



**2022 IRISH STATUTORY ACCOUNTS**

# **MALLINCKRODT PLC**

**Directors' Report and Consolidated Financial Statements  
For the Fiscal Year Ended December 30, 2022**

# MALLINCKRODT PLC

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## **DIRECTORS' REPORT**

**For the Fiscal Year Ended December 30, 2022**

*(dollars in millions, except share data and where indicated)*

### ***Basis of Presentation***

The directors present their report on the audited consolidated financial statements for the fiscal year ended December 30, 2022, beginning on page 50, and audited parent company financial statements for the fiscal year ended December 30, 2022, beginning on page 120.

The directors have elected to prepare the Irish statutory Mallinckrodt plc consolidated financial statements in accordance with Section 279 of the Irish Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Irish Companies Act 2014.

The directors have elected to prepare the Mallinckrodt plc parent company financial statements in accordance with FRS 102 *The Financial Reporting Standards applicable in the United Kingdom ("U.K.") and Republic of Ireland* together with the Irish Companies Act 2014.

The accompanying financial statements reflect the consolidated financial position of the parent company ("Mallinckrodt plc" or the "Company") and its subsidiaries (Mallinckrodt plc and all its subsidiaries, hereinafter referred to as "Mallinckrodt," the "Group," "us," "we," or "our") as an independent, publicly-traded company.

### ***Fiscal Year***

We report our results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2022 consisted of 53 weeks and fiscal 2021 consisted of 52 weeks. Unless otherwise indicated, fiscal 2022 and 2021 refer to the fiscal years ended on December 30, 2022 and December 31, 2021, respectively. All references to "fiscal" year are considered to be defined as "financial" year under FRS 102

### ***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 Directors' Report is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the United States ("U.S.") and other jurisdictions. Solely for convenience, we only use the <sup>TM</sup> or <sup>®</sup> symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks and trade names. Each trademark or trade name of any other company appearing in this Directors' Report is, to our knowledge, owned by such other company.

### ***Forward-Looking Statements***

We have made forward-looking statements in this Directors' 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 our possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements and 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 principal risks and uncertainties included in this Directors' Report could cause our results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business.

These forward-looking statements are made as of the issuance date of this Directors' Report. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

### ***Principal Activities***

Mallinckrodt plc is an Irish company maintaining its headquarters in Ireland since its spin-off in 2013. Mallinckrodt plc is the parent company of a global business consisting of multiple wholly owned subsidiaries whose principal activity is to develop, manufacture, market and distribute specialty pharmaceutical products and therapies.

On October 27, 2022, our ordinary shares commenced trading on the New York Stock Exchange American LLC ("NYSE American" under the ticker symbol "MNK."

Our principal executive offices are located at College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland (telephone number: +353 1 696 0000) where our Specialty Brands global external manufacturing operations are also located. In addition, we have other locations in the 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.

We operate our business in two reportable segments:

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

Additional information about our reportable business segments is included throughout this report. The results of operations of our reportable business segments are discussed in the heading "Consolidated Results of Operations." Across all of our reportable business segments, we generated total turnover of \$1,914.3 million and \$2,208.8 million in fiscal 2022 and 2021, respectively.

Our Specialty Brands segment 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;
- advance pipeline products and bring them to market; 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. 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.

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 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 stearate, 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 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.

The Group is incorporated in Ireland where we maintain our principal executive offices and continues to be subject to the U.S. Securities and Exchange Commission ("SEC") reporting requirements.

## ***Significant Events***

### ***INOmax***

On September 28, 2022, we submitted a 510(k) premarket notification to the U.S. Food and Drug Administration ("FDA") for an investigational inhaled nitric oxide delivery system for INOmax<sup>®</sup> (nitric oxide) gas, for inhalation ("INOmax"), 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<sup>®</sup> (terlipressin) ("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, we released our first commercial shipment of StrataGraft<sup>®</sup> (allogenic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat) ("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 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 for further information on the Plan and emergence from Chapter 11.

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 Predecessor (as defined below) 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 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");
- We adopted a management incentive plan providing for the issuance to management, key employees and directors of the Group of equity awards with respect to up to an aggregate of 1,829,068 shares;
- All stated claims of the Department of Justice ("DOJ") and other governmental parties relating to Acthar<sup>®</sup> Gel (repository corticotropin injection) ("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 Priority Review Voucher ("PRV") and \$20.0 million payable upon the achievement of (i) U.S. Food and Drug Administration ("FDA") approval of Terlivaz and (ii) cumulative turnover 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.

### ***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 predecessor senior secured revolving credit facility. We also entered into a \$200.0 million receivables financing facility, which was undrawn as of December 30, 2022.

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***

Upon emergence from Chapter 11, in so far as it does not contravene any provision of Part 6 of Irish Companies Act 2014, 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 under U.S. GAAP, but was considered the same legal entity under Irish Company Law. References to "Successor" relate to the financial position as of June 16, 2022 and results of operations of the reorganized Group 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 Group prior to, and including, June 16, 2022. All emergence-related transactions of the Predecessor were recorded as of June 16, 2022. The combination of the Successor and Predecessor results present a true and fair view of the assets and liabilities, financial position and profit or loss. For certain disclosures, the Group elected to reflect the Successor and Predecessor separately to accurately portray the impact of fresh-start accounting. Refer to Note 3 of the Notes to the Consolidated Financial Statements for further information.

### ***Reorganization items, net***

During fiscal 2022, we incurred expenses of \$1,505.9 million from reorganization items, net. These expenses were primarily driven by the loss on application of fresh-start accounting of \$2,206.4 million and professional and lender fees of \$228.6 million, partially offset by a \$943.7 million gain on settlement of liabilities subject to compromise ("LSTC") in accordance with the Plan. During fiscal 2021, we incurred expenses of \$428.2 million from reorganization items, net, primarily driven by professional fees and adjustments to reflect the carrying value of LSTC at their estimated allowed claim amounts.

### ***Likely Future Developments***

#### ***Specialty Brands***

Turnover of INOmax for fiscal 2022 decreased \$108.8 million or 24.3%, to \$339.7 million 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.

Turnover of Acthar Gel for fiscal 2022 decreased \$77.6 million, or 13.1%, to \$516.0 million 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 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.

Turnover of Amitiza<sup>®</sup> (lubiprostone) ("Amitiza") for fiscal 2022 decreased \$38.3 million, or 19.5%, to \$158.6 million 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.

Turnover of Therakos<sup>®</sup> photopheresis ("Therakos") for fiscal 2022 decreased \$26.4 million, or 9.9%, to \$240.1 million driven primarily by the lagging effect of the novel coronavirus (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***

Turnover of the Specialty Generics segment for fiscal 2022 decreased \$17.0 million, or 2.6%, to \$644.8 million driven primarily by a decrease in API(s) turnover of \$15.4 million and a decrease in generics turnover of \$1.6 million.

### ***Key Performance Indicators***

The financial measures discussed below are considered "non-U.S. GAAP" financial measures. The Group has provided these adjusted financial measures because they are used by management, along with financial measures in accordance with U.S. GAAP, to evaluate the Group's operating performance. In addition, management believes that these non-U.S. GAAP financial measures will be used by certain investors to measure the Group's operating results. Management believes that presenting these non-U.S. GAAP financial measures provides useful information about the Group's performance across reporting periods on a consistent basis by excluding items which may be favorable or unfavorable that the Group does not believe are indicative of its core operating performance. These adjusted measures are also utilized in the determination of management incentive compensation.

These non-U.S. GAAP financial measures should be considered supplemental to and not a substitute for financial information prepared in accordance with U.S. GAAP or FRS 102. The Group's definition of these non-U.S. GAAP financial measures may differ from similarly titled measures used by others.



We calculate our key performance indicators based upon results from ordinary activities as they reflect the ongoing operating performance of the Group and provide the best insight into current and future performance.

Adjusted gross profit, adjusted selling, general and administrative ("SG&A") expenses, adjusted research and development ("R&D") expense and adjusted earnings before interest, taxes, depreciation and amortization ("EBITDA") represent amounts prepared in accordance with U.S. GAAP and adjusted for certain items that management believes are not reflective of the operational performance of the business. Adjustments to U.S. GAAP amounts include, as applicable to each measure, depreciation; amortization; restructuring charges, net; non-restructuring impairment charges; changes in fair value of contingent consideration obligations; significant legal and environmental charges; divestitures; separation costs, gains on debt extinguishment, net; unrealized gain or loss on equity investment; reorganization items, net; share-based compensation; fresh-start related expenses and other items identified by the Group. A reconciliation of these historical adjusted financial measures to the most directly comparable U.S. GAAP, as required under Irish Companies Act 2014, financial measures is included in the following table:

*(in millions)*

	Fiscal Year					
	2022			2021		
	Gross Profit	SG&A	Adjusted EBITDA	Gross Profit	SG&A	Adjusted EBITDA
<b>U.S. GAAP</b>	\$ 610.0	\$ 554.3	\$ (1,381.7)	\$ 891.7	\$ 608.5	\$ (679.6)
Adjustments:						
Interest expense, net	—	—	428.4	—	—	220.7
Income taxes	—	—	(650.8)	—	—	(106.3)
Depreciation <sup>(1)</sup>	54.5	11.3	68.8	70.3	(17.6)	94.7
Amortization	598.9	1.6	600.5	577.7	(3.4)	581.1
Restructuring charges, net			20.7	—	—	26.9
Non-restructuring impairment charge	—	—	—	—	—	90.4
Income from discontinued operations	—	—	(1.1)	—	—	(6.1)
Change in contingent consideration fair value	—	0.5	0.5	—	(8.2)	8.2
Significant legal and environmental charges <sup>(2)</sup>	—	—	—	—	(45.4)	170.4
Losses on divestiture	—	—	—	—	—	0.8
Separation costs <sup>(3)</sup>	—	(30.2)	30.2	—	(1.2)	1.2
Unrealized losses (gains) on equity investment	—	—	13.0	—	—	(4.7)
Reorganization items, net	—	—	1,505.9	—	—	428.2
Share-based compensation	0.1	2.7	3.1	0.5	(8.1)	10.2
Japanese consumption tax credit	—	—	—	—	—	(6.8)
Gain on debt extinguishment at par	—	—	(21.4)	—	—	—
Fresh-start impact on debt extinguishment	—	—	22.4	—	—	—
Bad debt expense - customer bankruptcy	—	(6.4)	6.4	—	—	—
Fresh-start stocks-related expense <sup>(4)</sup>	30.0	—	30.0	—	—	—
<b>As adjusted:</b>	<u>\$ 1,293.5</u>	<u>\$ 533.8</u>	<u>\$ 674.9</u>	<u>\$ 1,540.2</u>	<u>\$ 524.6</u>	<u>\$ 829.3</u>

<sup>(1)</sup> Includes \$0.8 million and \$0.2 million of accelerated depreciation in cost of sales and SG&A, respectively, related to restructuring charges incurred during fiscal 2022 and \$2.1 million of accelerated depreciation in SG&A related to restructuring charges incurred during fiscal 2021.

<sup>(2)</sup> Fiscal 2021 include a \$125.0 million charge related to the opioid-related litigation settlement liability and a \$45.4 million increase in environmental liabilities.

<sup>(3)</sup> Fiscal 2022 represents costs included in SG&A expenses, primarily related to expenses incurred related to severance for the former Chief Executive Officer ("CEO") and certain former executives and 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.

<sup>(4)</sup> Includes \$30.0 million of fresh-start stocks-related expense primarily related to a change in accounting estimate during fiscal 2022.

Further information regarding non-U.S. GAAP financial measures can be found on the Investor Relations page of the Group's website.

### Consolidated Results of Operations

Loss after taxation of \$1,381.7 million and \$679.6 million for fiscal 2022 and 2021, respectively, were recorded to profit and loss account. No profits were distributed as dividends during fiscal 2022 and 2021 and the Group did not make any share repurchases under its authorized share repurchase program during fiscal 2022 and 2021. Refer to Note 28 of the Notes to the Consolidated Financial Statements for further information.

The following table presents the consolidated profit and loss account for fiscal 2022 and 2021 as reported in the Group's 2022 Consolidated Financial Statements. All discussions below are comparative between fiscal 2022 and 2021.

(in millions)	Fiscal Year							
	2022				2021			
	Ordinary Activities		Discontinued Operations	Total Group	Ordinary Activities		Discontinued Operations	Total Group
<b>Turnover</b>	\$ 1,914.3	100.0 %	\$ —	\$ 1,914.3	\$ 2,208.8	100.0 %	\$ —	\$ 2,208.8
Cost of sales	1,304.3	68.1	—	1,304.3	1,317.1	59.6	—	1,317.1
<b>Gross profit</b>	610.0	31.9	—	610.0	891.7	40.4	—	891.7
Distribution and administrative expenses	554.3	29.0	—	554.3	608.5	27.5	—	608.5
Research and development costs	129.7	6.8	—	129.7	205.2	9.3	—	205.2
Restructuring charges, net	20.7	1.1	—	20.7	26.9	1.2	—	26.9
Non-restructuring impairment charges	—	—	—	—	90.4	4.1	—	90.4
Profit on disposal of operations	—	—	(1.1)	(1.1)	0.8	—	(1.1)	(0.3)
Opioid-related litigation settlement loss	—	—	—	—	125.0	5.7	—	125.0
<b>Operating (loss) profit</b>	(94.7)	(4.9)	1.1	(93.6)	(165.1)	(7.5)	1.1	(164.0)
Interest payable and similar expenses	(432.9)	(22.6)	—	(432.9)	(222.6)	(10.1)	—	(222.6)
Interest receivable and similar income	4.5	0.2	—	4.5	1.9	0.1	—	1.9
Other (expense) income, net	(4.6)	(0.2)	—	(4.6)	22.0	1.0	—	22.0
Reorganization items, net	(1,505.9)	(78.7)	—	(1,505.9)	(428.2)	(19.4)	—	(428.2)
<b>(Loss) profit before taxation</b>	(2,033.6)	(106.2)	1.1	(2,032.5)	(792.0)	(35.9)	1.1	(790.9)
Taxation credit	(650.8)	(34.0)	—	(650.8)	(106.3)	(4.8)	(5.0)	(111.3)
<b>(Loss) profit after taxation</b>	<u>\$ (1,382.8)</u>	<u>(72.2)</u>	<u>\$ 1.1</u>	<u>\$ (1,381.7)</u>	<u>\$ (685.7)</u>	<u>(31.0)</u>	<u>\$ 6.1</u>	<u>\$ (679.6)</u>

*Turnover.* Turnover in fiscal 2022 decreased by \$294.5 million, or 13.3%, to \$1,914.3 million 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.

Turnover generated by our businesses in the U.S. was \$1,712.5 million and \$1,991.8 million in fiscal 2022 and 2021, respectively. Our non-U.S. businesses generated turnover of \$201.8 million and \$217.0 million in fiscal 2022 and 2021, respectively, which represented approximately 10.5% of our turnover in fiscal 2022 and 9.8% of our turnover in fiscal 2021.

*Gross profit.* Gross profit for fiscal 2022 decreased \$281.7 million, or 31.6%, to \$610.0 million driven by a decrease in net sales and a change in product mix, coupled with \$30.0 million in fresh-start stocks-related expenses and 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 15 of the Notes to the Consolidated Financial Statements.

*Distribution and administrative expenses.* D&A expenses for fiscal 2022 decreased \$54.2 million, or 8.9% to \$554.3 million. As a percentage of turnover, D&A expenses were 29.0% for fiscal 2022, compared to 27.5%, for fiscal 2021. The decrease in D&A expense for fiscal 2022 as compared to fiscal 2021 was primarily driven by continued cost containment initiatives coupled with a \$46.1 million increase to our environmental liabilities during fiscal 2021. The decrease was partially offset by \$30.2 million of separation costs incurred during fiscal 2022 related to the severance of the former CEO and certain former executives, expense associated with former 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, compared to \$1.2 million during fiscal 2021. Also included in the offset was \$6.4 million of bad debt expense attributable to a customer bankruptcy during fiscal 2022.

*Research and development costs.* R&D expenses for fiscal 2022 decreased \$75.5 million, or 36.8%, to \$129.7 million. As a percentage of turnover, R&D expenses were 6.8% and 9.3% for fiscal 2022 and 2021, respectively. 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 fiscal 2022, we recognized \$21.7 million of restructuring and related charges, net, of which \$0.8 million and \$0.2 million related to accelerated depreciation in cost of sales and D&A, respectively. During fiscal 2021, we recognized \$29.0 million of restructuring and related charges, net, of which \$2.1 million related to accelerated depreciation and was included in D&A. The remaining charges primarily relate to employee severance and benefits.

*Non-restructuring impairment charges.* Non-restructuring impairment charges were \$90.4 million for fiscal 2021 representing a partial impairment of the Amitiza intangible asset.

*Profit on disposal of operations.* We recorded income of \$1.1 million and \$6.1 million on discontinued operations, net of income taxes, during fiscal 2022 and 2021, respectively. The income during fiscal 2021 primarily related to the recognition of a taxation credit 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.

*Opioid-related litigation settlement loss.* During fiscal 2021, 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.

*Interest payable and similar expenses and interest receivable and similar income, net.* During fiscal 2022 and fiscal 2021, interest payable and similar expenses and interest receivable and similar income, net were \$428.4 million and \$220.7 million, respectively. During the fiscal 2022, interest payable and similar expenses included \$87.5 million and \$51.7 million of accretion expense associated with our settlement obligations and debt, respectively, and \$28.8 million in expense related to cash adequate protection payments on certain of our predecessor senior secured debt instruments. Fiscal 2022 also reflected increased interest rates on our variable interest rate debt as compared to fiscal 2021. Fiscal 2021 also included \$63.1 million in expense related to cash adequate protection payments on certain of our predecessor senior secured debt instruments coupled with the recognition of a \$15.8 million benefit to interest expense due to a lapse of certain statute of limitations.

*Other (expense) income, net.* During fiscal 2022 and 2021, we recorded other expense, net of \$4.6 million and other income, net of \$22.0 million, respectively. We recognized a \$13.0 million unrealized loss and a \$4.7 million unrealized gain on our equity investments for fiscal 2022 and 2021, respectively. Fiscal 2022 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.

*Reorganization items, net.* During fiscal 2022 and 2021, we recorded a loss of \$1,505.9 million in reorganization items, net driven primarily by the loss on fresh-start adjustments of \$2,206.4 million and professional fees and lender fees of \$228.6 million, partially offset by a gain on adjustments to LSTC of \$943.7 million. During fiscal 2021, 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.

*Taxation.* During fiscal 2022, we recognized a taxation credit of \$650.8 million on a loss from ordinary activities before taxation of \$2,033.6 million. This resulted in an effective tax rate of 32.0%. The fiscal 2022 taxation credit was comprised of \$51.0 million of current taxation credit and \$599.8 million of deferred taxation credit.

Our effective tax rate for fiscal 2022 was impacted by \$577.5 million of taxation credit associated with valuation allowance and \$31.6 million of taxation credit associated with emergence further detailed in Note 9 of the Notes to Consolidated Financial Statements. Additional impacts include \$44.0 million of taxation credit associated with \$318.7 million of intangible asset amortization expense, \$19.1 million of taxation credit associated with \$87.5 million of accretion expense related to our settlement obligations, \$12.7 million of taxation credit associated with \$51.7 million of accretion expense related to our debt and \$8.7 million of taxation credit associated with \$1,505.9 million of reorganization items, net, offset with \$4.7 million of withholding taxation charge associated with a Swiss distribution. The remaining \$38.1 million of taxation charge is predominately associated with pretax earnings in various jurisdictions.

During fiscal 2021, we recognized a taxation credit of \$106.3 million on a loss from ordinary activities before taxation of \$792.0 million. This resulted in an effective tax rate of 13.4%. The fiscal 2021 taxation credit was comprised of \$46.4 million of current taxation credit and \$59.9 million of deferred taxation credit. The current taxation credit was primarily the result of an increase to prepaid taxes and a decrease to uncertain tax positions. The deferred taxation credit was predominately related to intangible asset amortization, partially offset by utilization of loss carryforwards in non-valuation allowance jurisdictions.

Our effective tax rate for fiscal 2021 was impacted by the taxation credit of \$274.3 million predominately related to pretax earnings in various jurisdictions resulting from the fiscal 2020 reorganization of the Group's intercompany financing and associated asset and legal entity ownership and a \$9.7 million taxation credit associated with accrued income tax liabilities and uncertain tax positions, partially offset with \$177.7 million of taxation charge associated with valuation allowances recorded against our net deferred tax assets in applicable tax jurisdictions. Additional impacts to the fiscal 2021 effective tax rate include a taxation credit of \$49.9 million associated with \$428.2 million of reorganization items, net, \$21.1 million of taxation credit associated with the \$125.0 million opioid-related litigation settlement charge, \$20.3 million of taxation credit associated with the \$90.4 million non-restructuring impairment charge and \$10.2 million of taxation credit associated with the \$46.1 million increase to environmental liabilities. These additional impacts are significantly offset with the above referenced valuation allowance, thus resulting in a taxation credit of \$15.0 million included within our pretax earnings in various jurisdictions.

## ***Financial Position***

Our financial position is set out on page 62. As of December 30, 2022 and December 31, 2021 we had total assets of \$5,532.0 million and \$8,916.3 million, respectively, and total liabilities of \$4,399.9 million and \$8,614.0 million, respectively. As of December 30, 2022 and December 31, 2021 we had net current assets of \$1,359.9 million and net current liabilities of \$3,289.2 million, respectively. During fiscal 2022, we incurred a loss after taxation of \$1,381.7 million.

## ***Principal Risks and Uncertainties***

*You should carefully consider the risks described below in addition to all other information provided to you in this Directors' Report and accompanying financial statements. 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 the Group.*

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 Directors' 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.

***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 Group 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 Group 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 corporate integrity agreement ("CIA") with the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("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 Group 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 Group'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 Group'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 turnover. 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 turnover 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 turnover, 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 turnover, 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 turnover, marketing and pricing practices, including the DOJ and various other agencies including the OIG within the HHS, the FDA, the Federal Trade Commission ("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 U.S. Federal Food, Drug and Cosmetic Act ("FFDCA"), the False Claims Act ("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. The DOJ and the SEC have also

increased their focus on the enforcement of the Foreign Corrupt Practices Act of 1977 ("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 turnover 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 turnover volume or both.

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 27.0% of our fiscal 2022 turnover. 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.

***Turnover 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.***

Turnover 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 turnover of Acthar Gel.

In the European Union ("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 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 "*Turnover 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 Centers for Medicare and Medicaid Services ("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 of 2022 ("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 turnover 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, Health Resources and Services Administration ("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 Veteran Affairs ("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 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 Federal Ceiling Price ("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 Fiscal Year 2008, requires us to pay quarterly rebates to Department of Defense ("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 turnover, 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 Group 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 group purchasing organizations ("GPO(s)") 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 turnover to members of that GPO or IDN, having a contract is no assurance that turnover 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 turnover 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 turnover. 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 European Medicines Agency ("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 turnover, 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 Risk Evaluation and Mitigation Strategies ("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 Institutional review board ("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 current good manufacturing practice ("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 turnover, 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 investigational new drug 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 turnover volumes, we may be unable to replace lost turnover 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. Turnover to FFF Enterprises, Inc., one of our distributors that supplies our products to many end user customers accounted for 10.0% or more of our total turnover. 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 turnover. Our ability to maintain and increase turnover 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 turnover 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, turnover 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 turnover 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 turnover 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 cutaneous t-cell lymphoma and is available for several additional indications in markets outside the U.S. In the extracorporeal photopheresis ("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 Ultraviolet-A ("UVA") light activated drug, UVADEX<sup>®</sup> (methoxsalen) Sterile Solution, 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<sup>®</sup> Photopheresis System ("CELLEX"), which is the only FDA-approved closed ECP system, and the UVAR XTS<sup>®</sup> 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. The absence of such clinical trial data could cause physicians not to prescribe Acthar Gel, or payers not to reimburse the drug, which could negatively impact our business.***

Our turnover of Acthar Gel, which comprises 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 FDCA. 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 new drug application for use of Acthar Gel in treatment of infantile spasms ("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 multiple sclerosis 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 hypoxic respiratory failure 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 good laboratory practice or good clinical practice. 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 product liability losses and other litigation liability.***

As noted elsewhere in our Principal Risk and Uncertainties, we are or may become involved in various legal proceedings and certain 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 25 of the Notes to Consolidated Financial Statements. 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 the 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, 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, the best estimate within this range was \$36.9 million. For further information on our environmental obligations, refer to Note 25 of the Notes to Consolidated Financial Statements. 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 Controlled Substances Act of 1970 ("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 turnover and stocks 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 stocks 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 turnover 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. 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, 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 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 trade 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 trade debtors securing the borrowing capacity as well as certain financial covenants. The amount of trade debtors 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, 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. While we have or 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 Internal Revenue Service ("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 United Kingdom ("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 Group's principal executive offices were relocated from the U.K. to Ireland, which resulted in a change in the Group'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 Group'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 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.

### ***Financial Risk Management***

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. We have outlined in the Risks Related to Our Business within the Principal Risks and Uncertainties above the possible impacts of price risk. Refer to Note 26 of the Notes to the Consolidated Financial Statements for details of credit risk in relation to trade debtors.

### ***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, 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 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 turnover 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 profit and loss account 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, 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.

## ***Non-Financial Reporting***

The E.U. (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 (S.I. 360/2017) (as amended) require us to disclose certain non-financial information in our Directors' Report. Information is provided on these matters across this report, as well as in our Directors' Report, including the Principal Activities section on page 5 and the Principal Risks and Uncertainties section on pages 12 to 40.

## **Mallinckrodt's Business Model**

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

## **Environmental, Social and Governance ("ESG") - Our Commitment to Operating Responsibly**

Mallinckrodt strives to be a force for good. Now more than ever, businesses are important contributors to solving the many challenges we face as a society. We have a commitment to do more and are taking steps to ensure we are operating and growing responsibly. We believe ESG programs are foundational to creating long-term value for all our stakeholders, including patients, employees, customers, shareholders and our communities.

### ***ESG Governance***

Mallinckrodt's Board of Directors is responsible for incorporating ESG into long-term strategy and risk management. At the operational level, ESG is managed by Mallinckrodt's Executive Vice President and Chief Transformation Officer who leads an ESG Steering Committee responsible for strategy implementation, stakeholder engagement, disclosures, reporting and communications. Cross-functional working groups manage specific ESG programs and initiatives to ensure progress and accountability.

### ***Environmental, Health and Safety ("EHS")***

At Mallinckrodt, we are building a culture where environmental sustainability, as well as employee health and safety are promoted at every level within the organization. We believe that every employee is responsible for EHS - leading us to continuously improve our EHS performance by recognizing, evaluating and controlling risks. Some of the main features of our EHS efforts include:

- a well-established EHS management system, including internal protocols and standards adapted to meet or exceed compliance with applicable laws;
- continuous improvement to become a more sustainable and responsible business;
- enterprise-wide EHS management software with utilized and established metrics and measures, including both lagging and leading indicators, to evaluate and project Group performance; and
- an internal and external auditing program to assure compliance.

## ***Environmental Impact***

Mallinckrodt is committed to conducting our business in a manner that minimizes the environmental impacts of our operations and promotes responsible management of resources. We strive to design products and implement processes that reduce our environmental impact while meeting the needs of customers. Our product development process spans from extraction of raw materials to final disposition.

Aligned with our Supplier Code of Conduct, we source products and services from suppliers that share our commitment to quality, innovation, customer satisfaction and sustainability. We believe creating a sustainable supply base and deploying environmentally preferable business practices is critical to our long-term success and growth.

We continually seek opportunities to conserve resources by improving efficiencies, introducing renewable energy sources, reducing our consumption and minimizing waste. In particular, in 2022:

- our manufacturing site and office in Dublin, Ireland, sourced 100% renewable electricity;
- electric vehicle charging stations were installed at three of our corporate offices to encourage sustainable transportation;
- more than 87% of hazardous waste generated across the Group was recycled or reclaimed; and
- our manufacturing site located in St. Louis, Missouri reduced its water usage by more than 50% in the past 6 years, as part of an intensive water conservation program.

## ***Green House Gas Emissions***

We are committed to purchasing and managing energy in the most efficient, cost effective and environmentally conscious manner possible across all of our operations.

The following table shows scope 1 and scope 2 emissions data collected for Mallinckrodt's Specialty Brands and Specialty Generics segments for 2022:

<b>Key Performance Indicator</b>	<b>Specialty Brands</b>	<b>Specialty Generics</b>	<b>Total Group</b>
Global Scope 1 Emissions (metric tons CO <sub>2</sub> e)	7,188	82,363	89,551
Global Scope 2 Emissions (metric tons CO <sub>2</sub> e)	13,062	69,285	82,347

Both Scope 1 and Scope 2 emissions have been re-baselined in 2022 in accordance with the Greenhouse Gas protocol methodology and some updated emission factors. 2022 baseline is set based on operational control boundaries and includes all Mallinckrodt sites and leased vehicles. We will continue to monitor these indicators with the aim of reducing Mallinckrodt environmental impact.

## ***Product Quality***

For more than 155 years, we have held ourselves to the highest standards of quality and safety. Mallinckrodt's extensive quality management system governs all aspects of drug and device manufacturing, providing the foundation for safety that underpins our entire business. We are committed to communicating the Group's Quality Policy to all employees and third parties, and to provide the required leadership, management, and resources to achieve our quality objectives. The guiding principles driving our Quality Policy and our corporate commitment to excellence are:

- Patient safety as the highest priority, pre-eminent in every decision we make.
- Complying with applicable laws and regulations as well as internal requirements to position our Group as a model for compliance and integrity.
- Being recognized as an industry leader in providing quality products and services that meet or exceed the requirements and needs of our patients.
- Continuously challenging ourselves to improve the quality management system, our quality processes and operational excellence through the review and analysis of quality objectives and results.
- Encouraging participation and promotion of quality responsibilities among all employees and third parties through education, training and coaching, supervision, and effective communication.

## ***Employee Health & Safety***

At Mallinckrodt, we aim to develop an injury-free workplace and build assurance that our activities do not lead to adverse safety or health impacts. The following table sets out key performance indicators that we collected related to workplace safety of Mallinckrodt's Specialty Brands and Specialty Generics segments in 2022:

<b>Key Performance Indicator</b>	<b>Specialty Brands</b>	<b>Specialty Generics</b>	<b>Total Group</b>
Total Recordable Injury Rate (per 100 employees)	0.8	2.4	1.6
Number of Recordable Injuries	9 (*)	31	40
Lost Time Incident Rate (per 100 employees)	0.3	1.1	0.7
Number of Lost Time Injuries	3	14	17
Total Number of Hours Worked	2,334,838	2,577,408	4,912,246

These indicators are based on Occupational Safety and Health Administration definition and include (\*) 4 COVID-19 cases in Specialty Brands.

## ***Social and Employee Matters***

Our employees are our most important asset. We strive to create a workplace where our people can be themselves and feel supported personally and professionally, so they can contribute to their full potential and thrive in their careers. From offering competitive pay and benefits to investing in our employees' growth and development and creating a safe and healthy work environment – our human resources programs are inclusive, equitable, and meet the unique and evolving needs of our employees and their families. Mallinckrodt is also deeply committed to active social engagement by supporting and empowering individuals, groups and organizations in the communities where we live and work.

We employ a multi-national workforce of approximately 2,700 people as of December 30, 2022. We are a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. Our field-based employees make up 18% of our workforce and work across multiple countries engaging with healthcare professionals and facilities. Our products are developed by a workforce with specialized degrees in science, engineering and technology. Our manufacturing and distribution locations across the U.S., Ireland and Japan make up 60% of our workforce; 22% of our employees work within our science and technology and corporate services locations of Hampton, New Jersey; Hazelwood, Missouri; Webster Groves, Missouri; Washington DC, Staines, U.K. and Dublin, Ireland. Of our total workforce, 99% are full time. As an equal opportunity employer, we are committed to providing a safe and welcoming work environment where all team members are treated with individual respect and dignity. We have established policies and practices to protect all employees and applicants for employment from discrimination based on race, color, religion, gender, sexual orientation, gender identity and expression, national origin, age, disability, veteran status, or genetics. Additionally, we comply with applicable state and local laws governing nondiscrimination in employment in every location in which Mallinckrodt has facilities.

### *Employee Benefits and Compensation*

Our Total Rewards program is designed to provide comprehensive and competitive benefits that emphasize holistic wellness, supporting the physical, emotional and financial well-being of our employees and their families. Our rewards programs are assessed annually to ensure they are competitive. We also offer a variety of programs and resources to help colleagues manage work-life harmony and major events in their personal lives, such as paid time off and flexible work arrangements.

Mallinckrodt is committed to ensuring our pay practices are fair and equitable. Employee pay is continuously monitored to ensure internal pay equity, in line with our internal compensation structures and market data, which supports our efforts in attracting and retaining diverse talent.

### *Employee Training, Learning & Development:*

We are committed to a culture of continuous learning, aimed at advancing our workforce through personal and professional development. Our global talent strategy helps us identify and align individual employee aspirations with business needs to support development and succession planning across the organization. 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 also partner with external organizations and invest in programs specifically aimed at advancing diverse talent.

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 (“DEI”)*

At Mallinckrodt, we believe innovation stems from diversity of thought and experience. We strive to build an inclusive and equitable workplace that fosters the type of engaged culture that leads to better solutions and outcomes for the patients we serve.

We make it a top priority to foster a culture of belonging and to intentionally create a safe and welcoming environment where all team members are respected and celebrated for the unique identities, cultures, experiences and talent they bring to helping us achieve our mission. We have multiple policies in place to protect all employees such as the Inclusion, Diversity and Individual Respect policy and Harassment Free Workplace policies.

Our employee-led diversity, equity and inclusion ("DEI") Council and Business Resource Groups ("BRG"(s)) 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/or affiliations. Our BRGs offer employees unique networking and professional development opportunities and help promote greater cultural understanding throughout the organization. Our eight BRGs are African American, Champion Circles, Family First, International, LGBTQA+, Namaste Asia, Veterans and Women in Business.

Our BRGs frequently host 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 to achieve equality.
- LGBTQA+ BRG hosted a roundtable discussion around transgender and nonbinary inclusion and ally-ship.

Our approach to DEI continues to receive national recognition. Since 2017, 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 the best interests of our patients, communities and employees. 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 in the US and internationally in areas where we operate and support our employees with their own philanthropy through volunteerism and giving programs.

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 Mallinckrodt's therapeutic areas of focus.

Our community-based investments are centered in three strategic areas – improving health and wellness; advancing science, technology, engineering and mathematics ("STEM") education; and stimulating jobs and economic growth in life sciences.

Mallinckrodt continues to focus efforts on advancing health equity and improving outcomes for underrepresented communities. We supported STEM education helping to expand opportunities for female and minority students, as well as collaborated with patient advocacy organizations to improve engagement and promote greater awareness of health disparities in our key therapeutic areas of focus. For example Mallinckrodt supported:

- *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.

- *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 at high risk of developing, chronic kidney diseases.
- *The American Liver Foundation's* Think Liver Think Life national public health campaign that focuses on awareness and screening of liver disease.

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 volunteer program provides eight hours of 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, we match 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.

#### *Patient Support and Access to Medicines*

We are committed to transparency around our pricing decisions and to pricing our medicines in a manner that reflects the therapy's value to patients, providers and the healthcare system as a whole. We believe that the policy dialogue around improving affordability should include emphasis across the entire healthcare spectrum. We support policy solutions that lower patient out-of-pocket costs and increase timely access to treatments while maintaining a landscape that supports robust scientific innovation. We also offer a patient assistance program and co-pay assistance for certain branded pharmaceuticals to those who qualify.

#### ***Compliance Matters***

Compliance and ethics are the bedrock of our organization. Beginning with our Board of Directors and leadership team, and extending to every employee, Mallinckrodt's unwavering expectation is that team members act with the highest standards of integrity and ethical decision making always. Integrity & Compliance is an independent function at Mallinckrodt and our Chief Compliance Officer and the Governance and Compliance Committee of our Board of Directors oversee our Integrity & Compliance Program to ensure compliance policies and procedures meet the evolving requirements of our complex regulatory and legal landscape.

We are committed to maintaining an effective Integrity & Compliance Program based on the risks we face in our business, the pharmaceutical industry and guidance and enforcement by our regulators. We believe in continuous improvement to ensure our program aligns with industry best practices. Our global Integrity & Compliance Program is one of the key components of our commitment to the highest standards of integrity and ethical conduct, which are critical to earning and maintaining the trust and support of employees, patients, customers, healthcare professionals, shareholders and other stakeholders who rely on us every day.

In 2022, we launched a refreshed Code of Conduct-- Patients First, Integrity Always, the Mallinckrodt Code of Conduct-- that provides a set of principles and standards to guide ethical decision making. Employees, contractors, and others with whom we do business must comply with our Code of Conduct, policies, relevant laws, regulations, and codes. Our "Speak Up" culture encourages employees and others with whom we do business to come forward if they become aware of any potential violations of law or Mallinckrodt policy, including through anonymous reports using our Integrity Hotline. We investigate all matters that come to our attention and, where appropriate, take corrective action and implement measures to prevent future violations. All of our employees are required to be trained on the Mallinckrodt Code of Conduct and to certify annually both to their understanding and compliance. Our employees and officers own integrity and compliance and have a responsibility to model the principles outlined in the Code of Conduct. The Mallinckrodt Code of Conduct is available on Mallinckrodt's website, [www.mnk.com](http://www.mnk.com).

On March 3, 2022, Mallinckrodt entered into a five-year CIA with the HHS OIG that sets forth the government's expectations related to promotional activities, patient assistance, and pricing and transparency.

We also implemented an Opioid Product Operating Injunction for the Specialty Generics business in 2020, with new operating restrictions and requirements around manufacturing, sales, promotion, compensation, third-party grants and sponsorships, lobbying, prescription savings programs, manufacturing high-dose opioids, and monitoring and reporting of direct and downstream customers. The Operating Injunction is under the oversight of an Independent Monitor.

#### *Respect for Human Rights*

We are committed to conducting all of our activities in accordance with high standards of business conduct. Mallinckrodt forbids forced child labor, human trafficking and unsafe working conditions, and condemns behaviors that do not support human dignity and respect. We expect our businesses and suppliers to pay fair wages and provide safe working environments free of all human rights violations, as highlighted in our Supplier Code of Conduct.

Since 2014, we have annually published a Conflict Minerals Report detailing the use of cassiterite, columbite-tantalite (coltan), gold, wolframite, and their derivatives, which are limited to tin, tantalum and tungsten (“3TGs”), emanating from the Democratic Republic of the Congo region and nine adjoining countries (“covered countries”), which are necessary to the functionality or production of our products. We are currently preparing a similar report for fiscal 2022, as required by the U.S. SEC. Mallinckrodt’s policy with respect to the sourcing of conflict minerals can be found on our website at [mallinckrodt.com/about/partnering/suppliers/conflict-minerals-policy](http://mallinckrodt.com/about/partnering/suppliers/conflict-minerals-policy).

Since fiscal 2017, we have published an annual U.K. Modern Slavery Act Disclosure which sets forth information regarding the steps we have taken to mitigate the risks associated with modern slavery in our business and supply chain.

#### *Anti-bribery and anti-corruption*

Integrity is one of Mallinckrodt’s core values. It guides every action we take. We set high expectations and standards for operating our business in a responsible, ethical manner. We are committed to compliance with all applicable global anti-corruption laws, including the FCPA and U.K. Bribery Act of 2010. We maintain an anti-bribery and anti-corruption policy to ensure that all of our businesses and employees are aware of their associated responsibilities.

Mallinckrodt strives to abide by the highest ethical and professional standards. We follow strict international, national and local regulations, and industry codes of conduct. Mallinckrodt has voluntarily certified to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (PhRMA Code). The certification can be found on our website at [mallinckrodt.com/corporate-responsibility/interactions-with-health-care-professionals](http://mallinckrodt.com/corporate-responsibility/interactions-with-health-care-professionals).

#### *Data Privacy*

We also take a variety of steps to comply with data protection laws and regulations around the globe. Comprehensive privacy policies detail how we collect, use, share and safeguard personal information, so people can make informed decisions before providing their information to us. Employees receive periodic training and practical advice to increase their awareness about the importance of data privacy and their shared responsibility to protect personal information.

## **Research and Development**

*Specialty Brands.* Our 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 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.

### ***Acquisition of Own Shares***

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 fiscal 2022 and 2021. 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 Group's shareholders approved that the Group may make market purchases or overseas market purchases of a maximum of 1,317,093 Ordinary Shares of the Group. 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 NYSE American) 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 Group, 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 fiscal 2022.

As discussed further in Note 3 of the Notes to the Consolidated Financial Statement, pursuant to the Plan, all Predecessor's preferred and ordinary share and treasury shares were cancelled without distribution. As such, as of December 30, 2022, there were no ordinary shares classified as treasury shares.

Further information relating to the acquisition of our shares is set out at Note 28 of the Notes to the Consolidated Financial Statements and Note 8 of the Notes to the Company Financial Statements.

### ***Dividends***

We currently do not anticipate paying any cash dividend for the foreseeable future as we intend to retain earnings to finance acquisitions, R&D, and the operation and expansion of our business, while executing disciplined capital allocation. The recommendation, declaration and payment of any dividends in the future by us will be subject to the sole discretion of our Board of Directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our Board of Directors. Moreover, if we determine to pay dividends in the future, there can be no assurance that we will continue to pay such dividends. The payment of dividends is also subject to compliance with the Irish Companies Act 2014, including the requirement for Mallinckrodt plc to have sufficient realized profits available for distribution.

### ***Accounting Records***

The directors are responsible for ensuring that the Company and Group keep adequate accounting records and appropriate accounting systems. The measures taken by the directors to ensure compliance with the Company's and Group's obligation to keep adequate accounting records include the use of appropriate systems and procedures and the employment of competent persons. The directors have appointed a Chief Financial Officer who makes regular reports to the directors and ensures compliance with the requirements of Sections 281 to 285 of the Irish Companies Act 2014. The Group also has a Controller, who works closely with the Chief Financial Officer and who makes regular reports to the Audit Committee. In addition, the head of the Group's internal audit department makes regular reports to the Audit Committee regarding fraud and other financial-related irregularities. The Audit Committee, in turn, briefs the directors on significant financial matters arising from reports of the Chief Financial Officer, the Controller, the head of internal audit and the Company's or Group's external auditor.

The accounting records of Mallinckrodt plc are maintained at College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland.

## ***Important Events Since Year End***

### ***Income Taxes***

Through the date of this report, the Group received \$133.8 million of cash, plus interest, of the \$135.9 million U.S. Coronavirus Aid, Relief and Economic Security (CARES) Act income tax refund receivable that was included within debtors on the consolidated balance sheet as of December 30, 2022. The remaining refund is expected to be received during fiscal 2023.

### ***Interest Rate Cap***

On March 14, 2023, the Group entered into an interest rate cap agreement to manage its variable interest rate exposure with a total notional value of \$860.0 million and upfront premium of \$20.0 million. The interest rate cap agreement, designated as a cash flow hedge, provides the Group with interest rate protection (i) for the period March 16, 2023 through July 19, 2023 to the extent that one-month LIBOR exceeds 4.65%, and (ii) for the period July 20, 2023 through March 26, 2026 to the extent that one-month SOFR exceeds 3.84%.

### ***Commitments and Contingencies***

Certain litigation matters occurred prior to December 30, 2022 but had subsequent updates through the date of this report. See further discussion in Note 25 of Notes to the Consolidated Financial Statements.

### ***Directors***

Directors' remuneration is set forth in Note 12 of Notes to Consolidated Financial Statements. No director or company secretary of the Group had an interest in shares required to be disclosed under Section 329 of the Irish Companies Act 2014 either at the beginning of the financial year, or date of appointment if later, or at the end of the financial year. Note that where the aggregate interest in shares of any director or secretary (and his or her spouse (or civil partner) and children) represents less than 1% in nominal value of the Group's ordinary shares, the only interests of that director or secretary that are required to be disclosed constitute a right to subscribe for shares in the Group or that arise as a result of the exercise of such a right. Performance stock units where the director or secretary is an employee of the Group and does not make any payment to the Group in respect of the shares are not considered to be rights to subscribe for the purposes of this disclosure and no disclosure is required where they form part of an aggregate less than 1% holding.

In connection with the emergence from Chapter 11, on the Effective date, the Predecessor directors resigned from their roles as directors of the Group and a new set of directors was appointed. Set forth below are the names of the individuals serving as directors and the period in which they served:

<b>Name</b>	
<b>June 16, 2022 through December 30, 2022</b>	<b>Fiscal 2021 through June 16, 2022</b>
Sigurdur Olafsson	Mark C. Trudeau
Paul Bisaro	David R. Carlucci
Daniel Celentano	J. Martin Carroll
Riad El-Dada	Paul R. Carter
Neal Goldman	David Y. Norton
Karen Ling <sup>(1)</sup>	Carlos V. Paya, M.D., Ph.D.
Dr. Woodrow Myers M.D.	JoAnn A. Reed
Susan Silbermann <sup>(2)</sup>	Angus C. Russell
James Sulat	Anne C. Whitaker
	Kneeland C. Youngblood, M.D.

(1) Ms. Ling was appointed to the Board of Directors on August 12, 2022.

(2) Ms. Silbermann was appointed to the Board of Directors on October 5, 2022.

### ***Political Donations***

No political contributions that require disclosure under Irish law were made during the year.



### ***Subsidiary Companies and Branches***

Information regarding subsidiary undertakings, including information regarding branches, is provided in Note 30 of Notes to Consolidated Financial Statements.

### ***Audit Committee***

In accordance with Section 167 of the Irish Companies Act 2014, the Group has established an audit committee for the full financial year.

### ***Disclosure of Information to Auditor***

Each of the persons who is a director at the date of approval of this Directors' Report confirms that:

- so far as that director is aware, there is no relevant audit information of which the Group's auditor is unaware, and
- that director has taken all the steps that ought to have been taken as a director in order to be aware of any relevant audit information and to establish that the Group's auditor is aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Irish Companies Act 2014.

### ***Directors' Compliance Statement***

As required by Section 225 of the Irish Companies Act 2014, the directors acknowledge that they are responsible for securing Mallinckrodt plc's compliance with its "relevant obligations" (as defined in that legislation). The directors further confirm that a compliance policy statement has been drawn up, and that appropriate arrangements and structures have been put in place that are, in the directors' opinion, designed to secure material compliance with the relevant obligations. A review of those arrangements and structures was conducted in the financial year to which this Directors' Report relates. In discharging their responsibilities under Section 225, the directors relied on the advice of persons who the directors believe have the requisite knowledge and experience to advise Mallinckrodt plc on compliance with its relevant obligations.

### ***Going Concern***

The directors continue to adopt the going concern basis in preparing the financial statements. For further information, refer to Note 1 of the Notes to the Consolidated Financial Statements.

### ***Auditor***

Deloitte Ireland LLP, Chartered Accountants and Statutory Audit Firm, continue in office in accordance with Section 383(2) of the Irish Companies Act 2014.

On behalf of the Directors

/s/ James Sulat

James Sulat

Director

5 April, 2023

/s/ Sigurdur Olafsson

Sigurdur Olafsson

President, Chief Executive Officer and Director

5 April, 2023

**MALLINCKRODT PLC**  
**DIRECTORS' RESPONSIBILITIES STATEMENT**

The directors are responsible for preparing the directors' report and financial statements in accordance with the Irish Companies Act 2014 and the applicable regulations.

Irish company law requires the directors to prepare financial statements for each financial year. Under the law, the directors have elected to prepare the Irish statutory Mallinckrodt plc consolidated ("the Group") financial statements in accordance with Section 279 of the Irish Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with U.S. GAAP to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Irish Companies Act 2014.

The directors have elected to prepare the Mallinckrodt plc ("parent" or "Company") financial statements in accordance with the Financial Reporting Standards applicable in the United Kingdom and Republic of Ireland ("FRS 102") together with the Irish Companies Act 2014. Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the Group and Company for the financial year, the profit or loss of the Group for the year then ended and otherwise comply with the Irish Companies Act 2014.

In preparing the Group and Company financial statements, the directors are required to:

- select suitable accounting policies for the Group and Company financial statements and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with the applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group and Company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the company; enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy; enable them to ensure that the Group and Company financial statements and directors' report comply with the Irish Companies Act 2014; and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

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

## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF MALLINCKRODT PLC

### Report on the audit of the financial statements

#### Opinion on the financial statements of Mallinckrodt plc (the 'Group')

In our opinion the Group financial statements:

- give a true and fair view of the assets, liabilities and financial position of the Group as at 30 December 2022 and of the loss of the Group for the financial year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Consolidated Profit and Loss Account;
- the Consolidated Statement of Other Comprehensive Loss;
- the Consolidated Balance Sheet;
- the Consolidated Statement of Cash Flow;
- the Consolidated Statement of Changes in Equity; and
- the related notes 1 to 30, including a summary of significant accounting policies as set out in note 4.

The relevant financial reporting framework that has been applied in the preparation of the Group financial statements is the Companies Act 2014 and US Generally Accepted Accounting Principles (US GAAP), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene Part VI of the Companies Act 2014 (“the relevant financial reporting framework”).

We have reported separately on the parent company financial statements of Mallinckrodt plc for the financial year ended 30 December 2022.

#### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the “*Auditor's responsibilities for the audit of the financial statements*” section of our report.

We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

<b>Summary of our audit approach</b>	
<b>Key audit matters</b>	The key audit matters ("KAM") that we identified in the current year were: <ul style="list-style-type: none"> <li>• <i>Fresh-start Accounting, and</i></li> <li>• <i>Income Tax Impacts from Emergence from Voluntary Reorganization</i></li> </ul>
<b>Materiality</b>	The materiality that we used in the current year was \$17.5 million which was determined on the basis of 2.59% of adjusted EBITDA.
<b>Scoping</b>	We have determined the scope of our audit by obtaining an understanding of the Group and its environment, including group wide controls and assessing the risks of material misstatement at the Group level.
<b>Significant changes in our approach</b>	We identified 2 new key audit matters in the current year, arising from the emergence from bankruptcy. The prior year KAMs related to the valuation of intangible assets, liabilities subject to comprise arising from chapter 11 bankruptcy and the going concern basis of preparation were not deemed to be key audit matters in the current year.  Materiality of \$20.0 million in the prior year was based on a percentage of loss on ordinary activity before taxation, however in the current year due to the number of one off items, it was not determined as an appropriate benchmark in the current year.

### **Conclusions relating to going concern**

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

We have evaluated the directors' assessment of the Group's ability to continue as a going concern. Matters which may be relevant are:

- obtaining an understanding of the controls in place regarding going concern as part of our risk assessment procedures;
- reviewing documentation relating to the emergence from Chapter 11 bankruptcy and the Plan of Reorganization, details of which are included in note 2;
- challenging the reasonableness of the key assumptions applied by the directors in their going concern assessment;
- holding discussions with management on the directors' going concern assessment, the future plans for the Group and the feasibility of those plans;
- obtaining an understanding of the Group's controls over the development and approval of the projections and assumptions used in the forecasts to support the going concern assumption;
- completing an assessment of the consistency of the models used to prepare the forecasts in line with other areas of our audit; and
- assessing the adequacy of the disclosures in the financial statements.

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

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

### **Key audit matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial year and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team.

These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

<b>Fresh-start Accounting</b>	
<b>Key audit matter description</b>	<p>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 Group emerged from chapter 11 of title 11 of the United States Code. In connection with its emergence and in accordance with ASC 852, Reorganisations, the Group qualified for and adopted fresh-start accounting which resulted in a new basis of accounting and the Group becoming a new entity for financial reporting purposes. Management derived a reorganisation value from the Group’s enterprise value which was estimated to be \$5,223.0 million. Under fresh-start accounting, reorganization value represents the fair value of the Group’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 Group 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 Group engaged a third-party valuation advisor to assist with the determination of the fair value of certain assets, liabilities, and equity.</p> <p>Auditing the adoption of fresh-start accounting was complex due to the significant estimation uncertainty in determining the fair value of the Group’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.</p> <p>The fresh-start accounting valuation 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.</p> <p>Further information is provided and disclosed in Note 2 and the accounting policies in the Financial Statements.</p>

<p><b>How the scope of our audit responded to the key audit matter</b></p>	<p>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:</p> <ul style="list-style-type: none"> <li>• We tested the operating effectiveness of internal controls related to the Group's projected financial information and discount rates.</li> <li>• We evaluated the reasonableness of management's projected financial information by performing the following: <ul style="list-style-type: none"> <li>◦ 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.</li> <li>◦ Inspected internal communications from members of management to (1) other members of management and (2) the Board of Directors.</li> </ul> </li> <li>• With the assistance of our fair value specialists, we assessed the discount rates.</li> <li>• We evaluated the Group's third-party valuation advisor's experience and qualifications.</li> <li>• We obtained an understanding and evaluated the methodologies used by the Group's third-party valuation advisor for the development of the fair values of the intangible assets.</li> <li>• We obtained an understanding of the methodology used by the Group's third-party valuation advisor for determining the significant assumptions related to the discount rates, tax rates, and contributory asset charges. <ul style="list-style-type: none"> <li>◦ We evaluated the methods and significant assumptions used by management for the development of the fair values of the intangible assets.</li> <li>◦ 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.</li> </ul> </li> <li>• We assessed the impact of Irish company law on the ability of the Group to use fresh-start accounting.</li> </ul> <p>Our audit procedures related to management's significant assumptions related to the application of fresh-start accounting, specifically the determination of the equity value, included the following, among others:</p> <ul style="list-style-type: none"> <li>• We tested the operating effectiveness of internal controls related to the Group's determination of the equity value.</li> <li>• We evaluated the Group's third-party valuation advisor's experience and qualifications.</li> <li>• We evaluated the estimated enterprise value of the Group, which was estimated with the assistance of a third-party valuation advisor using various valuation methods.</li> <li>• We evaluated the adjustments made by management to the estimated enterprise value to determine the implied fair value of the Group's equity value.</li> </ul>
<p><b>Key observations</b></p>	<p>We have no observations that impact our audit report in respect of the fresh-start accounting.</p>

<b>Income Tax Impacts from Emergence from Voluntary Reorganization</b>	
<b>Key audit matter description</b>	<p>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 Group 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 Group may owe may differ from the amounts recognized, which the Group 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 Group's interpretation of, and compliance with multi-jurisdictional tax laws.</p> <p>Further information is provided and disclosed in Notes 2, 3,4 and 9 and the accounting policies in the Financial Statements.</p>
<b>How the scope of our audit responded to the key audit matter</b>	<p>Our audit procedures related to the income taxes associated with the restructuring transaction and emergence from voluntary reorganization included the following, among others:</p> <ul style="list-style-type: none"> <li>• We tested the operating effectiveness of the internal control related to the Group'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.</li> <li>• 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: <ul style="list-style-type: none"> <li>◦ Obtained an understanding of the Group's restructuring transactions.</li> <li>◦ Obtained and evaluated management and third-party tax specialist memoranda regarding the analysis of relevant tax laws and regulations.</li> <li>◦ Evaluated the Group's third-party tax specialists' experience and qualifications.</li> <li>◦ 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.</li> <li>◦ Evaluated the completeness and accuracy of the underlying data, calculations, and allocations supporting the amount of current and deferred income tax benefit recorded.</li> <li>◦ Tested significant assumptions and key inputs to assess the Group's recognition and measurement of current and deferred income tax benefit.</li> </ul> </li> </ul>
<b>Key observations</b>	<p>We have no observations that impact our audit in respect of the income tax impacts from emergence from voluntary reorganisation.</p>

Our audit procedures relating to these matters were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.

## Our application of materiality

We define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

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

<b>Group financial statements</b>	
<b>Materiality</b>	\$17.5 million (2021: \$20.0 million)
<b>Basis for determining materiality</b>	2.59% of Adjusted EBITDA  Based on the analysis performed, we concluded that 2.59% of adjusted EBITDA is a suitable metric as it is relevant to the users of the financial statements. The performance of the Group before tax was impacted by a number of items relating to the emergence from bankruptcy and hence was not determined to be an appropriate benchmark in the current year.
<b>Performance materiality</b>	80% of group materiality
<b>Basis and rationale for determining performance materiality</b>	In determining performance materiality, we considered the following factors: <ul style="list-style-type: none"><li>• our understanding of the Group and its environment</li><li>• the reliability of the Group's internal control over financial reporting and whether we were able to rely on controls</li><li>• the degree of centralisation and common controls and processes, and</li><li>• any changes to the business that would impact on our ability to forecast potential misstatements.</li></ul>

We agreed with the Audit Committee that we would report to them any audit differences in excess of \$0.875 million or 5.0% of materiality, as well as differences below that threshold which, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.

## An overview of the scope of our audit

Our Group audit was scoped by obtaining an understanding of the Group and its environment, including Group-wide controls, and assessing the risks of material misstatement at the Group level. Based on that assessment, we focused our Group audit scope primarily on the audit work in two significant components representing the Group's two reportable segments Specialty Brands and Specialty Generics, which were subject to a full scope audit. These two components represent the principal business units and account for the majority of the Group's net assets, revenue and loss before tax. They were also selected to provide an appropriate basis for undertaking audit work to address the risks of material misstatement identified above. Our audit work at the two components was executed at levels of materiality applicable to each individual component which were lower than Group materiality - \$12.6 million for Specialty Brands and \$11.2 million for Specialty Generics.

## Other information

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements for the financial year ended 30 December 2022, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the



work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

### **Responsibilities of directors**

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

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

### **Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on IAASA's website at: <https://iaasa.ie/publications/description-of-the-auditors-responsibilities-for-the-audit-of-the-financial-statements>. This description forms part of our auditor's report.

### **Extent to which the audit was considered capable of detecting irregularities, including fraud**

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

### **Identifying and assessing potential risks related to irregularities**

In identifying and assessing risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, we considered the following:

- the nature of the industry and sector, control environment and business performance including the design of the Group's remuneration policies, key drivers for directors' remuneration, bonus levels and performance targets;
- The Group's assessment of the risks that irregularities may occur either as a result of fraud or error that was discussed with the individual board members in January 2023.
- results of our enquiries of management, internal audit and the audit committee about their own identification and assessment of the risks of irregularities;
- any matters we identified having obtained and reviewed the Group's documentation of their policies and procedures relating to:
  - identifying, evaluating and complying with laws and regulations and whether they were aware of any instances of non-compliance
  - detecting and responding to the risks of fraud and whether they have knowledge of any actual, suspected or alleged fraud
  - the internal controls established to mitigate risks of fraud or non-compliance with laws and regulations
- the matters discussed among the audit engagement team including significant component audit teams and relevant internal specialists, including tax, valuations, fraud specialists, data specialists and bankruptcy and fresh-start accounting specialists and IT regarding how and where fraud might occur in the financial statements and any potential indicators of fraud.

As a result of these procedures, we considered the opportunities and incentives that may exist within the organisation for fraud and identified the greatest potential for fraud where there were no major areas. In common with all audits under ISAs (Ireland), we are also required to perform specific procedures to respond to the risk of management override and revenue recognition.

We also obtained an understanding of the legal and regulatory framework that the Group operates in, focusing on provisions of those laws and regulations that had a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the Irish Companies Act and tax legislation.

In addition, we considered provisions of other laws and regulations that do not have a direct effect on the financial statements but compliance with which may be fundamental to the Group's ability to operate or to avoid a material penalty. These include the United States Foreign Corrupt Practices Act.

### **Audit response to risks identified**

As a result of performing the above, we identified two key audit matters related to the potential risk of non-compliance with laws and regulations. The key audit matters section of our report explains the matters in more detail and also describes the specific procedures we performed in response to those key audit matters.

In addition to the above, our procedures to respond to risks identified included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with provisions of relevant laws and regulations described as having a direct effect on the financial statements;
- enquiring of management, the audit committee and in-house and external legal counsel concerning actual and potential litigation and claims;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud;
- reading minutes of meetings of those charged with governance and reviewing internal audit reports;
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business; and
- in addressing the presumed risk of fraud in revenue recognition, we have tested the operating effectiveness of relevant controls over the rebate arrangements in the Group and we assessed the sufficiency and accuracy of the underlying data used in the calculation of the rebate reserve.

We also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members including internal specialists and component audit teams, and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

### **Report on other legal and regulatory requirements**

#### **Opinion on other matters prescribed by the Companies Act 2014**

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion, the accounting records of the Group were sufficient to permit the financial statements to be readily and properly audited.
- The financial statements are in agreement with the accounting records.
- In our opinion the information given in those parts of the directors' report as specified for our review is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

### **Matters on which we are required to report by exception**

Based on the knowledge and understanding of the Group and its environment obtained in the course of the audit, we have not identified material misstatements in those parts of the directors' report as specified for our review.

The Companies Act 2014 also requires us to report to you if, in our opinion, the Group has not provided the information required by Regulation 5(2) to 5(7) of the European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 (as amended) for the financial year ended 30 December 2022. We have nothing to report in this regard.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

### **Use of our report**

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinion we have formed.

/s/ Richard Howard

Richard Howard

For and on behalf of Deloitte Ireland LLP

Chartered Accountants and Statutory Audit Firm

Deloitte & Touche House, Earlsfort Terrace, Dublin 2

Date: 5 April, 2023

**MALLINCKRODT PLC**  
**CONSOLIDATED PROFIT AND LOSS ACCOUNT**  
*(in millions, except per share data)*

	Note	Fiscal Year					
		2022			2021		
		Ordinary Activities	Discontinued Operations	Total	Ordinary Activities	Discontinued Operations	Total
Turnover	5, 6	\$ 1,914.3	\$ —	\$ 1,914.3	\$ 2,208.8	\$ —	\$ 2,208.8
Cost of sales		1,304.3	—	1,304.3	1,317.1	—	1,317.1
<b>Gross profit</b>		610.0	—	610.0	891.7	—	891.7
Distribution and administrative expenses		554.3	—	554.3	608.5	—	608.5
Research and development costs		129.7	—	129.7	205.2	—	205.2
Restructuring charges, net	7	20.7	—	20.7	26.9	—	26.9
Non-restructuring impairment charges	15	—	—	—	90.4	—	90.4
Profit on disposal of operations		—	(1.1)	(1.1)	0.8	(1.1)	(0.3)
Opioid-related litigation settlement loss		—	—	—	125.0	—	125.0
<b>Operating (loss) profit</b>		(94.7)	1.1	(93.6)	(165.1)	1.1	(164.0)
Interest payable and similar expenses	8	(432.9)	—	(432.9)	(222.6)	—	(222.6)
Interest receivable and similar income		4.5	—	4.5	1.9	—	1.9
Other (expense) income, net		(4.6)	—	(4.6)	22.0	—	22.0
Reorganization items, net	2	(1,505.9)	—	(1,505.9)	(428.2)	—	(428.2)
<b>(Loss) profit on ordinary activities before taxation</b>		(2,033.6)	1.1	(2,032.5)	(792.0)	1.1	(790.9)
Taxation credit	9	(650.8)	—	(650.8)	(106.3)	(5.0)	(111.3)
<b>(Loss) profit after taxation</b>		\$ (1,382.8)	\$ 1.1	\$ (1,381.7)	\$ (685.7)	\$ 6.1	\$ (679.6)

**MALLINCKRODT PLC**  
**CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE LOSS**  
*(in millions)*

	<b>Fiscal Year</b>	
	<b>2022</b>	<b>2021</b>
<b>Loss after taxation</b>	\$ (1,381.7)	\$ (679.6)
<b>Other comprehensive profit, net of taxation</b>		
Currency translation adjustments	0.6	(0.5)
Unrecognized gain on derivatives, net of tax charge	—	—
Unrecognized gain on benefit plans, net of tax charge	8.7	1.8
<b>Total other comprehensive profit, net of taxation</b>	9.3	1.3
<b>Comprehensive loss</b>	<u>\$ (1,372.4)</u>	<u>\$ (678.3)</u>

**MALLINCKRODT PLC**  
**CONSOLIDATED BALANCE SHEET**  
*(in millions)*

	Note	December 30, 2022	December 31, 2021
<b>Fixed Assets</b>			
Intangible assets	15	\$ 2,843.8	\$ 5,448.4
Tangible assets	16	495.7	811.0
Financial assets	17	170.7	191.3
		<u>3,510.2</u>	<u>6,450.7</u>
<b>Current Assets</b>			
Stocks	18	364.5	347.2
Debtors	19	1,247.8	773.4
Cash at bank and in hand		409.5	1,345.0
		<u>2,021.8</u>	<u>2,465.6</u>
Creditors (amounts falling due within one year)	20	661.9	5,754.8
<b>Net Current Assets (Liabilities)</b>		<u>1,359.9</u>	<u>(3,289.2)</u>
<b>Total Assets Less Current Liabilities</b>		4,870.1	3,161.5
Creditors (amounts falling due after one year)	21	3,558.0	153.5
Provisions for Liabilities	27	180.0	2,705.7
<b>Net Assets</b>		<u>\$ 1,132.1</u>	<u>\$ 302.3</u>
<b>Capital and Reserves</b>			
Called-up share capital presented as equity	28	\$ 0.1	\$ 18.9
Share premium account	28	211.7	5.7
Other reserves	28	1,990.1	1,586.9
Profit and loss account	28	(1,069.8)	(1,309.2)
<b>Shareholders' Funds</b>		<u>\$ 1,132.1</u>	<u>\$ 302.3</u>

Approved by the Board of Directors on 5 April, 2023 and signed on its behalf by:

/s/ James Sulat

James Sulat

Director

/s/ Sigurdur Olafsson

Sigurdur Olafsson

President, Chief Executive Officer and Director

**MALLINCKRODT PLC**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**  
*(in millions)*

	Fiscal Year	
	2022	2021
<b>Cash Flows From Ordinary Operating Activities:</b>		
Loss after taxation	\$ (1,381.7)	\$ (679.6)
Adjustments to reconcile net cash provided by ordinary operating activities:		
Depreciation and amortization	669.3	675.8
Share-based compensation	3.1	10.2
Deferred taxation	(599.4)	(59.9)
Non-cash impairment charges	—	90.4
Losses (gains) on divestiture	—	0.8
Non-cash accretion expense	139.2	—
Other non-cash items	41.0	(1.6)
Reorganization items, net	1,277.2	22.5
Changes in assets and liabilities, net of the effects of acquisitions:		
Trade debtors	31.7	98.2
Stocks	(34.0)	(14.0)
Trade creditors	4.5	(1.1)
Accrued consulting	(90.6)	14.3
Taxation	(57.0)	108.5
Opioid-related litigation settlement liability	—	125.0
Medicaid lawsuit	—	(4.2)
Payment of claims	(629.0)	—
Other	30.5	70.1
Net cash from ordinary operating activities	<u>(595.2)</u>	<u>455.4</u>
<b>Cash Flows From Ordinary Investing Activities:</b>		
Capital expenditures	(62.2)	(55.3)
Proceeds from divestitures, net of cash	70.0	15.7
Other	(13.3)	1.8
Net cash from ordinary investing activities	<u>(5.5)</u>	<u>(37.8)</u>
<b>Cash Flows From Ordinary Financing Activities:</b>		
Issuance of external debt	650.0	—
Repayment of external debt	(954.7)	(137.5)
Debt financing costs	(24.1)	—
Other	(4.0)	—
Net cash from ordinary financing activities	<u>(332.8)</u>	<u>(137.5)</u>
Effect of currency rate changes on cash at bank and in hand	(5.0)	(1.9)
<b>Net change in cash at bank and in hand and restricted cash</b>	<b>(938.5)</b>	<b>278.2</b>
<b>Cash at bank and in hand and restricted cash at beginning of period</b>	<b>1,405.2</b>	<b>1,127.0</b>
<b>Cash at bank and in hand and restricted cash at end of period</b>	<b><u>\$ 466.7</u></b>	<b><u>\$ 1,405.2</u></b>
<b>Cash at bank and in hand at end of period</b>	<b>409.5</b>	<b>1,345.0</b>
<b>Restricted Cash, current at end of period</b>	<b>20.6</b>	<b>24.0</b>
<b>Restricted Cash, noncurrent at end of period</b>	<b>36.6</b>	<b>36.2</b>
<b>Cash at bank and in hand and restricted cash at end of period</b>	<b><u>\$ 466.7</u></b>	<b><u>\$ 1,405.2</u></b>
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Cash paid for interest, net	\$ 275.6	\$ 243.2
Cash paid (received) for taxation, net	6.0	(160.0)

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

	Called-up Share Capital		Share Premium Account	Other Reserves			Profit and Loss Account	Total
	Number	Amount		Capital Redemption Reserve	Other	Accumulated Other Comprehensive Loss		
<b>Balance as of December 25, 2020</b>	94.1	\$ 18.8	\$ 5.7	\$ 5.3	\$ 1,579.7	\$ (9.6)	\$ (629.6)	\$ 970.3
Loss after taxation	—	—	—	—	—	—	(679.6)	(679.6)
Other comprehensive profit, net of tax	—	—	—	—	—	1.3	—	1.3
Vesting of restricted shares	0.2	0.1	—	—	—	—	—	0.1
Share-based compensation	—	—	—	—	10.2	—	—	10.2
<b>Balance as of December 31, 2021</b>	94.3	18.9	5.7	5.3	1,589.9	(8.3)	(1,309.2)	302.3
Loss after taxation	—	—	—	—	—	—	(1,381.7)	(1,381.7)
Other comprehensive profit, net of tax	—	—	—	—	—	9.3	—	9.3
Cancellation of Predecessor equity	(94.3)	(18.9)	(5.7)	(5.3)	(1,591.6)	9.8	1,611.2	(0.5)
Issuance of Successor common stock	13.2	0.1	211.7	—	1,977.9	—	—	2,189.7
Issuance of Opioid Warrants	—	—	—	—	13.9	—	—	13.9
Repurchase of Opioid Warrants	—	—	—	—	(13.9)	—	9.9	(4.0)
Share-based compensation	—	—	—	—	3.1	—	—	3.1
<b>Balance as of December 30, 2022</b>	\$ 13.2	\$ 0.1	\$ 211.7	\$ —	\$ 1,979.3	\$ 10.8	\$ (1,069.8)	\$ 1,132.1



**MALLINCKRODT PLC**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
*(dollars in millions, except share data and where indicated)*

## **1. Background and Basis of Presentation**

### ***Background***

Mallinckrodt plc is a public limited company incorporated in the Republic of Ireland with the registration number 522227. The business address of its registered office and principal executive offices is College Business and Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland.

Mallinckrodt plc is a global business of multiple wholly owned subsidiaries (collectively, "Mallinckrodt" or "the Group"), whose principal activities is to 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 Group 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 Group continues to be subject to United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements.

### ***Basis of Presentation***

The directors have elected to prepare the Irish statutory Mallinckrodt plc consolidated financial statements in accordance with Section 279 of the Irish Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP") to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Irish Companies Act 2014.

The directors have elected to prepare the Mallinckrodt plc parent company financial statements in accordance with FRS 102 *The Financial Reporting Standards applicable in the United Kingdom ("U.K.") and Republic of Ireland* together with the Irish Companies Act 2014 as they are prepared specifically to present to shareholders and file with the Companies Registration Office in Ireland. Accordingly, these consolidated financial statements represent the results and financial position of Mallinckrodt plc and include disclosures required by the Irish Companies Act 2014, in addition to those required under U.S. GAAP as well as any other adjustments required by Irish law.

The consolidated financial statements have been prepared in U.S. dollars and in accordance with U.S. GAAP. The preparation of the consolidated financial statements in conformity with U.S. 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 turnover and expenses. Actual results may differ from those estimates. The consolidated financial statements include the accounts of Mallinckrodt plc, 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 reflected as discontinued operations. Divestitures of product lines and businesses not meeting the criteria for discontinued operations have been reflected in operating loss within ordinary activities.

Under Irish law, the Group can only pay dividends and repurchase shares out of distributable reserves. Net loss after taxation has been included in the profit and loss account and is included in distributable reserves. The format of the consolidated profit and loss account has been adapted where necessary to better reflect the nature of the business.

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 Group's international subsidiaries (together with the Group, 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 Group 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, in so far as it does not contravene any provision of Part 6 of Irish Companies Act 2014, the Group 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 Group 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 Group prior to, and including, June 16, 2022. All emergence-related transactions of the Predecessor were recorded as of June 16, 2022. The combination of the Successor and Predecessor results present a true and fair view of the assets and liabilities, financial position and profit or loss. For certain disclosures, the Group elected to reflect the Successor and Predecessor separately to accurately portray the impact of fresh-start accounting within the Notes to the consolidated and Company financial statements. See Note 3 for further information.

The Group's significant accounting policies are described within Note 4. In connection with the adoption of fresh-start accounting, the Group 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 Group'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 Group made a change in estimate related to the Specialty Generics segment stocks 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 was \$19.9 million.

The Group also reassessed and updated its product line net sales presentation for its Specialty Generics segment. The Group'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.

### ***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. 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 Group, 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.

### ***Going Concern***

The directors have a reasonable expectation that Mallinckrodt plc and the Group have adequate resources to continue in operational existence for at least the next twelve months from the time of approving these financial statements. In arriving at this conclusion, the directors have reviewed cash flow forecasts prepared by management that took into account the current and anticipated uncertainties together with the current levels of debt and settlement obligations. Accordingly, the directors continue to adopt the going concern basis in preparing the financial statements.

## ***Fiscal Year***

The Group reports its results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2022 consisted of 53 weeks and fiscal 2021 consisted of 52 weeks. Unless otherwise indicated, fiscal 2022 and 2021 refer to the Group's fiscal years ended December 30, 2022 and December 31, 2021, respectively. All references to "fiscal" year are considered to be defined as "financial" year under FRS 102.

## **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 Group 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 Group'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 Group and its subsidiaries were deemed to have been settled, discharged, waived, released and extinguished in full against the Group and its subsidiaries, and the Group 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 Group 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 Group 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 Group'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 Group 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 stated claims of the U.S. Department of Justice ("DOJ") and other governmental parties relating to Acthar<sup>®</sup> Gel (repository corticotropin injection) ("Acthar Gel") against the Group were deemed to have been settled, discharged, waived, released and extinguished in full against the Group, and the Group 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 Group 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 Group entered into two settlement agreements with the U.S. and certain relators. Under the Acthar Gel-Related Settlement, which was conditioned upon the Group commencing its Chapter 11 proceeding and provided for the distributions the applicable claimants received under the Plan, the Group 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 turnover, 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 Group 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 Group 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 Group, 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<sup>®</sup> (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<sup>®</sup> (terlipressin) ("Terlivaz") and (2) cumulative turnover of \$100.0 million of Terlivaz.

On June 30, 2022, subsequent to the Effective Date, the Group 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 Group, 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 Group 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 Group 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 Group 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 (as defined within Note 22) based on a borrowing base with a maximum draw of up to \$200.0 million. See Note 22 for further information on these debt instruments.

## ***Financing***

### ***Predecessor Chapter 11 Financing***

The Group 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 Group 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 Group 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:

	Fiscal Year	
	2022	2021
Interest expense incurred for adequate protection payments	\$ 28.8	\$ 63.1
Cash paid for adequate protection payments	28.8	66.7

## ***Contractual interest***

While the Chapter 11 Cases were pending, the Group 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 Group's unsecured debt instruments, which the Group did not pay as the obligation was extinguished pursuant to the Plan, was \$46.5 million and \$93.0 million for fiscal 2022 and fiscal 2021, respectively.

## **3. Fresh-start Accounting**

The Group 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 Group 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 Group'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 Group 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 Group 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 Group 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 Group prepared projections that included a variety of estimates and assumptions. While the Group considers such estimates and assumptions reasonable, they are inherently subject to significant business, economic and competitive uncertainties, many of which are beyond the Group'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 Group's enterprise value.

In so far as to not contravene Part 6 of Irish Companies Act 2014, the reorganization value and shareholders' funds values have been adjusted to reflect the value of current assets at the lower of cost and net realizable value and any related impact to the corresponding deferred tax asset. As shown in the reconciliations below, the shareholders' funds and reorganization value have been reduced by \$696.5 million, respectively, to reflect stocks at the lower of cost and net realizable value rather than fair value, net of the related tax impact of such adjustment. The following table reconciles the enterprise value to the implied fair value of the Successor's shareholders' funds as of the Effective Date:

Enterprise value	\$	5,223.0
Plus: Enterprise value adjustments <sup>(1)</sup>		197.0
Adjusted enterprise value		<u>5,420.0</u>
Plus: Cash at bank and in hand		297.9
Plus: Non-operating assets, net <sup>(2)</sup>		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)
Less: Current and noncurrent asset value adjustment in accordance with Irish Company Law		(696.5)
Shareholders' Funds	\$	<u><u>1,507.1</u></u>

(1) Represents incremental taxation credits 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 Group 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 Group's enterprise value to its reorganization value as of the Effective Date:

Adjusted enterprise value	\$	5,420.0
Plus: Cash at bank and in hand		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
Less: Current and noncurrent asset value adjustment in accordance with Irish Company Law		(696.5)
Reorganization value of Successor assets	\$	<u><u>5,905.8</u></u>

### **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
<b>Fixed Assets</b>				
Intangible assets	\$ 5,166.6	\$ —	\$ (1,914.4) (i) (o)	\$ 3,252.2
Tangible assets	790.8	—	(300.7) (p)	\$ 490.1
Financial assets	164.9	91.6 (a)	(1.1) (q)	\$ 255.4
	<u>\$ 6,122.3</u>	<u>91.6</u>	<u>(2,216.2)</u>	<u>3,997.7</u>
<b>Current Assets</b>				
Stocks	375.2	—	—	\$ 375.2
Debtors	725.7	(20.2) (b)	529.5 (k) (r)	\$ 1,235.0
Cash at bank and in hand	1,392.6	(1,094.7) (c)	—	\$ 297.9
	2,493.5	(1,114.9)	529.5	1,908.1
Creditors (amounts falling due within one year)	5,732.8	(5,024.8) (d - h)	(0.1) (s)	\$ 707.9
<b>Net Current (Liabilities) Assets</b>	<u>(3,239.3)</u>	<u>3,909.9</u>	<u>529.6</u>	<u>1,200.2</u>
<b>Total Assets Less Current Liabilities</b>	<u>2,883.0</u>	<u>4,001.5</u>	<u>(1,686.6)</u>	<u>\$ 5,197.9</u>
Creditors (amounts falling due after one year)	150.5	3,398.8 (e - h)	(73.1) (s)	\$ 3,476.2
Provisions for Liabilities	2,683.6	(2,324.5) (f) (i - l)	(144.5) (l) (t)	\$ 214.6
<b>Net Assets</b>	<u>48.9</u>	<u>\$ 2,927.2</u>	<u>\$ (1,469.0)</u>	<u>\$ 1,507.1</u>
<b>Capital and Reserves</b>				
Called-up share capital presented as equity	\$ 18.9	(18.8) (m)	—	\$ 0.1
Share premium account	5.7	206.0 (m)	—	\$ 211.7
Other reserves	1,587.1	394.8 (m)	9.9 (u)	\$ 1,991.8
Profit and loss account	(1,562.8)	2,345.2 (n)	(1,478.9) (v)	\$ (696.5)
<b>Shareholders' Funds</b>	<u>\$ 48.9</u>	<u>\$ 2,927.2</u>	<u>\$ (1,469.0)</u>	<u>\$ 1,507.1</u>

#### Reorganization Adjustments

- (a) Represents the transfer of funds to a restricted cash account for purposes of funding the \$89.0 million professional fee reserve and debt issuance costs of \$2.6 million related to entering into a Receivables Financing Facility. These costs were capitalized as other financial assets as the facility was undrawn as of June 16, 2022. Refer to Note 22 for further information on the Receivables Financing Facility.
- (b) Represents the release of a \$10.9 million success fee prepayment as a result of emergence from bankruptcy and the write off of prepayments related to premiums for the former Group's directors' and officers' insurance policy coupled with a write-off of \$6.5 million of prepayments related to premiums for the former Group's directors' and officers' insurance policy.



(c) The table below reflects the sources and uses of cash at bank and in hand on the Effective Date:

<b>Sources:</b>	
Proceeds from New 1L Notes	\$ 637.0
<b>Total Sources</b>	<b>637.0</b>
<b>Uses:</b>	
Payment of 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)
<b>Total Uses</b>	<b>(1,731.7)</b>
<b>Net Uses of Cash</b>	<b>\$ (1,094.7)</b>

(d) Represents (i) \$43.5 million of professional fees paid to the Group's restructuring advisors upon the Group'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 liabilities subject to compromise ("LSTC") within trade creditors; (ii) payments of accrued interest on the Group's Existing Revolver, Existing Term Loans and Existing 2L Notes in accordance with the cash collateral order on the Effective Date; and (iii) reorganization adjustments to accruals and other creditors (amounts falling due within one year) as follows:

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
	<b>\$ 50.8</b>

(e) 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)
<b>Total fair value adjustment to debt instruments</b>	<b>\$ (492.1)</b>

Predecessor debt for certain of these instruments described above were classified in LSTC as of the Effective Date.

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

**Liabilities subject to compromise**

Trade creditors	\$	17.7
Accrued interest		35.2
Accruals and other creditors		54.1
Debt		3,746.2
Creditors (amounts falling due within one year)		<u>3,853.2</u>

Accruals and other creditors		19.6
Creditors (amounts falling due after one year)		<u>19.6</u>

Environmental provisions		67.2
Acthar Gel-Related Settlement liability		630.0
Opioid-Related Litigation Settlement liability		1,722.4
Other provisions		77.9
Pension and similar obligations		32.4
Provisions for liabilities		<u>2,529.9</u>
Total liabilities subject to compromise	\$	<u>6,402.7</u>

**To be reinstated on the Effective Date:**

Trade creditors	\$	(0.1)
Accruals and other creditors (amounts falling due within one year)		(15.4)
Accruals and other creditors (amounts falling due after one year)		(11.9)
Pension and similar obligations		(32.4)
Total liabilities reinstated	\$	<u>(59.8)</u>

**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 Terliviv CVR		(41.8)
Cash payment		(601.3)
Total consideration provided to settle amounts per the Plan	\$	<u>(5,399.2)</u>

**Gain on settlement of liabilities subject to compromise**

	\$	<u>943.7</u>
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(g) Pursuant to the Plan, the Group agreed to pay \$260.0 million to the DOJ and other parties over seven years to settle the Acthar Gel-related matters. The Group 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 Group 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 Group 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) As part of fresh-start accounting, the Group recorded a \$100.0 million intangible asset in relation to the Group'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 provision for 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 was classified as intangible asset and provision for liabilities. Refer to Note 15 for further information on the subsequent sale of the PRV.

- (j) Reinstatement of certain long-term pension and other postretirement plans from LSTC to provisions for liabilities.
- (k) 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 Group'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.
- (l) Reinstatement of the Group's \$16.8 million asbestos-related defense costs as a provision for liability 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 turnover milestone. The Group 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 Group determined the fair value of the CVR to be \$6.8 million as of the Effective Date.
- (m) 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 <sup>(1)</sup>		13.9
Additional paid in capital - Successor Common Stock		2,189.6
<b>Successor equity</b>	<b>\$</b>	<b>2,203.6</b>

- (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 Group; 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 Group's peer group with similar business models.

- (n) Profit and loss account - The cumulative effect of the consummation of the Plan on the Predecessor's profit and loss account 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 <sup>(1)</sup>		(9.2)
Accrual of severance for former CEO		(5.7)
Taxation charge on plan adjustments		(102.7)
Cancellation of Predecessor equity		1,621.6
Net impact on profit and loss account	<b>\$</b>	<b>2,345.2</b>

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

#### *Fresh-Start Adjustments*

- (o) Reflects the fair value adjustment related to the Group'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 15 for further information on intangible assets.
- (p) Reflects the fair value adjustment related to the Group'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.

In addition, the Group's lease obligations were revalued using the incremental borrowing rate applicable to the Group 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 Group'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.

- (q) Reflects the write-off of \$1.1 million of third party debt issuance costs.
- (r) Reflects (i) the reduction of \$54.0 million in prepaid taxation charges due to remeasurement as a result of fresh-start accounting; (ii) a write-off of \$4.3 million of asbestos indemnification debtor affiliated with asbestos-related defense costs in line with the Group's accounting policy change as outlined in Note 1; (iii) write-off of \$16.0 million of asbestos indemnification debtor affiliated with asbestos-related defense costs in line with the Group's accounting policy change as outlined in Note 1; (iv) write-off of \$3.9 million of spare parts that did not meet the Group's capitalization threshold; and (v) a decrease of \$0.9 million to taxation receivables associated with a change in uncertain tax positions as a result of fresh-start accounting.
- (s) Reflects (i) 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; (ii) an adjustment of \$6.9 million to increase the Group's total lease liabilities as a result of the revaluation of the lease obligations as described in footnote (p) above; and (iii) the reduction of liabilities for unrecognized tax benefits that are no longer required upon emergence from bankruptcy.
- (t) Reflects the write-off of \$6.1 million and \$16.7 million of provisions for liabilities of asbestos-related defense costs, respectively, in line with the Group's accounting policy change as outlined in Note 1.
- (u) Reflects the fair value adjustment to eliminate the accumulated other comprehensive loss 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 tax charges, which resulted in taxation credit of \$0.3 million.
- (v) The cumulative effect of the fresh-start accounting on the Successor's retained deficit is as follows:

Fresh-start adjustment:		
Tangible assets	\$	(300.7)
Intangible assets, net		(1,914.4)
Debt		18.4
Other assets and liabilities		(9.7)
Total fresh-start adjustments impacting reorganization items, net		(2,206.4)
Fresh-start adjustments to accumulated other comprehensive loss, net of \$0.3 million of taxation credit		(9.9)
Total fresh-start adjustments recorded to taxation credit		737.4
Net fresh-start impact to profit and loss account	\$	(1,478.9)

### ***Reorganization items, net***

Reorganization items, net, 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. After emergence, 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 fiscal 2022 and fiscal 2021 \$322.5 million and \$333.1 million, respectively.

Reorganization items, net, were comprised of the following:

	Fiscal Year	
	2022	2021
Gain on settlements of LSTC	\$ (943.7)	\$ —
Loss on fresh-start adjustments	2,206.4	—
Professional and other service provider fees	184.3	405.6
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
Adjustments of other claims	5.4	(0.5)
Total reorganization items, net	<u>\$ 1,505.9</u>	<u>\$ 428.2</u>

#### 4. Summary of Significant Accounting Policies

##### *Turnover Recognition*

###### *Product Turnover*

The Group 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 Group 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, turnover incentives, chargebacks, distribution service agreements fees, fees for services and administration fees and discounts with respect to the purchase of the Group's products.

###### *Reserve for Variable Considerations*

Product turnover is recorded at the turnover 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 turnover deductions that are offered within contracts between the Group and its customers, health care providers and payers relating to the Group's turnover of its products. These reserves are based on the amounts earned or to be claimed on the related turnover and are classified as reductions of trade debtors (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 Group's historical experience, estimated future trends, estimated customer stocks levels, current contracted turnover terms with customers, level of utilization of the Group's products and other competitive factors. Overall, these reserves reflect the Group'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 turnover 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 Group adjusts reserves for chargebacks, rebates, product returns and other turnover deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of turnover recognized in the period of adjustment.

Product turnover is recognized when the customer obtains control of the Group'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 Group'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 Group's determination of the measure that best aligns with how the obligation is satisfied. The Group's considerations of why such measures provide a faithful depiction of the transfer of its products are as follows:

- For those contracts whereby turnover is recognized over time based upon consumption of the product, the Group either has:
  1. the right to invoice the customer in an amount that directly corresponds with the value to the customer of the Group'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 turnover is recognized over time based upon the passage of time, the benefit that the customer receives from unlimited access to the Group's product does not vary, regardless of consumption. As a

result, the Group'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 Group's contracts have a term of less than one year; therefore, the related disclosure of 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 Group's contracts are short-term in nature, turnover commissions are generally expensed when incurred as the amortization period would have been less than one year. These costs are recorded within distribution and administrative expense ("D&A") in the consolidated profit and loss account. For contracts that extend beyond one year, the incremental expense recognition matches the recognition of related turnover.

#### *Costs to fulfill a contract*

The Group capitalizes the costs associated with the devices used in the Group'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 Group's cost to produce the asset, which is classified in tangible assets on the consolidated balance sheets and expensed to cost of sales over the useful life of the equipment.

#### *Product Royalty Turnover*

The Group licenses certain rights to Amitiza<sup>®</sup> (lubiprostone) ("Amitiza") to third parties in exchange for royalties on turnover of the product. The Group recognizes such royalties as the related turnover occurs.

#### *Contract Balances*

Trade debtors are recorded when the right to consideration becomes unconditional. Payments received from customers are typically based upon payment terms of 30 days. The Group does not maintain contract asset balances aside from the trade debtor 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 D&A on the consolidated profit and loss account. Contract liabilities are recorded when cash payments are received in advance of the Group's performance, including amounts that are refundable.

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

#### *Shipping and Handling Costs*

Shipping costs, which are costs incurred to physically move product from the Group's premises to the customer's premises, are classified as D&A expenses. Handling costs, which are costs incurred to store, move and prepare product for shipment, are classified as cost of sales. Shipping costs included in D&A expenses in continuing operations were \$26.7 million and \$23.6 million for fiscal 2022 and 2021, respectively.

### ***Research and Development***

Internal research and development ("R&D") costs are expensed as incurred. R&D costs 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 Group 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.

The information required by paragraph 63(4) of Schedule 3 of the Irish Companies Act 2014 is not provided as it would be prejudicial to the interest of the Group.

## ***Currency Translation***

For the Group'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. Turnover 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 loss. From time to time, the Group 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 loss after taxation.

## ***Cash at Bank and In Hand***

The Group 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 Group of three months or less, as cash at bank and in hand.

## ***Trade Debtors and Allowance for Doubtful Accounts***

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

## ***Stocks***

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

## ***Tangible Assets***

### ***Owned Tangible Assets***

Tangible assets are 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 tangible assets, 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 Group capitalizes certain computer software and development costs incurred in connection with developing or obtaining software for internal use.

Upon retirement or other disposal of tangible assets, 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 the profit and loss account.

The Group 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.

### ***Lease Assets***

The Group assesses all contracts at inception to determine whether a lease exists. The Group 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 Group recognizes lease expense for these leases on a straight-line basis over the lease term. The Group has lease agreements with lease and non-lease components, which

are accounted for separately. The Group'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 Group's leases do not generally provide an implicit rate, the Group utilized 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 Group'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 Group 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 Group allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

The Group'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 Group 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 Group 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***

Irish company law requires indefinite-lived intangible assets to be amortized; however, the directors do not believe that this gives a true and fair value because not all intangible assets decline in value. Therefore, to present a true and fair value of the economic reality certain other intangible assets are considered indefinite-lived and are not amortized.

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 subsequently 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 Group's intangible assets as of December 30, 2022 were the following:

Completed technology	3	to	20 years
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Amortization expense related to completed technology and certain other intangible assets is included in cost of sales.

When a triggering event occurs, the Group 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 Group 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 Group 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 Group 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 Group 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 25. The Group records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Group 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 Group 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. For more information about the Group's share-based awards, refer to Note 11.

### ***Restructuring***

The Group recognizes charges associated with the Group'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 Group accrues for costs when they are probable and reasonably estimable.

### ***Taxation***

Deferred tax assets and liabilities are recognized for the expected future taxation 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 Group determines whether it is more likely than not that a tax position will be sustained upon examination. The taxation credit 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 taxation credit is not

realized on the uncertain tax position, a tax liability, or a reduction to a deferred tax asset ("contra-DTA(s)") is established. Interest and penalties on tax obligations, associated with uncertain tax positions, are included in the provision for taxation.

The calculation of the Group's tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across the Group's global operations. The Group 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 Group'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 taxation credits being recognized in the period when it is determined that the liabilities are no longer necessary. Refer to Note 9 for further information regarding the classification of such amounts in the consolidated balance sheets.

## 5. Turnover from Contracts with Customers

### *Product Turnover*

See Note 6 for presentation of the Group's turnover by product family.

#### *Reserves for variable consideration*

The following table reflects activity in the Group's sales reserve accounts:

	Rebates and Chargebacks	Product Returns	Other Turnover Deductions	Total
<b>Balance as of December 25, 2020</b>	\$ 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)
<b>Balance as of December 30, 2021</b>	241.8	21.5	9.5	272.8
Provisions	1,497.8	12.2	53.8	1,563.8
Payments or credits	(1,474.3)	(17.7)	(50.6)	(1,542.6)
<b>Balance as of December 30, 2022</b>	<u>\$ 265.3</u>	<u>\$ 16.0</u>	<u>\$ 12.7</u>	<u>\$ 294.0</u>

Product turnover transferred to customers at a point in time and over time were as follows:

	Fiscal Year	
	2022	2021
Product turnover transferred at a point in time	82.0 %	79.4 %
Product turnover transferred over time	18.0	20.6

#### *Transaction price allocated to the remaining performance obligations*

The following table includes estimated turnover from contracts extending greater than one year for certain of the Group'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:

Fiscal 2023	\$ 115.4
Fiscal 2024	23.5
Thereafter	2.7

#### *Costs to fulfill a contract*

As of December 30, 2022 and December 31, 2021, the total book value of the devices used in the Group's portfolio of drug-device combination products, which are used in satisfying future performance obligations, reflected in tangible assets, on the consolidated balance sheets was \$10.3 million and \$25.8 million, respectively. The associated depreciation expense recognized during fiscal 2022 and 2021 was \$3.9 million and \$6.1 million, respectively.

## Product Royalty Turnover

The Group licenses certain rights to Amitiza to third parties in exchange for royalties on turnover of the product. The Group receives a double-digit royalty based on a percentage of the gross profits on the licensed products sold during the term of the agreements. The Group recognizes such royalty turnover as the related turnover occurs. The associated royalty turnover recognized during fiscal 2022 and 2021 was \$71.1 million and \$102.4 million, respectively.

## 6. Segment and Geographical Data

The Group 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 Group's operating segments based on segment turnover and operating profit. Management excludes corporate expenses from segment operating profit. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment turnover and operating profit 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 and changes related to the Opioid-Related Litigation Settlement. Although these amounts are excluded from segment turnover and operating profit, as applicable, they are included in reported consolidated turnover and operating loss and are reflected in the reconciliations presented below.

Management manages assets on a total Group basis, not by operating segment. The Group's chief operating decision maker does not regularly review any asset information by operating segment and, accordingly, the Group 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 and December 31, 2021, respectively.

Selected information by reportable segment was as follows:

	Fiscal Year	
	2022	2021
<b>Turnover:</b>		
Specialty Brands	\$ 1,269.5	\$ 1,547.0
Specialty Generics	644.8	661.8
<b>Turnover</b>	<b>\$ 1,914.3</b>	<b>\$ 2,208.8</b>
<b>Operating loss:</b>		
Specialty Brands	\$ 622.7	\$ 812.8
Specialty Generics <sup>(1)</sup>	88.7	107.9
Segment operating profit	711.4	920.7
Unallocated amounts:		
Corporate and unallocated expenses <sup>(2)</sup>	(76.4)	(156.3)
Depreciation and amortization	(669.3)	(675.8)
Share-based compensation	(3.1)	(10.2)
Restructuring charges, net	(20.7)	(26.9)
Non-restructuring impairment charges	—	(90.4)
Separation costs <sup>(3)</sup>	(30.2)	(1.2)
Opioid-related litigation settlement loss	—	(125.0)
Bad debt expense - customer bankruptcy	(6.4)	—
<b>Operating loss</b>	<b>\$ (94.7)</b>	<b>\$ (165.1)</b>
<b>Depreciation and amortization:</b>		
Specialty Brands	\$ 612.0	\$ 597.7
Specialty Generics	57.3	78.1
Depreciation and amortization	<b>\$ 669.3</b>	<b>\$ 675.8</b>

(1) Includes \$30.0 million of fresh-start stocks-related expense during fiscal 2022 primarily driven by the Group's change in accounting estimate as disclosed in Note 1.

- (2) Includes administration expenses and certain compensation, legal, environmental and other costs not charged to the Group's reportable segments.
- (3) Represents costs included in D&A expenses, primarily related to expenses incurred related to the severance for the former CEO and certain former executives, in addition to professional fees and costs incurred as the Group explores potential sales of non-core assets to enable further deleveraging post-emergence from bankruptcy. Costs incurred prior to emergence 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 are being classified on a go-forward basis as reorganization items, net.

Turnover by product family from continuing activities within the Group's segments was as follows:

	Fiscal Year	
	2022	2021
Acthar Gel	\$ 516.0	\$ 593.6
INOmax	339.7	448.5
Ofirmev	2.2	28.9
Therakos	240.1	266.5
Amitiza <sup>(1)</sup>	158.6	196.9
Other	12.9	12.6
Specialty Brands	<u>1,269.5</u>	<u>1,547.0</u>
Opioids	206.7	213.2
ADHD	45.9	37.4
Addiction treatment	65.0	68.3
Other	11.7	12.0
Generics	<u>329.3</u>	<u>330.9</u>
Controlled substances	84.6	93.4
APAP	207.9	215.9
Other	23.0	21.6
API	<u>315.5</u>	<u>330.9</u>
Specialty Generics	644.8	661.8
Turnover	<u>\$ 1,914.3</u>	<u>\$ 2,208.8</u>

- (1) Amitiza turnover consist of both product and royalty turnover. Refer to Note 5 for further details on Amitiza's revenues.

Selected information by geographic area was as follows:

	Fiscal Year	
	2022	2021
<b>Turnover <sup>(1)</sup>:</b>		
U.S.	\$ 1,712.5	\$ 1,991.8
Europe, Middle East and Africa	174.0	181.8
Other	27.8	35.2
Turnover	<u>\$ 1,914.3</u>	<u>\$ 2,208.8</u>
	<b>December 30, 2022</b>	<b>December 31, 2021</b>
<b>Long-lived assets <sup>(2)</sup>:</b>		
U.S.	\$ 287.3	\$ 629.3
Europe, Middle East and Africa <sup>(3)</sup>	178.0	156.2
Other	3.1	4.7
Long-lived assets	<u>\$ 468.4</u>	<u>\$ 790.2</u>

- (1) Turnover is attributed to regions based on the location of the entity that records the transaction, none of which relate to the country of Ireland.
- (2) Long-lived assets are primarily composed of owned tangible assets.
- (3) Includes long-lived assets located in Ireland of \$174.9 million and \$154.5 million as of December 30, 2022 and December 31, 2021, respectively.

## 7. Restructuring and Related Charges

During fiscal 2021 and 2018, the Group 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 program. Each program will generally commence upon substantial completion of the previous program. The 2021 program has not commenced as of December 30, 2022. In addition to the aforementioned restructuring programs, the Group has taken restructuring actions to generate synergies from its acquisitions.

Net restructuring and related charges by segment were as follows:

	Fiscal Year	
	2022	2021
Specialty Brands	\$ —	\$ 0.1
Specialty Generics	4.3	4.9
Corporate	17.4	24.0
Restructuring and related charges, net	21.7	29.0
Less: accelerated depreciation	(1.0)	(2.1)
Restructuring charges, net	<u>\$ 20.7</u>	<u>\$ 26.9</u>

Net restructuring and related charges by program from continuing operations were comprised of the following:

	Fiscal Year	
	2022	2021
2018 Program	\$ 21.7	\$ 29.0
Less: non-cash charges, including accelerated depreciation	(5.8)	(6.3)
Total charges expected to be settled in cash	<u>\$ 15.9</u>	<u>\$ 22.7</u>

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:

	<b>2018 Program</b>
<b>Balance as of December 25, 2020</b>	<u>\$ 11.0</u>
Charges	23.7
Changes in estimate	(4.3)
Cash payments	(12.8)
<b>Balance as of December 31, 2021</b>	<u>17.6</u>
Charges	19.8
Changes in estimate	(10.6)
Cash payments	(22.2)
<b>Balance as of December 30, 2022</b>	<u>\$ 4.6</u>

As of December 30, 2022, net restructuring and related charges incurred cumulative to date for the 2018 Program were as follows:

	<b>2018 Program <sup>(1)</sup></b>
Specialty Brands	<u>\$ 3.1</u>
Specialty Generics	19.3
Corporate	95.3
	<u>\$ 117.7</u>

(1) There is no specified time period associated with this restructuring program.

All of the restructuring reserves were included in provision for liabilities on the Group's consolidated balance sheets. Amounts paid in the future may differ from the amount currently recorded.

## 8. Interest Payable and Similar Expenses

Interest payable and similar expenses are primarily related to loans made to the Group by credit institutions and were comprised of:

	Fiscal Year	
	2022	2021
Interest on loans made to the Group by credit institutions <sup>(1)</sup>	\$ 292.0	\$ 233.4
Accretion on loans made to the Group by credit institutions	51.7	—
Accretion on settlement obligations	87.5	—
Amortization of debt issue costs	3.2	5.4
Capitalized interest	(1.8)	(0.5)
Other <sup>(2)</sup>	0.3	(15.7)
Interest payable and similar expenses	<u>\$ 432.9</u>	<u>\$ 222.6</u>

- (1) Includes interest expense incurred with respect to the incremental adequate protection payments on the senior secured revolving credit facility and the senior secured term loans of \$28.8 million and \$63.1 million during fiscal 2022 and 2021, respectively. Refer to Note 2 for further information.
- (2) Includes other non-cash interest and U.S. Internal Revenue Code ("IRC") Section 453A ("Section 453A") interest.

## 9. Taxation

The domestic and international components <sup>(1)</sup> of loss before taxation were as follows:

	Fiscal Year	
	2022	2021
Domestic	\$ (3,543.7)	\$ (512.2)
International	1,511.2	(278.7)
Total	<u>\$ (2,032.5)</u>	<u>\$ (790.9)</u>

- (1) Domestic reflects Ireland in fiscal 2022 and 2021.

Significant components of taxation were as follows:

	Fiscal Year	
	2022	2021
Current:		
Domestic	\$ 0.9	\$ (33.7)
International	(51.9)	(17.7)
Current taxation credit	(51.0)	(51.4)
Deferred:		
Domestic	(164.5)	(59.5)
International	(435.3)	(0.4)
Deferred taxation credit	(599.8)	(59.9)
Total	<u>\$ (650.8)</u>	<u>\$ (111.3)</u>

The domestic current taxation reflects taxation credits of \$12.0 million and \$2.2 million from using net operating loss ("NOL") carryforwards for fiscal 2022 and 2021, respectively. The international current taxation reflects taxation credits of \$61.1 million and \$1.2 million from using NOL carryforwards for fiscal 2022 and 2021, respectively.

During fiscal 2022, net cash payments for income taxes were \$6.0 million, and during fiscal 2021, net cash refunds for income taxes were \$160.0 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 U.S. Coronavirus Aid, Relief and Economic Security ("CARES") Act and net payments of \$18.8 million related to operational activity.

The reconciliation between domestic taxation at the statutory rate and the Group's taxation was as follows:

	Fiscal Year	
	2022	2021
Taxation credit at domestic statutory income tax rate <sup>(1)</sup>	\$ (254.2)	\$ (98.9)
Adjustments to reconcile to taxation charge (credit):		
Rate difference between domestic and international jurisdictions	194.4	(221.0)
Adjustments to accrued income tax liabilities and uncertain tax positions <sup>(2)</sup>	—	(14.7)
Interest and penalties on accrued income tax liabilities and uncertain tax positions	—	—
Credits, principally research and orphan drug	(0.9)	(4.7)
Permanently nondeductible and nontaxable items <sup>(3)</sup>	1.4	13.0
Emergence	(31.6)	—
Withholding tax on Swiss distribution	4.7	—
Reorganization items, net	17.4	36.7
Other	(4.5)	0.6
Valuation allowances	(577.5)	177.7
Taxation credit	<u>\$ (650.8)</u>	<u>\$ (111.3)</u>

(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, the permanently nondeductible and nontaxable items were primarily driven by the opioid-related litigation settlement loss that is partially permanently nondeductible.

The rate difference between domestic and international jurisdictions was \$194.4 million of taxation charge for fiscal 2022, consisting of \$163.5 million of taxation charge attributable to reorganization items, net, and \$46.1 million of taxation charge predominately attributable to the pretax earnings in various jurisdictions offset by \$8.9 million of taxation credit attributable to accretion expense associated with our settlement liabilities and \$6.3 million of taxation credit attributable to accretion expense associated with our debt.

The rate difference between domestic and international jurisdictions was \$221.0 million of taxation credit for fiscal 2021, consisting of \$182.8 million of taxation credit attributable to pretax earnings in various jurisdictions, \$27.6 million of taxation credit attributable to reorganization items, net and \$10.6 million of taxation credit attributable to the opioid-related litigation settlement loss.

As a result of the Plan, the Group 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 Group 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 Group 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 Group'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 Group'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 on the Group's income tax accounting policies.

During fiscal 2022, the Group recognized a taxation credit of \$31.6 million upon emergence from Chapter 11 bankruptcy. These impacts of emergence consist of a \$1,202.0 million taxation credit related to the revaluation of net deferred tax assets as a result of fresh-start accounting and a \$285.3 million taxation credit related to the release of uncertain tax positions, offset by \$1,209.8 million of taxation charge 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 taxation charge related to permanently nondeductible impacts on fair value adjustments, and \$54.0 million of taxation charge related to prepaid income taxes.

The Group's valuation allowance taxation credit was \$577.5 million for fiscal 2022, consisting of \$512.1 million of taxation credit for the reduction in the valuation allowance on the Group's deferred tax assets due to the alleviation of the previous substantial doubt about the Group's ability to continue as a going concern and \$65.4 million of taxation credit which mainly offsets impacts included within the taxation credit at the domestic statutory income tax rate and the rate difference between domestic and international jurisdictions.

The Group's valuation allowance taxation charge was \$177.7 million for fiscal 2021, consisting of \$112.4 million of taxation charge attributable to operational activity in applicable tax jurisdictions that are fully offset by a valuation allowance and a \$65.3 million taxation charge attributable to deferred remeasurement as a result of tax rate changes. The valuation allowance taxation charge mainly offsets impacts included within the taxation credit 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 Group's unrecognized tax benefits, excluding interest:

	Fiscal Year	
	2022	2021
Balance at beginning of period	\$ 333.5	\$ 349.0
Additions related to prior period tax positions	—	9.3
Reductions related to prior period tax positions	(306.1)	(2.8)
Settlements	(2.6)	(0.2)
Lapse of statute of limitations	—	(21.8)
Balance at end of period	<u>\$ 24.8</u>	<u>\$ 333.5</u>

Unrecognized tax benefits, excluding interest, were reported in the following consolidated balance sheet captions in the amounts shown:

	December 30, 2022	December 31, 2021
Debtors (falling due after one year) <sup>(1)</sup>	\$ 9.4	\$ 255.7
Creditors (amounts falling due after one year)	15.4	64.1
Provision for liabilities	—	13.7
	<u>\$ 24.8</u>	<u>\$ 333.5</u>

(1) Included as a reduction to deferred tax assets.

Total unrecognized tax benefits as of December 30, 2022 and December 31, 2021 were \$24.8 million and \$77.0 million, respectively, which if favorably settled, would benefit the effective tax rate. The remaining unrecognized tax benefits in fiscal 2021 are reflected as the write-off of related other tax assets. During fiscal 2021, due to a lapse of the statutes of limitations, \$5.1 million of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business were eliminated, and a taxation credit of \$5.1 million was recorded in discontinued operations within the consolidated profit and loss account. During fiscal 2022, the Group recorded \$2.3 million of additional interest and penalties and decreased accrued interest and penalties by \$18.4 million related to prior period reductions and settlements. During fiscal 2021, the Group had a net increase of interest and penalties activity of \$2.2 million. 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 and December 31, 2021, 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 Group'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.

Taxation payable, including uncertain tax positions and related interest accruals, was reported in the following consolidated balance sheet captions in the amounts shown:

	December 30, 2022	December 31, 2021
Creditors (amounts falling due within one year)	\$ 3.6	\$ 1.7
Creditors (amounts falling due after one year)	18.2	83.2
	<u>\$ 21.8</u>	<u>\$ 84.9</u>



Taxation receivables were included in the following consolidated balance sheet captions in the amounts shown:

	December 30, 2022	December 31, 2021
Debtors falling due within one year	\$ 179.5	\$ 36.5
Debtors falling due after one year	—	141.3
	<u>\$ 179.5</u>	<u>\$ 177.8</u>

Deferred taxation results from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The components of the net deferred tax liability at the end of each fiscal year were as follows:

	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	191.4	294.7
	<u>5,724.1</u>	<u>6,501.4</u>
Deferred tax liabilities:		
Intangible assets	—	(108.5)
Investment in partnership	(67.4)	(67.1)
Other	(87.0)	—
	<u>(154.4)</u>	<u>(175.6)</u>
Net deferred tax asset before valuation allowances	5,569.7	6,325.8
Valuation allowances	(4,993.0)	(6,346.7)
Net deferred tax asset (liability)	<u>\$ 576.7</u>	<u>\$ (20.9)</u>

The net deferred tax asset before valuation allowances was \$5,569.7 million as of December 30, 2022, compared to \$6,325.8 million as of December 31, 2021. This decrease consists of \$748.8 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 \$4.0 million increase predominately related to tax loss and other operational activity. The \$748.8 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 \$4,993.0 and \$6,346.7 million as of December 30, 2022 and December 31, 2021, respectively. The valuation allowance as of December 30, 2022 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, due to the alleviation of the previous substantial doubt about the Group'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 was related to the Group'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 taxation activity for fiscal 2022 was as follows:

As of December 31, 2021	\$ (20.9)
Provisions	595.4
Currency translation and other	2.2
As of December 30, 2022	<u>\$ 576.7</u>

Deferred taxation was reported in the following consolidated balance sheet captions in the amounts shown:

	December 30, 2022	December 31, 2021
Debtors (falling due after one year)	\$ 576.8	\$ —
Provision for liabilities	(0.1)	(20.9)
	<u>\$ 576.7</u>	<u>\$ (20.9)</u>

As of December 30, 2022, the Group 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, the Group had \$43.5 million of domestic NOL carryforwards measured at the applicable statutory rates, which have no expiration date.

As of December 30, 2022, the Group 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, the Group 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, the Group also had \$1.9 million of tax credits available to reduce future taxation payables, in international jurisdictions, which will expire in future years through 2043.

As of December 30, 2022, the Group'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 Group's legal entity structure as well as the timing, extent, and nature of any hypothetical realization.

## 10. Loss per Ordinary 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 Group reported a net loss after taxation during all periods presented and therefore, the impact would have been anti-dilutive.

As described in Note 3, pursuant to the Plan, as of the Effective Date, all Predecessor's preferred and ordinary shares were cancelled without any distribution and the Successor's common stock was issued. As such, the Group applied a true and fair view override to present the loss per ordinary share of the Predecessor and Successor entities separately. During the period from January 1, 2022 through June 16, 2022, the period from June 17, 2022 through December 30, 2022 and fiscal 2021, the weighted-average number of shares outstanding used in the computations of basic and diluted loss per ordinary share were 13.2 million, 84.8 million and 84.7 million, respectively. The basic and diluted (loss) profit per ordinary share 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
<b>Basic/diluted (loss) profit per ordinary share:</b>			
Loss from ordinary activities	\$ (81.81)	\$ (3.57)	\$ (8.10)
Profit from discontinued operations	0.02	0.01	0.07
Loss from total activities	\$ (81.80)	\$ (3.56)	\$ (8.02)

The computation of diluted weighted-average shares outstanding for the period from January 1, 2022 through June 16, 2022, the period from June 17, 2022 through December 30, 2022 and fiscal 2021 excluded approximately zero, 0.5 million and 5.2 million, respectively, shares of equity award because the effect would have been anti-dilutive.

## 11. Share Plans

Total share-based compensation cost was \$3.1 million and \$10.2 million for fiscal 2022 and 2021, respectively. These amounts are generally included within D&A expenses in the consolidated profit and loss account. The Group recognized a related taxation credit associated with this expense of zero for fiscal 2022 and 2021.

## 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 Group'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:

	<u>Share Options</u>	<u>Weighted-Average Exercise Price</u>
<b>Outstanding as of December 25, 2020</b>	6,069,712	\$ 35.95
Expired/Forfeited	(516,193)	45.63
<b>Outstanding as of December 31, 2021</b>	5,553,519	35.05
Expired/Forfeited	(5,553,519)	35.05
<b>Outstanding as of December 30, 2022</b>	<u>—</u>	<u>—</u>

*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 Group's ordinary shares on the date of grant.

RSU activity was as follows:

	<u>Shares</u>	<u>Weighted-Average Grant-Date Fair Value</u>
<b>Non-vested as of December 25, 2020</b>	490,671	20.96
Exercised	(186,930)	23.43
Expired/Forfeited	(60,844)	19.58
<b>Non-vested as of December 31, 2021</b>	242,897	19.40
Granted	890,485	12.03
Expired/Forfeited	(242,897)	(19.40)
<b>Non-vested as of December 30, 2022</b>	<u>890,485</u>	<u>12.03</u>

The total fair value of RSU awards granted during fiscal 2022 was \$10.7 million. As of December 30, 2022, 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 Group 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 Group'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 Group recognized \$0.1 million of equity-based compensation costs in fiscal 2022. The fair value of the liability-based awards is measured quarterly and is based on the Group's performance. Payment, if any, for the liability-based awards is expected to be made in fiscal 2024.

PSU activity was as follows <sup>(1)</sup>:

	Shares	Weighted-Average Grant-Date Fair Value
<b>Non-vested as of December 31, 2021</b>	—	\$ —
Granted	675,821	8.34
<b>Non-vested as of December 30, 2022</b>	<u>675,821</u>	<u>8.34</u>

(1) The number of shares disclosed within this table are at the target number of 100%.

The Group 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 fiscal 2022 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 fiscal 2022, 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.

## 12. Directors' Remuneration

Directors' remuneration is set forth in the table below. Mr. Trudeau and Mr. Olafsson, the Group's President and Chief Executive Officer ("CEO") and Director for the period January 1, 2022 through June 16, 2022 and the period June 17, 2022 through December 30, 2022, respectively, is not compensated for his services as a director. Accordingly, the amounts below for "Managerial Services" include compensation for Mr. Trudeau and Mr. Olafsson's services as President and CEO. The amounts below also include compensation for all non-executive directors in their capacities as such (referred to as "Director Services").

	Fiscal Year	
	2022	2021
<b>Director Services</b>		
Fees paid in cash	\$ 1.9	\$ 3.3
Benefits under long-term incentive schemes <sup>(1)</sup>	1.0	—
Total <sup>(2)</sup>	<u>\$ 2.9</u>	<u>\$ 3.3</u>
<b>Managerial Services</b>		
Emoluments	\$ 2.3	\$ 8.2
Benefits under long-term incentive schemes <sup>(1)</sup>	0.1	3.2
Group contributions to savings plans and other <sup>(3)</sup>	0.5	0.7
Loss of office payment	5.6	—
Total <sup>(2)</sup>	<u>\$ 8.5</u>	<u>\$ 12.1</u>

(1) Includes amounts expensed for outstanding equity awards for the nine directors serving during the period from June 16, 2022 through December 30, 2022 and both the former and current CEO.

(2) The gain on exercise of share options was zero for fiscal 2022 and 2021 for both directors and managerial services.

(3) Includes amounts for contributions to retirement and supplemental savings plan, tax reimbursement payments and other benefits. Total contributions for retirement savings plans were less than \$0.1 million for both fiscal 2022 and 2021, respectively.

*Indemnification Agreements.* Mallinckrodt plc has entered into deeds of indemnification with each of its directors and Secretary ("the Deeds of Indemnification"), and Sucampo Pharmaceuticals, Inc., a Delaware corporation and a wholly owned subsidiary of Mallinckrodt plc ("Sucampo"), has entered into indemnification agreements with each of Mallinckrodt plc's directors and Secretary ("the Indemnification Agreements"). The Deeds of Indemnification and Indemnification Agreements provide, respectively, that Mallinckrodt plc and Sucampo will, to the fullest extent permitted by law, indemnify each indemnitee against claims related to such indemnitee's service to Mallinckrodt, except (i) in respect of any claim as to which a final and non-appealable judgment is rendered against the indemnitee for an accounting of profits made from the purchase or sale by such indemnitee of securities of Mallinckrodt plc pursuant to the provisions of Section 16(b) of the U.S. Securities Exchange Act of 1934 or similar provision of any federal, state or local laws; (ii) in respect of any claim as to which a court of competent jurisdiction has determined in a final and non-appealable judgment that indemnification is not permitted under applicable law; or (iii) in respect of any claim as to which the indemnitee is convicted of a crime constituting a felony under the laws of the jurisdiction where the criminal action was brought (or, where a jurisdiction does not classify any crime as a felony, a crime for which the indemnitee is sentenced to death or imprisonment for a term exceeding one year).

### 13. Auditor's Remuneration

Auditor's remuneration was as follows:

	Fiscal Year	
	2022 <sup>(1)</sup>	2021 <sup>(1)</sup>
Audit of the group accounts <sup>(2)</sup>	\$ 0.2	\$ 0.2
Other assurance services <sup>(2)</sup>	0.2	0.3
Other non-audit services <sup>(2),(3)</sup>	—	0.3
	<u>\$ 0.4</u>	<u>\$ 0.8</u>

(1) No amounts were incurred for tax advisory services.

(2) The Group incurred additional fees of \$9.3 million and \$5.0 million during fiscal 2022 and 2021, respectively, payable to affiliates of Deloitte Ireland LLP. These additional amounts reflect fees for professional services rendered, including audit fees payable to Deloitte & Touche LLP in the U.S. for the audit of the Group's consolidated financial statements.

(3) Other non-audit services include fees for professional services rendered in the preparation of an independent expert's report that was submitted to the High Court of Ireland in conjunction with Mallinckrodt plc's commencement of the examinership process.

### 14. Employees

The average number of persons, including executive directors, employed by the Group during the year was as follows:

	Fiscal Year	
	2022	2021
Manufacturing	1,494	1,566
Turnover, marketing and distribution	614	603
Research and development	238	304
General and administrative	407	526
	<u>2,753</u>	<u>2,999</u>

Employee costs consisted of the following:

	Fiscal Year	
	2022	2021
Wages and salaries	\$ 419.5	\$ 500.7
Social insurance costs	25.1	30.5
Pension and postretirement costs	10.5	26.2
	<u>\$ 455.1</u>	<u>\$ 557.4</u>

For information on share based payments not included within the employee costs above, refer to Note 11.

## 15. Intangible Assets

Intangible asset activity for fiscal 2022 was as follows:

	Completed Technology	Licenses	Trademarks	In-process Research and Development	Total Intangible Assets
<b>Cost:</b>					
As of December 31, 2021	\$ 10,404.0	\$ 120.1	\$ 112.7	\$ 81.0	\$ 10,717.8
Fresh-start accounting adjustment <sup>(1)</sup>	(7,485.1)	(120.1)	(112.7)	152.3	(7,565.6)
Additions	17.5	—	—	—	17.5
Disposal	—	—	—	(7.2)	(7.2)
Transfers	104.8	—	—	(104.8)	—
As of December 30, 2022	<u>\$ 3,041.2</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 121.3</u>	<u>\$ 3,162.5</u>
<b>Accumulated Amortization:</b>					
As of December 31, 2021	\$ 5,160.4	\$ 82.1	\$ 26.9	\$ —	\$ 5,269.4
Amortization expense	597.1	1.8	1.6	—	600.5
Fresh-start accounting adjustment <sup>(1)</sup>	(5,438.8)	(83.9)	(28.5)	—	(5,551.2)
As of December 30, 2022	<u>\$ 318.7</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 318.7</u>
<b>Net book value:</b>					
As of December 31, 2021	\$ 5,243.6	\$ 38.0	\$ 85.8	\$ 81.0	\$ 5,448.4
As of December 30, 2022	2,722.5	—	—	121.3	2,843.8

(1) Write-downs/write-ups are a result of fresh-start accounting. Refer to Note 3.

### Long-Lived Asset Impairment Analysis

The Group recorded impairment charges related to its Specialty Brands segment totaling \$90.4 million during fiscal 2021 related to Amitiza as the undiscounted cash flows were less than its net book value. The valuation method used to approximate fair value was based on the estimated discounted cash flows for the respective asset.

As part of fresh-start accounting, as of the Effective Date, the Group 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 Group'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 Group 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.

#### Amitiza

Beginning January 1, 2022, the Group 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.

#### Terlivaz

On September 14, 2022, the Group announced that the FDA had approved Terlivaz for injection. Upon FDA approval, the Group 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.

The Group 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. Management relies on a number of qualitative factors when considering a potential impairment such as changes to planned revenue or earnings that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset.

### Intangible asset amortization expense

Finite-lived intangible asset amortization expense was \$600.5 million and \$581.1 million during fiscal 2022 and 2021, respectively. The estimated aggregate amortization expense on intangible assets owned by the Group 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

## 16. Tangible Assets

The gross carrying amount and accumulated depreciation of owned tangible assets were comprised of the following at the end of each period:

	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
	<u>485.0</u>	<u>1,886.6</u>
Less: accumulated depreciation	(27.4)	(1,110.6)
Total owned tangible assets	<u>457.6</u>	<u>776.0</u>
Lease assets	38.1	35.0
Total tangible assets	<u>\$ 495.7</u>	<u>\$ 811.0</u>

### Owned Tangible Assets

Owned tangible assets activity for fiscal 2022 was as follows:

	Land	Buildings	Capitalized Software	Machinery and Equipment	Construction in Process	Total Owned Tangible Assets
<b>Cost:</b>						
As of December 31, 2021	\$ 43.5	\$ 387.8	\$ 121.1	\$ 1,254.1	\$ 80.1	1,886.6
Additions	—	0.1	0.1	4.1	45.6	49.9
Disposal of tangible owned assets	—	(1.7)	(0.6)	(11.2)	—	(13.5)
Fresh-start accounting adjustment <sup>(1)</sup>	7.3	(264.6)	(104.7)	(1,047.8)	(27.4)	(1,437.2)
Transfers	—	7.5	1.7	18.4	(27.6)	—
Currency translation and other	0.2	(1.9)	(0.1)	(0.8)	1.8	(0.8)
As of December 30, 2022	<u>\$ 51.0</u>	<u>\$ 127.2</u>	<u>\$ 17.5</u>	<u>\$ 216.8</u>	<u>\$ 72.5</u>	<u>\$ 485.0</u>
<b>Accumulated Depreciation:</b>						
As of December 31, 2021	\$ —	\$ 170.5	\$ 91.5	\$ 848.6	\$ —	1,110.6
Depreciation expense	—	12.7	7.7	48.4	—	68.8
Disposal of tangible owned assets	—	(1.4)	(0.6)	(10.8)	—	(12.8)
Fresh-start accounting adjustment <sup>(1)</sup>	—	(175.6)	(95.5)	(866.9)	—	(1,138.0)
Currency translation and other	—	(0.6)	—	(0.6)	—	(1.2)
As of December 30, 2022	<u>\$ —</u>	<u>\$ 5.6</u>	<u>\$ 3.1</u>	<u>\$ 18.7</u>	<u>\$ —</u>	<u>\$ 27.4</u>
<b>Net book value:</b>						
As of December 31, 2021	43.5	217.3	29.6	405.5	80.1	776.0
As of December 30, 2022	51.0	121.6	14.4	198.1	72.5	457.6

(1) Write-ups/write-downs are a result of fresh-start accounting. Refer to Note 3.

Depreciation expense was \$68.8 million and \$94.7 million for fiscal 2022 and 2021, respectively. Gain on disposal of owned tangible assets was zero and \$1.2 million for fiscal 2022 and 2021, respectively.

### Lease Assets

Lease assets and liabilities related to the Group's operating leases are reported in the following consolidated balance sheet captions in the amounts shown:

	December 30, 2022	December 31, 2021
Tangible lease assets	\$ 38.1	\$ 35.0
Creditors (amounts falling due within one year)	\$ 10.3	\$ 11.1
Creditors (amounts falling due after one year)	30.4	20.0
Creditors (amount falling due within one year) subject to compromise	—	0.4
Total lease liabilities	\$ 40.7	\$ 31.5

Tangible lease assets activity for fiscal 2022 was as follows:

	Lease Assets
<b>Cost:</b>	
As of December 31, 2021	\$ 65.7
Additions	17.5
Disposal of tangible lease assets	(5.1)
Fresh-start accounting adjustment <sup>(1)</sup>	(34.0)
Currency translation and other	(1.0)
As of December 30, 2022	\$ 43.1
<b>Accumulated Amortization:</b>	
As of December 31, 2021	\$ 30.7
Amortization expense	12.1
Disposal of tangible lease assets	(3.2)
Fresh-start accounting adjustment <sup>(1)</sup>	(32.4)
Currency translation and other	(2.2)
As of December 30, 2022	\$ 5.0
<b>Net book value:</b>	
As of December 31, 2021	\$ 35.0
As of December 30, 2022	38.1

(1) Write-downs are a result of fresh-start accounting. Refer to Note 3.

Dependent on the nature of the leased asset, lease expense is included within cost of sales or D&A expenses. The primary components of lease expense were as follows:

	Fiscal Year	
	2022	2021
Lease cost:		
Operating lease cost	\$ 16.6	\$ 19.6
Short-term lease cost	2.0	1.1
Variable lease cost	2.7	2.4
Total lease cost	\$ 21.3	\$ 23.1



Lease terms and discount rates were as follows:

	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 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:

	Fiscal Year	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 18.6	\$ 20.4
Lease assets obtained in exchange for lease obligations:		
Operating leases	20.5	2.6

## 17. Financial Assets

The Group's financial asset activity during fiscal 2022 was as follows:

	Assets Held by Rabbi Trusts	Restricted Cash	Other Financial Assets	Total Financial Assets
As of December 31, 2021	\$ 83.5	\$ 60.2	\$ 47.6	\$ 191.3
Unrealized (loss) gain	(4.5)	0.4	(12.9)	(17.0)
Interest income	—	—	0.5	0.5
Additions	—	89.0	3.8	92.8
Cash disbursement	(3.0)	(92.4)	(0.5)	(95.9)
Currency translation and other	—	—	(1.0)	(1.0)
As of December 30, 2022	\$ 76.0	\$ 57.2	\$ 37.5	\$ 170.7

Refer to Note 26 for further discussion of the fair value and the valuation techniques utilized to measure the financial assets at fair value.

## 18. Stocks

Stocks were comprised of the following at the end of each period:

	December 30, 2022	December 31, 2021
Raw materials	\$ 80.2	\$ 59.8
Work in process	212.4	196.4
Finished goods	71.9	91.0
Stocks	<u>\$ 364.5</u>	<u>\$ 347.2</u>

## 19. Debtors

At the end of each period, debtors were comprised of:

	December 30, 2022	December 31, 2021
Trade debtors	\$ 405.3	\$ 439.1
Turnover taxation recoverable	7.6	11.9
Taxation receivable (Note 9)	179.5	36.5
Other debtors and prepayments	65.8	105.9
Amounts falling due within one year	<u>658.2</u>	<u>593.4</u>
Deferred taxation (Note 9)	576.8	—
Taxation receivable (Note 9)	—	141.3
Other debtors	12.8	38.7
Amounts falling due after one year	<u>589.6</u>	<u>180.0</u>
Total debtors	<u>\$ 1,247.8</u>	<u>\$ 773.4</u>

## 20. Creditors (amounts falling due within one year)

As of the end of each period, creditors (amounts falling due within one year) were comprised of:

	December 30, 2022	December 31, 2021
Debt (Note 22)	\$ 44.1	\$ 5,139.7
Trade creditors	114.0	165.9
Accrued payroll and employee benefits	49.5	84.6
Other taxes	14.2	15.3
Accrued interest	29.0	52.2
Accrued royalties	0.4	29.5
Lease liabilities (Note 16)	10.3	11.5
Accruals and other creditors	183.9	256.1
Acthar Gel-Related Litigation Liability	16.5	—
Opioid-Related Litigation Liability	200.0	—
Creditors (amounts falling due within one year)	<u>\$ 661.9</u>	<u>\$ 5,754.8</u>

## 21. Creditors (amounts falling due after one year)

As of the end of each period, creditors (amounts falling due after one year) were comprised of:

	December 30, 2022	December 31, 2021
Debt (Note 22)	\$ 3,027.8	\$ —
Taxation payable (Note 9)	18.2	83.2
Deferred compensation	26.0	36.9
Section 453A unrecognized benefit	—	12.4
Lease liabilities (Note 16)	30.4	20.0
Accruals and other creditors	0.7	1.0
Acthar Gel-Related Litigation Liability	75.0	—
Opioid-Related Litigation Liability	379.9	—
Creditors (amounts falling due after one year)	<u>\$ 3,558.0</u>	<u>\$ 153.5</u>

## 22. Debt

Debt was comprised of the following at the end of each period:

	December 30, 2022			December 31, 2021	
	Principal	Carrying Value <sup>(1)</sup>	Unamortized Discount and Debt Issuance Costs <sup>(1)</sup>	Principal	Unamortized Discount and Debt Issuance Costs
10.00% first lien senior secured notes due April 2025 <sup>(2)</sup>	\$ 495.0	\$ 475.9	\$ —	\$ 495.0	\$ 5.9
10.00% second lien senior secured notes due April 2025 <sup>(2)</sup>	321.9	242.2	—	—	—
2017 Replacement Term loan due September 2027 <sup>(3)</sup>	1,374.1	1,222.1	—	—	—
2018 Replacement Term loan due September 2027 <sup>(3)</sup>	364.8	326.9	—	—	—
11.50% first lien senior secured notes due December 2028 <sup>(4)</sup>	650.0	650.0	20.8	—	—
10.00% second lien senior secured notes due June 2029 <sup>(4)</sup>	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	—
<b>Total debt</b>	<u>3,534.1</u>	<u>3,092.6</u>	<u>20.8</u>	<u>5,145.8</u>	<u>6.1</u>
<b>Less: Current portion</b>	(44.1)	(44.1)	—	(1,395.0)	(6.1)
<b>Less: Amounts reclassified to liabilities subject to compromise</b>	—	—	—	(3,750.8)	—
<b>Total long-term debt, net of current portion</b>	<u>\$ 3,490.0</u>	<u>\$ 3,048.5</u>	<u>\$ 20.8</u>	<u>\$ —</u>	<u>\$ —</u>

- (1) Upon adoption of fresh-start accounting, the Group 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 Group 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 payable and similar expense on the consolidated profit and loss account.
- (2) Includes debt repayable within five years, otherwise than by installment, of \$816.9 million as of December 30, 2022.
- (3) Includes debt repayable within five years, by installment, of \$1,738.9 million as of December 30, 2022.
- (4) Includes debt repayable beyond five years, otherwise than by installment, of \$978.3 million as of December 30, 2022.

The commencement of the Chapter 11 Cases constituted an event of default under certain of the Group'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 Group 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 Group issued New 1L Notes and entered into a Receivables Financing Facility (discussed further below).

## ***Successor Group 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.

#### *Receivables 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 trade debtors 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, the Group had no outstanding borrowings on its Receivables Financing Facility.

As of December 30, 2022, the applicable interest rate and outstanding borrowings on the Group's variable-rate debt instruments were as follows:

	Applicable interest rate <sup>(1)</sup>	Outstanding borrowings
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 Group'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

## 23. Retirement Plans

### *Defined Benefit Plans*

The Group 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, U.S. plans represented 33.9% of the Group's remaining projected benefit obligation. The Group generally does not provide postretirement benefits other than retirement plan benefits for its employees; however, certain of the Group's U.S. employees participate in postretirement benefit plans that provide medical benefits. These plans are unfunded.

The pension and similar obligations recognized on the consolidated balance sheets were \$18.7 million and \$27.3 million as of December 30, 2022 and December 31, 2021, respectively, for pension benefits and \$26.8 million and \$37.3 million as of December 30, 2022 and December 31, 2021, respectively, for postretirement benefits. The weighted-average discount rate to determine benefit obligations for the Groups pension and postretirement benefit plans ranged from 1.0% to 5.5%. For the Group'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 Group 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 Group contribution of 3.0% of an eligible employee's pay, with an additional Group matching contribution generally equal to 50.0% of each employee's elective contribution to the plan up to 8.0% 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 \$17.4 million and \$22.2 million for fiscal 2022 and 2021, respectively.

## ***Rabbi Trusts and Other Investments***

The Group 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 Group's creditors in the event of the Group's insolvency. Plan participants are general creditors of the Group with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in financial assets on the consolidated balance sheets. Note 26 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 and December 31, 2021, respectively. These contracts had a total death benefit of \$81.0 million and \$86.4 million as of December 30, 2022 and December 31, 2021, respectively. However, there are outstanding loans against the policies amounting to \$21.6 million and \$20.8 million as of December 30, 2022 and December 31, 2021, respectively.

The Group has insurance contracts that serve as collateral for certain of the Group's non-U.S. pension plan benefits. These insurance contracts totaled \$7.3 million and \$7.9 million as of December 30, 2022 and December 31, 2021, respectively. These amounts were included in financial assets on the consolidated balance sheets.

## **24. Guarantees**

In disposing of assets or businesses, the Group 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 Group 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 Group 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 Group 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 provisions for liabilities as of December 31, 2021, 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. 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 Group. The Group 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 and December 31, 2021, \$19.3 million and \$19.0 million remained in financial assets on the consolidated balance sheets, respectively. As of December 30, 2022, the Group does not expect to make future payments related to these indemnification obligations.

The Group has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 25.

The Group is also liable for product performance; however the Group 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, the Group 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 Group's environmental liabilities.

## **25. Commitments and Contingencies**

The Group 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 Group 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, profit and loss account and cash flows.



## **Governmental Proceedings**

### Acthar Gel-Related Matters

*SEC Subpoena.* In August 2019, the Group received a subpoena from the SEC for documents related to the Group'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 Group filed against the Agency. The SEC issued subsequent subpoenas on January 7, 2022 and September 28, 2022, requesting additional documents from the Group.

In connection with the investigation, on January 13, 2023, the SEC staff issued Wells Notices to the Group 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 Group 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 Group 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 Group improperly omitted to disclose the dispute with the Agency prior to the litigation filed by the Group in federal court on May 21, 2019, and (b) the Group'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 Group'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 Group believes that it has complied with all applicable laws and regulations, and it has provided a submission explaining the Group's position and its belief that no enforcement action is warranted or appropriate. The Group understands that the Individuals have provided similar submissions to the SEC staff. The outcome of this matter is uncertain, and as a result, the Group is unable to estimate the potential exposure associated with this matter.

### Other Related Matters

*Florida Civil Investigative Demand.* In or around February 2019, the Group 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 Group has cooperated with the investigation.

*Generic Pricing Subpoena.* In March 2018, the Group 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 Group 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 Group's Methylphenidate ER in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("the Orange Book"). In November 2014, the Group 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 Group'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 Group's appeal of the MD Order in abeyance pending the outcome of the withdrawal proceedings. The parties exchanged documents and in April 2018, the Group filed its submission in support of its position in the withdrawal proceedings. A potential outcome of the withdrawal proceedings is that the Group's Methylphenidate ER products may lose their FDA approval and have to be withdrawn from the market.

## **Patent Litigation**

*Branded Products:* The Group 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 Group's ability to successfully maximize the value of individual Branded products and have an adverse effect on its financial condition, profit and loss account and cash flows. In the case of

litigation filed against potential generic or competing products to Group'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 Group 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 Group'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 Group 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 Group and Pharmascience Inc. ("Pharmascience") relating to the collaboration between Group 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 Group 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 Group 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<sup>®</sup> (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 Group 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 Group'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 Group 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 Group has been unjustly enriched as a result. The Group moved to dismiss the complaint, which motion was pending when the Group 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 Group 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 Group in the relevant settlement agreement. On February 17, 2023, this matter was dismissed as to the Group.

*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 Group 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 Group 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 Group'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 Group moved to transfer this case to the District of Delaware where the Group's Chapter 11 Cases are pending. Steamfitters Local Union No. 420 opposed transfer. On January 18, 2023, this matter was dismissed as to the Group.

*Acument Global.* In May 2019, Acument Global Technologies, Inc. ("Acument"), filed a non-class complaint against the Group 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 Group'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 Group 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 Group 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 Group's objections to which were denied by the court. In January 2021, the Group removed this case to the U.S. District Court for the EDPA. In March 2021, the EDPA granted the Group'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 Group 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 Group, 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 Group'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 expanded putative class period of May 3, 2016 through March 18, 2020 against the Group 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 Group, 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 Group filed a notice of discharge that, if approved by the court, would result in dismissal for the Group. The notice informed the court that (i) the Bankruptcy Court confirmed the Plan; (ii) the Group'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 Group 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 Group, this matter was resolved in bankruptcy with no further liability against the Group.

*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 Group 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 Group 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 Group is not able to reasonably estimate whether any injunctive relief will be granted, and if granted, whether it will materially impact the Group's financial position or operations; the Group does not intend to provide further disclosure unless this assessment changes.

### ***Environmental Remediation and Litigation Proceedings***

The Group 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 Group concluded that, as of December 30, 2022, it was probable that it would incur remediation costs in the range of \$18.4 million to \$48.5 million. The Group also concluded that, as of December 30, 2022, the best estimate within this range was \$36.9 million, which was included in provisions for liabilities on the consolidated balance sheet as of December 30, 2022. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Group 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 Group 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 Group'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 Group, 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, the Group estimated that its remaining liability related to the River was \$21.0 million, which was included within in environmental provisions for liabilities on the consolidated balance sheet as of December 30, 2022. 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 Group's allocable share of the remediation. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which the Group may be ultimately responsible and will be refined as the remediation progresses.

*Occidental Chemical Corp. v. 21st Century Fox America, Inc.* The Group 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 Group was not named as a defendant for the Belleville facility, the Group 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 Group. 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 Group, 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 Group 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 Group.

### ***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 Group 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 Group 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 Group 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 Group is not able to reasonably estimate the expected amount or range of cost or any loss associated with these appeals. The Group will continue to vigorously defend the Plan.

*Sanofi.* On October 12, 2021, in the Group'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 Group could not discharge alleged royalty obligations owed to Sanofi under an asset purchase agreement through which the Group 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 Group'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 Group 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 Group in its bankruptcy. On December 1, 2021, the Bankruptcy Court denied the motion, entering an order that the royalty agreement between the Group 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 Group 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 Group'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 Group's allegedly illegal turnover of Acthar Gel. The Group objected to the claims, arguing that the Group had no such liability. After a bench trial, the Bankruptcy Court, on December 6, 2021, sustained the Group'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 Group 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 Group, with no findings nor any admission of liability or wrongdoing against the Group, and the matter was dismissed on February 24, 2023.

*Stratatech.* As described in Note 26, consummation of the Plan discharged the Group'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 Group 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 Group is a defendant in a number of other pending legal proceedings relating to present and former operations, acquisitions and dispositions. The Group 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.

## 26. 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 Group 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	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 36.6	\$ 24.8	\$ 11.8	\$ —
Equity securities	25.5	25.5	—	—
	<u>\$ 62.1</u>	<u>\$ 50.3</u>	<u>\$ 11.8</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities	\$ 26.0	\$ —	\$ 26.0	\$ —
Contingent consideration liabilities	7.3	—	—	7.3
	<u>\$ 33.3</u>	<u>\$ —</u>	<u>\$ 26.0</u>	<u>\$ 7.3</u>

	December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 38.7	\$ 24.9	\$ 13.8	\$ —
Equity securities	36.5	36.5	—	—
	<u>\$ 75.2</u>	<u>\$ 61.4</u>	<u>\$ 13.8</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities <sup>(1)</sup>	\$ 36.9	\$ —	\$ 36.9	\$ —
Contingent consideration liabilities <sup>(2)</sup>	27.3	—	—	27.3
	<u>\$ 64.2</u>	<u>\$ —</u>	<u>\$ 36.9</u>	<u>\$ 27.3</u>

(1) On November 16, 2020, 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.

*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 fiscal 2022 the Group recognized an unrealized loss of \$13.0 million and during fiscal 2021 the Group recognized an unrealized gain of \$4.7 million, related to our investments within other income, net in the consolidated profit and loss account.

*Deferred compensation liabilities.* The Group maintains a non-qualified deferred compensation plan in the U.S., which permits eligible employees of the Group 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 Group's U.S. tax-qualified defined contribution retirement plan and the account balance fluctuates with the investment returns on those funds.

*Contingent consideration liabilities.* In accordance with the Plan and Scheme of Arrangement, the Group will provide consideration for a CVR associated with Terlivaz primarily in the form of the achievement of a cumulative turnover milestone. The Group 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 Group determined the fair value of the Terlivaz CVR to be \$7.3 million as of December 30, 2022.

As part of the acquisition of Stratatech, the Group 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 Group was responsible for a payment upon acceptance of the Group's submission and another upon approval by the FDA. The Group determined the fair value of the contingent consideration associated with the acquisition of Stratatech to be \$27.3 million as of December 31, 2021. These liabilities were governed by a contract and recorded at their estimated allowed claim amount within provisions for liabilities in the consolidated balance sheet as of December 31, 2021. 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 provisions for liabilities in the consolidated balance sheets as of December 30, 2022 and December 31, 2021, respectively. The following table summarizes the fiscal 2022 activity for contingent consideration:

Balance as of December 31, 2021	\$ 27.3
Impact of the Plan on Predecessor contingent consideration liabilities	(27.3)
Establishment of Terlivaz CVR	6.8
Fair value adjustments	0.5
Balance as of December 30, 2022	<u>\$ 7.3</u>

### Financial Instruments Not Measured at Fair Value

The following methods and assumptions were used by the Group in estimating fair values for financial instruments not measured at fair value as of December 30, 2022 and December 31, 2021:

- The carrying amounts of cash at bank in hand, trade debtors, trade creditors and the majority of other current assets and liabilities approximate fair value because of their short-term nature. The Group 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 at bank and in hand (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 and December 31, 2021, (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, the professional fee escrow balance was zero.
- The Group'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 and December 31, 2021, respectively. These contracts are included in financial assets on the consolidated balance sheets.
- Successor debt.* The Group'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 Group'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 Group's predecessor revolving credit facility approximated the fair value due to the short-term nature of this instrument, and was therefore classified as level 1. The Group's predecessor 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 Group's predecessor term loans and predecessor 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.

	December 30, 2022		December 31, 2021	
	Carrying Value	Fair Value	Carrying Value	Fair Value
<b>Level 1:</b>				
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
<b>Level 2:</b>				
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
<b>Total Debt</b>	<b>\$ 3,092.6</b>	<b>\$ 2,684.6</b>	<b>\$ 5,145.8</b>	<b>\$ 4,267.9</b>



### Concentration of Credit and Other Risks

Financial instruments that potentially subject the Group to concentrations of credit risk primarily consist of trade debtors. The Group generally does not require collateral from customers. A portion of the Group's trade debtors outside the U.S. includes turnover 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 turnover attributable to distributors that accounted for 10.0% or more of the Group's total segment turnover:

	Fiscal Year	
	2022	2021
FFF Enterprises, Inc.	19.6 %	*%
CuraScript, Inc.	*	26.1

The following table shows trade debtors attributable to distributors that accounted for 10.0% or more of the Group's gross trade debtors at the end of each period:

	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

\* Trade debtors attributable to this distributor was less than 10.0% of total gross trade debtors at the end of the respective period presented above.

The following table shows turnover attributable to products that accounted for 10.0% or more of the Group's total segment turnover:

	Fiscal Year	
	2022	2021
Acthar Gel	27.0 %	26.9 %
INOMax	17.7	20.3
Therakos	12.5	12.1
APAP	10.9	*

\* Turnover attributable to these products were less than 10.0% of total turnover during the respective periods presented above.

## 27. Provisions for Liabilities

As of December 30, 2022 and December 31, 2021, provisions for liabilities was comprised of:

	December 30, 2022	December 31, 2021
Pensions and similar obligations (Note 23)	\$ 45.8	\$ 65.0
Deferred taxation (Note 9)	0.1	20.9
Other provisions	134.1	260.1
Acthar Gel-Related Settlement Liability <sup>(1)</sup>	—	634.7
Opioid-Related Litigation Settlement Liability <sup>(1)</sup>	—	1,725.0
	<u>\$ 180.0</u>	<u>\$ 2,705.7</u>

(1) As a result of the emergence from bankruptcy, these liabilities were reclassified to Creditors (amounts falling due within and after one year). See Notes 2 and 3 for further information.

Other provision activity during fiscal 2022 was as follows:

	Environmental (Note 25)	Restructuring Reserves (Note 7)	Guarantees (Note 24)	Contingent Consideration (Note 26)	Other	Total
As of December 31, 2021	\$ 106.9	\$ 17.6	\$ 17.5	\$ 27.3	\$ 90.8	\$ 260.1
Charged to profit and loss account	(0.5)	15.9	(1.0)	—	173.8	188.2
Accretion	(0.8)	—	—	—	0.1	(0.7)
Fair market value adjustments	—	—	—	0.5	—	0.5
Utilization	(1.6)	(22.2)	—	—	(151.1)	(174.9)
Effects of the Plan (Note 3)	(67.2)	(6.7)	(15.0)	(20.5)	(29.6)	(139.0)
Other, including currency translation	0.1	—	0.1	—	(0.3)	(0.1)
As of December 30, 2022	<u>\$ 36.9</u>	<u>\$ 4.6</u>	<u>\$ 1.6</u>	<u>\$ 7.3</u>	<u>\$ 83.7</u>	<u>\$ 134.1</u>

## 28. Shareholders' Funds

*Called-up Share Capital presented as equity.* Pursuant to the Plan and Scheme of Arrangement, as of the Effective Date, all Predecessor's ordinary shares were cancelled. On the Effective Date, the Group authorized 500,000,000 ordinary shares, par value of \$0.01 per share, and issued 13,170,932 ordinary shares par value of \$0.01 per share. The value of these issued shares was \$211.8 million which included a share premium of \$211.7 million. As of December 30, 2022, the Group has authorized 500,000,000 ordinary shares, par value of \$0.01 per share, 13,170,932 of which were issued.

*Share Premium Account.* Pursuant to the Plan and Scheme of Arrangement, as of the Effective Date, all Predecessor share premiums were cancelled and a share premium of \$211.7 million reflective of the issuance of the Successor common stock was recorded.

*Other Reserves.* Pursuant to the Plan and Scheme of Arrangement, as of the Effective Date, the Predecessor other reserves of \$1,591.6 million was cancelled and \$1,977.9 million was recorded as a result of the difference between the value of shares issued upon emergence from bankruptcy and the values attributed to the net assets of the Group upon emergence under fresh-start accounting. Also included within this reserve is accumulated share-based compensation.

*Profit and Loss Account.* Pursuant to the Plan and Scheme of Arrangement, as of the Effective Date, the Predecessor's loss account of \$1,611.2 million was cancelled. The Group also 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 Group repurchased and cancelled all outstanding Opioid Warrants for \$4.0 million. For further information, refer to Note 2.

*Dividends.* Historically, the Group has not made any cash dividends payments, as the Group has retained earnings to finance acquisitions, R&D and the operation and expansion of its business, while executing disciplined capital allocation.

Other items affecting shareholders' funds, including *Preference Shares* and *Acquisition of Own Shares* are described in Note 8 to the Company's Notes to the Company Financial Statements.

## 29. Post-Balance Sheet Events

### *Taxation*

Through the date of this report, the Group received \$133.8 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. The remaining refund is expected to be received during fiscal 2023.

### *Interest Rate Cap*

On March 14, 2023, the Group entered into an interest rate cap agreement to manage its variable interest rate exposure with a total notional value of \$860.0 million and upfront premium of \$20.0 million. The interest rate cap agreement, designated as a cash flow hedge, provides the Group with interest rate protection (i) for the period March 16, 2023 through July 19, 2023 to the extent that one-month LIBOR exceeds 4.65%, and (ii) for the period July 20, 2023 through March 26, 2026 to the extent that one-month SOFR exceeds 3.84%.

### Commitments and Contingencies

Certain litigation matters occurred in fiscal 2022 or prior but had subsequent updates through the date of this report. See further discussion in Note 25.

### 30. Subsidiary Undertakings

The Group maintains subsidiary undertakings through ownership of the subsidiaries' ordinary shares. As of December 30, 2022, the Group had the following subsidiary undertakings:

Name	Nature of Business	Group Share %	Registered Office and Country of Incorporation
Acthar IP Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Cache Holdings Limited	Holding	100%	Victoria Hall, 5th Floor 31 Victoria Street Hamilton, HM EX Bermuda
Carnforth Limited	Other	100%	Victoria Hall, 5th Floor 31 Victoria Street Hamilton, HM EX Bermuda
Dritte CORSA Verwaltungsgesellschaft GmbH	Inactive	100%	Josef-Dietzgen-Strasse 1 53773 Hennef, Germany
Icaria Australia Pty Ltd	Operating	100%	Deacons L 15 485 Bourke Street Melbourne VIC 3000 Australia
Icaria Canada Inc.	Operating	100%	160 Elgin Street, Suite 2600 Ottawa, Ontario, K1P 13 Canada
IMC Exploration Company	Other	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Infacare Pharmaceutical Corporation	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
INO Therapeutics LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Ludlow LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
MAK LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt APAP LLC	Operating	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
Mallinckrodt ARD Finance LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt ARD Holdings Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt ARD Holdings Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt ARD IP Unlimited Company	Other	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt ARD LLC	Operating	100%	53 Frontage Road, STE 300 Hampton, NJ 08827 United States

Mallinckrodt Brand Pharmaceuticals LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Buckingham Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Canada Cooperatie U.A.	Holding	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Mallinckrodt Canada ULC	Operating	100%	400-6500 Trans-Canada Highway Pointe-Claire, Quebec H9R 0A5 Canada
Mallinckrodt CB LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Chemical Holdings (UK) Limited	Inactive	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Chemical Limited	Operating	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Critical Care Finance LLC	Finance and Administrative	100%	1209 Orange Street Wilmington, Delaware 19801 United States
Mallinckrodt Enterprises Holdings, Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Enterprises LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Enterprises UK Limited	Other	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Equinox Finance LLC	Other	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Equinox Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Finance Management Ireland Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Group S.a.r.l.	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt Holdings GmbH	Holding	100%	Solenbergstrasse 5 8207 Schaffhausen, Switzerland
Mallinckrodt Hospital Products Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Hospital Products IP Unlimited Company	Other	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt International Finance SA	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt International Holdings, S.a.r.l.	Holding	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt IP Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States

Mallinckrodt Lux IP S.a.r.l.	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt Manufacturing LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Medical Holdings (UK) Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Netherlands B.V.	Operating	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Mallinckrodt Petten Holdings B.V.	Other	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Mallinckrodt Pharma IP Trading Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Pharma K.K.	Operating	100%	ARK Mori Bldg., 30F 1-12-32 Akasaka, Minato-ku Tokyo, Japan
Mallinckrodt Pharmaceuticals Ireland Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Pharmaceuticals Limited	Operating	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Quincy S.a.r.l.	Holding	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt SAG Holdings GmbH	Inactive	100%	Solenbergstrasse 5 8207 Schaffhausen, Switzerland
Mallinckrodt Securitization S.a.r.l.	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt UK Finance LLP	Finance and Administrative	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt UK Ltd	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt US Holdings LLC	Other	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt US Pool LLC	Inactive	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Veterinary, Inc.	Other	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Windsor Ireland Finance Unlimited Company	Other	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Windsor S.a.r.l.	Holding	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
MCCH LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
MEH, Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
MHP Finance LLC	Finance and Administrative	100%	1209 Orange Street Wilmington, Delaware 19801 United States

MKG Medical UK Ltd	Inactive	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
MNK 2011 LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Montjeu Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
MUSHI UK Holdings Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
OCERA Therapeutics, Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Petten Holdings Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Profibrix B.V.	Inactive	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Questcor International Limited	Other	100%	Arthur Cox Building Earlsfort Terrace Dublin 2 Ireland
Sonorant Therapeutics Limited	Other	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
SpecGx Holdings LLC	Holding	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
SpecGx LLC	Operating	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
ST 2020 LLC	Other	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
ST Operations LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST Shared Services LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST US AR Finance LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST US Holdings LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST US Pool LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Stratatech Corporation	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo Finance Inc.	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo GmbH	Holding	100%	Baarerstrasse 75 6300 Zug Switzerland
Sucampo Holdings Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo International Holdings Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom

Sucampo Pharma Americas LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo Pharma, LLC	Operating	100%	NBF Building 10 F, Uschisaiwai-cho Chiyoda-ku, Tokyo 100-0011 Japan
Sucampo Pharmaceuticals LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Therakos (Belgium) SPRL	Operating	100%	Rue Royale 97 (4th Floor) B-1000 Brussels Belgium
Therakos (Canada) Company	Operating	100%	Suite 900, 1959 Upper Water Street P. O. Box 997 Halifax Nova Scotia B3J 3N2 Canada
Therakos (France) SAS	Operating	100%	105 Avenue Raymond Poincare 75116 Paris France
Therakos (Italia) S.r.l	Operating	100%	via Birmania 81 00144 Rome Italy
Therakos (UK), Ltd	Operating	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Therakos EMEA Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Therakos Europe Limited	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Therakos Germany GmbH	Operating	100%	Waltherr-Cronberg-Platz 12 60594 Frankfurt am Main Germany
Therakos, Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Vtesse LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
WebsterGx Holdco LLC	Holdings	100%	385 Marshall Ave. Webster Groves, MO 63119 United States

As of December 30, 2022, the Group had the following branches and representative offices outside of Ireland:

<b>Branch</b>	<b>Country</b>
Mallinckrodt Group S.a.r.l. Luxembourg (LU) Schaffhausen Branch	Switzerland
Mallinckrodt Medical Holdings (UK) Limited, Zweigniederlassung Deutschland German Branch	Germany
Therakos (UK), Limited Dutch Branch	Netherlands
Therakos (UK), Limited, Prywatna Spolka Z Ograniczona Odpowiedzialnoscia) Oddzial W Polsce	Poland
Therakos (UK), Ltd Sweden Filial	Sweden
Therakos (UK), Limited, Sucursal en Espana	Spain

# **MALLINCKRODT PLC**

## **Company Financial Statements**

**For the Fiscal Year Ended December 30, 2022**



# INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF MALLINCKRODT PLC

## Report on the audit of the financial statements

### Opinion on the financial statements of Mallinckrodt plc (the 'Company')

In our opinion the Company financial statements:

- give a true and fair view of the assets, liabilities and financial position of the Company as at 30 December 2022 and of the loss of the Company for the financial year ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Company Balance Sheet;
- the Company Statement of Changes in Equity; and
- the related notes 1 to 13, including a summary of significant accounting policies as set out in note 1.

The relevant financial reporting framework that has been applied in the preparation of the Company financial statements is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" issued by the Financial Reporting Council ("the relevant financial reporting framework").

### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "*Auditor's responsibilities for the audit of the financial statements*" section of our report.

We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Summary of our audit approach	
<b>Key audit matter</b>	There is one key audit matter ("KAM") that we identified in the current year, being the calculation and disclosure of the share premium arising on the issue of new shares during the year.
<b>Materiality</b>	The materiality that we used in the current year was \$8.1 million which was determined on the basis of 3% of net assets.
<b>Scoping</b>	We have determined the scope of our audit by obtaining an understanding of the Company and its environment, including assessing the risks of material misstatement at the Company level. The key audit matter identified in the prior year related to uncertainty related to the going concern basis of accounting. The Company has since emerged from bankruptcy proceedings and hence going concern is not deemed a key audit matter in the current year.

### Conclusions relating to going concern

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

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

- determining the net asset position of the Company as at 30 December 2022 and assessing the cash requirement of the Company for the foreseeable future based on management's forecasts;
- assessing the Company's ability to generate income from its financial holdings.

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

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

### Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial year and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team.

Other than the calculation and disclosure of the share premium arising on the issue of new shares during the year there were no other key audit matters identified or communicated with those charged with governance.

These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

<b>Calculation and disclosure of the share premium arising on the issue of new shares during the year</b>	
<b>Key audit matter description</b>	<p>On the Effective Date of emergence from bankruptcy, pursuant to the Plan and Scheme of Arrangement, as described in note 1, 13,170,932 ordinary shares were issued to holders of the former unsecured notes. On the Effective Date, the value of the unsecured notes was \$211,855,397.</p> <p>We identified the valuation of the share premium on the Effective Date as a key audit matter because of the significant judgment by management when developing the assumptions of the calculation and disclosures required in the financial statements. Significant assumptions included projected cash flows and discount rates. Our evaluation included assessing whether the assumptions used by management were reasonable and consistent with audit evidence obtained.</p>
<b>How the scope of our audit responded to the key audit matter</b>	<p>Our audit procedures related to share premium calculation and disclosure included the following, among others;</p> <ul style="list-style-type: none"> <li>• We assessed the basis on which management valued the share premium.</li> <li>• We reviewed the plan of reorganisation to determine the basis on which the fresh share capital is being issued.</li> <li>• We agreed the fair value amount to the underlying value of the debt forgiven.</li> <li>• We agreed the underlying values to documentation lodged with the Companies Registration Office. We evaluated the Company's disclosure for consistency with our knowledge of the status of the emergence from Chapter 11 and the reorganisation in the current year.</li> </ul>
<b>Key observations</b>	<p>We have no observations that impact our audit in respect of the calculation and disclosure of the share premium arising on the issue of new shares during the year.</p>

Our audit procedures relating to this matter were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.

### Our application of materiality

We define materiality as the magnitude of misstatement in the financial statements that makes it probable that the economic decisions of a reasonably knowledgeable person, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

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

<b>Parent Company financial statements</b>	
<b>Materiality</b>	\$8.1 million (2021: \$4.1 million)
<b>Basis for determining materiality</b>	3% of net assets  We have determined that it is appropriate to consider Shareholders Equity (Net Assets) as our benchmark in our determination of materiality for the Company. The balance sheet indicates net assets of \$269 million and as such the materiality for the Company financial statements is based on 3% of this metric.
<b>Rationale for the benchmark applied</b>	We have considered net assets to be the critical component for determining materiality because we determined net assets to be of most importance to the principal external users of the financial statements as this is the key balance in this legal entity and holding this investment is the purpose of the Company. In the prior year materiality was assessed as 2.57% of net liabilities.

We set performance materiality at a level lower than materiality to reduce the probability that, in aggregate, uncorrected and undetected misstatements exceed the materiality for the financial statements as a whole.

Performance materiality was set at 80% of materiality for the audit for the year ended 30 December 2022. In determining performance materiality, we considered the following factors:

- the reliability of the Company's internal control over financial reporting and whether we were able to rely on controls
- the degree of centralisation and common controls and processes, and
- any changes to the business that would impact on our ability to forecast potential misstatements.

We agreed with the Audit Committee that we would report to the Committee all audit differences in excess of \$405 thousand (2021: \$207 thousand) or 5.0% of materiality, as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.

### **An overview of the scope of our audit**

Our audit follows a risk-based approach taking into account the structure of the Company, our knowledge of the Company and industry in which the company operates and the accounting processes and controls in place.

### **Other information**

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

### **Responsibilities of directors**

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

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

### **Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on IAASA's website at: <https://iaasa.ie/publications/description-of-the-auditors-responsibilities-for-the-audit-of-the-financial-statements>. This description forms part of our auditor's report.

### **Extent to which the audit was considered capable of detecting irregularities, including fraud**

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

### **Identifying and assessing potential risks related to irregularities**

In identifying and assessing risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, we considered the following:

- the nature of the industry and sector, control environment and business performance including the design of the Company's remuneration policies, key drivers for directors' remuneration, bonus levels and performance targets;
- The Company's assessment of the risks that irregularities may occur either as a result of fraud or error that was discussed with the individual board members in January 2023.
- results of our enquiries of management, internal audit and the audit committee about their own identification and assessment of the risks of irregularities;
- any matters we identified having obtained and reviewed the Company's documentation of their policies and procedures relating to:
  - identifying, evaluating and complying with laws and regulations and whether they were aware of any instances of non-compliance
  - detecting and responding to the risks of fraud and whether they have knowledge of any actual, suspected or alleged fraud
  - the internal controls established to mitigate risks of fraud or non-compliance with laws and regulations
- the matters discussed among the audit engagement team including significant component audit teams and relevant internal specialists, including tax, valuations and IT regarding how and where fraud might occur in the financial statements and any potential indicators of fraud.

As a result of these procedures, we considered the opportunities and incentives that may exist within the organisation for fraud. In common with all audits under ISAs (Ireland), we are also required to perform specific procedures to respond to the risk of management override.

We also obtained an understanding of the legal and regulatory framework that the Company operates in, focusing on provisions of those laws and regulations that had a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the Irish Companies Act and tax legislation.

In addition, we considered provisions of other laws and regulations that do not have a direct effect on the financial statements but compliance with which may be fundamental to the Company's ability to operate or to avoid a material penalty. These include the United States Foreign Corrupt Practices Act.

### **Audit response to risks identified**

As a result of performing the above, we did not identify any key audit matters related to the potential risk of fraud or non-compliance with laws and regulations.

In addition to the above, our procedures to respond to risks identified included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with provisions of relevant laws and regulations described as having a direct effect on the financial statements;
- enquiring of management, the audit committee and in-house and external legal counsel; concerning actual and potential litigation and claims;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud;
- reading minutes of meetings of those charged with governance and reviewing internal audit reports; and
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

We also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members including internal specialists and component audit teams and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

### **Report on other legal and regulatory requirements**

#### **Opinion on other matters prescribed by the Companies Act 2014**

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the financial statements to be readily and properly audited.
- The Company Balance Sheet is in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

#### **Matters on which we are required to report by exception**

Based on the knowledge and understanding of the Company and its environment obtained in the course of the audit, we have not identified material misstatements in the directors' report.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

#### **Other Matters**

We have reported separately on the Consolidated Financial Statements of Mallinckrodt plc for the financial year ended 30 December 2022.

## **Use of our report**

This report is made solely to the Company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members as a body, for our audit work, for this report, or for the opinion we have formed.

/s/ Richard Howard

Richard Howard

For and on behalf of Deloitte Ireland LLP

Chartered Accountants and Statutory Audit Firm

Deloitte & Touche House, Earlsfort Terrace, Dublin 2

Date: 5 April, 2023

**MALLINCKRODT PLC**  
**COMPANY BALANCE SHEET**  
*(in millions)*

	Note	December 30, 2022	December 31, 2021
<b>Current Assets</b>			
Debtors	4	\$ 316.2	\$ 328.9
Cash at bank and in hand		2.1	12.7
		318.3	341.6
<b>Creditors (amounts falling due within one year)</b>			
Amounts owed to subsidiaries	5	46.3	10.9
Accruals and other creditors	5	2.6	2.8
		48.9	13.7
<b>Net Current Assets</b>		<b>269.4</b>	<b>327.9</b>
<b>Total Assets Less Current Liabilities</b>		<b>269.4</b>	<b>327.9</b>
Provision for liabilities		—	488.7
<b>Net Assets (Liabilities)</b>		<b>\$ 269.4</b>	<b>\$ (160.8)</b>
<b>Capital and Reserves</b>			
Called-up share capital presented as equity	8	\$ 0.1	\$ 18.9
Share premium account	8	211.7	5.7
Capital redemption reserve	8	—	5.3
Profit and loss account	8	57.6	(190.7)
Shareholders' Funds (Deficit)		<b>\$ 269.4</b>	<b>\$ (160.8)</b>

In accordance with Section 304(2) of the Irish Companies Act 2014, Mallinckrodt plc is availing itself of the exemption from presenting and filing its individual profit and loss account. Mallinckrodt plc's profit and loss as determined in accordance with FRS 102 was a profit of \$215.3 million and a loss of \$558.7 million for fiscal 2022 and 2021, respectively.

Approved by the Board of Directors on 5 April, 2023 and signed on its behalf by:

/s/ James Sulat

James Sulat

Director

/s/ Sigurdur Olafsson

Sigurdur Olafsson

Director

**MALLINCKRODT PLC**  
**COMPANY STATEMENT OF CHANGES IN EQUITY**  
*(in millions)*

	<u>Called-up Share Capital</u>							
	Number	Amount	Share Premium Account	Capital Redemption Reserve	Other Reserves	Profit and Loss Account	Total	
<b>Balance as of December 25, 2020</b>	94.1	\$ 18.8	\$ 5.7	\$ 5.3	\$ —	\$ 357.8	\$ 387.6	
Loss after taxation	—	—	—	—	—	(558.7)	(558.7)	
Vesting of restricted shares	0.2	0.1	—	—	—	—	0.1	
Share-based compensation	—	—	—	—	10.2	—	10.2	
Transfer to profit and loss account	—	—	—	—	(10.2)	10.2	—	
<b>Balance as of December 31, 2021</b>	94.3	18.9	5.7	5.3	—	(190.7)	(160.8)	
Profit after taxation	—	—	—	—	—	215.3	215.3	
Vesting of restricted shares	0.1	—	—	—	—	—	—	
Share-based compensation	—	—	—	—	3.1	—	3.1	
Transfer to profit and loss account	—	—	—	—	(3.1)	3.1	—	
Cancellation of common stock	(94.4)	(18.9)	(5.7)	(5.3)	—	29.9	—	
Issuance of common stock	13.2	0.1	211.7	—	—	—	211.8	
<b>Balance as of December 30, 2022</b>	13.2	\$ 0.1	\$ 211.7	\$ —	\$ —	\$ 57.6	\$ 269.4	



**MALLINCKRODT PLC**  
**NOTES TO COMPANY FINANCIAL STATEMENTS**  
*(dollars in millions, except share data and where indicated)*

**1. Basis of Presentation and Summary of Significant Accounting Policies**

***Basis of Preparation***

Mallinckrodt plc ("the Company") is a public limited company incorporated in the Republic of Ireland with the registration number 522227. The business address of its registered office and principal executive offices is College Business and Technology Park, Cruiseraith, Blanchardstown, Dublin 15, Ireland.

The principal activities of the Company and the Group have been set out on page 5 of the Directors' Report for fiscal year ended December 30, 2022.

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 of the Notes to the Consolidated Financial Statements for further information on the Plan and emergence from Chapter 11.

The fiscal year ended December 30, 2022 Mallinckrodt plc parent company financial statements have been prepared in accordance with FRS 102 *The Financial Reporting Standards applicable in the U.K. and Republic of Ireland* together with the Irish Companies Act 2014. The directors have elected to prepare the parent company financial statements in a manner different from the consolidated financial statements of Mallinckrodt plc as they are prepared specifically to comply with Irish legislative requirements and represent the results and financial position of the parent company.

***Going Concern***

The directors continue to adopt the going concern basis in preparing the financial statements. For further information, refer to Note 2 of the Notes to the Consolidated Financial Statements.

***Fiscal Year***

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2022 consisted of 52 weeks and fiscal 2021 consisted of 53 weeks. Unless otherwise indicated, fiscal 2022 and 2021 refer to the Company's fiscal years ended December 30, 2022 and December 31, 2021, respectively. All references to "fiscal" year are considered to be defined as "financial" year under Irish Companies Act 2014.

***Basis of Accounting***

The financial statements have been prepared under the historical cost convention and in accordance with FRS 102 issued by the Financial Reporting Council.

***Disclosure Exemptions for qualifying entities under FRS 102***

FRS 102 allows a qualifying entity certain disclosure exemptions. As a qualifying entity, the Company has availed of the exemption from the requirements of Section 7 of FRS 102 and FRS 102 paragraph 3.17(d) to present a statement of cash flows.

### ***Statement of Compliance***

The entity financial statements have been prepared on a going concern basis and comply with FRS 102 and the Irish Companies Act 2014.

### ***Significant Accounting Policies***

The significant accounting policies used in the preparation of the entity financial statements are set out below. These policies have been consistently applied to all financial periods presented.

### ***Functional Currency***

Items included in these financial statements are measured using the currency of the primary economic environment in which Mallinckrodt plc operates ("the functional currency"). The financial statements are presented in U.S. dollars ("USD"), which is the Company's functional and presentation currency.

### ***Currency Translation***

Transactions during the financial period denominated in foreign currencies have been translated at the rate of exchange ruling at the date of the transaction. Assets and liabilities denominated in foreign currencies are translated to USD at the rates of exchange ruling at the balance sheet date. The resulting profits or losses are dealt with in the profit and loss account.

### ***Investments in Subsidiary***

Mallinckrodt plc's investment in subsidiary is recorded at fair value of consideration given plus any directly attributable costs less impairment charges or recovery of the investment via dividend receipts. The investment is tested for impairment if circumstances or indicators suggest that impairment may exist.

### ***Debtors***

Debtor balances are carried at the original invoice or agreement amount, less any allowance for potentially uncollectable debts. A provision is recorded where there is evidence that the Company will not be in a position to collect the associated debt.

### ***Dividends***

Mallinckrodt plc currently does not anticipate paying any cash dividends for the foreseeable future, as it intends to retain any earnings to finance R&D, acquisitions and the operation and expansion of its subsidiaries' business, while executing disciplined capital allocation. The recommendation, declaration and payment of any dividends in the future by Mallinckrodt plc will be subject to the sole discretion of its Board of Directors and will depend upon many factors, including its financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of its debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by its Board of Directors. Moreover, if Mallinckrodt plc determines to pay any dividends in the future, there can be no assurance that it will continue to pay such dividends.

### ***Financial Instruments***

The Company has chosen to adopt Section 11 and 12 of FRS 102 with respect to financial instruments.

Financial assets and financial liabilities are recognized when the company becomes a party to the contractual provisions of the instrument.

Financial liabilities and equity instruments are classified according to the substance of the contractual arrangements entered into. An equity instrument is any contract that evidences a residual interest in the assets of the company after deducting all of its liabilities.

All financial assets and liabilities are initially measured at transaction price (including transaction costs), except for those financial assets classified at fair value through profit or loss, which are initially measured at fair value (which is normally the

transaction price excluding transaction costs), unless the arrangement constitutes a financing transaction. If an arrangement constitutes a financing transaction, the financial asset or financial liability is measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument.

Financial assets are derecognised when and only when a) the contractual rights to the cash flows from the financial asset expire or are settled, b) the company transfers to another party substantially all of the risks and rewards of ownership of the financial asset, or c) the company, despite having retained some, but not all, significant risks and rewards of ownership, has transferred control of the asset to another party.

Financial liabilities are derecognised only when the obligation specified in the contract is discharged, canceled or expires.

## 2. Critical accounting judgements and key sources of estimation uncertainty

In the application of the Company's accounting policies, which are described in Note 1, the directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods. The principal area of judgement relates to the assessment of the carrying value of investment in subsidiary. There were no material areas of estimation uncertainty in the Company financial statements.

## 3. Financial Assets

Mallinckrodt plc owns 100% of the share capital of Mallinckrodt International Finance S.A. ("MIFSA"), a company incorporated in the Grand Duchy of Luxembourg. MIFSA functions as a holding company, established to own, directly or indirectly, substantially all of the operating subsidiaries of the Group, as well as to issue debt securities and to perform treasury operations.

Mallinckrodt plc owns 100% of the share capital of ST 2020 LLC, a company incorporated in the State of Delaware, in the United States of America. No activity occurred in ST 2020 LLC, during fiscal 2021.

On March 11, 2022, the company sold the entire issued share capital of Mallinckrodt UK Limited to Mallinckrodt International Holdings S.à r.l for \$1. Mallinckrodt UK Limited is a company, incorporated in the United Kingdom.

As of December 30, 2022, the carrying amount of the Company's investments in subsidiary remained at zero.

## 4. Debtors

Debtors were comprised of the following at the end of each financial period:

	December 30, 2022	December 31, 2021
Due from subsidiary undertakings	\$ 309.5	\$ 314.9
Other debtors and prepayments	6.7	6.5
Amounts falling due within one year	316.2	321.4
Other debtors and prepayments	—	7.5
Amounts falling due after one year	—	7.5
Total debtors	<u>\$ 316.2</u>	<u>\$ 328.9</u>

Amounts due from subsidiary undertakings of \$261.6 million and \$302.9 million as of December 30, 2022 and December 31, 2021, respectively, relate to balances due from MIFSA as part of a cash management agreement. The balance is repayable on demand and is interest bearing.

Intercompany trade receivables of \$47.9 million and \$12.0 million as of December 30, 2022 and December 31, 2021, respectively, related to transactions in the normal course of business.

## 5. Creditors (amounts falling due within one year)

### Amounts Owed to Subsidiaries

Amounts due to subsidiary undertakings were comprised of \$46.3 million and \$10.9 million as of December 30, 2022 and December 31, 2021, respectively. Intercompany trade payables of \$46.3 million and \$10.9 million as of December 30, 2022 and December 31, 2021, respectively, relate to transactions in the normal course of business.

### Accruals and other creditors

Accruals and other creditors payable were \$2.6 million and \$2.8 million as of December 30, 2022 and December 31, 2021, respectively.

## 6. Guarantees and Contingencies

Mallinckrodt plc has entered into guarantee arrangements with various banks and third parties that provide Mallinckrodt Group companies with extensions of credit, including overdraft facilities, foreign exchange facilities and bank guarantee facilities. Under these arrangements, Mallinckrodt plc has unconditionally guaranteed all obligations of these Group companies to the banks and third parties, up to a maximum amount outstanding of approximately \$30.1 million as of December 30, 2022. The Company has assessed the fair value of these guarantees and determined them to be insignificant.

## 7. Financial Instruments

The carrying value of the Company's financial assets and liabilities are summarized by category below:

	Note	December 30, 2022	December 31, 2021
<b>Financial Assets</b>			
<i>Measured at undiscounted amount receivable</i>			
Amount due from subsidiary undertakings	4	\$ 316.2	\$ 314.9
<b>Financial liabilities</b>			
<i>Measured at undiscounted amount payable</i>			
Trade and other payables		\$ 2.6	\$ 2.8
Amount owed to subsidiary undertakings	5	46.3	10.9
		<u>\$ 48.9</u>	<u>\$ 13.7</u>

## 8. Shareholders' Funds

*Called-up Share Capital presented as equity.* Pursuant to the Plan and as ordered by the Scheme of Arrangement in respect to the Irish examinership proceedings, as of the Effective Date, all existing ordinary shares were cancelled and new ordinary shares were issued. On the Effective Date, the Company authorized 500,000,000 ordinary shares, par value of \$0.01 per share, and issued 13,170,932 ordinary shares par value of \$0.01 per share. The value of these issued shares was \$211.8 million which included a share premium of \$211.7 million. As of December 30, 2022, the Company has authorized 500,000,000 ordinary shares, par value of \$0.01 per share, 13,170,932 of which were issued. As of December 31, 2021, the Company had 500,000,000 authorized ordinary shares with a par value of \$0.20 per share, 94,296,235 of which were issued.

*Preference 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. 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. At the Effective Date, 500,000,000 Predecessor preferred shares with par \$0.20 were cancelled.

*Acquisition of Own Shares.* During fiscal 2022, Mallinckrodt plc acquired 30,225 shares at an average market price of \$0.11, which were accounted for as treasury shares within shareholders' funds and represent deemed acquisitions of shares issued in connection with the vesting of share-based awards to satisfy minimum statutory tax withholding obligations and are presented as "*Vesting of restricted shares*" in the statement of changes in equity.

Pursuant to the Plan and Scheme of Arrangement, all treasury shares were cancelled on the Effective date. The Company held zero treasury shares as of December 30, 2022.

Mallinckrodt plc held 9,569,645 treasury shares which had a nominal value of \$1.9 million as of December 31, 2021. Treasury shares represented 7.9% of Company capital as of December 31, 2021. As of December 31, 2021, the total cost of treasury shares acquired under both the share repurchase program and shares repurchased to cover statutory tax withholding obligations was \$1,616.1 million.

*Undistributable Reserves.* As of December 30, 2022, the share premium accounts amounted to \$211.7 million and is considered an undistributable reserve. Under Irish law, dividends and distributions cannot be made from undistributable reserves.

*Other Reserves.* The balance in other reserves is comprised of the contributed surplus on vested restricted stock and share-based compensation. The share-based compensation reflected in other reserves was \$3.1 million and \$10.2 million for fiscal 2022 and 2021, respectively. During fiscal 2022 and 2021, the Company transferred \$3.1 million and \$10.2 million from the other reserve to the profit and loss account reserve, respectively. Under Irish law, the Company can only pay dividends and repurchase shares out of distributable reserves. The Company did not declare or pay any dividends and the Company does not currently intend to pay dividends in the foreseeable future.

## 9. Directors' Remuneration and Key Management Personnel Compensation

Note 12 to the Group's Notes to Consolidated Financial Statements provides details of directors' remuneration. There were no other payments made to key management personnel from the Company during fiscal 2022 and 2021, respectively.

## 10. Auditor's Remuneration

Auditor's remuneration was as follows:

	Fiscal Year	
	2022	2021
Other assurance services	\$ 0.2	\$ 0.2
Other non-audit services	—	0.3
	<u>\$ 0.2</u>	<u>\$ 0.5</u>

Auditor's remuneration was \$0.2 million and less than \$0.1 million for the audit of individual accounts for fiscal 2022 and 2021, respectively. Other non-audit services include fees for professional services rendered in the preparation of an independent expert's report that was submitted to the High Court of Ireland in conjunction with Mallinckrodt plc's commencement of the examinership process. No amounts were incurred for tax advisory services. Note 13 to the Group's Notes to Consolidated Financial Statements provides additional details of fees paid by the Group.

## 11. Related Party Transactions

The Company is availing itself of the exemption provided under Schedule 3, paragraph 67 (3), Irish Companies Act 2014, which exempts disclosure of transactions entered into between two or more members of a group, provided that any subsidiary undertaking which is party to the transaction is wholly owned by a member of the group.

## 12. Subsidiary Undertakings

Mallinckrodt plc owns Mallinckrodt Inc. and MIFSA. Details of the subsidiaries are included in Note 30 to the Group's Notes to Consolidated Financial Statements.

## 13. Post-Balance Sheet Events

There have been no post balance sheet events which require the adjustment of or disclosure in the Company only financial statements.