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 27, 2019

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.)**

3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey TW18 3AG, United Kingdom
(Address of principal executive offices) (Zip Code)

Telephone: +44 017 8463 6700
(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	MNK	New York Stock Exchange

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 ☒

Indicate number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:
Ordinary shares, $0.20 par value - 84,093,367 shares as of November 1, 2019.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Net sales	$ 743.7	$ 799.9	$ 2,357.6	$ 2,380.7
Cost of sales	419.4	433.5	1,309.3	1,272.8
Gross profit	324.3	366.4	1,048.3	1,107.9
Selling, general and administrative expenses	205.7	193.4	661.8	594.5
Research and development expenses	103.1	86.1	268.0	260.7
Restructuring charges, net	7.2	14.8	11.2	101.8
Non-restructuring impairment charges	—	2.0	113.5	2.0
Loss on divestiture	—	0.6	—	0.6
Operating income (loss)	8.3	69.5	(6.2)	148.3
Interest expense	(77.6)	(93.6)	(231.8)	(280.1)
Interest income	2.9	2.0	6.6	6.6
Other income, net	37.9	13.4	128.6	17.8
Loss from continuing operations before income taxes	(28.5)	(8.7)	(102.8)	(107.4)
Income tax benefit	(27.6)	(122.9)	(256.6)	(203.9)
(Loss) income from continuing operations	(0.9)	114.2	153.8	96.5
(Loss) income from discontinued operations, net of income taxes	(0.2)	(0.4)	6.8	14.9
Net (loss) income	$ (1.1)	$ 113.8	$ 160.6	$ 111.4
Basic earnings per share (Note 7):				
(Loss) income from continuing operations	$ (0.01)	$ 1.37	$ 1.84	$ 1.15
(Loss) income from discontinued operations	—	—	0.08	0.18
Net (loss) income	$ (0.01)	$ 1.37	$ 1.92	$ 1.32
Basic weighted-average shares outstanding	84.0	83.2	83.8	84.2
Diluted earnings per share (Note 7):				
(Loss) income from continuing operations	$ (0.01)	$ 1.34	$ 1.83	$ 1.13
(Loss) income from discontinued operations	—	—	0.08	0.17
Net (loss) income	$ (0.01)	$ 1.34	$ 1.91	$ 1.31
Diluted weighted-average shares outstanding	84.0	85.0	84.2	85.2

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended		Nine Months Ended	
	September 27, 2019	**September 28, 2018**	**September 27, 2019**	**September 28, 2018**
Net (loss) income	$ (1.1)	$ 113.8	$ 160.6	$ 111.4
Other comprehensive (loss) income, net of tax:				
Currency translation adjustments	(2.1)	3.2	1.6	(4.1)
Derivatives, net of tax	0.3	0.2	1.0	0.7
Benefit plans, net of tax	(0.2)	(0.4)	(0.9)	(0.9)
Total other comprehensive (loss) income, net of tax	(2.0)	3.0	1.7	(4.3)
Comprehensive (loss) income	$ (3.1)	$ 116.8	$ 162.3	$ 107.1

See Notes to Condensed Consolidated Financial Statements.

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

	September 27, 2019	December 28, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 498.8	$ 348.9
Accounts receivable, less allowance for doubtful accounts of $4.5 and $5.0	538.8	623.3
Inventories	325.5	322.3
Prepaid expenses and other current assets	122.2	132.7
Assets held for sale	175.9	—
Total current assets	1,661.2	1,427.2
Property, plant and equipment, net	894.7	982.0
Intangible assets, net	7,496.1	8,282.8
Other assets	304.1	185.3
Total Assets	$ 10,356.1	$ 10,877.3
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 716.1	$ 22.4
Accounts payable	100.9	147.5
Accrued payroll and payroll-related costs	83.7	124.0
Accrued interest	90.9	77.6
Accrued and other current liabilities	506.5	572.2
Liabilities held for sale	55.8	—
Total current liabilities	1,553.9	943.7
Long-term debt	5,048.7	6,069.2
Pension and postretirement benefits	58.6	60.5
Environmental liabilities	60.3	59.7
Deferred income taxes	22.0	324.3
Other income tax liabilities	253.5	228.0
Other liabilities	278.7	304.6
Total Liabilities	7,275.7	7,990.0
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; 93,427,563 and 92,705,747 issued; 84,078,103 and 83,323,877 outstanding	18.7	18.5
Ordinary shares held in treasury at cost, 9,349,460 and 9,381,870	(1,615.6)	(1,617.4)
Additional paid-in capital	5,559.2	5,528.2
Retained deficit	(859.8)	(1,017.7)
Accumulated other comprehensive loss	(22.1)	(24.3)
Total Shareholders' Equity	3,080.4	2,887.3
Total Liabilities and Shareholders' Equity	$ 10,356.1	$ 10,877.3

See Notes to Condensed Consolidated Financial Statements.

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

	Nine Months Ended	
	September 27, 2019	**September 28, 2018**
Cash Flows From Operating Activities:		
Net income	$ 160.6	$ 111.4
Adjustments to reconcile net cash from operating activities:		
Depreciation and amortization	723.5	597.0
Share-based compensation	30.6	27.9
Deferred income taxes	(301.9)	(232.7)
Non-cash impairment charges	113.5	2.0
Loss on divestiture	—	0.6
Gain on repurchase of debt	(98.6)	(6.5)
Other non-cash items	(31.7)	2.8
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	68.7	(59.0)
Inventories	(32.0)	43.1
Accounts payable	(27.8)	(0.1)
Income taxes	17.2	16.7
Other	(88.0)	(22.1)
Net cash from operating activities	534.1	481.1
Cash Flows From Investing Activities:		
Capital expenditures	(108.7)	(93.3)
Acquisitions, net of cash	—	(699.9)
Proceeds from divestitures, net of cash	—	313.2
Other	13.7	28.8
Net cash from investing activities	(95.0)	(451.2)
Cash Flows From Financing Activities:		
Issuance of external debt	695.0	657.2
Repayment of external debt	(940.1)	(1,563.4)
Debt financing costs	—	(12.0)
Proceeds from exercise of share options	0.5	1.0
Repurchase of shares	(2.5)	(57.4)
Other	(18.1)	(24.3)
Net cash from financing activities	(265.2)	(998.9)
Effect of currency rate changes on cash	0.5	(0.9)
Net change in cash, cash equivalents and restricted cash, including cash classified within assets held for sale	174.4	(969.9)
Less: Net change in cash classified within assets held for sale	(15.1)	—
Net change in cash, cash equivalents and restricted cash	159.3	(969.9)
Cash, cash equivalents and restricted cash at beginning of period	367.5	1,279.1
Cash, cash equivalents and restricted cash at end of period	$ 526.8	$ 309.2
Cash and cash equivalents at end of period	$ 498.8	$ 290.7
Restricted cash included in other assets at end of period	28.0	18.5
Cash, cash equivalents and restricted cash at end of period	$ 526.8	$ 309.2

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
For the nine months ended September 27, 2019
(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
Currency translation adjustments	—	—	—	—	—	—	1.4	1.4
Change in derivatives, net of tax	—	—	—	—	—	—	0.2	0.2
Change in benefit plans, net of tax	—	—	—	—	—	—	(0.3)	(0.3)
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
Currency translation adjustments	—	—	—	—	—	—	2.3	2.3
Change in derivatives, net of tax	—	—	—	—	—	—	0.5	0.5
Change in benefit plans, net of tax	—	—	—	—	—	—	(0.4)	(0.4)
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 loss	—	—	—	—	—	(1.1)	—	(1.1)
Currency translation adjustments	—	—	—	—	—	—	(2.1)	(2.1)
Change in derivatives, net of tax	—	—	—	—	—	—	0.3	0.3
Change in benefit plans, net of tax	—	—	—	—	—	—	(0.2)	(0.2)
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

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
For the nine months ended September 28, 2018
(unaudited, in millions)

	Ordinary Shares		Treasury Shares		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Number	Par Value	Number	Amount				
Balance as of December 29, 2017	92.2	$ 18.4	5.9	$ (1,564.7)	$ 5,492.6	$ 2,588.6	$ (12.9)	$ 6,522.0
Impact of accounting standard adoptions, net of tax	—	—	—	—	—	2.6	(1.5)	1.1
Net loss	—	—	—	—	—	(18.0)	—	(18.0)
Currency translation adjustments	—	—	—	—	—	—	(2.3)	(2.3)
Change in derivatives, net of tax	—	—	—	—	—	—	0.4	0.4
Change in benefit plans, net of tax	—	—	—	—	—	—	(0.5)	(0.5)
Vesting of restricted shares	0.3	0.1	—	(1.4)	—	—	—	(1.3)
Share-based compensation	—	—	—	—	4.6	—	—	4.6
Reissuance of treasury shares	—	—	—	0.8	—	(0.3)	—	0.5
Repurchase of shares	—	—	2.9	(45.2)	—	—	—	(45.2)
Balance as of March 30, 2018	92.5	$ 18.5	8.8	$ (1,610.5)	$ 5,497.2	$ 2,572.9	$ (16.8)	$ 6,461.3
Net income	—	—	—	—	—	15.6	—	15.6
Currency translation adjustments	—	—	—	—	—	—	(5.0)	(5.0)
Change in derivatives, net of tax	—	—	—	—	—	—	0.1	0.1
Vesting of restricted shares	—	—	0.1	(0.2)	(0.1)	—	—	(0.3)
Share-based compensation	—	—	—	—	11.8	—	—	11.8
Reissuance of treasury shares	—	—	(0.1)	1.6	—	(0.7)	—	0.9
Repurchase of shares	—	—	0.7	(10.0)	—	—	—	(10.0)
Balance as of June 29, 2018	92.5	$ 18.5	9.5	$ (1,619.1)	$ 5,508.9	$ 2,587.8	$ (21.7)	$ 6,474.4
Net income	—	—	—	—	—	113.8	—	113.8
Currency translation adjustments	—	—	—	—	—	—	3.2	3.2
Change in derivatives, net of tax	—	—	—	—	—	—	0.2	0.2
Change in benefit plans, net of tax	—	—	—	—	—	—	(0.4)	(0.4)
Vesting of restricted shares	0.2	—	—	(0.6)	0.9	—	—	0.3
Share-based compensation	—	—	—	—	11.5	—	—	11.5
Reissuance of treasury shares	—	—	(0.1)	1.2	—	(0.6)	—	0.6
Balance as of September 28, 2018	92.7	$ 18.5	9.4	$ (1,618.5)	$ 5,521.3	$ 2,701.0	$ (18.7)	$ 6,603.6

See Notes to Condensed Consolidated Financial Statements.

1. Background and Basis of Presentation

Background

Mallinckrodt plc is a global business consisting 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 (inclusive of Amitiza® (lubiprostone) ("Amitiza"); and
- *Specialty Generics* includes niche specialty generic drugs and active pharmaceutical ingredients ("API(s)").

During the nine months ended September 27, 2019, the Company experienced a change in its reportable segments, which primarily served to move the results related to Amitiza to the Specialty Brands segment from the Specialty Generics segment. All prior period segment information has been recast to reflect the realignment of the Company's reportable segments on a comparable basis.

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% 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. 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 28, 2018 filed with the U.S. Securities and Exchange Commission ("SEC") on February 26, 2019.

Beginning in the first quarter through the third quarter of fiscal 2018, the historical financial results attributable to "the Specialty Generics Disposal Group" were reflected in the Company's interim unaudited condensed consolidated financial statements as discontinued operations. As a result of the December 6, 2018 spin-off announcement of the Specialty Generics business, the Specialty Generics Disposal Group no longer met the requirements to be classified as held for sale, and the historical financial results attributable to the Specialty Generics Disposal Group were recast as continuing operations in the Company's Annual Report on Form 10-K for the fiscal year ended December 28, 2018, as well as the unaudited condensed consolidated financial statements for the prior periods as presented herein. During the three months ended September 27, 2019, the Company announced that it had suspended for now its previously announced plans to spin off the Specialty Generics business.

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 27, 2019 refers to the thirteen and thirty-nine week periods ended September 27, 2019 and the three and nine months ended September 28, 2018 refers to the thirteen and thirty-nine week periods ended September 28, 2018.

2. Recently Issued Accounting Standards

The Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2018-02, "Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income," in February 2018. This ASU allows for a reclassification from accumulated other comprehensive income ("AOCI") to retained earnings for the stranded tax effects arising from the change in the reduction of the U.S. federal statutory income tax rate from 35% to 21%. The Company adopted this standard as of day 1 of fiscal 2019, which resulted in a reclassification between AOCI and retained deficit of $0.5 million, and had no impact on the Company's results of operations or financial position.

The FASB issued ASU 2016-02, "Leases," in February 2016. This ASU was issued to increase transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset. The FASB subsequently issued additional ASUs to clarify the guidance of ASU 2016-02 ("Topic 842,") as amended. The Company adopted this standard as of day 1 of fiscal 2019 utilizing the modified transition approach expedient, which allows an entity to elect not to recast its comparative periods in the period of adoption. In addition, the Company elected to use the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification. The Company also elected the hindsight practical expedient to determine the lease term for existing leases. Adoption of the new standard resulted in the recording of additional lease assets and corresponding liabilities of $83.1 million and $99.7 million, respectively, as of day 1 of fiscal 2019. Refer to Note 10 for further details on the Company's leases.

3. Revenue from Contracts with Customers

Product Sales Revenue

See Note 17 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 29, 2017	$ 327.4	$ 34.5	$ 14.7	$ 376.6
Provisions	1,644.5	32.0	47.5	1,724.0
Payments or credits	(1,623.9)	(30.5)	(47.2)	(1,701.6)
Balance as of September 28, 2018	$ 348.0	$ 36.0	$ 15.0	$ 399.0
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

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

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Product sales transferred at a point in time	81.4%	83.1%	81.7%	82.8%
Product sales transferred over time	18.6%	16.9%	18.3%	17.2%

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 27, 2019:

Remainder of Fiscal 2019	$ 44.6
Fiscal 2020	168.3
Fiscal 2021	72.4
Fiscal 2022	16.5
Thereafter	6.2

Costs to fulfill a contract

As of September 27, 2019 and December 28, 2018, 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 $26.4 million and $28.4 million, respectively, and are 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 27, 2019 and September 28, 2018 was $5.1 million and $8.5 million, respectively.

Product Royalty Revenues

The Company licenses certain rights to 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% to 26% with the royalty rate resetting every year. The associated royalty revenue recognized was as follows:

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Royalty revenue	$ 19.5	$ 22.5	$ 56.3	$ 52.1

Royalty revenue for the three and nine months ended September 28, 2018 reflects royalty revenue for the period subsequent to the Company's February 2018 acquisition of Sucampo Pharmaceuticals, Inc. ("Sucampo Acquisition").

Contract Liabilities

The following table reflects the balance of the Company's contract liabilities at the end of the respective periods:

	September 27, 2019	December 28, 2018
Accrued and other current liabilities	$ 5.9	$ 20.4
Other liabilities	0.6	15.1
Contract liabilities	$ 6.5	$ 35.5

Revenue recognized during the nine months ended September 27, 2019 from amounts included in contract liabilities at the beginning of the period was $10.3 million inclusive of the Company's wholly owned subsidiary BioVectra Inc. ("BioVectra"), which was classified as held for sale as of September 27, 2019.

4. Divestitures

In September 2019, the Company entered into an agreement to sell BioVectra to an affiliate of H.I.G. Capital for up to $250.0 million, including fixed consideration of $175.0 million, comprised of an upfront payment of $135.0 million and a long-term note for $40.0 million and contingent payments of up to $75.0 million. See Note 19 for updates to the deal structure that were made in conjunction with the completed sale of BioVectra on November 4, 2019.

The results related to BioVectra are reported under the Specialty Brands segment.

The following table summarizes the assets and liabilities of BioVectra that are classified as held for sale on the unaudited condensed consolidated balance sheet at the end of the respective period:

	September 27, 2019
Carrying amounts of major classes of assets included as held for sale	
Accounts receivable	$ 15.6
Inventories	14.7
Property, plant and equipment, net	103.4
Intangible assets, net	14.5
Other current and non-current assets	27.7
Total assets classified as held for sale on the balance sheet	$ 175.9
Carrying amounts of major classes of liabilities included as held for sale	
Accounts payable	$ 9.9
Other current and non-current liabilities	45.9
Total liabilities classified as held for sale on the balance sheet	$ 55.8

5. Restructuring and Related Charges

In July 2016, the Company's Board of Directors approved a $100.0 million to $125.0 million restructuring program (the "2016 Mallinckrodt Program"), designed to further improve its cost structure as the Company continues to transform its business. The 2016 Mallinckrodt Program included actions across the Specialty Brands segment and the Specialty Generics segment, as well as within the corporate functions. The 2016 Mallinckrodt Program was substantially completed in fiscal 2018.

In February 2018, the Company's Board of Directors approved a $100.0 million to $125.0 million restructuring program (the "2018 Mallinckrodt Program") that is of similar design as the 2016 Mallinckrodt Program. The utilization of the 2018 Mallinckrodt Program commenced upon substantial completion of the 2016 Mallinckrodt Program. There is no specified time period associated with the 2018 Mallinckrodt Program.

In addition to the 2018 and 2016 Mallinckrodt 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 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Specialty Brands	$ —	$ 4.9	$ 0.4	$ 52.4
Specialty Generics	6.7	0.1	9.3	5.3
Corporate	0.5	14.6	1.5	48.9
Restructuring and related charges, net	7.2	19.6	11.2	106.6
Less: accelerated depreciation	—	(4.8)	—	(4.8)
Restructuring charges, net	$ 7.2	$ 14.8	$ 11.2	$ 101.8

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

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
2018 Mallinckrodt Program	$ 6.7	$ 5.2	$ 9.3	$ 5.2
2016 Mallinckrodt Program	0.5	9.8	2.7	70.2
Acquisition Programs	—	4.6	(0.8)	31.2
Total	7.2	19.6	11.2	106.6
Less: non-cash charges, including accelerated depreciation	—	(4.8)	—	(4.8)
Total charges expected to be settled in cash	$ 7.2	$ 14.8	$ 11.2	$ 101.8

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

	2018 Mallinckrodt Program	2016 Mallinckrodt Program	Acquisition Programs	Total
Balance as of December 28, 2018	$ 2.2	$ 61.0	$ 7.8	$ 71.0
Charges	10.4	3.1	—	13.5
Changes in estimate	(1.1)	(0.4)	(0.8)	(2.3)
Cash payments	(6.9)	(12.3)	(1.9)	(21.1)
Reclassifications [1]	—	(5.0)	(4.3)	(9.3)
Currency translation	—	(1.7)	—	(1.7)
Balance as of September 27, 2019	$ 4.6	$ 44.7	$ 0.8	$ 50.1

(1) Represents the reclassification of lease liabilities, net to lease liabilities and lease assets, which are reflected within other liabilities and other assets on the unaudited condensed consolidated balance sheet, due to the adoption of ASU 2016-02.

As of September 27, 2019, net restructuring and related charges incurred cumulative to date were as follows:

	2018 Mallinckrodt Program	2016 Mallinckrodt Program
Specialty Brands	$ 3.0	$ 82.2
Specialty Generics	9.3	14.6
Corporate	2.2	28.1
	$ 14.5	$ 124.9

All of the restructuring reserves were included in accrued and other current liabilities on the Company's unaudited condensed consolidated balance sheets.

6. Income Taxes

The Company recognized 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, and an income tax benefit of $122.9 million on a loss from continuing operations before income taxes of $8.7 million for the three months ended September 28, 2018. This resulted in effective tax rates of 96.8% and 1,412.6% for the three months ended September 27, 2019 and September 28, 2018, respectively. 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, which was predominately related to previously acquired intangibles and the generation of tax loss and credit carryforwards net of valuation allowances. The income tax benefit for the three months ended September 28, 2018 was comprised of $8.5 million of current tax expense and $131.4 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles and the generation of net operating losses.

The Company recognized 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, and an income tax benefit of $203.9 million on a loss from continuing

operations before income taxes of $107.4 million for the nine months ended September 28, 2018. This resulted in effective tax rates of 249.6% and 189.9% for the nine months ended September 27, 2019 and September 28, 2018, respectively. 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 charge, as well as the reorganization of the Company's intercompany financing and associated legal entity ownership, which eliminated the interest-bearing deferred tax obligation. The income tax benefit for the nine months ended September 28, 2018 was comprised of $29.8 million of current tax expense and $233.7 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles and the generation of net operating losses.

The income tax benefit was $27.6 million for the three months ended September 27, 2019, compared with a tax benefit of $122.9 million for the three months ended September 28, 2018. The $95.3 million net decrease in the tax benefit included a $92.5 million decrease attributed to the tax benefit from the reorganization of the Company's intercompany financing and associated legal entity ownership, a $18.6 million decrease attributed to changes in the timing, amount and jurisdictional mix of income, partially offset by an increase in tax benefit of $9.3 million attributable to an adjustment to the fiscal 2018 income tax provision for various tax return filings and a $6.5 million increase attributed to separation costs.

The income tax benefit was $256.6 million for the nine months ended September 27, 2019, compared with a tax benefit of $203.9 million for the nine months ended September 28, 2018. The $52.7 million net increase in the tax benefit included an increase of $97.2 million attributed to the tax benefit from the reorganization of the Company's intercompany financing and associated legal entity ownership, a $10.1 million increase attributed to separation costs, and an $8.5 million increase attributed to the non-restructuring impairment charge, partially offset by a decrease in tax benefit of $41.8 million predominately attributed to changes in the timing, amount and jurisdictional mix of income, a $11.2 million decrease attributed to net restructuring and related charges and a $10.1 million decrease attributed to the gain on debt repurchased.

During the nine months ended September 27, 2019, the Company completed a reorganization of its intercompany financing and associated legal entity ownership in response to the changing global tax environment. As a result, during the nine months ended September 27, 2019, the Company recognized current income tax expense of $28.9 million and a deferred income tax benefit of $215.7 million with a corresponding reduction to net deferred tax liabilities. The reduction in net deferred tax liabilities was comprised of a decrease in interest-bearing deferred tax obligations which resulted in the elimination of the December 28, 2018 balance of $227.5 million, a $35.4 million increase to a deferred tax asset related to excess interest carryforwards, a $26.4 million increase in various other net deferred tax liabilities and a $20.8 million decrease to a deferred tax asset related to tax loss and credit carryforwards net of valuation allowances. The elimination of the interest-bearing deferred tax obligation also eliminated the annual Internal Revenue Code section 453A interest expense.

During the nine months ended September 27, 2019, and the fiscal year ended December 28, 2018, the net cash payments for income taxes were $30.1 million and $12.4 million, respectively. During the three months ended June 28, 2019, the Company filed its U.S. Federal income tax return for the period ended September 28, 2018 reporting a U.S. Federal net operating loss carryforward expiring in fiscal 2038. As of September 27, 2019, the Company’s U.S. Federal net operating loss carryforward was $849.3 million ($178.4 million measured at applicable statutory tax rates and net of uncertain tax positions).

On August 5, 2019, the Internal Revenue Service ("IRS") proposed an adjustment to the taxable income of Mallinckrodt Hospital Products Inc. (“MHP”) (formerly known as Cadence Pharmaceuticals, Inc.) as a result of its findings in the audit of MHP’s tax year ended September 26, 2014. The proposed adjustment to taxable income of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of the Company’s U.S. Federal net operating loss carryforward of $849.3 million. The Company strongly disagrees with the proposed adjustment and intends to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. See Note 15 for further details.

The Company's unrecognized tax benefits, excluding interest, totaled $439.4 million and $287.7 million as of September 27, 2019 and December 28, 2018, respectively. The net increase of $151.7 million primarily resulted from a net increase to current year tax positions of $152.3 million, net increases from prior period tax positions of $13.5 million, a net decrease from settlements of $1.0 million and a net decrease from a lapse of statute of limitations of $13.1 million. If favorably settled, $429.9 million of unrecognized tax benefits as of September 27, 2019 would benefit the effective tax rate, of which up to $20.0 million may be reported in discontinued operations. The total amount of accrued interest and penalties related to these obligations was $43.4 million and $37.1 million as of September 27, 2019 and December 28, 2018, respectively.

It is reasonably possible that within the next twelve months the unrecognized tax benefits could decrease by up to $111.2 million and the amount of related interest and penalties could decrease by up to $33.3 million as a result of payments or releases due to the resolution of various U.K. and non-U.K. examinations, appeals and litigation and the expiration of various statutes of limitation.

Due to a legislative change during the nine months ended September 27, 2019, the overall corporate income tax rate in Luxembourg has decreased from 26.0% to 24.9% effective January 1, 2019. As a result, the Company's net deferred tax assets associated with the Luxembourg jurisdiction decreased by approximately $65.8 million, and the associated valuation allowances were also decreased by this same amount.

7. Earnings per Share

Basic earnings per share is computed by dividing net income by the number of weighted-average shares outstanding during the period. Diluted earnings 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 calculates 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 per share were as follows (*in millions*):

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Basic	84.0	83.2	83.8	84.2
Dilutive impact of restricted share units and share options	—	1.8	0.4	1.0
Diluted	84.0	85.0	84.2	85.2

The computation of diluted weighted-average shares outstanding for both the three and nine months ended September 27, 2019 excluded approximately 7.1 million shares of equity awards, and for both the three and nine months ended September 28, 2018 excluded approximately 3.4 million shares of equity awards, because the effect would have been anti-dilutive.

8. Inventories

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

	September 27, 2019	December 28, 2018
Raw materials and supplies	$ 56.6	$ 69.2
Work in process	176.6	167.6
Finished goods	92.3	85.5
	$ 325.5	$ 322.3

9. 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 the respective period:

	September 27, 2019	December 28, 2018
Property, plant and equipment, gross	$ 1,880.9	$ 1,936.2
Less: accumulated depreciation	(986.2)	(954.2)
Property, plant and equipment, net	$ 894.7	$ 982.0

Depreciation expense for property, plant and equipment was as follows:

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Depreciation expense	$ 24.5	$ 15.7	$ 73.7	$ 50.5

10. Leases

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

Lease assets and liabilities are recognized based on the present value of the future minimum lease payments over the lease term as of the commencement date. As the Company's leases do not generally provide an implicit rate, the Company utilized its incremental borrowing rate based on the information available at commencement date in determining the present value of future lease payments. The Company used the incremental borrowing rate on December 29, 2018 for leases that commenced prior to that date. Most leases include one or more options to terminate or renew, with renewal terms that can extend the lease term from one to five years. The exercise of lease renewal options is at the Company's sole discretion. Termination and renewal options are included within the lease assets and liabilities only to the extent they are reasonably certain.

Lease assets and liabilities were reported in the following unaudited condensed consolidated balance sheet captions in the amounts shown:

	September 27, 2019
Other assets	$ 84.7
Accrued and other current liabilities	$ 18.8
Other liabilities	72.1
Total lease liabilities	$ 90.9

Dependent on the nature of the leased asset, lease expense is included within cost of sales or selling, general and administrative expenses ("SG&A"). The components of lease expense were as follows:

	Three Months Ended	Nine Months Ended
	September 27, 2019	September 27, 2019
Lease cost:		
Operating lease cost	$ 5.4	$ 15.6
Short-term lease cost	1.0	3.2
Sublease income	(0.2)	(0.6)
Total lease cost	$ 6.2	$ 18.2

Lease terms and discount rates were as follows:

	September 27, 2019
Weighted-average remaining lease term (in years) - operating lease	7.5
Weighted-average discount rate - operating leases	3.8%

Maturities of lease liabilities as of September 27, 2019 were as follows:

Remainder of Fiscal 2019	$	5.7
Fiscal 2020		21.6
Fiscal 2021		16.7
Fiscal 2022		12.6
Fiscal 2023		11.7
Thereafter		36.7
Total lease payments		105.0
Less: Interest		(14.1)
Present value of lease liabilities	$	90.9

Other supplemental cash flow information related to leases were as follows:

	Nine Months Ended	
	September 27, 2019	
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$	17.1
Lease assets obtained in exchange for lease obligations:		
Operating leases		7.7

11. Intangible Assets

Stannsoporfin

During the three months ended June 28, 2019, the Company recognized a full impairment on its in-process research and development ("IPR&D") asset related to stannsoporfin of $113.5 million as the Company will no longer pursue this development product.

VTS-270

VTS-270 is the Company's development product to treat Niemann-Pick Type C, a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. The results of the Company's completed registration trial for the product did not show a statistically significant separation from placebo. Neither the VTS-270 nor the placebo arm showed disease progression as would be expected for a neurodegenerative condition over 52 weeks of observation. The U.S. Food and Drug Administration ("FDA") indicated to the Company at a Type A meeting in August 2018 that their view on the potential approvability will be based on the totality of data, not a single study or endpoint. Accordingly, the Company's review of the data from the Phase 2b/3 trial, including the longer term open label portion, continues to proceed and is being assessed in combination with several other available data sources. A better understanding of the potential benefit of VTS-270 will emerge as the Company carefully considers the totality of data available and continues to work with the primary investigators and the FDA to define a viable path to a new drug application (NDA). The Company will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated IPR&D asset of $274.5 million included within intangible assets, net on the unaudited condensed consolidated balance sheet as of September 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.

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

	September 27, 2019		December 28, 2018	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 10,456.9	$ 3,621.0	$ 10,467.9	$ 2,980.6
License agreements	120.1	73.1	120.1	70.1
Trademarks	77.7	19.3	81.9	18.1
Customer relationships	—	—	27.5	14.1
Total	$ 10,654.7	$ 3,713.4	$ 10,697.4	$ 3,082.9
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	519.8		633.3	
Total	$ 554.8		$ 668.3	

Ofirmev®

Since the Company's acquisition of Ofirmev in March 2014, the related completed technology intangible asset had been amortized using the straight-line method over a useful life of eight years. As the product nears loss of exclusivity, the Company believes it is better positioned to reliably determine the pattern in which the remaining economic benefits of the intangible asset are consumed. As a result, during the three months ended March 29, 2019, the Company concluded that the sum of the years digits method, an accelerated method of amortization, would more accurately reflect the consumption of the economic benefits over the remaining useful life of the asset. This change in amortization method resulted in additional amortization expense of $23.8 million and $89.5 million during the three and nine months ended September 27, 2019, respectively, which impacted basic earnings per share for the respective periods by $0.28 and $1.07 per share.

Intangible asset amortization expense

Intangible asset amortization expense was as follows:

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Amortization expense	$ 210.4	$ 184.2	$ 649.8	$ 546.5

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

Remainder of Fiscal 2019	$ 203.6
Fiscal 2020	754.2
Fiscal 2021	657.6
Fiscal 2022	585.1
Fiscal 2023	581.1

12. Debt

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

	September 27, 2019		December 28, 2018	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
Current maturities of long-term debt:				
4.875% Senior Notes due April 2020	$ 698.0	$ 1.3	$ —	$ —
Term loan due September 2024	15.6	0.2	16.4	0.2
Term loan due February 2025	4.1	0.1	6.0	0.1
Other	—	—	0.3	—
Total current debt	717.7	1.6	22.7	0.3
Long-term debt:				
4.875% Senior Notes due April 2020	—	—	700.0	3.2
Variable-rate receivable securitization due July 2020	—	—	250.0	0.4
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% Senior Notes due August 2022	663.2	4.4	835.2	7.0
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% Senior Notes due April 2023	350.1	2.0	500.2	3.5
5.625% Senior Notes due October 2023	659.4	6.0	731.4	8.0
Term loan due September 2024	1,509.1	16.4	1,597.4	19.8
Term loan due February 2025	400.5	6.4	591.0	10.7
5.50% Senior Notes due April 2025	596.1	5.9	692.1	7.7
Revolving credit facility	900.0	3.4	220.0	4.5
Other	—	—	1.9	—
Total long-term debt	5,093.2	44.5	6,134.0	64.8
Total debt	$ 5,810.9	$ 46.1	$ 6,156.7	$ 65.1

In July 2019, Mallinckrodt Securitization S.à r.l., a wholly owned special purpose subsidiary of the Company, repaid $200.0 million of outstanding obligations under the Amended and Restated Note Purchase Agreement, dated as of July 28, 2017 (as amended, the "Note Purchase Agreement"), among Mallinckrodt Securitization S.à r.l., the persons from time to time party thereto as purchasers, PNC Bank, National Association, as administrative agent, and Mallinckrodt LLC, a wholly owned subsidiary of the Company, as initial servicer (the "Servicer").

Upon payment in full of such outstanding obligations under the Note Purchase Agreement, the $250.0 million receivables securitization program was automatically terminated (including (i) the Note Purchase Agreement, (ii) the Amended and Restated Purchase and Sale Agreement, dated as of July 28, 2017 (as amended, the "Purchase and Sale Agreement"), among certain wholly owned subsidiaries of the Company, the Servicer, and Mallinckrodt Securitization S.à r.l., (iii) the Sale Agreements (together, the "Sale Agreements"), between Mallinckrodt LLC and certain subsidiaries of the Company and (iv) all agreements and documents entered into in connection therewith, and all security interests, liens or other rights securing the receivables securitization program were automatically released and terminated. Certain indemnification and other obligations in the Note Purchase Agreement, the Purchase and Sale Agreement, the Sale Agreements and the documents related thereto, which by their terms expressly survive termination of such documents, will survive the termination of Mallinckrodt Securitization S.à r.l.'s receivables securitization program.

As of September 27, 2019, 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	5.08%	$ 1,524.7
Term loan due February 2025	5.18%	404.6
Revolving credit facility	4.52%	900.0

As of September 27, 2019, the Company was fully drawn on its $900.0 million revolving credit facility.

As of September 27, 2019, the Company continues to be in full compliance with the provisions and covenants associated with its debt agreements. 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 28, 2018.

13. Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss were as follows:

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized Gain (Loss) on Benefit Plans	Accumulated Other Comprehensive Loss
Balance as of December 28, 2018	$ (20.4)	$ (4.0)	$ 0.1	$ (24.3)
Impact of accounting standard adoptions	—	—	0.5	0.5
Other comprehensive income before reclassifications	1.6	—	0.2	1.8
Amounts reclassified from accumulated other comprehensive loss	—	1.0	(1.1)	(0.1)
Net current period other comprehensive income (loss)	1.6	1.0	(0.9)	1.7
Balance as of September 27, 2019	$ (18.8)	$ (3.0)	$ (0.3)	$ (22.1)

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized Loss on Benefit Plans	Accumulated Other Comprehensive Loss
Balance as of December 29, 2017	$ (8.2)	$ (4.7)	$ (1.5)	$ (14.4)
Other comprehensive (loss) income before reclassifications	(4.1)	—	4.3	0.2
Amounts reclassified from accumulated other comprehensive loss	—	0.7	(5.2)	(4.5)
Net current period other comprehensive (loss) income	(4.1)	0.7	(0.9)	(4.3)
Balance as of September 28, 2018	$ (12.3)	$ (4.0)	$ (2.4)	$ (18.7)

The following summarizes reclassifications from accumulated other comprehensive loss:

	Nine Months Ended		
	September 27, 2019	September 28, 2018	Line Item in the Unaudited Condensed Consolidated Statement of Income
Amortization and other of unrealized loss on derivatives	$ 1.0	$ 0.7	Interest expense
Amortization of pension and post-retirement benefit plans:			
Net actuarial loss	0.4	0.4	Other income, net
Prior service credit	(1.5)	(1.5)	Other income, net
Plan settlements	—	(4.1)	Other income, net
Total reclassifications for the period	$ (0.1)	$ (4.5)	

14. 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 Chemicals 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 27, 2019 and December 28, 2018 was $15.1 million and $14.6 million, respectively, of which $12.3 million and $11.8 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 27, 2019 and December 28, 2018. As of September 27, 2019, 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 $18.9 million and $18.6 million remained in restricted cash, included in other long-term assets on the unaudited condensed consolidated balance sheets as of September 27, 2019 and December 28, 2018, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 15.

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 27, 2019, the Company had various other letters of credit, guarantees and surety bonds totaling $35.6 million and restricted cash of $9.1 million held in segregated accounts collateralizing surety bonds for the Company's environmental liabilities.

15. 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. The Company believes that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, the Company believes, unless indicated below, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Governmental Proceedings

Opioid-Related Matters

Since 2017, multiple U.S. states, counties, 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 5, 2019, the cases the Company is aware of include, but are not limited to, approximately 2,315 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 207 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 104 cases filed by individuals and 14 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Hawaii, Nevada, South Dakota, New Hampshire, Illinois, and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of November 5, 2019, 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 September 12, 2019, the Attorney General for Ohio filed a motion in the Common Pleas Court of Ross County, Ohio to amend its complaint to add certain entities of the Company, but the court has not yet ruled on that motion. Certain of the lawsuits have been filed as putative class actions.

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 claim 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 allege 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 defendant to be heard in a subsequent trial. A hearing is scheduled for November 6, 2019 to discuss the next steps in the MDL, including potential remand of certain cases and which defendants will be included in subsequent trials.

Other lawsuits remain pending in various state courts. In some jurisdictions, such as California, Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas and West Virginia, certain of the 224 state lawsuits have been 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.

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, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment 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.

The Company will continue to vigorously defend itself against all of these lawsuits as detailed above and similar lawsuits that may be brought by others. As of the date of this report, the Company has been in discussions with certain plaintiffs in other pending opioid lawsuits and is likely to have further discussions and/or enter into additional discussions with other parties in connection with opioid lawsuits. Mallinckrodt may be required to pay material amounts and/or incur other material obligations as a result of any settlements that are entered into as a result of such discussions, but the Company is unable to predict outcomes or estimate a range of reasonably possible losses at this stage. Further, such matters or the resolution thereof, whether through judicial process or settlement or otherwise, may make it necessary or advisable for the Company and/or one or more of its subsidiaries to seek to restructure its or their obligations in a bankruptcy proceeding. The Company is exploring a wide array of such potential outcomes as part of its contingency planning, including the impact such actions could have on its business and operations. Should a bankruptcy occur, the Company would be subject to additional risks and uncertainties that could adversely affect the Company’s business prospects and ability to continue as a going concern.

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. Department of Justice ("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 is cooperating with the investigation.

The Attorneys General for Kentucky, Alaska, New York, and New Hampshire 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. Since these investigations and/or lawsuits are in early stages, the Company is unable to predict outcomes or estimate a range of reasonably possible losses.

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. The Company intends to vigorously assert its position in this matter. 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.

Other Matters

SEC Subpoena. In August 2019, the Company received a subpoena from the U.S. Securities and Exchange Commission ("SEC") for documents related to the Company's disclosure of its dispute with the U.S. Department of Health and Human Services ("HHS") and Centers for Medicare & Medicaid Services ("CMS" and together with HHS, the "Agency") concerning the base date average manufacturer price ("AMP") under the Medicaid Drug Rebate Program for Mallinckrodt's Acthar® Gel (repository corticotropin injection) ("Acthar Gel"), which is now the subject of litigation between the Company and the Agency (see *Medicaid Lawsuit* below). The Company is cooperating with the SEC's investigation.

Medicaid Lawsuit. In May 2019, the Company filed a lawsuit under the Administrative Procedure Act ("APA") in federal district court for the District of Columbia against the Agency. The dispute involves the base date AMP under the Medicaid Drug Rebate Program for 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 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's 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 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 Pharmaceuticals Inc. ("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 retroactively. The court held a hearing regarding this matter on August 2, 2019 and the court took the matter under advisement. While the Company believes that its lawsuit has strong factual and legal bases, as of September 27, 2019, the potential for retroactive non-recurring charges could range from zero to approximately $600.0 million.

Florida Civil Investigative Demand. In February 2019, the Company received a CID from the U.S. Attorney's Office for the Middle District of Florida for documents related to alleged payments to healthcare providers in Florida and whether those payments violated the Anti-Kickback Statute. The Company is cooperating with the investigation.

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 is cooperating with the Committee's investigation.

Boston Civil Investigative Demand. In January 2019, the Company received a CID from the U.S. Attorney's Office for the District of Massachusetts for documents related to the Company's participation in the Medicaid Drug Rebate Program. The Company is cooperating with the investigation.

Generic Pricing Subpoena. In March 2018, the Company received a grand jury subpoena issued by the U.S. District Court for the Eastern District of Pennsylvania pursuant to which the Antitrust Division of the DOJ is seeking documents regarding generic products and pricing, communications with generic competitors and other related matters. The Company is in the process of responding to this subpoena and intends to cooperate fully in the investigation.

Boston Subpoena. In December 2016, the Company received a subpoena from the USAO for the District of Massachusetts for documents related to the Company's provision of financial and other support to patients, including through charitable foundations, and related matters. The Company responded to these requests and continues to cooperate fully in the investigation.

Therakos® Subpoena. In March 2014, the USAO for the Eastern District of Pennsylvania requested the production of documents related to an investigation of the U.S. promotion of Therakos' drug/device system UVADEX/UVAR XTS and UVADEX/CELLEX (collectively, the "Therakos System"), for indications not approved by the FDA, including treatment of patients with graft versus host disease ("GvHD") and solid organ transplant patients, including pediatric patients. The investigation also includes Therakos' efforts to secure FDA approval for additional uses of, and alleged quality issues relating to, UVADEX/UVAR. In August 2015, the USAO for the Eastern District of Pennsylvania sent Therakos a subsequent request for documents related to the investigation and has since made certain related requests. The Company responded to these requests and continues to cooperate fully in the investigation.

MNK 2011 Inc. (formerly known as Mallinckrodt Inc.) v. U.S. Food and Drug Administration and United States of America. In November 2014, the FDA reclassified the Company's Methylphenidate ER in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("the Orange Book"). In November 2014, the Company filed a Complaint in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States (the "MD Complaint") for judicial review of the FDA's reclassification. In July 2015, the court granted the FDA's motion to dismiss with respect to three of the five counts in the MD Complaint and granted summary judgment in favor of the FDA with respect to the two remaining counts (the "MD Order"). On October 18, 2016, the FDA initiated proceedings, proposing to withdraw approval of the Company's Abbreviated New Drug Application ("ANDA") for Methylphenidate ER. On October 21, 2016, the U.S. Court of Appeals for the Fourth Circuit issued an order placing the Company's appeal of the MD Order in abeyance pending the outcome of the withdrawal proceedings. The parties exchanged documents and in April 2018, the Company filed its submission in support of its position in the withdrawal proceedings. A potential outcome of the withdrawal proceedings is that the Company's Methylphenidate ER products may lose their FDA approval and have to be withdrawn from the market.

Questcor Subpoena. 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. Questcor subsequently was informed by the USAO for the Eastern District of Pennsylvania that the USAO for the Southern District of New York and the SEC were participating in the investigation to review Questcor's promotional practices and related matters pertaining to Acthar Gel. The current investigation also relates to Questcor's provision of financial and other support to patients, including through charitable foundations and related matters. On March 9, 2015, the Company received a "No Action" letter from the SEC regarding its review of the Company's promotional practices related to Acthar Gel. On or about March 8, 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.

On or about June 4, 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. The Company intends to vigorously defend itself in this matter and on August 19, 2019, moved to dismiss the complaint. The Company's motion to dismiss remains pending. 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.

Patent Litigation

Ofirmev Patent Litigation: Altan Pharma Ltd. In March 2019, Mallinckrodt Hospital Products Inc. 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 Altan Pharma Ltd. ("Altan") alleging that Altan infringed U.S. Patent No. 6,992,218, U.S. Patent No. 9,399,012, U.S. Patent No. 9,610,265 and U.S. Patent No. 9,987,238 following receipt of a February 2019 notice from Altan concerning its submission of a new drug application, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On August 29, 2019, the parties entered into a settlement agreement under which Altan was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its New Drug Application (NDA) on or after December 6, 2020, or earlier under certain circumstances.

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 ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Amitiza. The Company intends to vigorously enforce its intellectual property rights relating to Amitiza.

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 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. As of the date of this report there has been limited commercial launch activity by Praxair. The Company intends to continue its efforts to vigorously enforce its intellectual property rights relating to Inomax in the Praxair litigation to prevent the marketing of infringing generic products prior to the expiration of the patents covering Inomax. An adverse final outcome in the appeal of the Praxair litigation decision (or a broad at-risk launch by Praxair prior to the final appellate decision) could 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.

Commercial and Securities Litigation

Shareholder Derivative Litigation (Brandhorst). On September 19, 2019, a purported shareholder of the Company's stock filed a shareholder derivative complaint in the United States District Court for the District of Columbia against the Company, as nominal defendant, as well as its Chief Executive Officer ("CEO") Mark Trudeau, its former Chief Financial Officer ("CFO") Matthew K. Harbaugh, its Executive Vice President Hugh O'Neill, and the following members of the Company's 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 "Individual 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 on January 23, 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 Individual Defendants caused the Company to make the allegedly false or misleading statements at issue in the *Shenk* lawsuit. The complaint seeks damages in an unspecified amount and corporate governance reforms. The Company and the Individual Defendants intend to vigorously defend themselves in this matter.

Humana Litigation. On August 8, 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 ("RICO") 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 Subpoena* above) and is proceeding as *Humana Inc. v. Mallinckrodt ARD LLC*. Plaintiff filed an Amended Complaint on October 2, 2019. The Company intends to vigorously defend itself in this matter, and on October 28, 2019, moved to dismiss the complaint. The Company's motion to dismiss remains pending.

Putative Class Action Securities Litigation (Strougo). On July 26, 2019, a putative class action lawsuit was filed against the Company, its CEO Mark 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. The Company intends to vigorously defend itself in this matter.

Putative Class Action Litigation - Plumbers & Pipefitters Local 322. On July 19, 2019, Pipefitters Local 322 filed a putative state class action lawsuit against the Company in the Superior Court of New Jersey, Camden County, proceeding as *United Assoc. of Plumbers & Pipefitters Local 322 of Southern New Jersey v. Mallinckrodt ARD, LLC.* The complaint made similar allegations as those alleged in related state and federal actions filed by the same plaintiff law firm filed in Illinois, Pennsylvania, Tennessee and Maryland, including references to allegations at issue in pending *qui tam* actions against the Company with the Eastern District of Pennsylvania. In particular, the complaint alleged violations of the New Jersey Consumer Fraud Act, the New Jersey Antitrust Act, violations of state RICO statutes, negligent misrepresentation, conspiracy and unjust enrichment associated with the commercialization of Acthar Gel. Plaintiff voluntarily dismissed the lawsuit on September 6, 2019.

Putative Class Action Litigation - Steamfitters Local Union No. 420. On July 12, 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, 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). In particular, 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. The Company intends to vigorously defend itself in this matter, and on August 22, 2019, moved to dismiss the complaint. The Company's motion to dismiss remains pending.

Acument Global. On May 21, 2019, Acument Global Technologies, Inc., 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.* The Company intends to vigorously defend itself in this matter, and on July 29, 2019, moved to dismiss the complaint. The Company's motion to dismiss remains pending.

Washington County Board of Education ("WCBE"). On May 21, 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 on June 24, 2019, alleges similar facts as those alleged in the *MSP* and *Rockford* matters below, and is captioned *Washington County Board of Education v. Mallinckrodt ARD Inc., et al.* The Company moved to dismiss the original complaint on July 1, 2019. Thereafter, Plaintiff filed an amended complaint, which the Company moved to dismiss on July 29, 2019. The Company's motion to dismiss the amended complaint remains pending. Plaintiff 's July 15, 2019 motion to remand the lawsuit to Maryland state court also remains pending.

Local 542. On May 25, 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 on August 27, 2018, the Company's objections to which were denied by the court. 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.

Grifols. On March 13, 2018, Grifols initiated arbitration against the Company, alleging breach of a Manufacturing and Supply Agreement entered into between the Company's predecessor-in-interest, Cadence Pharmaceuticals Inc., and Grifols. The Company has entered into a settlement for this matter and has appropriate reserves recorded.

Putative Class Action Litigation (MSP). On October 30, 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 on February 23, 2018, which was granted on January 25, 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. The complaint alleges 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 purports 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. The Company moved to dismiss the First Amended Class Action Complaint on May 24, 2019. The Company's motion to dismiss remains pending.

Employee Stock Purchase Plan ("ESPP") Securities Litigation. On July 20, 2017, a purported purchaser of Mallinckrodt stock through Mallinckrodt's ESPPs, filed a derivative 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. 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 putative class action securities litigation described in the *Shenk* 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* lawsuit below.

Putative Class Action Litigation (Rockford). On April 6, 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. On January 22, 2018, the Company filed a motion to dismiss the Second Amended Complaint, which was granted in part on January 25, 2019, dismissing 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 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 (Shenk). On January 23, 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. Since that time, two of the plaintiff groups have withdrawn their motions. 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. The Company intends to vigorously defend itself in this matter.

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 27, 2019, it was probable that it would incur remediation costs in the range of $36.8 million to $77.6 million. The Company also concluded that, as of September 27, 2019, the best estimate within this range was $62.0 million, of which $1.7 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 27, 2019. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Lower Passaic River, New Jersey. The Company and approximately 70 other companies ("Cooperating Parties Group" or "CPG") are parties to a May 2007 Administrative Order on Consent ("AOC") with the Environmental Protection Agency ("EPA") to perform a remedial investigation and feasibility study ("RI/FS") of the 17-mile stretch known as the Lower Passaic River ("the River") Study Area. The Company's potential liability stems from former operations at Lodi and Belleville, New Jersey.

In April 2014, the EPA issued a revised Focused Feasibility Study ("FFS"), with remedial alternatives to address cleanup of the lower 8-mile stretch of the River. The EPA estimated the cost for the remediation alternatives ranged from $365.0 million to $3.2 billion and the EPA's preferred approach had an estimated cost of $1.7 billion.

In April 2015, the CPG presented a draft of the RI/FS of the River to the EPA that included alternative remedial actions for the entire 17-mile stretch of the River.

On March 4, 2016, the EPA issued the Record of Decision ("ROD") for the lower 8 miles of the River with a slight modification on its preferred approach and a revised estimated cost of $1.38 billion. On October 5, 2016, the EPA announced that Occidental Chemicals Corporation ("OCC") had entered into an agreement to develop the remedial design.

On August 7, 2018, the EPA finalized a buyout offer of $280,600 with the Company, limited to its former Lodi facility, for the lower 8 miles of the River. During the three months ended September 28, 2018, the Company reduced the accrual associated with this matter by $11.8 million to $26.2 million, which represents the Company's estimate of its remaining liability related to the River.

Despite the issuance of the revised FFS and ROD by the EPA, the RI/FS by the CPG, and the cash out settlement by the EPA there are many uncertainties associated with the final agreed-upon remediation, potential future liabilities and the Company's allocable share of the remediation. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which the Company may be ultimately responsible and will be refined as the remediation progresses.

Occidental Chemical Corp. v. 21st Century Fox America, Inc. The Company and approximately 120 other companies were named as defendants in a lawsuit filed on June 30, 2018, by OCC, in which OCC seeks cost recovery and contribution for past and future costs in response to releases and threatened releases of hazardous substances into the lower 8 miles of the River. A former Mallinckrodt facility located in Jersey City, NJ (located in Newark Bay) and the former Belleville facility were named in the suit. Due to an indemnification agreement with AVON Inc., Mallinckrodt has tendered the liability for the Jersey City site to AVON Inc. and they have accepted. The Company retains a share of the liability for this suit related to the Belleville facility. A motion to dismiss several of the claims was denied by the court. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, 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.

Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois. Between 1967 and 1982, International Minerals and Chemicals Corporation ("IMC"), a predecessor in interest to the Company, leased portions of the Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the CO Site") from the government and manufactured various explosives for use in mining and other operations. In March 2002, the Department of Justice, the U.S. Department of the Interior and the EPA (together, "the Government Agencies") issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. ("General Dynamics"), one of the other potentially responsible parties ("PRPs") at the CO Site, to compel General Dynamics to perform the RI/FS for the AUS Operable Unit. General Dynamics negotiated an AOC with the Government Agencies to conduct an extensive RI/FS at the CO Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that the Company is jointly and severally liable, along with approximately eight other lessees and operators at the AUS Operable Unit, for costs associated with alleged contamination of soils and groundwater resulting from historic operations, and the parties have entered into a non-binding mediation process. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, 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.

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 27, 2019, there were approximately 11,700 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.

Interest-bearing Deferred Tax Obligation

As part of the integration of Questcor, the Company entered into an internal installment sale transaction related to certain Acthar Gel intangible assets during the three months ended December 26, 2014. The installment sale transaction resulted in a taxable gain. In accordance with Internal Revenue Code Section 453A ("Section 453A") the gain is considered taxable in the period in which installment payments are received. During the three months ended December 25, 2015, the Company entered into similar transactions with certain intangible assets acquired in the acquisitions of Ikaria, Inc. and Therakos, Inc.

During the three months ended March 29, 2019, the Company completed its reorganization of its intercompany financing and associated legal entity ownership. As a result, the Company had no remaining interest-bearing U.S. deferred tax liabilities as of September 27, 2019, compared to $227.5 million as of December 28, 2018. See Note 6 for further details regarding this reorganization. The GAAP calculation of interest associated with these deferred tax liabilities is subject to variable interest rates. The Company recognized interest expense associated with these deferred tax liabilities of $18.1 million during the nine months ended September 28, 2018.

The Company has reported Section 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 on the deferred tax liability. 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 $47.4 million and $56.0 million as of September 27, 2019 and December 28, 2018, respectively. The decrease of $8.6 million was recognized as a benefit to interest expense during the nine months ended September 27, 2019, due to a lapse 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 income.

Tax Matters

On August 5, 2019, the IRS proposed an adjustment to the taxable income of MHP as a result of its findings in the audit of MHP’s tax year ended September 26, 2014. MHP, formerly known as Cadence Pharmaceuticals, Inc. (“Cadence”), was acquired by the Company 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 a wholly owned non-U.S. subsidiary of the Company. The transfer occurred at a price (“Transfer Price”) determined in conjunction with the Company’s external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration paid by the Company to the shareholders of Cadence. The IRS asserts the value of the Transferred IP exceeds the value of the acquired Cadence shares and, further, partially disallows the Company’s control premium subtraction. The proposed adjustment to taxable income of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of the Company’s U.S. Federal net operating loss carryforward of $849.3 million. The Company strongly disagrees with the proposed increase to the Transfer Price and intends to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. The final outcome cannot be reasonably quantified at this time, however, the proposed adjustment may be material. The Company believes its reserve for income tax contingencies is adequate.

Other Matters

The Company is a defendant in a number of other pending legal proceedings relating to present and former operations, acquisitions and dispositions. The Company does not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on its financial condition, results of operations and cash flows.

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 28, 2018.

License Agreement

In July 2019, the Company entered into a license and collaboration agreement with Silence Therapeutics plc ("Silence") that will allow the companies to develop and commercialize ribonucleic acid interference ("RNAi") drug targets designed to inhibit the

complement cascade, a group of proteins that are involved in the immune system and that play a role in the development of inflammation.

During the three months ended September 27, 2019, the Company paid $20.0 million upfront with cash on hand, which was recorded within research and development ("R&D") expense, and gained an exclusive worldwide license to Silence's C3 complement asset, SLN500, with options to license up to two additional complement-targeted assets in Silence's preclinical complement-directed RNAi development program. The agreement also includes additional payments to Silence of up to $10.0 million in research milestones for SLN500, in addition to funding for Phase 1 clinical development including good manufacturing practices (GMP). Silence will be responsible for preclinical activities, and for executing the development program of SLN500 until the end of Phase 1, after which the Company will assume clinical development and responsibility for global commercialization. If approved, Silence could receive up to $563.0 million in commercial milestone payments and tiered low double-digit to high-teen royalties on net sales for SLN500.

16. 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 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	$ 35.7	$ 25.9	$ 9.8	$ —
Equity securities	11.4	11.4	—	—
	$ 47.1	$ 37.3	$ 9.8	$ —
Liabilities:				
Deferred compensation liabilities	$ 37.3	$ —	$ 37.3	$ —
Contingent consideration and acquired contingent liabilities	105.4	—	—	105.4
	$ 142.7	$ —	$ 37.3	$ 105.4

	December 28, 2018	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	$ 33.1	$ 22.4	$ 10.7	$ —
Liabilities:				
Deferred compensation liabilities	$ 38.5	$ —	$ 38.5	$ —
Contingent consideration and acquired contingent liabilities	151.4	—	—	151.4
	$ 189.9	$ —	$ 38.5	$ 151.4

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, 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.

In July 2019, the Company remitted $5.0 million of consideration to Silence in exchange for equity shares. As part of this equity investment, the Company took a non-executive Director seat on the Silence Board of Directors. The Company's investment in Silence qualifies for equity method accounting given its ability to exercise significant influence; however, the Company elected the fair value method to account for its investment in Silence.

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. 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 paid the required annual payment of $25.0 million during the nine months ended September 27, 2019. The fair value of the remaining contingent payments was measured based on the net present value of a probability-weighted assessment. As of September 27, 2019, the total remaining payments under the license agreement shall not exceed $90.0 million. The Company determined the fair value of the contingent consideration associated with the acquisition of Questcor to be $53.7 million and $76.2 million as of September 27, 2019 and December 28, 2018, respectively.

As part of the Stratatech acquisition, 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®. The Company assesses the likelihood and timing of making such payments. 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 Stratatech acquisition to be $35.1 million and $53.7 million as of September 27, 2019 and December 28, 2018, respectively.

As part of the Ocera acquisition, the Company provided contingent consideration to the prior shareholders of Ocera in the form of both patient enrollment clinical study milestones for intravenous ("IV") and oral formulations of MNK-6105 and MNK-6106, which represent the IV and oral formulations, respectively, 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 $16.6 million and $21.5 million as of September 27, 2019 and December 28, 2018, respectively.

Of the total fair value of the contingent consideration of $105.4 million, $48.2 million was classified as current and $57.2 million was classified as non-current in the unaudited condensed consolidated balance sheet as of September 27, 2019. The following table summarizes the activity for contingent consideration:

Balance as of December 28, 2018	$	151.4
Payments		(25.0)
Accretion expense		2.5
Fair value adjustments		(23.5)
Balance as of September 27, 2019	$	105.4

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 27, 2019 and December 28, 2018:

- 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 $28.0 million and $18.6 million as of September 27, 2019 and December 28, 2018, (level 1), respectively, which was included in other assets on the unaudited condensed consolidated balance sheets.
- The Company 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 during both the nine months ended September 27, 2019 and September 28, 2018. These securities are classified as held-to-maturity and are carried at amortized cost, which approximates fair value (level 3), of $18.9 million and $9.0 million as of September 27, 2019 and December 28, 2018, 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 $66.8 million and $66.4 million as of September 27, 2019 and December 28, 2018, 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 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% and 5.50% 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 27, 2019		December 28, 2018	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
4.875% Senior Notes due April 2020	$ 698.0	$ 457.9	$ 700.0	$ 676.6
Variable-rate receivable securitization due July 2020	—	—	250.0	250.0
5.75% Senior Notes due August 2022	663.2	250.3	835.2	713.6
4.75% Senior Notes due April 2023	350.1	99.8	500.2	336.7
5.625% Senior Notes due October 2023	659.4	217.9	731.4	557.0
5.50% Senior Notes due April 2025	596.1	179.2	692.1	479.1
Revolving credit facility	900.0	900.0	220.0	220.0
Level 2:				
9.50% debentures due May 2022	10.4	5.1	10.4	9.7
8.00% debentures due March 2023	4.4	1.6	4.4	3.8
Term loan due September 2024	1,524.7	1,136.9	1,613.8	1,472.4
Term loan due February 2025	404.6	300.9	597.0	548.0
Level 3:				
Other	—	—	2.2	2.2
Total debt	$ 5,810.9	$ 3,549.6	$ 6,156.7	$ 5,269.1

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 net sales:

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
CuraScript, Inc.	31.1%	35.9%	30.2%	35.7%
AmerisourceBergen Corporation	*	12.3%	*	*

*Net sales to this distributor were less than 10% of total net sales during the respective periods presented above.

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

	September 27, 2019	December 28, 2018
AmerisourceBergen Corporation	27.6%	25.7%
McKesson Corporation	14.1%	21.9%
CuraScript, Inc.	10.3%	13.1%

The following table shows net sales attributable to products that accounted for 10.0% or more of the Company's total net sales:

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Acthar Gel	30.9%	36.3%	30.5%	34.7%
Inomax	18.4%	16.7%	18.1%	17.0%
Ofirmev	11.6%	10.9%	11.5%	10.7%

17. Segment Data

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

- *Specialty Brands* includes innovative specialty pharmaceutical brands (inclusive of Amitiza); and
- *Specialty Generics* includes niche specialty generic drugs and APIs.

All prior period segment information has been reclassified to reflect the realignment of the Company's reportable segments on a comparable basis, as previously mentioned in Note 1.

Selected information by reportable segment was as follows:

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Net sales:				
Specialty Brands	$ 580.4	$ 640.0	$ 1,812.4	$ 1,844.3
Specialty Generics	163.3	159.9	545.2	536.4
Net sales	$ 743.7	$ 799.9	$ 2,357.6	$ 2,380.7
Operating income (loss):				
Specialty Brands	$ 267.3	$ 288.0	$ 864.2	$ 794.4
Specialty Generics	21.8	16.5	80.1	94.7
Segment operating income	289.1	304.5	944.3	889.1
Unallocated amounts:				
Corporate and unallocated expenses [1]	(23.4)	(29.2)	(105.6)	(85.7)
Intangible asset amortization	(210.4)	(184.2)	(649.8)	(546.5)
Restructuring and related charges, net	(7.2)	(19.6)	(11.2)	(106.6)
Non-restructuring impairment charges	—	(2.0)	(113.5)	(2.0)
Separation costs [2]	(19.8)	—	(50.4)	—
R&D upfront payment [3]	(20.0)	—	(20.0)	—
Operating income (loss) [4]	$ 8.3	$ 69.5	$ (6.2)	$ 148.3

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

(2) Represents costs incurred related to the separation of the Company's Specialty Generics segment, inclusive of costs related to the suspended spin-off of that business and rebranding costs associated with the Specialty Brands ongoing transformation, all of which are included in SG&A.

(3) Represents R&D expense incurred related to an upfront payment made to Silence in connection with the license and collaboration agreement entered into in July 2019. Refer to Note 15 for further details.

(4) The amount of operating loss included in the Company's unaudited condensed consolidated statement of income for the three and nine months ended September 28, 2018 related to the Sucampo Acquisition was $32.2 million and $99.9 million, respectively. Included within these results were $18.0 million and $45.0 million of amortization associated with intangibles recognized from this acquisition and $31.0 million and $77.5 million of expense associated with fair value adjustments of acquired inventory for the three and nine months ended September 28, 2018, respectively.

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

	Three Months Ended		Nine Months Ended	
	September 27, 2019	September 28, 2018	September 27, 2019	September 28, 2018
Acthar Gel	$ 229.8	$ 290.1	$ 720.1	$ 827.1
Inomax	136.8	133.2	427.6	404.0
Ofirmev	86.1	87.1	272.2	254.7
Therakos	60.9	60.0	183.6	174.2
Amitiza [1]	52.6	48.2	157.6	119.2
BioVectra	10.5	13.9	36.8	35.7
Other	3.7	7.5	14.5	29.4
Specialty Brands	580.4	640.0	1,812.4	1,844.3
Hydrocodone (API) and hydrocodone-containing tablets	15.7	15.5	51.2	46.3
Oxycodone (API) and oxycodone-containing tablets	17.2	13.6	53.3	43.3
Acetaminophen (API)	48.5	47.9	143.1	149.0
Other controlled substances	72.9	69.5	265.7	258.0
Other	9.0	13.4	31.9	39.8
Specialty Generics	163.3	159.9	545.2	536.4
Net sales	$ 743.7	$ 799.9	$ 2,357.6	$ 2,380.7

(1) Amitiza consists of both product net sales and royalties. Refer to Note 3 for further details on Amitiza's revenues.

18. Condensed Consolidating Financial Statements

Mallinckrodt International Finance S.A. ("MIFSA"), an indirectly 100%-owned subsidiary of Mallinckrodt plc established to own, directly or indirectly, substantially all of the operating subsidiaries of the Company, to issue debt securities and to perform treasury operations.

MIFSA is the borrower under the 4.75% Senior Notes due April 2023 ("the 2013 Notes"), which are fully and unconditionally guaranteed by Mallinckrodt plc. The following information provides the composition of the Company's comprehensive income, assets, liabilities, equity and cash flows by relevant group within the Company: Mallinckrodt plc as guarantor of the 2013 Notes, MIFSA as issuer of the 2013 Notes and the operating companies that represent assets of MIFSA. There are no subsidiary guarantees related to the 2013 Notes.

Set forth below are the condensed consolidating financial statements for the three and nine months ended September 27, 2019 and September 28, 2018, and as of September 27, 2019 and December 28, 2018. Eliminations represent adjustments to eliminate investments in subsidiaries and intercompany balances and transactions between or among Mallinckrodt plc, MIFSA and other subsidiaries. Condensed consolidating financial information for Mallinckrodt plc and MIFSA, on a standalone basis, has been presented using the equity method of accounting for subsidiaries.

MALLINCKRODT PLC
CONDENSED CONSOLIDATING BALANCE SHEET
As of September 27, 2019
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.7	$ 64.5	$ 433.6	$ —	$ 498.8
Accounts receivable, net	—	—	538.8	—	538.8
Inventories	—	—	325.5	—	325.5
Prepaid expenses and other current assets	11.8	0.2	110.2	—	122.2
Assets held for sale	—	—	175.9	—	175.9
Intercompany receivables	128.2	29.2	5,980.2	(6,137.6)	—
Total current assets	140.7	93.9	7,564.2	(6,137.6)	1,661.2
Property, plant and equipment, net	—	—	894.7	—	894.7
Intangible assets, net	—	—	7,496.1	—	7,496.1
Investment in subsidiaries	2,684.4	15,633.9	3,877.0	(22,195.3)	—
Intercompany loans receivable	447.9	—	2,709.8	(3,157.7)	—
Other assets	—	—	304.1	—	304.1
Total Assets	$ 3,273.0	$ 15,727.8	$ 22,845.9	$ (31,490.6)	$ 10,356.1
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 696.7	$ 19.4	$ —	$ 716.1
Accounts payable	0.1	—	100.8	—	100.9
Accrued payroll and payroll-related costs	—	—	83.7	—	83.7
Accrued interest	—	8.1	82.8	—	90.9
Accrued and other current liabilities	0.8	0.2	505.5	—	506.5
Liabilities held for sale	—	—	55.8	—	55.8
Intercompany payables	191.7	5,732.8	213.1	(6,137.6)	—
Total current liabilities	192.6	6,437.8	1,061.1	(6,137.6)	1,553.9
Long-term debt	—	2,250.5	2,798.2	—	5,048.7
Pension and postretirement benefits	—	—	58.6	—	58.6
Environmental liabilities	—	—	60.3	—	60.3
Deferred income taxes	—	—	22.0	—	22.0
Other income tax liabilities	—	—	253.5	—	253.5
Intercompany loans payable	—	3,157.7	—	(3,157.7)	—
Other liabilities	—	4.8	273.9	—	278.7
Total Liabilities	192.6	11,850.8	4,527.6	(9,295.3)	7,275.7
Shareholders' Equity	3,080.4	3,877.0	18,318.3	(22,195.3)	3,080.4
Total Liabilities and Shareholders' Equity	$ 3,273.0	$ 15,727.8	$ 22,845.9	$ (31,490.6)	$ 10,356.1

MALLINCKRODT PLC
CONDENSED CONSOLIDATING BALANCE SHEET
As of December 28, 2018
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.4	$ 140.8	$ 207.7	$ —	$ 348.9
Accounts receivable, net	—	—	623.3	—	623.3
Inventories	—	—	322.3	—	322.3
Prepaid expenses and other current assets	3.9	0.2	128.6	—	132.7
Intercompany receivables	131.1	29.2	1,087.9	(1,248.2)	—
Total current assets	135.4	170.2	2,369.8	(1,248.2)	1,427.2
Property, plant and equipment, net	—	—	982.0	—	982.0
Intangible assets, net	—	—	8,282.8	—	8,282.8
Investment in subsidiaries	2,481.6	25,506.1	8,362.1	(36,349.8)	—
Intercompany loans receivable	497.7	—	12,343.0	(12,840.7)	—
Other assets	—	—	185.3	—	185.3
Total Assets	$ 3,114.7	$ 25,676.3	$ 32,525.0	$ (50,438.7)	$ 10,877.3
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 22.1	$ 0.3	$ —	$ 22.4
Accounts payable	0.1	—	147.4	—	147.5
Accrued payroll and payroll-related costs	—	—	124.0	—	124.0
Accrued interest	—	48.7	28.9	—	77.6
Accrued and other current liabilities	0.6	0.4	571.2	—	572.2
Intercompany payables	226.7	827.8	193.7	(1,248.2)	—
Total current liabilities	227.4	899.0	1,065.5	(1,248.2)	943.7
Long-term debt	—	3,566.9	2,502.3	—	6,069.2
Pension and postretirement benefits	—	—	60.5	—	60.5
Environmental liabilities	—	—	59.7	—	59.7
Deferred income taxes	—	—	324.3	—	324.3
Other income tax liabilities	—	—	228.0	—	228.0
Intercompany loans payable	—	12,840.7	—	(12,840.7)	—
Other liabilities	—	7.6	297.0	—	304.6
Total Liabilities	227.4	17,314.2	4,537.3	(14,088.9)	7,990.0
Shareholders' Equity	2,887.3	8,362.1	27,987.7	(36,349.8)	2,887.3
Total Liabilities and Shareholders' Equity	$ 3,114.7	$ 25,676.3	$ 32,525.0	$ (50,438.7)	$ 10,877.3

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the three months ended September 27, 2019
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 743.7	$ —	$ 743.7
Cost of sales	0.4	—	419.0	—	419.4
Gross (loss) profit	(0.4)	—	324.7	—	324.3
Selling, general and administrative expenses	10.0	0.6	195.1	—	205.7
Research and development expenses	1.6	—	101.5	—	103.1
Restructuring charges, net	—	—	7.2	—	7.2
Operating (loss) income	(12.0)	(0.6)	20.9	—	8.3
Interest expense	(1.4)	(60.2)	(72.7)	56.7	(77.6)
Interest income	2.5	0.1	57.0	(56.7)	2.9
Other income, net	0.2	12.9	24.8	—	37.9
Intercompany fees	(4.6)	(0.1)	4.7	—	—
Equity in net income of subsidiaries	12.7	80.6	29.5	(122.8)	—
(Loss) income from continuing operations before income taxes	(2.6)	32.7	64.2	(122.8)	(28.5)
Income tax (benefit) expense	(1.5)	3.3	(29.4)	—	(27.6)
(Loss) income from continuing operations	(1.1)	29.4	93.6	(122.8)	(0.9)
Income (loss) from discontinued operations, net of income taxes	—	0.1	(0.3)	—	(0.2)
Net (loss) income	(1.1)	29.5	93.3	(122.8)	(1.1)
Other comprehensive loss, net of tax	(2.0)	(2.0)	(4.3)	6.3	(2.0)
Comprehensive (loss) income	$ (3.1)	$ 27.5	$ 89.0	$ (116.5)	$ (3.1)

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the three months ended September 28, 2018
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 799.9	$ —	$ 799.9
Cost of sales	0.7	—	432.8	—	433.5
Gross (loss) profit	(0.7)	—	367.1	—	366.4
Selling, general and administrative expenses	12.4	0.1	180.9	—	193.4
Research and development expenses	1.6	—	84.5	—	86.1
Restructuring charges, net	—	—	14.8	—	14.8
Non-restructuring impairment charge	—	—	2.0	—	2.0
Loss on divestiture	—	—	0.6	—	0.6
Operating (loss) income	(14.7)	(0.1)	84.3	—	69.5
Interest expense	(1.6)	(112.0)	(257.4)	277.4	(93.6)
Interest income	2.4	249.6	27.4	(277.4)	2.0
Other income (expense), net	2.3	(156.8)	167.9	—	13.4
Intercompany fees	(3.5)	(0.1)	3.6	—	—
Equity in net income of subsidiaries	127.8	238.9	221.9	(588.6)	—
Income (loss) from continuing operations before income taxes	112.7	219.5	247.7	(588.6)	(8.7)
Income tax benefit	(1.1)	(2.4)	(119.4)	—	(122.9)
Income from continuing operations	113.8	221.9	367.1	(588.6)	114.2
Loss from discontinued operations, net of income taxes	—	—	(0.4)	—	(0.4)
Net income	113.8	221.9	366.7	(588.6)	113.8
Other comprehensive income, net of tax	3.0	3.0	5.8	(8.8)	3.0
Comprehensive income	$ 116.8	$ 224.9	$ 372.5	$ (597.4)	$ 116.8

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the nine months ended September 27, 2019
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 2,357.6	$ —	$ 2,357.6
Cost of sales	1.7	—	1,307.6	—	1,309.3
Gross (loss) profit	(1.7)	—	1,050.0	—	1,048.3
Selling, general and administrative expenses	35.2	1.2	625.4	—	661.8
Research and development expenses	4.8	—	263.2	—	268.0
Restructuring charges, net	—	—	11.2	—	11.2
Non-restructuring impairment charge	—	—	113.5	—	113.5
Operating (loss) income	(41.7)	(1.2)	36.7	—	(6.2)
Interest expense	(14.0)	(192.3)	(209.2)	183.7	(231.8)
Interest income	17.5	0.4	172.4	(183.7)	6.6
Other income, net	8.9	43.6	76.1	—	128.6
Intercompany fees	(14.6)	(0.1)	14.7	—	—
Equity in net income of subsidiaries	200.8	448.7	292.0	(941.5)	—
Income (loss) from continuing operations before income taxes	156.9	299.1	382.7	(941.5)	(102.8)
Income tax (benefit) expense	(3.7)	9.9	(262.8)	—	(256.6)
Income from continuing operations	160.6	289.2	645.5	(941.5)	153.8
Income from discontinued operations, net of income taxes	—	2.8	4.0	—	6.8
Net income	160.6	292.0	649.5	(941.5)	160.6
Other comprehensive income, net of tax	1.7	1.7	2.4	(4.1)	1.7
Comprehensive income	$ 162.3	$ 293.7	$ 651.9	$ (945.6)	$ 162.3

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the nine months ended September 28, 2018
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 2,380.7	$ —	$ 2,380.7
Cost of sales	1.6	—	1,271.2	—	1,272.8
Gross (loss) profit	(1.6)	—	1,109.5	—	1,107.9
Selling, general and administrative expenses	30.1	0.5	563.9	—	594.5
Research and development expenses	3.8	—	256.9	—	260.7
Restructuring charges, net	—	—	101.8	—	101.8
Non-restructuring impairment charge	—	—	2.0	—	2.0
Loss on divestiture	—	—	0.6	—	0.6
Operating (loss) income	(35.5)	(0.5)	184.3	—	148.3
Interest expense	(6.2)	(323.2)	(272.2)	321.5	(280.1)
Interest income	6.8	251.6	69.7	(321.5)	6.6
Other income (expense), net	9.0	(154.0)	162.8	—	17.8
Intercompany fees	(12.0)	(0.1)	12.1	—	—
Equity in net income of subsidiaries	145.9	647.2	425.4	(1,218.5)	—
Income (loss) from continuing operations before income taxes	108.0	421.0	582.1	(1,218.5)	(107.4)
Income tax benefit	(3.4)	(4.4)	(196.1)	—	(203.9)
Income from continuing operations	111.4	425.4	778.2	(1,218.5)	96.5
Income from discontinued operations, net of income taxes	—	—	14.9	—	14.9
Net income	111.4	425.4	793.1	(1,218.5)	111.4
Other comprehensive loss, net of tax	(4.3)	(4.3)	(9.3)	13.6	(4.3)
Comprehensive income	$ 107.1	$ 421.1	$ 783.8	$ (1,204.9)	$ 107.1

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
For the nine months ended September 27, 2019
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash from operating activities	$ (32.7)	$ 108.3	$ 462.2	$ (3.7)	$ 534.1
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(108.7)	—	(108.7)
Intercompany loan investment, net	57.8	—	(662.1)	604.3	—
Investment in subsidiary	—	(678.6)	—	678.6	—
Other	—	—	13.7	—	13.7
Net cash from investing activities	57.8	(678.6)	(757.1)	1,282.9	(95.0)
Cash Flows From Financing Activities:					
Issuance of external debt	—	—	695.0	—	695.0
Repayment of external debt	—	(135.2)	(804.9)	—	(940.1)
Proceeds from exercise of share options	0.5	—	—	—	0.5
Repurchase of shares	(2.5)	—	—	—	(2.5)
Intercompany loan borrowings, net	(24.9)	629.2	—	(604.3)	—
Intercompany dividends	—	—	(3.7)	3.7	—
Capital contribution	—	—	678.6	(678.6)	—
Other	2.1	—	(20.2)	—	(18.1)
Net cash from financing activities	(24.8)	494.0	544.8	(1,279.2)	(265.2)
Effect of currency rate changes on cash	—	—	0.5	—	0.5
Net change in cash, cash equivalents and restricted cash, including cash classified within assets held for sale	0.3	(76.3)	250.4	—	174.4
Less: Net change in cash classified within assets held for sale	—	—	(15.1)	—	(15.1)
Net change in cash, cash equivalents and restricted cash	0.3	(76.3)	235.3	—	159.3
Cash, cash equivalents and restricted cash at beginning of period	0.4	140.8	226.3	—	367.5
Cash, cash equivalents and restricted cash at end of period	$ 0.7	$ 64.5	$ 461.6	$ —	$ 526.8
Cash and cash equivalents at end of period	$ 0.7	$ 64.5	$ 433.6	$ —	$ 498.8
Restricted cash, included in other assets at end of period	—	—	28.0	—	28.0
Cash, cash equivalents and restricted cash at end of period	$ 0.7	$ 64.5	$ 461.6	$ —	$ 526.8

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
For the nine months ended September 28, 2018
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash from operating activities	$ 447.6	$ 43.0	$ 1,420.5	$ (1,430.0)	$ 481.1
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(93.3)	—	(93.3)
Acquisitions, net of cash	—	—	(699.9)	—	(699.9)
Proceeds from divestitures, net of cash	—	—	313.2	—	313.2
Intercompany loan investment, net	(393.6)	(85.2)	(367.2)	846.0	—
Investment in subsidiary		(168.3)	—	168.3	—
Other	—	—	28.8	—	28.8
Net cash from investing activities	(393.6)	(253.5)	(818.4)	1,014.3	(451.2)
Cash Flows From Financing Activities:					
Issuance of external debt	—	600.0	57.2	—	657.2
Repayment of external debt	—	(1,166.8)	(396.6)	—	(1,563.4)
Debt financing costs	—	(12.0)	—	—	(12.0)
Proceeds from exercise of share options	1.0	—	—	—	1.0
Repurchase of shares	(57.4)	—	—	—	(57.4)
Intercompany loan borrowings, net	—	846.0	—	(846.0)	—
Intercompany dividends	—	(814.2)	(615.8)	1,430.0	—
Capital contribution	—	—	168.3	(168.3)	—
Other	2.0	—	(26.3)	—	(24.3)
Net cash from financing activities	(54.4)	(547.0)	(813.2)	415.7	(998.9)
Effect of currency rate changes on cash	—	—	(0.9)	—	(0.9)
Net change in cash, cash equivalents and restricted cash	(0.4)	(757.5)	(212.0)	—	(969.9)
Cash, cash equivalents and restricted cash at beginning of period	0.7	908.8	369.6	—	1,279.1
Cash, cash equivalents and restricted cash at end of period	$ 0.3	$ 151.3	$ 157.6	$ —	$ 309.2
Cash and cash equivalents at end of period	$ 0.3	$ 151.3	$ 139.1	$ —	$ 290.7
Restricted cash, included in other assets at end of period	—	—	18.5	—	18.5
Cash, cash equivalents and restricted cash at end of period	$ 0.3	$ 151.3	$ 157.6	$ —	$ 309.2

19. Subsequent Events

Divestitures

On November 4, 2019, the Company announced it has completed the sale of BioVectra. Subsequent to September 27, 2019, the terms of the transaction were updated, with total consideration of up to $250.0 million including an upfront payment of $135.0 million and contingent consideration of $115.0 million based on the long-term performance of the business.

Financing Activities

On November 5, 2019, upon the terms and conditions set forth in a confidential offering memorandum dated November 5, 2019, Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC, each a wholly owned subsidiary of the Company (the "Issuers") commenced private offers to exchange (the "Exchange Offers") any and all of (i) the 4.875% Senior Notes due April 2020 issued by the Issuers for new 10.000% Second Lien Senior Secured Notes due 2025 to be issued by the Issuers (the "New Notes") and (ii) the 5.750% Senior Notes due August 2022, 4.750% Senior Notes due April 2023, 5.625% Senior Notes due October 2023 and 5.500% Senior Notes due April 2025 issued by the Issuers (collectively, and together with the 4.875% Senior Notes due April 2020, the "Notes") for up to $355.0 million of New Notes. In connection with the Exchange Offers, the Issuers also commenced solicitations of consents from the holders of each series of Notes (other than the 4.750% Senior Notes due April 2023) to amend the indentures governing such series of Notes to eliminate certain of the covenants, restrictive provisions, events of default and related provisions therein.

On November 5, 2019, Deerfield Partners, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Private Design Fund IV, L.P. (the "Exchanging Holders") entered into an exchange agreement (the "Exchange Agreement") with the Issuers pursuant to which such Exchanging Holders agreed to, among other things, exchange with the Issuers on the settlement date of the Exchange Offers, separate from such Exchange Offers, their holdings of Notes (comprised of approximately $67.6 million aggregate principal amount 4.875% Senior Notes due April 2020, approximately $258.7 million aggregate principal amount of the 4.750% Senior Notes due April 2023, approximately $98.5 million aggregate principal amount of the 5.625% Senior Notes due October 2023 and approximately $75.2 million aggregate principal amount of 5.500% Senior Notes due April 2025) for approximately $227.0 million aggregate principal amount of New Notes. The consummation of the Exchange Offers may have a material impact on the Company's financial condition, results of operations and cash flows.

Commitments and Contingencies

Certain litigation matters occurred during the nine months ended September 27, 2019 or prior, but had subsequent updates through the issuance of this report. See further discussion in Note 15.

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 28, 2018, filed with the United States ("U.S.") Securities and Exchange Commission ("SEC") on February 26, 2019.

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 (inclusive of Amitiza® (lubiprostone) ("Amitiza"); and
- *Specialty Generics* includes niche specialty generic drugs and active pharmaceutical ingredients ("API(s)").

During the nine months ended September 27, 2019, we experienced a change in our reportable segments, which primarily served to move the results related to Amitiza to the Specialty Brands segment from the Specialty Generics segment. All prior period segment information has been recast to reflect the realignment of our reportable segments on a comparable basis. Refer below for an update on our plans for the Specialty Generics business.

For further information on our business and products, refer to our Annual Report on Form 10-K for the fiscal year ended December 29, 2018, filed with the SEC on February 26, 2019.

Significant Events

Separation

Our long-standing goal remains to be an innovation-driven biopharmaceutical company focused on improving outcomes for underserved patients with severe and critical conditions. However, on August 6, 2019, we announced that based on current market conditions and developments, including increasing uncertainties created by the opioid litigation, we decided to suspend for now our previously announced plans to spin off the Specialty Generics company. We continue to actively consider a range of options intended to lead to the ultimate separation of the Specialty Generics business, consistent with our previously stated strategy.

Beginning in the first quarter through the third quarter of fiscal 2018, the historical financial results attributable to "the Specialty Generics Disposal Group" were reflected in our interim unaudited condensed consolidated financial statements as discontinued operations. As a result of the December 6, 2018 spin-off announcement of the Specialty Generics business, the Specialty Generics Disposal Group no longer met the requirements to be classified as held for sale, and the historical financial results attributable to the Specialty Generics Disposal Group were recast as continuing operations in our Annual Report on Form 10-K for the fiscal year ended December 28, 2018, as well as the unaudited condensed consolidated financial statements for the prior periods as presented herein.

During the three and nine months ended September 27, 2019, we incurred $19.8 million and $50.4 million in separation costs, respectively. These costs, which are included in selling, general and administrative ("SG&A") expenses, primarily relate to professional fees, incremental costs incurred to build out the corporate infrastructure of the previously planned Specialty Generics new company, costs incurred as we actively consider a range of options intended to lead to the ultimate separation of the Specialty Generics business, as well as rebranding initiatives associated with the Specialty Brands ongoing transformation.

Tax Matters

On August 5, 2019, the Internal Revenue Service ("IRS") proposed an adjustment to the taxable income of Mallinckrodt Hospital Products Inc. (“MHP”) as a result of its findings in the audit of MHP’s tax year ended September 26, 2014. MHP, formerly known as Cadence Pharmaceuticals, Inc. (“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 (“Transfer Price”) determined in conjunction with our 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 asserts the value of the Transferred IP exceeds the value of the acquired Cadence shares and, further, partially disallows our control premium subtraction. The proposed adjustment to taxable income of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of our U.S. Federal net operating loss carryforward of $849.3 million. We strongly disagree with the proposed increase to the Transfer Price and intend to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. The final outcome cannot be reasonably quantified at this time, however, the proposed adjustment may be material. We believe our reserve for income tax contingencies is adequate.

Medicaid Lawsuit

In May 2019, we filed a lawsuit in federal district court against the U.S. Department of Health and Human Services ("HHS") and Centers for Medicare & Medicaid Services ("CMS" and together with 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 (repository corticotropin injection) ("Acthar Gel"), which has the practical effect of imposing a prospective reduction in Acthar Gel net sales of $90.0 million to $100.0 million, which corresponds with the approximate amount of annualized Medicaid net sales for Acthar Gel. While we believe that our lawsuit has strong factual and legal bases, as of September 27, 2019, the potential for retroactive non-recurring charges could range from zero to approximately $600.0 million. This matter is further described in Note 15 to the unaudited condensed consolidated financial statements.

Reorganization of Intercompany Financing and Legal Entity Ownership

During the nine months ended September 27, 2019, we completed a reorganization of our intercompany financing and associated legal entity ownership in response to the changing global tax environment. As a result, during the nine months ended September 27, 2019, we recognized current income tax expense of $28.9 million and a deferred income tax benefit of $215.7 million with a corresponding reduction to net deferred tax liabilities. The reduction in net deferred tax liabilities was comprised of a decrease in interest-bearing deferred tax obligations, which resulted in the elimination of the December 28, 2018 balance of $227.5 million, a $35.4 million increase to a deferred tax asset related to excess interest carryforwards, a $26.4 million increase in various other net deferred tax liabilities and a $20.8 million decrease to a deferred tax asset related to tax loss and credit carryforwards net of valuation allowances. The elimination of the interest-bearing deferred tax obligation also eliminated the annual Internal Revenue Code section 453A interest expense.

Stannsoporfin

During the three months ended June 28, 2019, we recognized a full impairment on our in-process research and development ("IPR&D") asset related to stannsoporfin of $113.5 million as we will no longer pursue this development product.

VTS-270

VTS-270 is our development product to treat Niemann-Pick Type C, a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. The results of our completed registration trial for the product did not show a statistically significant separation from placebo. Neither the VTS-270 nor the placebo arm showed disease progression as would be expected for a neurodegenerative condition over 52 weeks of observation. The U.S. Food and Drug Administration ("FDA") indicated to us at a Type A meeting in August 2018 that their view on the potential approvability will be based on the totality of data, not a single study or endpoint. Accordingly, our review of the data from the Phase 2b/3 trial, including the longer term open label portion, continues to proceed and is being assessed in combination with several other available data sources. A better understanding of the potential benefit of VTS-270 will emerge as we carefully consider the totality of data available and continue to work with the primary investigators and the FDA to define a viable path to a new drug application (NDA). We will continue to assess the impact of any

changes to planned revenue or earnings on the fair value of the associated IPR&D asset of $274.5 million included within intangible assets, net on the unaudited condensed consolidated balance sheet as of September 27, 2019.

CPP-1X/sulindac

In May 2019, we along with Cancer Prevention Pharmaceuticals, Inc. ("CPP"), announced that CPP's pivotal Phase 3 clinical trial for CPP-1X/sulindac in patients with familial adenomatous polyposis ("FAP") did not meet its primary endpoint. Specifically, the reduction of time to the first occurrence of an FAP-related event for the combination of CPP-1X/sulindac did not reach statistical significance compared to the two control arms. Based on the topline results, we are no longer pursuing the commercialization of the CPP-1X/sulindac program under our collaborative agreement.

BioVectra

In September 2019, we entered into an agreement to sell our wholly owned subsidiary BioVectra Inc. ("BioVectra") to an affiliate of H.I.G. Capital. On November 4, 2019, we completed the sale of BioVectra with updated terms of total consideration of up to $250.0 million including an upfront payment of $135.0 million and contingent consideration of $115.0 million based on the long-term performance of the business.

Business Factors Influencing the Results of Operations

Specialty Brands

Net sales of Acthar Gel for the three months ended September 27, 2019 decreased $60.3 million, or 20.8%, to $229.8 million driven primarily by continued reimbursement challenges impacting new and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending.

Specialty Generics

After experiencing contraction over the last several years, the Specialty Generics business has returned to growth in fiscal 2019, primarily driven by share recapture in specialty generic products, partially offset by opioid market contraction. Net sales from the Specialty Generics segment increased $3.4 million or 2.1% to $163.3 million for the three months ended September 27, 2019 compared to $159.9 million for the three months ended September 28, 2018.

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 and others in the supply chain by state and federal agencies. We, along with other opioid manufacturers and others in the supply chain, have been the subject of federal and state government investigations and enforcement actions, as well as lawsuits by private parties, focused on the misuse and abuse of opioid medications in the U.S. Similar investigations, lawsuits and other actions may be initiated in the future.

On September 30, 2019, we 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 in connection with lawsuits pending in multidistrict opioid litigation ("MDL") in the U.S. District Court for the Northern District of Ohio ("Track 1 Cases"). 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. The Track 1 Cases assert various claims related to the opioid business operated by SpecGx LLC. Under the agreement, we paid $24.0 million in cash on October 1, 2019. In addition, we 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, we have 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.

As of the date of this report, we have been in preliminary discussions with certain plaintiffs in other pending opioid lawsuits and are likely to have further discussions and/or enter into additional discussions with other parties in connection with opioid lawsuits. We may be required to pay material amounts and/or incur other material obligations as a result of any settlements that are entered into as a result of such discussions, but we are unable to predict outcomes or estimate a range of reasonably possible losses at this stage. Further, such matters or the resolution thereof, whether through judicial process or settlement or otherwise, may make it necessary or advisable for us and/or one or more of our subsidiaries to seek to restructure our or their obligations in a bankruptcy proceeding. We are exploring a wide array of such potential outcomes as part of our contingency planning, including the impact such actions could have on our business and operations. Should a bankruptcy occur, we would be subject to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, as further described in Part II, Item 1A. "Risk Factors." Such litigation and related matters are further described in Note 15 to the unaudited condensed consolidated financial statements.

Research and Development Investment

We devote significant resources to research and development ("R&D") of products and proprietary drug technologies. We incurred R&D expenses of $103.1 million and $268.0 million for the three and nine months ended September 27, 2019, respectively, and $86.1 million and $260.7 million for the three and nine months ended September 28, 2018, 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.

Silence Therapeutics

In July 2019, we entered into a license and collaboration agreement with Silence Therapeutics plc ("Silence") that will allow the companies to develop and commercialize ribonucleic acid interference ("RNAi") drug targets designed to inhibit the complement cascade, a group of proteins that are involved in the immune system and that play a role in the development of inflammation. These proteins are known to contribute to the pathogenesis of many diseases, including autoimmune disease.

During the three months ended September 27, 2019, we paid $20.0 million upfront, which was recorded within R&D expense, and gained an exclusive worldwide license to Silence's C3 complement asset, SLN500, with options to license up to two additional complement-targeted assets in Silence's preclinical complement-directed RNAi development program. The agreement also includes additional payments to Silence of up to $10.0 million in research milestones for SLN500, in addition to funding for Phase 1 clinical development including good manufacturing practices (GMP). Silence will be responsible for preclinical activities, and for executing the development program of SLN500 until the end of Phase 1, after which we will assume clinical development and responsibility for global commercialization. If approved, Silence could receive up to $563.0 million in commercial milestone payments and tiered low double-digit to high-teen royalties on net sales for SLN500.

In addition to the aforementioned agreement, in July 2019 we acquired an equity investment of $5.0 million in Silence, which was valued at $11.4 million and included within other assets in the unaudited condensed consolidated balance sheet as of September 27, 2019. Refer to Note 16 to the unaudited condensed consolidated financial statements for further information regarding this investment.

Results of Operations

Three Months Ended September 27, 2019 Compared with Three Months Ended September 28, 2018

Net Sales

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

	Three Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
U.S.	$ 648.0	$ 706.2	(8.2)%
Europe, Middle East and Africa	70.3	63.0	11.6
Other geographic areas	25.4	30.7	(17.3)
Net sales	$ 743.7	$ 799.9	(7.0)

Net sales for the three months ended September 27, 2019 decreased $56.2 million, or 7.0%, to $743.7 million, compared with $799.9 million for the three months ended September 28, 2018. This decrease in net sales was primarily driven by a decrease in net sales of Acthar Gel, as previously mentioned, partially offset by increased net sales from the Specialty Generics segment. 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 27, 2019 decreased $42.1 million, or 11.5%, to $324.3 million, compared with $366.4 million for the three months ended September 28, 2018, primarily driven by the $56.2 million decrease in net sales. Gross profit margin was 43.6% for the three months ended September 27, 2019, compared with 45.8% for the three months ended September 28, 2018. The decrease in gross profit and gross profit margin was impacted by an additional $23.8 million of amortization for the Ofirmev intangible asset resulting from a change in amortization method as discussed further in Note 11 to the unaudited condensed consolidated financial statements. The additional amortization was partially offset by a decrease in the amortization of the inventory fair value adjustments related to Amitiza, which was fully amortized during the first quarter of 2019.

Selling, general and administrative expenses. SG&A expenses for the three months ended September 27, 2019 were $205.7 million, compared with $193.4 million for the three months ended September 28, 2018, an increase of $12.3 million, or 6.4%. The three months ended September 27, 2019 included a $28.2 million charge associated with the settlement of the MDL Track 1 Cases and $19.8 million in separation costs, partially offset by a $25.8 million decrease in the fair value of our contingent consideration liabilities primarily due to an increase in discount rates. The three months ended September 28, 2018 included an $11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability. The remaining decrease was attributable to various factors, including cost benefits gained from restructuring actions, including lower employee compensation costs, partially offset by increased professional fees and legal expense. As a percentage of net sales, SG&A expenses were 27.7% and 24.2% for the three months ended September 27, 2019 and September 28, 2018, respectively.

Research and development expenses. R&D expenses increased $17.0 million, or 19.7%, to $103.1 million for the three months ended September 27, 2019, compared with $86.1 million for the three months ended September 28, 2018. This increase is primarily driven by the $20.0 million upfront payment made to Silence during 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 13.9% and 10.8% for the three months ended September 27, 2019 and September 28, 2018, respectively.

Restructuring charges, net. During the three months ended September 27, 2019, we incurred $7.2 million of restructuring and related charges, net, related to employee severance and benefits. During the three months ended September 28, 2018, we incurred $19.6 million of restructuring and related charges, net, including $4.8 million of accelerated depreciation in SG&A and cost of sales, primarily related to employee severance and benefits and exiting certain facilities.

Non-Operating Items

Interest expense and interest income. During the three months ended September 27, 2019 and September 28, 2018, net interest expense was $74.7 million and $91.6 million, respectively. This decrease was primarily attributable to a $9.8 million decrease in interest expense due to a lower average outstanding debt balance during the three months ended September 27, 2019. Additionally, the interest accrued on deferred tax liabilities associated with our previously outstanding installment notes resulted in a decrease of $6.4 million. Interest income increased to $2.9 million for the three months ended September 27, 2019, compared with $2.0 million for the three months ended September 28, 2018, primarily related to interest on preferred equity certificates received as contingent consideration associated with the sale of the Nuclear Imaging business.

Other income, net. During the three months ended September 27, 2019 and September 28, 2018, we recorded other income, net, of $37.9 million and $13.4 million, respectively. The increase was primarily attributable to a gain of $18.7 million on debt repurchased, as well as an unrealized gain on equity securities of $6.5 million related to our investment in Silence.

Income tax benefit. We recognized 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, and an income tax benefit of $122.9 million on a loss from continuing operations before income taxes of $8.7 million for the three months ended September 28, 2018. This resulted in effective tax rates of 96.8% and 1,412.6% for the three months ended September 27, 2019 and September 28, 2018, respectively. 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, which was predominately related to previously acquired intangibles and the generation of tax loss and credit carryforwards net of valuation allowances. The income tax benefit for the three months ended September 28, 2018

was comprised of $8.5 million of current tax expense and $131.4 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles and generation of net operating losses.

The income tax benefit was $27.6 million for the three months ended September 27, 2019, compared with a tax benefit of $122.9 million for the three months ended September 28, 2018. The $95.3 million net decrease in the tax benefit included a $92.5 million decrease attributed to the tax benefit from the reorganization of the Company's intercompany financing and associated legal entity ownership, an $18.6 million decrease attributed to changes in the timing, amount and jurisdictional mix of income, partially offset by an increase in tax benefit of $9.3 million attributable to an adjustment to the fiscal 2018 income tax provision for various tax return filings and a $6.5 million increase attributed to separation costs.

Nine Months Ended September 27, 2019 Compared with Nine Months Ended September 28, 2018

Net Sales

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

	Nine Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
U.S.	$ 2,044.9	$ 2,105.5	(2.9)%
Europe, Middle East and Africa	218.6	187.1	16.8
Other geographic areas	94.1	88.1	6.8
Net sales	$ 2,357.6	$ 2,380.7	(1.0)

Net sales for the nine months ended September 27, 2019 decreased $23.1 million, or 1.0%, to $2,357.6 million, compared with $2,380.7 million for the nine months ended September 28, 2018. This decrease was primarily driven by the decrease in net sales of Acthar Gel, partially offset by the increase in net sales of Amitiza, which was acquired during the first quarter of 2018, and continued strength in Inomax®, Ofirmev and Therakos®. In addition, we experienced increased net sales in the Specialty Generics segment. 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 nine months ended September 27, 2019 decreased $59.6 million, or 5.4%, to $1,048.3 million, compared with $1,107.9 million for the nine months ended September 28, 2018, due in part to the $23.1 million decrease in net sales. Gross profit margin was 44.5% for the nine months ended September 27, 2019, compared with 46.5% for the nine months ended September 28, 2018. The decrease in gross profit and gross profit margin was primarily attributable to an additional $89.5 million of amortization for the Ofirmev intangible asset resulting from a change in amortization method during the three months ended March 29, 2019, as discussed further in Note 11 to the unaudited condensed consolidated financial statements. The additional amortization was partially offset by a decrease in the amortization of the inventory fair value adjustments related to Amitiza, which was fully amortized during the first quarter of 2019. Gross profit during the nine months ended September 28, 2018 also benefited from the exclusion of $18.0 million of depreciation and amortization for the Specialty Generics Disposal Group given its classification as held for sale through the third quarter of fiscal 2018.

Selling, general and administrative expenses. SG&A expenses for the nine months ended September 27, 2019 were $661.8 million, compared with $594.5 million for the nine months ended September 28, 2018, an increase of $67.3 million, or 11.3%. This increase was primarily attributable to $50.4 million in separation costs incurred during the nine months ended September 27, 2019, an increase in legal expense, primarily related to opioid defense costs, and a $28.2 million charge associated with the settlement of the MDL Track 1 Cases, partially offset by a $23.5 million decrease in the fair value of our contingent consideration liabilities primarily due to an increase in discount rates. Additionally, during the nine months ended September 28, 2018 we recorded a $35.0 million decrease in the fair value of the contingent consideration liability related to stannsoporfin and an $11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability. These changes were partially offset by cost benefits gained from restructuring actions, including lower employee compensation costs. As a percentage of net sales, SG&A expenses were 28.1% and 25.0% for the nine months ended September 27, 2019 and September 28, 2018, respectively.

Research and development expenses. R&D expenses increased $7.3 million, or 2.8%, to $268.0 million for the nine months ended September 27, 2019, compared with $260.7 million for the nine months ended September 28, 2018. This increase was

primarily related to the $20.0 million upfront payment to Silence. 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 11.4% and 11.0% for the nine months ended September 27, 2019 and September 28, 2018, respectively.

Restructuring charges, net. During the nine months ended September 27, 2019 we incurred $11.2 million of restructuring and related charges, net, related to employee severance and benefits. During the nine months ended September 28, 2018, we incurred $106.6 million of restructuring and related charges, net, including $4.8 million of accelerated depreciation in SG&A and cost of sales, primarily attributable to contract termination costs related to the production of Raplixa, as well as employee severance and benefits and exiting certain facilities.

Non-restructuring impairment charges. Non-restructuring impairment charges were $113.5 million for the nine months ended September 27, 2019 related to the full impairment of our stannsoporfin IPR&D asset, as previously mentioned. Non-restructuring impairment charges were $2.0 million for the nine months ended September 28, 2018 related to an impairment of a license associated with a product we elected to discontinue.

Non-Operating Items

Interest expense and interest income. During the nine months ended September 27, 2019 and September 28, 2018, net interest expense was $225.2 million and $273.5 million, respectively. This decrease was primarily attributable to a lower average outstanding debt balance during the nine months ended September 27, 2019, which yielded a decrease in interest expense of $19.9 million, an $18.0 million decrease in interest accrued on deferred tax liabilities associated with our previously outstanding installment notes and the recognition of an $8.6 million benefit to interest expense during the nine months ended September 27, 2019, due to a lapse of certain statute of limitations. For further information, refer to Note 15 to the unaudited condensed consolidated financial statements. Additionally, non-cash interest expense decreased by $1.7 million over the comparable period. During both the nine months ended September 27, 2019 and September 28, 2018, we also recognized interest income of $6.6 million.

Other income, net. During the nine months ended September 27, 2019 and September 28, 2018, we recorded other income, net, of $128.6 million and $17.8 million, respectively. 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 on the equity securities of $6.5 million related to our investment in Silence, partially offset by a $9.4 million write-off of unamortized debt discount and fees. The nine months ended September 28, 2018 included a gain of $6.5 million on debt repurchased and royalty income of $8.2 million, partially offset by a $3.8 million write-off of unamortized debt discount and fees. The remaining amounts in both periods represented items including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Income tax benefit. We recognized 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, and an income tax benefit of $203.9 million on a loss from continuing operations before income taxes of $107.4 million for the nine months ended September 28, 2018. This resulted in effective tax rates of 249.6% and 189.9% for the nine months ended September 27, 2019 and September 28, 2018, respectively. 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 charge, as well as the reorganization of our intercompany financing and associated legal entity ownership, which eliminated the interest-bearing deferred tax obligation. The income tax benefit for the nine months ended September 28, 2018 was comprised of $29.8 million of current tax expense and $233.7 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles and the generation of net operating losses.

The income tax benefit was $256.6 million for the nine months ended September 27, 2019, compared with a tax benefit of $203.9 million for the nine months ended September 28, 2018. The $52.7 million net increase in the tax benefit included an increase of $97.2 million attributed to the tax benefit from the reorganization of our intercompany financing and associated legal entity ownership, a $10.1 million increase attributed to separation costs, and an $8.5 million increase attributed to the non-restructuring impairment charge, partially offset by a decrease in tax benefit of $41.8 million predominately attributed to changes in the timing, amount and jurisdictional mix of income, a $11.2 million decrease attributed to net restructuring and related charges and a $10.1 million decrease attributed to the gain on debt repurchased.

Income from discontinued operations, net of income taxes. We recorded income from discontinued operations of $6.8 million and $14.9 million during the nine months ended September 27, 2019 and September 28, 2018, respectively, 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 operating income because management evaluates the operating results of the segments excluding such items. These items may include, but are not limited to, intangible asset amortization, net restructuring and related charges, non-restructuring impairment charges and separation costs. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated operating income and in the reconciliations presented below. Selected information by business segment is as follows:

Three Months Ended September 27, 2019 Compared with Three Months Ended September 28, 2018

Net Sales

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

	Three Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
Specialty Brands	$ 580.4	$ 640.0	(9.3)%
Specialty Generics	163.3	159.9	2.1
Net sales	$ 743.7	$ 799.9	(7.0)

Specialty Brands. Net sales for the three months ended September 27, 2019 decreased $59.6 million to $580.4 million, compared with $640.0 million for the three months ended September 28, 2018. The decrease in net sales was primarily driven by a $60.3 million or 20.8% 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.

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

	Three Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
U.S.	$ 513.9	$ 576.4	(10.8)%
Europe, Middle East and Africa	45.4	36.9	23.0
Other	21.1	26.7	(21.0)
Net sales	$ 580.4	$ 640.0	(9.3)

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

	Three Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
Acthar Gel	$ 229.8	$ 290.1	(20.8)%
Inomax	136.8	133.2	2.7
Ofirmev	86.1	87.1	(1.1)
Therakos	60.9	60.0	1.5
Amitiza	52.6	48.2	9.1
BioVectra	10.5	13.9	(24.5)
Other	3.7	7.5	(50.7)
Specialty Brands	$ 580.4	$ 640.0	(9.3)

Specialty Generics. Net sales for the three months ended September 27, 2019 increased $3.4 million, or 2.1%, to $163.3 million, compared with $159.9 million for the three months ended September 28, 2018. The increase in net sales was driven by Oxycodone and Other controlled substances products of $3.6 million and $3.4 million, respectively. These increases were partially

offset by a $4.4 million decrease in Other Specialty Generics products net sales compared to the three months ended September 28, 2018.

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

	Three Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
U.S.	$ 134.1	$ 129.8	3.3 %
Europe, Middle East and Africa	24.9	26.1	(4.6)
Other	4.3	4.0	7.5
Net sales	$ 163.3	$ 159.9	2.1

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

	Three Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 15.7	$ 15.5	1.3 %
Oxycodone (API) and oxycodone-containing tablets	17.2	13.6	26.5
Acetaminophen (API)	48.5	47.9	1.3
Other controlled substances	72.9	69.5	4.9
Other	9.0	13.4	(32.8)
Specialty Generics	$ 163.3	$ 159.9	2.1

Operating Income

Operating income by segment and as a percentage of segment net sales for the three months ended September 27, 2019 and September 28, 2018 is shown in the following table *(dollars in millions)*:

	Three Months Ended			
	September 27, 2019		September 28, 2018	
Specialty Brands [1]	$ 267.3	46.1%	$ 288.0	45.0%
Specialty Generics	21.8	13.3	16.5	10.3
Segment operating income	289.1	38.9	304.5	38.1
Unallocated amounts:				
Corporate and allocated expenses	(23.4)		(29.2)	
Intangible asset amortization	(210.4)		(184.2)	
Restructuring and related charges, net	(7.2)		(19.6)	
Non-restructuring impairment charges	—		(2.0)	
Separation costs	(19.8)		—	
R&D upfront payment [2]	(20.0)		—	
Total operating income	$ 8.3		$ 69.5	

(1) Includes $31.0 million of inventory fair-value step up expense, primarily related to Amitiza, during the three months ended September 28, 2018.

(2) Represents R&D expense incurred related to an upfront payment made to Silence in connection with the license and collaboration agreement entered into in July 2019.

Specialty Brands. Operating income for the three months ended September 27, 2019 decreased $20.7 million to $267.3 million, compared with $288.0 million for the three months ended September 28, 2018, primarily driven by the $59.6 million decrease in net sales. Operating margin increased to 46.1% for the three months ended September 27, 2019 compared with 45.0% for the three months ended September 28, 2018. Operating income and margin were both impacted by an additional $31.0 million of expense recorded during the three months ended September 28, 2018 related to the inventory fair value adjustment for Amitiza, which was fully amortized in the first quarter of 2019.

Specialty Generics. Operating income for the three months ended September 27, 2019 increased $5.3 million to $21.8 million, compared with $16.5 million for the three months ended September 28, 2018. Operating margin increased to 13.3% for the three

months ended September 27, 2019, compared with 10.3% for the three months ended September 28, 2018. The increase in operating income and margin was impacted by a $3.6 million increase in gross profit primarily due to the increase in net sales.

Corporate and allocated expenses. Corporate and allocated expenses were $23.4 million and $29.2 million for the three months ended September 27, 2019 and September 28, 2018, respectively. The three months ended September 27, 2019 included a $28.2 million charge associated with the settlement of the MDL Track 1 Cases, partially offset by a $25.8 million decrease in the fair value of our contingent consideration liabilities primarily due to an increase in discount rates. Three months ended September 28, 2018 included an $11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability and a $7.0 million decrease in fair value of the contingent consideration liability related to stannsoporfin. The remaining decrease was attributable to various factors, primarily driven by cost benefits gained from restructuring actions, including lower employee compensation costs.

Nine Months Ended September 27, 2019 Compared with Nine Months Ended September 28, 2018

Net Sales

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

	Nine Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
Specialty Brands	$ 1,812.4	$ 1,844.3	(1.7)%
Specialty Generics	545.2	536.4	1.6
Net sales	$ 2,357.6	$ 2,380.7	(1.0)

Specialty Brands. Net sales for the nine months ended September 27, 2019 decreased $31.9 million to $1,812.4 million, compared with $1,844.3 million for the nine months ended September 28, 2018. The decrease in net sales was primarily driven by a $107.0 million, or 12.9% decrease in Acthar Gel net sales, and a $14.9 million, or 50.7% decrease in Other Specialty Brands products compared with the nine months ended September 28, 2018. These decreases are partially offset by continued strength in Ofirmev, Inomax and Therakos compared with the nine months ended September 28, 2018. The decrease in Other Specialty Brands products net sales was primarily attributable to the sale of Recothrom during the first quarter of 2018.

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

	Nine Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
U.S.	$ 1,604.5	$ 1,669.0	(3.9)%
Europe, Middle East and Africa	126.4	101.0	25.1
Other	81.5	74.3	9.7
Net sales	$ 1,812.4	$ 1,844.3	(1.7)

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

	Nine Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
Acthar Gel	$ 720.1	$ 827.1	(12.9)%
Inomax	427.6	404.0	5.8
Ofirmev	272.2	254.7	6.9
Therakos	183.6	174.2	5.4
Amitiza	157.6	119.2	32.2
BioVectra	36.8	35.7	3.1
Other	14.5	29.4	(50.7)
Specialty Brands	$ 1,812.4	$ 1,844.3	(1.7)

Specialty Generics. Net sales for the nine months ended September 27, 2019 increased $8.8 million, or 1.6%, to $545.2 million, compared with $536.4 million for the nine months ended September 28, 2018. The increase in net sales was primarily driven by Oxycodone and Other controlled substances products of $10.0 million and $7.7 million, respectively. These increases were partially offset by a $7.9 million and $5.9 million decrease in Other Specialty Generics and acetaminophen products net sales, respectively, compared to the nine months ended September 28, 2018.

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

	Nine Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
U.S.	$ 440.4	$ 436.5	0.9 %
Europe, Middle East and Africa	92.2	86.1	7.1
Other	12.6	13.8	(8.7)
Net sales	$ 545.2	$ 536.4	1.6

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

	Nine Months Ended		
	September 27, 2019	September 28, 2018	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 51.2	$ 46.3	10.6 %
Oxycodone (API) and oxycodone-containing tablets	53.3	43.3	23.1
Acetaminophen (API)	143.1	149.0	(4.0)
Other controlled substances	265.7	258.0	3.0
Other	31.9	39.8	(19.8)
Specialty Generics	$ 545.2	$ 536.4	1.6

Operating Income

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

	Nine Months Ended			
	September 27, 2019		September 28, 2018	
Specialty Brands [1]	$ 864.2	47.7%	$ 794.4	43.1%
Specialty Generics	80.1	14.7	94.7	17.7
Segment operating income	944.3	40.1	889.1	37.3
Unallocated amounts:				
Corporate and allocated expenses	(105.6)		(85.7)	
Intangible asset amortization	(649.8)		(546.5)	
Restructuring and related charges, net	(11.2)		(106.6)	
Non-restructuring impairment charges	(113.5)		(2.0)	
Separation costs	(50.4)		—	
R&D upfront payment [2]	(20.0)		—	
Total operating (loss) income	$ (6.2)		$ 148.3	

(1) Includes $10.0 million and $77.5 million of inventory fair-value step up expense, primarily related to Amitiza, during the nine months ended September 27, 2019 and September 28, 2018, respectively.

(2) Represents R&D expense incurred related to an upfront payment made to Silence in connection with the license and collaboration agreement entered into in July 2019.

Specialty Brands. Operating income for the nine months ended September 27, 2019 increased $69.8 million to $864.2 million, compared with $794.4 million for the nine months ended September 28, 2018. Operating margin increased to 47.7% for the nine months ended September 27, 2019, compared with 43.1% for the nine months ended September 28, 2018. The increase in operating income and margin includes a $35.2 million increase in gross profit primarily driven by an additional $67.5 million of expense recorded during the nine months ended September 28, 2018 related to the inventory fair value adjustment for Amitiza,

which was fully amortized in the first quarter of 2019. The increase in operating income and margin was also attributable to a $29.7 million decrease in SG&A expenses compared to the nine months ended September 28, 2018, primarily due to cost benefits gained from restructuring actions, including lower employee compensation costs, partially offset by increased legal expense and professional fees and a decrease in R&D expenses of $5.4 million.

Specialty Generics. Operating income for the nine months ended September 27, 2019 decreased $14.6 million to $80.1 million, compared with $94.7 million for the nine months ended September 28, 2018. Operating margin decreased to 14.7% for the nine months ended September 27, 2019, compared with 17.7% for the nine months ended September 28, 2018. The decrease in operating income and margin was primarily impacted by an increase in SG&A primarily due to higher legal expense related to opioid defense costs, partially offset by an $8.4 million decrease in R&D expenses. Operating income and margin during the nine months ended September 28, 2018 benefited from the exclusion of $17.7 million of depreciation for the Specialty Generics Disposal Group given its classification as held for sale through the third quarter of fiscal 2018.

Corporate and allocated expenses. Corporate and allocated expenses were $105.6 million and $85.7 million for the nine months ended September 27, 2019 and September 28, 2018, respectively. The nine months ended September 27, 2019 included a $28.2 million charge associated with the settlement of the MDL Track 1 Cases, partially offset by a $23.5 million decrease the fair value of our contingent consideration liabilities primarily due to an increase in discount rates. The nine months ended September 28, 2018 included a $35.0 million decrease in fair value of the contingent consideration liability related to stannsoporfin and an $11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability. The remaining decrease was primarily driven by cost benefits gained from restructuring actions, including lower employee compensation costs, partially offset by increased professional 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 believe that our future cash from operations and access to capital markets will provide adequate resources to fund our working capital needs, capital expenditures and strategic investments for the foreseeable future.

From time to time, we may seek to enter into certain transactions to reduce the extent of our leverage and/or to extend the maturities of our outstanding indebtedness. For example, on November 5, 2019, we announced the commencement of a private exchange offering as discussed further in "Debt and Capitalization" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Furthermore, resolution of the previously mentioned opioid-related matters could have a material adverse impact on our financial position, cash flows or liquidity. We have been in preliminary discussions with certain plaintiffs in other pending opioid lawsuits and are likely to have further discussions and/or enter into additional discussions with other parties in connection with opioid lawsuits. We may be required to pay material amounts and/or incur other material obligations as a result of any settlements that are entered into as a result of such discussions. Further information on these risks are described in Part II, Item 1A. "Risk Factors".

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 27, 2019	September 28, 2018
Net cash from:		
Operating activities	$ 534.1	$ 481.1
Investing activities	(95.0)	(451.2)
Financing activities	(265.2)	(998.9)
Effect of currency exchange rate changes on cash and cash equivalents	0.5	(0.9)
Net increase (decrease) in cash and cash equivalents	$ 174.4	$ (969.9)

Operating Activities

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 from operating activities. Included within this change in working capital was a $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 Pharmaceuticals, Inc. (“Questcor”) U.S. Department of Justice ("DOJ") settlement. This was partially offset by a $68.7 million decrease in accounts receivable primarily attributable to a shift in customer mix and the timing of receipts, in addition to a higher balance of gross receivables at the end of fiscal 2018.

Net cash provided by operating activities of $481.1 million for the nine months ended September 28, 2018 was primarily attributable to net income of $111.4 million, adjusted for non-cash items of $391.1 million driven by depreciation and amortization of $597.0 million, partially offset by $232.7 million related to a reduction in our deferred income tax liabilities and a $21.4 million outflow from net investment in working capital. Included within this change in working capital were a $22.1 million net cash outflow related to other assets and liabilities, a $59.0 million increase in accounts receivable, partially offset by a $43.1 million decrease in inventory and a $16.7 million increase in net payables related to income taxes. The net cash outflow from other assets and liabilities was primarily attributable to the payment of liabilities assumed from the acquisition of Sucampo Pharmaceuticals, Inc. ("Sucampo Acquisition") in February 2018.

Investing Activities

Net cash used in investing activities was $95.0 million for the nine months ended September 27, 2019, compared with $451.2 million for the nine months ended September 28, 2018. The $356.2 million change primarily resulted from the cash outflows related to the Sucampo Acquisition of $698.0 million, partially offset by the $159.2 million of proceeds received, net of transaction costs, from the divestiture of a portion of the Hemostasis business, inclusive of the PreveLeak and Recothrom products during the nine months ended September 28, 2018; proceeds received of $154.0 million related to the note receivable from the purchaser of the Intrathecal Therapy business, which was sold during the three months ended March 31, 2017; and a $25.5 million cash inflow related to the sale of the remaining portion of our investment in Mesoblast Limited during the nine months ended September 28, 2018. The cash used in investing activities during the nine months ended September 27, 2019 was primarily attributable to $108.7 million 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 $265.2 million for the nine months ended September 27, 2019, compared with $998.9 million for the nine months ended September 28, 2018. The $733.7 million decrease in cash outflows was attributable to a $661.1 million decrease in debt repayments, net of issuances, and a $54.9 million decrease in shares repurchased. The significant components of our current year debt repayments 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. The nine months ended September 28, 2018 included debt repayment of $600.0 million related to our revolving credit facility, a $225.0 million voluntary repayment of the variable-rate term loan maturing in 2024, repayment of $366.0 million of assumed debt from the Sucampo Acquisition, a $300.0 million repayment of fully matured unsecured fixed rate notes and open market debt repurchases that aggregated to a total principal amount of $33.0 million.

Debt and Capitalization

As of September 27, 2019, the total debt principal was $5,810.9 million, of which $717.7 million was classified as current.

The total debt principal as of September 27, 2019 was comprised of the following:

Variable-rate instruments:		
Term loan due September 2024	$	1,524.7
Term loan due February 2025		404.6
Revolving credit facility		900.0
Fixed-rate instruments		2,981.6
Debt principal	$	5,810.9

The variable-rate term loan interest rates are based on 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 27, 2019, our fixed-rate instruments have a weighted-average interest rate of 5.37% and pay interest at various dates throughout the fiscal year. As of September 27, 2019, 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 market conditions warrant, we may from time to time repurchase debt securities issued by us, in the open market, in privately negotiated transactions, by tender offer or otherwise. Such repurchases, if any, will depend on prevailing market conditions, our liquidity requirements and other factors. The amounts involved may be material.

Debt reduction continues to be one of the primary focuses of our capital allocation strategy for fiscal 2019. Total principal debt reduction during the nine months ended September 27, 2019 was $345.8 million, inclusive of debt repurchases of total principal amount of $492.1 million, repayment of $250.0 million on our variable-rate receivable securitization due July 2020, thus automatically terminating this facility, and voluntary prepayments of $25.0 million and $175.0 million on our outstanding term loans due September 2024 and February 2025, respectively. In making the voluntary prepayments, we satisfied certain obligations included within external debt agreements to reinvest proceeds from the sale of assets and businesses within one year of the respective transaction or use the proceeds to pay down debt. These repayments were partially offset by $680.0 million of aggregate draws on our revolving credit facility during the nine months ended September 27, 2019.

As of September 27, 2019, we were, and expect to remain, in full compliance with the provisions and covenants associated with our debt agreements.

On November 5, 2019, upon the terms and conditions set forth in a confidential offering memorandum dated November 5, 2019, Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC, each a wholly owned subsidiary of ours (the "Issuers") commenced private offers to exchange (the "Exchange Offers") any and all of (i) the 4.875% Senior Notes due April 2020 issued by the Issuers for new 10.000% Second Lien Senior Secured Notes due 2025 to be issued by the Issuers (the "New Notes") and (ii) the 5.750% Senior Notes due August 2022, 4.750% Senior Notes due April 2023, 5.625% Senior Notes due October 2023 and 5.500% Senior Notes due April 2025 issued by the Issuers (collectively, and together with the 4.875% Senior Notes due April 2020, the "Notes") for up to $355.0 million of New Notes. In connection with the Exchange Offers, the Issuers also commenced solicitations of consents from the holders of each series of Notes to (other than the 4.750% Senior Notes due April 2023) amend the indentures governing such series of Notes to eliminate certain of the covenants, restrictive provisions, events of default and related provisions therein. Refer to Part II, Item 1A. "Risk Factors" for information regarding the risks related to the Exchange Offers.

On November 5, 2019, Deerfield Partners, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Private Design Fund IV, L.P. (the "Exchanging Holders") entered into an exchange agreement (the "Exchange Agreement") with the Issuers pursuant to which such Exchanging Holders agreed to, among other things, exchange with the Issuers on the settlement date of the Exchange Offers, separate from such Exchange Offers, their holdings of Notes (comprised of approximately $67.6 million aggregate principal amount 4.875% Senior Notes due April 2020, approximately $258.7 million aggregate principal amount of the 4.750% Senior Notes due April 2023, approximately $98.5 million aggregate principal amount of the 5.625% Senior Notes due October 2023 and approximately $75.2 million aggregate principal amount of 5.500% Senior Notes due April 2025) for approximately $227.0 million aggregate principal amount of New Notes.

Commitments and Contingencies

Legal Proceedings

See Note 15 of the notes to the unaudited condensed consolidated financial statements for a description of the legal proceedings and claims as of September 27, 2019.

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 14 of the notes to the unaudited condensed consolidated financial statements.

Off-Balance Sheet Arrangements

As of September 27, 2019, we had various letters of credit, guarantees and surety bonds totaling $35.6 million. There has been no change in our off-balance sheet arrangements during the nine months ended September 27, 2019.

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 27, 2019, 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 28, 2018.

Refer to Note 10 to the unaudited condensed consolidated financial statements for our adoption of ASU 2016-02, "Leases," and its related amendments.

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 and the effects of competition, litigation and 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," "should," "will," "would," "could" 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 28, 2018 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 27, 2019, our outstanding debt included $1,929.3 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 $7.1 million.

The remaining outstanding debt as of September 27, 2019 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 income 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 27, 2019 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 $1.8 million aggregate potential as of September 27, 2019. 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.

The financial results of our international operations are translated into U.S. dollars, further exposing us to currency exchange rate fluctuations. We have performed a sensitivity analysis as of September 27, 2019 that measures the change in the net financial position arising from a hypothetical 10.0% adverse movement in the exchange rates of all foreign currencies used, including the Euro and the Canadian Dollar, our most widely used foreign currencies, relative to the U.S. dollar, with all other variables held constant. The aggregate potential change in net financial position from a hypothetical 10.0% adverse change in the above currencies was $15.7 million as of September 27, 2019. The change in the net financial position associated with the translation of these currencies is generally recorded as an unrealized gain or loss on foreign currency translation within accumulated other comprehensive loss in shareholders' equity of our unaudited condensed consolidated balance sheets.

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.

As previously disclosed under “Part II - Item 9A - Controls and Procedures” in our Annual Report on Form 10-K for the fiscal year ended December 28, 2018, the Company did not design and maintain sufficiently precise or effective review and approval controls over the future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets. Management concluded that this control deficiency represented a material weakness. This material weakness did not result in a material misstatement to the Company’s financial statements or disclosures.

Management’s Remediation Initiatives

During the three months ended March 29, 2019, management, under the oversight of the executive leadership team and those charged with governance, completed the remedial actions below to improve the Company’s internal control over financial reporting and remediated the design of the material weakness:

- Continued to emphasize the importance of, and monitor the sustained compliance with, the execution of our internal controls over financial reporting through, among other activities, numerous meetings and trainings.
- Enhanced, and will continue to enhance, the design of internal controls governing oversight and evaluation of future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets.
- Tested the design effectiveness of the enhanced internal controls by performing them to re-evaluate the appropriateness, and test the accuracy, of information used to develop future cash flow forecasts in 2018.
- Concluded the enhanced controls were designed effectively and developed a plan to implement them to support future cash flow forecasts in 2019.

During the three months ended March 29, 2019, we successfully completed the actions above of testing the design of the enhanced internal controls to the extent necessary to conclude that the deficiencies in the design of the internal controls over future cash flows have been remediated. We will test and conclude on the operating effectiveness of these controls as they occur in 2019. Based on the activities and evaluation described above, our CEO and CFO concluded that, as of September 27, 2019, our disclosure controls and procedures were effective.

The remediation efforts were intended both to address the identified material weakness and to enhance our overall financial control environment. Management is committed to continuous improvement of the Company's internal control over financial reporting and will continue to diligently review the Company's internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 27, 2019 that have materially affected, or are likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

We are subject to various legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, employment disputes, contractual disputes and other commercial disputes, including those described below. We believe these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, we believe, unless indicated below, given the information currently available, that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

Opioid-Related Matters

Since 2017, multiple U.S. states, counties, other governmental persons or entities and private plaintiffs have filed lawsuits against certain entities of our 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 our products. As of November 5, 2019, the cases we are aware of include, but are not limited to, approximately 2,315 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 207 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 104 cases filed by individuals and 14 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Hawaii, Nevada, South Dakota, New Hampshire, Louisiana, Illinois and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of November 5, 2019, 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 September 12, 2019, the Attorney General for Ohio filed a motion in the Common Pleas Court of Ross County, Ohio to amend its complaint to add certain entities of our Company, but the court has not yet ruled on that motion. Certain of the lawsuits have been filed as putative class actions.

Federal Lawsuits

Most pending federal lawsuits have been coordinated in a federal 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. The counties claim 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 allege that opioid manufacturers' and distributors' failure to maintain effective controls against diversion was a substantial cause of the opioid crisis.

Summit County filed a complaint on December 20, 2017, an amended complaint that added us on April 25, 2018, and a second amended complaint on May 18, 2018. The manufacturer defendants jointly moved to dismiss the second amended complaint on May 25, 2018. Judge Polster, who is presiding over the MDL, denied the motion on December 19, 2018. Summit County filed a third amended complaint on March 21, 2019, which alleges violations of Racketeer-Influenced and Corrupt Organizations ("RICO"), the Ohio Corrupt Practices Act, statutory public nuisance, common law absolute public nuisance, negligence, common law fraud,

violations of Injury Through Criminal Acts, unjust enrichment, and civil conspiracy. Summit County seeks damages including but not limited to actual damages, treble damages, equitable and/or injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, attorneys' fees, all costs and expenses of suit, and pre- and post-judgment interest. Cuyahoga County filed a complaint on October 21, 2017, and an amended complaint on April 25, 2018 that added us. Cuyahoga County filed a third amended complaint on May 10, 2019. The third amended complaint contains causes of action and damages similar to those in the Summit County litigation. In June 2019, the parties filed motions for summary judgment and Daubert motions in Summit County and Cuyahoga County. In August and September 2019, the MDL court ruled on the summary judgment and Daubert motions, granting some and denying most others, including Mallinckrodt's Motion for Partial Summary Judgment. On September 6, 2019, the Company announced that it had reached a settlement in principle with Summit County and Cuyahoga County. 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. The Track 1 Cases assert various claims related to the opioid business operated by SpecGx LLC. Under the agreement, we paid a total sum of $24.0 million in cash during the three months ending December 27, 2019. In addition, we will provide $6.0 million in generic products, including addiction treatment products, and 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, we have 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 defendant to be heard in a subsequent trial. A hearing is scheduled for November 6, 2019 to discuss the next steps in the MDL, including potential remand of certain cases and which defendants will be included in subsequent trials.

We are also named in 224 similar state court cases in 29 states. These state court cases include actions filed by (1) state attorneys general; (2) counties, cities, and other municipalities; (3) district attorneys; (4) hospitals and other health systems; (5) individuals; (6) third-party payers; and (7) a Native American Tribe. There are differences among these cases. For instance, counties and cities often seek to recoup governmental expenses related to public services, while hospitals and other health systems typically seek compensation for opioid-related medical services. These cases also contain different causes of action. For example, state attorneys general complaints often utilize consumer protection statutes whereas third-party payers tend to focus on claims of fraud and breach of implied warranties. Further, not all lawsuits name the same defendants - some name manufacturers and distributors, while others also include pharmacies, pain clinics, doctors, and/or other individuals as defendants.

On June 14, 2019, MDL Plaintiffs filed a Notice of Motion and Motion for Certification of Rule 23(b)(3) Cities/Counties Negotiation Class. On July 9, 2019, the Plaintiffs' Executive Committee filed an Amended Motion for Class Certification. In July 2019, parties and third parties filed responses and replies to Plaintiffs' Amended Motion for Class Certification. A hearing on the Amended Motion took place on August 6, 2019. On September 11, 2019, the MDL court certified the Rule 23(b)(3) negotiation class.

State Court Lawsuits

A. Lawsuits Filed by State Attorneys General

Fourteen state attorneys general have filed lawsuits against us in their respective state courts. The Florida Attorney General was the first attorney general to file suit against us on May 15, 2018. The Illinois Attorney General filed the most recent attorney general lawsuit against us on October 28, 2019. In general, the state attorneys general allege that opioid manufacturers engaged in fraudulent or misleading marketing activities that led to increases in the sales of their prescription opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. For example, on August 14, 2018, the New York Attorney General brought an action against Purdue in the coordinated opioid litigation in Suffolk County, New York. An amended complaint was filed on March 28, 2019, naming us, among other opioid manufacturers, distributors, and individuals. The amended complaint alleges state law violations of the New York State Finance Law, the New York Social Service Law, the New York General Business Law, the New York Controlled Substance Act, and the New York Executive Law, as well as public nuisance, fraud, gross negligence, willful misconduct, and unjust enrichment against us. The amended complaint seeks, among other remedies, declaratory judgment, injunctive relief, the creation of an abatement fund, damages, civil penalties, and the disgorgement of profits. Certain defendants, including us, filed motions to dismiss on May 31, 2019. The State of New York opposed the motions on July 31, 2019 and defendants filed their reply briefs on August 30, 2019. Oral argument on these motions was subsequently held on October 7, 2019, and the motions are still pending. While the New York Attorney General action is illustrative, there are differences between the cases filed by state attorneys general. Each lawsuit contains different causes of action, including different common law claims and alleged violations of state-specific statutes. The lawsuits also contain different claims for damages. For instance, the Kentucky and Hawaii actions seek punitive damages, but the Florida action does not. Further, not all lawsuits name the same defendants - some name manufacturers and distributors, while others also include pharmacies and/or individuals as defendants. The New York Attorney General action is currently part of the Track One cases in the New York consolidated proceedings in Suffolk County, New York, with a trial currently scheduled to begin on March 2, 2020. Trial dates have also been set in Louisiana (September 14, 2020), Alaska (January 5, 2021), and New Mexico (September 7, 2021).

B. Lawsuits Filed by Cities, Counties, and Other Municipalities

There are currently more than 186 lawsuits against us filed by cities, counties, and other municipalities, pending in various state courts in 18 states. The earliest lawsuit that remains in state court was filed by the County of Northampton, Pennsylvania on December 28, 2017. In general, the complaints allege that opioid manufacturers engaged in fraudulent or misleading marketing activities that led to increases in the sales of their prescription opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. For example, on September 18, 2018, City of Reno filed a complaint in the Second Judicial District Court of Nevada and named us as a defendant, among other opioid manufacturers, distributors, and healthcare providers. An amended complaint was filed in December 3, 2018, following removal to and remand from the U.S. District Court for the District of Nevada. The amended complaint alleges violations of statutory public nuisance, common law public nuisance, negligence, negligent misrepresentation, negligence, and unjust enrichment. City of Reno seeks damages including but not limited to, general and special damages, punitive damages, a fund for establishing a medical monitoring program, restitution and reimbursement, disgorgement, and attorneys' fees and costs. Defendants, including us, filed motions to dismiss on March 4, 2019; the motions are pending, and a hearing is set for January 2020. On September 16, 2019, City of Reno filed supplemental argument in opposition to the motions to dismiss, to which Defendants filed a response on October 4, 2019. While the City of Reno action is illustrative, there are differences between the cases filed by cities, counties and other municipalities. These lawsuits contain different causes of action, including different common law claims and alleged violations of state-specific statutes. For example, municipalities in Maryland, Pennsylvania, and Virginia assert violations of their state consumer protection statutes, while many other states do not. The lawsuits also contain different claims for damages. For example, the City of Granite City and the County of Jersey, Illinois seek damages for particular public health expenditures, while municipalities in other states allege damages related more generally to costs for public services. Further, not all lawsuits name the same defendants - some name manufacturers and distributors, while others also include pharmacies and/or individuals as defendants.

In some jurisdictions, such as California, Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas and West Virginia, certain of the 186 state lawsuits filed by counties, cities and other municipalities have been coordinated for pre-trial proceedings before a single court within their respective state court systems. The first coordinated proceeding was formed in New York on July 31, 2017. The most recent state coordinated proceeding was formed in California on September 6, 2019. We are not named as a defendant in each case that may be pending in a particular state court MDL or coordinated proceeding. For example, approximately 44 cases filed by Texas counties are consolidated in the *In re: Texas Opioid Litigation*, No. 2018-63587, MDL No. 18-0358 (the "Texas MDL"), of which we are named in 13 cases. The Texas complaints generally allege violations of public nuisance, negligence, the Texas Controlled Substances Act, the Deceptive Trade Practices-Consumer Protection Act, unjust enrichment, common law fraud, and civil conspiracy, though there are differences among the complaints. Plaintiffs seek damages including but not limited to injunctive relief, economic and treble damages arising from alleged violations of the Texas Deceptive Trade Practices-Consumer Protection Act, civil penalties for violations of the Texas Controlled Substances Act, abatement of public nuisance, injunctive relief, punitive and actual damages, restitution, and attorneys' fees. We have filed answers in certain cases. A hearing on bellwether selection and other trial scheduling matters occurred on July 26, 2019, in which eight bellwether counties and alternates were selected as candidates for four trials, the first two of which are scheduled to occur in January 2021 and April 2021. We are currently named in six out of the eight selected bellwether counties but plaintiffs may amend their complaints to add us to the other two cases. Since the bellwether candidates were selected on July 26, 2019, three of the eight bellwether cases have been removed to federal court, one of which has been transferred to the federal MDL. Motions to remand have been filed in the other two cases; no replacement bellwethers have been selected while those cases remain in federal court. At present, we are named in three of the five bellwether candidates that remain in state court, and all three of the bellwethers that have been removed, although we may still be amended into others. Pursuant to the Docket Control Order entered by the court on October 18, 2019, trials are scheduled to begin on January 19, 2021 and April 12, 2021. While the Texas MDL is illustrative, there are differences between the coordinated cases. Each states' coordinated proceedings contain different causes of action, including different common law claims and alleged violations of state-specific statutes. For example, municipalities in Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, and Texas assert violations of their state unfair or deceptive trade practices acts, while other plaintiffs do not. The lawsuits also contain different claims for damages. For example, some of the cases in the Texas MDL request exemplary and punitive damages for gross negligence, while other cases do not. Further, not all lawsuits name the same defendants-some name manufacturers and distributors, while others also include pharmacies and/or individuals as defendants. A Case Management Order has been entered in the New York consolidated cases in Suffolk County, which provides for two separate case tracks to proceed to discovery and ultimately to trial. We are named in the three Track One cases with a trial currently scheduled to begin on March 2, 2020.

C. Lawsuits Filed by District Attorneys

Six District Attorneys ("DAs") have also filed lawsuits in state court against us that remain in state court. In general, the DA suits filed in Tennessee allege that defendants engaged in false and deceptive promotion of opioids and contributed to the oversupply and diversion of those products. They also allege that defendants' actions caused high addiction rates, overdose deaths, and increased rates of neonatal abstinence syndrome. The DAs have initiated lawsuits against opioid manufacturers, distributors, prescribers, retailers, and other individuals. The DAs allege that defendants participated in an illegal opioids market and that plaintiffs suffered damages related to increased law enforcement and health care costs, expenses related to rehabilitation and addiction treatment, prosecution costs, and foster care expenses, among others. *Staubus et al. v. Purdue Pharma, LP et al.*, No. C-41916 was filed in the Circuit Court for Sullivan

County on June 13, 2017 and amended on July 27, 2017 and February 15, 2018. We joined a motion to dismiss filed by the manufacturer defendants and filed a supplemental motion to dismiss regarding Company-specific claims on March 23, 2018. The court held a hearing on the motion to dismiss, in addition to other motions, on May 8, 2018. The court denied the motions to dismiss in an order filed on June 12, 2018. We filed an answer to the second amended complaint on June 29, 2018. The parties are currently engaged in discovery, and the court has set a trial date to begin on May 18, 2020. *Effler et al. v. Purdue Pharma, LP et al.*, No. 16596 was filed in the Circuit Court for Campbell County on September 29, 2017 and amended on October 6, 2017, January 10, 2018 and May 21, 2018. We joined a motion to dismiss filed by the manufacturer defendants on July 27, 2018. The court held a hearing on the motion to dismiss on October 4, 2018 and issued an order granting the manufacturer defendants' motion to dismiss on October 5, 2018. Plaintiffs filed a Notice of Appeal on November 1, 2018. We joined defendants-appellees' response brief which was filed on May 28, 2019. Plaintiff-appellants' filed their reply brief on July 11, 2019, and oral argument occurred on July 18, 2019. On September 11, 2019, the court granted Plaintiffs' appeal, reversing the trial court's judgment and remanding the case for further proceedings. Any party that wishes to appeal this ruling must petition the Tennessee Supreme Court by November 12, 2019. *Dunaway et al. v. Purdue Pharma, LP et al., No. CCI-2018-cv-6347* was filed in the Circuit Court for Cumberland County on January 10, 2018 and amended on August 7, 2018. We joined a motion to dismiss filed by the manufacturer defendants on September 21, 2018. Plaintiffs filed a second amended complaint on April 1, 2019, adding new defendants. A distributor defendant removed the action on May 3, 2019, and the district court remanded the case on May 22, 2019. We joined a motion to dismiss filed by the manufacturer defendants on July 15, 2019. Plaintiffs' opposition to defendants' motions to dismiss were filed on September 30, 2019. Replies are due on November 13, 2019, and oral argument is scheduled for December 16, 2019. Other than *Staubus et al. v. Purdue Pharma, LP et al*., there are currently no trials set in these cases.

With respect to the DA lawsuits filed in Pennsylvania, the first lawsuit that remains in state court was filed by the Commonwealth of Pennsylvania by John T. Adams, District Attorney of Berks County in the Berks County Court of Common Pleas on October 16, 2019. The most recent DA lawsuit that remains in state court was filed by the Commonwealth of Pennsylvania, acting by and through Francis T. Chardo, the District Attorney of Dauphin County in the Dauphin County Court of Common Pleas on October 23, 2019. In general, these DA cases allege that opioid manufacturers engaged in fraudulent or misleading marketing activities that led to increased use of prescription opioid products. They also allege that distributors failed to maintain effective controls over the opioid distribution system and attempted to evade restrictions on opioid distribution. Plaintiffs in all three cases bring claims for alleged violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law and Civil Conspiracy. Plaintiffs in all three cases seek damages related to services associated with addiction, overdoses, adverse health conditions, emergency response, hospitalization, and public safety conditions attributable to the opioid products manufactured and distributed by defendants, among other relief. There are currently no trials set in these cases.

D. Lawsuits Filed by Hospitals and Health Systems

Hospitals and other health systems have also filed lawsuits in state courts against us, and there are currently six such lawsuits. The first lawsuit that remains in state court was filed by Tucson Medical Center ("TMC") in Arizona on October 9, 2018. The other five lawsuits that remain in state court were filed by (1) various hospitals and other health systems in West Virginia on April 29, 2019; (2) various hospitals and other health systems in Arizona on June 18, 2019; (3) various hospitals and other health systems in Florida on September 16, 2019; (4) Mobile County Board of Health and Family Oriented Primary Health Care Clinic in Alabama on October 15, 2019; and (5) various hospitals and other health systems in Mississippi on October 16, 2019. The plaintiffs allege that opioid manufacturers have engaged in fraudulent or misleading marketing activities that led to increases in the sales of their opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. For example, on October 9, 2018, TMC filed a complaint in the Pima County Superior Court, Arizona against us, among other opioid manufacturers and distributors. On July 15, 2019, TMC filed a First Amended Complaint, which asserts claims for negligence, wanton negligence, negligence per se, negligent marketing, negligent distribution, nuisance, unjust enrichment, fraud and deceit, civil conspiracy, fraudulent concealment, and violations of Arizona's RICO Act and Consumer Fraud Act. TMC seeks damages and costs. Defendants, including us, filed motions to dismiss the complaint, which were denied by the court on September 16, 2019. While the TMC action is illustrative, there are differences between these cases. Each lawsuit contains different causes of action, including different common law claims and alleged violations of state-specific statutes. Further, not all lawsuits name the same defendants. For example, TMC and the other Arizona plaintiffs names manufacturers, distributors and pharmacies as defendants, while the West Virginia, Florida, Alabama and Mississippi plaintiffs also include individuals as defendants. There are currently no trials set in these cases.

E. Lawsuits Filed by Individuals

Individuals have filed lawsuits in state courts against us, and there are currently five such lawsuits. The first lawsuit that remains in state court was initially filed by the Estate of Bruce Brockel in the Circuit Court of Mobile County, Alabama, on October 25, 2017, and amended to add us to plaintiff's first amended complaint on February 5, 2018. The most recent lawsuit that remains in state court was filed by plaintiff Elizabeth Lavoise in the 22nd Judicial Circuit Court, City of St. Louis, Missouri, on August 21, 2019. In general, these lawsuits allege that opioid manufacturers have engaged in fraudulent or misleading marketing activities that led to increases in the sales of their opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. Individual plaintiffs generally claim that they suffered damages

related to increased healthcare costs, or wrongful death. For example, on December 5, 2018, the Estate of Bruce Brockel filed a third amended complaint in the Circuit Court of Mobile County, Alabama against us, among other prescription opioid manufacturers and individual doctors. The complaint contains a variety of causes of actions, including medical malpractice, negligence, wantonness, Alabama extended manufacturer's doctrine, fraud and misrepresentation, suppression and concealment, deceit, unjust enrichment and civil conspiracy. The plaintiff alleges that manufacturers engaged in the false and deceptive promotion of opioids, which led to the oversupply of opioids and caused decedent's death. The plaintiff seeks damages in an unspecified amount. We moved to dismiss the complaint on March 26, 2019. An opposition to the motion to dismiss was filed on April 25, 2019. The motion is currently pending. While the *Brockel* action is illustrative, there are differences among the cases filed by individuals. Many of these lawsuits contain different causes of action. For example, *Brockel* asserts a claim for civil conspiracy, while two of the individual actions filed in Missouri state court do not. One of the cases, *Robert Ruth*, is a putative class action, asserting claims on behalf of Missouri citizens who purchased or paid for health insurance policies. Further, not all lawsuits name the same defendants. For example, some lawsuits name only us as defendants, while others also include other manufacturers, pharmacies, and/or individuals. There are currently no trials set in these cases.

F. Lawsuits Filed by Third-Party Payers

Third-party payers, such as insurers, have also filed lawsuits in state courts against us. There are currently seven such lawsuits. The first lawsuit that remains in state court was filed by United Food and Commercial Workers (UFCW), Local 23 and Employers Health Fund in Pennsylvania on April 24, 2018. The most recent lawsuit that remains in state court, was filed by Steamfitters Local 449 Medical and Benefit Fund, on September 11, 2019. In general, plaintiffs allege that opioid manufacturers have engaged in fraudulent or misleading marketing activities that led to increases in the sales of their opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. Third-party payer plaintiffs claim that they paid costs for health issues stemming from opioid overuse.

The *Illinois Public Risk Fund* case asserts state law claims against the Company such as violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, fraudulent misrepresentation, insurance fraud, negligence, public nuisance and unjust enrichment. *Fire and Police Retiree Health Care Fund*, filed in Bexar County District Court in Texas and transferred to the Texas MDL, asserts similar state law claims against us, including public nuisance, common law fraud, negligence, gross negligence, unjust enrichment, civil conspiracy and fraudulent concealment. The remaining five cases are in Pennsylvania state court, where they have all been consolidated in the coordinated proceedings in Delaware County, Pennsylvania. The Pennsylvania complaints assert state law claims such as violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law statute, public nuisance, negligence, unjust enrichment, common law fraud, breach of implied warranties, negligence per se, negligent misrepresentation, negligent marketing and civil conspiracy. The Court denied the manufacturer defendants' preliminary objections on October 30, 2019 and certain test cases are proceeding to discovery. There are differences between these cases. Certain of these lawsuits contain different causes of action. For example, a case filed by Carpenters Health and Welfare Fund of Philadelphia and Vicinity asserts a claim for public nuisance, while a case filed by the International Union of Painters and Allied Trades, District Council 21 Welfare Fund does not. The lawsuits also contain different claims for damages. For instance, *Carpenters Health* seeks a declaratory judgment regarding plaintiffs' public nuisance claims, but *Painters and Allied Trades* does not. Further, not all lawsuits name the same defendants - some name manufacturers, while at least one lawsuit includes individuals as defendants. There are currently no trials set in these cases.

G. Lawsuits Filed by Native American Tribes

One Native American tribe has also filed a lawsuit in state court against us that remains in state court. The Apache Tribe of Oklahoma filed a lawsuit in Oklahoma state court on July 26, 2019. The plaintiff alleges that defendants downplayed the risks of prescription opioids, overstated their benefits, used third-parties to promote false information about prescription opioids, and failed to prevent the diversion of prescription opioid products. The complaint asserts claims for public nuisance, actual and constructive fraud, negligence and negligent misrepresentation, civil conspiracy and unjust enrichment. Plaintiff seeks punitive damages, actual damages, compensation for past and future costs of abatement, an abatement fund and attorneys' fees and costs. We have not yet filed a response to the complaint.

We will continue to vigorously defend ourselves against all of these lawsuits as detailed above and similar lawsuits that may be brought by others. As of the date of this report, we have held preliminary discussions with certain plaintiffs in other pending opioid lawsuits and are likely to have further discussions and/or enter into additional discussions with other parties in connection with opioid lawsuits. We may be required to pay material amounts and/or incur other material obligations as a result of any settlements that are entered into as a result of such discussions, but we are unable to predict outcomes or estimate a range of reasonably possible losses. Further, such matters or the resolution thereof, whether through judicial process or settlement or otherwise, may make it necessary or advisable for us and/or one or more of our subsidiaries to seek to restructure our or their obligations in a bankruptcy proceeding. We are exploring a wide array of such potential outcomes as part of our contingency planning, including the impact such actions could have on our business and operations. Should a bankruptcy occur, we would be subject to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, as further described in Part II, Item 1A. "Risk Factors."

Investigations and Other Inquiries

In addition to the lawsuits described above, certain entities of the Company have received subpoenas and civil investigative demands ("CIDs") for information concerning the sale, marketing and/or distribution of prescription opioid medications and the Company's suspicious order monitoring programs, including from the DOJ and the Attorneys General for Missouri, New Hampshire, Kentucky, Washington, Alaska, South Carolina, Puerto Rico, New York, West Virginia, Indiana and 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. We have 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, we 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, we 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, we received a rider from the USAO for EDNY requesting additional documents regarding our anti-diversion program. We are responding or have responded to these subpoenas, CIDs and any informal requests for documents.

The Attorneys General for Kentucky, Alaska and New York, and New Hampshire have subsequently filed lawsuits against us. Similar subpoenas and investigations may be brought by others or the foregoing matters may be expanded or result in litigation. Since these investigations and/or lawsuits are in early stages, we are unable to predict outcomes or estimate a range of reasonably possible losses.

New York State Opioid Stewardship Act

On October 24, 2018, we 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 our motion for preliminary injunctive relief. On January 17, 2019, the State of New York appealed the court's decision. We intend to vigorously assert our position in this matter. 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.

U.S. Drug Enforcement Administration Investigation

In November 2011 and October 2012, we received subpoenas from the U.S. Drug Enforcement Administration ("DEA") requesting production of documents relating to our suspicious order monitoring program for controlled substances. The USAO for the Eastern District of Michigan investigated the possibility that we 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 we failed to maintain appropriate records and security measures with respect to manufacturing of certain controlled substances at our Hobart facility during the period 2012-2013. In July 2017, we 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, we paid $35.0 million in fiscal 2017 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 of our controlled substance products and to report to the DEA when we conclude that chargeback data or other information indicates that a downstream registrant poses a risk of diversion, among other things. The MOA remains in effect until July 10, 2020, but we will continue utilizing all available transaction information to identify suspicious orders for reporting to the DEA beyond that date.

House Energy and Commerce Committee Investigation of Opioid Marketing and Distribution

In August 2018, we 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 our marketing and distribution of opioids. We completed our response to this letter in December 2018. We are cooperating with the investigation.

See Note 15 of the notes to the unaudited condensed consolidated financial statements for further description of the litigation, legal and administrative proceedings as of September 27, 2019.

Item 1A. Risk Factors.

Except for the risk factors described below, there have been no other 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 28, 2018, filed with the U.S. SEC on February 26, 2019.

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 5, 2019, the cases we are aware of include, but are not limited to, approximately 2,315 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 207 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 104 cases filed by individuals and 14 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Hawaii, Nevada, South Dakota, New Hampshire, Louisiana, Illinois and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of November 5, 2019, 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 RICO or similar state laws, violations of state Controlled Substances Act ("CSA") or state False Claims Act, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment 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. 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 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. As of November 5, 2019, we have been in preliminary discussions with certain plaintiffs in pending opioid lawsuits and are likely to have further discussions and/or enter into additional discussions with other parties in connection with opioid lawsuits and/or incur other material obligations. We may be required to pay material amounts and/or incur other material obligations as a result of any settlements that are entered into as a result of such discussions.

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. Further, such matters or the resolution thereof, whether through judicial process or settlement or otherwise may make it necessary or advisable for us and/or one or more of our subsidiaries to seek to restructure our or their obligations in a bankruptcy proceeding. We are exploring a wide array of such potential outcomes as part of our contingency planning, including the impact such actions could have on our business and operations. Should a bankruptcy occur, we would be subject to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, including, but not limited to by causing increased difficulty obtaining and maintaining commercial relationships on competitive terms with customers, suppliers and other counterparts; increased difficulty retaining and motivating key employees, as well as attracting new employees; diversion of management's time and attention to dealing with bankruptcy and restructuring activities rather than focusing exclusively on business operations; incurrence of substantial costs, fees and other expenses associated

with bankruptcy proceedings; and loss of ability to maintain or obtain sufficient financing sources for operations or to fund any reorganization plan and meet future obligations. We would in that event also be subject to risks and uncertainties caused by the actions of creditors and other third parties who have interests that may be inconsistent with our plans.

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 OSA, which went into effect on July 1, 2018 and established an aggregate $100 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. The litigation is still pending. 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, 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 other 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” previously disclosed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 28, 2018 filed with the U.S. SEC on February 26, 2019 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.

We previously identified a material weakness in our internal control over financial reporting, which has now been remediated by management. If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to report our financial results timely and accurately, which could adversely affect our business or the market price of our ordinary shares.

As disclosed in our Form 10-K for the fiscal year 2018, we previously identified a material weakness in our internal control over financial reporting related to review and approval controls over future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets. This control deficiency did not result in a material misstatement of our current or prior period consolidated financial statements. During the three months ended March 29, 2019, our management, under the oversight of our executive leadership team and those charged with governance, completed the remedial actions below to improve our internal control over financial reporting and remediated the design of the material weakness:

- Continued to emphasize the importance of, and monitor the sustained compliance with, the execution of our internal controls over financial reporting through, among other activities, numerous meetings and trainings.
- Enhanced, and will continue to enhance, the design of internal controls governing oversight and evaluation of future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets.
- Tested the design effectiveness of the enhanced internal controls by performing them to re-evaluate the appropriateness, and test the accuracy, of information used to develop future cash flow forecasts in 2018.
- Concluded the enhanced controls were designed effectively and developed a plan to implement them to support future cash flow forecasts in 2019.

Although we have remediated this material weakness in our internal controls over financial reporting, any failure to maintain effective internal control over financial reporting or disclosure controls and procedures could adversely affect our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses and could result in negative publicity or other negative actions that could harm investor confidence in our financial statements. If any or all of these

events occur, it could have a material adverse effect on our business, financial condition, results of operations and cash flows or adversely affect the market price of our ordinary shares.

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 federal district court against the Agency seeking to hold unlawful and set aside this decision. We plan to vigorously defend our position. If we are unsuccessful in our efforts to set aside CMS's decision, Medicaid net sales of Acthar Gel could be substantially eliminated and our efforts to continue building on our investment in non-sales and marketing activities to modernize Acthar Gel could be significantly undermined.

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. 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 Court of Appeals' decision with respect to the Praxair litigation ultimately could result in the launch of a competitive nitric oxide product before the expiration of the last of the patents listed in the FDA Orange Book, which could adversely affect our ability to successfully maximize the value of Inomax and have an adverse effect on the company's 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, which is an autologous immune cell therapy that is indicated in the U.S. for skin manifestations of cutaneous T-cell lymphoma and is available for several additional indications in markets outside the U.S. In the extracorporeal photopheresis ("ECP") process, blood is drawn from the patient, separating white blood cells from plasma and red blood cells (which are immediately returned to the patient). The separated white blood cells are treated with 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 the company no longer manufactures 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.

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

In the U.S. over the past several years, a significant number of pharmaceutical and biotechnology companies have been subject to inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales, marketing and pricing practices, including the DOJ and various other agencies including the Office of the Inspector General within the HHS, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the U.S. Federal Food, Drug and Cosmetic Act (FFDCA), the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, data and patient privacy laws, export and import laws, consumer protection laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. The DOJ and the SEC have also increased their focus on the enforcement of the Foreign Corrupt Practices Act of 1977 (FCPA), particularly as it relates to the conduct of pharmaceutical companies.

Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a "qui tam" suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If the government declines to intervene and prosecute the case, the individual may pursue the case alone. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses in connection with past or future activities, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as the possible exclusion from federal healthcare programs including Medicare and Medicaid, consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions could have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Specific to our business, in September 2012, prior to our acquisition of Questcor in August 2014, a subpoena was received from the USAO for the Eastern District of Pennsylvania, requesting documents pertaining to an investigation of its promotional practices. On or about March 8, 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 have since been consolidated. In September 2019, we executed a settlement agreement to resolve the portion of the investigation and the litigation involving promotional practices for $15.4 million. If any of our current practices related to the legacy Questcor business are found to be unlawful, we will have to change those practices, which could have a material adverse effect on our business, financial condition and results of operations. Further, if as a result of this investigation or litigation we are found to have violated one or more applicable laws, we could be subject to a variety of fines, penalties, and related administrative sanctions, and our business, financial condition, results of operations and cash flows could be materially adversely affected.

In addition, there has recently been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. If we are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, actions against executives overseeing our business, and burdensome remediation measures. As discussed above, the USAO for the Eastern District of Pennsylvania is investigating this issue and the U.S. District Court for the Eastern District of Pennsylvania has unsealed two qui tam actions involving the allegations that are the subject of this investigation. In addition, in December 2016, we received a subpoena from the USAO for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to patients and documents concerning our provision of financial assistance to patients prescribed Acthar Gel. Other companies have disclosed similar inquiries. We are cooperating with this inquiry. It is possible that any actions taken by the DOJ or one of the USAOs as a result of this inquiry or any future action taken by federal or local governments, legislative bodies and enforcement agencies on this subject could result in civil penalties or injunctive relief, negative publicity or other negative actions that could harm our reputation, and could reduce demand for our products and/or reduce coverage of our products, including by federal healthcare programs such as Medicare and Medicaid and

state health care, which would negatively impact sales of our products. If any or all of these events occur, it could have an adverse effect on our business, financial condition, results of operations and cash flows.

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

The DEA is the U.S. federal agency responsible for domestic enforcement of the CSA. The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Schedule II controlled substances include molecules such as oxycodone, oxymorphone, morphine, fentanyl and hydrocodone. The manufacture, storage, distribution and sale of these controlled substances are permitted, but highly regulated. The DEA regulates the availability of API, products under development and marketed drug products that are in the Schedule II category by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our needs. In 2018, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the U.S. in 2018 by 20% and could take similar actions in the future. In December 2018, the DEA reduced the amount of the six most frequently misused opioids that may be manufactured in the U.S. in calendar year 2019 by an average of 10% as compared to the 2018 amount. On September 13, 2019, the DEA proposed that benzylfentanyl and 4-anilinopiperidine be controlled as list I chemicals under the CSA. On September 17, 2019, the DEA proposed to designate norfentanyl as an immediate precursor (i.e., a substance from which another is formed) for fentanyl and to make it a Schedule II controlled substance under the CSA. The DEA could take similar actions in the future. Future delay or refusal by the DEA to grant, in whole or in part, our quota requests could delay or result in stopping the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials. Such delay or refusal also could require us to allocate marketed drug products among our customers. These factors, along with any delay or refusal by the DEA to provide customers who purchase API from us with sufficient quota, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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

The regulations regarding reporting and payment obligations with respect to Medicare and Medicaid reimbursement programs, and rebates and other governmental programs, are complex. Because our processes for these calculations and the judgments used in making these calculations involve subjective decisions and complex methodologies, these accruals may have a higher inherent risk for material changes in estimates. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material adjustments to amounts previously paid. See "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."

Any governmental agencies that have commenced, or may commence, an investigation of us relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal healthcare programs including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments, and even in the absence of any such ambiguity, a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. For example, from time to time, state attorneys general have brought cases against us that allege generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and generally seek monetary damages and attorneys' fees. Any such penalties or sanctions that we might become subject to in this or other actions could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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

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

- incur, assume or guarantee additional indebtedness;
- declare or pay dividends, make other distributions with respect to equity interests, or purchase or otherwise acquire or retire equity interests;
- make any principal payment on, or redeem or repurchase, subordinated debt;
- make loans, advances or other investments;
- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- incur liens;
- enter into transactions with affiliates;
- enter into sale and lease-back transactions; and
- consolidate or merge with or into, or sell all or substantially all of our assets to, another person or entity.

In addition, the restrictive covenants in the credit agreement governing our senior secured credit facilities require us to comply with a financial maintenance covenant in certain circumstances. Our ability to satisfy this financial maintenance covenant can be affected by events beyond our control and we cannot assure holders that we will be able to comply.

A breach of the covenants under the agreements that govern the terms of any of our indebtedness could result in an event of default under the applicable indebtedness. Such default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. In addition, an event of default under the credit agreement that governs our senior secured credit facilities would permit the lenders under such facilities to terminate all commitments to extend further credit thereunder. Furthermore, if we are unable to repay the amounts due and payable under our senior secured credit facilities or the New Notes, those lenders or investors will be able to proceed against the collateral granted to them to secure that indebtedness. If the holders of our debt accelerate the repayment of our borrowings, we may not have sufficient assets to repay that indebtedness.

As a result of these restrictions, we may be:

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

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

If the conditions to the Exchange Offers are not met, the Exchange Offers may not be completed, in which case our liquidity may be limited and we may be unable to pay principal and interest on the Notes when due.

Consummation of each Exchange Offer is subject to the satisfaction or waiver of a number of conditions.

We are highly leveraged. In the event that the Exchange Offers and the transactions contemplated by the Exchange Agreement are not completed, we will remain highly leveraged, which may result in the inability to pay principal and interest on the Notes when due, which may result in holders of the Notes not realizing a full recovery on their investment in the Notes, or an event of default under the terms of the Notes, which may lead to acceleration of our other indebtedness by the holders thereof.

If the proposed amendments to the indentures governing the Notes become operative, our future subsidiaries will not be required to guarantee the Notes and such future subsidiaries may incur significant indebtedness, and the Issuers and the existing subsidiary guarantors of the Notes may make investments in or transfer assets to such non-guarantor subsidiaries.

The proposed amendments to the indentures governing the Notes would eliminate the requirement that any of our future subsidiaries become guarantors of the Notes. As a result, the Notes will be structurally subordinated to any indebtedness of any such future subsidiaries of ours, including, as applicable, the New Notes. The indentures governing the Notes (as amended by the proposed amendments) will not limit the transfer of assets to, or investments in, any such non-guarantor subsidiaries. There can be no assurance that the Issuers and the subsidiary guarantors of the Notes will not transfer significant amounts of assets to, or make significant investments in, such non-guarantor subsidiaries, or any other persons.

We will incur significant costs in conducting the Exchange Offers and Consent Solicitations.

The Exchange Offers and conduction of simultaneous solicitations of consents by us ("Consent Solicitations") have resulted, and will continue to result, in significant costs to us, including advisory and professional fees paid in connection with evaluating our alternatives under the Notes and pursuing the Exchange Offers and Consent Solicitations.

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 27, 2019. The repurchase activity presented below includes both market repurchases of shares and deemed repurchases in connection with the vesting of restricted share units under employee benefit plans to satisfy minimum statutory tax withholding obligations.

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, and the Company currently expects to fully utilize the program.

	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 29, 2019 to July 26, 2019	1,500	$ 9.07	—	$ 564.2
July 27, 2019 to August 30, 2019	553	6.62	—	564.2
August 31, 2019 to September 27, 2019	6,468	3.06	—	564.2
June 29, 2019 to September 27, 2019	**8,521**	**4.35**		

Item 6. Exhibits.

Exhibit Number	Exhibit
10.1	Form of Deed of Indemnification by and between Mallinckrodt plc and Directors and Secretary (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.2	Form of Deed of Indemnification by and between Mallinckrodt plc and Officers (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.3	Form of Indemnification Agreement by and between Sucampo Pharmaceuticals, Inc. and Directors and Secretary (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.4	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.5	Separation of Employment Agreement and General Release by and between Matthew Harbaugh and Mallinckrodt Enterprises LLC.
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 27, 2019 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 5, 2019

Exhibit 10.5

SEPARATION OF EMPLOYMENT AGREEMENT AND GENERAL RELEASE

THIS SEPARATION OF EMPLOYMENT AGREEMENT AND GENERAL RELEASE ("**Agreement**") by and between Matthew Harbaugh ("**Executive**") and Mallinckrodt Enterprises LLC, (the "Company"), is provided to Executive on September 6, 2019.

WHEREAS, Executive was employed by the Company through September 6, 2019 ("**Separation Date**") and performed services for the Company and/or one or more of its affiliates;

WHEREAS, Executive and the Company mutually desire to terminate Executive's employment on an amicable basis, and have agreed to terms set forth herein and for the resolution of any and all disputes between them.

NOW, THEREFORE, IT IS HEREBY AGREED:

1. Benefits Upon Termination of Employment. Whether or not Executive signs this Agreement, Executive will be entitled to the following:

(a) Earned But Unpaid Amounts. Subject to the provisions of the paragraph entitled "Deductions for Amounts Owed to Company," Executive shall receive any amounts earned, accrued or owing but not paid to Executive as of the Separation Date including unpaid base salary earned by Executive through the Separation Date.

(b) COBRA Continuation Coverage. Executive (and Executive's spouse, domestic partner or child(ren), as applicable) shall be eligible for continued coverage under the Company's group health plans as required by and pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**"). Executive acknowledges the Company will provide COBRA coverage only if such coverage is timely elected by Executive (or other qualified beneficiary as defined by COBRA) and Executive is solely responsible for electing such coverage. If Executive does not elect COBRA coverage timely, Executive will not be eligible to receive COBRA coverage. Executive will be required to pay the entire premium for COBRA coverage and acknowledges COBRA coverage will end upon the expiration of the maximum period required under COBRA or earlier than such time if Executive does not pay the required premium within the applicable time period, if Executive terminates COBRA coverage, or if an event occurs that, pursuant to COBRA, permits the earlier termination of COBRA coverage.

2. Consideration to Executive for Signing This Agreement. In consideration for Executive signing this Agreement, the Company agrees to provide Executive with severance benefits, in addition to those benefits described in the section entitled "Benefits Upon Termination of Employment," and modify certain benefits described in such section as follows:

(a) Base Salary Payment. As soon as is administratively possible after the end of any applicable revocation period for this Agreement, Executive will receive a lump sum payment in the gross amount of $600,000.00, minus any applicable deductions or withholdings or other reductions required by applicable law, which is equivalent to twelve (12) months of Executive's current base salary. Executive expressly authorizes the Company to make any necessary deductions, withholdings, or other reductions from amounts paid pursuant to this paragraph.

(b) Subsidized COBRA Premium. As soon as is administratively possible after the end of any applicable revocation period for this Agreement, Executive will receive a lump sum payment in the gross amount of $21,116.16, minus any applicable deductions or withholdings or other reductions required

by applicable law, which shall be equal to twelve times the difference between (i) the applicable monthly COBRA premium in effect on the Separation Date for the medical, dental, vision and EAP plan options in which Executive is enrolled on the Separation Date, and (ii) the monthly premium paid for such coverage by Executive as of the Separation Date. Executive expressly authorizes the Company to make any necessary deductions, withholdings, or other reductions from amounts paid pursuant to this paragraph.

(c) Annual Incentive Bonus. In lieu of a bonus under the Global Bonus Plan for the Company Fiscal Year 2019, the Company shall pay Executive a lump sum in the gross amount of $290,769.23, minus any applicable deductions or withholdings or other reductions required by applicable law, which shall be paid as soon as is administratively possible after the end of any applicable revocation period for this Agreement. The Company shall have no further obligations to Executive under the Global Bonus Program or any other bonus program except as expressly set forth herein.

(d) Outplacement Services. The Company shall pay the cost of outplacement services for the Executive at the outplacement agency the Company regularly uses for such purpose for a period of twelve (12) months and at the level of services offered to similarly-situated Company employees.

(e) No Further Benefits. Except as provided in this Agreement or as required by the terms of a Company-sponsored employee benefit plan in which Executive is participating on the Separation Date, no payment, compensation, leave time, insurance or other benefits will be furnished or paid to Executive. Except as specifically provided for in this Agreement or the terms of the applicable employee benefit plan, as of the Separation Date, Executive will cease to be eligible to participate under, or be covered by, any compensation or employee benefit plan and has no rights under any of those plans.

3. Release of Claims

(a) Executive's Release of Claims. Executive, for and in consideration of the commitments of the Company, including those set forth in the section entitled "Consideration to Executive for Signing This Agreement," and intending to be legally bound, does hereby REMISE, RELEASE AND FOREVER DISCHARGE the Company, its affiliates, subsidiaries and parents, and its officers, directors, employees, and agents, and its and their respective successors and assigns, heirs, executors, and administrators (collectively, "**Releasees**") from all causes of action, suits, debts, claims and demands whatsoever in law or in equity, which Executive ever had, now has, or hereafter may have, whether known or unknown, or which Executive's heirs, executors, or administrators may have, by reason of any matter, cause or thing whatsoever, from the beginning of Executive's employment to the date Executive signs this Agreement, and particularly, but without limitation of the foregoing general terms, any claims arising from, or relating in any way to, Executive's employment relationship with Company, the terms and conditions of that employment relationship, and the termination of that employment relationship, including, but not limited to, any claims arising under the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act ("**OWBPA**"), Title VII of The Civil Rights Act of 1964, Sections 1981 and 1983 of the Civil Rights Act of 1866, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974, the Workers Adjustment Retraining Notification ("**WARN**") Act, the Family and Medical Leave Act of 1993, the Genetic Information Non-Discrimination Act of 2008, the Fair Credit Reporting Act, the Equal Pay Act, the Rehabilitation Act of 1973, the Uniform Services Employment and Reemployment Rights Act ("**USERRA**"), the National Labor Relations Act, the False Claims Act, and any other claims under any federal, state or local common law, statutory, or regulatory provision, now or hereafter recognized, and any claims for attorneys' fees and costs. Executive specifically acknowledges during Executive's employment, (i) Executive was provided notice of all rights permitted under the Family and Medical Leave Act of 1993 ("**FMLA**"), understood those rights, was allowed to take all leave and afforded all other rights to which

Executive is entitled under the FMLA, (ii) the Company has not in any way interfered with, restrained or denied Executive's exercise of (or attempt to exercise) any FMLA rights, nor terminated or otherwise discriminated against Executive for exercising (or attempting to exercise) any such rights, (iii) Executive has been paid for all hours worked (including overtime) to which Executive is entitled, and (iv) Executive was not treated differently or in any way discriminated against because of Executive's age. This Agreement is effective without regard to the legal nature of the claims raised and without regard to whether any such claims are based upon tort, equity, implied or express contract or discrimination of any sort. Notwithstanding anything in this Agreement to the contrary, this release of claims shall not apply to Executive's rights or claims (A) to indemnification, advancement of expenses or insurance related to Executive's service as a director, officer or employee of the Company or any of its affiliated corporations or entities, (B) to vested benefits under any employee benefit plan or (C) to enforce Executive's contractual rights under this Agreement. Nothing in this Agreement shall be interpreted to require Executive to release any claims that cannot lawfully be released, and nothing in this section shall be interpreted to provide Executive with indemnification rights beyond those which Executive may have had during his employment with the Company.

(b) Executive's Representations. To the fullest extent permitted by law, and subject to the provisions of the section entitled "Permissible Disclosures," Executive represents and affirms (i) Executive has not filed or caused to be filed on Executive's behalf any claim for relief against the Company or any Releasee and, to the best of Executive's knowledge and belief, no outstanding claims for relief have been filed or asserted against the Company or any Releasee on Executive's behalf, (ii) Executive has no knowledge of any improper, unethical or illegal conduct or activities by or on behalf of the Company, other than those which have already been reported to a human resources representative, to any member of the Company's legal or compliance departments, or to the Integrity Hotline and (iii) Executive will not file, charge, claim, sue or cause or permit to be filed, charged or claimed, any civil action, suit or legal proceeding seeking equitable or monetary relief (including damages, injunctive, declaratory, monetary or other relief) for Executive involving any matter released in this Agreement. Furthermore, Executive will withdraw with prejudice any such lawsuit or other legal action that may already be pending. In the event suit is filed in breach of this covenant not to sue, it is expressly understood and agreed this covenant shall constitute a complete defense to any such suit. In the event any Releasee is required to institute litigation to enforce the terms of this subsection, Releasees shall be entitled to recover reasonable costs and attorneys' fees incurred in such enforcement. Executive further agrees and covenants should any person, organization, or other entity file, charge, claim, sue, or cause or permit to be filed any civil action, suit or legal proceeding involving any matter occurring at any time in the past, Executive will not seek or accept personal equitable or monetary relief in such civil action, suit or legal proceeding. Although this Agreement does not preclude Executive from filing a charge of discrimination with the Equal Employment Opportunity Commission or related state agency or from participating in an investigation by such agency, Executive promises never to seek or accept any damages, remedies, or other relief for Executive personally (any right to which is hereby waived) with respect to any claim purportedly released by this Agreement.

(c) No Unresolved Claims. This Agreement has been entered into with the understanding there are no unresolved claims of any nature which Executive has against the Company. Executive acknowledges and agrees, except as specified in the section entitled "Consideration to Executive for Signing This Agreement," all compensation, benefits, and other obligations due Executive by the Company, whether by contract or by law, have been paid or otherwise satisfied in full or have been provided for in this Agreement. Executive further agrees the representations and understandings set forth in this Agreement have been relied upon by the Company and constitute consideration for the Company's execution of this Agreement.

4. Restrictions. Any agreement signed by Executive at the time of hire or during employment regarding non-disclosure; trade secrets; confidential or proprietary information; disclosure or ownership of inventions, methods, processes or improvements; non-solicitation; or non-competition shall continue in full force and effect. The Company has provided copies of any and all such agreements to Executive.

5. Continued Cooperation. Executive acknowledges the Company may need to consult with Executive from time to time on a reasonable basis after the Separation Date on matters Executive had worked on prior to the Separation Date, including with respect to litigation involving Executive and/or the Company. Executive agrees to continue to cooperate with the Company and to provide any such information as is reasonably requested by the Company. The Company will reimburse Executive for any reasonable pre-approved expenses incurred in providing this cooperation and will not unreasonably interfere with any professional or personal needs or obligations of Executive in these requests.

6. Rehire. Executive agrees and recognizes Executive has permanently and irrevocably severed Executive's employment relationship with the Company, Executive shall not seek employment or seek to provide services as an employee, consultant, independent contractor or otherwise with the Company or any affiliated entity at any time in the future, and the Company has no obligation to employ, or retain the services of, Executive in the future.

7. Non-Disparagement. Subject to the provisions of the section entitled "Permissible Disclosures," Executive agrees Executive will not disparage or subvert the Company, or make any statement reflecting negatively on the Company, its affiliated corporations or entities, or any of their officers, directors, employees, agents or representatives, including, but not limited to, any matters relating to the operation or management of the Company, Executive's employment and the termination thereof. The Company will instruct Mark Trudeau, Ian Watkins, Hugh O'Neill, Steve Romano, Mark Casey, Bryan Reasons, Dagmar Rosa-Björkeson, and Frank Scholz that they shall not disparage or make any statement reflecting negatively on Executive in any manner, including matters relating to his employment and the termination thereof. It is the Company's current reference policy to confirm only the Executive's dates of employment, job title and most recent salary upon receipt of a reference request.

8. Understanding of Consideration. Executive understands and agrees the payments, benefits and agreements provided in this Agreement, including those set forth in the section entitled "Consideration to Executive for Signing This Agreement," are being provided to Executive in consideration for Executive's acceptance and execution of, and in reliance upon, Executive's representations in this Agreement, and they are greater than the payments, benefits and agreements, if any, to which the Executive would have received if Executive had not executed this Agreement.

9. Satisfaction of Company Obligations. Executive acknowledges and agrees the Company has satisfied any and all obligations owed to Executive under any employment agreement or offer letter Executive has with the Company and this Agreement fully supersedes any and all prior agreements or understandings, whether written or oral, between the parties, regarding the subject matter of this Agreement. Executive acknowledges, except as set forth expressly herein, neither the Company, the Releasees, nor their agents or attorneys have made any promise, representation or warranty whatsoever, either express or implied, or written or oral.

10. Company Property.

(a) Company Records. Executive represents Executive does not have in Executive's possession any records or business documents, in electronic or hard copy, or other materials (including but

not limited to computer storage devices, computer programs, files and software, correspondence, customer lists, technical information, customer information, pricing information, business strategies and plans, sales records and all copies thereof) (collectively, the "**Corporate Records**") provided by the Company and/or its predecessors, subsidiaries or affiliates or obtained as a result of Executive's employment with the Company and/or its predecessors, subsidiaries or affiliates, or created by Executive while employed by or rendering services to the Company and/or its predecessors, subsidiaries or affiliates. Executive acknowledges all Corporate Records are the Company's property.

(b) Company Property. Executive represents Executive has returned all company property to Company, including, but not limited to, building I.D. and name tags, office keys and company car keys, Executive's Company computer (including laptop), cell phone or other handheld communication device (e.g., iPhone or iPad), samples, cases, or brochures Executive acquired by virtue of Executive's employment.

11. Permissible Disclosures. Nothing in this Agreement shall prohibit or restrict Executive from: (a) making any disclosure of information required by law, (b) disclosing the contents of the section of this Agreement entitled Restrictions to potential or subsequent employers, (c) providing information to, or testifying or otherwise assisting in any investigation or proceeding brought by, any federal or state regulatory or law enforcement agency or legislative body, any self-regulatory organization, or the Company's designated legal, compliance or human resources personnel, (d) reporting, filing, testifying, participating in or otherwise assisting in a proceeding relating to an alleged violation of any federal, state or municipal law relating to fraud, or any rule or regulation of the Securities and Exchange Commission or any self-regulatory organization, or (e) making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation.

12. Non-Admission. The Company and Executive mutually agree and acknowledge the provision of benefits by the Company pursuant to this Agreement and the settlement and termination of any asserted or unasserted claims against the Releasees are not and shall not be construed to be an admission of any violation of any federal, state or local statute or regulation, or of any duty owed by any of the Releasees to Executive.

13. Breach. Executive agrees and recognizes should Executive materially breach any of the obligations or covenants set forth in this Agreement, the Company will have no further obligation to provide Executive with the consideration set forth herein, and will have the right to seek repayment of all consideration paid up to the time of any such breach. Further, Executive acknowledges in the event of a breach of this Agreement, Releasees may seek any and all appropriate relief for any such material breach, including equitable relief and/or money damages, attorney's fees and costs.

14. Injunctive Relief. Executive further agrees the Company shall be entitled to preliminary and permanent injunctive relief, without the necessity of proving actual damages, as well as to an equitable accounting of all earnings, profits and other benefits relating to or arising out of any violations of this Agreement, which rights shall be cumulative and in addition to any other rights or remedies to which the Company may be entitled. Executive irrevocably and unconditionally (a) agrees any suit, action or other legal proceeding relating to or arising out of this Agreement, including without limitation, any action commenced by the Company for preliminary and permanent injunctive relief or other equitable relief, may be brought in the State of Missouri, (b) consents to the non-exclusive jurisdiction of any such court in any such suit, action or proceeding, and (c) waives any objection which Executive may have to the laying of venue of any such suit, action or proceeding in any such court. Executive also irrevocably and unconditionally consents to the service of any process, pleadings, notices or other papers by personal service or by registered

or certified mail, return receipt requested, or by overnight express courier service, addressed to Executive at the home address which the Company has on file for Executive at the time such mailing occurs.

15. Choice of Law. The Company's primary place of business is in the State of Missouri. Therefore, this Agreement and the obligations of the parties hereunder shall be construed, interpreted and enforced in accordance with the laws of the State of Missouri, without giving effect to any conflict of law principles that would result in the application of any law other than the law of the State of Missouri.

16. Survival of Provisions. The obligations in any section containing obligations to be performed following the termination of Executive's employment with the Company or any affiliate or subsidiary shall survive such termination and shall be fully enforceable thereafter.

17. Savings Clause. If any term contained in this Agreement is found by a court of competent jurisdiction to be unenforceable or invalid to any extent, such finding will not affect the validity or enforceability of any other term or provision of this Agreement.

18. Binding Effect; Assignment. The rights and obligations of this Agreement shall bind and inure to the benefit of any successor of the Company by reorganization, merger or consolidation, or any assignee of all or substantially all of the Company's business. The Company may assign its rights and obligations under this Agreement to any of its subsidiaries or affiliates without Executive's consent, but shall remain liable for any payments provided hereunder not timely made by any such assignee. Executive's rights or obligations under this Agreement may not be assigned by Executive.

19. Section 409A Compliance. To the extent applicable, this Agreement will be interpreted in accordance with Internal Revenue Code Section 409A and the regulations and other interpretive guidance issued thereunder including, without limitation, any such regulations or other guidance that may be issued after the date this Agreement is executed.

20. Certification and Acknowledgment. Executive certifies and acknowledges:

(a) Executive has read the terms of this Agreement, and Executive understands its terms and effects, including the fact Executive has agreed to RELEASE AND FOREVER DISCHARGE the Company and each and every one of its affiliated entities from any legal action arising out of Executive's employment relationship with the Company and the termination of that employment relationship;

(b) Executive has signed this Agreement voluntarily and knowingly in exchange for the consideration described herein, which Executive acknowledges is adequate and sufficient to Executive and which Executive acknowledges is in addition to any other benefits to which Executive is otherwise entitled;

(c) Executive has been and is hereby advised in writing to consult with an attorney prior to signing this Agreement;

(d) The Company has provided Executive with a period of twenty-one (21) days within which to consider this Agreement, and Executive has signed on the date indicated below after concluding this Agreement is satisfactory to Executive;

(e) Executive acknowledges this Agreement may be revoked by Executive within seven (7) days after Executive's execution and this Agreement shall not become effective until the expiration of such seven (7) day revocation period. Any revocation must be submitted, in writing, to the Company, and

state, “I hereby revoke my acceptance of our Agreement.” The revocation must be personally delivered or mailed to Mallinckrodt Pharmaceuticals, Attn: Human Resources Operations Manager, 675 McDonnell Blvd., Building 10-2-S, Hazelwood, MO, 63042, and hand-delivered or postmarked within seven (7) calendar days of Executive’s execution of this Agreement. If the last day of the revocation period is a Saturday, Sunday, or legal holiday in Missouri, then the revocation period shall not expire until the next following day which is not a Saturday, Sunday, or legal holiday. In the event of a timely revocation by Executive, this Agreement will be deemed null and void and the Company will have no obligations hereunder; and

(f) Executive does not waive rights or claims that may arise after the date this Agreement is executed.

Intending to be legally bound hereby, Executive and the Company (by its duly authorized agent) hereby execute the foregoing Separation of Employment Agreement and General Release.

MATTHEW HARBAUGH

Signature

Date

COMPANY

By:

Signature

Date

Name:

Title:

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 5, 2019

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 5, 2019

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 27, 2019 ("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 5, 2019

By: /s/ Bryan M. Reasons

Bryan M. Reasons

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

November 5, 2019