor)	—	—

Restricted share units. Recipients of restricted share units ("RSUs") have no voting rights and receive dividend equivalent units that vest upon the vesting of the related shares. RSUs generally vest in equal annual installments over a period of three years. Restrictions on RSUs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSUs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the service period. The fair market value of RSUs granted is determined based on the market value of the Company's shares on the date of grant.

RSU activity was as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested as of 12/27/2019 (Predecessor)	1,419,020	22.68
Exercised	(647,167)	24.23
Expired/Forfeited	(281,182)	22.11
Non-vested as of 12/25/2020 (Predecessor)	490,671	20.96
Exercised	(186,930)	23.43
Expired/Forfeited	(60,844)	19.58
Non-vested as of 12/31/2021 (Predecessor)	242,897	19.40
Expired/Forfeited	(242,897)	19.40
Non-vested as of June 16, 2022 (Predecessor)	—	—
Non-vested as of June 17, 2022 (Successor)	—	—
Granted	890,485	12.03
Non-vested as of December 30, 2022 (Successor)	890,485	12.03

The total fair value of RSU awards granted during the period from June 17, 2022 through December 30, 2022 (Successor) was $10.7 million. As of December 30, 2022 (Successor), there was $9.4 million of total unrecognized compensation cost related to non-vested RSUs granted, which is expected to be recognized over a weighted-average period of 2.2 years.

Performance share units. Similar to recipients of RSUs, recipients of performance share units ("PSUs") have no voting rights and receive dividend equivalent units. The grant-date fair value of PSUs, adjusted for estimated forfeitures, is generally recognized as expense on a straight-line basis from the grant-date through the end of the performance period. The vesting of PSUs and related dividend equivalent units is generally based on various performance metrics and relative total shareholder return (total shareholder return for the Company as compared to total shareholder return of the PSU peer group), measured over a three year performance period. The PSU peer group is comprised of various healthcare companies which attempts to replicate the Company's mix of businesses. Depending on Mallinckrodt's relative performance during the performance period, a recipient of the award is entitled to receive a number of ordinary shares equal to a percentage, ranging from 0.0% to 200.0%, of the award granted.

A portion of the PSUs granted in fiscal 2022 will be settled in shares and are classified as equity-based awards, and a portion of the PSUs have the ability to be settled in either shares or cash and are classified as liability-based awards. The Company recognized $0.1 million of equity-based compensation costs during the period from June 17, 2022 through December 30, 2022 (Successor). The fair value of the liability-based awards is measured quarterly and is based on the Company's performance. Payment, if any, for the liability-based awards is expected to be made in fiscal 2024.

PSU activity was as follows [(1)]:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested as of December 27, 2019 (Predecessor)	1,195,505	23.85
Forfeited	(1,195,505)	23.85
Non-vested as of December 25, 2020 (Predecessor)	—	—
Non-vested as of June 17, 2022 (Successor)	—	—
Granted	675,821	8.34
Non-vested as of December 30, 2022 (Successor)	675,821	8.34

(1) The number of shares disclosed within this table are at the target number of 100.0%.

The Company generally uses the Monte Carlo model to estimate the probability of satisfying the performance criteria and the resulting fair value of PSU awards. The assumptions used in the Monte Carlo model for PSUs granted during the period June 17, 2022 through December 30, 2022 (Successor) were as follows:

Expected stock price volatility	38.9 %
Peer group stock price volatility	128.0
Correlation of returns	24.4

The weighted-average grant-date fair value per share of PSUs granted was $8.34 and $2.51 for the equity-based and liability-based awards from the period from June 17, 2022 through December 30, 2022 (Successor), respectively. As of December 30, 2022, there was $5.5 million and $1.7 million of unrecognized compensation cost related to the equity-based and liability-based awards, respectively, which are both expected to be recognized over a weighted average period of 1.9 years.

18. Guarantees

In disposing of assets or businesses, the Company has from time to time provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. The Company assesses the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company believes, given the information currently available, that the ultimate resolutions will not have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemical business (formerly known as Mallinckrodt Baker) in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The liability was $14.9 million and included in LSTC on the Company's consolidated balance sheet as of December 31, 2021 (Predecessor), of which $12.1 million related to environmental, health and safety matters. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value as of December 31, 2021 (Predecessor). The liability relating to all of these indemnification obligations was governed by a contract that was rejected as part of Chapter 11 and is no longer a liability of the Successor Company. The Company was required to pay $30.0 million into an escrow account as collateral to the purchaser. The contract governing the escrow account was assumed in the Chapter 11 proceedings. As of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), $19.3 million and $19.0 million remained in restricted cash, included in other long-term assets on the consolidated balance sheets, respectively. As of December 30, 2022 (Successor), the Company does not expect to make future payments related to these indemnification obligations.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 19.

The Company is also liable for product performance; however the Company believes, given the information currently available, that the ultimate resolution of any such claims will not have a material adverse effect on its financial condition, results of operations and cash flows.

As of December 30, 2022 (Successor), the Company had various other letters of credit, guarantees and surety bonds totaling $30.1 million and restricted cash of $37.9 million held in segregated accounts primarily to collateralize surety bonds for the Company's environmental liabilities.

19. Commitments and Contingencies

The Company is subject to various legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and other legal proceedings, all in the ordinary course of business, including those described below. Although it is not feasible to predict the outcome of these matters, the Company believes, unless otherwise indicated below, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Governmental Proceedings

Acthar Gel-Related Matters

SEC Subpoena. In August 2019, the Company received a subpoena from the SEC for documents related to the Company's disclosure of its dispute with the HHS and CMS (together with HHS, the "Agency") concerning the base date average manufacturer price for Acthar Gel under the Medicaid Drug Rebate Program, which was also the subject of litigation that the Company filed against the Agency. The SEC issued subsequent subpoenas on January 7, 2022 and September 28, 2022, requesting additional documents from the Company.

In connection with the investigation, on January 13, 2023, the SEC staff issued Wells Notices to the Company and individuals, including certain of its current and former executive officers, who were employed during 2019 (collectively, the "Individuals"). The notices indicate that the SEC staff has made a preliminary determination to recommend that the SEC file an enforcement action against the Company that would allege violations of the federal securities laws, and against the Individuals that would allege violations of the federal securities laws and/or aiding and abetting violations of the federal securities laws. The recommendation as to the Company may involve an injunction, a cease-and-desist order and/or other appropriate relief.

The actions recommended by the SEC staff would allege, among other things, that (a) the Company improperly omitted to disclose the dispute with the Agency prior to the litigation filed by the Company in federal court on May 21, 2019, and (b) the Company's disclosure of the civil investigative demand received from the U.S. Attorney's Office for the District of Massachusetts in January 2019 (the "Boston CID") should have stated that the Boston CID related to the Company's dispute with the Agency.

A Wells Notice is neither a formal charge of wrongdoing nor a final determination that the recipient has violated any law. Under the SEC procedures, a recipient of a Wells Notice has an opportunity to respond and make a submission to the SEC staff setting forth the recipient's interests and position in regard to the subject matter of the investigation.

The Company believes that it has complied with all applicable laws and regulations, and it has provided a submission explaining the Company's position and its belief that no enforcement action is warranted or appropriate. The Company understands that the Individuals have provided similar submissions to the SEC staff. The outcome of this matter is uncertain, and as a result, the Company is unable to estimate the potential exposure associated with this matter.

Other Related Matters

Florida Civil Investigative Demand. In or around February 2019, the Company received a civil investigative demand ("CID") from the U.S. Attorney's Office for the Middle District of Florida for documents related to alleged payments to healthcare providers in Florida and whether those payments violated the Anti-Kickback Statute. The Company has cooperated with the investigation.

Generic Pricing Subpoena. In March 2018, the Company received a grand jury subpoena issued by the U.S. District Court for the EDPA pursuant to which the Antitrust Division of the DOJ is seeking documents regarding generic products and pricing, communications with generic competitors and other related matters. The Company is in the process of responding to this subpoena and intends to cooperate in the investigation.

MNK 2011 Inc. (formerly known as Mallinckrodt Inc.) v. U.S. Food and Drug Administration and United States of America. In November 2014, the FDA reclassified the Company's Methylphenidate ER in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("the Orange Book"). In November 2014, the Company filed a Complaint in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the U.S. ("MD Complaint") for judicial review of the FDA's reclassification. In July 2015, the court granted the FDA's motion to dismiss with respect to three of the five counts in the MD Complaint and granted summary judgment in favor of the FDA with respect to the two remaining counts ("MD Order"). On October 18, 2016, the FDA initiated proceedings, proposing to withdraw approval of the Company's Abbreviated New Drug Application ("ANDA") for Methylphenidate ER. On October 21, 2016, the U.S. Court of Appeals for the Fourth Circuit issued an order placing the Company's appeal of the MD Order in abeyance pending the outcome of the withdrawal proceedings. The parties exchanged documents and in April 2018, the Company filed its submission in support of its position in the withdrawal proceedings. A potential outcome of the withdrawal proceedings is that the Company's Methylphenidate ER products may lose their FDA approval and have to be withdrawn from the market.

Patent Litigation

Branded Products: The Company will continue to vigorously enforce its intellectual property rights relating to its Branded products to prevent the marketing of infringing generic or competing products prior to the expiration of patents covering those products, which, if unsuccessful, could adversely affect the Company's ability to successfully maximize the value of individual Branded products and have an adverse effect on its financial condition, results of operations and cash flows. In the case of litigation filed against potential generic or competing products to Company's Branded products, those litigation matters can either be settled or the litigation pursued through a trial and any potential appeals of the lower court decision.

Generic Products: The Company continues to pursue development of a portfolio of generic products, some of which require submission of a Paragraph IV certification against patents listed in the FDA's Orange Book for the Branded product asserting that the Company's proposed generic product does not infringe and/or the Orange Book patent(s) are invalid and/or unenforceable. In the case of litigation filed against Company for such potential generic products, those litigation matters can either be settled or the litigation pursued through a trial and any potential appeals of the lower court decision in order to successfully launch those generic products in the future.

Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV v. Pharmascience Inc. and SpecGx LLC. In December 2019, Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively "Janssen") initiated litigation against the Company and Pharmascience Inc. ("Pharmascience") relating to the collaboration between Company and Pharmascience that resulted in Pharmascience's ANDA submission, containing a Paragraph IV patent certification, with the FDA for a competing version of Invega Sustenna. Janssen alleges that the Company and Pharmascience infringe U.S. Patent No. 9,439,906. On July 13, 2022, the court administratively closed this case pending the outcome of the Federal Circuit's decision in *Janssen Pharmaceuticals, Inc. v. Mylan Laboratories Limited*, Case No. 22-1307.

Mallinckrodt Pharmaceuticals Ireland Limited et al. v. Airgas Therapeutics LLC et al. On December 30, 2022, the Company initiated litigation against Airgas Therapeutics LLC, Airgas USA LLC, and Air Liquide S.A. (collectively "Airgas") in the District of Delaware following notice from Airgas of its ANDA submission seeking approval from FDA for a generic version of INOmax® (nitric oxide) gas, for inhalation ("INOmax"). Many of the patents asserted against Airgas were previously asserted in the District of Delaware against Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair") in 2015 and 2016 following Praxair's submissions with FDA seeking approval for a nitric oxide drug product and delivery system. The litigation against Praxair resulted in Praxair's launch of a competitive nitric oxide product. The Company continues to develop and pursue patent protection of next generation nitric oxide delivery systems and additional uses of nitric oxide and intends to vigorously enforce its intellectual property rights against any parties that may seek to market a generic version of Company's INOmax product and/or next generation delivery systems.

Commercial and Securities Litigation

City of Marietta Litigation. In February 2020, the City of Marietta, Georgia filed a putative civil class action complaint against the Company in the U.S. District Court for the Northern District of Georgia relating to the price of Acthar Gel. The complaint, which pleads one claim for unjust enrichment, purports to be brought on behalf of third-party payers and their beneficiaries as well as people without insurance in the U.S. and its Territories who paid for Acthar Gel from four years prior to the filing of the Complaint until the date of trial. The case is proceeding as *City of Marietta v. Mallinckrodt ARD LLC*. Marietta alleges that it has paid $2.0 million to cover the cost of an Acthar Gel prescription of an employee and that the Company has been unjustly enriched as a result. The Company moved to dismiss the complaint, which motion was pending when the Company filed the Chapter 11 Cases. On October 16, 2020, the court ordered the case administratively closed in light of the Chapter 11 Cases. As a result of the Plan, the litigation was discharged against the Company and the claims thereunder are now the obligation of the trust established by the Plan for the benefit of allowed general unsecured claims ("GUC Trust"). The GUC Trust can settle the claims as long as there is no agreement to any findings nor any admission of liability or wrongdoing against the Company in the relevant settlement agreement. On February 17, 2023, this matter was dismissed as to the Company.

Putative Class Action Litigation - Steamfitters Local Union No. 420. In July 2019, Steamfitters Local Union No. 420 filed a putative class action lawsuit against the Company and United BioSource Corporation in the U.S. District Court for the EDPA, proceeding as *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC, et al.* The complaint makes similar allegations as those alleged in related state and federal actions that were filed by the same plaintiff's law firm in New Jersey, Illinois, Pennsylvania, Tennessee and Maryland (now dismissed), and includes references to allegations at issue in a qui tam action that was filed against the Company in the U.S. District Court for the EDPA. The complaint alleges the violations of Racketeer Influenced and Corrupt Organizations Act ("RICO") under 18 U.S.C. Section 1962(c); conspiracy to violate RICO under 18 U.S.C. Section 1962(c); violations of the Pennsylvania (and other states) Unfair Trade Practices and Consumer Protection laws; negligent misrepresentation; aiding and abetting/conspiracy; and unjust enrichment. The complaint also seeks declaratory and injunctive relief. In December 2019, the court denied the Company's motion to dismiss the complaint, and the matter was stayed during bankruptcy. Following lifting of the automatic stay of this litigation pursuant to Section 362 of the Bankruptcy Code and subsequent reopening of the case in the EDPA, in January 2021, the Company moved to transfer this case to the District of Delaware where the Company's Chapter 11 Cases are pending. Steamfitters Local Union No. 420 opposed transfer. On January 18, 2023, this matter was dismissed as to the Company.

Acument Global. In May 2019, Acument Global Technologies, Inc. ("Acument"), filed a non-class complaint against the Company and other defendants in Tennessee state court alleging violations of Tennessee Consumer Protection Laws, unjust enrichment, fraud and conspiracy to defraud and is captioned as *Acument Global Technologies, Inc., v. Mallinckrodt ARD Inc., et al.* In February 2020, the court granted-in-part and denied-in-part the Company's motion to dismiss. While the court dismissed Acument's fraud-based claims and its claim under the Tennessee Consumer Protection Act, the court ruled that the antitrust and unjust enrichment claims may proceed. Following lifting of the automatic stay of this litigation pursuant to Section 362 of the Bankruptcy Code, on

September 29, 2022, the court remanded the case to state court; no further action has been taken. At this stage, the Company will vigorously defend itself in this matter both on the merits and as discharged through the bankruptcy.

Local 542. In May 2018, the International Union of Operating Engineers Local 542 filed a non-class complaint against the Company and other defendants in Pennsylvania state court alleging improper pricing and distribution of Acthar Gel, in violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, aiding and abetting, unjust enrichment and negligent misrepresentation captioned as *Int'l Union of Operating Engineers Local 542 v. Mallinckrodt ARD Inc., et al.* Plaintiff filed an amended complaint in August 2018, the Company's objections to which were denied by the court. In January 2021, the Company removed this case to the U.S. District Court for the EDPA. In March 2021, the EDPA granted the Company's motion to transfer the case to the District of Delaware and denied without prejudice Local 542's motion to remand the case to state court. In June 2021, the District of Delaware referred this case to the Bankruptcy Court in Delaware. On November 17, 2022, Local 542 filed a motion to withdraw the reference to the District Court, and the case was transferred back to the District of Delaware at Case No. 22-cv-01502. On December 22, 2022, Local 542 filed a request for the motion to withdraw the reference to be decided by the EDPA and to permit remand to state court. On December 28, 2022, the case was assigned to Judge Ambro of the United States Court of Appeals for the Third Circuit due to related cases. At this stage, the Company will vigorously defend itself in this matter both on the merits and as discharged through the bankruptcy.

Other Commercial and Securities Litigation Matters

Putative Class Action Securities Litigation (Strougo). In July 2019, a putative class action lawsuit was filed against the Company, its former CEO Mark C. Trudeau, its Chief Financial Officer ("CFO") Bryan M. Reasons, its former Interim CFO George A. Kegler and its former CFO Matthew K. Harbaugh, in the U.S. District Court for the Southern District of New York, captioned *Barbara Strougo v. Mallinckrodt plc, et al*. The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt's securities between February 28, 2018 and July 16, 2019. The lawsuit generally alleges that the defendants made false and/or misleading statements in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder related to the Company's clinical study designed to assess the efficacy and safety of its Acthar Gel in patients with amyotrophic lateral sclerosis. The lawsuit seeks monetary damages in an unspecified amount. A lead plaintiff was designated by the court on June 25, 2020, and on July 30, 2020, the court approved the transfer of the case to the U.S. District Court for the District of New Jersey. On August 10, 2020, an amended complaint was filed by the lead plaintiff alleging an expended putative class period of May 3, 2016 through March 18, 2020 against the Company and Mark C. Trudeau, Bryan M. Reasons, George A. Kegler and Matthew K. Harbaugh, as well as newly named defendants Kathleen A. Schaefer, Angus C. Russell, Melvin D. Booth, JoAnn A. Reed, Paul R. Carter, and Mark J. Casey (collectively with Trudeau, Reasons, Kegler and Harbaugh, the "Strougo Defendants"). The amended complaint claims that the defendants made various false and/or misleading statements and/or failed to disclose various material facts regarding Acthar Gel and its results of operations. On October 1, 2020, the defendants filed a motion to dismiss the amended complaint. As to the Company, this litigation is subject to the automatic stay under Section 362 of the Bankruptcy Code, and on December 4, 2020, the Bankruptcy Court also enjoined proceedings against the Strougo Defendants. The plaintiffs subsequently appealed the Bankruptcy Court action to the U.S. District Court in Delaware through a motion for reconsideration, which was denied by that court on January 27, 2021. The Bankruptcy Court extended the injunction staying the proceedings against the Strougo Defendants on August 30, 2021, and further extended the injunction on November 29, 2021 and on March 17, 2022. On March 17, 2022, the *Strougo* action was administratively closed. On March 29, 2022, the *Strougo* action was reinstated only with respect to the individual defendants, and the individual defendants filed their reply in support of their motion to dismiss on May 2, 2022. On July 21, 2022, the Company filed a notice of discharge that, if approved by the court, would result in dismissal for the Company. The notice informed the court that (i) the Bankruptcy Court confirmed the Plan; (ii) the Company's discharge pursuant to Section 1141(d) of the Bankruptcy Code of the claims asserted against it in the *Strougo* action had taken effect; and (iii) the Plan and the discharge injunction enjoin any party from, among other things, continuing to pursue claims against the Company in the *Strougo* action. On December 16, 2022, the District Court issued an order denying the individual defendants' motion to dismiss in all respects. The individual defendants have answered the complaint and the case is now proceeding into the discovery phase. As to the Company, this matter was resolved in bankruptcy with no further liability against the Company.

Employee Stock Purchase Plan Securities Litigation. On November 28, 2022, the court entered an order pursuant to which all derivative claims were dismissed without prejudice, all remaining claims were dismissed with prejudice as to the plaintiffs and without prejudice as to all other members of the putative class, and the case was closed.

Generic Pharmaceutical Antitrust Multi-District Litigation.

In August 2016, a multi-district litigation ("MDL") was established in the EDPA relating to allegations of antitrust violations with respect to generic pharmaceutical pricing ("Generic Pricing MDL"). Plaintiffs in the Generic Pricing MDL, captioned *In re: Generic Pharmaceuticals Pricing Antitrust Litigation*, allege a conspiracy of price-fixing and customer allocation among generic drug manufacturers beginning in or around July 2009. The Generic Pricing MDL includes lawsuits against the Company and dozens of other pharmaceutical companies, including a complaint filed by Attorneys General for 51 States, Territories and the District of Columbia seeking monetary damages and injunctive relief. While the Company is not subject to monetary damages in connection with

these matters as a result of the Plan and vigorously disagrees with the plaintiffs' characterization of the facts and law, the Company is not able to reasonably estimate whether any injunctive relief will be granted, and if granted, whether it will materially impact the Company's financial position or operations; the Company does not intend to provide further disclosure unless this assessment changes.

Environmental Remediation and Litigation Proceedings

The Company is involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. The Company concluded that, as of December 30, 2022 (Successor), it was probable that it would incur remediation costs in the range of $18.4 million to $48.5 million. The Company also concluded that, as of December 30, 2022 (Successor), the best estimate within this range was $36.9 million, of which $1.1 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet as of December 30, 2022 (Successor). While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Lower Passaic River, New Jersey. The Company and approximately 70 other companies ("Cooperating Parties Group" or "CPG") are parties to a May 2007 Administrative Order on Consent ("AOC") with the Environmental Protection Agency ("EPA") to perform a remedial investigation and feasibility study ("RI/FS") of the 17-mile stretch known as the Lower Passaic River ("the River") Study Area. The Company's potential liability stems from former operations at Lodi and Belleville, New Jersey. In April 2014, the EPA issued a revised Focused Feasibility Study ("FFS"), with remedial alternatives to address cleanup of the lower 8-mile stretch of the River. The EPA estimated the cost for the remediation alternatives ranged from $365.0 million to $3.2 billion and the EPA's preferred approach had an estimated cost of $1.7 billion. In April 2015, the CPG presented a draft of the RI/FS of the River to the EPA that included alternative remedial actions for the entire 17-mile stretch of the River. In March 2016, the EPA issued the Record of Decision ("ROD") for the lower 8 miles of the River with a slight modification on its preferred approach and a revised estimated cost of $1.38 billion. In October 2016, the EPA announced that Occidental Chemicals Corporation ("OCC") had entered into an agreement to develop the remedial design.

In August 2018, the EPA finalized a buyout offer of $280,600 with the Company, limited to its former Lodi facility, for the lower 8 miles of the River. On September 28, 2021, the EPA issued the Record of Decision for the upper 9 miles of the River selecting source control as the remedy for the upper 9 miles with an estimated cost of $441.0 million. As of December 30, 2022 (Successor), the Company estimated that its remaining liability related to the River was $21.0 million, which was included within in environmental liabilities on the consolidated balance sheet as of December 30, 2022 (Successor). Despite the issuance of the revised FFS and the RODs for both the lower and upper River by the EPA, the RI/FS by the CPG, and the cash out settlement by the EPA, there are many uncertainties associated with the final agreed-upon remediation, potential future liabilities and the Company's allocable share of the remediation. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which the Company may be ultimately responsible and will be refined as the remediation progresses.

Occidental Chemical Corp. v. 21st Century Fox America, Inc. The Company and approximately 120 other companies were named as defendants in a lawsuit filed in June 2018, by OCC, in which OCC seeks cost recovery and contribution for past and future costs in response to releases and threatened releases of hazardous substances into the lower 8 miles of the River. A former Mallinckrodt facility located in Jersey City, NJ (located in Newark Bay) and the former Belleville facility were named in the suit. Due to an indemnification agreement with AVON Inc., Mallinckrodt has tendered the liability for the Jersey City site to AVON Inc. and they have accepted. Although the Company was not named as a defendant for the Belleville facility, the Company retains a share of the liability for this suit. A motion to dismiss several of the claims was denied by the court. As a result of the Plan, the lawsuit was discharged against the Company. Any reserves associated with this contingency were included in LSTC as of the Effective Date, as any related liabilities were discharged under the U.S. Bankruptcy Code.

Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois. Between 1967 and 1982, International Minerals and Chemicals Corporation ("IMC"), a predecessor in interest to the Company, leased portions of the Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the CO Site") from the government and manufactured various explosives for use in mining and other operations. In March 2002, the DOJ, the U.S. Department of the Interior and the EPA (together, "the Government Agencies") issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. ("General Dynamics"), one of the other potentially responsible parties at the CO Site, to compel General Dynamics to perform the RI/FS for the AUS Operable Unit. General Dynamics negotiated an AOC with the Government Agencies to conduct an extensive RI/FS at the CO Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that the Company is jointly and severally liable, along with approximately eight other lessees and operators at the AUS Operable Unit, for costs associated with alleged contamination of soils and groundwater resulting from historic operations, and the parties have entered into a non-binding mediation process. However, the mediation process has indefinitely stalled due to an "internal issue" that the U.S. is facing and cannot seem to resolve. As a result of the Plan, this matter was discharged against the Company.

Bankruptcy Litigation and Appeals

First Lien Noteholder Matters. As set forth in greater detail in Note 2, the Plan proposed to reinstate the Existing First Lien Notes. Certain holders of the Existing First Lien Notes and the trustee in respect thereof (collectively, the "Noteholder Parties"), objected to the proposed reinstatement, arguing, among other things, that the Company was required to pay a significant make-whole premium as a condition to reinstatement of the Existing First Lien Notes. In the course of confirming the Plan, the Bankruptcy Court overruled these objections.

On March 30, 2022, the Noteholder Parties appealed the confirmation order's approval of the reinstatement of the Existing First Lien Notes to the United States District Court for the District of Delaware. The Company and the Existing First Lien Notes Trustee reached an agreement to hold the trustee's appeal in abeyance, to be determined by the result of the holders' appeals, subject to certain conditions, which was approved by the District Court. Briefing on the merits of the Noteholder Parties' appeals was completed on July 1, 2022. On the same date, the Company moved to dismiss the Noteholder Parties' appeals as equitably moot. Briefing on the motion was completed on August 5, 2022 and supplemental declarations have been filed in the appeal. The Noteholder Parties' appeals and the related motion to dismiss remain pending.

At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with these appeals. The Company will continue to vigorously defend the Plan.

Sanofi. On October 12, 2021, in the Company's bankruptcy, sanofi-aventis U.S. LLC ("Sanofi") filed a motion asking the Bankruptcy Court for an order determining that, under the Bankruptcy Code, the Company could not discharge alleged royalty obligations owed to Sanofi under an asset purchase agreement through which the Company acquired certain intellectual property from Sanofi's predecessor ("Sanofi Motion"). On November 8, 2021, the Bankruptcy Court denied the Sanofi Motion and ordered that any royalty obligations allegedly owed to Sanofi constitute prepetition unsecured claims that may be discharged under the Bankruptcy Code. On November 19, 2021, Sanofi appealed the Bankruptcy Court's ruling of the Sanofi Motion to the District Court. Briefing was completed on March 10, 2022 and the District Court affirmed on December 20, 2022, for which Sanofi filed a notice of appeal on January 17, 2023. Sanofi had also appealed the Bankruptcy Court's confirmation order, on February 18, 2022, and briefing has been completed. As of the date of this annual report, the appeal regarding the confirmation order remains pending and will likely remain pending until Sanofi's Third Circuit appeal of the Sanofi Motion is resolved.

Glenridge. On October 21, 2021, in the Company's bankruptcy, Kenneth Greathouse, Stuart Rose, and Lloyd Glenn (collectively, the "Glenridge Principals") filed a joinder to the Sanofi Motion and asked the Bankruptcy Court for an order similarly determining that royalty obligations owed by the Company to the Glenridge Principals under a royalty agreement were not dischargeable under the Bankruptcy Code and that the royalty agreement could not be rejected by the Company in its bankruptcy. On December 1, 2021, the Bankruptcy Court denied the motion, entering an order that the royalty agreement between the Company and the Glenridge Principals could be rejected under the Bankruptcy Code and that any royalties owed under the agreement were prepetition unsecured claims that could be discharged under the Bankruptcy Code. On December 15, 2021, the Glenridge Principals appealed the Bankruptcy Court's ruling to the District Court. Briefing has not been completed at this time. The parties mutually agreed to extend the briefing deadlines. Subsequently, on March 16, 2022, the Glenridge Principals appealed the confirmation order and thereafter the parties stipulated to the dismissal of both appeals on November 16, 2022 and are awaiting entry of an order approving such stipulation. The GUC Trust, the Company and the Glenridge Principals reached a settlement, which was approved by the Bankruptcy Court on October 28, 2022. Thereafter, the parties stipulated to dismissal of both appeals on November 16, 2022 and are awaiting court order closing the appeals.

Acthar Insurance Claimants. In the Company's bankruptcy, Attestor Limited and Humana Inc. (collectively, the "Acthar Insurance Claimants") filed administrative claims with the Bankruptcy Court seeking hundreds of millions of dollars based on the Company's allegedly illegal sales of Acthar Gel. The Company objected to the claims, arguing that the Company had no such liability. After a bench trial, the Bankruptcy Court, on December 6, 2021, sustained the Company's objection and disallowed the administrative claims filed by the Acthar Insurance Claimants. The Acthar Insurance Claimants appealed that ruling to the District Court on December 20, 2021. On February 4, 2022, the Acthar Insurance Claimants moved to have the District Court certify their appeal directly to the Third Circuit. Meanwhile, on July 1, 2022, the Company moved to dismiss the Acthar Insurance Claimants' appeal as equitably moot. Briefing on that motion was completed on August 5, 2022. On October 31, 2022, the District Court denied the Acthar Insurance Claimants motion for direct appeal to the Third Circuit. On February 20, 2023, the parties entered into a settlement agreement in an amount immaterial to the Company, with no findings nor any admission of liability or wrongdoing against the Company, and the matter was dismissed on February 24, 2023.

Stratatech. As described in Note 20, consummation of the Plan discharged the Company's liability with respect to certain contingent consideration provided to the prior securityholders of Stratatech Corporation ("Stratatech"). However, Russell Smestad, as the representative of these securityholders, has filed a motion in the Bankruptcy Court for an order either (i) granting allowance and immediate payment of an administrative expense claim in the amount of the liability of $20 million or (ii) finding that the claim was not susceptible to discharge and should be paid in full. The Company believes that the securityholders’ motion is without merit and intends to vigorously oppose it.

Banks et al. v. Cotter Corporation et al. v. Mallinckrodt LLC, et al. On January 29, 2023, the named plaintiffs in *Banks et al. v. Cotter Corporation et al. v. Mallinckrodt LLC, et al.* No. 20-CV-1227 (E.D. Mo.) filed a motion to amend their class-action petition to add Mallinckrodt LLC as a defendant. Mallinckrodt LLC filed a motion in the Bankruptcy Court to enjoin this petition on the grounds that these alleged claims were discharged pursuant to the Plan and confirmation order. Both motions remain pending until the Bankruptcy Court adjudicates the motion to enjoin.

Other Matters

The Company is a defendant in a number of other pending legal proceedings relating to present and former operations, acquisitions and dispositions. The Company does not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on its financial condition, results of operations and cash flows.

20. Financial Instruments and Fair Value Measurements

Fair value is defined as the exit price that would be received from the sale of an asset or paid to transfer a liability, using assumptions that market participants would use in pricing an asset or liability. The fair value guidance establishes a three-level fair value hierarchy, which maximizes the use of observable inputs and minimizes the use of unobservable inputs used in measuring fair value. The levels within the hierarchy are as follows:

Level 1— observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2— significant other observable inputs that are observable either directly or indirectly; and

Level 3— significant unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions.

The following tables provide a summary of the significant assets and liabilities that are measured at fair value on a recurring basis at the end of each period:

	December 30, 2022 (Successor)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 36.6	$ 24.8	$ 11.8	$ —
Equity securities	25.5	25.5	—	—
	$ 62.1	$ 50.3	$ 11.8	$ —
Liabilities:				
Deferred compensation liabilities	$ 26.0	$ —	$ 26.0	$ —
Contingent consideration liabilities	7.3	—	—	7.3
	$ 33.3	$ —	$ 26.0	$ 7.3

	December 31, 2021 (Predecessor)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 38.7	$ 24.9	$ 13.8	$ —
Equity securities	36.5	36.5	—	—
	$ 75.2	$ 61.4	$ 13.8	$ —
Liabilities:				
Deferred compensation liabilities [(1)]	$ 36.9	$ —	$ 36.9	$ —
Contingent consideration liabilities [(2)]	27.3	—	—	27.3
	$ 64.2	$ —	$ 36.9	$ 27.3

(1) On November 16, 2020 (Predecessor), the Debtors received approval from the Bankruptcy Court to maintain existing postretirement benefit plans during the pendency of the Chapter 11 Cases.

(2) These liabilities are governed by executory contracts and recorded at their estimated allowed claim amount within liabilities subject to compromise on the consolidated balance sheet as of December 31, 2021 (Predecessor).

Debt and equity securities held in rabbi trusts. Debt securities held in rabbi trusts primarily consist of U.S. government and agency securities and corporate bonds. When quoted prices are available in an active market, the investments are classified as level 1. When quoted market prices for a security are not available in an active market, they are classified as level 2. Equity securities held in rabbi trusts primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges.

Equity securities. Equity securities consist of shares in Silence Therapeutics plc and Panbela Therapeutics, Inc. for which quoted prices are available in an active market; therefore, these investments are classified as level 1 and are valued based on quoted market prices reported on internationally recognized securities exchanges.

During the period from June 17, 2022 through December 30, 2022 (Successor), fiscal 2021 (Predecessor) and 2020 (Predecessor), the Company recognized an unrealized gain of $9.2 million, $4.7 million and $3.8 million, respectively, and during the period from January 1, 2022 through June 16, 2022 (Predecessor), the Company recognized an unrealized loss of $22.2 million related to our investments within other income (expense), net in the consolidated statement of operations.

Deferred compensation liabilities. The Company maintains a non-qualified deferred compensation plan in the U.S., which permits eligible employees of the Company to defer a portion of their compensation. A recordkeeping account is set up for each participant and the participant chooses from a variety of funds for the deemed investment of their accounts. The recordkeeping accounts generally correspond to the funds offered in the Company's U.S. tax-qualified defined contribution retirement plan and the account balance fluctuates with the investment returns on those funds.

Successor contingent consideration liabilities. In accordance with the Plan and Scheme of Arrangement, the Company will provide consideration for a CVR associated with Terlivaz primarily in the form of the achievement of a cumulative net sales milestone. The Company assesses the likelihood and timing of making such payments at each balance sheet date. The fair value of the contingent payment was measured based on the net present value of a probability-weighted assessment. The Company determined the fair value of the Terlivaz CVR to be $7.3 million as of December 30, 2022 (Successor).

Predecessor contingent consideration liabilities. As part of the acquisition of Stratatech, the Company provided contingent consideration to the prior shareholders of Stratatech, primarily in the form of regulatory filing and approval milestones associated with the deep partial-thickness and full-thickness indications associated with StrataGraft. For each indication, the Company was responsible for a payment upon acceptance of the Company's submission and another upon approval by the FDA. The Company determined the fair value of the contingent consideration associated with the acquisition of Stratatech to be $27.3 million as of December 31, 2021 (Predecessor). These liabilities were governed by a contract and recorded at their estimated allowed claim amount within LSTC in the consolidated balance sheet as of December 31, 2021 (Predecessor). The contract governing this liability was rejected and the liability was discharged pursuant to the Plan on the Effective Date.

All contingent consideration liabilities were classified within other liabilities and LSTC in the consolidated balance sheets as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively. The following table summarizes the fiscal 2022 activity for contingent consideration:

Balance as of December 31, 2021(Predecessor)	$	27.3
Impact of the Plan on Predecessor contingent consideration liabilities		(27.3)
Establishment of Terlivaz CVR		6.8
Balance as of June 16, 2022 (Successor)	$	6.8

Balance as of June 17, 2022 (Successor)	$	6.8
Fair value adjustments		0.5
Balance as of December 30, 2022 (Successor)	$	7.3

Financial Instruments Not Measured at Fair Value

The following methods and assumptions were used by the Company in estimating fair values for financial instruments not measured at fair value as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor):

- The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the majority of other current assets and liabilities approximate fair value because of their short-term nature. The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original

maturity of three months or less, as cash and cash equivalents (level 1). The fair value of restricted cash was equivalent to its carrying value of $57.2 million and $60.2 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), (level 1), respectively. Included within the balance as of the Effective Date was $89.0 million related to the funding of a professional fee escrow account upon emergence from Chapter 11. Refer to Note 3 for further information. As of December 30, 2022 (Successor), the professional fee escrow balance was zero.

- The Company's life insurance contracts are carried at cash surrender value, which is based on the present value of future cash flows under the terms of the contracts (level 3). Significant assumptions used in determining the cash surrender value include the amount and timing of future cash flows, interest rates and mortality charges. The fair value of these contracts approximates the carrying value of $46.7 million and $51.3 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively. These contracts are included in other assets on the consolidated balance sheets.
- *Successor debt.* The Company's Existing 1L Notes, New 2L Notes, New 1L Notes and Takeback 2L Notes are classified as level 1, as quoted prices are available in an active market for these notes. Since quoted market prices for the Company's term loans are not available in an active market, they are classified as level 2 for purposes of developing an estimate of fair value.

  Predecessor debt. The carrying value of the Company's former revolving credit facility approximated the fair value due to the short-term nature of this instrument, and was therefore classified as level 1. The Company's former 5.75%, 4.75%, 5.625%, 5.50% senior notes and 10.00% first and second lien senior secured notes were classified as level 1, as quoted prices were available in an active market for these notes. Since the quoted market prices for the Company's former term loans and former 9.50% and 8.00% debentures were not available in an active market, they were classified as level 2 for purposes of developing an estimate of fair value.

	Successor		Predecessor	
	December 30, 2022		December 31, 2021	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
10.00% first lien senior secured notes due April 2025	$ 475.9	$ 425.9	$ 495.0	$ 523.7
10.00% second lien senior secured notes due April 2025	242.2	216.8	—	—
11.50% first lien senior secured notes due December 2028	650.0	552.6	—	—
10.00% second lien senior secured notes due June 2029	175.5	176.7	—	—
Revolving credit facility due February 2022	—	—	900.0	900.0
5.75% senior notes due August 2022	—	—	610.3	324.1
4.75% senior notes due April 2023	—	—	133.7	48.9
5.625% senior notes due October 2023	—	—	514.7	279.1
10.00% second lien senior secured notes due April 2025	—	—	322.9	312.7
5.50% senior notes due April 2025	—	—	387.2	211.6
Level 2:				
2017 Replacement Term loan due September 2027	1,222.1	1,037.8	—	—
2018 Replacement Term loan due September 2027	326.9	274.8	—	—
9.50% debentures due May 2022	—	—	10.4	7.7
8.00% debentures due March 2023	—	—	4.4	3.2
Term loan due September 2024	—	—	1,396.5	1,309.2
Term loan due February 2025	—	—	370.7	347.7
Total Debt	$ 3,092.6	$ 2,684.6	$ 5,145.8	$ 4,267.9

Concentration of Credit and Other Risks

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of accounts receivable. The Company generally does not require collateral from customers. A portion of the Company's accounts receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries' national economies.

The following table shows net sales attributable to distributors that accounted for 10.0% or more of the Company's total segment net sales, which excludes the one-time charge related to the Medicaid lawsuit:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
FFF Enterprises, Inc.	26.1 %	11.8 %	*%	*%
CuraScript, Inc.	*	15.6	26.1	27.4

* Net sales to this distributor were less than 10.0% of total net sales during the respective periods presented above.

The following table shows accounts receivable attributable to distributors that accounted for 10.0% or more of the Company's gross accounts receivable at the end of each period:

	Successor	Predecessor
	December 30, 2022	December 31, 2021
AmerisourceBergen Corporation	23.3%	30.0%
McKesson Corporation	17.3	15.0
FFF Enterprises, Inc.	16.2	*
CuraScript, Inc.	*	12.7

* Accounts receivable attributable to this distributor was less than 10.0% of total gross accounts receivable at the end of the respective period presented above.

The following table shows net sales attributable to products that accounted for 10.0% or more of the Company's total segment net sales, which excludes the one-time charge related to the Medicaid lawsuit:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Acthar Gel	28.3 %	25.4 %	26.9 %	27.9 %
INOmax	16.7	19.0	20.3	20.9
Therakos	12.5	12.5	12.1	*
APAP	10.7	11.0	*	*
Ofirmev	*	*	*	10.1

* Net sales attributable to these products were less than 10.0% of total net sales during the respective periods presented above.

21. Segment and Geographical Data

The Company operates in two reportable segments, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and API(s).

Management measures and evaluates the Company's operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment net sales and operating income because management and the chief operating decision maker evaluate the operating results of the segments excluding such items. These items may include, but are not limited to, depreciation and amortization, share-based compensation, net restructuring charges, non-restructuring impairment charges, separation costs, R&D upfront payments, changes related to the Opioid-Related Litigation Settlement and the Medicaid lawsuit. Although these amounts are excluded from segment net sales and operating income, as applicable, they are included in reported consolidated net sales and operating loss and are reflected in the reconciliations presented below.

Management manages assets on a total company basis, not by operating segment. The Company's chief operating decision maker does not regularly review any asset information by operating segment and, accordingly, the Company does not report asset

information by operating segment. Total assets were approximately $6,013.8 million and $8,916.3 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively.

Selected information by reportable segment was as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Net sales:				
Specialty Brands [1]	$ 682.4	$ 587.1	$ 1,547.0	$ 2,059.6
Specialty Generics	357.3	287.5	661.8	689.8
Segment net sales	1,039.7	874.6	2,208.8	2,749.4
Medicaid lawsuit [1]	—	—	—	(536.0)
Net sales	$ 1,039.7	$ 874.6	$ 2,208.8	$ 2,213.4
Operating loss:				
Specialty Brands	$ 113.8	$ 267.2	$ 812.8	$ 1,015.7
Specialty Generics [2]	(3.6)	65.3	107.9	206.4
Segment operating income	110.2	332.5	920.7	1,222.1
Unallocated amounts:				
Corporate and unallocated expenses [3]	(39.3)	(48.2)	(129.6)	(166.1)
Depreciation and amortization	(347.5)	(321.8)	(675.8)	(885.2)
Share-based compensation	(1.4)	(1.7)	(10.2)	(25.3)
Restructuring charges, net	(11.1)	(9.6)	(26.9)	(37.5)
Non-restructuring impairment charges	—	—	(154.9)	(63.5)
Separation costs [4]	(21.2)	(9.0)	(1.2)	(93.4)
R&D upfront payment [5]	—	—	—	(5.0)
Opioid-related litigation settlement gain (loss)	—	—	(125.0)	43.4
Medicaid lawsuit [1]	—	—	—	(641.1)
Bad debt expense - customer bankruptcy	(6.4)	—	—	—
Operating loss	$ (316.7)	$ (57.8)	$ (202.9)	$ (651.6)
Depreciation and amortization:				
Specialty Brands	$ 323.6	$ 288.4	$ 597.7	$ 799.3
Specialty Generics	23.9	33.4	78.1	85.9
	$ 347.5	$ 321.8	$ 675.8	$ 885.2

(1) Specialty Brands net sales for fiscal 2020 (Predecessor) includes the prospective change to the Medicaid rebate calculation, which served to reduce Acthar Gel net sales by $40.4 million for the period from June 15, 2020 through December 25, 2020 (Predecessor).

(2) Includes $30.0 million of fresh-start inventory-related expense during the period from June 17, 2022 through December 30, 2022 (Successor) primarily driven by the Company's change in accounting estimate as disclosed in Note 1.

(3) Includes administration expenses and certain compensation, legal, environmental and other costs not charged to the Company's reportable segments.

(4) Represents costs included in SG&A expenses, primarily related to expenses incurred related to the severance for the former CEO and certain former executives of the Predecessor, in addition to professional fees and costs incurred as the Company explores potential sales of non-core assets to enable further deleveraging post-emergence from bankruptcy during the period from June 17, 2022 through December 30, 2022 (Successor). Costs incurred during the Predecessor periods include professional fees and costs incurred in preparation for the Chapter 11 proceedings. As of the Petition Date, professional fees directly related to the Chapter 11 proceedings that were previously reflected as separation costs were classified on a go-forward basis as reorganization items, net.

(5) Represents R&D expense incurred related to an upfront payment made to acquire product rights in Japan for Terlivaz during fiscal 2020.

Net sales by product family within the Company's reportable segments were as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Acthar Gel [1]	$ 294.1	$ 221.9	$ 593.6	$ 767.9
INOmax	173.9	165.8	448.5	574.1
Ofirmev	(0.3)	2.5	28.9	276.5
Therakos	130.5	109.6	266.5	238.6
Amitiza [2]	77.1	81.5	196.9	188.8
Other	7.1	5.8	12.6	13.7
Specialty Brands	682.4	587.1	1,547.0	2,059.6
Opioids	117.9	88.8	213.2	233.9
ADHD	28.4	17.5	37.4	48.3
Addiction treatment	35.0	30.0	68.3	68.9
Other	6.8	4.9	12.0	7.3
Generics	188.1	141.2	330.9	358.4
Controlled substances	47.0	37.6	93.4	98.3
APAP	111.4	96.5	215.9	213.0
Other	10.8	12.2	21.6	20.1
API	169.2	146.3	330.9	331.4
Specialty Generics	357.3	287.5	661.8	689.8
Segment net sales	1,039.7	874.6	2,208.8	2,749.4
Medicaid lawsuit	—	—	—	(536.0)
Net Sales	$ 1,039.7	$ 874.6	$ 2,208.8	$ 2,213.4

(1) Fiscal 2020 (Predecessor) includes the prospective change to the Medicaid rebate calculation of $40.4 million for the period from June 15, 2020 through December 25, 2020 (Predecessor).

(2) Amitiza net sales consist of both product and royalty net sales. Refer to Note 5 for further details on Amitiza's revenues.

Selected information by geographic area was as follows:

	Successor	Predecessor		
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Year Ended December 31, 2021	Year Ended December 25, 2020
Net sales [1]:				
U.S.	$ 928.3	$ 784.2	$ 1,991.8	$ 2,465.5
Europe, Middle East and Africa	100.4	73.6	181.8	227.5
Other	11.0	16.8	35.2	56.4
Geographic area net sales	1,039.7	874.6	2,208.8	2,749.4
Medicaid lawsuit	—	—	—	(536.0)
Net Sales	$ 1,039.7	$ 874.6	$ 2,208.8	$ 2,213.4

(1) Net sales are attributed to regions based on the location of the entity that records the transaction, none of which relate to the country of Ireland.

	Successor	Predecessor
	December 30, 2022	December 31, 2021
Long-lived assets [1]:		
U.S.	$ 287.3	$ 629.3
Europe, Middle East and Africa [2]	178.0	156.2
Other	3.1	4.7
	$ 468.4	$ 790.2

(1) Long-lived assets are primarily composed of property, plant and equipment, net.

(2) Includes long-lived assets located in Ireland of $174.9 million and $154.5 million as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor), respectively.

22. Subsequent Events

Income Taxes

On February 28, 2023, the Company received $112.1 million of cash, plus interest, of the $135.9 million CARES Act income tax refund receivable that was included within prepaid expense and other current assets on the consolidated balance sheet as of December 30, 2022 (Successor). The remaining refund is expected to be received during fiscal 2023.

Commitments and Contingencies

Certain litigation matters occurred prior to December 30, 2022 (Successor) but had subsequent updates through the date of this report. See further discussion in Note 19.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended ("Exchange Act"), is recorded, processed, summarized and reported within the specified time periods, and that such information is accumulated and communicated to management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act) as of December 30, 2022 (Successor). Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

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

Management assessed the effectiveness of our internal control over financial reporting as of December 30, 2022 (Successor). 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)*. Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting.

Our internal control over financial reporting as of December 30, 2022 (Successor) has been audited by Deloitte & Touche LLP, the independent registered public accounting firm that audited and reported on the consolidated financial statements included in this Annual Report. This report is included below.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 30, 2022 (Successor) that have materially affected, or are likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Mallinckrodt plc (the "Company") as of December 30, 2022 (Successor Company), based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 30, 2022, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of December 30, 2022 and for the periods from June 17, 2022 through December 30, 2022 (Successor Company) and January 1, 2022 through June 16, 2022 (Predecessor Company) of the Company and our report dated March 3, 2023, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the Company's adoption of fresh-start accounting.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Deloitte & Touche LLP
St. Louis, Missouri
March 3, 2023

Item 9B. Other Information.

None

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

Not applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding our directors required under this Item 10. Directors, Executive Officers and Corporate Governance will be filed with the SEC within 120 days after December 30, 2022 pursuant to General Instruction G(3) to Form 10-K.

Information regarding our executive officers required under this Item 10. Directors, Executive Officers and Corporate Governance is included in Item 1. Business of this Annual Report.

We have adopted the Mallinckrodt Code of Conduct, which meets the requirements of a "code of ethics" as defined in Item 406 of Regulation S-K, as well as the requirements of a code of business conduct and ethics under the listing standards of the New York Stock Exchange. Our Code of Conduct applies to all employees, officers and directors of Mallinckrodt, including, without limitation, our CEO, CFO and other senior financial officers. Our Code of Conduct is posted on our website at mallinckrodt.com under the heading "Investor Relations - Corporate Governance." We will also provide a copy of our Code of Conduct to shareholders upon request. We intend to disclose any amendments to our Code of Conduct, as well as any waivers for executive officers or directors, on our website.

Item 11. Executive Compensation.

Information regarding the compensation of our named executive officers and directors required under this Item 11. Executive Compensation will be filed with the SEC within 120 days after December 30, 2022 pursuant to General Instruction G(3) to Form 10-K.

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

Information regarding individuals or groups which own more than 5.0% of our ordinary shares, as well as information regarding the security ownership of our executive officers and directors, and other shareholder matters required under this Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters will be filed with the SEC within 120 days after December 30, 2022 pursuant to General Instruction G(3) to Form 10-K.

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

Information regarding transactions with related parties and director independence required under this Item 13. Certain Relationships and Related Transactions, and Director Independence will be filed with the SEC within 120 days after December 30, 2022 pursuant to General Instruction G(3) to Form 10-K.

Item 14. Principal Accounting Fees and Services.

Information regarding the services provided by and the fees paid to Deloitte & Touche LLP, our independent auditors, required under this Item 14. Principal Accounting Fees and Services will be filed with the SEC within 120 days after December 30, 2022 pursuant to General Instruction G(3) to Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Documents filed as part of this report:

1) *Financial Statements*. The following are included within Item 8. Financial Statements and Supplementary Data of this Annual Report.

- Report of Independent Registered Public Accounting Firm
- Consolidated Statements of Operations for the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022, through June 16, 2022 (Predecessor), and the fiscal years ended December 31, 2021 (Predecessor) and December 25, 2020 (Predecessor)
- Consolidated Statements of Comprehensive Operations for the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022, through June 16, 2022 (Predecessor), and the fiscal years ended December 31, 2021 (Predecessor) and December 25, 2020 (Predecessor)
- Consolidated Balance Sheets as of December 30, 2022 (Successor) and December 31, 2021 (Predecessor)
- Consolidated Statements of Cash Flows for the period from June 17, 2022 through December 30, 2022 (Successor), the period from January 1, 2022, through June 16, 2022 (Predecessor), and the fiscal years ended December 31, 2021 (Predecessor) and December 25, 2020 (Predecessor)
- Consolidated Statements of Changes in Shareholders' Equity for the period from December 27, 2019 (Predecessor) to December 30, 2022 (Successor)
- Notes to Consolidated Financial Statements

2) *Financial Statement Schedules.* The financial statement schedule is included below. All other schedules have been omitted because they are not applicable, not required or the information is included in the financial statements or notes thereto.

Schedule II - Valuation and Qualifying Accounts
(in millions)

Description	Balance at Beginning of Period	Charged to Operations	Additions and Other	Deductions	Balance at End of Period
Allowance for doubtful accounts:					
Fiscal year ended Period from June 17, 2022 through December 30, 2022 (Successor)	$ 5.9	$ 0.5	$ —	$ (2.0)	$ 4.4
Fiscal year ended Period from January 1, 2022 through June 16, 2022 (Predecessor)	4.7	1.2	—	—	5.9
Fiscal year ended December 31, 2021 (Predecessor)	4.5	1.2	—	(1.0)	4.7
Fiscal year ended December 25, 2020 (Predecessor)	4.0	1.2	—	(0.7)	4.5
Sales reserve accounts:					
Fiscal year ended Period from June 17, 2022 through December 30, 2022 (Successor)	$ 276.9	$ 848.1	$ —	$ (831.0)	$ 294.0
Fiscal year ended Period from January 1, 2022 through June 16, 2022 (Predecessor)	$ 272.8	715.7	—	(711.6)	$ 276.9
Fiscal year ended December 31, 2021 (Predecessor)	235.4	2,166.0	—	(2,128.6)	272.8
Fiscal year ended December 25, 2020 (Predecessor) [(1)]	337.4	2,154.3	536.0	(2,792.3)	235.4
Tax valuation allowance:					
Fiscal year ended Period from June 17, 2022 through December 30, 2022 (Successor)	$ 5,129.7	$ (136.0)	$ (0.8)	$ —	$ 4,992.9
Fiscal year ended Period from January 1, 2022 through June 16, 2022 (Predecessor)	6,344.2	(1,213.5)	(1.0)	—	$ 5,129.7
Fiscal year ended December 31, 2021 (Predecessor)	6,110.8	233.4	—	—	6,344.2
Fiscal year ended December 25, 2020 (Predecessor)	3,131.5	2,979.3	—	—	6,110.8

(1) The $536.0 million charge to the sales reserve accounts during fiscal 2020 relates to the Medicaid lawsuit.

3) *Exhibits.* The exhibits are included in the Exhibit Index that appears at the end of this Annual Report.

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.

MALLINCKRODT PLC

March 3, 2023

By: /s/ Bryan M. Reasons

Bryan M. Reasons
Executive Vice President and Chief Financial Officer
(principal financial and accounting officer)

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/ Sigurdur Olafsson Sigurdur Ofalsson	President, Chief Executive Officer and Director *(principal executive officer)*	March 3, 2023
/s/ Bryan M. Reasons Bryan M. Reasons	Executive Vice President and Chief Financial Officer *(principal financial and accounting officer)*	March 3, 2023
/s/ Paul Bisaro Paul Bisaro	Chairman of the Board of Directors	March 3, 2023
/s/ Daniel Celentano Daniel Celentano	Director	March 3, 2023
/s/ Riad El-Dada Riad El-Dada	Director	March 3, 2023
/s/ Neal Goldman Neal Goldman	Director	March 3, 2023
/s/ Karen Ling Karen Ling	Director	March 3, 2023
/s/ Dr. Woodrow Myers Dr. Woodrow Myers	Director	March 3, 2023
/s/ Susan Silbermann Susan Silbermann	Director	March 3, 2023
/s/ James Sulat James Sulat	Director	March 3, 2023

EXHIBIT INDEX

Exhibit Number	Exhibit
2.1	Share Purchase Agreement, dated as of August 24, 2016, by and among Mallinckrodt Chemical Holdings (U.K.) Limited, Mallinckrodt Netherlands Holdings B.V., GLO Dutch Bidco B.V. and GLO US Bidco, LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed August 24, 2016).
2.2	First Amendment to Share Purchase Agreement, dated as of December 15, 2016, by and among Mallinckrodt Chemical Holdings (U.K.) Limited, Mallinckrodt Netherlands Holdings B.V., GLO Dutch Bidco B.V. and GLO US Bidco, LLC. (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed January 27, 2017).
2.3	Amended Proposals for a Scheme of Arrangement Between Mallinckrodt Public Limited Company and Its Members and Creditors (included as Schedule 1 to the Order of the High Court of Ireland, dated as of April 27, 2022) (incorporated by reference to Exhibit 2.2 to Mallinckrodt plc's Current Report on Form 8-K filed with the SEC on May 3, 2022).
2.4	Fourth Amended Joint Plan of Reorganization (with Technical Modifications) of Mallinckrodt Plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code (included as Schedule 2 to the Order of the High Court of Ireland, dated as of April 27, 2022) (incorporated by reference to Exhibit 2.1 to Mallinckrodt plc's Current Report on Form 8-K filed with the SEC on May 3, 2022).
2.5	Modified Fourth Amended Joint Plan of Reorganization (with Technical Modifications) of Mallinckrodt Plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code, filed June 21, 2022. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 22, 2022).
3.1	Certificate of Incorporation of Mallinckrodt plc (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
3.2	New Memorandum and Articles of Association of Mallinckrodt plc (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.1	Indenture, dated as of April 7, 2020, among the Issuers and the Note Guarantors party thereto from time to time and Wilmington Savings Fund Society, FSB, as first lien trustee and Deutsche Bank AG New York Branch, as first lien collateral agent (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed April 7, 2020).**
4.2	Warrant Agreement, dated June 16, 2022. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.3	11.500% First Lien Senior Secured Notes due 2028 Indenture, dated June 16, 2022. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.4	Form of 11.500% First Lien Senior Secured Note due 2028 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.5	Supplemental Indenture No. 4, dated June 16, 2022 (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.6	10.000% Second Lien Senior Secured Notes due 2025 Indenture, dated June 16, 2022. (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.7	Form of 10.000% Second Lien Senior Secured Notes due 2025 (incorporated by reference to Exhibit 4.6 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.8	10.000% Second Lien Senior Secured Notes due 2029 Indenture, dated June 16, 2022. (incorporated by reference to Exhibit 4.7 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.9	Form of 10.000% Second Lien Senior Notes due 2029 (incorporated by reference to Exhibit 4.8 to the Company's Current Report on Form 8-K filed June 22, 2022).
4.10	Amendment to the Warrant Agreement, dated as of December 8, 2022, by and among Mallinckrodt plc and Computershare Inc. and its affiliate, Computershare Trust Company, N.A. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed December 8, 2022).
4.11	Description of Mallinckrodt plc's Registered Securities.
10.1	Form of Employment Agreement by and between ST Shared Services LLC and Executive Officers (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 24, 2020).
10.2	Form of First Amendment to Employment Agreement by and between ST Shared Services LLC and Executive Officers (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 2, 2021).
10.3	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives, amended September 8, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 10-Q filed November 2, 2021).
10.4	Mallinckrodt Pharmaceuticals Change in Control Severance Plan for Certain U.S. Officers and Executives, amended May 18, 2017 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed August 8, 2017).

10.5	Mallinckrodt Pharmaceuticals Stock and Incentive Plan, as amended and restated effective February 23, 2022 (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K filed March 15, 2022).
10.6	Intercreditor Agreement, dated as of December 6, 2019, among Deutsche Bank AG New York Branch, as first lien collateral agent and first lien credit agreement representative, Wilmington Savings Fund Society, FSB, as second lien collateral agent and initial second lien document representative, each other first lien representative party thereto from time to time and each other second lien representative party thereto from time to time and acknowledged and agreed to by Mallinckrodt plc, Mallinckrodt International Finance S.A, Mallinckrodt CB LLC and each other obligor party thereto from time to time (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed December 9, 2019).
10.7	Support and Exchange Agreement, dated as February 25, 2020, by and among Mallinckrodt plc, Mallinckrodt International Finance S.A., Mallinckrodt CB LLC and the Exchanging Holders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 25, 2020).
10.8	Support Agreement, dated as of February 25, 2020, by and among Mallinckrodt plc, Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the Noteholder Parties and the Lender Parties (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 25, 2020).
10.9	Restructuring Support Agreement, dated October 11, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 13, 2020).
10.10	Joinder Agreement and Amendment to Restructuring Support Agreement, dated March 10, 2021 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed March 10, 2021).
10.11	Joinder Agreement to the Restructuring Support Agreement for the Multi-State Governmental Entities Group, dated November 13, 2020 (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the fiscal year ended December 25, 2020).
10.12	Settlement Agreement, dated as of March 7, 2022, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Mallinckrodt plc, Mallinckrodt ARD LLC and James Landolt (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 11, 2022).
10.13	Settlement Agreement, dated as of March 7, 2022, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Mallinckrodt plc, Mallinckrodt ARD LLC, Charles Strunck, Lisa Pratta and Scott Clark (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed March 11, 2022).
10.14	Opioid Deferred Cash Payments Agreement, dated as of June 16, 2022, by and among Mallinckrodt plc, Mallinckrodt LLC, SpecGx Holdings LLC, SpecGx LLC and the Opioid Master Disbursement Trust II (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.15	Registration Rights Agreement, dated as of June 16, 2022, by and among Mallinckrodt plc and MNK Opioid Abatement Fund, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.16	Credit Agreement, dated as of June 16, 2022, by and among Mallinckrodt plc, Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the Lenders party thereto, Acquiom Agency Services LLC, Seaport Loan Products LLC and Deutsche Bank AG New York Branch (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.17	Purchase Agreement, dated as of June 15, 2022, by and among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, Mallinckrodt plc and the purchasers thereunder (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.18	ABL Credit Agreement, dated as of June 16, 2022, by and among ST US AR Finance LLC, the Lenders and L/C Issuers Party thereto and Barclays Bank plc (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.19	Purchase and Sale Agreement, dated as of June 16, 2022, by and among the various entities listed on Schedule I thereto or that become parties thereto from time to time pursuant to Section 4.3 thereof, MEH, Inc. and ST US AR Finance LLC (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.20*	Separation of Employment Agreement and General Release, dated as of June 16, 2022, by and between Mark Trudeau and ST Shared Services LLC (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.21*	Employment Agreement dated as of June 16, 2022, by and between Mallinckrodt plc and Sigurdur Olafsson (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.22*	Letter Agreement, by and between Hugh O'Neill and Mallinckrodt plc (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.23*	Letter Agreement by and between Steven Romano and Mallinckrodt plc (incorporated by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.24*	Mallinckrodt Pharmaceuticals 2022 Stock and Incentive Plan, dated June 16, 2022 (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.25	Form of Deed of Indemnification by and between Mallinckrodt plc and Directors and Secretary (incorporated by reference to Exhibit 10.14 to the Company's Current Report on Form 8-K filed June 22, 2022).

10.26	Form of Deed of Indemnification by and between Mallinckrodt plc and Officers (incorporated by reference to Exhibit 10.15 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.27	Form of Indemnification Agreement by and between Sucampo Pharmaceuticals, Inc. and Directors and Secretary (incorporated by reference to Exhibit 10.16 to the Company's Current Report on Form 8-K filed June 22, 2022).
10.28**	Asset Purchase Agreement, dated as of June 30, 2022, by and between Novartis Pharma AG and Stratatech Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 30, 2022).
10.29*	Form of Mallinckrodt Pharmaceuticals 2022 Stock and Incentive Plan Terms and Conditions of Restricted Unit Award to Non-Employee Director (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed November 8, 2022).
10.30	Warrant Termination Agreement, dated as of December 8, 2022, by and among MNK Opioid Abatement Fund, LLC, Opioid Master Disbursement Trust II and Mallinckrodt plc (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 8, 2022).
10.31*	Amended and Restated Employment Agreement dated February 22, 2023 between ST Shared Services LLC and Sigurdur Olafsson.
10.32*	Amended and Restated Employment Agreement dated February 22, 2023 between ST Shared Services LLC and Bryan Reasons.
10.33*	Amended and Restated Employment Agreement dated February 22, 2023 between ST Shared Services LLC and Henriette Nielsen.
10.34*	Amended and Restated Employment Agreement dated February 22, 2023 between ST Shared Services LLC and Lisa French.
10.35*	Amended and Restated Employment Agreement dated February 22, 2023 between ST Shared Services LLC and Mark Tydnall.
10.36*	Employment Agreement dated January 12, 2023 between ST Shared Services LLC and Dr. Peter C. Richardson.
10.37*	Amended and Restated Employment Agreement dated February 22, 2023 between Mallinckrodt Enterprises, LLC and Stephen Welch.
10.38*	Amended and Restated Employment Agreement dated February 22, 2023 between ST Shared Services LLC and Jason Goodson.
10.39*	Amended and Restated Employment Agreement dated February 22, 2023 between ST Shared Services LLC and Kassie Harrold.
21.1	Subsidiaries of Mallinckrodt plc.
23.1	Consent of Deloitte & Touche LLP.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of the Chief Executive Officer and Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1	Order Confirming the Fourth Amended Joint Plan of Reorganization (with Technical Modifications) of Mallinckrodt Plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code, including the full text of the Fourth Amended Joint Plan of Reorganization (with Technical Modifications) as Exhibit A thereto (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed March 3, 2022).
99.2	Order of the High Court of Ireland, dated as of April 27, 2022 (incorporated by reference to Exhibit 99.1 to Mallinckrodt plc's Current Report on Form 8-K filed with the SEC on May 3, 2022).
101	The following materials from the Mallinckrodt plc Annual Report on Form 10-K for the fiscal year ended December 30, 2022 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Operations, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statements of Shareholders' Equity and (vi) related notes. The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

*Compensation plans or arrangements.
**Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulations S-K.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.