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 June 28, 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 - 84,008,556 shares as of August 2, 2019.

MALLINCKRODT PLC
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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		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Net sales	$ 823.3	$ 825.5	$ 1,613.9	$ 1,580.8
Cost of sales	434.4	431.5	889.9	839.3
Gross profit	388.9	394.0	724.0	741.5
Selling, general and administrative expenses	225.9	189.9	456.1	401.1
Research and development expenses	79.6	92.6	164.9	174.6
Restructuring charges, net	(0.2)	58.8	4.0	87.0
Non-restructuring impairment charge	113.5	—	113.5	—
Operating (loss) income	(29.9)	52.7	(14.5)	78.8
Interest expense	(71.5)	(95.1)	(154.2)	(186.5)
Interest income	2.2	1.4	3.7	4.6
Other income (expense), net	74.4	(0.2)	90.7	4.4
Loss from continuing operations before income taxes	(24.8)	(41.2)	(74.3)	(98.7)
Income tax benefit	(24.3)	(44.4)	(229.0)	(81.0)
(Loss) income from continuing operations	(0.5)	3.2	154.7	(17.7)
Income from discontinued operations, net of income taxes	7.3	12.4	7.0	15.3
Net income (loss)	$ 6.8	$ 15.6	$ 161.7	$ (2.4)
Basic earnings per share (Note 6):				
(Loss) income from continuing operations	$ (0.01)	$ 0.04	$ 1.85	$ (0.21)
Income from discontinued operations	0.09	0.15	0.08	0.18
Net income (loss)	$ 0.08	$ 0.19	$ 1.93	$ (0.03)
Basic weighted-average shares outstanding	83.8	83.2	83.7	84.7
Diluted earnings per share (Note 6):				
(Loss) income from continuing operations	$ (0.01)	$ 0.04	$ 1.84	$ (0.21)
Income from discontinued operations	0.09	0.15	0.08	0.18
Net income (loss)	$ 0.08	$ 0.19	$ 1.92	$ (0.03)
Diluted weighted-average shares outstanding	83.8	83.5	84.3	84.7

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended		Six Months Ended	
	June 28, 2019	**June 29, 2018**	**June 28, 2019**	**June 29, 2018**
Net income (loss)	$ 6.8	$ 15.6	$ 161.7	$ (2.4)
Other comprehensive income (loss), net of tax:				
Currency translation adjustments	2.3	(5.0)	3.7	(7.3)
Derivatives, net of tax	0.5	0.1	0.7	0.5
Benefit plans, net of tax	(0.4)	—	(0.7)	(0.5)
Total other comprehensive income (loss), net of tax	2.4	(4.9)	3.7	(7.3)
Comprehensive income (loss)	$ 9.2	$ 10.7	$ 165.4	$ (9.7)

See Notes to Condensed Consolidated Financial Statements.

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

	June 28, 2019	December 28, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 241.1	$ 348.9
Accounts receivable, less allowance for doubtful accounts of $4.7 and $5.0	528.4	623.3
Inventories	337.4	322.3
Prepaid expenses and other current assets	112.5	132.7
Total current assets	1,219.4	1,427.2
Property, plant and equipment, net	994.2	982.0
Intangible assets, net	7,721.1	8,282.8
Other assets	287.0	185.3
Total Assets	$ 10,221.7	$ 10,877.3
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 717.9	$ 22.4
Accounts payable	148.6	147.5
Accrued payroll and payroll-related costs	79.8	124.0
Accrued interest	45.9	77.6
Accrued and other current liabilities	565.3	572.2
Total current liabilities	1,557.5	943.7
Long-term debt	4,823.0	6,069.2
Pension and postretirement benefits	59.5	60.5
Environmental liabilities	60.5	59.7
Deferred income taxes	53.4	324.3
Other income tax liabilities	262.5	228.0
Other liabilities	330.1	304.6
Total Liabilities	7,146.5	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; 93,339,914 and 92,705,747 issued; 83,918,620 and 83,323,877 outstanding	18.7	18.5
Ordinary shares held in treasury at cost, 9,421,294 and 9,381,870	(1,617.4)	(1,617.4)
Additional paid-in capital	5,551.5	5,528.2
Retained deficit	(857.5)	(1,017.7)
Accumulated other comprehensive loss	(20.1)	(24.3)
Total Shareholders' Equity	3,075.2	2,887.3
Total Liabilities and Shareholders' Equity	$ 10,221.7	$ 10,877.3

See Notes to Condensed Consolidated Financial Statements.

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

	Six Months Ended	
	June 28, 2019	**June 29, 2018**
Cash Flows From Operating Activities:		
Net income (loss)	$ 161.7	$ (2.4)
Adjustments to reconcile net cash from operating activities:		
Depreciation and amortization	488.6	397.1
Share-based compensation	22.8	16.4
Deferred income taxes	(271.2)	(101.0)
Non-cash impairment charge	113.5	—
Other non-cash items	(76.0)	(19.0)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	95.5	(21.8)
Inventories	(23.8)	18.4
Accounts payable	7.2	2.1
Income taxes	22.4	7.4
Other	(73.3)	(35.4)
Net cash from operating activities	467.4	261.8
Cash Flows From Investing Activities:		
Capital expenditures	(77.6)	(67.1)
Acquisitions, net of cash	—	(699.9)
Proceeds from divestitures, net of cash	—	298.3
Other	8.2	12.4
Net cash from investing activities	(69.4)	(456.3)
Cash Flows From Financing Activities:		
Issuance of external debt	200.0	657.2
Repayment of external debt	(685.9)	(1,392.8)
Debt financing costs	—	(12.0)
Proceeds from exercise of share options	0.5	—
Repurchase of shares	(2.5)	(56.8)
Other	(18.5)	(24.9)
Net cash from financing activities	(506.4)	(829.3)
Effect of currency rate changes on cash	0.8	(1.2)
Net change in cash, cash equivalents and restricted cash	(107.6)	(1,025.0)
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	$ 259.9	$ 254.1
Cash and cash equivalents at end of period	$ 241.1	$ 235.7
Restricted cash included in other assets at end of period	18.8	18.4
Cash, cash equivalents and restricted cash at end of period	$ 259.9	$ 254.1

See Notes to Condensed Consolidated Financial Statements.

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

	Ordinary Shares		Treasury Shares					
	Number	Par Value	Number	Amount	Additional Paid-In Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
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
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

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.

On May 28, 2019, as an update to the Company's planned separation of the previously reported Specialty Generics and Amitiza® (lubiprostone) ("Amitiza") segment, the Company announced that given the strong, return-to-growth performance of the Specialty Generics business, the Amitiza product should remain with the Specialty Brands business. As a result of this announcement, the Company identified two reportable segments that align with the operations of the two independent publicly traded companies anticipated post-separation, which are further described below:

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

All prior period segment information has been recast to reflect the realignment of the Company's reportable segments on a comparable basis. Refer to Note 18 for an update on the Company's plans for the Specialty Generics business.

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 announcement of the planned separation 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.

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 six months ended June 28, 2019 refers to the thirteen and twenty-six week periods ended June 28, 2019 and the three and six months ended June 29, 2018 refers to the thirteen and twenty-six week periods ended June 29, 2018.

2. Recently Issued Accounting Standards

Adopted

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 9 for further details on the Company's leases.

3. Revenue from Contracts with Customers

Product Sales Revenue

See Note 16 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	1,029.0	23.2	29.5	1,081.7
Payments or credits	(999.2)	(22.5)	(31.1)	(1,052.8)
Balance as of June 29, 2018	$ 357.2	$ 35.2	$ 13.1	$ 405.5
Balance as of December 28, 2018	$ 354.3	$ 34.0	$ 17.1	$ 405.4
Provisions	1,214.3	11.7	34.7	1,260.7
Payments or credits	(1,240.2)	(15.6)	(35.9)	(1,291.7)
Balance as of June 28, 2019	$ 328.4	$ 30.1	$ 15.9	$ 374.4

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

	Three Months Ended		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Product sales transferred at a point in time	82.9%	84.0%	81.8%	82.7%
Product sales transferred over time	17.1%	16.0%	18.2%	17.3%

Transaction price allocated to the remaining performance obligations

The following table includes estimated revenue from contracts extending greater than one year for certain of the Company's hospital products that are expected to be recognized in the future related to performance obligations that were unsatisfied or partially unsatisfied as of June 28, 2019:

Remainder of Fiscal 2019	$ 81.5
Fiscal 2020	154.2
Fiscal 2021	60.3
Fiscal 2022	9.2
Thereafter	6.2

Costs to fulfill a contract

As of June 28, 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 $27.5 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 six months ended June 28, 2019 and June 29, 2018 was $3.4 million and $6.8 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		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Royalty revenue	$ 19.4	$ 21.6	$ 36.8	$ 29.6

Royalty revenue for the three and six months ended June 29, 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:

	June 28, 2019	December 28, 2018
Accrued and other current liabilities	$ 20.3	$ 20.4
Other liabilities	16.9	15.1
Contract liabilities	$ 37.2	$ 35.5

Revenue recognized during the six months ended June 28, 2019 from amounts included in contract liabilities at the beginning of the period was $9.2 million.

4. 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		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Specialty Brands	$ (0.1)	$ 47.0	$ 0.4	$ 47.5
Specialty Generics	(0.9)	0.1	2.6	5.2
Corporate	0.8	11.7	1.0	34.3
Restructuring and related charges, net	(0.2)	58.8	4.0	87.0
Less: accelerated depreciation	—	—	—	—
Restructuring charges, net	$ (0.2)	$ 58.8	$ 4.0	$ 87.0

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

	Three Months Ended		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
2018 Mallinckrodt Program	$ (0.9)	$ —	$ 2.6	$ —
2016 Mallinckrodt Program	1.5	52.3	2.2	60.5
Acquisition programs	(0.8)	6.5	(0.8)	26.5
Total charges expected to be settled in cash	$ (0.2)	$ 58.8	$ 4.0	$ 87.0

The following table summarizes cash activity for restructuring reserves, substantially all of which related to contract termination costs, employee severance and benefits, and exiting 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	3.5	2.4	—	5.9
Changes in estimate	(0.9)	(0.2)	(0.8)	(1.9)
Cash payments	(1.4)	(11.0)	(1.4)	(13.8)
Reclassifications [1]	—	(5.0)	(4.3)	(9.3)
Balance as of June 28, 2019	$ 3.4	$ 47.2	$ 1.3	$ 51.9

(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 June 28, 2019, net restructuring and related charges incurred cumulative to date related to the 2018 and 2016 Mallinckrodt Programs were as follows:

	2018 Mallinckrodt Program	2016 Mallinckrodt Program
Specialty Brands	$ 3.0	$ 82.2
Specialty Generics	2.6	14.6
Corporate	2.2	27.6
	$ 7.8	$ 124.4

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

5. Income Taxes

The Company recognized an income tax benefit of $24.3 million on a loss from continuing operations before income taxes of $24.8 million for the three months ended June 28, 2019, and an income tax benefit of $44.4 million on a loss from continuing operations before income taxes of $41.2 million for the three months ended June 29, 2018. This resulted in effective tax rates of 98.0% and 107.8% for the three months ended June 28, 2019 and June 29, 2018, respectively. The income tax benefit for the three months ended June 28, 2019 was comprised of $5.6 million of current tax expense and $29.9 million of deferred tax benefit, which was predominately related to previously acquired intangibles, the generation of tax loss and credit carryforwards net of valuation allowances and the non-restructuring impairment charge, as further discussed in Note 10. The income tax benefit for the three months ended June 29, 2018 was comprised of $10.2 million of current tax expense and $54.6 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles.

The Company recognized an income tax benefit of $229.0 million on a loss from continuing operations before income taxes of $74.3 million for the six months ended June 28, 2019, and an income tax benefit of $81.0 million on a loss from continuing operations before income taxes of $98.7 million for the six months ended June 29, 2018. This resulted in effective tax rates of 308.2% and 82.1% for the six months ended June 28, 2019 and June 29, 2018, respectively. The income tax benefit for the six months ended June 28, 2019 was comprised of $44.1 million of current tax expense and $273.1 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 six months ended June 29, 2018 was comprised of $21.4 million of current tax expense and $102.4 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles.

The income tax benefit was $24.3 million for the three months ended June 28, 2019, compared with a tax benefit of $44.4 million for the three months ended June 29, 2018. The $20.1 million net decrease in the tax benefit included a $20.7 million decrease attributed to changes in the timing, amount and jurisdictional mix of income, a $7.1 million decrease attributed to the gain on debt repurchased and a $3.4 million decrease attributed to restructuring and related charges, partially offset by an increase in tax benefit of $8.5 million attributed to the non-restructuring impairment charge and $2.6 million increase attributed to separation costs.

The income tax benefit was $229.0 million for the six months ended June 28, 2019, compared with a tax benefit of $81.0 million for the six months ended June 29, 2018. The $148.0 million net increase in the tax benefit included an increase of $189.8 million attributed to the tax benefit from the reorganization of the Company's intercompany financing and associated legal entity ownership, a $8.5 million increase attributed to the non-restructuring impairment charge and a $3.6 million increase attributed to separation costs, partially offset by a decrease in tax benefit of $35.2 million predominately attributed to changes in the timing, amount and jurisdictional mix of income, a $9.8 million decrease attributed to restructuring and related charges and a $8.9 million decrease attributed to the gain on debt repurchased.

During the three months ended March 29, 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 six months ended June 28, 2019, the Company recognized current income tax expense of $28.9 million and a deferred income tax benefit of $218.7 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 $42.3 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 $24.7 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 six months ended June 28, 2019, and the fiscal year ended December 28, 2018, the net cash payments for income taxes were $21.5 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 June 28, 2019, the Company's U.S. Federal net operating loss carryforward was $815.4 million ($171.2 million measured at applicable statutory tax rates and net of uncertain tax positions).

The Company's unrecognized tax benefits, excluding interest, totaled $448.9 million and $287.7 million as of June 28, 2019 and December 28, 2018, respectively. The net increase of $161.2 million primarily resulted from a net increase to current year tax positions of $151.7 million, net increases from prior period tax positions of $13.7 million, a net decrease from settlements of $0.9 million and a net decrease from a lapse of statute of limitations of $3.3 million. If favorably settled, $437.4 million of unrecognized tax benefits as of June 28, 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 $44.6 million and $37.1 million as of June 28, 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 $102.8 million and the amount of related interest and penalties could decrease by up to $32.5 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 three months ended June 28, 2019, the overall corporate income tax rate in Luxembourg has decreased from 26.01% to 24.94% effective January 1, 2019. As a result, the Company's net deferred tax assets decreased by approximately $65.8 million, and the associated valuation allowances were also decreased by this same amount.

6. 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		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Basic	83.8	83.2	83.7	84.7
Dilutive impact of restricted share units and share options	—	0.3	0.6	—
Diluted	83.8	83.5	84.3	84.7

The computation of diluted weighted-average shares outstanding for both the three and six months ended June 28, 2019 excluded approximately 4.6 million shares of equity awards, and for both the three and six months ended June 29, 2018 excluded approximately 3.6 million shares of equity awards, because the effect would have been anti-dilutive.

7. Inventories

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

	June 28, 2019	December 28, 2018
Raw materials and supplies	$ 63.8	$ 69.2
Work in process	177.3	167.6
Finished goods	96.3	85.5
	$ 337.4	$ 322.3

8. 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:

	June 28, 2019	December 28, 2018
Property, plant and equipment, gross	$ 1,987.8	$ 1,936.2
Less: accumulated depreciation	(993.6)	(954.2)
Property, plant and equipment, net	$ 994.2	$ 982.0

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

	Three Months Ended		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Depreciation expense	$ 24.4	$ 14.2	$ 49.2	$ 34.8

9. 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:

	June 28, 2019
Other assets	$ 90.6
Accrued and other current liabilities	$ 19.6
Other liabilities	77.7
Total lease liabilities	$ 97.3

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	Six Months Ended
	June 28, 2019	June 28, 2019
Lease cost:		
Operating lease cost	$ 5.3	$ 10.2
Short-term lease cost	1.1	2.2
Sublease income	(0.2)	(0.4)
Total lease cost	$ 6.2	$ 12.0

Lease terms and discount rates were as follows:

	June 28, 2019
Weighted-average remaining lease term (in years) - operating lease	7.4
Weighted-average discount rate - operating leases	3.8%

Maturities of lease liabilities as of June 28, 2019 were as follows:

	Operating Leases
Remainder of Fiscal 2019	$ 11.8
Fiscal 2020	21.6
Fiscal 2021	16.3
Fiscal 2022	12.3
Fiscal 2023	11.7
Thereafter	39.2
Total lease payments	112.9
Less: Interest	(15.6)
Present value of lease liabilities	$ 97.3

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

	Six Months Ended
	June 28, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 11.3
Lease assets obtained in exchange for lease obligations:	
Operating leases	6.9

10. 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 Company is in the process of evaluating this portion of the study in order to ensure the data was properly captured and of the highest quality. 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 determine the best path forward. 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 June 28, 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:

	June 28, 2019		December 28, 2018	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 10,456.9	$ 3,413.3	$ 10,467.9	$ 2,980.6
License agreements	120.1	72.1	120.1	70.1
Trademarks	82.0	20.0	81.9	18.1
Customer relationships	28.5	15.8	27.5	14.1
Total	$ 10,687.5	$ 3,521.2	$ 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 six months ended June 28, 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 $29.8 million and $65.7 million during the three and six months ended June 28, 2019, respectively, which impacted basic earnings per share for the respective periods by $0.36 and $0.78 per share.

Intangible asset amortization expense

Intangible asset amortization expense was as follows:

	Three Months Ended		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Amortization expense	$ 216.6	$ 184.3	$ 439.4	$ 362.3

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

Remainder of Fiscal 2019	$ 414.7
Fiscal 2020	756.7
Fiscal 2021	659.9
Fiscal 2022	587.3
Fiscal 2023	583.1

11. Debt

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

	June 28, 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% notes due April 2020	$ 700.0	$ 2.0	$ —	$ —
Term loan due September 2024	15.6	0.1	16.4	0.2
Term loan due February 2025	4.1	0.1	6.0	0.1
Other	0.4	—	0.3	—
Total current debt	720.1	2.2	22.7	0.3
Long-term debt:				
4.875% notes due April 2020	—	—	700.0	3.2
Variable-rate receivable securitization due July 2020	200.0	0.3	250.0	0.4
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% notes due August 2022	663.2	4.7	835.2	7.0
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% notes due April 2023	400.1	2.4	500.2	3.5
5.625% notes due October 2023	680.2	6.6	731.4	8.0
Term loan due September 2024	1,509.1	17.3	1,597.4	19.8
Term loan due February 2025	400.5	6.7	591.0	10.7
5.50% notes due April 2025	596.1	6.1	692.1	7.7
Revolving credit facility	405.0	3.8	220.0	4.5
Other	1.9	—	1.9	—
Total long-term debt	4,870.9	47.9	6,134.0	64.8
Total debt	$ 5,591.0	$ 50.1	$ 6,156.7	$ 65.1

As of June 28, 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	5.53%	404.6
Variable-rate receivable securitization	3.30%	200.0
Revolving credit facility	4.64%	405.0

As of June 28, 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.

12. 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	3.7	—	—	3.7
Amounts reclassified from accumulated other comprehensive loss	—	0.7	(0.7)	—
Net current period other comprehensive income (loss)	3.7	0.7	(0.7)	3.7
Balance as of June 28, 2019	$ (16.7)	$ (3.3)	$ (0.1)	$ (20.1)

	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	(7.3)	—	0.9	(6.4)
Amounts reclassified from accumulated other comprehensive loss	—	0.5	(1.4)	(0.9)
Net current period other comprehensive (loss) income	(7.3)	0.5	(0.5)	(7.3)
Balance as of June 29, 2018	$ (15.5)	$ (4.2)	$ (2.0)	$ (21.7)

The following summarizes reclassifications from accumulated other comprehensive loss:

	Amount Reclassified from Accumulated Other Comprehensive Loss		
	Six Months Ended		
	June 28, 2019	June 29, 2018	Line Item in the Unaudited Condensed Consolidated Statement of Income
Amortization and other of unrealized loss on derivatives	$ 0.7	$ 0.5	Interest expense
Amortization of pension and post-retirement benefit plans:			
Net actuarial loss	0.3	0.3	Other income, net
Prior service credit	(1.0)	(1.0)	Other income, net
Plan settlements	—	(0.7)	Other income, net
Total reclassifications for the period	$ —	$ (0.9)	

13. 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 June 28, 2019 and December 28, 2018 was $15.0 million and $14.6 million, respectively, of which $12.6 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 June 28, 2019 and December 28, 2018. As of June 28, 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 $18.8 million and $18.6 million remained in restricted cash, included in other long-term assets on the unaudited condensed consolidated balance sheets as of June 28, 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 14.

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 June 28, 2019, the Company had various other letters of credit, guarantees and surety bonds totaling $36.2 million.

14. 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 August 6, 2019, the cases the Company is aware of include, but are not limited to, approximately 2,153 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 140 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 103 cases filed by individuals and 10 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Hawaii, Nevada and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. 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. 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.

Other lawsuits remain pending in various state courts. In some jurisdictions, such as Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas and West Virginia, certain of the 235 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 abuse and diversion.

The Company intends to vigorously defend itself against all of these lawsuits as detailed above and similar lawsuits that may be brought by others. Since these lawsuits are in early stages, the Company is unable to predict outcomes or estimate a range of reasonably possible losses.

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 and the Divisions of Consumer Protection and Occupational and Professional Licensing of the Utah Department of Commerce. 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 will cooperate with the investigation, which is expected to continue and may ultimately result in a congressional hearing in the second half of 2019.

The Attorneys General for Kentucky, Alaska and New York 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

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 Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services. The dispute involves the base date average manufacturer price ("AMP") under the Medicaid Drug Rebate Program for Mallinckrodt's Acthar® Gel (repository corticotropin injection) ("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 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, 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 in the process of responding to this demand for documents and intends to cooperate 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 in the process of responding to this demand for documents and intends to cooperate 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 the Company 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 have since been consolidated. The Company has reached an agreement in principle with the DOJ and the *qui tam* plaintiffs to resolve the portion of the investigation and the litigation involving promotional practices for $15.4 million, and has appropriate reserves for that purpose.

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 defend the lawsuit in court. At this stage of the lawsuit, 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 ("the '218 patent"), U.S. Patent No. 9,399,012 ("the '012 patent"), U.S. Patent No. 9,610,265 ("the '265 patent") and U.S. Patent No. 9,987,238 ("the '238 patent") 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. The Company has previously asserted the ‘218 patent and maintained their validity in both litigation and proceedings at the U.S. Patent and Trademark Office. In addition, the Company has also previously asserted the ‘012, ‘265 and ‘238 patents. The Company will continue to vigorously enforce its intellectual property rights relating to Ofirmev to prevent the marketing of infringing generic or competing products prior to December 6, 2020, which, if unsuccessful, could adversely affect the Company's ability to successfully maximize the value of Ofirmev and have an adverse effect on its financial condition, results of operations and cash flows.

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 generic version of Inomax. 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 a generic version of Inomax. The infringement claims in the second suit have been 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 recently added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for a generic version of Inomax.

The Company intends 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. Trial of 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 has 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. An adverse outcome in the appeal of the Praxair litigation decision (or a broad at-risk launch by Praxair prior to the appellate decision) could result in the 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

Putative Class Action Securities Litigation (Strougo). On July 26, 2019, a putative class action lawsuit was filed against the Company, its Chief Executive Officer ("CEO"), its Chief Financial Officer ("CFO") Bryan M. Reasons, its former Interim CFO George A. Kegler and its former CFO Matthew K. Harbaugh, in the U.S. District Court for the Southern District of New York, captioned *Barbara Strougo v. Mallinckrodt plc, et al*. The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt's securities between February 28, 2018 and July 16, 2019. The lawsuit generally alleges that the defendants made false and 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 makes similar allegations as alleged in related state and federal actions filed by the same plaintiff law firm filed in Illinois, Pennsylvania, Tennessee and Maryland, including references to pending *qui tam* allegations within the Eastern District of Pennsylvania. In particular, the complaint alleges violations of the New Jersey Consumer Fraud Act, the New Jersey Antitrust Act, violation of state RICO statutes, negligent misrepresentation, conspiracy and unjust enrichment associated with the commercialization of Acthar Gel. The Company intends to vigorously defend itself in this matter.

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 various pharmaceutical distributors 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 alleged in related state and federal actions filed by the same plaintiff law firm filed in Illinois, Pennsylvania, Tennessee and Maryland. In particular, the Complaint alleges claims of RICO violations under 18 U.S.C. § 1962(c); conspiracy to violate 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.

Acument Global. On May 21, 2019, Acument Global Technologies, Inc., filed a non-class complaint in the state court of Tennessee, against the Company and other defendants alleging violation of Tennessee Consumer Protection Laws, unjust enrichment, fraud and conspiracy to defraud. The case alleges similar facts as the MSP and Rockford matters below, and is captioned *Acument Global Technologies, Inc., v. Mallinckrodt ARD et al.* The Company intends to vigorously defend itself in this matter.

Washington County Board of Education ("WCBE"). On May 21, 2019, WCBE filed a non-class complaint in the state court of Maryland, against the Company and other defendants alleging violation of Maryland Consumer Protection Act, negligent misrepresentation, fraud, unjust enrichment, and conspiracy to defraud. The case alleges similar facts as the MSP and Rockford matters below, and is captioned *Washington County Board of Education v. Mallinckrodt ARD Inc., et al.* The Company intends to vigorously defend itself in this matter.

Local 542. On May 25, 2018, the International Union of Operating Engineers Local 542 filed a non-class complaint in the state court of Pennsylvania against the Company and other defendants 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. Mallinckodt ARD Inc. et al.* Plaintiff filed an amended complaint on August 27, 2018. The Company intends to vigorously defend itself in this matter.

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 for that purpose.

Putative Class Action Litigation (MSP). On October 30, 2017, a putative class action lawsuit was filed against the Company and United BioSource Corporation ("UBC") 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, 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. The motion to dismiss was granted on January 25, 2019. MSP was provided with leave to amend its complaint, and filed the operative First Amended Class Action Complaint on April 10, 2019 asserting claims under federal antitrust law, 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 intends to vigorously defend itself in this matter.

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 following paragraph. 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* matter below.

Putative Class Action Litigation (Rockford). On April 6, 2017, a putative class action lawsuit was filed against the Company and UBC 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, most recently on December 8, 2017, to 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. The Company filed a motion to dismiss the complaint, which was granted in part by the court on January 25, 2019, dismissing one of two named plaintiffs and all claims with the exception of 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, the suit 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 vigorously defend itself in this matter.

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 June 28, 2019, it was probable that it would incur remediation costs in the range of $36.9 million to $86.1 million. The Company also concluded that, as of June 28, 2019, the best estimate within this range was $62.3 million, of which $1.8 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 June 28, 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 June 28, 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 June 28, 2019, compared to $227.5 million as of December 28, 2018. See Note 5 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 $11.7 million during the six months ended June 29, 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 June 28, 2019 and December 28, 2018, respectively. The decrease of $8.6 million was recognized as a benefit to interest expense during the three months ended June 28, 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.

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.

15. 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:

	June 28, 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	$ 35.4	$ 25.6	$ 9.8	$ —
Liabilities:				
Deferred compensation liabilities	$ 45.4	$ —	$ 45.4	$ —
Contingent consideration and acquired contingent liabilities	130.4	—	—	130.4
	$ 175.8	$ —	$ 45.4	$ 130.4

	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.

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 six months ended June 28, 2019. The fair value of the remaining contingent payments was measured based on the net present value of a probability-weighted assessment. As of June 28, 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 $52.9 million and $76.2 million as of June 28, 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 $55.6 million and $53.7 million as of June 28, 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 $21.9 million and $21.5 million as of June 28, 2019 and December 28, 2018, respectively.

Of the total fair value of the contingent consideration of $130.4 million, $52.4 million was classified as current and $78.0 million was classified as non-current in the unaudited condensed consolidated balance sheet as of June 28, 2019. The following table summarizes the fiscal 2019 activity for contingent consideration:

Balance as of December 28, 2018	$	151.4
Payments		(25.0)
Accretion expense		1.7
Fair value adjustments		2.3
Balance as of June 28, 2019	$	130.4

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 June 28, 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 $18.8 million and $18.6 million as of June 28, 2019 and December 28, 2018, (level 1), respectively, which was included in prepaid expenses and other current assets and 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 six months ended June 28, 2019 and June 29, 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 June 28, 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 $66.6 million and $66.4 million as of June 28, 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 and variable-rate receivable securitization approximates fair value due to the short-term nature of these instruments, and is therefore classified as level 1. The Company's 4.875%, 5.75%, 4.75%, 5.625% and 5.50% 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 fair value of the "other" loan is based on the present value of future cash flows under the terms of the agreement with future cash flows and interest rates as significant assumptions, and therefore classified as level 3. The following table presents the carrying values and estimated fair values of the Company's debt as of the end of each period:

	June 28, 2019		December 28, 2018	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
4.875% notes due April 2020	$ 700.0	$ 675.1	$ 700.0	$ 676.6
Variable-rate receivable securitization due July 2020	200.0	200.0	250.0	250.0
5.75% notes due August 2022	663.2	567.7	835.2	713.6
4.75% notes due April 2023	400.1	281.1	500.2	336.7
5.625% notes due October 2023	680.2	513.5	731.4	557.0
5.50% notes due April 2025	596.1	399.8	692.1	479.1
Revolving credit facility	405.0	405.0	220.0	220.0
Level 2:				
9.50% debentures due May 2022	10.4	9.5	10.4	9.7
8.00% debentures due March 2023	4.4	3.7	4.4	3.8
Term loan due September 2024	1,524.7	1,365.8	1,613.8	1,472.4
Term loan due February 2025	404.6	363.3	597.0	548.0
Level 3:				
Other	2.3	2.2	2.2	2.2
Total debt	$ 5,591.0	$ 4,786.7	$ 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		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
CuraScript, Inc.	31.9%	35.6%	29.8%	35.6%

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:

	June 28, 2019	December 28, 2018
AmerisourceBergen Corporation	27.7%	25.7%
McKesson Corporation	13.4%	21.9%
CuraScript, Inc.	15.7%	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		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Acthar Gel	32.4%	35.5%	30.4%	34.0%
Inomax	17.0%	15.9%	18.0%	17.1%
Ofirmev	11.0%	10.4%	11.5%	10.6%

16. Segment Data

As part of the May 28, 2019 update to the Company's planned separation described within Note 1, the Company's two reportable segments were realigned and 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. Refer to Note 18 for an update on the Company's plans for the Specialty Generics business.

Selected information by reportable segment was as follows:

	Three Months Ended		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Net sales:				
Specialty Brands	$ 627.8	$ 631.7	$ 1,232.0	$ 1,204.3
Specialty Generics	195.5	193.8	381.9	376.5
Net Sales	$ 823.3	$ 825.5	$ 1,613.9	$ 1,580.8
Operating (loss) income:				
Specialty Brands	$ 321.4	$ 265.2	$ 596.9	$ 506.4
Specialty Generics	33.9	43.1	58.3	78.2
Segment operating income	355.3	308.3	655.2	584.6
Unallocated amounts:				
Corporate and unallocated expenses [1]	(36.4)	(12.5)	(82.2)	(56.5)
Intangible asset amortization	(216.6)	(184.3)	(439.4)	(362.3)
Restructuring and related charges, net	0.2	(58.8)	(4.0)	(87.0)
Non-restructuring impairments	(113.5)	—	(113.5)	—
Separation costs [2]	(18.9)	—	(30.6)	—
Operating (loss) income [3]	$ (29.9)	$ 52.7	$ (14.5)	$ 78.8

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

(2) Represents costs incurred related to the separation of the Company's Specialty Generics segment, inclusive of rebranding costs, which are included in SG&A.

(3) The amount of operating loss included in the Company's unaudited condensed consolidated statement of income for the three and six months ended June 29, 2018 related to the Sucampo Acquisition was $37.0 million and $67.7 million, respectively. Included within these results were $17.9 million and $27.0 million of amortization associated with intangibles recognized from this acquisition and $31.5 million and $46.5 million of expense associated with fair value adjustments of acquired inventory for the three and six months ended June 29, 2018, respectively.

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

	Three Months Ended		Six Months Ended	
	June 28, 2019	June 29, 2018	June 28, 2019	June 29, 2018
Acthar Gel	$ 266.4	$ 293.2	$ 490.3	$ 537.0
Inomax	139.7	131.0	290.8	270.8
Ofirmev	90.5	85.6	186.1	167.6
Therakos	60.9	56.8	122.7	114.2
Amitiza [1]	52.0	48.0	105.0	71.0
BioVectra	13.9	11.3	26.3	21.8
Other	4.4	5.8	10.8	21.9
Specialty Brands	627.8	631.7	1,232.0	1,204.3
Hydrocodone (API) and hydrocodone-containing tablets	18.1	16.9	35.5	30.8
Oxycodone (API) and oxycodone-containing tablets	19.6	13.1	36.1	29.7
Acetaminophen (API)	48.4	51.7	94.6	101.1
Other controlled substances	98.6	99.5	192.8	188.5
Other	10.8	12.6	22.9	26.4
Specialty Generics	195.5	193.8	381.9	376.5
Net Sales	$ 823.3	$ 825.5	$ 1,613.9	$ 1,580.8

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

17. Condensed Consolidating Financial Statements

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% 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 six months ended June 28, 2019 and June 29, 2018, and as of June 28, 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 June 28, 2019
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.1	$ 4.9	$ 236.1	$ —	$ 241.1
Accounts receivable, net	—	—	528.4	—	528.4
Inventories	—	—	337.4	—	337.4
Prepaid expenses and other current assets	0.3	0.3	111.9	—	112.5
Intercompany receivables	134.1	28.9	5,885.7	(6,048.7)	—
Total current assets	134.5	34.1	7,099.5	(6,048.7)	1,219.4
Property, plant and equipment, net	—	—	994.2	—	994.2
Intangible assets, net	—	—	7,721.1	—	7,721.1
Investment in subsidiaries	2,673.5	12,937.0	3,849.3	(19,459.8)	—
Intercompany loans receivable	462.3	—	2,613.9	(3,076.2)	—
Other assets	—	—	287.0	—	287.0
Total Assets	$ 3,270.3	$ 12,971.1	$ 22,565.0	$ (28,584.7)	$ 10,221.7
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ —	$ 717.9	$ —	$ 717.9
Accounts payable	—	—	148.6	—	148.6
Accrued payroll and payroll-related costs	—	—	79.8	—	79.8
Accrued interest	—	4.0	41.9	—	45.9
Accrued and other current liabilities	0.8	0.2	564.3	—	565.3
Intercompany payables	194.3	5,638.9	215.5	(6,048.7)	—
Total current liabilities	195.1	5,643.1	1,768.0	(6,048.7)	1,557.5
Long-term debt	—	397.6	4,425.4	—	4,823.0
Pension and postretirement benefits	—	—	59.5	—	59.5
Environmental liabilities	—	—	60.5	—	60.5
Deferred income taxes	—	—	53.4	—	53.4
Other income tax liabilities	—	—	262.5	—	262.5
Intercompany loans payable	—	3,076.2	—	(3,076.2)	—
Other liabilities	—	4.9	325.2	—	330.1
Total Liabilities	195.1	9,121.8	6,954.5	(9,124.9)	7,146.5
Shareholders' Equity	3,075.2	3,849.3	15,610.5	(19,459.8)	3,075.2
Total Liabilities and Shareholders' Equity	$ 3,270.3	$ 12,971.1	$ 22,565.0	$ (28,584.7)	$ 10,221.7

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 June 28, 2019
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 823.3	$ —	$ 823.3
Cost of sales	0.7	—	433.7	—	434.4
Gross (loss) profit	(0.7)	—	389.6	—	388.9
Selling, general and administrative expenses	13.9	0.4	211.6	—	225.9
Research and development expenses	1.8	—	77.8	—	79.6
Restructuring charges, net	—	—	(0.2)	—	(0.2)
Non-restructuring impairment charge	—	—	113.5	—	113.5
Operating loss	(16.4)	(0.4)	(13.1)	—	(29.9)
Interest expense	(1.5)	(61.8)	(97.4)	89.2	(71.5)
Interest income	2.8	0.2	88.4	(89.2)	2.2
Other income, net	5.5	29.5	39.4	—	74.4
Intercompany fees	(3.5)	—	3.5	—	—
Equity in net income of subsidiaries	18.8	69.7	33.5	(122.0)	—
Income (loss) from continuing operations before income taxes	5.7	37.2	54.3	(122.0)	(24.8)
Income tax (benefit) expense	(1.1)	6.6	(29.8)	—	(24.3)
Income (loss) from continuing operations	6.8	30.6	84.1	(122.0)	(0.5)
Income from discontinued operations, net of income taxes	—	2.9	4.4	—	7.3
Net income	6.8	33.5	88.5	(122.0)	6.8
Other comprehensive income, net of tax	2.4	2.4	4.3	(6.7)	2.4
Comprehensive income	$ 9.2	$ 35.9	$ 92.8	$ (128.7)	$ 9.2

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the three months ended June 29, 2018
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 825.5	$ —	$ 825.5
Cost of sales	0.7	—	430.8	—	431.5
Gross (loss) profit	(0.7)	—	394.7	—	394.0
Selling, general and administrative expenses	11.3	0.2	178.4	—	189.9
Research and development expenses	1.7	—	90.9	—	92.6
Restructuring charges, net	—	—	58.8	—	58.8
Operating (loss) income	(13.7)	(0.2)	66.6	—	52.7
Interest expense	(1.6)	(110.0)	(7.7)	24.2	(95.1)
Interest income	2.2	0.3	23.1	(24.2)	1.4
Other income (expense), net	0.6	—	(0.8)	—	(0.2)
Intercompany fees	(4.0)	—	4.0	—	—
Equity in net income of subsidiaries	31.0	232.9	124.3	(388.2)	—
Income (loss) from continuing operations before income taxes	14.5	123.0	209.5	(388.2)	(41.2)
Income tax benefit	(1.1)	(1.2)	(42.1)	—	(44.4)
Income from continuing operations	15.6	124.2	251.6	(388.2)	3.2
Income from discontinued operations, net of income taxes	—	0.1	12.3	—	12.4
Net income	15.6	124.3	263.9	(388.2)	15.6
Other comprehensive loss, net of tax	(4.9)	(4.9)	(9.9)	14.8	(4.9)
Comprehensive income	$ 10.7	$ 119.4	$ 254.0	$ (373.4)	$ 10.7

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the six months ended June 28, 2019
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 1,613.9	$ —	$ 1,613.9
Cost of sales	1.3	—	888.6	—	889.9
Gross (loss) profit	(1.3)	—	725.3	—	724.0
Selling, general and administrative expenses	25.2	0.6	430.3	—	456.1
Research and development expenses	3.2	—	161.7	—	164.9
Restructuring charges, net	—	—	4.0	—	4.0
Non-restructuring impairment charge	—	—	113.5	—	113.5
Operating (loss) income	(29.7)	(0.6)	15.8	—	(14.5)
Interest expense	(12.6)	(132.1)	(136.4)	126.9	(154.2)
Interest income	15.0	0.3	115.3	(126.9)	3.7
Other income, net	8.7	30.7	51.3	—	90.7
Intercompany fees	(10.0)	—	10.0	—	—
Equity in net income of subsidiaries	188.1	368.1	262.5	(818.7)	—
Income (loss) from continuing operations before income taxes	159.5	266.4	318.5	(818.7)	(74.3)
Income tax (benefit) expense	(2.2)	6.6	(233.4)	—	(229.0)
Income from continuing operations	161.7	259.8	551.9	(818.7)	154.7
Income from discontinued operations, net of income taxes	—	2.7	4.3	—	7.0
Net income	161.7	262.5	556.2	(818.7)	161.7
Other comprehensive income, net of tax	3.7	3.7	6.7	(10.4)	3.7
Comprehensive income	$ 165.4	$ 266.2	$ 562.9	$ (829.1)	$ 165.4

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the six months ended June 29, 2018
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 1,580.8	$ —	$ 1,580.8
Cost of sales	0.9	—	838.4	—	839.3
Gross (loss) profit	(0.9)	—	742.4	—	741.5
Selling, general and administrative expenses	17.7	0.4	383.0	—	401.1
Research and development expenses	2.2	—	172.4	—	174.6
Restructuring charges, net	—	—	87.0	—	87.0
Operating (loss) income	(20.8)	(0.4)	100.0	—	78.8
Interest expense	(4.6)	(211.2)	(14.8)	44.1	(186.5)
Interest income	4.4	2.0	42.3	(44.1)	4.6
Other income (expense), net	6.7	2.8	(5.1)	—	4.4
Intercompany fees	(8.5)	—	8.5	—	—
Equity in net income of subsidiaries	18.1	408.3	203.5	(629.9)	—
(Loss) income from continuing operations before income taxes	(4.7)	201.5	334.4	(629.9)	(98.7)
Income tax benefit	(2.3)	(2.0)	(76.7)	—	(81.0)
(Loss) income from continuing operations	(2.4)	203.5	411.1	(629.9)	(17.7)
Income from discontinued operations, net of income taxes	—	—	15.3	—	15.3
Net (loss) income	(2.4)	203.5	426.4	(629.9)	(2.4)
Other comprehensive loss, net of tax	(7.3)	(7.3)	(15.1)	22.4	(7.3)
Comprehensive (loss) income	$ (9.7)	$ 196.2	$ 411.3	$ (607.5)	$ (9.7)

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
For the six months ended June 28, 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	$ (16.2)	$ 56.5	$ 430.8	$ (3.7)	$ 467.4
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(77.6)	—	(77.6)
Acquisitions, net of cash	—	—	—	—	—
Proceeds from divestitures, net of cash	—	—	—	—	—
Intercompany loan investment, net	40.9	—	(580.8)	539.9	—
Investment in subsidiary	—	(658.6)	—	658.6	—
Other	—	—	8.2	—	8.2
Net cash from investing activities	40.9	(658.6)	(650.2)	1,198.5	(69.4)
Cash Flows From Financing Activities:					
Issuance of external debt	—	—	200.0	—	200.0
Repayment of external debt and capital lease obligation	—	(98.6)	(587.3)	—	(685.9)
Debt financing costs	—	—	—	—	—
Proceeds from exercise of share options	0.5	—	—	—	0.5
Repurchase of shares	(2.5)	—	—	—	(2.5)
Intercompany loan borrowings, net	(24.9)	564.8	—	(539.9)	—
Intercompany dividends	—	—	(3.7)	3.7	—
Capital contribution	—	—	658.6	(658.6)	—
Other	1.9	—	(20.4)	—	(18.5)
Net cash from financing activities	(25.0)	466.2	247.2	(1,194.8)	(506.4)
Effect of currency rate changes on cash	—	—	0.8	—	0.8
Net change in cash, cash equivalents and restricted cash	(0.3)	(135.9)	28.6	—	(107.6)
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	$ 0.1	$ 4.9	$ 254.9	$ —	$ 259.9
Cash and cash equivalents at end of period	$ 0.1	$ 4.9	$ 236.1	$ —	$ 241.1
Restricted Cash, included in other assets at end of period	—	—	18.8	—	18.8
Cash, cash equivalents and restricted cash at end of period	$ 0.1	$ 4.9	$ 254.9	$ —	$ 259.9

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
For the six months ended June 29, 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	$ 453.6	$ 102.3	$ 1,135.9	$ (1,430.0)	$ 261.8
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(67.1)	—	(67.1)
Acquisitions, net of cash	—	—	(699.9)	—	(699.9)
Proceeds from divestitures, net of cash	—	—	298.3	—	298.3
Intercompany loan investment, net	(398.3)	(85.2)	(12.4)	495.9	—
Investment in subsidiary	—	(163.1)	41.3	121.8	—
Other	—	—	12.4	—	12.4
Net cash from investing activities	(398.3)	(248.3)	(427.4)	617.7	(456.3)
Cash Flows From Financing Activities:					
Issuance of external debt	—	600.0	57.2	—	657.2
Repayment of external debt and capital lease obligation	—	(1,011.2)	(381.6)	—	(1,392.8)
Debt financing costs	—	(12.0)	—	—	(12.0)
Proceeds from exercise of share options	—	—	—	—	—
Repurchase of shares	(56.8)	—	—	—	(56.8)
Intercompany loan borrowings, net	—	495.9	—	(495.9)	—
Intercompany dividends	—	(814.2)	(615.8)	1,430.0	—
Capital contribution	—	—	121.8	(121.8)	—
Other	1.4	—	(26.3)	—	(24.9)
Net cash from financing activities	(55.4)	(741.5)	(844.7)	812.3	(829.3)
Effect of currency rate changes on cash	—	—	(1.2)	—	(1.2)
Net change in cash, cash equivalents and restricted cash	(0.1)	(887.5)	(137.4)	—	(1,025.0)
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	$ 0.6	$ 21.3	$ 232.2	$ —	$ 254.1
Cash and cash equivalents at end of period	$ 0.6	$ 21.3	$ 213.8	$ —	$ 235.7
Restricted Cash, included in other assets at end of period	—	—	18.4	—	18.4
Cash, cash equivalents and restricted cash at end of period	$ 0.6	$ 21.3	$ 232.2	$ —	$ 254.1

18. Subsequent Events

Specialty Generics Separation Update

On August 6, 2019, the Company announced that based on current market conditions and developments, including increasing uncertainties created by the opioid litigation, the Company is suspending for now its previously announced plans to spin off the Specialty Generics company.

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, then 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 $815.4 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 adjustment may be material. The Company believes its allowance for income tax contingencies is adequate.

License Agreement

On July 18, 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. These proteins are known to contribute to the pathogenesis of many diseases, including autoimmune disease. Under the terms of the agreement, the Company will obtain 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. Silence will be responsible for preclinical activities, and for executing the development program of each asset until the end of Phase 1, after which the Company will assume clinical development and responsibility for global commercialization.

During the three months ending September 27, 2019, the Company will provide Silence with an upfront payment of $20.0 million. Silence is also eligible to receive up to $10.0 million in research milestones for SLN500 and for each optioned asset, in addition to funding for Phase 1 clinical development including good manufacturing practices (GMP) manufacturing. Silence will fund all other preclinical activities. The collaboration provides for potential added clinical and regulatory milestone payments of up to $100.0 million for SLN500, as well as commercial milestone payments of up to $563.0 million for SLN500. Should the Company opt to license one or two additional assets, Silence could receive up to $703.0 million in similar clinical, regulatory, and commercial milestone payments per asset. Silence would also receive tiered, low double-digit to high-teen royalties on net sales for SLN500 and each optioned asset.

In addition to the aforementioned agreement, on July 24, 2019, the Company acquired an equity investment of $5.0 million in Silence Therapeutics.

Financing Activities

On July 11, 2019, the Company borrowed an additional $400.0 million on its revolving credit facility, bringing total outstanding borrowings to $805.0 million for this instrument as of the date of this report.

On July 19, 2019, the Company repaid $200.0 million of its outstanding obligations under its variable-rate receivable securitization, thus automatically terminating this facility, which was classified as long-term on the unaudited condensed consolidated balance sheet as of June 28, 2019.

Subsequent to June 28, 2019 and up through the date of this filing, the Company repurchased fixed-rate debt that aggregated to a principal amount of $70.9 million, which resulted in a gain on repurchase of $18.0 million.

Commitments and Contingencies

Certain litigation matters occurred during the six months ended June 28, 2019 or prior, but had subsequent updates through the issuance of this report. See further discussion in Note 14.

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.

On May 28, 2019, as an update to our planned separation of the previously reported Specialty Generics and Amitiza® (lubiprostone) ("Amitiza") segment discussed further below, we announced that given the strong, return-to-growth performance of the Specialty Generics business, the Amitiza product should remain with the Specialty Brands business. As a result of this announcement, we identified two reportable segments that align with the operations of the two independent publicly traded companies anticipated post-separation, which are further described below:

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

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, based on current market conditions and developments, including increasing uncertainties created by the opioid litigation, subsequent to June 28, 2019, we decided to suspend for now our previously announced plans to spin off the Specialty Generics company (the "Separation"). 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 Separation announcement, 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 as presented herein.

During the three and six months ended June 28, 2019, we incurred $18.9 million and $30.6 million in costs related to the Separation, respectively. These costs, which are included in selling, general and administrative ("SG&A") expenses, primarily relate to professional fees and incremental costs incurred to build out the corporate infrastructure of the new company, as well as rebranding initiatives.

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, then 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 $815.4 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 adjustment may be material. We believe our allowance for income tax contingencies is adequate.

Medicaid Lawsuit

In May 2019, we filed a lawsuit in federal district court against the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services. This lawsuit is in response to a decision by CMS to require that we revert to the prior 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 approximately $600.0 million in retroactive rebates and prospective rebate increases of approximately $100.0 million annually. This matter is further described in Note 14 to the unaudited condensed consolidated financial statements.

Reorganization of Intercompany Financing and Legal Entity Ownership

During the three months ended March 29, 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 six months ended June 28, 2019, we recognized current income tax expense of $28.9 million and a deferred income tax benefit of $218.7 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 $42.3 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 $24.7 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. We are in the process of evaluating this portion of the study in order to ensure the data was properly captured and of the highest quality. 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 determine the best path forward. We will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated in-process research and development asset of $274.5 million included within intangible assets, net on the unaudited condensed consolidated balance sheet as of June 28, 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.

Silence Therapeutics

On July 18, 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. Under the terms of the agreement, we will obtain 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. Silence will be responsible for preclinical activities, and for executing the development program of each asset until the end of Phase 1, after which we will assume clinical development and responsibility for global commercialization.

During the three months ending September 27, 2019, we will provide Silence with an upfront payment of $20.0 million. Silence is also eligible to receive up to $10.0 million in research milestones for SLN500 and for each optioned asset, in addition to funding for Phase 1 clinical development including good manufacturing practices (GMP) manufacturing. Silence will fund all other preclinical activities. The collaboration provides for potential added clinical and regulatory milestone payments of up to $100.0 million for SLN500, as well as commercial milestone payments of up to $563.0 million for SLN500. Should we opt to license one or two additional assets, Silence could receive up to $703.0 million in similar clinical, regulatory, and commercial milestone payments per asset. Silence would also receive tiered, low double-digit to high-teen royalties on net sales for SLN500 and each optioned asset.

In addition to the aforementioned agreement, on July 24, 2019, we acquired an equity investment of $5.0 million in Silence Therapeutics.

Business Factors Influencing the Results of Operations

Products

Specialty Brands

Net sales of Acthar Gel for the three months ended June 28, 2019 decreased $26.8 million, or 9.1%, to $266.4 million driven primarily by continued reimbursement challenges impacting new and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending. This is partially offset by strength in Ofirmev, Inomax® and Therakos®, as well as an increase in Amitiza® net sales.

Specialty Generics

After experiencing contraction over the last several years, the Specialty Generics business is projected to return to growth in fiscal 2019, as compared to fiscal 2018, primarily driven by share recapture in specialty generic products. Net sales from the Specialty Generics segment increased $1.7 million or 0.9% to $195.5 million for the three months ended June 28, 2019 compared to $193.8 million for the three months ended June 29, 2018.

The U.S. generic market is growing overall in volume, but has been declining in value over the past several years due to pricing pressure. Hydrocodone, oxycodone and other controlled substances have experienced significant volume declines due to continued downward pressure on the use of opioids in the U.S. Despite this market contraction, acetaminophen and opioids are still viewed as the standard of care for many types of pain. Pain management represents the second largest therapeutic area in the U.S. based upon prescriptions dispensed, with pain medications accounting for approximately one out of every 11 dispensed prescriptions in 2018. We expect the decline in usage rates for opioids in the U.S. to continue, stabilizing at levels consistent with historical prescribing patterns and aligning with treatment guidelines being developed by the medical community. Globally, we expect the use of acetaminophen and opioids to trend with population rates for the foreseeable future.

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, distributors, 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. 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. Such litigation and related matters are described in Note 14 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 $79.6 million and $164.9 million for the three and six months ended June 28, 2019, respectively, and $92.6 million and $174.6 million for the three and six months ended June 29, 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.

Results of Operations

Three Months Ended June 28, 2019 Compared with Three Months Ended June 29, 2018

Net Sales

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

	Three Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
U.S.	$ 717.2	$ 729.1	(1.6)%
Europe, Middle East and Africa	73.5	64.2	14.5
Other geographic areas	32.6	32.2	1.2
Net sales	$ 823.3	$ 825.5	(0.3)

Net sales for the three months ended June 28, 2019 decreased $2.2 million, or 0.3%, to $823.3 million, compared with $825.5 million for the three months ended June 29, 2018. This decrease in net sales was primarily driven by a decrease in net sales of Acthar Gel, partially offset by continued strength in Ofirmev, Inomax, Therakos and Amitiza, as well as increased net sales from the Specialty Generics segment as it continues in its return to growth. 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 June 28, 2019 decreased $5.1 million, or 1.3%, to $388.9 million, compared with $394.0 million for the three months ended June 29, 2018. Gross profit margin was 47.2% for the three months ended June 28, 2019, compared with 47.7% for the three months ended June 29, 2018. The decrease in gross profit and gross profit margin was primarily attributable to an additional $29.8 million of amortization for the Ofirmev intangible asset resulting from a change in amortization method as discussed further in Note 10 to the unaudited condensed consolidated financial statements, as well as higher depreciation expense. The additional amortization and depreciation expense 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 June 28, 2019 were $225.9 million, compared with $189.9 million for the three months ended June 29, 2018, an increase of $36.0 million, or 19.0%. This increase was primarily driven by a $27.5 million decrease in the fair value of the contingent consideration liability related to stannsoporfin recorded during the three months ended June 29, 2018. The remaining increase was attributable to various factors, including $18.9 million in costs related to the Separation, inclusive of rebranding initiatives, and an increase in legal expense, partially offset by cost benefits gained from restructuring actions, including lower employee compensation costs and advertising costs. SG&A

expenses were 27.4% of net sales for the three months ended June 28, 2019 and 23.0% of net sales for the three months ended June 29, 2018.

Research and development expenses. R&D expenses decreased $13.0 million, or 14.0%, to $79.6 million for the three months ended June 28, 2019, compared with $92.6 million for the three months ended June 29, 2018. Current R&D activities focus on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic activities and patient outcomes. As a percentage of net sales, R&D expenses were 9.7% and 11.2% for the three months ended June 28, 2019 and June 29, 2018, respectively.

Restructuring charges, net. During the three months ended June 28, 2019, we recognized a net benefit of $0.2 million, primarily related to employee severance and benefits. During the three months ended June 29, 2018, we recorded $58.8 million of restructuring charges, net, primarily related to contract termination costs related to the production of Raplixa, as well as the exiting of certain facilities and employee severance and benefits associated with the acquisition of Sucampo Pharmaceuticals, Inc. ("the Sucampo Acquisition") in February 2018.

Non-Operating Items

Interest expense and interest income. During the three months ended June 28, 2019 and June 29, 2018, net interest expense was $69.3 million and $93.7 million, respectively. This decrease was primarily attributable to the recognition of an $8.6 million benefit to interest expense during the three months ended June 28, 2019, due to a lapse of certain statute of limitations, in addition to a $6.3 million decrease in interest accrued on deferred tax liabilities associated with our previously outstanding installment notes. For further information, refer to Note 14 to the unaudited condensed consolidated financial statements. Additionally, a lower average outstanding debt balance during the three months ended June 28, 2019 yielded a decrease in interest expense of $7.8 million over the comparable period. Interest income increased to $2.2 million for the three months ended June 28, 2019, compared with $1.4 million for the three months ended June 29, 2018, primarily related to interest on preferred equity certificates received as contingent consideration associated with the sale of the Nuclear Imaging business.

Other income (expense), net. During the three months ended June 28, 2019, we recorded other income, net, of $74.4 million and during the three months ended June 29, 2018, we recorded other expense, net, of $0.2 million. The increase was primarily attributable to a gain of $65.0 million on debt repurchased, as well as royalty income, partially offset by a write-off of unamortized debt discount and fees during the three months ended June 28, 2019. The other expense, net, recorded during the three months ended June 29, 2018 represented items including gains on intercompany financing, foreign currency transactions losses and related hedging instruments.

Income tax benefit. We recognized an income tax benefit of $24.3 million on a loss from continuing operations before income taxes of $24.8 million for the three months ended June 28, 2019, and an income tax benefit of $44.4 million on a loss from continuing operations before income taxes of $41.2 million for the three months ended June 29, 2018. This resulted in effective tax rates of 98.0% and 107.8% for the three months ended June 28, 2019 and June 29, 2018, respectively. The income tax benefit for the three months ended June 28, 2019 was comprised of $5.6 million of current tax expense and $29.9 million of deferred tax benefit, which was predominately related to previously acquired intangibles, the generation of tax loss and credit carryforwards net of valuation allowances and the non-restructuring impairment charge, as further discussed in Note 10 of the unaudited condensed consolidated financial statements. The income tax benefit for the three months ended June 29, 2018 was comprised of $10.2 million of current tax expense and $54.6 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles.

The income tax benefit was $24.3 million for the three months ended June 28, 2019, compared with a tax benefit of $44.4 million for the three months ended June 29, 2018. The $20.1 million net decrease in the tax benefit included a $20.7 million decrease attributed to changes in the timing, amount and jurisdictional mix of income, a $7.1 million decrease attributed to the gain on debt repurchased and a $3.4 million decrease attributed to restructuring and related charges, partially offset by an increase in tax benefit of $8.5 million attributed to the non-restructuring impairment charge and $2.6 million increase attributed to separation costs.

Income from discontinued operations, net of income taxes. We recorded income from discontinued operations of $7.3 million and $12.4 million during the three months ended June 28, 2019 and June 29, 2018, respectively, primarily related to the receipt of contingent consideration associated with the sale of the Nuclear Imaging business.

Six Months Ended June 28, 2019 Compared with Six Months Ended June 29, 2018

Net Sales

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

	Six Months Ended		Percentage Change
	June 28, 2019	June 29, 2018	
U.S.	$ 1,396.9	$ 1,399.3	(0.2)%
Europe, Middle East and Africa	148.3	124.1	19.5
Other geographic areas	68.7	57.4	19.7
Net sales	$ 1,613.9	$ 1,580.8	2.1

Net sales for the six months ended June 28, 2019 increased $33.1 million, or 2.1%, to $1,613.9 million, compared with $1,580.8 million for the six months ended June 29, 2018. This increase was primarily driven by net sales of Amitiza, which was acquired during the first quarter of 2018, and continued strength in Ofirmev, Inomax and Therakos. These increases were partially offset by decreased net sales of Acthar Gel, as previously mentioned. In addition, we experienced lower net sales in Other branded products primarily due to the sale of Recothrom during the first quarter of 2018. 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 six months ended June 28, 2019 decreased $17.5 million, or 2.4%, to $724.0 million, compared with $741.5 million for the six months ended June 29, 2018. Gross profit margin was 44.9% for the six months ended June 28, 2019, compared with 46.9% for the six months ended June 29, 2018. The decrease in gross profit and gross profit margin was primarily attributable to an additional $65.7 million of amortization for the Ofirmev intangible asset resulting from a change in amortization method as discussed further in Note 10 to the unaudited condensed consolidated financial statements. This 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 six months ended June 28, 2019 were $456.1 million, compared with $401.1 million for the six months ended June 29, 2018, an increase of $55.0 million, or 13.7%. This increase was primarily attributable to $30.6 million in costs related to the Separation, inclusive of rebranding initiatives, and increased legal expenses. Additionally, during the six months ended June 29, 2018 we recorded a $28.0 million decrease in the fair value of the contingent consideration liability related to stannsoporfin. These increases were partially offset by cost benefits gained from restructuring actions, including lower employee compensation costs and lower advertising costs. SG&A expenses were 28.3% of net sales for the six months ended June 28, 2019 and 25.4% of net sales for the six months ended June 29, 2018.

Research and development expenses. R&D expenses decreased $9.7 million, or 5.6%, to $164.9 million for the six months ended June 28, 2019, compared with $174.6 million for the six months ended June 29, 2018. Current R&D activities focus 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 10.2% and 11.0% for the six months ended June 28, 2019 and June 29, 2018, respectively.

Restructuring charges, net. During the six months ended June 28, 2019 we recorded $4.0 million of restructuring and related charges, net, primarily related to employee severance and benefits. During the six months ended June 29, 2018, we recorded $87.0 million of restructuring and related charges, net, primarily attributable to contract termination costs related to the production of Raplixa, as well as employee severance and benefits, and exiting certain facilities.

Non-Operating Items

Interest expense and interest income. During the six months ended June 28, 2019 and June 29, 2018, net interest expense was $150.5 million and $181.9 million, respectively. This decrease was primarily attributable to an $11.6 million decrease in interest accrued on deferred tax liabilities associated with our previously outstanding installment notes, in addition to the recognition of an $8.6 million benefit to interest expense during the three months ended June 28, 2019, due to a lapse of certain statute of limitations. For further information, refer to Note 14 to the unaudited condensed consolidated financial statements. Additionally, a lower average outstanding debt balance during the six months ended June 28, 2019 yielded a decrease in interest expense of $10.0

million and non-cash interest expense decreased by $2.0 million over the comparable period. During the six months ended June 28, 2019, we also recognized interest income of $3.7 million compared to $4.6 million during the six months ended June 29, 2018, due to a decrease in interest rates resulting in lower interest earned on our money market funds.

Other income (expense), net. During the six months ended June 28, 2019 and June 29, 2018, we recorded other income, net, of $90.7 million and $4.4 million, respectively. The increase was primarily attributable to a gain of $79.9 million on debt repurchased, as well as royalty income, partially offset by a write-off of unamortized debt discount and fees during the six months ended June 28, 2019. The six months ended June 29, 2018 included a gain of $6.5 million on debt repurchased. 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 $229.0 million on a loss from continuing operations before income taxes of $74.3 million for the six months ended June 28, 2019, and an income tax benefit of $81.0 million on a loss from continuing operations before income taxes of $98.7 million for the six months ended June 29, 2018. This resulted in effective tax rates of 308.2% and 82.1% for the six months ended June 28, 2019 and June 29, 2018, respectively. The income tax benefit for the six months ended June 28, 2019 was comprised of $44.1 million of current tax expense and $273.1 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 six months ended June 29, 2018 was comprised of $21.4 million of current tax expense and $102.4 million of deferred tax benefit. The deferred tax benefit was predominantly related to previously acquired intangibles.

The income tax benefit was $229.0 million for the six months ended June 28, 2019, compared with a tax benefit of $81.0 million for the six months ended June 29, 2018. The $148.0 million net increase in the tax benefit included an increase of $189.8 million attributed to the tax benefit from the reorganization of our intercompany financing and associated legal entity ownership, a $8.5 million increase attributed to the non-restructuring impairment charge and a $3.6 million increase attributed to separation costs, partially offset by a decrease in tax benefit of $35.2 million predominately attributed to changes in the timing, amount and jurisdictional mix of income, a $9.8 million decrease attributed to restructuring and related charges and a $8.9 million decrease attributed to the gain on debt repurchased.

Income from discontinued operations, net of income taxes. We recorded income from discontinued operations of $7.0 million and $15.3 million during the six months ended June 28, 2019 and June 29, 2018, respectively, primarily related to the receipt of contingent consideration associated with the sale of the Nuclear Imaging business. These were 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 impairments 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 June 28, 2019 Compared with Three Months Ended June 29, 2018

Net Sales

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

	Three Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
Specialty Brands	$ 627.8	$ 631.7	(0.6)%
Specialty Generics	195.5	193.8	0.9
Net sales	$ 823.3	$ 825.5	(0.3)

Specialty Brands. Net sales for the three months ended June 28, 2019 decreased $3.9 million to $627.8 million, compared with $631.7 million for the three months ended June 29, 2018. The decrease in net sales was primarily driven by a $26.8 million or 9.1% 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, partially offset by strength in Inomax, Ofirmev, Therakos and Amitiza resulting in increased net sales of $8.7 million, $4.9 million, $4.1 million and $4.0 million, respectively, compared with the three months ended June 29, 2018.

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

	Three Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
U.S.	$ 559.4	$ 570.6	(2.0)%
Europe, Middle East and Africa	40.2	34.0	18.2
Other	28.2	27.1	4.1
Net sales	$ 627.8	$ 631.7	(0.6)

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

	Three Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
Acthar Gel	$ 266.4	$ 293.2	(9.1)%
Inomax	139.7	131.0	6.6
Ofirmev	90.5	85.6	5.7
Therakos	60.9	56.8	7.2
Amitiza	52.0	48.0	8.3
BioVectra	13.9	11.3	23.0
Other	4.4	5.8	(24.1)
Specialty Brands	$ 627.8	$ 631.7	(0.6)

Specialty Generics. Net sales for the three months ended June 28, 2019 increased $1.7 million, or 0.9%, to $195.5 million, compared with $193.8 million for the three months ended June 29, 2018. The increase in net sales was driven by Oxycodone and Hydrocodone products of $6.5 million and $1.2 million, respectively. These increases were partially offset by a $3.3 million decrease in acetaminophen products net sales compared to the three months ended June 29, 2018.

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

	Three Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
U.S.	$ 157.8	$ 158.5	(0.4)%
Europe, Middle East and Africa	33.3	30.2	10.3
Other	4.4	5.1	(13.7)
Net sales	$ 195.5	$ 193.8	0.9

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

	Three Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 18.1	$ 16.9	7.1 %
Oxycodone (API) and oxycodone-containing tablets	19.6	13.1	49.6
Acetaminophen (API)	48.4	51.7	(6.4)
Other controlled substances	98.6	99.5	(0.9)
Other	10.8	12.6	(14.3)
Specialty Generics	$ 195.5	$ 193.8	0.9

Operating Income

Operating income by segment and as a percentage of segment net sales for the three months ended June 28, 2019 and June 29, 2018 is shown in the following table *(dollars in millions)*:

	Three Months Ended			
	June 28, 2019		June 29, 2018	
Specialty Brands [1]	$ 321.4	51.2%	$ 265.2	42.0%
Specialty Generics	33.9	17.3	43.1	22.2
Segment operating income	355.3	43.2	308.3	37.3
Unallocated amounts:				
Corporate and allocated expenses	(36.4)		(12.5)	
Intangible asset amortization	(216.6)		(184.3)	
Restructuring and related charges, net	0.2		(58.8)	
Non-restructuring impairment	(113.5)		—	
Separation costs	(18.9)		—	
Total operating (loss) income	$ (29.9)		$ 52.7	

(1) Includes $31.5 million of inventory fair-value step up expense, primarily related to Amitiza, during the three months ended June 29, 2018.

Specialty Brands. Operating income for the three months ended June 28, 2019 increased $56.2 million to $321.4 million, compared with $265.2 million for the three months ended June 29, 2018. Operating margin increased to 51.2% for the three months ended June 28, 2019 compared with 42.0% for the three months ended June 29, 2018. While net sales decreased, gross margin increased $24.7 million primarily driven by an additional $31.5 million of expense recorded during the three months ended June 29, 2018 related to the inventory fair value adjustments for Amitiza, which was fully amortized in the first quarter of 2019. The increase in operating income and margin was also attributable to decreases in SG&A expenses of $18.6 million, primarily driven by lower employee compensation costs, and R&D expenses of $13.1 million.

Specialty Generics. Operating income for the three months ended June 28, 2019 decreased $9.2 million to $33.9 million, compared with $43.1 million for the three months ended June 29, 2018. Operating margin decreased to 17.3% for the three months ended June 28, 2019, compared with 22.2% for the three months ended June 29, 2018. The decrease in operating income and margin was impacted by a $12.1 million increase in SG&A primarily due to higher legal expense related to opioid defense costs, partially offset by a $2.5 million increase in gross profit.

Corporate and allocated expenses. Corporate and allocated expenses were $36.4 million and $12.5 million for the three months ended June 28, 2019 and June 29, 2018, respectively. This increase was primarily driven by a $27.5 million decrease in the fair value of the contingent consideration liability related to stannsoporfin recorded during the during the three months ended June 29, 2018, in addition to higher professional and legal expenses, partially offset by lower employee compensation costs.

Six Months Ended June 28, 2019 Compared with Six Months Ended June 29, 2018

Net Sales

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

	Six Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
Specialty Brands	$ 1,232.0	$ 1,204.3	2.3%
Specialty Generics	381.9	376.5	1.4
Net sales	$ 1,613.9	$ 1,580.8	2.1

Specialty Brands. Net sales for the six months ended June 28, 2019 increased $27.7 million to $1,232.0 million, compared with $1,204.3 million for the six months ended June 29, 2018. The increase in net sales was primarily driven by net sales of Amitiza, which was acquired during the first quarter of 2018, and continued strength in Ofirmev, Inomax and Therakos compared with the six months ended June 29, 2018. These increases were partially offset by a $46.7 million or 8.7% decrease in Acthar Gel net sales, as previously mentioned, and an $11.1 million or 50.7% decrease in Other products compared with the six months ended June 29, 2018. The decrease in Other products net sales was primarily attributable to the sale of Recothrom during the first quarter of 2018, which contributed net sales of $10.5 million during the six months ended June 29, 2018.

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

	Six Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
U.S.	$ 1,090.6	$ 1,092.6	(0.2)%
Europe, Middle East and Africa	81.0	64.1	26.4
Other	60.4	47.6	26.9
Net sales	$ 1,232.0	$ 1,204.3	2.3

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

	Six Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
Acthar Gel	$ 490.3	$ 537.0	(8.7)%
Inomax	290.8	270.8	7.4
Ofirmev	186.1	167.6	11.0
Therakos	122.7	114.2	7.4
Amitiza	105.0	71.0	47.9
BioVectra	26.3	21.8	20.6
Other	10.8	21.9	(50.7)
Specialty Brands	$ 1,232.0	$ 1,204.3	2.3

Specialty Generics. Net sales for the six months ended June 28, 2019 increased $5.4 million, or 1.4%, to $381.9 million, compared with $376.5 million for the six months ended June 29, 2018. The increase in net sales was driven by Oxycodone and Hydrocodone products of $6.4 million and $4.7 million, respectively. These increases were partially offset by a $6.5 million decrease in acetaminophen products net sales compared to the six months ended June 29, 2018.

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

	Six Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
U.S.	$ 306.3	$ 306.7	(0.1)%
Europe, Middle East and Africa	67.3	60.0	12.2
Other	8.3	9.8	(15.3)
Net sales	$ 381.9	$ 376.5	1.4

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

	Six Months Ended		
	June 28, 2019	June 29, 2018	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 35.5	$ 30.8	15.3 %
Oxycodone (API) and oxycodone-containing tablets	36.1	29.7	21.5
Acetaminophen (API)	94.6	101.1	(6.4)
Other controlled substances	192.8	188.5	2.3
Other	22.9	26.4	(13.3)
Specialty Generics	$ 381.9	$ 376.5	1.4

Operating Income

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

	Six Months Ended			
	June 28, 2019		June 29, 2018	
Specialty Brands [1]	$ 596.9	48.4%	$ 506.4	42.0%
Specialty Generics	58.3	15.3	78.2	20.8
Segment operating income	655.2	40.6	584.6	37.0
Unallocated amounts:				
Corporate and allocated expenses	(82.2)		(56.5)	
Intangible asset amortization	(439.4)		(362.3)	
Restructuring and related charges, net	(4.0)		(87.0)	
Non-restructuring impairment	(113.5)		—	
Separation costs	(30.6)		—	
Total operating income	$ (14.5)		$ 78.8	

(1) Includes $10.0 million and $46.5 million of inventory fair-value step up expense, primarily related to Amitiza, during the three months ended June 28, 2019 and June 29, 2018, respectively.

Specialty Brands. Operating income for the six months ended June 28, 2019 increased $90.5 million to $596.9 million, compared with $506.4 million for the six months ended June 29, 2018. Operating margin increased to 48.4% for the six months ended June 28, 2019, compared with 42.0% for the six months ended June 29, 2018. The increase in operating income and margin includes a $57.6 million increase in gross profit primarily driven by an additional $36.5 million of expense recorded during the six months ended June 29, 2018 related to the inventory fair value adjustments for Amitiza, which was fully amortized in the first quarter of 2019. Additionally, SG&A expenses decreased $32.5 million compared to the six months ended June 29, 2018 primarily due to cost benefits gained from restructuring actions, including lower employee compensation costs, in addition to lower advertising expenses.

Specialty Generics. Operating income for the six months ended June 28, 2019 decreased $19.9 million to $58.3 million, compared with $78.2 million for the six months ended June 29, 2018. Operating margin decreased to 15.3% for the six months ended June 28, 2019, compared with 20.8% for the six months ended June 29, 2018. The decrease in operating income and margin

was primarily impacted by a $31.9 million increase in SG&A primarily due to higher legal expense related to opioid defense costs, partially offset by a $9.9 million decrease in R&D expense.

Corporate and allocated expenses. Corporate and allocated expenses were $82.2 million and $56.5 million for the six months ended June 28, 2019 and June 29, 2018, respectively. This increase was primarily driven by a $28.0 million decrease in fair value of the contingent consideration liability related to stannsoporfin recorded during the six months ended June 29, 2018.

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, borrowing capacity under our revolving credit facility and access to capital markets will provide adequate resources to fund our working capital needs, capital expenditures and strategic investments for the foreseeable future.

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

	Six Months Ended	
	June 28, 2019	June 29, 2018
Net cash from:		
Operating activities	$ 467.4	$ 261.8
Investing activities	(69.4)	(456.3)
Financing activities	(506.4)	(829.3)
Effect of currency exchange rate changes on cash and cash equivalents	0.8	(1.2)
Net decrease in cash and cash equivalents	$ (107.6)	$ (1,025.0)

Operating Activities

Net cash provided by operating activities of $467.4 million for the six months ended June 28, 2019 was primarily attributable to net income of $161.7 million, adjusted for non-cash items of $277.7 million, driven by depreciation and amortization of $488.6 million and a non-cash impairment charge of $113.5 million, partially offset by a $271.2 million reduction in our deferred income tax liabilities and other non-cash adjustments, including a $79.9 million gain on debt repurchased. Net investment in working capital contributed $28.0 million of cash flow from operating activities. Included within this change in working capital was a $95.5 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. This was partially offset by a $73.3 million net cash outflow related to other assets and liabilities, which included decreases in accrued payroll and accrued interest of $44.2 million and $31.8 million, respectively.

Net cash provided by operating activities of $261.8 million for the six months ended June 29, 2018 was primarily attributable to a net loss of $2.4 million, adjusted for non-cash items of $293.5 million driven by depreciation and amortization of $397.1 million, partially offset by a $29.3 million outflow from net investment in working capital. Included within this change in working capital were a $35.4 million net cash outflow related to other assets and liabilities, a $21.8 million increase in accounts receivable, a $2.1 million increase in accounts payable, and a $7.4 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 Sucampo Acquisition in February 2018.

Investing Activities

Net cash used in investing activities was $69.4 million for the six months ended June 28, 2019, compared with $456.3 million for the six months ended June 29, 2018. The $386.9 million change primarily resulted from the cash outflows during the three months ended March 30, 2018 related to the Sucampo Acquisition of $698.0 million, partially offset by the $144.3 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 three months ended March 30, 2018, we also received payment of the $154.0 million note receivable from the purchaser of the Intrathecal Therapy business, which was sold during the three months ended March 31, 2017. The cash used in investing activities during the six months ended June 28, 2019 was primarily attributable to $77.6 million in capital expenditures, partially offset by cash received from the disposal of certain long-lived assets.

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 $506.4 million for the six months ended June 28, 2019, compared with $829.3 million for the six months ended June 29, 2018. The $322.9 million decrease in cash outflows was attributable to a $249.7 million decrease in debt repayments, net of issuances, and a $54.3 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 $419.2 million, and a repayment of $50.0 million on the receivable securitization program. These repayments were partially offset by a net draw of $185.0 million on our revolving credit facility. The six months ended June 29, 2018 included debt repayment of $450.0 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 June 28, 2019, the total debt principal was $5,591.0 million, of which $720.1 million was classified as current.

The total debt principal as of June 28, 2019 was comprised of the following:

Variable-rate instruments:		
Term loan due September 2024	$	1,524.7
Term loan due February 2025		404.6
Variable-rate receivable securitization		200.0
Revolving credit facility		405.0
Fixed-rate instruments		3,056.7
Debt principal	$	5,591.0

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 June 28, 2019, our fixed-rate instruments have a weighted-average interest rate of 5.36% and pay interest at various dates throughout the fiscal year. Prior to termination of this facility on July 19, 2019, as discussed further below, our receivable securitization program bore interest based on one-month LIBOR plus a margin of 0.90% and had a capacity of $250.0 million. As of June 28, 2019, we had $495.0 million available under 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 six months ended June 28, 2019 was $565.7 million, inclusive of debt repurchases of total principal amount of $419.2 million, voluntary prepayments of $25.0 million and $175.0 million on our outstanding term loans due September 2024 and February 2025, respectively. In making these 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.

As of June 28, 2019, we were, and expect to remain, in full compliance with the provisions and covenants associated with our debt agreements.

On July 11, 2019, we borrowed an additional $400.0 million on our revolving credit facility, bringing total outstanding borrowings to $805.0 million for this instrument as of the date of this report, with $95.0 million of remaining availability. The proceeds from this draw will be used to continue to execute on a capital allocation strategy focused primarily on debt reduction, as well as general business needs. The additional liquidity better positions the Company to continue to redeem higher cost or discounted debt and accelerate progress toward its stated deleveraging goals.

On July 19, 2019, we repaid $200.0 million of outstanding obligations under our variable-rate receivable securitization, thus automatically terminating this facility.

Subsequent to June 28, 2019 and up through the date of this filing, we repurchased fixed-rate debt that aggregated to a principal amount of $70.9 million, which resulted in a gain on repurchase of $18.0 million.

Commitments and Contingencies

Legal Proceedings

See Note 14 of the notes to the unaudited condensed consolidated financial statements for a description of the legal proceedings and claims as of June 28, 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 13 of the notes to the unaudited condensed consolidated financial statements.

Off-Balance Sheet Arrangements

As of June 28, 2019, we had various letters of credit, guarantees and surety bonds totaling $36.2 million. There has been no change in our off-balance sheet arrangements during the six months ended June 28, 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 six months ended June 28, 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 9 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 June 28, 2019, our outstanding debt included $1,929.3 million variable-rate debt on our senior secured term loans, $405.0 million outstanding borrowings on our senior unsecured revolving credit facility and $200.0 million variable-rate debt on our receivables securitization program. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, quarterly interest expense would increase by approximately $6.3 million.

The remaining outstanding debt as of June 28, 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 June 28, 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 $0.2 million aggregate potential as of June 28, 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 June 28, 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 $14.6 million as of June 28, 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 June 28, 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 June 28, 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 August 6, 2019, the cases we are aware of include, but are not limited to, approximately 2,153 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 140 cases filed by hospitals, health systems,

unions, health and welfare funds or other third-party payers; approximately 103 cases filed by individuals and 10 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Hawaii, Nevada and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. Certain of the lawsuits have been filed as putative class actions.

Federal Lawsuits

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. 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. The parties are in the process of briefing the summary judgment and Daubert motions and anticipate that all briefs will be submitted by the end of August 2019.

We are also named in 235 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) Native American Tribes. 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.

State Court Lawsuits

A. Lawsuits Filed by State Attorneys General

Nine 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 Nevada Attorney General filed the most recent attorney general lawsuit against us on June 17, 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 have until August 30, 2019 to reply. 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 scheduled to begin on March 2, 2020.

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

There are currently more than 198 lawsuits against us filed by cities, counties, and other municipalities, pending in various state courts in 21 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 May 16, 2018, Clark County filed an amended complaint in the Eighth Judicial District Court of Nevada and named us as a defendant, among other opioid manufacturers, distributors, and pharmacies. The amended complaint alleges violations of statutory public nuisance, common law public nuisance, negligent misrepresentation, negligence, and unjust enrichment. Clark County seeks damages including but not limited to compensatory and punitive damages, general damages, special damages, a fund for establishing a medical monitoring program, restitution and reimbursement, and attorneys' fees and costs. Defendants filed motions to dismiss on October 19, 2018, which were denied on March 19, 2019. On June 4, 2019, the court denied defendants' motion for partial reconsideration concerning their motions to dismiss. Several defendants, including us, have petitioned the Nevada Supreme Court for a writ of mandamus to dismiss the case, as well as a stay of proceedings pending resolution of that petition. While the Clark County 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 Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas and West Virginia, certain of the 198 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 Massachusetts on June 13, 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 49 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 16 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 tentatively scheduled to occur in October 2020 and January 2021. We are currently named in four out of the eight selected bellwether counties but plaintiffs may amend their complaints to add us to the other four cases. 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 scheduled to begin on March 2, 2020.

C. Lawsuits Filed by District Attorneys General

Three District Attorneys General ("DAGs") have also filed lawsuits in state court against us. In general, they 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 DAGs have initiated lawsuits against opioid manufacturers, distributors, prescribers, retailers, and other individuals. The DAGs 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. *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. *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 are due on September 30, 2019. Replies are due on October 30, 2019, and oral argument is scheduled for December 16, 2019. 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 three such lawsuits. The first lawsuit that remains in state court was filed by various hospitals and other health systems in West Virginia on April 29, 2019. The second lawsuit that remains in state court was filed by various hospitals and other health systems in Arizona on June 18, 2019. The third lawsuit that remains in state court was filed by various hospitals and other health systems in Tennessee on July 12, 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 April 29, 2019, various hospitals and other health systems in West Virginia filed a complaint in the Circuit Court of Marshall County, West Virginia against us, among other opioid manufacturers, distributors, pharmacies and individuals. A first amended complaint was filed on June 7, 2019, which asserts claims for negligence, nuisance, unjust enrichment, fraud and deceit, violation of Kentucky's Consumer Protection Act, civil conspiracy, fraudulent concealment and negligent and intentional diversion and distribution against an individual defendant. The plaintiffs seek judgment against defendants, jointly and severely, and they also seek damages and costs. This case will likely be transferred to West Virginia's Mass Litigation Panel. While the West Virginia 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. The lawsuits also name different defendants: the Arizona plaintiff names manufacturers, distributors and pharmacies as defendants, while the West Virginia and Tennessee 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 nine 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 Tina Batts in the 22nd Judicial Circuit Court, City of St. Louis, Missouri, on July 29, 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 five 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 name manufacturers, while others also include individuals as defendants. 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 six such lawsuits. The first lawsuit that remains in state court was filed by UFCW, Local 23 and Employers Health Fund in Pennsylvania on April 24, 2018. The most recent lawsuit that remains in state court, the Illinois Public Risk Fund, was filed on May 10, 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 four cases are in Pennsylvania state court and have been consolidated in the coordinated proceedings in Delaware County, Pennsylvania. The Pennsylvania complaints assert state law claims for 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. Defendants' joint preliminary objections await rulings 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

Seven Native American tribes have also filed lawsuits in state court against us that remain in state court. All seven cases were filed in state courts in Oklahoma. The first lawsuit that remains in state court was filed by Citizen Potawatomi Nation on July 15, 2019. The most recent lawsuits that remain in state court were filed by the Thlopthlocco Indian Tribal Town and Pawnee Nation of Oklahoma on July 30, 2019. In general, the Native American tribes allege 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. All seven complaints assert claims for public nuisance, actual and constructive fraud, negligence and negligent misrepresentation, civil conspiracy and unjust enrichment. Plaintiffs in all seven cases seek 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 any of the seven complaints.

We intend to vigorously defend ourselves against all of these lawsuits as detailed above and similar lawsuits that may be brought by others. Since these lawsuits are in early stages, we are unable to predict outcomes or estimate a range of reasonably possible losses.

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 U.S. Department of Justice 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. 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 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.

DEA Investigation

In November 2011 and October 2012, we received subpoenas from the 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 will cooperate with the investigation, which is expected to continue and may ultimately result in a congressional hearing in the second half of 2019.

See Note 14 of the notes to the unaudited condensed consolidated financial statements for further description of the litigation, legal and administrative proceedings as of June 28, 2019.

Item 1A. Risk Factors.

There have been no material changes to the risk factors previously disclosed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 28, 2018, filed with the SEC on February 26, 2019.

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 June 28, 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)
March 30, 2019 to April 26, 2019	32,151	$ 22.80	—	$ 564.2
April 27, 2019 to May 31, 2019	80,759	15.21	—	564.2
June 1, 2019 to June 28, 2019	2,492	9.06	—	564.2
March 30, 2019 to June 28, 2019	**115,402**	**17.19**		

Item 6. Exhibits.

Exhibit Number	Exhibit
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 June 28, 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.

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 PUBLIC LIMITED COMPANY

By: /s/ Bryan M. Reasons

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

Date: August 6, 2019

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: August 6, 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: August 6, 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 June 28, 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)

August 6, 2019

By: /s/ Bryan M. Reasons

Bryan M. Reasons

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

August 6, 2019