UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 25, 2020
or

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

Commission File Number : 001-35803

Mallinckrodt plc

(Exact name of registrant as specified in its charter)

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

College Business & Technology Park, Cruiserath,
Blanchardstown, Dublin 15, Ireland
(Address of principal executive offices) (Zip Code)

Telephone: +353 1 696 0000
(Registrant's telephone number, including area code)

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

(Title of each class)	(Trading Symbol(s))	(Name of each exchange on which registered)
Ordinary shares, par value $0.20 per share	MNKKQ[(1)]	N/A[(1)]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large Accelerated Filer	☒	Accelerated Filer	☐	Emerging Growth Company	☐
Non-accelerated Filer	☐	Smaller Reporting Company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of October 30, 2020, the registrant had 84,604,862 ordinary shares outstanding at $0.20 par value.

(1) - On October 13, 2020, the New York Stock Exchange ("NYSE") filed a Form 25 with the U.S. Securities and Exchange Commission to delist the ordinary shares, $0.20 par value, of the registrant from the NYSE. The delisting became effective October 26, 2020. The deregistration of the ordinary shares under Section 12(b) of the Exchange Act will become effective 90 days, or such shorter period as the Securities and Exchange Commission may determine, after the filing date of the Form 25, at which point the ordinary shares will be deemed registered under Section 12(g) of the Exchange Act. The registrant's ordinary shares began trading on the OTC Pink Marketplace on October 13, 2020 under the symbol "MNKKQ."

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended		Nine Months Ended	
	September 25, 2020	**September 27, 2019**	**September 25, 2020**	**September 27, 2019**
Net sales (includes refined estimate of the retrospective one-time charge of $0.7 and $535.1 related to the Medicaid lawsuit for the three and nine months ended September 25, 2020, respectively)	$ 698.3	$ 743.7	$ 1,530.6	$ 2,357.6
Cost of sales	403.0	419.4	1,171.7	1,309.3
Gross profit	295.3	324.3	358.9	1,048.3
Selling, general and administrative expenses	220.8	205.7	683.2	661.8
Research and development expenses	65.5	103.1	225.8	268.0
Restructuring charges, net	3.2	7.2	15.8	11.2
Non-restructuring impairment charges	—	—	63.5	113.5
Gains on divestiture	(9.7)	—	(10.1)	—
Opioid-related litigation settlement (Note 11)	(25.8)	—	(34.1)	—
Medicaid lawsuit (Note 11)	(0.2)	—	105.1	—
Operating income (loss)	41.5	8.3	(690.3)	(6.2)
Interest expense	(62.2)	(77.6)	(200.9)	(231.8)
Interest income	0.9	2.9	5.4	6.6
Other income, net	—	37.9	1.1	128.6
Loss from continuing operations before income taxes	(19.8)	(28.5)	(884.7)	(102.8)
Income tax benefit	(211.6)	(27.6)	(69.2)	(256.6)
Income (loss) from continuing operations	191.8	(0.9)	(815.5)	153.8
(Loss) income from discontinued operations, net of income taxes	(0.2)	(0.2)	23.8	6.8
Net income (loss)	$ 191.6	$ (1.1)	$ (791.7)	$ 160.6
Basic earnings (loss) per share (Note 5):				
Income (loss) from continuing operations	$ 2.27	$ (0.01)	$ (9.66)	$ 1.84
(Loss) income from discontinued operations	—	—	0.28	0.08
Net income (loss)	$ 2.26	$ (0.01)	$ (9.38)	$ 1.92
Basic weighted-average shares outstanding	84.6	84.0	84.4	83.8
Diluted earnings (loss) per share (Note 5):				
Income (loss) from continuing operations	$ 2.27	$ (0.01)	$ (9.66)	$ 1.83
(Loss) income from discontinued operations	—	—	0.28	0.08
Net income (loss)	$ 2.26	$ (0.01)	$ (9.38)	$ 1.91
Diluted weighted-average shares outstanding	84.6	84.0	84.4	84.2

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS
(unaudited, in millions)

	Three Months Ended		Nine Months Ended	
	September 25, 2020	**September 27, 2019**	**September 25, 2020**	**September 27, 2019**
Net income (loss)	$ 191.6	$ (1.1)	$ (791.7)	$ 160.6
Other comprehensive income (loss), net of tax:				
Currency translation adjustments	1.0	(2.1)	0.7	1.6
Derivatives, net of tax	—	0.3	0.1	1.0
Benefit plans, net of tax	(0.6)	(0.2)	(1.3)	(0.9)
Total other comprehensive income (loss), net of tax	0.4	(2.0)	(0.5)	1.7
Comprehensive income (loss)	$ 192.0	$ (3.1)	$ (792.2)	$ 162.3

See Notes to Condensed Consolidated Financial Statements.

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

	September 25, 2020	December 27, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 844.2	$ 790.9
Accounts receivable, less allowance for doubtful accounts of $3.7 and $4.0	516.1	577.5
Inventories	343.3	312.1
Prepaid expenses and other current assets	360.9	150.2
Total current assets	2,064.5	1,830.7
Property, plant and equipment, net	851.4	896.5
Intangible assets, net	6,355.9	7,018.0
Other assets	433.1	593.7
Total Assets	$ 9,704.9	$ 10,338.9
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 5,241.3	$ 633.6
Accounts payable	79.1	139.8
Accrued payroll and payroll-related costs	73.1	105.2
Accrued interest	89.1	62.9
Medicaid lawsuit (Note 11)	640.2	—
Accrued and other current liabilities	381.0	485.4
Total current liabilities	6,503.8	1,426.9
Long-term debt	—	4,741.2
Opioid-related litigation settlement liability (Note 11)	1,609.3	1,643.4
Pension and postretirement benefits	61.4	62.4
Environmental liabilities	60.0	60.0
Other income tax liabilities	118.5	227.1
Other liabilities	186.2	237.2
Total Liabilities	8,539.2	8,398.2
Shareholders' Equity:		
Preferred shares, $0.20 par value, 500,000,000 authorized; none issued and outstanding	—	—
Ordinary A shares, €1.00 par value, 40,000 authorized; none issued and outstanding	—	—
Ordinary shares, $0.20 par value, 500,000,000 authorized; 94,104,519, and 93,459,206 issued; 84,598,497 and 84,105,786 outstanding	18.8	18.7
Ordinary shares held in treasury at cost, 9,506,022 and 9,353,420	(1,616.1)	(1,615.7)
Additional paid-in capital	5,580.0	5,562.5
Retained deficit	(2,808.6)	(2,016.9)
Accumulated other comprehensive loss	(8.4)	(7.9)
Total Shareholders' Equity	1,165.7	1,940.7
Total Liabilities and Shareholders' Equity	$ 9,704.9	$ 10,338.9

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in millions)

	Nine Months Ended	
	September 25, 2020	**September 27, 2019**
Cash Flows From Operating Activities:		
Net (loss) income	$ (791.7)	$ 160.6
Adjustments to reconcile net cash from operating activities:		
Depreciation and amortization	675.5	723.5
Share-based compensation	17.6	30.6
Deferred income taxes	304.0	(301.9)
Non-cash impairment charges	63.5	113.5
Gains on divestiture	(10.1)	—
Gain on repurchase of debt	—	(98.6)
Other non-cash items	(21.6)	(31.7)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	61.1	68.7
Inventories	(43.9)	(32.0)
Accounts payable	(52.4)	(27.8)
Income taxes	(431.2)	17.2
Medicaid lawsuit (Note 11)	640.2	—
Other	(116.3)	(88.0)
Net cash from operating activities	294.7	534.1
Cash Flows From Investing Activities:		
Capital expenditures	(42.4)	(108.7)
Proceeds from divestitures, net of cash	(0.7)	—
Other	6.7	13.7
Net cash from investing activities	(36.4)	(95.0)
Cash Flows From Financing Activities:		
Issuance of external debt	—	695.0
Repayment of external debt	(134.6)	(940.1)
Debt financing costs	(9.3)	—
Repurchase of shares	(0.4)	(2.5)
Other	(36.3)	(17.6)
Net cash from financing activities	(180.6)	(265.2)
Effect of currency rate changes on cash	0.2	0.5
Net change in cash, cash equivalents and restricted cash, including cash classified within assets held for sale	77.9	174.4
Less: Net change in cash classified within assets held for sale	—	(15.1)
Net change in cash, cash equivalents and restricted cash	77.9	159.3
Cash, cash equivalents and restricted cash at beginning of period	822.6	367.5
Cash, cash equivalents and restricted cash at end of period	$ 900.5	$ 526.8
Cash and cash equivalents at end of period	$ 844.2	$ 498.8
Restricted cash included in prepaid expenses and other assets at end of period	20.2	—
Restricted cash included in other long-term assets at end of period	36.1	28.0
Cash, cash equivalents and restricted cash at end of period	$ 900.5	$ 526.8

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(unaudited, in millions)

	Ordinary Shares		Treasury Shares					
	Number	Par Value	Number	Amount	Additional Paid-In Capital	Retained Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
Balance as of December 28, 2018	92.7	$ 18.5	9.4	$ (1,617.4)	$ 5,528.2	$ (1,017.7)	$ (24.3)	$ 2,887.3
Impact of accounting standard adoptions, net of tax	—	—	—	—	—	(0.5)	0.5	—
Net income	—	—	—	—	—	154.9	—	154.9
Other comprehensive income	—	—	—	—	—	—	1.3	1.3
Share options exercised	—	—	—	—	0.3	—	—	0.3
Vesting of restricted shares	0.2	0.1	—	(0.5)	—	—	—	(0.4)
Share-based compensation	—	—	—	—	10.0	—	—	10.0
Reissuance of treasury shares	—	—	—	0.9	—	(0.4)	—	0.5
Balance as of March 29, 2019	92.9	$ 18.6	9.4	$ (1,617.0)	$ 5,538.5	$ (863.7)	$ (22.5)	$ 3,053.9
Net income	—	—	—	—	—	6.8	—	6.8
Other comprehensive income	—	—	—	—	—	—	2.4	2.4
Share options exercised	—	—	—	—	0.2	—	—	0.2
Vesting of restricted shares	0.4	0.1	0.1	(2.0)	—	—	—	(1.9)
Share-based compensation	—	—	—	—	12.8	—	—	12.8
Reissuance of treasury shares	—	—	(0.1)	1.6	—	(0.6)	—	1.0
Balance as of June 28, 2019	93.3	$ 18.7	9.4	$ (1,617.4)	$ 5,551.5	$ (857.5)	$ (20.1)	$ 3,075.2
Net income	—	—	—	—	—	(1.1)	—	(1.1)
Other comprehensive income	—	—	—	—	—	—	(2.0)	(2.0)
Vesting of restricted shares	0.1	—	—	—	(0.1)	—	—	(0.1)
Share-based compensation	—	—	—	—	7.8	—	—	7.8
Reissuance of treasury shares	—	—	(0.1)	1.8	—	(1.2)	—	0.6
Balance as of September 27, 2019	93.4	$ 18.7	9.3	$ (1,615.6)	$ 5,559.2	$ (859.8)	$ (22.1)	$ 3,080.4
Balance as of December 27, 2019	93.5	$ 18.7	9.4	$ (1,615.7)	$ 5,562.5	$ (2,016.9)	$ (7.9)	$ 1,940.7
Net loss	—	—	—	—	—	(50.2)	—	(50.2)
Other comprehensive loss	—	—	—	—	—	—	(1.3)	(1.3)
Vesting of restricted shares	0.1	—	—	—	(0.1)	—	—	(0.1)
Share-based compensation	—	—	—	—	6.7	—	—	6.7
Balance as of March 27, 2020	93.6	$ 18.7	9.4	$ (1,615.7)	$ 5,569.1	$ (2,067.1)	$ (9.2)	$ 1,895.8
Net loss	—	—	—	—	—	(933.1)	—	(933.1)
Other comprehensive income	—	—	—	—	—	—	0.4	0.4
Vesting of restricted shares	0.5	0.1	0.1	(0.3)	—	—	—	(0.2)
Share-based compensation	—	—	—	—	6.6	—	—	6.6
Balance as of June 26, 2020	94.1	$ 18.8	9.5	$ (1,616.0)	$ 5,575.7	$ (3,000.2)	$ (8.8)	$ 969.5
Net income	—	—	—	—	—	191.6	—	191.6
Other comprehensive income	—	—	—	—	—	—	0.4	0.4
Vesting of restricted shares	—	—	—	(0.1)	—	—	—	(0.1)
Share-based compensation	—	—	—	—	4.3	—	—	4.3
Balance as of September 25, 2020	94.1	$ 18.8	9.5	$ (1,616.1)	$ 5,580.0	$ (2,808.6)	$ (8.4)	$ 1,165.7

See Notes to Condensed Consolidated Financial Statements.

1. Background and Basis of Presentation

Background

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

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

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

The Company owns or has rights to use the trademarks and trade names that are used in conjunction with the operation of its business. One of the more important trademarks that the Company owns or has rights to use that appears in this Quarterly Report on Form 10-Q 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, the Company only uses the ™ or ® symbols the first time any trademark or trade name is mentioned in the following notes. Such references are not intended to indicate in any way that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks and trade names. Each trademark or trade name of any other company appearing in the following notes is, to the Company's knowledge, owned by such other company.

Basis of Presentation

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

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

The fiscal year end balance sheet data was derived from audited consolidated financial statements, but do not include all of the annual disclosures required by GAAP; accordingly these unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited annual consolidated financial statements included in its Annual Report on Form 10-K for the fiscal year ended December 27, 2019 filed with the U.S. Securities and Exchange Commission ("SEC") on February 26, 2020.

Going Concern

The accompanying unaudited condensed consolidated financial statements are prepared in accordance with GAAP applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

On October 12, 2020, Mallinckrodt plc and certain of its subsidiaries voluntarily initiated proceedings (the "Chapter 11 Cases") under chapter 11 of title 11 ("Chapter 11") of the United States Code (the "Bankruptcy Code"), to modify its capital structure, including restructuring portions of its debt, and resolve potential legal liabilities, including but not limited to those described in Note 11 as *Opioid-Related Matters* and *Acthar Gel-Related Matters*. In connection with the filing of the Chapter 11 Cases, the Company entered into a Restructuring Support Agreement (as defined in Note 14) as part of a prearranged plan of reorganization. See Note 14 for further information on the voluntary petitions for reorganization and the Restructuring Support Agreement.

Substantial doubt about the Company's ability to continue as a going concern exists in light of its Chapter 11 Cases. The Company's ability to continue as a going concern is contingent upon, among other things, its ability to, subject to the approval by the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"), implement a plan of reorganization, emerge from the

Chapter 11 proceedings and generate sufficient liquidity following the reorganization to meet its obligations, most notably its opioid and Acthar Gel®-related claims and outstanding debt, and operating needs.

Although management believes that the reorganization of the Company through the Chapter 11 proceedings will appropriately position the Company upon emergence, the commencement of these proceedings constituted an event of default under certain of the Company's debt agreements, enforcement of any remedies in respect of which is automatically stayed as a result of the Chapter 11 proceedings. There are a number of risks and uncertainties associated with the Company's bankruptcy, including, among others that: (a) the Company's prearranged plan of reorganization may never be confirmed or become effective, (b) the Restructuring Support Agreement may be terminated by one or more of the parties thereto, (c) the Bankruptcy Court may grant or deny motions in a manner that is adverse to the Company and its subsidiaries, and (d) the Chapter 11 Cases may be converted into cases under chapter 7 of the Bankruptcy Code.

The transactions contemplated by the Restructuring Support Agreement are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated. As a result, the Company has concluded that management's plans at this stage do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The unaudited condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts and classification of liabilities that might result from the outcome of this uncertainty.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. Unless otherwise indicated, the three and nine months ended September 25, 2020 refers to the thirteen and twenty-six week periods ended September 25, 2020 and the three and nine months ended September 27, 2019 refers to the thirteen and twenty-six week periods ended September 27, 2019.

2. Revenue from Contracts with Customers

Product Sales Revenue

See Note 13 for presentation of the Company's net sales by product family.

Reserves for variable consideration

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

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
Balance as of December 28, 2018	$ 354.3	$ 34.0	$ 17.1	$ 405.4
Provisions	1,772.9	18.8	50.7	1,842.4
Payments or credits	(1,844.4)	(22.9)	(41.2)	(1,908.5)
Balance as of September 27, 2019	$ 282.8	$ 29.9	$ 26.6	$ 339.3
Balance as of December 27, 2019	$ 295.8	$ 28.4	$ 13.2	$ 337.4
Provisions	1,453.7	22.3	44.3	1,520.3
Provision for Medicaid lawsuit (Note 11) [1]	535.1	—	—	535.1
Payments or credits	(1,461.3)	(24.3)	(45.8)	(1,531.4)
Balance as of September 25, 2020 [1]	$ 823.3	$ 26.4	$ 11.7	$ 861.4

(1) Excludes the $105.1 million that is reflected as a component of operating expenses as it represents a pre-acquisition contingency related to the portion of the liability that arose from sales of Acthar Gel prior to the Company's acquisition of Questcor Pharmaceuticals Inc. ("Questcor") in August 2014. See Note 11 for further detail on the status of the Medicaid lawsuit.

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

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Product sales transferred at a point in time	79.5 %	81.4 %	78.5 %	81.7 %
Product sales transferred over time	20.5	18.6	21.5	18.3

Transaction price allocated to the remaining performance obligations

The following table includes estimated revenue from contracts extending greater than one year for certain of the Company's hospital products that are expected to be recognized in the future related to performance obligations that were unsatisfied or partially unsatisfied as of September 25, 2020:

Remainder of Fiscal 2020	$ 49.3
Fiscal 2021	106.0
Fiscal 2022	41.0
Fiscal 2023	9.9
Thereafter	0.3

Costs to fulfill a contract

As of September 25, 2020 and December 27, 2019, the total net book value of the devices used in the Company's portfolio of drug-device combination products, which are used in satisfying future performance obligations, were $26.8 million and $26.5 million, respectively, and were classified in property, plant and equipment, net, on the unaudited condensed consolidated balance sheets. The associated depreciation expense recognized during the nine months ended September 25, 2020 and September 27, 2019 was $4.0 million and $5.1 million, respectively.

Product Royalty Revenues

The Company licenses certain rights to Amitiza® (lubiprostone) ("Amitiza") to a third party in exchange for royalties on net sales of the product. The Company recognizes such royalty revenue as the related sales occur. The royalty rates consist of several tiers ranging from 18.0% to 26.0% with the royalty rate resetting every year. The associated royalty revenue recognized was as follows:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Royalty revenue	$ 20.4	$ 19.5	$ 52.3	$ 56.3

Contract Liabilities

The following table reflects the balance of the Company's contract liabilities at the end of each period:

	September 25, 2020	December 27, 2019
Accrued and other current liabilities	$ 3.0	$ 5.6
Other liabilities	0.4	0.6
Contract liabilities	$ 3.4	$ 6.2

Revenue recognized during the nine months ended September 25, 2020 and September 27, 2019 from amounts included in contract liabilities at the beginning of the period was $4.7 million and $10.3 million, respectively, inclusive of the Company's wholly owned subsidiary BioVectra Inc. ("BioVectra"), prior to the completion of the sale of this business in November 2019.

3. Restructuring and Related Charges

During fiscal 2018 and 2016, the Company launched restructuring programs designed to improve its cost structure. Charges of $100.0 million to $125.0 million were provided for under each program. Each program generally commenced upon substantial completion of the previous program. In addition to the aforementioned programs, the Company has taken restructuring actions to generate synergies from its acquisitions.

Net restructuring and related charges by segment were as follows:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Specialty Brands	$ —	$ —	$ 0.1	$ 0.4
Specialty Generics	—	6.7	0.1	9.3
Corporate	3.2	0.5	15.6	1.5
Restructuring charges, net	$ 3.2	$ 7.2	$ 15.8	$ 11.2

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

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
2018 Program	$ 3.2	$ 6.7	$ 17.8	$ 9.3
2016 Program	—	0.5	(0.1)	2.7
Acquisition Programs	—	—	(1.9)	(0.8)
Total charges expected to be settled in cash	$ 3.2	$ 7.2	$ 15.8	$ 11.2

The following table summarizes cash activity for restructuring reserves, substantially all of which related to contract termination costs, employee severance and benefits and exiting of certain facilities:

	2018 Program	2016 Program	Acquisition Programs	Total
Balance as of December 27, 2019	$ 2.7	$ 31.3	$ 0.2	$ 34.2
Charges	18.1	0.1	—	18.2
Changes in estimate	(0.3)	(0.2)	(1.9)	(2.4)
Cash payments	(19.3)	(30.7)	(0.2)	(50.2)
Currency translation and other	—	—	1.9	1.9
Balance as of September 25, 2020	$ 1.2	$ 0.5	$ —	$ 1.7

As of September 25, 2020, net restructuring and related charges incurred cumulative to date were as follows:

	2018 Program	2016 Program
Specialty Brands	$ 3.0	$ 68.1
Specialty Generics	10.1	14.6
Corporate	19.7	28.8
	$ 32.8	$ 111.5

All of the restructuring reserves were included in accrued and other current liabilities on the Company's unaudited condensed consolidated balance sheets. Amounts paid in the future may differ from the amount currently recorded.

4. Income Taxes

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security ("CARES") Act. The CARES Act was a response to the market volatility and instability resulting from the novel coronavirus ("COVID-19") pandemic. It includes provisions to support individuals and businesses in the form of loans, grants, and tax changes among other types of relief. Estimates of the effects of the changes to the U.S. tax code have been incorporated into the Company's nine months ended September 25, 2020 provision for income taxes, as applicable.

The CARES Act income tax provisions applicable to the Company include, but are not limited to (1) carrybacks of certain net operating losses ("NOL(s)") generated in tax years beginning after December 31, 2017 and before January 1, 2021 to the preceding five taxable years, (2) suspension of the 80.0% taxable income limitation for NOLs generated in tax years beginning after December 31, 2017 and before January 1, 2021, (3) increase in the limitation of the interest expense deduction under Internal Revenue Code ("IRC") §163(j) from 30.0% to 50.0% of adjusted taxable income for any taxable year beginning in 2019 or 2020, (4) expansion of the charitable contribution deduction limit to 25.0% of taxable income versus the previous 10.0% limitation for contributions made during

2020, and (5) acceleration of alternative minimum tax credits being refunded incrementally in tax years 2018, 2019, 2020 and 2021 to recover the entire remaining balance in either the 2018 or 2019 tax year.

As a result of the CARES Act, the Company is able to carryback a portion of its prior year and estimated current year U.S. Federal NOLs resulting in anticipated cash tax refunds of $201.0 million and $117.4 million, respectively. A tax benefit of $285.3 million has been recognized during the nine months ended September 25, 2020. The carryback of the U.S. Federal NOLs has an ancillary effect on the Company's unrecognized tax benefits, as disclosed below.

As further discussed in Note 1, the Company concluded that there is substantial doubt about its ability to continue as a going concern within one year from the date of issuance of the unaudited condensed consolidated financial statements. The Company considered this in determining that certain net deferred tax assets were no longer more likely than not realizable. As a result, an increase in valuation allowance of $341.6 million on the Company's net deferred tax assets was recorded for the three months ended June 26, 2020. Approximately $202.7 million of this increase was a valuation allowance placed on prior year deferred tax assets predominantly related to U.S. Federal NOLs and the Opioid-Related Litigation Settlement charge (as defined in Note 11). The remaining $138.9 million increase was placed on the Company's net deferred tax assets resulting from current year activity predominantly related to the Acthar Gel Medicaid Retrospective Rebate (as defined in Note 11) accrual. As a result, all of the Company's net deferred tax assets as of the nine months ended September 25, 2020 are fully offset by a valuation allowance.

The Company recognized an income tax benefit of $211.6 million on a loss from continuing operations before income taxes of $19.8 million for the three months ended September 25, 2020, and an income tax benefit of $27.6 million on a loss from continuing operations before income taxes of $28.5 million for the three months ended September 27, 2019. This resulted in effective tax rates of 1,068.7% and 96.8% for the three months ended September 25, 2020 and September 27, 2019, respectively. The income tax benefit for the three months ended September 25, 2020 was comprised of $201.4 million of current tax benefit and $10.2 million of deferred tax benefit. The current tax benefit was primarily the result of the CARES Act and unrecognized tax benefits, partially offset by the fiscal 2020 reorganization of the Company's intercompany financing and associated legal entity ownership. The deferred tax benefit was predominantly related to the fiscal 2020 reorganization of the Company's intercompany financing and associated legal entity ownership. The income tax benefit for the three months ended September 27, 2019 was comprised of $3.3 million of current tax expense and $30.9 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles and the generation of tax loss and credit carryforwards net of valuation allowances.

The Company recognized an income tax benefit of $69.2 million on a loss from continuing operations before income taxes of $884.7 million for the nine months ended September 25, 2020, and an income tax benefit of $256.6 million on a loss from continuing operations before income taxes of $102.8 million for the nine months ended September 27, 2019. This resulted in effective tax rates of 7.8% and 249.6% for the nine months ended September 25, 2020 and September 27, 2019, respectively. The income tax expense for the nine months ended September 25, 2020 was comprised of $370.3 million of current tax benefit and $301.1 million of deferred tax expense. The current tax benefit was primarily the result of the CARES Act and unrecognized tax benefits, partially offset by the fiscal 2020 reorganization of the Company's intercompany financing and associated legal entity ownership. The deferred tax expense was predominantly related to the valuation allowance noted above, recorded against the Company's net deferred tax assets, and unrecognized tax benefits, partially offset by a tax benefit predominantly related to the fiscal 2020 reorganization of the Company's intercompany financing and associated legal entity ownership. The income tax benefit for the nine months ended September 27, 2019 was comprised of $47.4 million of current tax expense and $304.0 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles, the generation of tax loss and credit carryforwards net of valuation allowances, the non-restructuring impairment charges, as well as the 2019 reorganization of the Company's intercompany financing and associated legal entity ownership, which eliminated the interest bearing deferred tax obligation.

The income tax benefit was $211.6 million for the three months ended September 25, 2020, compared with an income tax benefit of $27.6 million for the three months ended September 27, 2019. The $184.0 million net increase in the tax benefit included an increase of $235.7 million attributed to the CARES Act, and an increase of $1.2 million attributed to the fiscal 2019 gain on debt repurchased partially offset by a decrease of $32.0 million attributed to the fiscal 2020 reorganization of the Company's intercompany financing and associated legal entity ownership, a decrease of $12.3 million attributed to changes in the timing, amount and jurisdictional mix of income, a decrease of $6.5 million attributed to separation costs and a decrease of $2.1 million attributed to net restructuring.

The income tax benefit was $69.2 million for the nine months ended September 25, 2020, compared with an income tax benefit of $256.6 million for the nine months ended September 27, 2019. The $187.4 million net decrease in the tax benefit included a decrease of $229.1 million predominantly attributed to the fiscal 2019 reorganization of the Company's intercompany financing and associated legal entity ownership including related adjustments to elections on the fiscal 2019 U.S. tax return primarily as a result of changes to the NOL carryback provisions in the CARES Act, a decrease of $202.7 million attributed to a valuation allowance recorded against the Company's net deferred tax assets, a decrease of $30.0 million attributed to changes in the timing, amount and jurisdictional mix of income, a decrease of $9.9 million attributed to separation costs, a decrease of $8.5 million attributed to non-restructuring impairment charges, a decrease of $2.6 million attributed to net restructuring, partially offset by an increase of $285.3 million attributed to the CARES Act and an increase of $10.1 million attributed to the fiscal 2019 gain on debt repurchased.

During the nine months ended September 25, 2020, and fiscal 2019, the net cash payments for income taxes were $42.9 million and $30.7 million, respectively.

On July 15, 2020, the activities of the Company's principal executive offices were relocated from the United Kingdom ("U.K.") to Ireland, which resulted in a change in the Company's tax residence to Ireland. Mallinckrodt plc has always been and remains incorporated in Ireland. Relocation of Mallinckrodt plc's tax residence to Ireland allows the Company to mitigate the potential impacts of the U.K.'s departure from the European Union and align with the Company's commercial activity in Ireland. The Company continues to be subject to taxation in various tax jurisdictions worldwide. Accordingly, in fiscal 2020 the Company will report the Irish tax jurisdiction as the Company's domestic jurisdiction using an Irish statutory tax rate of 12.5% versus the U.K. statutory rate of 19.0%, and the International jurisdiction will represent areas outside the Irish tax jurisdiction. There is no material financial impact to this change.

In August 2020, a settlement was reached with the Internal Revenue Service ("IRS") related to the audit of Mallinckrodt Hospital Products Inc.'s ("MHP") (formerly known as Cadence Pharmaceuticals, Inc. ("Cadence")) tax year ended September 26, 2014. Cadence was acquired as a U.S. subsidiary on March 19, 2014. Following the acquisition of Cadence, the Company transferred certain rights and risks in Ofirmev intellectual property ("Transferred IP") to one of the Company's wholly owned non-U.S. subsidiaries. The transfer occurred at a price determined in conjunction with external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration the Company paid to the shareholders of Cadence. The IRS asserted the transfer price of the Transferred IP was understated. The settlement increased the transfer price of the Transferred IP, resulting in an increase to taxable income of $356.5 million and underpayment interest of $11.8 million. The increase to taxable income was satisfied through a noncash offset against the Company's U.S. Federal NOLs and interest expense for the tax year ended September 25, 2020, while the underpayment interest was satisfied through a cash payment of $11.8 million. The Company was adequately reserved for this; therefore there were no impacts to the unaudited condensed consolidated statement of operations for the three months ended September 25, 2020.

During the three months ended September 25, 2020, the Company commenced the fiscal 2020 reorganization of its intercompany financing and associated legal entity ownership to align its Specialty Brands and Specialty Generics businesses in preparation for the Chapter 11 bankruptcy filing, described in Note 14. As a result, for the three months ended September 25, 2020, the Company recognized current income tax expense of $44.2 million and a deferred income tax benefit of $12.2 million with a corresponding reduction to net deferred tax liabilities. In addition, a current tax benefit of $234.7 million was recognized due to the impact of the CARES Act on the fiscal 2020 reorganization, as described above. Finally, the fiscal 2020 reorganization substantially contributed to a deferred tax asset of $312.2 million for the portion of the Company's estimated fiscal 2020 U.S. Federal NOL that is not impacted by the CARES Act, which is fully offset with a valuation allowance.

The Company's unrecognized tax benefits, excluding interest, totaled $336.9 million and $398.6 million as of September 25, 2020 and December 27, 2019, respectively. The net decrease of $61.7 million primarily resulted from settlements of $80.3 million, a lapse of statute of limitations of $35.7 million, and a net decrease of prior period tax positions of $4.3 million, offset by an increase to current period tax positions of $58.6 million. If favorably settled, $77.0 million of unrecognized tax benefits as of September 25, 2020 would benefit the effective tax rate. The total amount of accrued interest and penalties related to these obligations was $15.7 million and $32.9 million as of September 25, 2020 and December 27, 2019, respectively. Due to a lapse of the statute of limitations noted above, $18.1 million of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business were eliminated, and a benefit of $17.3 million was recorded in discontinued operations within the unaudited condensed consolidated statement of operations for the nine months ended September 25, 2020.

It is reasonably possible that within the next twelve months the unrecognized tax benefits could decrease by up to $25.0 million and the amount of related interest and penalties could decrease by up to $6.0 million as a result of payments or releases due to the resolution of examinations, appeals and litigation and the expiration of various statutes of limitation.

5. Earnings (Loss) per Share

Basic earnings (loss) per share is computed by dividing net income (loss) by the number of weighted-average shares outstanding during the period. Diluted earnings (loss) per share is computed using the weighted-average shares outstanding and, if dilutive, potential ordinary shares outstanding during the period. Potential ordinary shares represent the incremental ordinary shares issuable for restricted share units and share option exercises. The Company calculated the dilutive effect of outstanding restricted share units and share options on earnings per share by application of the treasury stock method. Dilutive securities, including participating securities, are not included in the computation of loss per share when the Company reports a net loss from continuing operations as the impact would be anti-dilutive.

The weighted-average number of shares outstanding used in the computations of basic and diluted earnings (loss) per share were as follows (*in millions*):

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Basic	84.6	84.0	84.4	83.8
Dilutive impact of restricted share units and share options	—	—	—	0.4
Diluted	84.6	84.0	84.4	84.2

The computation of diluted weighted-average shares outstanding for both the three and nine months ended September 25, 2020 excluded approximately 5.8 million shares of equity awards, and for both the three and nine months ended September 27, 2019 excluded approximately 7.1 million shares of equity awards, respectively, because the effect would have been anti-dilutive.

6. Inventories

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

	September 25, 2020	December 27, 2019
Raw materials and supplies	$ 52.6	$ 62.7
Work in process	204.9	166.5
Finished goods	85.8	82.9
	$ 343.3	$ 312.1

7. Property, Plant and Equipment

The gross carrying amount and accumulated depreciation of property, plant and equipment were comprised of the following at the end of each period:

	September 25, 2020	December 27, 2019
Property, plant and equipment, gross	$ 1,901.2	$ 1,900.1
Less: accumulated depreciation	(1,049.8)	(1,003.6)
Property, plant and equipment, net	$ 851.4	$ 896.5

Depreciation expense was as follows:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Depreciation expense	$ 25.5	$ 24.5	$ 75.7	$ 73.7

8. Intangible Assets

The gross carrying amount and accumulated amortization of intangible assets were comprised of the following at the end of each period:

	September 25, 2020		December 27, 2019	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 10,394.6	$ 4,417.0	$ 10,456.9	$ 3,822.8
License agreements	120.1	77.1	120.1	74.1
Trademarks	77.7	22.7	77.7	20.1
Total	$ 10,592.4	$ 4,516.8	$ 10,654.7	$ 3,917.0
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	245.3		245.3	
Total	$ 280.3		$ 280.3	

Ofirmev®

During the three months ended June 26, 2020, due to decreased demand as a result of the deprioritization of non-critical medical treatment in the face of the COVID-19 pandemic, along with increased generic competition anticipated in the marketplace post the product's loss of exclusivity in December 2020, the Company identified a triggering event with respect to the Ofirmev intangible asset within the Specialty Brands segment and assessed the recoverability of the definite-lived asset. Additionally, the Company evaluated whether these events warranted a revision to the remaining period of amortization that previously extended to March 2022. As a result of this analysis, the Company revised the useful life to end December 25, 2020, commensurate with the final period of market exclusivity. After this change in estimate of the asset's useful life, the Company determined that the undiscounted cash flows related to the Ofirmev intangible asset were less than its net book value, which required the Company to record an impairment charge for the difference between the fair value of the Ofirmev intangible asset and its net book value.

The Company determined the fair value of the Ofirmev intangible asset using the income approach, a level three measurement technique. For purposes of determining fair value, the Company made various assumptions regarding estimated future cash flows, the discount rate and other factors in determining the fair value of the intangible asset. The Company's projections in relation to the Ofirmev intangible asset included long-term net sales and operating income at lower than historical levels. These changes in assumptions resulted in a fair value of the Ofirmev intangible asset that was less than its net book value. Therefore, the Company recorded an impairment charge of $63.5 million during the three months ended June 26, 2020. The remaining intangible asset value of $26.1 million as of September 25, 2020 will be amortized prospectively over the remaining useful life.

Terlipressin

During September 2020, the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") regarding the Company's New Drug Application ("NDA") seeking approval for the investigational agent terlipressin to treat adults with hepatorenal syndrome type 1 ("HRS-1"). The CRL stated that, based on the available data, the agency cannot approve the terlipressin NDA in its current form and requires more information to support a positive risk-benefit profile for terlipressin for patients with HRS-1.

In response to receipt of the CRL, on October 26, 2020, the Company had an End of Review Meeting with the FDA where both parties engaged in constructive dialogue in an effort to clarify a viable path to approval. As the Company continues to engage with the FDA over the coming months, it will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated in-process research and development asset of $81.0 million included within intangible assets, net on the unaudited condensed consolidated balance sheets as of September 25, 2020 and December 27, 2019.

The Company annually tests the indefinite-lived intangible assets for impairment, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable by either a qualitative or income approach. 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

Intangible asset amortization expense was as follows:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Amortization expense	$ 210.6	$ 210.4	$ 599.8	$ 649.8

The estimated aggregate amortization expense on intangible assets owned by the Company is expected to be as follows:

Remainder of Fiscal 2020	$ 171.4
Fiscal 2021	581.1
Fiscal 2022	581.1
Fiscal 2023	581.1
Fiscal 2024	581.1

9. Debt

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

	September 25, 2020		December 27, 2019	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
Current maturities of long-term debt [1]:				
4.875% senior notes due April 2020	$ —	$ —	$ 614.8	$ 0.6
9.50% debentures due May 2022	10.4	—	—	—
5.75% senior notes due August 2022	610.3	2.5	—	—
8.00% debentures due March 2023	4.4	—	—	—
4.75% senior notes due April 2023	133.7	0.6	—	—
5.625% senior notes due October 2023	514.7	3.6	—	—
Term loan due September 2024	1,509.1	13.1	15.6	0.2
Term loan due February 2025	400.5	5.3	4.1	0.1
5.50% senior notes due April 2025	387.2	3.1	—	—
10.00% first lien senior notes due April 2025	495.0	8.2	—	—
10.00% second lien senior notes due April 2025	322.9	8.5	—	—
Revolving credit facility	900.0	2.0	—	—
Total current debt	5,288.2	46.9	634.5	0.9
Long-term debt:				
9.50% debentures due May 2022	—	—	10.4	—
5.75% senior notes due August 2022	—	—	610.3	3.7
8.00% debentures due March 2023	—	—	4.4	—
4.75% senior notes due April 2023	—	—	133.7	0.8
5.625% senior notes due October 2023	—	—	514.7	4.4
Term loan due September 2024	—	—	1,505.2	15.5
Term loan due February 2025	—	—	399.5	6.1
5.50% senior notes due April 2025	—	—	387.2	3.6
10.00% first lien senior notes due April 2025	—	—	—	—
10.00% second lien senior notes due April 2025	—	—	322.9	9.9
Revolving credit facility	—	—	900.0	3.1
Total long-term debt	—	—	4,788.3	47.1
Total debt	$ 5,288.2	$ 46.9	$ 5,422.8	$ 48.0

(1) As of September 25, 2020, the Company was in full compliance with the provisions and covenants associated with its debt agreements. The commencement of the Chapter 11 Cases on October 12, 2020 constituted an event of default under certain of the Company's debt agreements. Accordingly, all long-term debt was classified as current on the unaudited condensed consolidated balance sheet as of September 25, 2020. However, any efforts to enforce payment obligations under the debt instruments are automatically stayed as a result of the Chapter 11 Cases. See Note 14 for further information. The Company's debt instruments are further described within the notes to the financial statements included within the Company's Annual Report filed on Form 10-K for the fiscal year ended December 27, 2019.

As of September 25, 2020, the applicable interest rate and outstanding borrowings on the Company's variable-rate debt instruments were as follows:

	Applicable interest rate	Outstanding borrowings
Term loan due September 2024	3.50 %	$ 1,509.1
Term loan due February 2025	3.75	400.5
Revolving credit facility	2.52	900.0

As of September 25, 2020, the Company was fully drawn on its $900.0 million revolving credit facility.

On April 7, 2020, the Company, Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC ("the Issuers") entered into an exchange agreement (the "Exchange Agreement") with certain third parties (collectively, the "Exchanging Holders"). Pursuant to the Exchange Agreement, the Exchanging Holders agreed to exchange with the Issuers, on April 7, 2020, their holdings of 4.875% senior unsecured notes that had a maturity date of April 15, 2020 ("2020 Notes") issued by the Issuers (the "Existing Notes")

(consisting of approximately $495.0 million aggregate principal amount of the Existing Notes) for new 10.00% First Lien Senior Secured Notes due 2025 issued by the Issuers (the "First Lien 2025 Notes"), at a rate of $1,000 of First Lien 2025 Notes for every $1,000 of Existing Notes exchanged (such exchange, the "Exchange"). The Issuers and Exchanging Holders consummated the Exchange on April 7, 2020.

Interest on the First Lien 2025 Notes is payable semi-annually in cash on April 15th and October 15th of each year, commencing on October 15, 2020.

The Issuers may redeem some or all of the First Lien 2025 Notes prior to April 15, 2022 by paying a "make-whole" premium. The Issuers may redeem some or all of the First Lien 2025 Notes on or after April 15, 2022 at specified redemption prices. In addition, prior to April 15, 2022, the Issuers may redeem up to 40% of the aggregate principal amount of the First Lien 2025 Notes with the net proceeds of certain equity offerings. The Issuers may also redeem all, but not less than all, of the First Lien 2025 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 First Lien 2025 Notes.

The Issuers are obligated to offer to repurchase (a) all of the First Lien 2025 Notes 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) First Lien 2025 Notes using asset sale proceeds at a price of 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain asset sales. These obligations are subject to certain qualifications and exceptions.

The First Lien 2025 Notes are subject to an indenture that 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 indenture could result in the acceleration of the First Lien 2025 Notes and could cause a cross-default that could result in the acceleration of other indebtedness of the Company and its subsidiaries.

The First Lien 2025 Notes are jointly and severally guaranteed, subject to certain exceptions, on a secured, unsubordinated basis by the Company and each of its subsidiaries (other than the Issuers) (the "Note Guarantors") that guarantees the obligations under the Issuers' existing senior secured credit facilities.

The First Lien 2025 Notes and the guarantees thereof are secured by liens on the same assets of the Issuers and the Note Guarantors that are subject to liens securing the existing senior secured credit facilities, subject to certain exceptions.

On April 15, 2020, the Company paid in full the remaining approximately $119.8 million in principal amount of outstanding 2020 Notes at the maturity thereof with cash on hand.

10. Guarantees

In disposing of assets or businesses, the Company has from time to time provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. The Company assesses the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company believes, given the information currently available, that the ultimate resolutions will not have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemical business (formerly known as Mallinckrodt Baker) in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on the Company's unaudited condensed consolidated balance sheets as of September 25, 2020 and December 27, 2019 was $15.5 million and $15.0 million, respectively, of which $12.8 million and $12.3 million, respectively, related to environmental, health and safety matters. The value of the environmental, health and safety indemnity was measured based on the probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value as of September 25, 2020 and December 27, 2019. As of September 25, 2020, the maximum future payments the Company could be required to make under these indemnification obligations were $70.2 million. The Company was required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $19.0 million and $18.9 million remained in restricted cash, included in other long-term assets on the unaudited condensed consolidated balance sheets as of September 25, 2020 and December 27, 2019, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 11.

The Company is also liable for product performance; however, the Company believes, given the information currently available, that the ultimate resolution of any such claims will not have a material adverse effect on its financial condition, results of operations and cash flows.

As of September 25, 2020, the Company had various other letters of credit, guarantees and surety bonds totaling $31.2 million and restricted cash of $37.3 million held in segregated accounts primarily to collateralize surety bonds for the Company's environmental liabilities.

11. Commitments and Contingencies

The Company is subject to various legal proceedings and claims, including patent infringement claims, product liability matters, personal injury, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described below. Although it is not feasible to predict the outcome of these matters, the Company believes, unless otherwise indicated below, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Subsequent to September 25, 2020, the Company announced that Mallinckrodt plc and certain of its subsidiaries voluntarily initiated the Chapter 11 Cases under the Bankruptcy Code in the Bankruptcy Court. As a result of initiating the Chapter 11 Cases, all litigations and proceedings against the Company have been automatically stayed, subject to certain limited exceptions. In addition, the Company has requested an order from the Bankruptcy Court enjoining all litigations against the Company and various individuals named in certain of the litigations described below that might otherwise be subject to such an exception. For further information about the Chapter 11 cases, refer to Note 14.

Governmental Proceedings

Opioid-Related Matters

Since 2017, multiple U.S. states, counties, a territory, other governmental persons or entities and private plaintiffs have filed lawsuits against certain entities of the Company, as well as various other manufacturers, distributors, pharmacies, pharmacy benefit managers, individual doctors and/or others, asserting claims relating to defendants' alleged sales, marketing, distribution, reimbursement, prescribing, dispensing and/or other practices with respect to prescription opioid medications, including certain of the Company's products. As of November 3, 2020, the cases the Company is aware of include, but are not limited to, approximately 2,618 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 270 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 128 cases filed by individuals; approximately six cases filed by schools and school boards; and 17 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Nevada, South Dakota, New Hampshire, Louisiana, Illinois, Mississippi, West Virginia, Puerto Rico, Ohio, and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of November 3, 2020, the Mallinckrodt defendants in these cases consist of Mallinckrodt plc and the following subsidiaries of Mallinckrodt plc: Mallinckrodt Enterprises LLC, Mallinckrodt LLC, SpecGx LLC, Mallinckrodt Brand Pharmaceuticals Inc., Mallinckrodt Inc., MNK 2011 Inc., and Mallinckrodt Enterprises Holdings, Inc. On November 22, 2019, the Delaware Attorney General filed a motion in the Superior Court of the State of Delaware to amend its complaint to add certain entities of the Company, which the court granted on December 18, 2019. The Delaware Attorney General has not yet filed its amended complaint. The Hawaii Attorney General filed a complaint against the Company on June 3, 2019. On December 27, 2019, the First Circuit Court entered a written order dismissing the Hawaii Attorney General's claims against all defendants without prejudice, finding that the allegations in the State's complaint failed to give notice of the claims against the defendants. Certain of the lawsuits have been filed as putative class actions. On October 8, 2020, the State of Rhode Island filed a lawsuit against the Company's President and Chief Executive Officer, Mark C. Trudeau, asserting similar claims relating to the marketing and distribution of prescription opioid medications.

Most pending federal lawsuits have been coordinated in a federal multi-district litigation ("MDL") pending in the U.S. District Court for the Northern District of Ohio. The MDL court has issued a series of case management orders permitting motion practice addressing threshold legal issues in certain cases, allowing discovery, setting pre-trial deadlines and setting a trial date on October 21, 2019 for two cases originally filed in the Northern District of Ohio by Summit County and Cuyahoga County against opioid manufacturers, distributors, and pharmacies ("Track 1 Cases"). The counties claimed that opioid manufacturers' marketing activities changed the medical standard of care for treating both chronic and acute pain, which led to increases in the sales of their prescription opioid products. They also alleged that opioid manufacturers' and distributors' failure to maintain effective controls against diversion was a substantial cause of the opioid crisis. On September 30, 2019, the Company announced that Mallinckrodt plc, along with its wholly owned subsidiaries Mallinckrodt LLC and SpecGx LLC, had executed a definitive settlement agreement and release with Cuyahoga and Summit Counties in Ohio. The settlement fully resolves the Track 1 cases against all named Mallinckrodt entities that were scheduled to go to trial in October 2019 in the MDL. Under the agreement, the Company paid $24.0 million in cash on October

1, 2019. In addition, the Company will provide $6.0 million in generic products, including addiction treatment products, and will also provide a $0.5 million payment in two years in recognition of the counties' time and expenses. Further, in the event of a comprehensive resolution of government-related opioid claims, the Company has agreed that the two plaintiff counties will receive the value they would have received under such a resolution, less the payments described above. All named Mallinckrodt entities were dismissed with prejudice from the lawsuit. The value of the settlement should not be extrapolated to any other opioid-related cases or claims. On October 21, 2019, the MDL court issued a Stipulated Dismissal Order dismissing the claims against the remaining manufacturers and distributors pursuant to a settlement agreement, and severing the claims against the remaining pharmacy defendants to be heard in a subsequent trial, currently scheduled for November 9, 2020. Judge Polster issued Suggestions of Remand for City and County of San Francisco, California and City of Chicago, Illinois. Both cases have been remanded, respectively, to the Northern District of California and the Northern District of Illinois. Manufacturer defendants moved to dismiss the City of San Francisco action on April 20, 2020, which the Company joined. The motion was granted in part and denied in part on September 30, 2020. On October 23, 2020, the MDL court set a trial for October 25, 2021. Additionally, all manufacturer defendants, including us, were severed from the "Track Two" MDL cases, City of Huntington and Cabell County Commission, West Virginia. Those cases have subsequently been remanded to the Southern District of West Virginia.

Other lawsuits remain pending in various state courts. In some jurisdictions, such as Arizona, California, Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas, Utah and West Virginia, certain of the 247 state lawsuits have been consolidated or coordinated for pre-trial proceedings before a single court within their respective state court systems. State cases are generally at the pleading and/or discovery stage. Trials have been set in certain state cases, including in Arizona (June 1, 2021), Florida (April 4, 2022), Georgia (May 26, 2022), Maryland (December 7, 2021), Missouri (June 2022), 2021), Nevada (April 18, 2022), New Mexico (September 6, 2022), Rhode Island (January 19, 2021), and West Virginia (November 1, 2021). In Texas, the first of two bellwether trials is set to be ready for jury trial on September 27, 2021. The Company is not named as a defendant in the primary bellwether for that first trial, but is named as a defendant in the alternate bellwether for the first trial. The date and candidates for the second bellwether trial have not yet been selected. On March 26, 2020, the Supreme Court of Tennessee granted defendants' application for permission to appeal the judgment of the Tennessee Court of Appeals *in Effler et al. v. Purdue Pharma*, LP et al., No. 16596, which reversed the Circuit Court for Campbell County's grant of defendants' motion to dismiss plaintiffs' claims under Tennessee's Drug Dealer Liability Act (DDLA). Oral argument in the *Effler* appeal was held on September 2, 2020. A successful ruling from the Tennessee Supreme Court in *Effler* would also require dismissal of the DDLA claim brought by the district attorney general plaintiffs in *Staubus et al. v. Purdue Pharma, LP et al.*, No. C-41916. The *Staubus* trial has been continued in the Circuit Court for Sullivan County. There is no trial date set at this time.

The lawsuits assert a variety of claims, including, but not limited to, public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") or similar state laws, violations of state Controlled Substances Acts or state False Claims Acts ("FCA"), product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment, negligence and negligent misrepresentation, and other common law and statutory claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent diversion.

Opioid-Related Litigation Settlement. On February 25, 2020, the Company announced that it had reached an agreement in principle with a court-appointed plaintiffs' executive committee representing the interest of thousands of plaintiffs in the MDL and supported by a broad-based group of 48 state and U.S. Territory Attorneys General on the terms of a global settlement that would resolve all opioid-related claims against the Company and its subsidiaries (the "Opioid-Related Litigation Settlement"). The Opioid-Related Litigation Settlement contemplated the filing of voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code ("Chapter 11") by certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the "Specialty Generics Subsidiaries") and the establishment of a trust for the benefit of plaintiffs holding opioid-related claims against the Company (the "Opioid Claimant Trust"). Subject to the Settlement Closing (as defined below), the Opioid-Related Litigation Settlement also provided that the Company would make certain structured payments to the Opioid Claimant Trust. It was contemplated that, pursuant to the terms of a channeling injunction and third-party release, which would be subject to court approval, all persons or entities asserting opioid-related claims against the Company would recover solely from the Opioid Claimant Trust on account of such claims. The Opioid-Related Litigation Settlement provided for:

- the payment of $300.0 million upon Specialty Generics' emergence from the completed Chapter 11 case;
- the payment to the Opioid Claimant Trust of additional cash totaling $1,300.0 million, consisting of $200.0 million on each of the first and second anniversaries of emergence and $150.0 million on each of the third through eighth anniversaries of emergence; and
- the issuance of warrants ("Settlement Warrants") upon emergence from the contemplated Chapter 11 process to the Opioid Claimant Trust to purchase ordinary shares of the Company with an eight year term at a strike price of $3.15 per ordinary share that would represent approximately 19.99% of the Company's fully diluted outstanding shares, including

after giving effect to the exercise of the warrants, provided that such warrants could not be exercised during any calendar quarter in a quantity that would exceed 5.0% of the number of shares outstanding.

The Opioid-Related Litigation Settlement included a number of conditions to its consummation (such consummation, the "Settlement Closing") such as, among other things, bankruptcy court approval of the bankruptcy plan effectuating the Opioid-Related Litigation Settlement, the emergence of the Specialty Generics Subsidiaries from bankruptcy and other conditions.

In connection with New York State's support of the Opioid-Related Litigation Settlement, on March 9, 2020, the State of New York and Suffolk County, together with Mallinckrodt LLC and SpecGx LLC, jointly filed a motion to sever, or remove, Mallinckrodt LLC and SpecGx LLC from the New York State opioid trial, which, as of March 10, 2020, was postponed due to COVID-19. Nassau County opposed the motion. On May 12, 2020, the Court denied the motion to sever without prejudice to renewal after a new trial date has been set. On October 28, 2020, the presiding judge said the trial may begin in January 2021.

As a result of the Opioid-Related Litigation Settlement, the Company recorded an accrual for this contingency of $1,600.0 million related to the structured cash payments and $43.4 million related to the Settlement Warrants in the consolidated balance sheet as of December 27, 2019. As of September 25, 2020, the Settlement Warrants were valued at $9.3 million. Refer to Note 12 for further information regarding the valuation of the Settlement Warrants.

In conjunction with the Company's Chapter 11 filing on October 12, 2020, the Company entered into a Restructuring Support Agreement (as defined in Note 14) which includes a proposed resolution of all opioid-related claims against the Company and its subsidiaries that supersedes the Opioid-Related Litigation Settlement. For further information on the terms of this proposed resolution, refer to Note 14.

Other Opioid-Related Matters. In addition to the lawsuits described above, certain entities of the Company have received subpoenas and civil investigative demands ("CID(s)") for information concerning the sale, marketing and/or distribution of prescription opioid medications and the Company's suspicious order monitoring programs, including from the U.S. DOJ and the Attorneys General for Missouri, New Hampshire, Kentucky, Washington, Alaska, South Carolina, Puerto Rico, New York, West Virginia, Indiana, the Divisions of Consumer Protection and Occupational and Professional Licensing of the Utah Department of Commerce, and the New York State Department of Financial Services. The Company has been contacted by the coalition of State Attorneys General investigating the role manufacturers and distributors may have had in contributing to the increased use of opioids in the U.S. On January 27, 2018, the Company received a grand jury subpoena from the U.S. Attorneys' Office ("USAO") for the Southern District of Florida for documents related to the distribution, marketing and sale of generic oxymorphone products. On April 17, 2019, the Company received a grand jury subpoena from the USAO for the Eastern District of New York ("EDNY") for documents related to the sales and marketing of controlled substances, the policies and procedures regarding controlled substances, and other related documents. On June 4, 2019, the Company received a rider from the USAO for EDNY requesting additional documents regarding the Company's anti-diversion program. The Company is responding or has responded to these subpoenas, CIDs and any informal requests for documents.

In August 2018, the Company received a letter from the leaders of the Energy and Commerce Committee in the U.S. House of Representatives requesting a range of documents relating to its marketing and distribution of opioids. The Company completed its response to this letter in December 2018. The Company received a follow-up letter in January 2020 and provided the committee a response. The Company is cooperating with the investigation.

The Attorneys General for Kentucky, Alaska, New York, New Hampshire, West Virginia and Puerto Rico have subsequently filed lawsuits against the Company. Similar subpoenas and investigations may be brought by others or the foregoing matters may be expanded or result in litigation. The Company intends to vigorously defend itself in these matters. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with these investigations and/or lawsuits.

On April 21, 2020, New York Governor Andrew Cuomo announced that the New York State Department of Financial Services had filed a Statement of Charges against Mallinckrodt, including allegations that it misrepresented the safety and efficacy of its branded and unbranded opioid products and downplayed the risks of negative outcomes to patients, resulting in claims for payment of medically unnecessary opioid prescriptions to commercial insurance companies. The Statement of Charges claims that Mallinckrodt violated Section 403 of the New York Insurance Law, which prohibits fraudulent insurance acts and includes penalties of up to $5,000 plus the amount of the fraudulent claim for each violation. It further alleges that Mallinckrodt violated Section 408 of the Financial Services Law, which prohibits intentional fraud or intentional misrepresentation of a material fact with respect to a financial product or service and includes penalties of up to $5,000 per violation. The Department claims that each fraudulent prescription constitutes a separate violation of these laws. A hearing on the Statement of Charges was scheduled for January 25, 2021, but the Department of Financial Services agreed to a voluntary stay on October 15, 2020. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

On June 1, 2020, a putative class action lawsuit was filed against Mallinckrodt plc, Mallinckrodt Canada ULC, the Canadian Ministry of Health ("Province") and the College of Pharmacists of British Columbia ("College") in the Supreme Court of British Columbia, captioned Laura Shaver v. Mallinckrodt Canada ULC, et al., No. VLC-S-S-205793. The action purports to be brought on

behalf of any persons (1) prescribed Methadose for opioid agonist treatment in British Columbia after March 1, 2014, (2) covered by Pharmacare Plan C within British Columbia who were prescribed Methadose for opioid agonist treatment after February 1, 2014, (3) who transitioned from compounded methadone to Methadose for opioid agonist treatment in British Columbia after March 1, 2014, or (4) covered by Pharmacare Plan C within British Columbia who were transitioned from compounded methadone to Methadose for opioid agonist treatment after February 1, 2014. The suit generally alleges that the Province's decision to grant Methadose coverage under Pharmacare Plan C and remove compounded methadone from coverage under Pharmacare Plan C had adversely affected those being treated for opioid use disorder. The suit asserts that the Province, the College and the Mallinckrodt defendants failed to warn patients about, and made false representations concerning, the efficacy of Methadose and the risks of switching from compounded methadone to Methadose. The suit seeks general, special, aggravated, punitive and exemplary damages in an unspecified amount, costs and interest and injunctive relief against the Province, the College and the Mallinckrodt defendants. Pursuant to two orders granted by the Ontario Superior Court of Justice (Commercial List) on October 15, 2020, the Chapter 11 proceedings commenced by Mallinckrodt plc and Mallinckrodt Canada ULC pursuant to the U.S. Bankruptcy Code were recognized and given effect in Canada. Among other things, the Canadian Court has stayed all proceedings against the Mallinckrodt defendants, including the British Columbia class action proceedings. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

New York State Opioid Stewardship Act. On October 24, 2018, the Company filed suit in the U.S. District Court for the Southern District of New York against the State of New York, asking the court to declare New York State's Opioid Stewardship Act ("OSA") unconstitutional and to enjoin its enforcement. On December 19, 2018, the court declared the OSA unconstitutional and granted the Company's motion for preliminary injunctive relief. On January 17, 2019, the State of New York appealed the court's decision. 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 the Company's (and other parties') challenges to the OSA for lack of subject matter jurisdiction. The Company disagrees with the decision and continues to evaluate its options with respect to the decision. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that if the OSA decision is reversed on appeal, the OSA would apply only to the sale or distribution of certain opioids in New York for 2017 and 2018 and, effective July 1, 2019, imposed an excise tax on certain opioids.

DEA Investigation. In November 2011 and October 2012, the Company received subpoenas from the U.S. Drug Enforcement Administration ("DEA") requesting production of documents relating to its suspicious order monitoring program for controlled substances. The USAO for the Eastern District of Michigan investigated the possibility that the Company failed to report suspicious orders of controlled substances during the period 2006-2011 in violation of the Controlled Substances Act and its related regulations. The USAO for the Northern District of New York and Office of Chief Counsel for the U.S. DEA investigated the possibility that the Company failed to maintain appropriate records and security measures with respect to manufacturing of certain controlled substances at its Hobart facility during the period 2012-2013. In July 2017, the Company entered into a final settlement with the DEA and the USAOs for the Eastern District of Michigan and the Northern District of New York to settle these investigations. As part of the agreement, the Company paid $35.0 million to resolve all potential claims and agreed, as part of a Memorandum of Agreement ("MOA"), to utilize all available transaction information to identify suspicious orders of any Mallinckrodt controlled substance product and to report to the DEA when it concludes that chargeback data or other information indicates that a downstream registrant poses a risk of diversion, among other things. The MOA remained in effect until July 10, 2020, but the Company is continuing to utilize all available transaction information to identify suspicious orders for reporting to the DEA beyond that date.

Acthar Gel-Related Matters

Medicaid Lawsuit. In May 2019, the Company filed a lawsuit under the Administrative Procedure Act ("APA") in the U.S. District Court for the District of Columbia (the "District Court") against the U.S. Department of Health and Human Services ("HHS") and CMS (collectively, the "Agency"). The dispute involves the base date AMP under the Medicaid Drug Rebate Program for Mallinckrodt's Acthar Gel. A drug's "base date AMP" is used to calculate the Medicaid rebate amount payable by the drug's manufacturer to state Medicaid agencies when the drug is prescribed to Medicaid beneficiaries. At issue in the lawsuit is whether the FDA's 2010 approval of a new drug application for use of Acthar Gel in treating infantile spasms rendered Acthar Gel eligible for a new base date AMP, as indicated by CMS' written communications in 2012. In May 2019, CMS indicated that if the Company failed to revert to use of the original base date AMP in its calculation of Acthar Gel Medicaid rebates, CMS would identify the Company as being out of compliance with its Medicaid Drug Rebate Program reporting requirements, among other potential actions, triggering certain negative consequences. As such, the Company filed a lawsuit alleging (i) that CMS has violated the Medicaid drug rebate statute, (ii) that CMS has violated its own regulations defining "single source drug," (iii) that CMS has failed to adequately explain its change in position based on two letters that CMS sent Questcor in 2012 regarding the base date AMP for Acthar Gel, (iv) that CMS failed to give the Company fair notice of its latest position, and (v) that CMS should be prohibited from applying its new position retrospectively. The District Court held a hearing regarding this matter in August 2019.

In March 2020, the Company received an adverse decision from the District Court, which upheld CMS' decision to reverse its previous determination of the base date AMP used to calculate Acthar Gel rebates. On March 16, 2020, the Company filed an Emergency Motion for Reconsideration and Stay of Entry of Judgment Pending Reconsideration Or, Alternatively, Injunction Pending

Appeal with the District Court. In response, the government agreed that CMS would not require the Company to change the Medicaid rebate calculation for Acthar Gel until June 14, 2020, to allow the District Court time to decide the Company's reconsideration motion. The District Court denied the Company's motion for reconsideration on May 29, 2020. On June 2, 2020, the Company appealed the District Court's decision to the U.S. Court of Appeals for the D.C. Circuit (the "Court of Appeals") and filed an Emergency Motion for Injunction Pending Appeal and to Expedite Briefing and Argument. The Court of Appeals denied the Company's request for an injunction pending appeal on June 15, 2020. The Company appealed the District Court's decision to the Court of Appeals, which heard oral argument on September 24, 2020.

As previously disclosed, the Company recorded an accrual of $640.2 million related to the retrospective liability (the "Acthar Gel Medicaid Retrospective Rebate") in the unaudited condensed consolidated balance sheet as of September 25, 2020, of which $535.1 million and $105.1 million have been reflected as a component of net sales and operating expenses, respectively, in the unaudited condensed consolidated statement of operations for the nine months ended September 25, 2020. The $105.1 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to the Company's acquisition of Questcor in August 2014.

On October 12, 2020, the Company announced a settlement in principle, which is conditioned upon the Company entering the Chapter 11 restructuring process, to resolve various Acthar Gel-related matters, including the Medicaid lawsuit, an associated FCA lawsuit and an FCA lawsuit relating to Acthar Gel's previous owner's interactions with an independent charitable foundation (the "Acthar Gel-Related Settlement"). The Company has agreed to pay $260.0 million over seven years and to reset Acthar Gel's Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the settlement, the Company will dismiss its appeal, which is currently pending in the Court of Appeals. The Company expects that the Acthar Gel-Related Settlement – which would resolve the Medicaid lawsuit, the associated FCA lawsuit in Boston and an FCA lawsuit in the Eastern District of Pennsylvania relating to Acthar's previous owner's interactions with an independent charitable foundation – will be completed over the next several months, subject to Bankruptcy Court approval.

U.S. House Committee Investigation. In January 2019, the Company along with 11 other pharmaceutical companies, received a letter from the U.S. House Committee on Oversight and Reform requesting information relating to the Company's pricing strategy for Acthar Gel and related matters. The Company cooperated with the Committee's investigation. The Company's President and Chief Executive Officer Mark C. Trudeau accepted an invitation from the Committee to discuss the Company's pricing policies and modernization strategy for Acthar Gel at a hearing before the Committee, which took place on October 1, 2020.

Boston Civil Investigative Demand. In January 2019, the Company received a CID from the USAO for the District of Massachusetts for documents related to the Company's participation in the Medicaid Drug Rebate Program. The Company responded to the government's requests and cooperated with the investigation.

In March 2020, the U.S. District Court for the District of Massachusetts unsealed a *qui tam* complaint under the federal FCA against the Company in which the DOJ and 28 states have intervened alleging that the Company had failed to pay the correct amount of rebates for its Acthar Gel product. Other related legal proceedings involving the Company, including the litigation described as the *Medicaid Lawsuit*, are discussed above. The Company disagrees with the government's characterization of the facts and applicable law. The Company moved to dismiss the DOJ's Complaint in Intervention in July 2020 and moved to dismiss the complaint of the intervening states in September 2020. As previously disclosed, in the event that the Company does not prevail in its Medicaid lawsuit the potential for damages in this matter could be up to approximately $1,280.0 million, after subtracting out potential restitution, related to the Acthar Gel Medicaid Retrospective Rebate. The Company has not recognized an accrual for this contingency in its financial results for the nine months ended September 25, 2020.

As discussed above, on October 12, 2020, the Company announced a settlement in principle to resolve various Acthar Gel-related matters, including the Medicaid lawsuit and this associated Boston FCA lawsuit as well as an FCA lawsuit relating to Acthar Gel's previous owner's interactions with an independent charitable foundation (see "Acthar Gel-Related Settlement" above). On October 14, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code.

Questcor EDPA Qui Tam Litigation. In September 2012, Questcor received a subpoena from the USAO for the Eastern District of Pennsylvania for information relating to its promotional practices related to Acthar Gel. The investigation eventually expanded to include Questcor's provision of financial and other support to patients, including through charitable foundations and related matters. The Company cooperated with the investigation. In March 2019, the U.S. District Court for the Eastern District of Pennsylvania unsealed two *qui tam* actions involving the allegations under investigation by the USAO for the Eastern District of Pennsylvania. The DOJ intervened in both actions, which were later consolidated. In September 2019, the Company executed a settlement agreement with the DOJ for $15.4 million and finalized settlements with the three *qui tam* plaintiffs. These settlements were paid during the three months ended September 27, 2019 and resolve the portion of the investigation and litigation involving Questcor's promotional practices related to Acthar Gel. In June 2019, the DOJ filed its Complaint in Intervention in the litigation, alleging claims under the federal False Claim Act based on Questcor's relationship with and donations to an independent charitable patient co-pay

foundation. The Company disagrees with the DOJ's characterization of the facts and applicable law. In January 2020, the court denied the Company's motion to dismiss the Complaint in Intervention.

As discussed above, on October 12, 2020, the Company announced a settlement in principle to resolve various Acthar Gel-related matters, including the Medicaid lawsuit and associated Boston FCA lawsuit as well as this Questcor EDPA Qui Tam lawsuit (see "Acthar Gel-Related Settlement" above). On October 15, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code.

Patent Litigation

Amitiza Patent Litigation: Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. In October 2018, Sucampo AG, Sucampo Pharmaceuticals, Inc. and Sucampo Pharma LLC, all subsidiaries of the Company, and Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively "Takeda," the exclusive licensee under the patents in litigation) filed suit in the U.S. District Court for the District of New Jersey against Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively "Sun") alleging that Sun infringed U.S. Patent Nos. 7,795,312, 8,026,393, 8,097,653, 8,338,639, 8,389,542, 8,748,481 and 8,779,187 following receipt of a September 2018 notice from Sun concerning its submission of an abbreviated new drug application ("ANDA") containing a Paragraph IV patent certification with the FDA for a competing generic of Amitiza. On June 4, 2020, the parties entered into a settlement agreement under which Sun was granted the non-exclusive right to market a competing generic version of Amitiza in the U.S. under its ANDA on or after January 1, 2023, or earlier under certain circumstances.

INOmax® Patent Litigation: Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair"). In February 2015, INO Therapeutics LLC and Ikaria, Inc., both subsidiaries of the Company, filed suit in the U.S. District Court for the District of Delaware against Praxair following receipt of a January 2015 notice from Praxair concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a nitric oxide drug product delivery system. In July 2016, the Company filed a second suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning three additional patents recently added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for its nitric oxide drug product delivery system. The infringement claims in the second suit were added to the original suit. In September 2016, the Company filed a third suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning a fourth patent added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for its nitric oxide drug product delivery system.

Trial for the suit filed in February 2015 was held in March 2017 and a decision was rendered September 5, 2017 that ruled five patents invalid and six patents not infringed. The Company appealed the decision to the Court of Appeals for the Federal Circuit. The oral arguments in the appeal occurred on February 6, 2019. Praxair received FDA approval of their ANDA for their Noxivent nitric oxide and clearance of their 510(k) for their NOxBOXi device on October 2, 2018. The appeal decision, issued on August 27, 2019, substantively affirmed the U.S. District Court decision with respect to the invalidity of the heart failure (HF) patents and the non-infringement of the delivery system infrared (DSIR) patents. The Company filed a petition for en banc review at the Federal Circuit on September 26, 2019, which the Federal Circuit denied on November 19, 2019. The Company filed a petition for a writ of certiorari with the United States Supreme Court on March 6, 2020 and the petition was denied on April 6, 2020. The adverse final outcome in the appeal of the Praxair litigation decision is expected to result in the broader-scale launch of a competitive nitric oxide product before the expiration of the last of the listed patents on May 3, 2036 (November 3, 2036 including pediatric exclusivity), which could adversely affect the Company's ability to successfully maximize the value of INOmax and have an adverse effect on its financial condition, results of operations and cash flows.

Ofirmev Patent Litigation: Baxter Healthcare Corporation. In March 2020, MHP and Mallinckrodt Hospital Products IP Limited, both subsidiaries of the Company, and New Pharmatop LP, the current owner of the U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against Baxter Healthcare Corporation ("BHC") alleging that BHC infringed U.S. Patent No. 6,992,218, U.S. Patent No. 9,399,012, U.S. Patent No. 9,610,265, U.S. Patent No. 9,987,238 and U.S. Patent No. 10,383,834 following receipt of a February 2020 notice from Baxter concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On April 23, 2020, the parties entered into a settlement agreement under which BHC was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its ANDA on or after December 6, 2020, or earlier under certain circumstances.

Commercial and Securities Litigation

Shareholder Litigation (HealthCor). In October 2020, four purported shareholders of the Company’s stock filed a complaint in the U.S. District Court for the District of Columbia against the Company, its Chief Executive Officer ("CEO") Mark C. Trudeau and its former Chief Financial Officer ("CFO") Matthew K. Harbaugh. The lawsuit, captioned *HealthCor Offshore Master Fund, L.P., et al. v. Mallinckrodt plc, et al.*, asserts claims for false and misleading statements in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, common law fraud, and negligent misrepresentation arising from substantially

similar allegations as those contained in the *Shenk* class action lawsuit below. The complaint seeks damages in an unspecified amount. The defendants intend to vigorously defend themselves in this matter. As this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. As to the Company, this litigation is subject to the automatic stay under §362 of the Bankruptcy Code and the Company has requested an order from the Bankruptcy Court enjoining proceedings against the individual named defendants.

Health Care Service Corporation Litigation. In February 2020, Health Care Service Corporation ("HCSC") filed a non-class complaint against the Company in California state court alleging improper pricing and distribution of Acthar Gel, in violation of the New Jersey RICO statute and various states' antitrust laws. HCSC also brings claims against the Company for conspiracy to violate the New Jersey RICO statute, fraud, unlawful restraint of trade, unfair and deceptive trade practices, insurance fraud, tortious interference with contract and unjust enrichment. The case, which is proceeding as *Health Care Service Corp. v. Mallinckrodt ARD LLC, et al.*, alleges similar facts as those alleged in the *Humana* matter below. The Company intends to vigorously defend itself in this matter, and moved to dismiss the complaint in June 2020. As this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

City of Marietta Litigation. In February 2020, the City of Marietta, Georgia filed a putative civil class action complaint against the Company in the U.S. District Court for the Northern District of Georgia relating to the price of Acthar Gel. The complaint, which pleads one claim for unjust enrichment, purports to be brought on behalf of third-party payers and their beneficiaries as well as people without insurance in the U.S. and its Territories who paid for Acthar Gel from four years prior to the filing of the complaint until the date of trial. The case is proceeding as *City of Marietta v. Mallinckrodt ARD LLC*. Marietta alleges that it has paid $2.0 million to cover the cost of an Acthar Gel prescription of an employee and that the Company has been unjustly enriched as a result. The Company intends to vigorously defend itself in this matter, and has moved to dismiss the complaint. The Company's motion to dismiss remains pending. On October 16, 2020, the court ordered the case administratively closed in light of the Company's Chapter 11 Cases.

Local 322. In November 2019, the United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey ("Local 322") filed a putative class action complaint against the Company and other defendants in New Jersey state court on behalf of New Jersey and third party payers for alleged deceptive marketing and anti-competitive conduct related to the sale and distribution of Acthar Gel. The complaint asserts claims under the New Jersey Consumer Fraud Act, the New Jersey Antitrust Act, the New Jersey RICO statute, negligent misrepresentation, conspiracy/aiding and abetting and unjust enrichment. The proposed class is defined as "All third-party payors and their beneficiaries (1) who are current citizens and residents of the State of New Jersey, and (2) who, for purposes other than resale, purchased or paid for Acthar Gel from August 27, 2007 through the present." In January 2020, after removing the complaint to federal court in New Jersey, the Company moved to dismiss or stay the case. On August 18, 2020 the court dismissed all claims against the Company other than Local 322's antitrust claim relating to the former owner of Acthar Gel's acquisition of Synacthen. The Company intends to vigorously defend itself in this matter, and moved to dismiss the complaint in June 2020. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. On October 14, 2020, the court ordered the case administratively closed in light of the Company's Chapter 11 Cases.

Shareholder Derivative Litigation (Brandhorst). In September 2019, a purported shareholder of the Company's stock filed a shareholder derivative complaint in the U.S. District Court for the District of Columbia against the Company, as nominal defendant, as well as its CEO Mark Trudeau, its former CFO Matthew K. Harbaugh, its Executive Vice President Hugh O'Neill, and the following members of the Board of Directors: Angus Russell, David Carlucci, J. Martin Carroll, David Norton, JoAnn Reed and Kneeland Youngblood (collectively with Trudeau, Harbaugh and O'Neill, the "Brandhorst Defendants"). The lawsuit is captioned *Lynn Brandhorst, derivatively on behalf of nominal defendant Mallinckrodt PLC v. Mark Trudeau et al.* and relies on the allegations from the putative class action securities litigation that was filed against the Company and certain of its officers in January 2017, captioned *Patricia A. Shenk v. Mallinckrodt plc, et al*. described further below. The complaint asserts claims for contribution, breaches of fiduciary duty, unjust enrichment, abuse of control, and gross mismanagement, and is premised on allegations that the Brandhorst Defendants caused the Company to make the allegedly false or misleading statements at issue in the *Shenk* class action lawsuit. The complaint seeks damages in an unspecified amount and corporate governance reforms. On November 20, 2019, this matter was stayed by agreement of the parties pending resolution of the *Shenk* lawsuit below. The Company intends to vigorously defend itself in this matter. As to the Company, this litigation is subject to the automatic stay under §362 of the Bankruptcy Code, and the Company has requested an order from the Bankruptcy Court enjoining proceedings against the individual named defendant.

Humana Litigation. In August 2019, Humana Inc. filed a lawsuit against the Company in the U.S. District Court for the Central District of California alleging violations of federal and state antitrust laws; racketeering violations under 18 U.S.C. § 1962(c); conspiracy to violate RICO under 18 U.S.C. § 1962(d); violations of state unfair competition, consumer fraud and deceptive trade practice laws; state insurance fraud; tortious interference with contract; and unjust enrichment related to the pricing of Acthar Gel. Humana alleges that it paid more than $700.0 million for Acthar Gel and seeks undisclosed damages from 2011 through present. The case alleges similar facts as those alleged in the *MSP* and *Rockford* matters below, and includes references to allegations at issue in a pending *qui tam* action against the Company in the U.S. District Court for the Eastern District of Pennsylvania (see *Questcor EDPA Qui Tam Litigation* above). The case is proceeding as *Humana Inc. v. Mallinckrodt ARD LLC*. In March 2020, the court granted-in-part and denied-in-part the Company's motion to dismiss Humana's claims. The court dismissed Humana's antitrust and tortious

interference claims with leave to amend. The court denied the Company's motion to dismiss Humana's RICO and other fraud-based claims. Humana filed an amended complaint in May 2020, which the Company has moved to dismiss. In August 2020, the court granted-in-part and denied-in-part the Company's motion to dismiss the amended complaint. The court dismissed with prejudice Humana's claims under most state antitrust laws dismissed with prejudice Humana's tortious interference claims. The court ruled that Humana's federal antitrust and federal and state-law analog RICO claims may proceed. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. On October 13, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code.

Putative Class Action Litigation - Steamfitters Local Union No. 420. In July 2019, Steamfitters Local Union No. 420 filed a putative class action lawsuit against the Company and United BioSource Corporation in the U.S. District Court for the Eastern District of Pennsylvania, 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 Illinois, Pennsylvania, Tennessee and Maryland (now dismissed; see WCBE below), and includes references to allegations at issue in a pending qui tam actions against the Company in the U.S. District Court for the Eastern District of Pennsylvania (see Questcor Subpoena above). The complaint alleges RICO violations under 18 U.S.C. § 1962(c); conspiracy to violate RICO under 18 U.S.C. § 1962(c); violations of the Pennsylvania (and other states) Unfair Trade Practices and Consumer Protection laws; negligent misrepresentation; aiding and abetting/conspiracy; and unjust enrichment. The complaint also seeks declaratory and injunctive relief. In December 2019, the court denied the Company's motion to dismiss the complaint. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Putative Class Action Securities Litigation (Strougo). In July 2019, a putative class action lawsuit was filed against the Company, its CEO Mark C. Trudeau, its 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 misleading statements in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder related to the Company's clinical study designed to assess the efficacy and safety of its Acthar Gel in patients with amyotrophic lateral sclerosis. The lawsuit seeks monetary damages in an unspecified amount. A lead plaintiff was designated by the court on June 25, 2020, and on July 30, 2020, the court approved the transfer of the case to the U.S. District Court for the District of New Jersey. On August 10, 2020, an amended complaint was filed by the lead plaintiff alleging an expended putative class period of May 3, 2016 through March 18, 2020 against the Company and Mark C. Trudeau, Bryan M. Reasons, George A. Kegler and Matthew K. Harbaugh, as well as newly named defendants Kathleen A. Schaefer, Angus C. Russell, Melvin D. Booth, JoAnn A. Reed, Paul R. Carter, and Mark J. Casey (collectively with Trudeau, Reasons, Kegler and Harbaugh, the "Strougo Defendants"). The amended complaint claims that the defendants made false and/or misleading statements and/or failed disclose that: (i) the CMS had informed the Company that it was using the wrong base date AMP for calculating the Medicaid rebate the Company owed CMS for Acthar Gel each quarter since 2014; (ii) the Company's reported net income was improperly inflated in violation of GAAP; (iii) the Company's contingent liabilities associated with the rebates owed to CMS for Acthar Gel were misrepresented; (iv) the Company's fiscal year 2019 guidance for Acthar Gel net sales was false; (v) the Company failed to disclose material information regarding the cases captioned Landolt v. Mallinckrodt ARD LLC, No. 1:18-cv-11931-PBS (D. Mass.) (Landolt) and U.S. ex rel. Strunck v. Mallinckrodt ARD LLC, No. 2:12-cv-0175-BMS (E.D. Pa.) (Strunck), or the related investigation by the Department of Justice (DOJ) and (vi) the Company failed to disclose that the clinical trials for Acthar Gel were purportedly initiated in order to make it appear that alternative revenue opportunities for Acthar Gel existed and thus offset the expected 10% decline in net sales as a result of the rebates the Company now had to pay. On October 1, 2020, the defendants filed a motion to dismiss the amended complaint. The defendants intend to vigorously defend themselves in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. As to the Company, this litigation is subject to the automatic stay under §362 of the Bankruptcy Code, and the Company has requested an order from the Bankruptcy Court enjoining proceedings against the individual named defendants.

Acument Global. In May 2019, Acument Global Technologies, Inc. ("Acument"), filed a non-class complaint against the Company and other defendants in Tennessee state court alleging violations of Tennessee Consumer Protection laws, unjust enrichment, fraud and conspiracy to defraud. The case alleges similar facts as those alleged in the *MSP* and *Rockford* matters below, and is captioned *Acument Global Technologies, Inc., v. Mallinckrodt ARD Inc., et al.* In February 2020, the court granted-in-part and denied-in-part the Company's motion to dismiss. While the court dismissed Acument's fraud-based claims and its claim under the Tennessee Consumer Protection Act, the court ruled that the antitrust and unjust enrichment claims may proceed. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Washington County Board of Education ("WCBE"). In May 2019, WCBE filed a non-class complaint against the Company and other defendants in Maryland state court alleging violations of Maryland Consumer Protection Act, negligent misrepresentation, fraud, unjust enrichment and conspiracy to defraud. The case, which was removed to the U.S. District Court for the District of Maryland in June 2019, alleges similar facts as those alleged in the MSP and Rockford matters above, and is captioned *Washington County Board of Education v. Mallinckrodt ARD Inc., et al.* On January 4, 2020, the court dismissed the complaint. Thereafter, the plaintiff filed a

notice of voluntary dismissal, which the Company moved to strike. The U.S. District Court granted the motion to strike, and the plaintiff appealed that order to the U.S. Court of Appeals for the Fourth Circuit in June 2020. The Fourth Circuit dismissed plaintiff's appeal in September 2020.

Local 542. In May 2018, the International Union of Operating Engineers Local 542 filed a non-class complaint against the Company and other defendants in Pennsylvania state court alleging improper pricing and distribution of Acthar Gel, in violation of Pennsylvania's Unfair Trade Practices and Consumer Protection law, aiding and abetting, unjust enrichment and negligent misrepresentation. The case alleges similar facts as the *MSP* and *Rockford* matters below, and is captioned *Int'l Union of Operating Engineers Local 542 v. Mallinckrodt ARD Inc., et al.* Plaintiff filed an amended complaint in August 2018, the Company's objections to which were denied by the court. Although the court temporarily stayed proceedings in January 2020, the court lifted the stay in February 2020. The Company intends to continue to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Putative Class Action Litigation (MSP). In October 2017, a putative class action lawsuit was filed against the Company and United BioSource Corporation in the U.S. District Court for the Central District of California. Pursuant to a motion filed by the defendants, the case was transferred to the U.S. District Court for the Northern District of Illinois in January 2018, and is currently proceeding as *MSP Recovery Claims, Series II, LLC, et al. v. Mallinckrodt ARD, Inc., et al.* The Company filed a motion to dismiss in February 2018, which was granted in January 2019 with leave to amend. MSP filed the operative First Amended Class Action Complaint on April 10, 2019, in which it asserts claims under federal and state antitrust laws and state consumer protection laws and names additional defendants. The complaint alleged that the Company unlawfully maintained a monopoly in a purported ACTH product market by acquiring the U.S. rights to Synacthen® Depot ("Synacthen") and reaching anti-competitive agreements with the other defendants by selling Acthar Gel through an exclusive distribution network. The complaint purported to be brought on behalf of all third-party payers, or their assignees, in the U.S. and its territories, who have, as indirect purchasers, in whole or in part, paid for, provided reimbursement for, and/or possess the recovery rights to reimbursement for the indirect purchase of Acthar Gel from August 1, 2007 to present. In March 2020, the court granted the Company's motion to dismiss the complaint with leave to amend. MSP filed an amended complaint on July 3, 2020. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. On October 13, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code.

Employee Stock Purchase Plan (ESPP) Securities Litigation. In July 2017, a purported purchaser of Mallinckrodt stock through Mallinckrodt's ESPPs, filed a derivative and class action lawsuit in the Federal District Court in the Eastern District of Missouri, captioned *Solomon v. Mallinckrodt plc, et al.*, against the Company, its CEO Mark C. Trudeau, its former CFO Matthew K. Harbaugh, its Controller Kathleen A. Schaefer, and current and former directors of the Company (collectively, the "Solomon Defendants"). On September 6, 2017, plaintiff voluntarily dismissed its complaint in the Federal District Court for the Eastern District of Missouri and refiled virtually the same complaint in the U.S. District Court for the District of Columbia. The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt stock between November 25, 2014, and January 18, 2017, through the ESPPs. In the alternative, the plaintiff alleges a class action for those same purchasers/acquirers of stock in the ESPPs during the same period. The complaint asserts claims under Section 11 of the Securities Act, and for breach of fiduciary duty, misrepresentation, non-disclosure, mismanagement of the ESPPs' assets and breach of contract arising from substantially similar allegations as those contained in the *Shenk* class action lawsuit below. Stipulated co-lead plaintiffs were approved by the court on March 1, 2018. Co-lead Plaintiffs filed an amended complaint on June 4, 2018 having a class period of July 14, 2014 to November 6, 2017. On July 6, 2018, this matter was stayed by agreement of the parties pending resolution of the *Shenk* class action lawsuit below. The defendants intends to vigorously defend themselves in this matter. On October 13, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code, and the Company has requested an order from the Bankruptcy Court enjoining proceedings against the individual named defendants.

Putative Class Action Litigation (Rockford). In April 2017, a putative class action lawsuit was filed against the Company and United BioSource Corporation in the U.S. District Court for the Northern District of Illinois. The case is captioned *City of Rockford v. Mallinckrodt ARD, Inc., et al.* The complaint was subsequently amended to, among other things, include an additional named plaintiff and additional defendants. As amended, the complaint purports to be brought on behalf of all self-funded entities in the U.S. and its Territories, excluding any Medicare Advantage Organizations, related entities and certain others, that paid for Acthar Gel from August 2007 to the present. Plaintiff alleges violations of federal antitrust and RICO laws, as well as various state law claims in connection with the distribution and sale of Acthar Gel. In January 2018, the Company filed a motion to dismiss the Second Amended Complaint, which was granted in part in January 2019. The court dismissed one of two named plaintiffs and all claims with the exception of Plaintiff's federal and state antitrust claims. The remaining allegation in the case is that the Company engaged in anti-competitive acts to artificially raise and maintain the price of Acthar Gel. To this end, Plaintiff alleges that the Company unlawfully maintained a monopoly in a purported ACTH product market by acquiring the U.S. rights to Synacthen and conspired with the other named defendants by selling Acthar Gel through an exclusive distributor. The Company intends to continue defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. On October 13, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code.

Putative Class Action Securities Litigation (Shenk). In January 2017, a putative class action lawsuit was filed against the Company and its CEO in the U.S. District Court for the District of Columbia, captioned *Patricia A. Shenk v. Mallinckrodt plc, et al*. The complaint purports to be brought on behalf of all persons who purchased Mallinckrodt's publicly traded securities on a domestic exchange between November 25, 2014 and January 18, 2017. The lawsuit generally alleges that the Company made false or misleading statements related to Acthar Gel and Synacthen to artificially inflate the price of the Company's stock. In particular, the complaint alleges a failure by the Company to provide accurate disclosures concerning the long-term sustainability of Acthar Gel revenues, and the exposure of Acthar Gel to Medicare and Medicaid reimbursement rates. On January 26, 2017, a second putative class action lawsuit, captioned *Jyotindra Patel v. Mallinckrodt plc, et al.* was filed against the same defendants named in the *Shenk* lawsuit in the U.S. District Court for the District of Columbia. The *Patel* complaint purports to be brought on behalf of shareholders during the same period of time as that set forth in the *Shenk* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 13, 2017, a third putative class action lawsuit, captioned *Amy T. Schwartz, et al., v. Mallinckrodt plc, et al.,* was filed against the same defendants named in the *Shenk* lawsuit in the U.S. District Court for the District of Columbia. The *Schwartz* complaint purports to be brought on behalf of shareholders who purchased shares of the Company between July 14, 2014 and January 18, 2017 and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 23, 2017, a fourth putative class action lawsuit, captioned *Fulton County Employees' Retirement System v. Mallinckrodt plc, et al.,* was filed against the Company, its CEO and former CFO in the U.S. District Court for the District of Columbia. The *Fulton County* complaint purports to be brought on behalf of shareholders during the same period of time as that set forth in the *Schwartz* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 27, 2017, four separate plaintiff groups moved to consolidate the pending cases and to be appointed as lead plaintiffs in the consolidated case. Lead plaintiff was designated by the court on March 9, 2018. Lead plaintiff filed a consolidated complaint on May 18, 2018, alleging a class period from July 14, 2014 to November 6, 2017, the Company, its CEO, its former CFO, and Executive Vice President, Hugh O'Neill, as defendants, and containing similar claims, but further alleging misstatements regarding payer reimbursement restrictions for Acthar Gel. On August 30, 2018, the lead plaintiff voluntarily dismissed the claims against Mr. O'Neill without prejudice. The Company filed a motion to dismiss the complaint which was granted in part, and denied in part by the court on July 30, 2019. On September 1, 2020, the case deadlines were suspended to allow the parties to pursue a mediation. The defendants intends to vigorously defend themselves in this matter. On October 13, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code, and the Company has requested an order from the Bankruptcy Court enjoining proceedings against the individual named defendants.

Generic Price Fixing Litigation

Generic Pharmaceutical Antitrust MDL. In August 2016, a multidistrict litigation was established in the Eastern District of Pennsylvania relating to allegations of antitrust violations with respect to generic pharmaceutical pricing (the "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. Since its establishment, the Generic Pricing MDL has expanded to encompass dozens of pharmaceutical companies and more than 100 generic pharmaceutical drugs. The Company was recently named in three cases associated with this litigation. There was a status conference on September 10, 2020, at which time the court stated that any new or amended complaints are due by December 15, 2020. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

State Attorneys General Litigation. In June 2020, the Company, along with more than 20 other pharmaceutical manufacturers, was named as a defendant in a lawsuit brought by Attorneys General for 51 States, Territories, and the District of Columbia. The lawsuit, filed in the U.S. District Court for the District of Connecticut, alleges that manufacturers of generic drugs conspired to fix prices for certain generic drugs by communicating in advance of price increases and agreeing to certain market share allocations amongst competitors to thwart competition. The lawsuit alleges that prices for the generic drugs at issue were inflated as a result of the alleged conspiracies, causing harm to the U.S. healthcare system. The complaint seeks monetary damages and injunctive relief for violations of Section 1 of the Sherman Antitrust Act and various state antitrust, consumer protection, and unjust enrichment claims. In July 2020, this lawsuit was consolidated with the Generic Pricing MDL. The Company disagrees with the Attorneys Generals' characterization of the facts and applicable law. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Rite Aid Litigation. In July 2020, a direct action complaint filed in the U.S. District Court for the Eastern District of Pennsylvania named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *Rite Aid Corp. et al. v. Actavis Holdco U.S., Inc. et al.* The lawsuit purports to be brought by entities that directly purchased generic drugs from defendants or a co-conspirator. The complaint seeks monetary damages and injunctive relief for violations of Section 1 of the Sherman Antitrust Act, and is premised on facts similar to those alleged in the *State Attorneys General Litigation*. The Company expects this lawsuit to be consolidated with the Generic Pricing MDL. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Suffolk County, N.Y. Litigation. In August 2020, a direct action complaint filed in the U.S. District Court for the Eastern District of New York named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *County of*

Suffolk v. Actavis Holdco U.S., Inc. et al. The lawsuit purports to be brought by Suffolk County, New York, which directly and indirectly purchased generic drugs from defendants or a co-conspirator. The complaint seeks monetary damages and injunctive relief for violations of Sections 1 and 3 of the Sherman Antitrust Act, the Donnelly Act, New York General Business Law § 340, and New York Social Services Law § 145-b, and is premised on facts similar to those alleged in the *State Attorneys General Litigation*. This lawsuit has been transferred to the U.S. District Court for the Eastern District of Pennsylvania and consolidated with the Generic Pricing MDL. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

J M Smith Litigation. In September 2020, a direct action complaint filed in the U.S. District Court for the Eastern District of Pennsylvania named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *J M Smith Corporation v. Actavis Holdco U.S., Inc. et al.* The lawsuit purports to be brought by entities that directly purchased generic drugs from defendants or a co-conspirator. The complaint seeks monetary damages and injunctive relief for violations of Section 1 of the Sherman Antitrust Act, and is premised on facts similar to those alleged in the *State Attorneys General Litigation*. This lawsuit has been consolidated with the Generic Pricing MDL. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Xyrem Litigation

Self-Insured Schools Litigation. In August 2020, a complaint filed in the U.S. District Court for the Southern District of New York named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *Self-Insured Schools of California v. Jazz Pharmaceuticals Plc et al.* The lawsuit is brought on behalf of a purported class of individuals and entities that indirectly purchased Xyrem (sodium oxybate). The complaint alleges that Jazz Pharmaceuticals delayed generic competition by the Company and others by providing substantial consideration to the Company and others to delay market entry for sodium oxybate, causing consumers to pay supracompetitive prices for Xyrem and its generic bioequivalent products. The complaint seeks monetary damages and declaratory and injunctive relief for violations of Sections 1 and 3 of the Sherman Antitrust Act, Section 16 of the Clayton Antitrust Act, and various state antitrust laws and, state consumer protection statutes, and state laws prohibiting unfair and deceptive practices. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Hollman Litigation. In September 2020, a complaint filed in the U.S. District Court for the Northern District of California named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *Ruth Hollman v. Jazz Pharmaceuticals Plc et al.* The lawsuit is brought on behalf of a purported class of individuals and entities that indirectly purchased Xyrem (sodium oxybate). The complaint alleges that Jazz Pharmaceuticals delayed generic competition by the Company and others by providing substantial consideration to the Company and others to delay market entry for sodium oxybate, causing consumers to pay supracompetitive prices for Xyrem and its generic bioequivalent products. The complaint seeks monetary damages and declaratory and injunctive relief for violations of Sections 1 and 3 of the Sherman Antitrust Act, Section 16 of the Clayton Antitrust Act, and various state antitrust laws, state consumer protection statutes, and state laws prohibiting unfair and deceptive practices. On November 3, 2020, the plaintiff dismissed the case against the Company and certain other defendants without prejudice. The lawsuit remains pending against several other defendants.

Environmental Remediation and Litigation Proceedings

The Company is involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. The Company concluded that, as of September 25, 2020, it was probable that it would incur remediation costs in the range of $37.8 million to $86.9 million. The Company also concluded that, as of September 25, 2020, the best estimate within this range was $61.3 million, of which $1.3 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the unaudited condensed consolidated balance sheet as of September 25, 2020. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Mallinckrodt Veterinary, Inc., Millsboro, Delaware. The Company previously operated a facility in Millsboro, Delaware ("the Millsboro Site") where various animal healthcare products were manufactured. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ("TCE") in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. The Company, and another former owner, have assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the Environmental Protection Agency ("EPA"). The companies have entered into three Administrative Orders on Consent ("AOC(s)") with the EPA to perform

investigations to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site and to conduct an Engineering Evaluation/Cost Analysis ("EE/CA") to characterize the nature and extent of the contamination. In January 2017, the EPA issued its Action Memorandum regarding the EE/CA. In March 2020, the EPA approved the Final Action Report documenting the remedial construction activities completed in accordance with Paragraph 8.12 of AOC 3 for Removal Response Action. The report recommended decommissioning the Directed Groundwater Recirculation system and commencing Long Term Monitoring. Upon receipt of the EPA approved Final Action Report, the Company believes, given the information currently available, that the ultimate 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.

Products Liability Litigation

Beginning with lawsuits brought in July 1976, the Company is named as a defendant in personal injury lawsuits based on alleged exposure to asbestos-containing materials. A majority of the cases involve product liability claims based principally on allegations of past distribution of products containing asbestos. A limited number of the cases allege premises liability based on claims that individuals were exposed to asbestos while on the Company's property. Each case typically names dozens of corporate defendants in addition to the Company. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to products containing asbestos. The Company's involvement in asbestos cases has been limited because it did not mine or produce asbestos. Furthermore, in the Company's experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. The Company has not suffered an adverse verdict in a trial court proceeding related to asbestos claims and intends to continue to defend these lawsuits. When appropriate, the Company settles claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of September 25, 2020, there were approximately 11,800 asbestos-related cases pending against the Company.

The Company estimates pending asbestos claims, claims that were incurred but not reported and related insurance recoveries, which are recorded on a gross basis in the unaudited condensed consolidated balance sheets. The Company's estimate of its liability for pending and future claims is based on claims experience over the past five years and covers claims either currently filed or expected to be filed over the next seven years. The Company believes that it has adequate amounts recorded related to these matters. While it is not possible at this time to determine with certainty the ultimate outcome of these asbestos-related proceedings, the Company believes, given the information currently available, that the ultimate resolution of all known and anticipated future claims, after taking into account amounts already accrued, along with recoveries from insurance, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Internal Revenue Code Section 453A Interest

As a result of historical internal installment sales, the Company has reported IRC §453A interest on its tax returns on the basis of its interpretation of the U.S. Internal Revenue Code and Regulations. Alternative interpretations of these provisions could result in additional interest payable. Due to the inherent uncertainty in these interpretations, the Company has deferred the recognition of the benefit associated with the Company's interpretation and maintains a corresponding liability of $28.2 million and $47.4 million as of September 25, 2020 and December 27, 2019, respectively. The decrease of $19.2 million was recognized as a benefit to interest expense during the nine months ended September 25, 2020, due to lapses of certain statute of limitations. Further favorable resolution of this uncertainty would likely result in a material reversal of this liability and a benefit being recorded to interest expense within the unaudited condensed consolidated statements of operations.

Tax Matters

As further discussed in Note 4, in August 2020, a settlement was reached with the IRS related to the audit of MHP's (formerly known as Cadence) tax year ended September 26, 2014. The settlement increased the transfer price of the Transferred IP, resulting in an increase to taxable income of $356.5 million and underpayment interest of $11.8 million. The increase to taxable income was satisfied through a noncash offset against the Company’s U.S. Federal NOLs and interest expense for the tax year ended September 25, 2020, while the underpayment interest was satisfied through a cash payment of $11.8 million. The Company was adequately reserved for this item; therefore there were no impacts to the unaudited condensed consolidated statement of operations for the three months ended September 25, 2020.

Other Matters

The Company's legal proceedings and claims are further described within the notes to the financial statements included within the Company's Annual Report filed on Form 10-K for the fiscal year ended December 27, 2019.

12. Financial Instruments and Fair Value Measurements

Fair value is defined as the exit price that would be received from the sale of an asset or paid to transfer a liability, using assumptions that market participants would use in pricing an asset or liability. The fair value guidance establishes a three-level fair value hierarchy, which maximizes the use of observable inputs and minimizes the use of unobservable inputs used in measuring fair value. The levels within the hierarchy are as follows:

Level 1— observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2— significant other observable inputs that are observable either directly or indirectly; and

Level 3— significant unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions.

The following tables provide a summary of the significant assets and liabilities that are measured at fair value on a recurring basis at the end of each period:

	September 25, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 31.8	$ 22.5	$ 9.3	$ —
Equity securities	28.0	28.0	—	—
	$ 59.8	$ 50.5	$ 9.3	$ —
Liabilities:				
Deferred compensation liabilities	$ 33.2	$ —	$ 33.2	$ —
Contingent consideration and acquired contingent liabilities	27.2	—	—	27.2
Settlement Warrants	9.3	—	—	9.3
	$ 69.7	$ —	$ 33.2	$ 36.5

	December 27, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 30.6	$ 21.0	$ 9.6	$ —
Equity securities	26.2	26.2	—	—
	$ 56.8	$ 47.2	$ 9.6	$ —
Liabilities:				
Deferred compensation liabilities	$ 39.2	$ —	$ 39.2	$ —
Contingent consideration and acquired contingent liabilities	69.3	—	—	69.3
Settlement Warrants	43.4	—	—	43.4
	$ 151.9	$ —	$ 39.2	$ 112.7

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 ("Silence"), for which quoted prices are available in an active market; therefore, the investment is classified as level 1 and is valued based on quoted market prices reported on an internationally recognized securities exchange.

Deferred compensation liabilities. The Company maintains a non-qualified deferred compensation plan in the U.S., which permits eligible employees of the Company to defer a portion of their compensation. A recordkeeping account is set up for each participant

and the participant chooses from a variety of funds for the deemed investment of their accounts. The recordkeeping accounts generally correspond to the funds offered in the Company's U.S. tax-qualified defined contribution retirement plan and the account balance fluctuates with the investment returns on those funds.

Contingent consideration and acquired contingent liabilities. As of September 25, 2020, the Company maintains various contingent consideration and acquired contingent liabilities associated with the acquisitions of Questcor, Stratatech Corporation ("Stratatech"), and Ocera Therapeutics, Inc. ("Ocera").

The contingent liability associated with the acquisition of Questcor pertains to the Company's license agreement with Novartis AG and Novartis Pharma AG (collectively "Novartis") related to Synacthen, otherwise known as the Company's development product MNK-1411. Under the terms of this agreement, the Company made a $25.0 million payment during the nine months ended September 25, 2020 and subsequently suspended its rights and obligations to Novartis under such agreement. As of September 25, 2020 there are no further contingent liabilities associated with Synacthen. The Company determined the fair value of the contingent consideration associated with the acquisition of Questcor to be zero and $24.5 million as of September 25, 2020 and December 27, 2019, respectively.

As part of the acquisition of Stratatech, the Company provided contingent consideration to the prior shareholders of Stratatech, primarily in the form of regulatory filing and approval milestones associated with the deep partial thickness and full thickness indications associated with StrataGraft®. For each indication, the Company is responsible for a payment upon acceptance of the Company's submission and another upon approval by the FDA. Accordingly, upon acceptance by the FDA of the Company's deep partial thickness submission during the three months ended September 25, 2020, the Company made a $20.0 million payment to the prior shareholders of Stratatech. The Company assesses the likelihood and timing of making such payments at each balance sheet date. The fair value of the contingent payments was measured based on the net present value of a probability-weighted assessment. The Company determined the fair value of the contingent consideration associated with the acquisition of Stratatech to be $15.8 million and $29.0 million as of September 25, 2020 and December 27, 2019, respectively.

As part of the acquisition of Ocera, the Company provided contingent consideration to the prior shareholders of Ocera in the form of both patient enrollment clinical study milestones and sales-based milestones associated with MNK-6105 and MNK-6106. The Company determined the fair value of the contingent consideration based on an option pricing model to be $11.4 million and $15.8 million as of September 25, 2020 and December 27, 2019, respectively.

Of the total fair value of the contingent consideration of $27.2 million, $13.2 million was classified as current and $14.0 million was classified as non-current in the unaudited condensed consolidated balance sheet as of September 25, 2020. The following table summarizes the activity for contingent consideration:

Balance as of December 27, 2019	$	69.3
Payments		(45.0)
Accretion expense		0.5
Fair value adjustments		2.4
Balance as of September 25, 2020	$	27.2

Settlement Warrants. Under the Opioid-Related Litigation Settlement, it was contemplated that the Company would issue Settlement Warrants upon emergence from the contemplated Chapter 11 process to the Opioid Claimant Trust to purchase ordinary shares of the Company with an eight year term at a strike price of $3.15 per ordinary share that would represent approximately 19.99% of the Company's fully diluted outstanding shares, including after giving effect to the exercise of the warrants, provided that such warrants may not be exercised during any calendar quarter in a quantity that would exceed 5.0% of the number of shares outstanding.

The fair value of the Settlement Warrants has been estimated using the Black-Scholes pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The expected volatility assumption is based on the historical and implied volatility of the Company's peer group with similar business models. The expected term assumption is based on the contractual term of the Settlement Warrants, including the maximum exercise restriction of 5.0% per calendar quarter, which resulted in the valuation of four separate tranches. The expected annual dividend per share is based on the Company's current intentions regarding payment of cash dividends. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term assumed. The estimated fair value for the Settlement Warrants will be subject to revaluation at each balance sheet date with any changes in fair value recorded as a non-cash gain or (loss) in the unaudited condensed consolidated statements of operations until the Settlement Warrants are issued, at which point they will be recorded as equity or as a liability based upon the facts and circumstances at the time of issuance.

The key assumptions used to estimate the fair value of the Settlement Warrants were as follows:

	September 25, 2020	December 27, 2019
Expected share price volatility	60.1 %	54.4 %
Weighted-average risk-free rate	0.5 %	1.8 %
Expected annual dividend per share	— %	— %
Weighted-average expected term (in years)	7.6	7.6
Share price	$ 1.14	$ 3.45

Subsequent to September 25, 2020, the Company announced that Mallinckrodt plc and certain of its subsidiaries voluntarily initiated the Chapter 11 Cases under the Bankruptcy Code in the Bankruptcy Court. In conjunction with the Chapter 11 filing, the Company entered into a Restructuring Support Agreement (as defined in Note 14) which includes a proposed resolution of all opioid-related claims against the Company and its subsidiaries that supersedes the Opioid-Related Litigation Settlement. The Restructuring Support Agreement includes new terms whereby the warrants equal to approximately 19.99% of the post-emergence fully diluted outstanding shares. These new terms may have a material impact to the recorded fair value of the warrants as of September 25, 2020, but such impact cannot be reasonably estimated at this time. For further information on the terms of this proposed resolution, refer to Note 14.

Financial Instruments Not Measured at Fair Value

The following methods and assumptions were used by the Company in estimating fair values for financial instruments not measured at fair value as of September 25, 2020 and December 27, 2019:

- The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the majority of other current assets and liabilities approximate fair value because of their short-term nature. The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity of three months or less, as cash and cash equivalents (level 1). The fair value of restricted cash was equivalent to its carrying value of $56.3 million and $31.7 million as of September 25, 2020 and December 27, 2019, (level 1), respectively. As of September 25, 2020, $20.2 million and $36.1 million of the restricted cash balance was included in prepaid and other current assets and other assets, respectively, on the unaudited condensed consolidated balance sheet. As of December 27, 2019, substantially all of the restricted cash was included in other assets on the consolidated balance sheet.
- The Company has received a portion of consideration as part of contingent earn-out payments related to the sale of the Nuclear Imaging business in the form of preferred equity certificates. These securities are classified as held-to-maturity and are carried at amortized cost, which approximates fair value (level 3), of $29.8 million and $18.9 million as of September 25, 2020 and December 27, 2019, respectively. These securities are included in other assets on the unaudited condensed consolidated balance sheets.
- The Company's life insurance contracts are carried at cash surrender value, which is based on the present value of future cash flows under the terms of the contracts (level 3). Significant assumptions used in determining the cash surrender value include the amount and timing of future cash flows, interest rates and mortality charges. The fair value of these contracts approximates the carrying value of $51.3 million and $51.1 million as of September 25, 2020 and December 27, 2019, respectively. These contracts are included in other assets on the unaudited condensed consolidated balance sheets.
- The carrying value of the Company's revolving credit facility approximates the fair value due to the short-term nature of this instrument, and is therefore classified as level 1. The Company's 4.875%, 5.75%, 4.75%, 5.625%, 5.50% and 10.00% first and second lien senior notes are classified as level 1, as quoted prices are available in an active market for these notes. Since the quoted market prices for the Company's term loans and 9.50% and 8.00% debentures are not available in an active market, they are classified as level 2 for purposes of developing an estimate of fair value. The following table presents the carrying values and estimated fair values of the Company's debt as of the end of each period:

	September 25, 2020		December 27, 2019	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
4.875% senior notes due April 2020	$ —	$ —	$ 614.8	$ 480.0
5.75% senior notes due August 2022	610.3	159.8	610.3	251.0
4.75% senior notes due April 2023	133.7	19.8	133.7	53.7
5.625% senior notes due October 2023	514.7	125.5	514.7	193.2
5.50% senior notes due April 2025	387.2	93.1	387.2	135.5
10.00% first lien senior notes due April 2025	495.0	516.1	—	—
10.00% second lien senior notes due April 2025	322.9	252.6	322.9	253.8
Revolving credit facility	900.0	900.0	900.0	900.0
Level 2:				
9.50% debentures due May 2022	10.4	4.2	10.4	5.4
8.00% debentures due March 2023	4.4	1.3	4.4	2.0
Term loan due September 2024	1,509.1	1,318.8	1,520.8	1,240.0
Term loan due February 2025	400.5	349.1	403.6	326.2
Total Debt	$ 5,288.2	$ 3,740.3	$ 5,422.8	$ 3,840.8

Concentration of Credit and Other Risks

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

The following table shows net sales attributable to distributors that accounted for 10.0% or more of the Company's total segment net sales, which excludes the one-time charge related to the Medicaid lawsuit:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
CuraScript, Inc.	28.1 %	31.1 %	27.7 %	30.2 %

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

	September 25, 2020	December 27, 2019
AmerisourceBergen Corporation	26.5 %	31.3 %
McKesson Corporation	18.1	15.3
CuraScript, Inc.	13.2	12.1

The following table shows net sales attributable to products that accounted for 10.0% or more of the Company's total segment net sales, which excludes the one-time charge related to the Medicaid lawsuit:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Acthar Gel	27.9 %	30.9 %	27.9 %	30.5 %
INOmax	20.3	18.4	21.2	18.1
Ofirmev	12.7	11.6	10.5	11.5

13. Segment Data

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

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and APIs.

Management measures and evaluates the Company's operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment net sales and operating income because management and the chief operating decision maker evaluate the operating results of the segments excluding such items. These items may include, but are not limited to, depreciation and amortization, share-based compensation, net restructuring and related charges, non-restructuring impairment charges, separation costs, research and development ("R&D") upfront payments, changes related to the Opioid-Related Litigation Settlement and the Acthar Gel Medicaid Retrospective Rebate incurred as a result of the Medicaid lawsuit. During the three months ended September 25, 2020, the Company began excluding depreciation and share-based compensation from its evaluation of the operating results of its segments. As a result, prior period segment operating income has been recast to reflect this change on a comparable basis. Although these amounts are excluded from segment net sales and operating income, as applicable, they are included in reported consolidated net sales and operating income (loss) and are reflected in the reconciliations presented below.

Selected information by reportable segment was as follows:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Net sales:				
Specialty Brands	$ 539.6	$ 580.4	$ 1,553.0	$ 1,812.4
Specialty Generics	159.4	163.3	512.7	545.2
Segment net sales	699.0	743.7	2,065.7	2,357.6
Medicaid lawsuit (Note 11)	(0.7)	—	(535.1)	—
Net sales	$ 698.3	$ 743.7	$ 1,530.6	$ 2,357.6
Operating income:				
Specialty Brands	$ 291.8	$ 277.0	$ 765.0	$ 894.2
Specialty Generics	43.1	36.3	155.5	125.4
Segment operating income	334.9	313.3	920.5	1,019.6
Unallocated amounts:				
Corporate and unallocated expenses [1]	(42.1)	(15.3)	(152.3)	(76.6)
Depreciation and amortization	(236.1)	(234.9)	(675.5)	(723.5)
Share-based compensation	(4.3)	(7.8)	(17.6)	(30.6)
Restructuring and related charges, net	(3.2)	(7.2)	(15.8)	(11.2)
Non-restructuring impairment charges	—	—	(63.5)	(113.5)
Separation costs [2]	(33.0)	(19.8)	(75.0)	(50.4)
R&D upfront payment [3]	—	(20.0)	(5.0)	(20.0)
Opioid-related litigation settlement [4]	25.8	—	34.1	—
Medicaid lawsuit (Note 11)	(0.5)	—	(640.2)	—
Operating income (loss)	$ 41.5	$ 8.3	$ (690.3)	$ (6.2)

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

(2) These costs, which are included in SG&A expenses, primarily relate to professional fees, costs incurred in preparation for the Chapter 11 proceedings as the Company works to resolve opioid and other legal uncertainties, incremental costs incurred to build out the corporate infrastructure of the previously planned spin-off of the Company's Specialty Generics segment, as well as rebranding initiatives associated with the Specialty Brands ongoing transformation.

(3) Represents R&D expense incurred related to an upfront payment made to acquire product rights in Japan for terlipressin during the nine months ended September 25, 2020 and an upfront payment made to Silence in connection with the license and collaboration agreement entered into during the three and nine months ended September 27, 2019.

(4) Represents the change in the Settlement Warrants' fair value. Refer to Note 12 for further information regarding the valuations of the Settlement Warrants.

Net sales by product family within the Company's reportable segments were as follows:

	Three Months Ended		Nine Months Ended	
	September 25, 2020	September 27, 2019	September 25, 2020	September 27, 2019
Acthar Gel [1]	$ 195.3	$ 229.8	$ 576.6	$ 720.1
INOmax	141.9	136.8	438.5	427.6
Ofirmev	88.7	86.1	216.0	272.2
Therakos	62.6	60.9	174.1	183.6
Amitiza [2]	47.7	52.6	138.2	157.6
Other [3]	3.4	14.2	9.6	51.3
Specialty Brands	539.6	580.4	1,553.0	1,812.4
Hydrocodone (API) and hydrocodone-containing tablets	20.0	15.7	71.9	51.2
Oxycodone (API) and oxycodone-containing tablets	16.1	17.2	48.0	53.3
Acetaminophen (API)	54.9	48.5	154.5	143.1
Other controlled substances	62.4	72.9	223.8	265.7
Other	6.0	9.0	14.5	31.9
Specialty Generics	159.4	163.3	512.7	545.2
Segment net sales	699.0	743.7	2,065.7	2,357.6
Medicaid lawsuit (Note 11)	(0.7)	—	(535.1)	—
Net sales	$ 698.3	$ 743.7	$ 1,530.6	$ 2,357.6

(1) The three and nine months ended September 25, 2020 includes the prospective change to the Medicaid rebate calculation beginning in June 2020, which impacted Acthar Gel net sales by $22.2 million and $30.8 million, respectively. See Note 11 for further detail on the status of the Medicaid lawsuit.

(2) Amitiza consists of both product net sales and royalties. Refer to Note 2 for further details on Amitiza's revenues.

(3) The three and nine months ended September 27, 2019 includes $10.5 million and $36.8 million of net sales, respectively, related to BioVectra prior to the completion of the sale of this business in November 2019.

14. Subsequent Events

Commitments and Contingencies

Certain litigation matters occurred during the nine months ended September 25, 2020 or prior, but had subsequent updates through the issuance of this report. See further discussion in Note 11.

Chapter 11 Restructuring

Voluntary Petitions for Reorganization

On October 12, 2020 (the "Petition Date"), Mallinckrodt plc and certain of its subsidiaries voluntarily initiated the Chapter 11 Cases under the Bankruptcy Code in the Bankruptcy Court. The entities that filed the Chapter 11 Cases include the Company, substantially all of the Company's U.S. subsidiaries, including certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the "Specialty Generics Subsidiaries") and the Specialty Brands business (the "Specialty Brands Subsidiaries"), and certain of the Company's international subsidiaries (together with the Company, Specialty Generics Subsidiaries and Specialty Brands Subsidiaries, the "Debtors"). The Debtors have filed a motion with the Bankruptcy Court seeking joint administration of the Chapter 11 Cases under the caption *In re Mallinckrodt plc,* Case No. 20-12522 (JTD).

On October 14, 2020, the Company received Bankruptcy Court approval of its customary motions filed on the Petition Date seeking court authorization to continue to support its business operations during the Chapter 11 Cases, including the continued payment of employee wages and benefits without interruption, payment of critical and foreign vendors, and continuation of customer programs. Under the interim Court order, the Company will make adequate protection payments of an incremental 200 basis points on the senior secured term loans and senior secured revolving credit facility during the Chapter 11 Cases. These adequate protection payments are expected to be classified as interest expense, beginning during the three months ending December 25, 2020.

Restructuring Support Agreement

On October 11, 2020, the Company and the other Debtors entered into a Restructuring Support Agreement (the "RSA") with creditors holding approximately 84%, by aggregate principal amount, of the Company's outstanding guaranteed unsecured senior notes and with a group of governmental plaintiffs in the opioid litigation pending against the Company and certain of its subsidiaries,

including 50 state and territory attorneys general and the court-appointed plaintiffs' executive committee in the opioid multidistrict litigation (collectively, the "Supporting Parties").

The RSA incorporates the terms agreed to by the parties reflected in the term sheets attached to the RSA, including an agreement by the Supporting Parties to support the following:

- *A proposed resolution of all opioid-related claims against the Company and its subsidiaries*. Under the terms of the amended proposed settlement (the "Amended Proposed Opioid-Related Litigation Settlement"), which would become effective upon Mallinckrodt's emergence from the Chapter 11 process, subject to court approval and other conditions:
    - Opioid claims would be channeled to one or more trusts, which would receive $1,600.0 million in structured payments consisting of (i) a $450.0 million payment upon the Company's emergence from Chapter 11; (ii) a $200.0 million payment upon each of the first and second anniversaries of emergence; and (iii) a $150.0 million payment upon each of the third through seventh anniversaries of emergence with a one-year prepayment option at a discount for all but the first payment.
    - Opioid claimants would also receive warrants for approximately 19.99% of the Company's fully diluted outstanding shares, including after giving effect to the exercise of the warrants, exercisable at a strike price reflecting an aggregate equity value of $1,551.0 million.
    - Upon commencing the Chapter 11 filing, the Company will comply with an agreed-upon operating injunction with respect to the operation of its opioid business.
- *A proposed resolution with the U.S. Department of Justice and other governmental parties to settle a range of litigation matters and disputes relating to Acthar Gel*.
    - The Company has reached an agreement in principle with the DOJ and other governmental parties to settle a range of litigation matters and disputes relating to Acthar Gel, referred to herein as the Acthar Gel-Related Settlement. Under the settlement in principle, which is conditioned upon the Company entering the Chapter 11 restructuring process, the Company has agreed to pay $260.0 million to the DOJ and other parties over seven years and reset Acthar Gel's Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the settlement, the Company will dismiss its appeal of the Medicaid lawsuit, currently pending in the Court of Appeals for the D.C. Circuit. In turn, the U.S. Government will drop its demand for approximately $640 million in retrospective Medicaid rebates for Acthar Gel and agree to dismiss a FCA lawsuit in Boston relating to the Medicaid lawsuit and an unrelated FCA suit in the Eastern District of Pennsylvania relating to legacy Questcor interactions with an independent charitable foundation.

      Mallinckrodt has entered into the agreement in principle to settle with the DOJ and other governmental parties solely to move past these litigation matters and disputes and will make no admission of liability or wrongdoing. The Company expects to complete the settlement with the DOJ, as well as various states that are party to the Boston FCA litigation, over the next several months, subject to court approval.
- *The reinstatement of the agreements associated with the Company's senior secured term loans, senior secured revolving credit facility, 10.00% first and second lien senior notes*. At the end of the court-supervised process, all allowed claims under these agreements are expected to be reinstated at existing rates and maturities.
- *A restructuring of the Company's unsecured notes under the Guaranteed Unsecured Notes Indentures (as defined below).* At the end of the court-supervised process, holders of allowed claims under the Guaranteed Unsecured Notes Indentures and the Guaranteed Unsecured Notes (as defined below) are expected to receive their pro rata share of $375.0 million of new secured second lien notes due seven years after emergence and 100% of the ordinary shares of Mallinckrodt, subject to dilution by the warrants described above and certain other equity.
- *A proposed resolution of other remaining claims and treatment of equity holders.* At the end of the court-supervised process, trade creditors and holders of allowed general unsecured claims are expected to share in $150.0 million in cash, and equity holders and holders of the 9.50% debentures due May 2022, the 8.00% debentures due March 2023 and the 4.75% senior notes due April 2023 are expected to receive no recovery.

The restructuring transactions contemplated by the RSA will be effectuated through a plan of reorganization to be proposed by the Debtors (the "Plan"), which among other things as outlined above, provides for a financial restructuring that would reduce the Company's total debt by approximately $1,300.0 million. Pursuant to the RSA, each of the Debtors and the Supporting Parties has made certain customary commitments to each other in connection with the pursuit of the transactions contemplated by the term sheets attached thereto. The Debtors have agreed, among other things, to use commercially reasonable efforts to make all requisite filings with the Bankruptcy Court; continue to involve and update the Supporting Parties' representatives in the bankruptcy process; and satisfy certain other covenants. The Supporting Parties have committed to support and vote for the Plan and have agreed to use commercially reasonable efforts to take, or refrain from taking, certain actions in furtherance of such support.

The RSA contains milestones for the progress of the Chapter 11 Cases (the "Milestones"), which include the dates by which the Debtors are required to, among other things, obtain certain orders of the Court and consummate the Debtors' emergence from bankruptcy. Among other dates set forth in the RSA, the agreement contemplates that the Court shall have entered an order confirming the Plan no later than eleven months after the Petition Date and that the Debtors shall have emerged from bankruptcy no later than fifteen months after the Petition Date.

Each of the parties to the RSA may terminate the agreement (and thereby their support for the Plan) under certain limited circumstances. Any Debtor may terminate the RSA upon, among other circumstances: (i) its board of directors, after consultation with legal counsel, reasonably determining in good faith that performance under the RSA would be inconsistent with its fiduciary duties; and (ii) certain actions by the Bankruptcy Court, including dismissing the Chapter 11 Cases or converting the Chapter 11 Cases into cases under chapter 7 of the Bankruptcy Code.

The Supporting Parties also have specified termination rights, including, among other circumstances, termination rights that arise if any of the Milestones have not been achieved, extended, or waived. Termination by one of these creditor groups will result in the termination of the RSA as to the terminating group only, with the RSA remaining in effect with respect to the Debtors and the non-terminating group.

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

Event of default

The commencement of the Chapter 11 Cases above constituted an event of default under certain of the Company's debt agreements. Subject to any applicable provisions of the Bankruptcy Code, the Company's debt instruments and agreements described within the notes to the financial statements included within the Company's Annual Report filed on Form 10-K for the fiscal year ended December 27, 2019 (other than the 9.50% debentures due May 2022, the 8.00% debentures due March 2023 and the 4.75% senior notes due April 2023) provide that, as a result of the commencement of the Chapter 11 Cases, the principal amount, together with accrued and unpaid interest thereon, and in the case of the indebtedness outstanding under the senior notes, premium, if any, thereon, shall be immediately due and payable. Accordingly, all long-term debt was classified as current on the unaudited condensed consolidated balance sheet as of September 25, 2020. However, any efforts to enforce payment obligations under the debt instruments are automatically stayed as a result of the Chapter 11 Cases and the creditors' rights in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code.

Adoption of Accounting Standards Codification ("ASC") 852 - Reorganizations

For periods occurring after the Petition Date, the Company will adopt Financial Accounting Standards Board ASC Topic 852 - Reorganizations, which specifies the accounting and financial reporting requirements for entities reorganizing through Chapter 11 bankruptcy proceedings. These requirements include distinguishing transactions associated with the reorganization separate from activities related to the ongoing operations of the business.

The Company is currently assessing whether or not it qualifies for fresh start accounting upon emergence from Chapter 11. If the Company were to meet the requirements to adopt the fresh start accounting rules, its assets and liabilities would be recorded at fair value as of the fresh start reporting date, which may differ materially from the recorded values of assets and liabilities on our unaudited condensed consolidated balance sheets.

While the Chapter 11 Cases are pending, the Debtors do 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 paid pursuant to the Company's unsecured debt instruments that were outstanding as of September 25, 2020 was $64.2 million and $147.3 million during the nine months ended September 25, 2020 and the fiscal year ended December 27, 2019, respectively. The total aggregate amount of interest payments due under the Company's unsecured debt instruments for the remainder of 2020, which it does not expect to pay is $28.8 million.

Notice of Delisting

On October 12, 2020, the Company was notified by the staff of NYSE Regulation, Inc. ("NYSE Regulation") that it had determined to commence proceedings to delist the ordinary shares of the Company from the NYSE. NYSE Regulation reached its decision that the Company is no longer suitable for listing pursuant to NYSE Listed Company Manual Section 802.01D after the Company announced that it had commenced the Chapter 11 Cases. Trading in the Company's ordinary shares was also suspended on October 12, 2020. On October 13, 2020, the Company's ordinary shares began trading on the OTC Pink Marketplace under the symbol "MNKKQ." The Company decided not to appeal NYSE's determination and, on October 13, 2020, NYSE filed a Form 25 with the U.S. Securities and Exchange Commission to remove the Company's ordinary shares from listing and registration on the NYSE.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs and involve risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Item 1A. Risk Factors of our Annual Report on Form 10-K for the fiscal year ended December 27, 2019, filed with the United States ("U.S.") Securities and Exchange Commission ("SEC") on February 26, 2020 and within Part II, Item 1A of this Quarterly Report on Form 10-Q.

We own or have rights to use the trademarks and trade names that we use in conjunction with the operation of our business. One of the more important trademarks that we own or have rights to use that appears in this Quarterly Report on Form 10-Q is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the U.S. and other jurisdictions. Solely for convenience, we only use the ™ or ® symbols the first time any trademark or trade name is mentioned in the following discussion. 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 the following discussion is, to our knowledge, owned by such other company.

Overview

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

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

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

For further information on our business and products, refer to our Annual Report on Form 10-K for the fiscal year ended December 27, 2019, filed with the U.S. Securities and Exchange Commission ("SEC") on February 26, 2020.

Significant Events

Voluntary Petitions for Reorganization

On October 12, 2020, we voluntarily initiated Chapter 11 proceedings (the "Chapter 11 Cases") under chapter 11 of title 11 ("Chapter 11") of the United States Code (the "Bankruptcy Code") in the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") to modify our capital structure, including restructuring portions of our debt, and resolve otherwise unmanageable potential legal liabilities. We are continuing to operate and supply customers and patients with products as normal.

We intend to use the Chapter 11 process to provide a fair, orderly, efficient and legally binding mechanism to implement a restructuring support agreement ("RSA") pursuant to which, among other things, the parties thereto have agreed to support:

- A financial restructuring that would, among other things, reduce our total debt by approximately $1,300.0 million, improving our financial position and better positioning us for long-term growth;
- A proposed resolution of all opioid-related claims against us (the "Amended Proposed Opioid-Related Litigation Settlement"); and
- A proposed resolution of various Acthar® Gel ("Acthar Gel")-related matters, including the Medicaid lawsuit, an associated False Claims Act ("FCA") lawsuit and an FCA lawsuit relating to Acthar Gel's previous owner's interactions with an independent charitable foundation (the "Acthar Gel-Related Settlement").

Taken together, these actions are intended to enable us to move forward with our vision to become an innovation-driven biopharmaceutical company meeting the needs of underserved patients with severe and critical conditions.

For further information, refer to Note 14 of the notes to the unaudited condensed consolidated financial statements.

Medicaid Lawsuit

In May 2019, we filed a lawsuit under the Administrative Procedure Act in the U.S. District Court for the District of Columbia (the "District Court") against the U.S. Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid ("CMS") (and together with the HHS, the "Agency"). This lawsuit is in response to a decision by CMS to require that we revert to the original base date average manufacturer price ("AMP") used to calculate Medicaid drug rebates for Acthar Gel. In March 2020, we received an adverse decision from the District Court, which upheld CMS' decision to reverse its previous determination of the base date AMP used to calculate Acthar Gel rebates. On March 16, 2020, we filed an Emergency Motion for Reconsideration and Stay of Entry of Judgment Pending Reconsideration Or, Alternatively, Injunction Pending Appeal. In response, the government agreed that CMS would not require us to change the Medicaid rebate calculation for Acthar Gel until June 14, 2020, to allow the District Court time to decide our reconsideration motion. The District Court subsequently denied our reconsideration motion and in June 2020 we appealed the District Court's decision to the U.S. Court of Appeals for the District of Columbia Circuit (the "Court of Appeals") and filed an Emergency Motion for Injunction Pending Appeal and to Expedite Briefing and Argument. The Court of Appeals subsequently denied our request for an injunction pending appeal on June 15, 2020.

As previously disclosed, we incurred a retrospective one-time charge of $640.2 million (the "Acthar Gel Medicaid Retrospective Rebate"), of which $535.1 million and $105.1 million have been reflected as a component of net sales and operating expenses, respectively, in the unaudited condensed consolidated statement of operations for the nine months ended September 25, 2020. The $105.1 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to our acquisition of Questcor Pharmaceuticals Inc. ("Questcor") in August 2014. The three and nine months ended September 25, 2020 includes the prospective change to the Medicaid rebate calculation beginning in June 2020, which impacted Acthar Gel net sales by $22.2 million and $30.8 million, respectively.

On October 12, 2020, we announced a settlement in principle to resolve various Acthar Gel-related matters, including the Medicaid lawsuit, an associated FCA lawsuit and an FCA lawsuit relating to Acthar Gel's previous owner's interactions with an independent charitable foundation (the "Acthar Gel-Related Settlement"). We have agreed to pay $260.0 million over seven years and to reset Acthar Gel's Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the settlement, we will dismiss our appeal, which is currently pending in the U.S. Court of Appeals for the D.C. Circuit. We expect that the Acthar Gel-Related Settlement – which would resolve the Medicaid lawsuit, the associated FCA lawsuit in Boston and an FCA lawsuit in the Eastern District of Pennsylvania relating to Acthar Gel's previous owner's interactions with an independent charitable foundation – will be completed over the next several months, subject to Bankruptcy Court approval.

This report contains certain financial measures, including net sales, gross profit, gross profit margin, selling, general and administrative ("SG&A") expenses as a percentage of net sales and research and development ("R&D") expenses as a percentage of net sales, which exclude the one-time charge related to the Medicaid lawsuit that is included as a component of net sales.

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

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

Opioid-Related Matters

As a result of the greater 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. 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. During the three and nine months ended September 25, 2020, we incurred $13.4 million and $53.1 million in opioid defense costs, respectively, and $7.8 million and $42.3 million during the three and nine months ended September 27, 2019, respectively, which are included in SG&A expenses.

Opioid-Related Litigation Settlement

On February 25, 2020, we, certain of our subsidiaries operating the Specialty Generics business (the "Specialty Generics Subsidiaries") and certain other affiliates announced an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against us, which we refer to herein as the "Opioid-Related Litigation Settlement." The Opioid-Related Litigation Settlement was reached with a court-appointed plaintiffs' executive committee representing the interests of thousands of

plaintiffs in the federal multi-district litigation ("MDL") and supported by a broad-based group of 48 state and U.S. Territory Attorneys General. The Opioid-Related Litigation Settlement contemplated the filing of voluntary petitions under Chapter 11 by the Specialty Generics Subsidiaries and the establishment of a trust for the benefit of plaintiffs holding opioid-related claims against Mallinckrodt (the "Opioid Claimant Trust"). Furthermore, under the terms of the Opioid-Related Litigation Settlement, subject to court approval and other conditions, it was contemplated that we would (1) make cash payments of $1,600.0 million in structured payments over eight years, beginning upon the Specialty Generics Subsidiaries' emergence from the completed Chapter 11 case, the substantial majority of which would be expected to be contributed to the Opioid Claimant Trust and (2) issue warrants with an eight year term to the Opioid Claimant Trust exercisable at a strike price of $3.15 per share to purchase our ordinary shares that would represent approximately 19.99% of our fully diluted outstanding shares, including after giving effect to the exercise of the warrants (the "Settlement Warrants"). As a result of the Opioid-Related Litigation Settlement, we recorded an accrual for this contingency of $1,600.0 million related to the structured cash payments and $43.4 million related to the Settlement Warrants in the consolidated balance sheet as of December 27, 2019. During the nine months ended September 25, 2020, we recorded a non-cash gain of $34.1 million as a result of the change in the Settlement Warrants' fair value.

On October 12, 2020, we voluntarily initiated the Chapter 11 Cases under the Bankruptcy Code in the Bankruptcy Court on October 12, 2020. In conjunction with the Chapter 11 filing, we entered into a RSA which includes an amended proposed settlement of all opioid-related claims against the Company and its subsidiaries that supersedes the Opioid-Related Litigation Settlement. For further information on the terms of this proposed resolution, refer to Note 14 of the notes to the unaudited condensed consolidated financial statements.

Separation

In fiscal 2016, the Board of Directors began to explore a range of strategic alternatives for our Specialty Generics business. Consistent with that strategy, on December 6, 2018, we announced our plans to spin off to our shareholders a new independent public company that would hold the Specialty Generics business. On August 6, 2019, based on market conditions and developments, including increasing uncertainties created by the opioid litigation, we announced the suspension of our previously announced plans to spin off the Specialty Generics business. On October 12, 2020, we voluntarily initiated Chapter 11 proceedings. Separating the Specialty Generics and Specialty Brands businesses remains one of our goals. We will continue to evaluate strategic options for the Specialty Generics business at an appropriate time and when market conditions are favorable.

During the three and nine months ended September 25, 2020, we incurred $33.0 million and $75.0 million in separation costs, respectively, compared to $19.8 million and $50.4 million for the three and nine months ended September 27, 2019, respectively. These costs, which are included in SG&A expenses, primarily relate to professional fees, costs incurred in preparation for the Chapter 11 proceedings as we work to resolve opioid and other legal uncertainties, incremental costs incurred to build out the corporate infrastructure of the previously planned spin-off of the Specialty Generics business, as well as rebranding initiatives associated with the Specialty Brands ongoing transformation.

Tax Matters

In August 2020 a settlement was reached with the Internal Revenue Service ("IRS") related to the audit of Mallinckrodt Hospital Products Inc.'s ("MHP") (formerly known as Cadence Pharmaceuticals, Inc. ("Cadence")) tax year ended September 26, 2014. Cadence was acquired as a U.S. subsidiary on March 19, 2014. Following the acquisition of Cadence, we transferred certain rights and risks in Ofirmev intellectual property ("Transferred IP") to one of our wholly owned non-U.S. subsidiaries. The transfer occurred at a price determined in conjunction with external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration we paid to the shareholders of Cadence. The IRS asserted the transfer price of the Transferred IP was understated. The settlement increased the transfer price of the Transferred IP, resulting in an increase to taxable income of $356.5 million and underpayment interest of $11.8 million. The increase to taxable income was satisfied through a noncash offset against our U.S. Federal NOLs and interest expense for the tax year ended September 25, 2020, while the underpayment interest was satisfied through a cash payment of $11.8 million. We were adequately reserved for this item; therefore there were no impacts to the unaudited condensed consolidated statement of operations for the three months ended September 25, 2020.

On July 15, 2020, the activities of our principal executive offices were relocated from the United Kingdom ("U.K.") to Ireland, which resulted in a change in our tax residence to Ireland. Mallinckrodt plc has always been and remains incorporated in Ireland. Relocation of Mallinckrodt plc's tax residence to Ireland allows us to mitigate the potential impacts of the U.K.'s departure from the European Union and align with our commercial activity in Ireland. We continue to be subject to taxation in various tax jurisdictions worldwide. Accordingly, in fiscal 2020 we will report the Irish tax jurisdiction as our Domestic jurisdiction using an Irish statutory tax rate of 12.5% versus the U.K. statutory rate of 19.0%, and the International jurisdiction will represent areas outside the Irish tax jurisdiction. There is no material financial impact to this change.

Ofirmev®

During the three months ended June 26, 2020, due to decreased demand as a result of the deprioritization of non-critical medical treatment in the face of the novel coronavirus ("COVID-19") pandemic, along with increased generic competition anticipated in the marketplace post the product's loss of exclusivity in December 2020, we identified a triggering event with respect to the Ofirmev intangible asset within the Specialty Brands segment and assessed the recoverability of the definite-lived asset. Additionally, we evaluated whether these events warranted a revision to the remaining period of amortization that previously extended to March 2022. As a result of this analysis, we revised the useful life to end December 25, 2020, commensurate with the final period of market exclusivity. After this change in estimate of the asset's useful life, we determined that the undiscounted cash flows related to the Ofirmev intangible asset were less than its net book value, which required us to record an impairment charge of $63.5 million for the difference between the fair value of the Ofirmev intangible asset and its net book value. The remaining intangible asset value of $26.1 million as of September 25, 2020 will be amortized prospectively over the remaining useful life.

Terlipressin

During September 2020, the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") regarding our New Drug Application ("NDA") seeking approval for the investigational agent terlipressin to treat adults with hepatorenal syndrome type 1 ("HRS-1"). The CRL stated that, based on the available data, the agency cannot approve the terlipressin NDA in its current form and requires more information to support a positive risk-benefit profile for terlipressin for patients with HRS-1.

In response to receipt of the CRL, on October 26, 2020 we had an End of Review Meeting with the FDA where both parties engaged in constructive dialogue in an effort to clarify a viable path to approval. As we continue to engage with the FDA over the coming months, we will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated in-process research and development ("IPR&D") asset of $81.0 million included within intangible assets, net on the unaudited condensed consolidated balance sheets as of September 25, 2020 and December 28, 2019.

Business Factors Influencing the Results of Operations

COVID-19 Business Update

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world. As we navigate the unprecedented challenges created by the COVID-19 pandemic, we remain committed to supporting our employees, customers, patients and the broader communities in which we operate.

Since the onset of the COVID-19 pandemic, we have continued to manufacture, supply and deliver our products largely without interruption. At present, we do not anticipate significant COVID-19-related manufacturing or supply chain disruptions, and we continue to evaluate our end-to-end supply chain and assess opportunities to refine our processes going forward.

We are supporting the fight against COVID-19 in a number of ways, including by partnering with Novoteris, LLC and Massachusetts General Hospital to study inhaled nitric oxide for use as a therapeutic option for COVID-19 patients; giving medically trained employees paid time off to volunteer to treat or care for COVID-19 patients; providing funding and therapies to hospitals to conduct treatment-related research; adapting certain of our manufacturing facilities to produce hand sanitizers for designated counties, state health departments and emergency operation distribution centers located in states where we have operations; donating excess personal protective equipment (PPE) and other resources to healthcare providers, first responders, and medical facilities; and partnering with advocacy groups to help mitigate the impact of the pandemic on patients.

We expect the coming months to be challenging due to the impact of COVID-19, as some of our products are sensitive to reduced numbers of surgical procedures and doctor visits. Our business performance was significantly impacted by COVID-19 during the second and third quarters of 2020, and we continue to expect to see challenges for the remainder of the year. The ultimate business impact for the remainder of the year will largely be determined by the ongoing return to work guidance issued by international, national, and local governments and health officials and organizations. We are monitoring the demand for our products, including the duration and degree to which we may see declines in customer orders or delays in starting new patients on a product, such as Acthar Gel, due to the limited ability of our sales representatives to meet with physicians and patients to visit their doctors and pharmacists to receive prescriptions for certain of our products. In regards to Acthar Gel, we continue to see a reduction in new patients, which is anticipated to impact results for the remainder of the year. In addition, due to the deprioritization of non-critical medical treatment in the face of this pandemic, demand for Ofirmev was affected in the second and third quarters and may continue to be impacted the remainder of the year. We also experienced and may continue to experience reduced demand for Therakos® due to immunosuppressed patients who have been instructed to stay-at-home during the COVID-19 pandemic. Furthermore, while we are supporting the continuation of ongoing patients in our clinical trials, as much as possible, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials.

Given the rapid and evolving nature of the COVID-19 virus, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted. For additional information on the various risks posed by the COVID-19 pandemic, please read Part II, Item 1A. Risk Factors included in this report.

Specialty Brands

Net sales of Acthar Gel for the three months ended September 25, 2020 decreased $34.5 million, or 15.0%, to $195.3 million driven primarily by the marketplace impact of the COVID-19 pandemic and continued payer scrutiny on overall specialty pharmaceutical spending. The prospective change to the Medicaid rebate calculation also served to reduce Acthar Gel net sales by $22.2 million during the three months ended September 25, 2020. We estimate the annualized prospective change to the Medicaid rebate calculation will reduce Acthar Gel annual net sales by roughly $90.0 million to $100.0 million. Net sales of INOmax® for the three months ended September 25, 2020 increased $5.1 million, or 3.7%, to $141.9 million driven by an overall increase in consumption of nitric oxide by our customers primarily attributable to strong utilization within COVID-19 patients, as well as benefits of INOmax contracting.

Research and Development

We devote significant resources to R&D of products and proprietary drug technologies. We incurred R&D expenses of $65.5 million and $225.8 million for the three and nine months ended September 25, 2020 and September 27, 2019, respectively, and $103.1 million and $268.0 million for the three and nine months ended September 27, 2019, respectively. We expect to continue to pursue targeted investments in R&D activities, both for existing products and the development of new portfolio assets. We intend to focus our R&D investments in the specialty pharmaceuticals areas, specifically investments to support our Specialty Brands business, where we believe there is the greatest opportunity for growth and profitability.

We have completed the Phase 3 clinical studies for two of our development programs, terlipressin for the treatment of hepatorenal syndrome (HRS) type 1 and StrataGraft® for the treatment of deep partial thickness burns, both of which had positive top line results.

- *Terlipressin.* In March 2020, we submitted the NDA filing to the FDA for terlipressin, and in April 2020 the FDA accepted the NDA for review. In June 2020, the Company paid $5.0 million to acquire products rights for terlipressin in Japan. Upon FDA approval, we would be responsible for a one-time milestone payment related to terlipressin of $12.5 million in relation to product rights in the U.S., in addition to a $5.0 million one-time milestone payment in relation to product rights in Japan after we paid $5.0 million to acquire such rights during the three months ended June 26, 2020. For further information on the development of this asset and receipt of the CRL during September 2020, refer to "Significant Events" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.
- *StrataGraft.* In April 2020, we initiated a rolling submission of a biologics license application filing to the FDA for StrataGraft, a regenerative skin tissue therapy for the treatment of adult patients with deep partial-thickness thermal burns, and we completed the submission in June 2020. In July 2020, the FDA accepted our submission. As part of the acquisition of Stratatech, we made a $20.0 million payment to the prior shareholders of Stratatech and we are responsible for another $20.0 million payment upon approval by the FDA.

Specialty Generics

Net sales from the Specialty Generics segment decreased $3.9 million or 2.4% to $159.4 million for the three months ended September 25, 2020 compared to $163.3 million for the three months ended September 27, 2019.

Results of Operations

Three Months Ended September 25, 2020 Compared with Three Months Ended September 27, 2019

Net Sales

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

	Three Months Ended		Percentage Change
	September 25, 2020	September 27, 2019	
U.S.	$ 632.3	$ 648.0	(2.4)%
Europe, Middle East and Africa	53.3	70.3	(24.2)
Other geographic areas	13.4	25.4	(47.2)
Geographic area net sales	699.0	743.7	(6.0)
Medicaid lawsuit (Note 11)	(0.7)	—	*
Net sales	$ 698.3	$ 743.7	(6.1)

*Not meaningful

Net sales for the three months ended September 25, 2020 decreased $45.4 million or 6.1%, to $698.3 million compared with $743.7 million for the three months ended September 27, 2019. This decrease was primarily driven by a decrease in our Specialty Brands segment including a significant decrease in net sales of Acthar Gel, as previously mentioned, as well as Other Specialty Brands products including $10.5 million of net sales during the three months ended September 27, 2019 related to BioVectra, Inc. ("BioVectra") prior to the completion of the sale of this business in November 2019. For further information on changes in our net sales, refer to "Segment Results" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Income

Gross profit. Gross profit for the three months ended September 25, 2020 was $295.3 million compared with $324.3 million for the three months ended September 27, 2019, which was a decrease of $29.0 million or 8.9% primarily driven by the decrease in net sales and a change in product mix. Gross profit margin as a percentage of net sales was 42.3% for the three months ended September 25, 2020, compared with 43.6% for the three months ended September 27, 2019. The decrease in gross profit margin was primarily attributable to the decrease in net sales.

Selling, general and administrative expenses. SG&A expenses for the three months ended September 25, 2020 were $220.8 million, compared with $205.7 million for the three months ended September 27, 2019, an increase of $15.1 million, or 7.3%. This increase was primarily related to an $8.1 million increase in the fair value of our contingent consideration liabilities during the three months ended September 25, 2020, compared to a $25.8 million decrease during the three months ended September 27, 2019, as well as a $13.2 million increase in separation costs for the three months ended September 25, 2020 compared to the three months ended September 27, 2019. This increase was partially offset by various factors, including lower professional fees, lower legal expenses, and lower travel expense due to temporary travel restrictions as a result of COVID-19 in addition to cost benefits gained from restructuring actions. As a percentage of net sales, SG&A expenses were 31.6% and 27.7% for the three months ended September 25, 2020 and September 27, 2019, respectively.

Research and development expenses. R&D expenses decreased $37.6 million, or 36.5%, to $65.5 million for the three months ended September 25, 2020, compared with $103.1 million for the three months ended September 27, 2019. The Company continues to focus current R&D activities on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic activities and patient outcomes. As a percentage of net sales, R&D expenses were 9.4% and 13.9% for the three months ended September 25, 2020 and September 27, 2019, respectively.

Restructuring charges, net. During the three months ended September 25, 2020 and September 27, 2019, we incurred $3.2 million and $7.2 million of restructuring charges, net, respectively, primarily related to employee severance and benefits.

Gains on divestiture. During the three months ended September 25, 2020, we recorded a gain of $10.0 million related to the achievement of a milestone related to the sale of a portion of our Hemostasis business in fiscal 2018 to Baxter International, Inc. ("Baxter").

Opioid-related litigation settlement. During the three months ended September 25, 2020, we recorded a non-cash gain of $25.8 million as a result of the change in the Settlement Warrants' fair value primarily driven by the decreased value of our share price. For further information, refer to Note 12 of the notes to the unaudited condensed consolidated financial statements.

Non-Operating Items

Interest expense and interest income. During the three months ended September 25, 2020 and September 27, 2019, net interest expense was $61.3 million and $74.7 million, respectively. The three months ended September 25, 2020 included the recognition of an $8.4 million benefit to interest expense due to a lapse of certain statute of limitations. The remaining decrease was primarily attributable to a lower average outstanding debt balance during the three months ended September 25, 2020, which yielded a decrease in interest expense of $6.9 million. Interest income decreased to $0.9 million for the three months ended September 25, 2020, compared with $2.9 million for the three months ended September 27, 2019 primarily driven by lower interest rates.

Other income, net. During the three months ended September 25, 2020 and September 27, 2019 we recorded other income, net, of zero and $37.9 million, respectively. The three months ended September 25, 2020 included gains on intercompany financing and foreign currency transactions, offset by $0.1 million of unrealized loss on equity securities, net of foreign currency loss, related to our investment in Silence Therapeutics plc ("Silence"). The three months ended September 27, 2019 included a gain of $18.7 million on debt repurchased, as well as a $6.4 million unrealized gain on equity securities, net of foreign currency loss, related to our investment in Silence.

Income tax expense (benefit). We recognized an income tax benefit of $211.6 million on a loss from continuing operations before income taxes of $19.8 million for the three months ended September 25, 2020, and an income tax benefit of $27.6 million on a loss from continuing operations before income taxes of $28.5 million for the three months ended September 27, 2019. This resulted in effective tax rates of 1,068.7% and 96.8% for the three months ended September 25, 2020 and September 27, 2019, respectively. The income tax benefit for the three months ended September 25, 2020 was comprised of $201.4 million of current tax benefit and $10.2 million of deferred tax benefit. The current tax benefit was primarily the result of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act and unrecognized tax benefits, partially offset by the fiscal 2020 reorganization of our intercompany financing and associated legal entity ownership. The deferred tax benefit was predominantly related to the fiscal 2020 reorganization of our intercompany financing and associated legal entity ownership. The income tax benefit for the three months ended September 27, 2019 was comprised of $3.3 million of current tax expense and $30.9 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles and the generation of tax loss and credit carryforwards net of valuation allowances.

The income tax benefit was $211.6 million for the three months ended September 25, 2020, compared with an income tax benefit of $27.6 million for the three months ended September 27, 2019. The $184.0 million net increase in the tax benefit included an increase of $235.7 million attributed to the CARES Act, and an increase of $1.2 million attributed to the fiscal 2019 gain on debt repurchased partially offset by a decrease of $32.0 million attributed to the fiscal 2020 reorganization of our intercompany financing and associated legal entity ownership, a decrease of $12.3 million attributed to changes in the timing, amount and jurisdictional mix of income, a decrease of $6.5 million attributed to separation costs, and a decrease of $2.1 million attributed to net restructuring.

Nine Months Ended September 25, 2020 Compared with Nine Months Ended September 27, 2019

Net Sales

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

	Nine Months Ended		Percentage Change
	September 25, 2020	September 27, 2019	
U.S.	$ 1,836.0	$ 2,044.9	(10.2)%
Europe, Middle East and Africa	185.0	218.6	(15.4)
Other geographic areas	44.7	94.1	(52.5)
Geographic area net sales	2,065.7	2,357.6	(12.4)
Medicaid lawsuit (Note 11)	(535.1)	—	*
Net sales	$ 1,530.6	$ 2,357.6	(35.1)

*Not meaningful

Net sales for the nine months ended September 25, 2020 decreased $827.0 million or 35.1%, to $1,530.6 million compared with $2,357.6 million for the nine months ended September 27, 2019. This decrease was primarily driven by a retrospective one-time charge of $535.1 million reflected as a component of net sales related to the Medicaid lawsuit. For further information, refer to Note 11 of the notes to the unaudited condensed consolidated financial statements.

Net sales (excluding the one-time charge related to the Medicaid lawsuit, as discussed below) for the nine months ended September 25, 2020 decreased $291.9 million, or 12.4%, to $2,065.7 million, compared with $2,357.6 million for the nine months

ended September 27, 2019. This decrease was primarily driven by a decrease in our Specialty Brands segment including a significant decrease in net sales of Acthar Gel, as well as decreases in net sales of Ofirmev, Amitiza® (lubiprostone) ("Amitiza") and Therakos. In addition, Other Specialty Brands products during the nine months ended September 27, 2019 includes $36.8 million of net sales related to BioVectra prior to the completion of the sale of this business in November 2019. For further information on changes in our net sales, refer to "Segment Results" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Loss

Gross profit. Gross profit for the nine months ended September 25, 2020 decreased $689.4 million or 65.8% to $358.9 million compared with $1,048.3 million. This decrease was primarily driven by a retrospective one-time charge of $535.1 million reflected as a component of net sales related to the Medicaid lawsuit. For further information, refer to Note 11 of the notes to the unaudited condensed consolidated financial statements.

Gross profit (excluding the one-time charge related to the Medicaid lawsuit, as discussed above) for the nine months ended September 25, 2020 decreased $154.3 million, or 14.7%, to $894.0 million, compared with $1,048.3 million for the nine months ended September 27, 2019, due in part to the $291.9 million decrease in net sales. Gross profit as a percentage of net sales was 23.4% for the nine months ended September 25, 2020. Gross profit margin (excluding the one-time charge related to the Medicaid lawsuit) was 43.3% for the nine months ended September 25, 2020, compared with 44.5% for the nine months ended September 27, 2019. The decrease in gross profit margin was primarily attributable to the decrease in net sales, as well as a change in product mix.

Selling, general and administrative expenses. SG&A expenses for the nine months ended September 25, 2020 were $683.2 million, compared with $661.8 million for the nine months ended September 27, 2019, an increase of $21.4 million, or 3.2%. This increase was primarily attributable to a $2.4 million increase in the fair value of our contingent consideration liabilities during the nine months ended September 25, 2020, compared to a $23.5 million decrease during the nine months ended September 27, 2019. Additionally, there was an increase in employee compensation and benefits driven by certain changes made to the design of our long-term incentive compensation program in an effort to manage share usage and dilution and the approval of a key employee incentive program during the nine months ended September 25, 2020, both of which reflect the shorter-term nature of our new target opportunities. Also contributing to the increase was an $24.6 million increase in separation costs for the nine months ended September 25, 2020 compared to the nine months ended September 27, 2019. These increases were partially offset by decreases in professional fees, decreased legal expenses driven by a $28.2 million charge associated with the settlement of the MDL Track 1 Cases during the nine months ended September 27, 2019, and a decrease in travel expense due to temporary travel restrictions as a result of COVID-19. As a percentage of net sales, SG&A expenses were 44.6% for the nine months ended September 25, 2020. As a percentage of net sales, (excluding the one-time charge related to the Medicaid lawsuit, as previously discussed above), SG&A expenses were 33.1% and 28.1% for the nine months ended September 25, 2020 and September 27, 2019, respectively.

Research and development expenses. R&D expenses decreased $42.2 million, or 15.7%, to $225.8 million for the nine months ended September 25, 2020, compared with $268.0 million for the nine months ended September 27, 2019. The Company continues to focus current R&D activities on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic activities and patient outcomes. As a percentage of net sales, R&D expenses were 14.8% for the nine months ended September 25, 2020. As a percentage of net sales, (excluding the one-time charge related to the Medicaid lawsuit, as previously discussed above), R&D expenses were 10.9% and 11.4% for the nine months ended September 25, 2020 and September 27, 2019, respectively.

Restructuring charges, net. During the nine months ended September 25, 2020 and September 27, 2019, we incurred $15.8 million and $11.2 million of restructuring charges, net, primarily related to employee severance and benefits.

Non-restructuring impairment charges. During the nine months ended September 25, 2020, we recognized a partial impairment charge on our Ofirmev intangible asset of $63.5 million as previously described above. During the nine months ended September 27, 2019, we recognized a full impairment on our IPR&D asset related to stannsoporfin of $113.5 million as we are no longer pursuing this development product.

Gains on divestiture. During the nine months ended September 25, 2020, we recorded a gain of $10.0 million related to the achievement of a milestone related to the sale of a portion of our Hemostasis business in fiscal 2018 to Baxter.

Opioid-related litigation settlement. During the nine months ended September 25, 2020, we recorded a non-cash gain of $34.1 million as a result of the change in the Settlement Warrants' fair value primarily driven by a decline in the value of our share price. For further information, refer to Note 12 of the notes to the unaudited condensed consolidated financial statements.

Medicaid lawsuit. During the nine months ended September 25, 2020, we incurred a retrospective one-time charge of $105.1 million, which represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to our acquisition of Questcor in August 2014. For further information, refer to Note 11 of the notes to the unaudited condensed consolidated financial statements.

Non-Operating Items

Interest expense and interest income. During the nine months ended September 25, 2020 and September 27, 2019, net interest expense was $195.5 million and $225.2 million, respectively. This decrease was primarily attributable to a lower average outstanding debt balance during the nine months ended September 25, 2020, which yielded a decrease in interest expense of $22.3 million. Additionally, the nine months ended September 25, 2020 and September 27, 2019 included the recognition of a $19.2 million and $8.6 million benefit to interest expense, respectively, due to a lapse of certain statute of limitations. The Company recognized interest income of $5.4 million and $6.6 million during the nine months ended September 25, 2020 and September 27, 2019, respectively. The decrease in interest income was primarily driven by lower interest rates during the nine months ended September 25, 2020, partially offset by interest earned on our preferred equity certificates that were received as contingent consideration related to the sale of the Nuclear Imaging business.

Other income, net. During the nine months ended September 25, 2020 and September 27, 2019, we recorded other income, net, of $1.1 million and $128.6 million, respectively. The nine months ended September 25, 2020 included a $1.8 million unrealized gain on the equity securities, net of foreign currency loss, related to our investment in Silence, partially offset by losses on intercompany financing, foreign currency transactions and related hedging instruments. The nine months ended September 27, 2019 included a gain of $98.6 million on debt repurchased, royalty income of $30.3 million and an unrealized gain of $6.4 million, net of foreign currency loss, related to our investment in Silence, partially offset by a $9.4 million write-off of unamortized debt discount and fees.

Income tax expense (benefit). We recognized an income tax benefit of $69.2 million on a loss from continuing operations before income taxes of $884.7 million for the nine months ended September 25, 2020, and an income tax benefit of $256.6 million on a loss from continuing operations before income taxes of $102.8 million for the nine months ended September 27, 2019. This resulted in effective tax rates of 7.8% and 249.6% for the nine months ended September 25, 2020 and September 27, 2019, respectively. The income tax expense for the nine months ended September 25, 2020 was comprised of $370.3 million of current tax benefit and $301.1 million of deferred tax expense. The current tax benefit was primarily the result of the CARES Act and unrecognized tax benefits, partially offset by the fiscal 2020 reorganization of our intercompany financing and associated legal entity ownership. The deferred tax expense was predominantly related to the valuation allowance noted above, recorded against our net deferred tax assets, and unrecognized tax benefits, partially offset by a tax benefit predominantly related to the fiscal 2020 reorganization of our intercompany financing and associated legal entity ownership. The income tax benefit for the nine months ended September 27, 2019 was comprised of $47.4 million of current tax expense and $304.0 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles, the generation of tax loss and credit carryforwards net of valuation allowances, the non-restructuring impairment charges, as well as the 2019 reorganization of the Company's intercompany financing and associated legal entity ownership, which eliminated the interest bearing deferred tax obligation.

The income tax benefit was $69.2 million for the nine months ended September 25, 2020, compared with an income tax benefit of $256.6 million for the nine months ended September 27, 2019. The $187.4 million net decrease in the tax benefit included a decrease of $229.1 million predominantly attributed to the fiscal 2019 reorganization of our intercompany financing and associated legal entity ownership including related adjustments to elections on the fiscal 2019 U.S. tax return primarily as a result of changes to the NOL carryback provisions in the CARES Act, a decrease of $202.7 million attributed to a valuation allowance recorded against our net deferred tax assets, a decrease of $30.0 million attributed to changes in the timing, amount and jurisdictional mix of income, a decrease of $9.9 million attributed to separation costs, a decrease of $8.5 million attributed to non-restructuring impairment charges, a decrease of $2.6 million attributed to net restructuring, partially offset by an increase of $285.3 million attributed to the CARES Act, and an increase of $10.1 million attributed to the fiscal 2019 gain on debt repurchased.

Income from discontinued operations, net of income taxes. We recorded income from discontinued operations of $23.8 million and $6.8 million during the nine months ended September 25, 2020 and September 27, 2019, respectively. The income during the nine months ended September 25, 2020 primarily related to the recognition of a tax benefit related to a release of tax and interest on unrecognized tax benefits due to a lapse of certain statute of limitations related to the Nuclear Imaging business. The remaining income during the nine months ended September 25, 2020 and September 27, 2019 primarily related to the receipt of contingent consideration associated with the sale of the Nuclear Imaging business, partially offset by various post-sale adjustments associated with our previous divestitures.

Segment Results

Management measures and evaluates our operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment net sales and operating income because management and the chief operating decision maker evaluate the operating results of the segments excluding such items. These items may include, but are not limited to, depreciation and amortization, share-based compensation, net restructuring and related charges, non-restructuring impairment charges, separation costs, R&D upfront payments, changes related to the Opioid-Related Litigation Settlement and the Acthar Gel Medicaid

Retrospective Rebate incurred as a result of the Medicaid lawsuit. During the three months ended September 25, 2020, management began excluding depreciation and share-based compensation from its evaluation of the operating results of its segments. As a result, prior period segment operating income has been recast to reflect this change on a comparable basis. Although these amounts are excluded from segment net sales and operating income, as applicable, they are included in reported consolidated net sales and operating income (loss) and are reflected in the following reconciliations presented below. Selected information by business segment is as follows:

Three Months Ended September 25, 2020 Compared with Three Months Ended September 27, 2019

Net Sales

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

	Three Months Ended		
	September 25, 2020	**September 27, 2019**	**Percentage Change**
Specialty Brands	$ 539.6	$ 580.4	(7.0)%
Specialty Generics	159.4	163.3	(2.4)
Segment net sales	699.0	743.7	(6.0)
Medicaid lawsuit (Note 11)	(0.7)	—	*
Net sales	$ 698.3	$ 743.7	(6.1)

*Not meaningful

Specialty Brands. Net sales for the three months ended September 25, 2020 decreased $40.8 million to $539.6 million, compared with $580.4 million for the three months ended September 27, 2019. The decrease in net sales was primarily driven by a $34.5 million or 15.0% decrease in Acthar Gel net sales driven the marketplace impact of the COVID-19 pandemic, continued payer scrutiny on overall specialty pharmaceutical spending and the prospective change to the Medicaid rebate calculation. In addition, Other Specialty Brands products during the three months ended September 27, 2019 includes $10.5 million of net sales related to BioVectra prior to the completion of the sale of this business in November 2019. These decreases were partially offset by a $5.1 million, or 3.7%, $2.6 million, or 3.0%, and $1.7 million, or 2.8% increase in net sales related to INOmax, Ofirmev and Therakos, respectively.

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

	Three Months Ended		
	September 25, 2020	**September 27, 2019**	**Percentage Change**
U.S.	$ 504.7	$ 513.9	(1.8)%
Europe, Middle East and Africa	24.9	45.4	(45.2)
Other	10.0	21.1	(52.6)
Net sales	$ 539.6	$ 580.4	(7.0)

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

	Three Months Ended		
	September 25, 2020	**September 27, 2019**	**Percentage Change**
Acthar Gel	$ 195.3	$ 229.8	(15.0)%
INOmax	141.9	136.8	3.7
Ofirmev	88.7	86.1	3.0
Therakos	62.6	60.9	2.8
Amitiza	47.7	52.6	(9.3)
Other	3.4	14.2	(76.1)
Specialty Brands	$ 539.6	$ 580.4	(7.0)

Specialty Generics. Net sales for the three months ended September 25, 2020 decreased $3.9 million, or 2.4%, to $159.4 million, compared with $163.3 million for the three months ended September 27, 2019. The decrease in net sales was driven by a decrease in Other controlled substances products and Other Specialty Generics products net sales of $10.5 million and $3.0 million, respectively.

These decreases were partially offset by increases of $6.4 million and $4.3 million in acetaminophen and hydrocodone-related products net sales, respectively compared to the three months ended September 27, 2019.

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

	Three Months Ended		
	September 25, 2020	September 27, 2019	Percentage Change
U.S.	$ 127.6	$ 134.1	(4.8)%
Europe, Middle East and Africa	28.4	24.9	14.1
Other	3.4	4.3	(20.9)
Net sales	$ 159.4	$ 163.3	(2.4)

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

	Three Months Ended		
	September 25, 2020	September 27, 2019	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 20.0	$ 15.7	27.4 %
Oxycodone (API) and oxycodone-containing tablets	16.1	17.2	(6.4)
Acetaminophen (API)	54.9	48.5	13.2
Other controlled substances	62.4	72.9	(14.4)
Other	6.0	9.0	(33.3)
Specialty Generics	$ 159.4	$ 163.3	(2.4)

Operating Income

Operating income by segment and as a percentage of segment net sales for the three months ended September 25, 2020 and September 27, 2019 is shown in the following table *(dollars in millions)*:

	Three Months Ended			
	September 25, 2020		September 27, 2019	
Specialty Brands	$ 291.8	54.1 %	$ 277.0	47.7 %
Specialty Generics	43.1	27.0	36.3	22.2
Segment operating income	334.9	47.9	313.3	42.1
Unallocated amounts:				
Corporate and unallocated expenses [1]	(42.1)		(15.3)	
Depreciation and amortization	(236.1)		(234.9)	
Share-based compensation	(4.3)		(7.8)	
Restructuring and related charges, net	(3.2)		(7.2)	
Separation costs	(33.0)		(19.8)	
R&D upfront payment [2]	—		(20.0)	
Opioid-related litigation settlement [3]	25.8		—	
Medicaid lawsuit (Note 11)	(0.5)		—	
Total operating loss	$ 41.5		$ 8.3	

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

(2) Represents R&D expense incurred related to an upfront payment made to Silence in connection with the license and collaboration agreement entered into during the three months ended September 27, 2019.

(3) Represents the change in the Settlement Warrants' fair value. Refer to Note 12 of the notes to the unaudited condensed consolidated financial statements for further information regarding the valuations of the Settlement Warrants.

Specialty Brands. Operating income for the three months ended September 25, 2020 increased $14.8 million, to $291.8 million, compared with $277.0 million for the three months ended September 27, 2019. Operating margin increased to 54.1% for the three months ended September 25, 2020 compared with 47.7% for the three months ended September 27, 2019. This increase in operating income and margin was primarily driven by a $26.1 million, or 19.4%, decrease in SG&A expenses compared with the three months ended September 27, 2019, primarily due to decreased professional fees, cost benefits gained from restructuring actions and decreased travel expense due to temporary travel restrictions from COVID-19. Additionally, R&D expenses decreased $17.0 million, or 23.8%,

compared with the three months ended September 27, 2019. These cost reductions were partially offset by a $28.3 million, or 5.9%, decrease in gross profit driven by the $40.8 million, or 7.0% decrease in net sales.

Specialty Generics. Operating income for the three months ended September 25, 2020 increased $6.8 million to $43.1 million, compared with $36.3 million for the three months ended September 27, 2019. Operating margin increased to 27.0% for the three months ended September 25, 2020, compared with 22.2% for the three months ended September 27, 2019. The increase in operating income and margin was primarily due to the $5.2 million decrease in SG&A expenses for the three months ended September 25, 2020, compared to the three months ended September 27, 2019. The decrease in SG&A was driven by opioid defense costs being considered non-recurring and excluded from segment operating income and presented as a corporate and unallocated expense on a go-forward basis, beginning in the first quarter of fiscal 2020, as a result of the Opioid-Related Litigation Settlement. In comparison, there were $7.8 million of opioid defense costs reflected in operating income during the three months ended September 27, 2019.

Corporate and unallocated expenses. Corporate and unallocated expenses were $42.1 million and $15.3 million for the three months ended September 25, 2020 and September 27, 2019, respectively. This increase was primarily driven by an $8.1 million increase in the fair value of our contingent consideration liabilities during the three months ended September 25, 2020, compared to a $25.8 million decrease during the three months ended September 27, 2019. The remaining decrease was attributable to a $28.2 million charge associated with the settlement of the MDL Track 1 Cases during the three months ended September 27, 2019, partially offset by opioid defense costs of $13.4 million being presented as a corporate and unallocated expense beginning in the first quarter of fiscal 2020, as a result of the Opioid-Related Litigation Settlement, as previously discussed.

Nine Months Ended September 25, 2020 Compared with Nine Months Ended September 27, 2019

Net Sales

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

	Nine Months Ended		Percentage Change
	September 25, 2020	September 27, 2019	
Specialty Brands	$ 1,553.0	$ 1,812.4	(14.3)%
Specialty Generics	512.7	545.2	(6.0)
Segment net sales	2,065.7	2,357.6	(12.4)
Medicaid lawsuit (Note 11)	(535.1)	—	*
Net sales	$ 1,530.6	$ 2,357.6	(35.1)

*Not meaningful

Specialty Brands. Net sales for the nine months ended September 25, 2020 decreased $259.4 million to $1,553.0 million, compared with $1,812.4 million for the nine months ended September 27, 2019. The decrease in net sales compared with the nine months ended September 27, 2019 was primarily driven by a $143.5 million, or 19.9% decrease in Acthar Gel net sales driven primarily by continued reimbursement challenges impacting new and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending, the prospective change to the Medicaid rebate calculation and reduced patient demand due to COVID-19 stay-at-home orders. Net sales for Ofirmev, Amitiza and Therakos decreased $56.2 million, or 20.6%, $19.4 million, or 12.3%, and $9.5 million, or 5.2%, respectively. The decrease in Ofirmev and Therakos net sales were primarily driven by the overall reduction in elective surgeries and stay-at-home directives, respectively, due to public health orders implemented as part of the COVID-19 pandemic, while the decrease in Amitiza net sales was primarily driven by volume. In addition, Other Specialty Brands products during the nine months ended September 27, 2019 includes $36.8 million of net sales related to BioVectra prior to the completion of the sale of this business in November 2019.

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

	Nine Months Ended		Percentage Change
	September 25, 2020	September 27, 2019	
U.S.	$ 1,421.6	$ 1,604.5	(11.4)%
Europe, Middle East and Africa	97.2	126.4	(23.1)
Other	34.2	81.5	(58.0)
Net sales	$ 1,553.0	$ 1,812.4	(14.3)

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

	Nine Months Ended		
	September 25, 2020	September 27, 2019	Percentage Change
Acthar Gel	$ 576.6	$ 720.1	(19.9)%
INOmax	438.5	427.6	2.5
Ofirmev	216.0	272.2	(20.6)
Therakos	174.1	183.6	(5.2)
Amitiza	138.2	157.6	(12.3)
Other	9.6	51.3	(81.3)
Specialty Brands	$ 1,553.0	$ 1,812.4	(14.3)

Specialty Generics. Net sales for the nine months ended September 25, 2020 decreased $32.5 million, or 6.0%, to $512.7 million, compared with $545.2 million for the nine months ended September 27, 2019. The decrease in net sales was primarily driven by decreases in Other controlled substances and Other Specialty Generics products of $41.9 million and $17.4 million, respectively. These decreases were partially offset by a $20.7 million or 40.4% increase in net sales for hydrocodone-related products compared to the nine months ended September 27, 2019.

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

	Nine Months Ended		
	September 25, 2020	September 27, 2019	Percentage Change
U.S.	$ 414.4	$ 440.4	(5.9)%
Europe, Middle East and Africa	87.8	92.2	(4.8)
Other	10.5	12.6	(16.7)
Net sales	$ 512.7	$ 545.2	(6.0)

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

	Nine Months Ended		
	September 25, 2020	September 27, 2019	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 71.9	$ 51.2	40.4 %
Oxycodone (API) and oxycodone-containing tablets	48.0	53.3	(9.9)
Acetaminophen (API)	154.5	143.1	8.0
Other controlled substances	223.8	265.7	(15.8)
Other	14.5	31.9	(54.5)
Specialty Generics	$ 512.7	$ 545.2	(6.0)

Operating Loss

Operating income by segment and as a percentage of segment net sales were as follows (dollars in millions):

	Nine Months Ended			
	September 25, 2020		September 27, 2019	
Specialty Brands [1]	$ 765.0	49.3 %	$ 894.2	49.3 %
Specialty Generics	155.5	30.3	125.4	23.0
Segment operating income	920.5	44.6	1,019.6	43.2
Unallocated amounts:				
Corporate and unallocated expenses [2]	(152.3)		(76.6)	
Depreciation and amortization	(675.5)		(723.5)	
Share-based compensation	(17.6)		(30.6)	
Restructuring and related charges, net	(15.8)		(11.2)	
Non-restructuring impairment charges	(63.5)		(113.5)	
Separation costs	(75.0)		(50.4)	
R&D upfront payment [3]	(5.0)		(20.0)	
Opioid-related litigation settlement [4]	34.1		—	
Medicaid lawsuit (Note 11)	(640.2)		—	
Total operating loss	$ (690.3)		$ (6.2)	

(1) Includes $10.0 million of inventory fair-value step up expense, primarily related to Amitiza, during the nine months ended September 27, 2019.

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

(3) Represents R&D expense incurred related to an upfront payment made to acquire product rights in Japan for terlipressin during the nine months ended September 25, 2020, and an upfront payment made to Silence in connection with the license and collaboration agreement entered into during the nine months ended September 27, 2019.

(4) Represents the change in the Settlement Warrants' fair value. Refer to Note 12 of the notes to the unaudited condensed consolidated financial statements for further information regarding the valuations of the Settlement Warrants.

Specialty Brands. Operating income for the nine months ended September 25, 2020 decreased $129.2 million to $765.0 million, compared with $894.2 million for the nine months ended September 27, 2019. Operating margin remained consistent at 49.3% for the nine months ended September 25, 2020 and the nine months ended September 27, 2019. The decrease in operating income is primarily driven by the $259.4 million, or 14.3%, decrease in net sales over the same period, which resulted in a $188.0 million decrease in gross profit. This was partially offset by a $38.8 million or 9.7% decrease in SG&A expenses primarily driven by lower professional fees, lower travel costs due to temporary travel restrictions for COVID-19, lower consulting and professional fees and a $20.0 million or 9.5% decrease in R&D expenses.

Specialty Generics. Operating income for the nine months ended September 25, 2020 increased $30.1 million to $155.5 million, compared with $125.4 million for the nine months ended September 27, 2019. Operating margin increased to 30.3% for the nine months ended September 25, 2020, compared with 23.0% for the nine months ended September 27, 2019. As a result of the Opioid-Related Litigation Settlement announced during the three months ended March 27, 2020, the corresponding opioid defense costs are considered to be non-recurring; therefore, such costs are excluded from segment operating income and presented as a corporate and unallocated expense on a go-forward basis. In comparison, there were $42.3 million of opioid defense costs reflected in operating income during the nine months ended September 27, 2019. This was partially offset by a decrease in gross profit driven by the decrease in net sales.

Corporate and unallocated expenses. Corporate and unallocated expenses were $152.3 million and $76.6 million for the nine months ended September 25, 2020 and September 27, 2019, respectively. This increase was primarily driven by opioid defense costs of $53.1 million being presented as a corporate and unallocated expense beginning during the nine months ended September 25, 2020, as a result of the Opioid-Related Litigation Settlement, as previously discussed, and a $2.4 million increase in the fair value of our contingent consideration liabilities during the nine months ended September 25, 2020, compared to a $23.5 million decrease during the three months ended September 27, 2019. The remaining increase is primarily related to employee compensation and benefits driven by certain changes made to the design of our long-term incentive compensation program in an effort to manage share usage and dilution and the approval of a key employee incentive program during the nine months ended September 25, 2020, both of which reflect the shorter-term nature of our new target opportunities. These increases were partially offset by a $28.2 million charge associated with the settlement of the MDL Track 1 Cases during the three months ended September 27, 2019 and lower professional and fees.

Liquidity and Capital Resources

Significant factors driving our liquidity position include cash flows generated from operating activities, financing transactions, capital expenditures, cash paid in connection with acquisitions and licensing agreements and cash received as a result of our

divestitures. We have historically generated and expect to continue to generate positive cash flows from operations. Our ability to fund our capital needs is impacted by our ongoing ability to generate cash from operations and access to capital markets.

On October 12, 2020, we voluntarily initiated Chapter 11 proceedings in the Bankruptcy Court to modify our capital structure, including restructuring portions of our debt, and resolve potential legal liabilities. We intend to use the Chapter 11 process to provide a fair, orderly, efficient and legally binding mechanism to implement a RSA that provides for a financial restructuring designed to strengthen our balance sheet and reduce our total debt by approximately $1,300.0 million, improving our financial position and allowing us to continue driving our strategic priorities and investing in the business to develop and commercialize therapies to improve health outcomes.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming we will continue as a going concern. The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated. As a result, we have concluded that management's plans at this stage do not alleviate substantial doubt about our ability to continue as a going concern. Consequently, our future cash from operations and access to capital markets may not provide adequate resources to fund our working capital needs, capital expenditures and strategic investments for the foreseeable future.

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

	Nine Months Ended	
	September 25, 2020	September 27, 2019
Net cash from:		
Operating activities	$ 294.7	$ 534.1
Investing activities	(36.4)	(95.0)
Financing activities	(180.6)	(265.2)
Effect of currency exchange rate changes on cash and cash equivalents	0.2	0.5
Net increase (decrease) in cash and cash equivalents	$ 77.9	$ 174.4

Operating Activities

Net cash provided by operating activities of $294.7 million for the nine months ended September 25, 2020 was attributable to a net loss of $791.7 million, adjusted for non-cash items of $1,028.9 million, driven by depreciation and amortization of $675.5 million, a $304.0 million reduction in our deferred income tax assets, and a non-cash impairment charge of $63.5 million. This net loss was offset by cash provided from net investment in working capital of $57.5 million, which was primarily driven by the recognition of the $640.2 million retrospective one-time charge related to the Acthar Gel Medicaid Retrospective Rebate as previously mentioned. Also included within this change in working capital was a $61.1 million decrease in accounts receivable, offset by a $431.2 million increase in net receivables related to income taxes driven by tax benefits from the CARES Act , a $116.3 million net cash outflow related to other assets and liabilities primarily driven by decreases in accrued payroll and accrued restructuring, a $52.4 million decrease in accounts payable and a $43.9 million increase in inventory.

Net cash provided by operating activities of $534.1 million for the nine months ended September 27, 2019 was primarily attributable to net income of $160.6 million, adjusted for non-cash items of $435.4 million driven by depreciation and amortization of $723.5 million and a non-cash impairment charge of $113.5 million, partially offset by a $301.9 million reduction in our deferred income tax liabilities and a $98.6 million gain on debt repurchased. Net investment in working capital utilized $61.9 million of cash flow from operating activities. Included within this change in working capital was an $88.0 million net cash outflow related to other assets and liabilities primarily driven by a $37.8 million decrease in accrued payroll liabilities, a $32.0 million increase in inventory, a $27.8 million decrease in accounts payable and a one-time payment of $15.4 million related to the legacy Questcor U.S. Department of Justice ("DOJ") settlement. This was partially offset by a $68.7 million decrease in accounts receivable.

Investing Activities

Net cash used in investing activities was $36.4 million for the nine months ended September 25, 2020, compared with $95.0 million for the nine months ended September 27, 2019. The $58.6 million change was primarily attributable to the $66.3 million decrease in capital expenditures. Under our term loan credit agreement, the proceeds from the sale of assets and businesses must be either reinvested into capital expenditures or business development activities within one year of the respective transaction or we are required to make repayments on our term loan. For further information, refer to "Debt and Capitalization" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Financing Activities

Net cash used in financing activities was $180.6 million for the nine months ended September 25, 2020, compared with $265.2 million for the nine months ended September 27, 2019. The $84.6 million decrease in cash outflows was attributable to a $110.5 million decrease in debt repayments, net of issuances, and a $2.1 million decrease in shares repurchased. Our current year debt repayments included a $119.8 million payment on the remaining principal amount of 2020 Notes and $14.8 million in aggregate payments on our variable-rate term loans. The significant components of our debt repayments during the nine months ended September 27, 2019 included aggregate debt repayments of $281.4 million on our variable-rate term loans, open market debt repurchases that aggregated to a total principal amount of $492.1 million and a repayment of $250.0 million on the receivable securitization program. These repayments were partially offset by a net draw of $680.0 million on our revolving credit facility.

Debt and Capitalization

As of September 25, 2020, the total debt principal was $5,288.2 million, all of which was classified as current as a result of the filing of the Chapter 11 Cases. The total debt principal as of September 25, 2020 was comprised of the following:

Variable-rate instruments:		
Term loan due September 2024	$	1,509.1
Term loan due February 2025		400.5
Revolving credit facility		900.0
Fixed-rate instruments		2,478.6
Debt principal	$	5,288.2

The variable-rate term loan interest rates are based on the London Inter-bank Offered Rate ("LIBOR"), subject to a minimum LIBOR level of 0.75% with interest payments generally expected to be payable every 90 days, and requires quarterly principal payments equal to 0.25% of the principal amount. As of September 25, 2020, our fixed-rate instruments have a weighted-average interest rate of 7.05% and pay interest at various dates throughout the fiscal year. As of September 25, 2020, we were fully drawn on our $900.0 million revolving credit facility.

In November 2015, our Board of Directors authorized us to reduce our outstanding debt at our discretion. As conditions warrant, and subject to limitations under Chapter 11, we may repurchase debt securities issued by us, in the open market, in privately negotiated transactions, by tender offer or otherwise.

2020 Notes

On April 7, 2020, we and Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC, two of our wholly owned subsidiaries ("Issuers"), entered into an exchange agreement (the "Exchange Agreement") with certain third parties (collectively, the "Exchanging Holders"). Pursuant to the Exchange Agreement, the Exchanging Holders agreed to exchange with the Issuers, on April 7, 2020, their holdings of the 2020 Notes issued by the Issuers (the "Existing Notes") (consisting of approximately $495.0 million aggregate principal amount of the Existing Notes) for new 10.00% First Lien Senior Secured Notes due 2025 issued by the Issuers (the "First Lien 2025 Notes"), at a rate of $1,000 of First Lien 2025 Notes for every $1,000 of Existing Notes exchanged (such exchange, the "Exchange"). The Issuers and Exchanging Holders consummated the Exchange on April 7, 2020.

Interest on the First Lien 2025 Notes is payable semi-annually in cash on April 15th and October 15th of each year, commencing on October 15, 2020.

The Issuers may redeem some or all of the First Lien 2025 Notes prior to April 15, 2022 by paying a "make-whole" premium. The Issuers may redeem some or all of the First Lien 2025 Notes on or after April 15, 2022 at specified redemption prices. In addition, prior to April 15, 2022, the Issuers may redeem up to 40% of the aggregate principal amount of the First Lien 2025 Notes with the net proceeds of certain equity offerings. The Issuers may also redeem all, but not less than all, of the First Lien 2025 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 First Lien 2025 Notes.

The Issuers are obligated to offer to repurchase (a) all of the First Lien 2025 Notes 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) First Lien 2025 Notes using asset sale proceeds at a price of 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain asset sales. These obligations are subject to certain qualifications and exceptions.

The First Lien 2025 Notes are subject to an indenture that 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 indenture could result in the acceleration of the First Lien 2025 Notes and could cause a cross-default that could result in the acceleration of our other indebtedness.

The First Lien 2025 Notes are jointly and severally guaranteed, subject to certain exceptions, on a secured, unsubordinated basis by us and each of our subsidiaries (other than the Issuers) (the "Note Guarantors") that guarantees the obligations under the Issuers' existing senior secured credit facilities.

The First Lien 2025 Notes and the guarantees thereof are secured by liens on the same assets of the Issuers and the Note Guarantors that are subject to liens securing the existing senior secured credit facilities, subject to certain exceptions.

On April 15, 2020, we paid in full the remaining approximately $119.8 million in principal amount of outstanding 2020 Notes at the maturity thereof with cash on hand.

As of September 25, 2020, we were in full compliance with the provisions and covenants associated with our debt agreements. The commencement of the Chapter 11 Cases on October 12, 2020 constituted an event of default under certain of our debt agreements. Accordingly, all long-term debt was classified as current on the unaudited condensed consolidated balance sheet as of September 25, 2020. However, any efforts to enforce payment obligations under the debt instruments are automatically stayed as a result of the Chapter 11 Cases. See Note 14 of the notes to the unaudited condensed consolidated financial statements for further information.

Commitments and Contingencies

Legal Proceedings

See Note 11 of the notes to the unaudited condensed consolidated financial statements for a description of the legal proceedings and claims as of September 25, 2020.

Guarantees

In disposing of assets or businesses, we have historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. We assess the probability of potential liabilities related to such representations, warranties and indemnities and adjust potential liabilities as a result of changes in facts and circumstances. We believe, given the information currently available, that their ultimate resolutions will not have a material adverse effect on our financial condition, results of operations and cash flows. These representations, warranties and indemnities are discussed in Note 10 of the notes to the unaudited condensed consolidated financial statements.

Off-Balance Sheet Arrangements

As of September 25, 2020, we had various letters of credit, guarantees and surety bonds totaling $31.2 million. There has been no change in our off-balance sheet arrangements during the nine months ended September 25, 2020.

Critical Accounting Policies and Estimates

The preparation of our unaudited condensed consolidated financial statements in conformity with accounting principles generally accepted in the U.S. (GAAP) requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities.

We believe that our accounting policies for revenue recognition, intangible assets, acquisitions, contingencies and income taxes are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. During the nine months ended September 25, 2020, there were no significant changes to these policies or in the underlying accounting assumptions and estimates used in the above critical accounting policies from those disclosed in our Annual Report on Form 10-K for the year ended December 27, 2019.

Forward-Looking Statements

We have made forward-looking statements in this Quarterly Report on Form 10-Q 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, 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," "could," "should" or the negative of these terms or similar expressions.

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

The risk factors included within Item 1A. of our Annual Report on Form 10-K for the fiscal year ended December 27, 2019 and within Part II, Item 1A of this Quarterly Report on Form 10-Q 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 filing date of this Quarterly Report on Form 10-Q. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of September 25, 2020, our outstanding debt included $1,909.6 million variable-rate debt on our senior secured term loans and $900.0 million outstanding borrowings on our senior secured revolving credit facility. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, quarterly interest expense would increase by approximately $7.0 million.

The remaining outstanding debt as of September 25, 2020 is fixed-rate debt. Changes in market interest rates generally affect the fair value of fixed-rate debt, but do not impact earnings or cash flows.

Currency Risk

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

The unaudited condensed consolidated statement of operations is exposed to currency risk from intercompany financing arrangements, which primarily consist of intercompany debt and intercompany cash pooling, where the denominated currency of the transaction differs from the functional currency of one or more of our subsidiaries. We performed a sensitivity analysis for these arrangements as of September 25, 2020 that measured the potential unfavorable impact to income from continuing operations before income taxes from a hypothetical 10.0% adverse movement in foreign exchange rates relative to the U.S. dollar, with all other variables held constant. The aggregate potential unfavorable impact from a hypothetical 10.0% adverse change in foreign exchange rates was $0.5 million aggregate potential as of September 25, 2020. This hypothetical loss does not reflect any hypothetical benefits that would be derived from hedging activities, including cash holdings in similar foreign currencies that we have historically utilized to mitigate our exposure to movements in foreign exchange rates.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended ("the Exchange Act"), is recorded, processed, summarized and reported within the specified time periods, and that such information is accumulated and communicated to management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 25, 2020 that have materially affected, or are likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

See Note 11 of the notes to the unaudited condensed consolidated financial statements for further description of the litigation, legal and administrative proceedings as of September 25, 2020.

Item 1A. Risk Factors.

Except for the risk factors included below, there have been no material changes to the risk factors previously disclosed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 27, 2019, filed with the SEC on February 26, 2020.

The plan of reorganization under Chapter 11 of the Bankruptcy Code (the "Plan") contemplates the cancellation of our ordinary shares without any value being delivered to shareholders. Any trading in our ordinary shares during the pendency of our Chapter 11 Cases is highly speculative and poses substantial risks to purchasers of our ordinary shares.

The Plan contemplates the cancellation of our ordinary shares. We have a significant amount of indebtedness and other liabilities that are senior to our current ordinary shares in our capital structure, and the Plan contemplates value being distributed in respect of such indebtedness and liabilities and not our shares. In addition, our existing ordinary shares have substantially decreased in value leading up to and during the Chapter 11 Cases. Accordingly, any trading in our ordinary shares during the pendency of our Chapter 11 Cases is highly speculative and poses substantial risks to purchasers of our ordinary shares.

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

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

Other significant risks associated with the Chapter 11 Cases that could result in material adverse effects on our business, financial condition, results of operations, and cash flows include or relate to the following:

- our ability to obtain the Bankruptcy Court’s approval with respect to motions or other requests made to the Bankruptcy Court in the Chapter 11 Cases, including maintaining control as debtors-in-possession;
- our ability to consummate the Plan;
- the effects of the filing of the Chapter 11 Cases on our business and the interests of various constituents, including our shareholders;
- the high costs of Chapter 11 Cases and related fees;
- our ability to maintain relationships with suppliers, customers, employees and other third parties as a result of the Chapter 11 Cases;
- Bankruptcy Court rulings in the Chapter 11 Cases as well as the outcome of all other pending litigation and the outcome of the Chapter 11 Cases in general;
- the length of time that we will operate with Chapter 11 protection and any resulting risk that we will not satisfy the milestones specified in the RSA and in our agreement with our secured lenders with respect to our use of their cash collateral;
- the availability of operating capital during the pendency of the Chapter 11 Cases, including any event that could terminate our right to continued access to the cash collateral of our lenders to use as operating capital;
- third-party motions in the Chapter 11 Cases, including motions which may be filed by the creditors’ committee that will be appointed in the Chapter 11 Cases, which may interfere with our ability to consummate the Plan;
- the potential adverse effects of the Chapter 11 Cases on our liquidity and results of operations;

- the feasibility of the Plan in light of possible changes in our business and its prospects;
- the adequacy of our cash balances at the time of our projected exit from the Chapter 11 Cases; and
- our ability to continue as a going concern.

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

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

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

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

There are certain material conditions we must satisfy under the RSA, including the timely satisfaction of milestones in the Chapter 11 Cases, which include the consummation of the Plan. Our ability to timely complete such milestones is subject to risks and uncertainties, many of which are beyond our control.

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

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

The Amended Proposed Opioid-Related Litigation Settlement and the Acthar Gel-Related Settlement are subject to certain contingencies and may not go into effect in their current form or at all, which may have an adverse impact on our ability to consummate the Plan and our business, financial condition, results of operations and cash flows.

The Amended Proposed Opioid-Related Litigation Settlement and the Acthar Gel-Related Settlement (collectively, the "Proposed Settlements") are neither final nor binding and there is no assurance that the necessary parties will agree to definitive documentation, that the contingencies to any agreement will be fulfilled or that any potential settlement agreement entered into by us will be on terms as favorable as the Proposed Settlements. In particular, each of the Proposed Settlements is subject to a number of conditions, many of which may not be satisfied. Among other things, the Proposed Settlements are intended to be implemented through the Plan, the timing and consummation of which is subject to various risks and uncertainties as described elsewhere in this Item 1A of this Quarterly Report on Form 10-Q.

Furthermore, subject to the satisfaction of the conditions to the Proposed Settlements, the consummation of the Proposed Settlements would become effective upon our emergence from the Chapter 11 bankruptcy process, the timing of which emergence is uncertain. The settlement process may use a significant portion of our resources and divert management’s attention from our day-to-day operations, all of which could harm our business. Furthermore, one or both of the Proposed Settlements may not be implemented or consummated in its or their current form, or at all, as a result of which we would be subject to continued litigation, which, in turn, could adversely impact our ability to consummate the Plan and result in us and/or our subsidiaries becoming subject to some or all of the liabilities that would have otherwise been settled. In such circumstances, our business, financial condition, results of operations and cash flows could be materially and adversely affected.

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

Even if the Plan or any other Chapter 11 plan of reorganization is consummated, we may continue to face a number of risks, such as changes in economic conditions, changes in our industry, changes in demand for our services and increasing expenses. Some of these risks become more acute when a case under the Bankruptcy Code continues for a protracted period without indication of how or when the case may be completed. As a result of these risks and others, we cannot guarantee that the Plan will achieve our stated goals or that we will be able to continue as a going concern.

Furthermore, even if our debts and other liabilities are reduced or discharged through the Plan, we may need to raise additional funds through public or private debt or equity financing or other various means to fund our business after the completion of the Chapter 11 Cases. Among other things, our revolving credit facility is set to expire on February 28, 2022, shortly after when we anticipate completing the Chapter 11 restructuring process, and will need to be paid off or refinanced at that time. Our access to additional financing may be limited, if it is available at all. Therefore, adequate funds may not be available when needed or may not be available on favorable terms, or at all.

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

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

Termination of our exclusive right to file a Chapter 11 plan and the exclusive right to solicit acceptances could result in competing plans of reorganization, which could have less favorable terms or result in significant litigation and expenses.

We currently have the exclusive right to file a Chapter 11 plan through and including February 9, 2021, and the exclusive right to solicit acceptances of any such plan through April 10, 2021. Such deadlines may be extended from time to time by the Bankruptcy Court "for cause" (as permitted by section 1121(d) of the Bankruptcy Code). However, it is also possible that (a) parties in interest could seek to shorten or terminate such exclusive plan filing and solicitation periods "for cause" (as permitted by section 1121(d) of the Bankruptcy Code)) or (b) that such periods could expire without extension.

If our exclusive plan filing and solicitation periods expire or are terminated, other parties in interest will be permitted to file alternative plans of reorganization. There can be no assurances that recoveries under any such alternative plan would be as favorable to creditors as the Plan. In addition, the proposal of competing plans of reorganization may entail significant litigation and significantly increase the expenses of administration of the Debtors' cases, which could deplete creditor recoveries under any plan.

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

During the Chapter 11 Cases, we expect our financial results to continue to be volatile as restructuring activities and expenses, contract terminations and rejections, and claims assessments significantly impact our Consolidated Financial Statements. As a result, our historical financial performance is likely not indicative of our financial performance after the date of the filing of the Chapter 11 Cases. In addition, if we emerge from Chapter 11, the amounts reported in subsequent consolidated financial statements may materially change relative to our historical consolidated financial statements, including as a result of revisions to our operating plans pursuant to the Plan. We also may be required to adopt fresh start accounting, in which case our assets and liabilities will be recorded at fair value as of the fresh start reporting date, which may differ materially from the recorded values of assets and liabilities on our consolidated balance sheets. Our financial results after the application of fresh start accounting may be different from historical trends.

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

The Bankruptcy Code provides that the confirmation of a plan of reorganization discharges a debtor from substantially all debts arising prior to consummation of a plan of reorganization. With few exceptions, all claims that arose prior to confirmation of a plan of reorganization (i) would be subject to compromise and/or treatment under the plan of reorganization and/or (ii) would be discharged in accordance with the Bankruptcy Code and the terms of the plan of reorganization. Any claims not ultimately discharged pursuant to

the plan of reorganization could be asserted against the reorganized entities and may have an adverse effect on our business, financial condition, results of operations and cash flows on a post-reorganization basis.

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

While the Chapter 11 Cases continue, our management will be required to spend a significant amount of time and effort focusing on the Chapter 11 Cases instead of focusing exclusively on our business operations. This diversion of attention may materially adversely affect the conduct of our business, and, as a result, our financial condition and results of operations, particularly if the Chapter 11 Cases are protracted.

Furthermore, during the pendency of the Chapter 11 Cases, we may experience increased levels of employee attrition, and our employees may face considerable distraction and uncertainty. A loss of key personnel or material erosion of employee morale could adversely affect our business and results of operations. Our ability to engage, motivate and retain key employees or take other measures intended to motivate and incentivize key employees to remain with us through the pendency of the Chapter 11 Cases is limited by restrictions on implementation of incentive programs under the Bankruptcy Code. The loss of services of members of our senior management team could impair our ability to execute our strategy and implement operational initiatives, which would be likely to have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, the longer the Chapter 11 Cases continue, the more likely it is that vendors and employees will lose confidence in our ability to reorganize our business successfully.

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

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

Our ordinary shares are quoted on the Pink Open Market, and thus may have a limited market and lack of liquidity.

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

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 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. 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 of November 3, 2020, the cases the Company is aware of include, but are not limited to, approximately 2,618 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 270 cases

filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 128 cases filed by individuals; approximately six cases filed by schools and school boards; and 17 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Nevada, South Dakota, New Hampshire, Louisiana, Illinois, Mississippi, West Virginia, Puerto Rico, Ohio, and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of November 3, 2020, the Mallinckrodt defendants in these cases consist of Mallinckrodt plc and the following subsidiaries of Mallinckrodt plc: Mallinckrodt Enterprises LLC, Mallinckrodt LLC, SpecGx LLC, Mallinckrodt Brand Pharmaceuticals Inc., Mallinckrodt Inc., MNK 2011 Inc., and Mallinckrodt Enterprises Holdings, Inc. However, there can be no assurance that plaintiffs will not assert claims against additional Mallinckrodt plc subsidiaries in the future. The lawsuits assert a variety of claims, including, but not limited to, public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") or similar state laws, violations of state CSA or state FCA, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment, negligence and negligent misrepresentation, and other common law and statutory claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent diversion. Other parties may file similar lawsuits against us in the future.

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. While we are vigorously defending ourselves in these matters, the nature and scope of these matters is unique and current public perceptions of the public health issue of opioid abuse, together with the manner in which other defendants in those cases resolve opioid-related lawsuits and other actions, may present challenges to favorable resolution of these claims. Accordingly, it is not feasible to predict the ultimate outcome of these investigations, enforcement actions and lawsuits if the Amended Proposed Opioid-Related Litigation Settlement is not consummated. The allegations against us may negatively affect our business in various ways, including through harm to our reputation. We will continue to incur significant legal costs in defending these matters and if the Amended Proposed Opioid-Related Litigation Settlement is not fully implemented or consummated, we could in the future be required to pay significant amounts as a result of fines, penalties, settlements or judgments, potentially in excess of established accruals. We may be unable to obtain or maintain insurance in the future on acceptable terms or with adequate coverage against potential liabilities or other losses. Any such potential liabilities or losses could also require us to seek financing, which may not be available on terms acceptable to us, or at all, when required. Such matters or the resolution thereof, or increase in accruals thereof, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 (the "OSA"), which went into effect on July 1, 2018 and established an aggregate $100.0 million annual assessment on sales of certain opioid medications in New York. The OSA was successfully 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. We disagree with the decision and continue to evaluate our options with respect to the decision. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that if the OSA decision is reversed on appeal, the OSA would apply only to the sale or distribution of certain opioids in New York for 2017 and 2018 and, effective July 1, 2019, imposed an excise tax on certain opioids. Furthermore, Rhode Island and Delaware have enacted opioid taxes, Minnesota and Maine have enacted increased licensure and registration fees and other states are considering 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 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 "Extensive laws and regulations govern the industry in which we operate, and any failure to comply with such laws and regulations, including any changes to those laws and regulations may materially adversely affect us." for more information.

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

Our business may be adversely affected by public health crises and epidemics/pandemics, including the recent coronavirus outbreak.

A pandemic, epidemic or outbreak of an infectious disease occurring in the U.S., or elsewhere, could result in our business being adversely affected. In December 2019, COVID-19, was identified in China, which has now spread to countries throughout the world, including Ireland, the United Kingdom and the U.S. and has resulted in the World Health Organization declaring the outbreak as a pandemic. Our business performance was significantly impacted by COVID-19 during the second quarter, and we continue to expect to see challenges while the pandemic persists and potentially thereafter.

We may experience significant and unpredictable increases or decreases in demand for certain of our products as the needs of health care providers and patients evolve during this pandemic. For example, as we are among the world's largest manufacturers of bulk acetaminophen and the only producer of acetaminophen in the North American and European regions, we could experience an increase in demand which we may not be able to meet in accordance with the needs of the market. Additionally, our INOmax product is a potential treatment for acute respiratory distress syndrome (ARDS), which is a known clinical manifestation of infection with many respiratory viruses including coronaviruses, which could be subject to similar dynamics. Alternatively, due to the deprioritization of non-critical medical treatment in the face of this pandemic, demand for our Ofirmev product was negatively affected in the second quarter and may continue to be negatively impacted. We also experienced and may continue to experience reduced demand for Therakos due to immunosuppressed patients who have been instructed to stay-at-home during the COVID-19 pandemic.

Furthermore, earlier this year U.S. President Trump invoked emergency powers under the Defense Production Act, which allows the U.S. government to direct private companies to meet the needs of the nation in the time of an emergency. Given the critical nature of some of the products we manufacture, as well as our pharmaceutical and medical device manufacturing capabilities, we may be impacted by governmental action taken under this or similar legislation.

Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Such disruptions could materially delay potential FDA approval with respect to our clinical trials and product candidates, including the FDA’s decision on our NDA for terlipressin. Other factors caused by the COVID-19 virus have already impacted and could materially delay or otherwise impact clinical trials we are conducting related to our products, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to the COVID-19 virus. Furthermore, business pressures driven by the ongoing COVID-19 pandemic have led us to prioritize certain investments over others, resulting in the termination of two of our Phase 4 studies related to Acthar Gel, and such pressures could result in similar decisions across our product portfolio. Any delays in our clinical trials or regulatory review resulting from such disruptions could materially affect the development or approval of our product candidates or our lifecycle management efforts.

In addition, the economic impact of the spread of the COVID-19 virus', which has caused a broad impact globally, has adversely impacted our business and may continue to adversely affect us. In particular, the COVID-19 virus has negatively affected demand for our products due to limitations on the ability of our sales representatives to meet with physicians, and a reduction in patient visits to their doctors and pharmacists in order to receive prescriptions for our products, all of which may continue so long as the pandemic does not abate. There is also an increased risk of supply interruption at our third-party suppliers to deliver components as well as our manufacturing facilities to produce finished products on a timely basis, which could result in business or operational disruption. Additionally, while the potential long-term economic impact of the COVID-19 virus may be difficult to assess or predict, COVID-19 pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital, thereby negatively affecting our liquidity. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted.

Given the rapid and evolving nature of the COVID-19 virus, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted.

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

Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities, private health coverage insurers and other third-party payers. The ability of patients to obtain appropriate reimbursement for products and services from these third-party payers affects the selection of products they purchase and the prices they are willing to pay. In the U.S., there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that third-party payers may pay to reimburse the cost of drugs, for example 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.

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 carriers, there are a large number of guideline updates issued each year.

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.

In addition, a number of markets 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. In May 2019, CMS issued a decision requiring that we revert to the base date AMP used to calculate Medicaid drug rebates for Acthar Gel. We subsequently filed suit in District Court against the HHS and CMS seeking to hold unlawful and set aside this decision. In March 2020, we received an adverse decision from the District Court which upheld CMS' decision to reverse its previous determination of the base date AMP used to calculate Acthar Gel rebates. On March 16, 2020, we filed an Emergency Motion for Reconsideration and Stay of Entry of Judgment Pending Reconsideration Or, Alternatively, Injunction Pending Appeal. In response, the government agreed that CMS would not require us to change the Medicaid rebate calculation for Acthar Gel until June 14, 2020, to allow the District Court time to decide our reconsideration motion. The District Court subsequently denied our reconsideration motion and in June 2020 we appealed the District Court's decision to the Court of Appeals and filed an Emergency Motion for Injunction Pending Appeal and to Expedite Briefing and Argument. The Court of Appeals subsequently denied our request for an injunction pending appeal on June 15, 2020.

As previously disclosed, we recorded an accrual of $640.2 million related to the Acthar Gel Medicaid Retrospective Rebate in the unaudited condensed consolidated balance sheet as of September 25, 2020, of which $535.1 million and $105.1 million have been reflected as a component of net sales and operating expenses, respectively, in the unaudited condensed consolidated statement of operations for the nine months ended September 25, 2020. The $105.1 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to the Company’s acquisition of Questcor in August 2014.

On October 12, 2020, we announced a settlement in principle, which is conditioned upon the Company entering the Chapter 11 restructuring process, to resolve various Acthar Gel-related matters, including the Medicaid lawsuit, an associated FCA lawsuit and an FCA lawsuit relating to the Acthar Gel-Related Settlement. We have agreed to pay $260.0 million over seven years and to reset Acthar Gel’s Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the settlement, we will dismiss its appeal, which is currently pending in the U.S. Court of Appeals for the D.C. Circuit. We expect that the Acthar Gel-Related Settlement – which would resolve the Medicaid lawsuit, the associated FCA lawsuit in Boston and an FCA lawsuit in the Eastern District of Pennsylvania relating to Acthar’s previous owner’s interactions with an independent charitable foundation – will be completed over the next several months, subject to Bankruptcy Court approval. The failure of the settlement in principle may subject us to additional risk and uncertainties that could adversely affect our business prospects, as further described above in the risk factor "The Amended Proposed Opioid-Related Litigation Settlement and the Acthar Gel-Related Settlement are subject to certain contingencies and may not go into effect in their current form or at all, which may have an adverse impact on our ability to consummate the Plan and 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, most notably in relation to Acthar Gel,

Ofirmev, INOmax, Therakos and Amitiza products. 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.

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.

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. (collectively "Praxair") 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 September 5, 2017 that ruled five patents invalid and six patents not infringed. We appealed the decision to the Court of Appeals for the Federal Circuit, which upheld the lower court's decision on August 27, 2019. We filed a petition for en banc review at the Federal Circuit on September 26, 2019, which the Federal Circuit denied on November 19, 2019. We filed a petition for a writ of certiorari with the United States Supreme Court on March 6, 2020 and the petition was denied on April 6, 2020. There has been limited commercial launch activity by Praxair. While Praxair received FDA approval of their Abbreviated New Drug Application ("ANDA") for their Noxivent nitric oxide and clearance of their 510(k) for their NOxBOXi device on October 2, 2018, the Noxivent product received an AA-rating and the Noxivent label states that Noxivent must be delivered using the NOxBOXi device. The adverse final outcome in the appeal of the Praxair litigation decision could result in the broader-scale launch of a competitive nitric oxide product before the expiration of the last of the patents listed in the FDA Orange Book: Approved Drug Products with Therapeutic Equivalence, which could adversely affect our ability to successfully maximize the value of INOmax and have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The active ingredient in Ofirmev is acetaminophen. Patent protection is not available for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as Ofirmev so long as the competitors do not infringe any process or formulation patents that we have in-licensed from Bristol Myers Squibb and its licensor, New Pharmatop LLC and any method-of-use patents that we subsequently obtained. The latest expiration date of the in-licensed patents is 2021 whereas the latest expiration date of the subsequently obtained Company-owned patents is 2032. Settlement agreements have been reached in association with certain challenges to the in-licensed patents, which allow for generic competition to Ofirmev in December 2020, or earlier under certain circumstances.

Our Therakos products focus on extracorporeal photopheresis ("ECP"), which is an autologous immune cell therapy that is indicated in the U.S. for skin manifestations of cutaneous T-cell lymphoma ("CTCL") and is available for several additional indications in markets outside the U.S. In the extracorporeal photopheresis 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 an Ultraviolet-A ("UVA") light activated drug, UVADEX® (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® Photopheresis System ("CELLEX"), which is the only FDA-approved closed ECP system, and the UVAR XTS® Photopheresis System ("UVAR XTS"). While we no longer manufacture the UVAR XTS system, disposable, sterile kits are still supplied to customers for each of the systems. The kits are single use and discarded after a treatment. Certain key patents related to the UVAR XTS system, disposable kit and overall photopheresis method expire in 2020. Key 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. Patent applications were filed in 2016 relating to improvements to the CELLEX system, disposable kit and overall photopheresis method, that, if approved, may offer patent protection through approximately 2036.

Our pending patent applications may not result in the issuance of patents, or the patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors. Existing patents may be found to be invalid or insufficiently broad to preclude our competitors from using methods or making or selling products similar or identical to those covered by our patents and patent applications. Regulatory agencies may refuse to grant us the market exclusivity that we were anticipating, or may unexpectedly

grant market exclusivity rights to other parties. In addition, our ability to obtain and enforce intellectual property rights is limited by the unique laws of each country. In some countries, it may be particularly difficult to adequately obtain or enforce intellectual property rights, which could make it easier for competitors to capture market share in such countries by utilizing technologies and product features that are similar or identical to those developed or licensed by us. Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our patents, including by coupling separate technologies to replicate what our products accomplish through a single system. Competitors may diminish the value of our trade secrets by reverse engineering or by independent invention. Additionally, current or former employees may improperly disclose such trade secrets to competitors or other third parties. We may not become aware of any such improper disclosure, and, in the event we do become aware, we may not have an adequate remedy available to us.

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(c) Issuer Purchases of Securities

The following table summarizes the repurchase activity of our ordinary shares during the three months ended September 25, 2020. The repurchase activity presented below is limited to deemed repurchases in connection with the vesting of restricted share units under employee benefit plans to satisfy minimum statutory tax withholding obligations as there were no market repurchases during the three months ended September 25, 2020.

On March 1, 2017, the Company's Board of Directors authorized a $1.0 billion share repurchase program (the "March 2017 Program") which commenced upon the completion of the March 2016 Program. The March 2017 Program has no expiration date.

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under Plans or Programs (in millions)
June 27, 2020 to July 24, 2020	4,861	$ 2.43	—	$ 564.2
July 25, 2020 to August 28, 2020	5,222	2.22	—	564.2
August 29, 2020 to September 25, 2020	652	1.79	—	564.2
June 27, 2020 to September 25, 2020	**10,735**	**2.29**		

Item 3. Defaults Upon Senior Securities.

The information set forth in Note 14 of the notes to the unaudited condensed consolidated financial statements included under Part 1. "Item 1. Financial Statements" of this quarterly report is incorporated into this item by reference.

Item 5. Other Information.

On November 3, 2020, the Company’s Board of Directors approved the waiver of share ownership requirements applicable to non-employee directors and executive officers for the duration of the Chapter 11 Cases.

Item 6. Exhibits.

Exhibit Number	Exhibit
10.1	Form of 2020/2021 ERBP Award Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 8, 2020).
10.2	Restructuring Support Agreement, dated October 11, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 13, 2020).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File (Form 10-Q for the quarterly period ended September 25, 2020 filed in XBRL). The financial information contained in the XBRL-related documents is "unaudited" and "unreviewed." The instance document does not appear in the interactive file because its XBRL tags are embedded within the inline XBRL document.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MALLINCKRODT PLC

By: /s/ Bryan M. Reasons

Bryan M. Reasons
Executive Vice President and Chief Financial Officer
(principal financial officer)

Date: November 3, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark C. Trudeau, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Mallinckrodt plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2020

By: /s/ Mark C. Trudeau
Mark C. Trudeau
President and Chief Executive Officer and Director (principal executive officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Bryan M. Reasons, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Mallinckrodt plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2020

By: /s/ Bryan M. Reasons
Bryan M. Reasons
Executive Vice President and Chief Financial Officer (principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned officers of Mallinckrodt plc ("the Company") hereby certify to their knowledge that the Company's quarterly report on Form 10-Q for the period ended September 25, 2020 ("the Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Mark C. Trudeau

Mark C. Trudeau

President and Chief Executive Officer and Director (principal executive officer)

November 3, 2020

By: /s/ Bryan M. Reasons

Bryan M. Reasons

Executive Vice President and Chief Financial Officer (principal financial officer)

November 3, 2020