

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

---

**FORM 10-Q**

---

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

For the quarterly period ended September 28, 2018  
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**  
(State or other jurisdiction of  
incorporation or organization)

**98-1088325**  
(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)

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 - 83,313,240 shares as of November 2, 2018

---

**MALLINCKRODT PLC  
INDEX**

	<b>Page</b>	
<b><u>PART I.</u></b>	<b><u>FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	<u>Financial Statements (Unaudited).</u>	
	<u>Condensed Consolidated Statements of Income for the three and nine months ended September 28, 2018 and September 29, 2017.</u>	<u>2</u>
	<u>Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 28, 2018 and September 29, 2017.</u>	<u>3</u>
	<u>Condensed Consolidated Balance Sheets as of September 28, 2018 and December 29, 2017.</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 28, 2018 and September 29, 2017.</u>	<u>5</u>
	<u>Condensed Consolidated Statement of Changes in Shareholders' Equity for the period from December 29, 2017 to September 28, 2018.</u>	<u>6</u>
	<u>Notes to Condensed Consolidated Financial Statements.</u>	<u>7</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	<u>49</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk.</u>	<u>62</u>
<u>Item 4.</u>	<u>Controls and Procedures.</u>	<u>62</u>
<b><u>PART II.</u></b>	<b><u>OTHER INFORMATION</u></b>	
<u>Item 1.</u>	<u>Legal Proceedings.</u>	<u>63</u>
<u>Item 1A.</u>	<u>Risk Factors.</u>	<u>63</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds.</u>	<u>63</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities.</u>	<u>63</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures.</u>	<u>63</u>
<u>Item 5.</u>	<u>Other Information.</u>	<u>64</u>
<u>Item 6.</u>	<u>Exhibits.</u>	<u>65</u>
<b><u>SIGNATURES</u></b>		<b><u>66</u></b>

---

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
<b>Net sales</b>	\$ 640.0	\$ 600.6	\$ 1,844.3	\$ 1,760.7
Cost of sales	326.2	268.0	936.7	808.3
<b>Gross profit</b>	313.8	332.6	907.6	952.4
Selling, general and administrative expenses	164.0	186.3	520.7	618.5
Research and development expenses	78.5	46.9	223.9	144.2
Restructuring charges, net	14.7	15.4	96.5	26.3
Losses (gains) on divestiture	0.6	0.4	0.6	(56.6)
<b>Operating income</b>	56.0	83.6	65.9	220.0
Interest expense	(93.6)	(92.6)	(280.1)	(279.0)
Interest income	2.0	1.3	6.6	2.8
Other income (expense), net	13.4	3.0	17.5	(70.6)
<b>Loss from continuing operations before income taxes</b>	(22.2)	(4.7)	(190.1)	(126.8)
Income tax benefit	(125.2)	(57.8)	(222.0)	(153.4)
<b>Income from continuing operations</b>	103.0	53.1	31.9	26.6
Income from discontinued operations, net of income taxes	10.8	10.6	79.5	499.1
<b>Net income</b>	\$ 113.8	\$ 63.7	\$ 111.4	\$ 525.7
<b>Basic earnings per share (Note 8):</b>				
Income from continuing operations	\$ 1.24	\$ 0.55	\$ 0.38	\$ 0.27
Income from discontinued operations	0.13	0.11	0.94	5.02
Net income	\$ 1.37	\$ 0.66	\$ 1.32	\$ 5.28
Basic weighted-average shares outstanding	83.2	96.7	84.2	99.5
<b>Diluted earnings per share (Note 8):</b>				
Income from continuing operations	\$ 1.21	\$ 0.55	\$ 0.37	\$ 0.27
Income from discontinued operations	0.13	0.11	0.93	5.00
Net income	\$ 1.34	\$ 0.66	\$ 1.31	\$ 5.27
Diluted weighted-average shares outstanding	85.0	97.0	85.2	99.8

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
<b>Net income</b>	\$ 113.8	\$ 63.7	\$ 111.4	\$ 525.7
<b>Other comprehensive income (loss), net of tax:</b>				
Currency translation adjustments	3.2	5.6	(4.1)	13.0
Derivatives, net of \$-, \$-, \$- and \$0.2 tax	0.2	0.3	0.7	0.9
Benefit plans, net of \$-, \$-, \$- and (\$31.4) tax	(0.4)	(0.5)	(0.9)	45.4
Investments, net of \$-, \$-, \$-, and \$- tax	—	(10.5)	—	0.1
<b>Total other comprehensive income (loss), net of tax</b>	<u>3.0</u>	<u>(5.1)</u>	<u>(4.3)</u>	<u>59.4</u>
<b>Comprehensive income</b>	<u>\$ 116.8</u>	<u>\$ 58.6</u>	<u>\$ 107.1</u>	<u>\$ 585.1</u>

See Notes to Condensed Consolidated Financial Statements.

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

	September 28, 2018	December 29, 2017
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 290.7	\$ 1,260.9
Accounts receivable, less allowance for doubtful accounts of \$3.4 and \$2.8	349.6	275.4
Inventories	143.4	128.7
Prepaid expenses and other current assets	117.7	74.7
Notes receivable	—	154.0
Current assets held for sale	1,136.8	391.5
<b>Total current assets</b>	<b>2,038.2</b>	<b>2,285.2</b>
Property, plant and equipment, net	439.3	413.2
Goodwill	3,675.4	3,482.7
Intangible assets, net	8,585.2	8,261.0
Long-term assets held for sale	—	742.7
Other assets	170.5	156.2
<b>Total Assets</b>	<b>\$ 14,908.6</b>	<b>\$ 15,341.0</b>
<b>Liabilities and Shareholders' Equity</b>		
Current Liabilities:		
Current maturities of long-term debt	\$ 16.7	\$ 313.7
Accounts payable	76.6	77.3
Accrued payroll and payroll-related costs	89.0	78.4
Accrued interest	77.0	57.0
Income taxes payable	43.4	15.5
Accrued and other current liabilities	437.5	368.5
Current liabilities held for sale	182.4	140.0
<b>Total current liabilities</b>	<b>922.6</b>	<b>1,050.4</b>
Long-term debt	6,174.0	6,420.9
Pension and postretirement benefits	65.2	67.1
Environmental liabilities	49.8	62.8
Deferred income taxes	668.9	749.1
Other income tax liabilities	127.6	94.1
Long-term liabilities held for sale	—	22.6
Other liabilities	296.9	352.0
<b>Total Liabilities</b>	<b>8,305.0</b>	<b>8,819.0</b>
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; 92,678,152 and 92,196,662 issued; 83,243,748 and 86,336,232 outstanding	18.5	18.4
Ordinary shares held in treasury at cost, 9,434,404 and 5,860,430	(1,618.5)	(1,564.7)
Additional paid-in capital	5,521.3	5,492.6
Retained earnings	2,701.0	2,588.6
Accumulated other comprehensive loss	(18.7)	(12.9)
<b>Total Shareholders' Equity</b>	<b>6,603.6</b>	<b>6,522.0</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 14,908.6</b>	<b>\$ 15,341.0</b>

See Notes to Condensed Consolidated Financial Statements.

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

	Nine Months Ended	
	September 28, 2018	September 29, 2017
<b>Cash Flows From Operating Activities:</b>		
Net income	\$ 111.4	\$ 525.7
Adjustments to reconcile net cash from operating activities:		
Depreciation and amortization	597.0	606.5
Share-based compensation	27.9	46.1
Deferred income taxes	(232.7)	(128.7)
Loss (gain) on divestiture	0.6	(418.1)
Other non-cash items	(3.7)	40.8
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	(59.0)	(34.7)
Inventories	43.1	(18.2)
Accounts payable	(0.1)	(30.2)
Income taxes	16.7	(68.1)
Other	(20.1)	(72.6)
Net cash from operating activities	<u>481.1</u>	<u>448.5</u>
<b>Cash Flows From Investing Activities:</b>		
Capital expenditures	(93.3)	(151.3)
Acquisitions, net of cash	(699.9)	(35.9)
Proceeds from divestitures, net of cash	313.2	576.9
Other	28.8	0.5
Net cash from investing activities	<u>(451.2)</u>	<u>390.2</u>
<b>Cash Flows From Financing Activities:</b>		
Issuance of external debt	657.2	540.0
Repayment of external debt and capital lease obligation	(1,563.4)	(887.5)
Debt financing costs	(12.0)	(12.7)
Proceeds from exercise of share options	1.0	4.0
Repurchase of shares	(57.4)	(437.7)
Other	(24.3)	(18.6)
Net cash from financing activities	<u>(998.9)</u>	<u>(812.5)</u>
Effect of currency rate changes on cash	(0.9)	2.7
<b>Net change in cash, cash equivalents and restricted cash</b>	<u>(969.9)</u>	<u>28.9</u>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<u>1,279.1</u>	<u>361.1</u>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<u>\$ 309.2</u>	<u>\$ 390.0</u>
Cash and cash equivalents at end of period	\$ 290.7	\$ 371.8
Restricted cash included in other assets at end of period	18.5	18.2
<b>Cash, cash equivalents and restricted cash at end of period</b>	<u>\$ 309.2</u>	<u>\$ 390.0</u>

See Notes to Condensed Consolidated Financial Statements.

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

	Ordinary Shares		Treasury Shares		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Number	Par Value	Number	Amount				
<b>Balance at December 29, 2017</b>	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 income	—	—	—	—	—	111.4	—	111.4
Currency translation adjustments	—	—	—	—	—	—	(4.1)	(4.1)
Change in derivatives, net of tax	—	—	—	—	—	—	0.7	0.7
Change in benefit plans, net of tax	—	—	—	—	—	—	(0.9)	(0.9)
Vesting of restricted shares	0.5	0.1	0.1	(2.2)	0.8	—	—	(1.3)
Share-based compensation	—	—	—	—	27.9	—	—	27.9
Reissuance of treasury shares	—	—	(0.2)	3.6	—	(1.6)	—	2.0
Repurchase of shares	—	—	3.6	(55.2)	—	—	—	(55.2)
<b>Balance at September 28, 2018</b>	<u>92.7</u>	<u>\$ 18.5</u>	<u>9.4</u>	<u>\$ (1,618.5)</u>	<u>\$ 5,521.3</u>	<u>\$ 2,701.0</u>	<u>\$ (18.7)</u>	<u>\$ 6,603.6</u>

See Notes to Condensed Consolidated Financial Statements.

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

**1. Background and Basis of Presentation**

***Background***

Mallinckrodt plc and its subsidiaries (collectively, "Mallinckrodt" or "the Company") is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies.

On February 22, 2018, the Company's Board of Directors authorized commencement of a process to dispose of (1) its Specialty Generics business comprised of the previously reported Specialty Generics segment, with the exception of BioVectra, Inc. - a wholly-owned subsidiary of the Company that operates a contract manufacturing business in Canada ("BioVectra"), (2) certain of its non-promoted brands business, which was previously reflected in the Specialty Brands segment; and (3) its ongoing, post-divestiture supply agreement with the acquirer of the contrast media and delivery systems ("CMDS") business, which was previously reflected in the Other non-operating segment (referred to collectively as the "Specialty Generics Disposal Group"). The Company evaluated the criteria prescribed by United States ("U.S.") Generally Accepted Accounting Principles ("GAAP") for recording a disposal group as held for sale and discontinued operations. This criteria was met during the three months ended March 30, 2018, and as a result, prior year balances have been recast to present the financial results of the disposal group as a discontinued operation.

As the Specialty Generics Disposal Group is reported as a discontinued operation, the Company's continuing operations are limited to the results of operations from the Specialty Brands segment. The Specialty Brands segment markets branded pharmaceutical products for autoimmune and rare diseases in the specialty areas of neurology, rheumatology, nephrology, ophthalmology and pulmonology; immunotherapy and neonatal respiratory critical care therapies, analgesics and gastrointestinal products. The Company's diversified, in-line portfolio of both marketed and development products is focused on patients with significant unmet medical needs.

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 U.S. and other jurisdictions. Solely for convenience, the Company only uses the <sup>TM</sup> or <sup>®</sup> 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 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 period ended December 29, 2017 filed with the Securities and Exchange Commission ("SEC") on February 27, 2018.

***Fiscal Year***

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. Unless otherwise indicated, the three and nine months ended September 28, 2018 refers to the thirteen and thirty-nine week periods ended September 28, 2018 and the three and nine months ended September 29, 2017 refers to the thirteen and thirty-nine week periods ended September 29, 2017.



## 2. Recently Issued Accounting Standards

### *Adopted*

The Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2018-05, "Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update)," in March 2018. This update adds SEC paragraphs pursuant to the SEC's Staff Accounting Bulletin ("SAB") 118, which provides guidance on accounting for the tax effects of the Tax Cuts and Jobs Act ("TCJA") that was enacted in December 2017. SAB 118 provides a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete their accounting for the tax effects of the TCJA. The amendments are effective upon addition to the FASB Accounting Standards Codification ("ASC"). The Company adopted this guidance in fiscal 2018. See Note 7 for additional details of the Company's assessment of impact of this adoption.

The FASB issued ASU 2017-09, "Compensation - Stock Compensation: Scope of Modification Accounting," in May 2017. Under the new guidance, the effects of a modification should be accounted for unless all of the following are met: (1) the fair value or calculated intrinsic value of the modified award is the same as the fair value of the original award immediately before the original award is modified; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The Company adopted this standard in fiscal 2018 and will apply this standard to prospective modifications. The adoption of this guidance did not result in any material changes to the unaudited condensed consolidated financial statements.

The FASB issued ASU 2017-07, "Compensation - Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Post Retirement Benefit Cost," in March 2017. This update requires that the service cost component be disaggregated from the other components of net benefit cost. Service cost should be reported in the same line item or items as other compensation costs arising from services rendered by pertinent employees during the period. The other components of net benefit cost should be presented in the income statement separately from the service cost component and outside a subtotal of income from operations, if one is presented. The Company adopted this guidance in fiscal 2018 which required retroactive application resulting in the reclassification of \$72.4 million of other components of net benefit costs to other income (expense), net for the nine months ended September 29, 2017 from selling, general and administrative expenses ("SG&A") of \$70.8 million, cost of sales of \$1.2 million, and research and development expenses ("R&D") of \$0.4 million. The adoption of this guidance did not result in any material changes to the unaudited condensed consolidated financial statements.

The FASB issued ASU 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business," in January 2017. This update provides a screen to determine whether or not a set of assets is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets is not a business. If the screen is not met, the amendments in this update require that (1) to be considered a business, a set of assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The Company adopted this guidance in fiscal 2018, which did not have a material impact to the unaudited condensed consolidated financial statements.

The FASB issued ASU 2016-01, "Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities," in January 2016. This update addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. Under the new guidance, equity investments, other than equity method investments, are to be measured at fair value with changes in fair value recognized through net income. The Company adopted this guidance in fiscal 2018, resulting in a \$1.5 million increase to beginning retained earnings with an offsetting decrease to accumulated other comprehensive loss relating to the unrealized gain on its investment in Mesoblast Limited ("Mesoblast"). The adoption of this standard did not result in any material changes to the unaudited condensed consolidated financial statements.

The FASB issued ASU 2014-09, "Revenue from Contracts with Customers," in May 2014. The issuance of ASU 2014-09 and International Financial Reporting Standards ("IFRS") 15, "Revenue from Contracts with Customers," completes the joint effort by the FASB and the International Accounting Standards Board to clarify the principles for recognizing revenue and develop a common revenue standard for GAAP and IFRS. Under the new guidance, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services, applying the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract(s); (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract(s); and (5) recognize revenue when (or as) the entity satisfies a performance obligation. The FASB subsequently issued additional ASUs to clarify the guidance in ASU 2014-09. The additional ASUs issued include ASU 2016-08, "Revenue from Contracts with Customers;" ASU 2016-10 "Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing;" and ASU 2016-12, "Narrow-Scope Improvements and Practical Expedients."

The Company adopted ASU 2014-09 and its related amendments (collectively known as "ASC 606") effective on December 30, 2017 using the modified retrospective transition approach. The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the delivery of the Company's products and will provide financial statement readers with enhanced disclosures, which have been included in Note 3. The cumulative effect of applying the new standard to contracts not completed at December 30, 2017 was recorded as a \$1.1 million increase, net of tax, to beginning retained earnings. The prior periods were not restated. The adoption of this standard did not result in any material changes to the unaudited condensed consolidated financial statements.

#### ***Not Yet Adopted***

The FASB issued ASU 2018-15, "Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract," in August 2018. This update aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The amendments in this update also require the entity (customer) to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. Upon adoption, the update will be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. This guidance is effective for the Company in the first quarter of fiscal 2020; however, early adoption is permitted. The Company is currently assessing the impact of this guidance on the unaudited condensed consolidated financial statements.

The FASB issued ASU 2016-02, "Leases," in February 2016. This update 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 (as defined under ASU 2016-02). This guidance is effective for the Company in the first quarter of fiscal 2019. The FASB subsequently issued additional ASUs to clarify the guidance in ASU 2016-02. The ASUs include ASU 2018-10, "Codification Improvements to Topic 842, Leases" and ASU 2018-11 "Leases, (Topic 842), Targeted Improvements." The Company currently expects to utilize the additional transition approach as provided under ASU 2018-11, which allows for the initial application of the new leasing standard at the adoption date (day 1 of fiscal 2019) with a cumulative-effect adjustment to the opening balance of retained earnings. The Company has identified its population of lease agreements and is currently assessing other arrangements such as supply and service agreements for embedded leases. Although the Company is in the process of determining the potential impact on its consolidated financial statements, it anticipates that the most significant change will be related to the Company recording additional assets and corresponding liabilities on the balance sheet for operating leases. The ultimate impact of the new standard will depend on the total amount of the Company's lease commitments as of the adoption date.

### **3. Revenue from Contracts with Customers**

#### ***Product Sales Revenue***

The Company sells its products through distributors who resell the products to institutions and end user customers, while certain products are sold and distributed directly to hospitals. The Company also enters into arrangements with indirect customers, such as health care providers and payers, to establish contract pricing for certain products that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products.

#### ***Reserves for variable consideration***

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

The following table reflects activity in the Company's sales reserve accounts, on a continuing operations basis:

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
<b>Balance at December 29, 2017</b>	\$ 60.3	\$ 4.1	\$ 1.1	\$ 65.5
Provisions	221.2	6.6	7.4	235.2
Payments or credits	(205.8)	(5.9)	(7.4)	(219.1)
<b>Balance at September 28, 2018</b>	<u>\$ 75.7</u>	<u>\$ 4.8</u>	<u>\$ 1.1</u>	<u>\$ 81.6</u>

See Note 19 for presentation of the Company's net sales by product family.

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

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

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

	<u>Three Months Ended</u> <u>September 28,</u> <u>2018</u>	<u>Nine Months Ended</u> <u>September 28,</u> <u>2018</u>
Product sales transferred at a point in time	78.9%	77.9%
Product sales transferred over time	21.1%	22.1%

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

The majority of the Company's contracts (as defined under ASC 606) are less than one year; therefore, the related disclosure of the amount of transaction price allocated to the performance obligations that are unsatisfied at period end has been omitted, with the exception of those noted below. The following table includes estimated revenue from certain of the Company's products that are expected to be recognized in the future related to performance obligations that are unsatisfied or partially unsatisfied at September 28, 2018:

Remainder of Fiscal 2018	\$ 71.7
Fiscal 2019	135.3
Fiscal 2020	118.6
Fiscal 2021	23.9
Thereafter	3.2

#### *Costs to obtain a contract*

As the majority of the Company's contracts are short-term in nature, sales commissions are generally expensed when incurred as the amortization period would have been less than one year. These costs are recorded within SG&A expenses. For contracts that extend beyond one year, the incremental expense recognition matches the recognition of related revenue and therefore, no costs to obtain a contract were capitalized upon adoption of ASC 606.

#### *Costs to fulfill a contract*

The Company capitalizes the costs associated with the devices used in the Company's portfolio of drug-device combination products, which are used in satisfaction of future performance obligations. Capital expenditures for these devices represent cash outflows for the Company's cost to produce the asset, which is classified in property, plant and equipment, net on the unaudited condensed consolidated balance sheet and expensed to cost of sales over the useful life of the equipment. As of September 28, 2018, the total net book value of these devices was \$27.6 million. The associated depreciation expense recognized during the nine months ended September 28, 2018 was \$8.5 million.

#### **Product Royalty Revenues**

In relation to the Company's acquisition of Sucampo Pharmaceuticals, Inc. on February 13, 2018, as discussed in further detail in Note 5, it acquired an arrangement under which the Company licenses certain rights to Amitiza® (lubiprostone) ("Amitiza") to a third party in exchange for royalties on net sales of the product. The Company recognizes such royalty revenue as the related sales occur. The associated royalty revenue recognized during the three and nine months ended September 28, 2018 was \$22.5 million and \$52.1 million, respectively.

#### **Contract Balances**

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

Contract liabilities are recorded when cash payments are received in advance of the Company's performance, including amounts which are refundable. Contract liabilities as of September 28, 2018 and December 29, 2017 were as follows:

	September 28, 2018	December 29, 2017
Accrued and other current liabilities	\$ 21.2	\$ 13.9
Other liabilities	14.0	6.3
<b>Contract liabilities</b>	<b>\$ 35.2</b>	<b>\$ 20.2</b>

Revenue recognized during the nine months ended September 28, 2018 from amounts included in contract liabilities at the beginning of the period was approximately \$14.9 million.

#### **4. Discontinued Operations and Divestitures**

##### **Discontinued Operations**

*Specialty Generics Disposal Group:* On February 22, 2018, the Specialty Generics Disposal Group met the criteria for held for sale classification and discontinued operation presentation upon commencement of a process to dispose of the group.

The following table summarizes the financial results of the Specialty Generics Disposal Group presented in the unaudited condensed consolidated statements of income:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
<b>Major line items constituting income from discontinued operations:</b>				
Net sales	\$ 159.9	\$ 193.3	\$ 536.4	\$ 668.6
Cost of sales	107.3	125.3	336.1	384.5
Selling, general and administrative expenses	29.4	19.3	73.8	56.6
Research and development expenses	7.6	12.6	36.8	46.3
Restructuring charges, net	0.1	(1.1)	5.3	5.8
Non-restructuring impairment charges	2.0	—	2.0	—
Other income, net	—	0.6	0.3	4.4
<b>Income from discontinued operations</b>	<b>13.5</b>	<b>37.8</b>	<b>82.7</b>	<b>179.8</b>
Income tax expense	2.3	26.6	18.1	42.6
<b>Income from discontinued operations, net of income taxes</b>	<b>\$ 11.2</b>	<b>\$ 11.2</b>	<b>\$ 64.6</b>	<b>\$ 137.2</b>

The following table summarizes the assets and liabilities of the Specialty Generics Disposal Group that are classified as held for sale on the unaudited condensed consolidated balance sheets:

	September 28, 2018	December 29, 2017
<b>Carrying amounts of major classes of assets included as part of discontinued operations:</b>		
Accounts receivable	\$ 189.0	\$ 170.4
Inventories	205.9	211.7
Property, plant and equipment, net	561.7	553.6
Intangible assets, net	110.3	114.0
Other current and non-current assets	69.9	84.5
<b>Total assets classified as held for sale in the balance sheet</b>	<b>\$ 1,136.8</b>	<b>\$ 1,134.2</b>

	September 28, 2018	December 29, 2017
<b>Carrying amounts of major classes of liabilities included as part of discontinued operations:</b>		
Accounts payable	\$ 39.0	\$ 36.0
Other current and non-current liabilities	143.4	126.6
<b>Total liabilities classified as held for sale in the balance sheet</b>	<b>\$ 182.4</b>	<b>\$ 162.6</b>

The following table summarizes significant cash and non-cash transactions of the Specialty Generics Disposal Group that are included within the unaudited condensed consolidated statements of cash flows for the respective periods:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Depreciation, including accelerated depreciation	\$ 0.6	\$ 15.3	\$ 12.1	\$ 45.7
Amortization	—	3.9	1.7	14.6
Capital expenditures	5.9	11.1	21.7	41.7

All other notes to the unaudited condensed consolidated financial statements that were impacted by this discontinued operation have been reclassified accordingly.

*Nuclear Imaging:* On January 27, 2017, the Company completed the sale of its Nuclear Imaging business to IBA Molecular ("IBAM") for approximately \$690.0 million before tax impacts, including up-front consideration of approximately \$574.0 million, up to \$77.0 million of contingent consideration and the assumption of certain liabilities. The Company recorded a pre-tax gain on the sale

of the Nuclear Imaging business of \$362.8 million during the nine months ended September 29, 2017, which excluded any potential proceeds from the contingent consideration and reflects a charge of \$0.6 million during the three months ended September 29, 2017 primarily as a result of ongoing working capital adjustments associated with the purchase agreement. During the nine months ended September 28, 2018 the Company received a total of \$15.0 million in contingent consideration related to the sale of the Nuclear Imaging business, consisting of a \$6.0 million cash payment and the issuance of \$9.0 million par value non-voting preferred equity certificates. The preferred equity certificates accrue interest at a rate of 10.0% per annum and are redeemable on the retirement date of July 27, 2025, or earlier if elected by the issuer, for cash at a price equal to the par value and any accrued but unpaid interest. The Company recorded tax expense of \$1.5 million associated with the \$6.0 million contingent consideration cash payment. The \$9.0 million in preferred equity certificates is presented as a non-cash investing activity on the unaudited condensed consolidated statement of cash flows. The \$13.5 million of contingent consideration received, net of tax, was recorded as income from discontinued operations.

The following table summarizes the financial results of the Nuclear Imaging business presented in the unaudited condensed consolidated statements of income:

	<u>Three Months Ended</u> <u>September 29,</u> <u>2017</u>	<u>Nine Months Ended</u> <u>September 29,</u> <u>2017</u>
<b>Major line items constituting income from discontinued operations:</b>		
Net sales	\$ —	\$ 31.6
Cost of sales	—	15.6
Selling, general and administrative expenses	—	7.8
Other	—	(0.2)
Income from discontinued operations	—	8.4
(Loss) gain on divestiture of discontinued operations	(0.6)	362.8
<b>(Loss) income from discontinued operations, before income taxes</b>	<b>(0.6)</b>	<b>371.2</b>
Income tax (benefit) expense	(0.1)	5.2
<b>(Loss) income from discontinued operations, net of income taxes</b>	<b>\$ (0.5)</b>	<b>\$ 366.0</b>

During the three months ended September 29, 2017, there was income tax benefit of \$0.1 million associated with the \$0.6 million loss recognized on divestiture. During the nine months ended September 29, 2017, there was income tax expense of \$0.9 million associated with the \$362.8 million gain on divestiture and a \$4.3 million income tax expense associated with the \$8.4 million income from discontinued operations. The tax impact of the gain recognized on divestiture was favorably impacted by a benefit from permanently deductible items.

The Company incurred \$0.3 million of capital expenditures related to the Nuclear Imaging business that are included within the unaudited condensed consolidated statements of cash flows for the nine months ended September 29, 2017.

All other notes to the unaudited condensed consolidated financial statements that were impacted by this discontinued operation have been reclassified accordingly.

### **Divestitures**

*PreveLeak/Recothrom:* On March 16, 2018, the Company completed the sale of a portion of its Hemostasis business, inclusive of its PreveLeak™ Surgical Sealant ("PreveLeak") and RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") products to Baxter International, Inc. ("Baxter") for approximately \$185.0 million, with a base payment of \$153.0 million, inclusive of existing inventory and subject to a closing inventory adjustment, with the remainder in potential future milestones. Baxter assumed other expenses, including contingent liabilities associated with PreveLeak. During the nine months ended September 28, 2018, the Company recorded a pre-tax loss on the sale of \$0.6 million, which excluded any potential proceeds from the attainment of future milestones and reflected a post-sale closing inventory adjustment of \$13.7 million. The financial results of the PreveLeak and Recothrom operations are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations presentation.

As part of the divestiture and calculation of the gain, the Company wrote off intangible assets of \$49.9 million and goodwill of \$51.5 million, from the Specialty Brands segment, ascribed to the PreveLeak and Recothrom operations. The remaining items included in the loss calculation are primarily attributable to inventory transferred, contingent consideration transferred and transaction costs incurred by the Company.

*Intrathecal Therapy:* On March 17, 2017, the Company completed the sale of its Intrathecal Therapy business to Piramal Enterprises Limited's subsidiary in the United Kingdom ("U.K."), Piramal Critical Care ("Piramal"), for approximately \$203.0 million, including fixed consideration of \$171.0 million and contingent consideration of up to \$32.0 million. The \$171.0 million of fixed consideration consisted of \$17.0 million received at closing and a \$154.0 million note receivable that was due one year from the transaction closing date. During the nine months ended September 29, 2017, the Company recorded a pre-tax gain on the sale of the business of \$56.6 million, which excluded any potential proceeds from the contingent consideration and reflects a post-sale adjustment of \$0.4 million during the three months ended September 29, 2017. On February 28, 2018, the Company received \$154.0 million from Piramal for the settlement of the aforementioned note receivable. The financial results of the Intrathecal Therapy business are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations presentation.

As part of the divestiture and calculation of the gain, the Company wrote off intangible assets of \$48.7 million and goodwill of \$49.8 million, from the Specialty Brands segment, ascribed to the Intrathecal Therapy business. The Company is committed to reimburse up to \$7.3 million of product development expenses incurred by Piramal, of which \$3.1 million was included in accrued and other current liabilities on the unaudited condensed consolidated balance sheet as of September 28, 2018. The remaining items included in the gain calculation are attributable to inventory transferred and transaction costs incurred by the Company.

## 5. Acquisitions

### *Sucampo Pharmaceuticals, Inc.*

On February 13, 2018, the Company acquired Sucampo Pharmaceuticals, Inc. ("Sucampo") through the acquisition of all the outstanding common stock of Sucampo. Consideration for the transaction consisted of approximately \$1.2 billion, including the assumption of Sucampo's third-party debt ("the Sucampo Acquisition"). The acquisition was funded through the issuance of \$600.0 million aggregate principal amount of senior secured notes, a \$900.0 million borrowing under the Company's revolving credit facility, as discussed further in Note 12, and cash on hand. Sucampo's commercialized products include Amitiza, a leading global product in the branded constipation market, and Rescula® (unoprostone isopropyl ophthalmic solution) 0.15% ("Rescula"), which is indicated for ocular hypertension and open-angle glaucoma, and marketed solely in Japan. Through this acquisition, the Company acquired VTS-270, a Phase 3 development product for Niemann-Pick Type C, a rare neurodegenerative and ultimately fatal disease that can present at any age. Also acquired was an option to exercise a collaborative agreement with Cancer Prevention Pharmaceuticals ("CPP") associated with the development of CPP-1X/sulindac, a Phase 3 development product for Familial Adenomatous Polyposis ("FAP").

Upon completion of the Sucampo Acquisition, Sucampo's 3.25% convertible senior notes due 2021 ("the Sucampo Notes") became eligible to receive increased consideration in conjunction with a make-whole fundamental change, such that each \$1,000 principal face amount of Sucampo Notes could be converted into \$1,221 in cash. As of September 28, 2018, the issued convertible debt of \$300.0 million had been converted and paid in full by the Company.

### *Fair value allocation*

The following amounts represent the preliminary allocations of the fair value of the identifiable assets acquired and liabilities assumed for the Sucampo Acquisition, including preliminary goodwill, intangible assets and the related deferred tax balances. The Company expects to complete its valuation analysis and finalize deferred tax balances as of the acquisition date no later than twelve months from the date of the acquisition. The changes in the purchase price allocation and preliminary goodwill based on the final valuation may include, but are not limited to, finalization of working capital settlements, the impact of U.S. state tax rates in determining the deferred tax balances and changes in assumptions utilized in the preliminary valuation report.

Cash and cash equivalents	\$ 149.6
Accounts receivable	35.7
Inventory	153.2
Intangible assets	919.5
Goodwill	244.7
Other current and non-current assets	25.9
<b>Total assets acquired</b>	<u>1,528.6</u>
Current liabilities	108.3
Deferred tax liabilities, net (non-current)	170.2
Debt	366.3
Other noncurrent liabilities	36.2
<b>Total liabilities assumed</b>	<u>681.0</u>
<b>Net assets acquired</b>	<u>\$ 847.6</u>

The following is a reconciliation of the total consideration to net assets acquired:

Total consideration, net of cash	\$ 698.0
Plus: cash assumed in acquisition	149.6
<b>Total consideration/net assets acquired</b>	<u>\$ 847.6</u>

Intangible assets acquired consist of the following:

	Amount	Amortization Period	Discount Rate
Completed technology - Amitiza	\$ 634.0	9 years	14.0%
Completed technology - Rescula	11.0	8 years	14.0%
In-process research and development - VTS-270	274.5	Non-Amortizable	15.0%

The fair value of the completed technology and in-process research and development ("IPR&D") was determined using the income approach, which is a valuation technique that provides an estimate of fair value of the assets based on the market participant expectations of cash flows the asset would generate. The cash flows were discounted commensurate with the level of risk associated with each asset or its projected cash flows. The discount rates were developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in the U.S. Food and Drug Administration ("FDA") approval process and risks associated with commercialization of a new product. Based on the Company's preliminary estimate, the excess of purchase price over net tangible and intangible assets acquired resulted in goodwill, which represents future product development, the assembled workforce, and the tax status of the transaction. The goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Brands segment.

*Financial results* - The amount of net sales and loss included in the Company's results for the periods presented were as follows:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Net sales	\$ 50.7	\$ —	\$ 124.5	\$ —
Operating loss	(32.2)	—	(99.9)	—

The following was included within cost of sales for the periods presented:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Intangible asset amortization	\$ 18.0	\$ —	\$ 45.0	\$ —
Inventory fair value step-up expense	31.0	—	77.5	—

Acquisition-related costs incurred for the acquisition of \$3.2 million were recognized during the nine months ended September 28, 2018.



## Licenses

On April 5, 2018 (the "Exercise Date"), the Company exercised the option under its collaborative agreement with CPP to negotiate terms of an exclusive license to develop and commercialize CPP-1X/sulindac in North America. In addition, the Company provided CPP with a \$10.0 million upfront R&D payment for expenses related to the FAP pivotal trial incurred during the "Negotiation Period," or the period from the Exercise Date through the execution of such license agreement. CPP shall return to the Company any portion of the R&D payment that is not utilized during the Negotiation Period. Of the \$10.0 million upfront payment, \$7.3 million was utilized during the nine months ended September 28, 2018 and recorded as R&D expense within the condensed consolidated statement of income. The remaining \$2.7 million was included in prepaid expenses and other current assets on the unaudited condensed consolidated balance sheet as of September 28, 2018.

On August 4, 2018, the license agreement with CPP was executed and the Company paid \$5.0 million upfront with cash on hand and gained exclusive rights to develop and commercialize the product in North America, if approved. The agreement includes additional payments of up to \$185.0 million dependent on developmental, regulatory and sales milestones, subject to reduction up to \$15.0 million related to amounts provided by the Company in advance of entering into this agreement, and provides for both parties' reimbursement of R&D expenses from future profits. Following the commercialization of the product, CPP and the Company will share profits in accordance with the agreement. The Company will manage the development of the product in North America.

## 6. 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 the Company's cost structure as it continues to transform the business. The 2016 Mallinckrodt Program is expected to include actions across both the Specialty Brands segment and the Specialty Generics Disposal Group, as well as within corporate functions. The 2016 Mallinckrodt Program is substantially complete.

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 2016 and 2018 Mallinckrodt Programs, the Company takes certain restructuring actions to generate synergies from its acquisitions.

Net restructuring and related charges reflected in continuing operations by segment are as follows:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Specialty Brands	\$ 3.2	\$ 14.6	\$ 73.7	\$ 24.1
Corporate	16.4	1.5	27.7	4.3
<b>Restructuring and related charges, net</b>	<b>19.6</b>	<b>16.1</b>	<b>101.4</b>	<b>28.4</b>
Less: accelerated depreciation	(4.9)	(0.7)	(4.9)	(2.1)
<b>Restructuring charges, net</b>	<b>\$ 14.7</b>	<b>\$ 15.4</b>	<b>\$ 96.5</b>	<b>\$ 26.3</b>

Net restructuring and related charges reflected in continuing operations by program are comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
2018 Mallinckrodt Program	\$ 5.2	\$ —	\$ 5.2	\$ —
2016 Mallinckrodt Program	9.7	16.1	65.1	28.4
Acquisition programs	4.7	—	31.1	—
<b>Total</b>	<b>19.6</b>	<b>16.1</b>	<b>101.4</b>	<b>28.4</b>
Less: non-cash charges, including accelerated depreciation and impairments	(4.9)	(0.7)	(4.9)	(2.1)
<b>Total charges expected to be settled in cash</b>	<b>\$ 14.7</b>	<b>\$ 15.4</b>	<b>\$ 96.5</b>	<b>\$ 26.3</b>

The following table summarizes cash activity for restructuring reserves reflected in continuing operations, substantially all of which are related to contract termination costs and employee severance and benefits:

	2018 Mallinckrodt Program	2016 Mallinckrodt Program	Acquisition Programs	Total
<b>Balance at December 29, 2017</b>	\$ —	\$ 14.1	\$ 0.8	\$ 14.9
Charges	2.2	68.4	29.9	100.5
Changes in estimate	—	(3.3)	(0.7)	(4.0)
Cash payments	—	(11.5)	(21.9)	(33.4)
Reclassifications	—	(1.0)	—	(1.0)
Currency translation	—	0.7	—	0.7
<b>Balance at September 28, 2018</b>	<u>\$ 2.2</u>	<u>\$ 67.4</u>	<u>\$ 8.1</u>	<u>\$ 77.7</u>

Total Company net restructuring and related charges, including associated asset impairments, 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	\$ 80.0
Corporate	2.2	26.5
Specialty Generics Disposal Group	—	14.4
	<u>\$ 5.2</u>	<u>\$ 120.9</u>

On January 8, 2018, the Company announced that it would discontinue marketing of Raplix<sup>®</sup> after an evaluation of strategic options. During the nine months ended September 29, 2018, the Company incurred restructuring expenses of \$48.8 million under the 2016 Mallinckrodt Program, consisting primarily of contract termination costs related to the production of Raplix. Amounts paid in the future may differ from the amount currently recorded.

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

## 7. Income Taxes

The Company recognized an income tax benefit of \$125.2 million on a loss from continuing operations before income taxes of \$22.2 million for the three months ended September 28, 2018, and an income tax benefit of \$57.8 million on a loss from continuing operations before income taxes of \$4.7 million for the three months ended September 29, 2017. This resulted in effective tax rates of 564.0% and 1,229.8% for the three months ended September 28, 2018 and September 29, 2017, respectively. The income tax benefit for the three months ended September 28, 2018 is comprised of \$16.1 million of current tax expense and \$141.3 million of deferred tax benefit which is predominantly related to acquired intangible assets and the generation of net operating losses. The income tax benefit for the three months ended September 29, 2017 is comprised of \$81.4 million of current tax benefit and \$23.6 million of deferred tax expense. The net deferred tax expense of \$23.6 million includes \$50.7 million of deferred tax benefit which is predominantly related to acquired intangible assets offset by \$74.3 million of deferred tax expense related to utilization of tax attributes.

The Company recognized an income tax benefit of \$222.0 million on a loss from continuing operations before income taxes of \$190.1 million for the nine months ended September 28, 2018, and an income tax benefit of \$153.4 million on a loss from continuing operations before income taxes of \$126.8 million for the nine months ended September 29, 2017. This resulted in effective tax rates of 116.8% and 121.0% for the nine months ended September 28, 2018 and September 29, 2017, respectively. The income tax benefit for the nine months ended September 28, 2018 is comprised of \$29.2 million of current tax expense and \$251.2 million of deferred tax benefit which is predominantly related to acquired intangible assets and the generation of net operating losses. The income tax benefit for the nine months ended September 29, 2017 is comprised of \$13.6 million of current tax benefit and \$139.8 million of deferred tax benefit. The net deferred tax benefit of \$139.8 million includes \$241.3 million of deferred tax benefit, which is predominantly related to acquired intangible assets offset by \$101.5 million of deferred tax expense related to utilization of tax attributes.

The income tax benefit was \$125.2 million for the three months ended September 28, 2018, compared with a tax benefit of \$57.8 million for the three months ended September 29, 2017. The \$67.4 million net increase in the tax benefit includes an increase of \$82.3 million attributable to the tax benefit from the reorganization of the Company's intercompany financing and associated legal entity

ownership which occurred during the three months ended September 28, 2018, an increase of \$17.3 million attributable to tax expense from a reorganization of legal entity ownership which occurred during the three months ended September 29, 2017, an increase of \$9.1 million attributable to the tax benefit from an adjustment to the provisional estimate of the remeasurement of its net U.S. deferred tax liabilities resulting from U.S. Tax Reform, and an increase in tax benefit of \$3.7 million attributable to the impact of acquisitions occurring since September 29, 2017; partially offset by a decrease to tax benefit of \$36.7 million attributable to the reduction in the U.S. federal corporate statutory rate resulting from U.S. Tax Reform, and a decrease in tax benefit of \$8.3 million attributable to changes in the amount and jurisdictional mix of operating income.

The income tax benefit was \$222.0 million for the nine months ended September 28, 2018, compared with a tax benefit of \$153.4 million for the nine months ended September 29, 2017. The \$68.6 million net increase in the tax benefit includes an increase of \$82.3 million attributable to the tax benefit from reorganization of the Company's intercompany financing and associated legal entity ownership which occurred during the nine months ended September 28, 2018, an increase of \$27.1 million attributable to tax expense from the impact of dispositions predominately occurring during the nine months ended September 29, 2017, an increase of \$17.3 million attributable to tax expense from a reorganization of legal entity ownership which occurred during the nine months ended September 29, 2017, an increase in tax benefit of \$11.8 million attributable to the impact of acquisitions occurring since September 29, 2017, an increase of \$9.1 million attributable to the tax benefit from an adjustment to the provisional estimate of the remeasurement of its net U.S. deferred tax liabilities resulting from U.S. Tax Reform, and an increase in tax benefit of \$9.1 million attributable to changes in the amount and jurisdictional mix of operating income; partially offset by a decrease to tax benefit of \$70.0 million attributable to the reduction in the U.S. federal corporate statutory rate from U.S. Tax Reform, and a decrease of \$18.1 million attributable to tax benefit from the termination of the defined benefit pension plans which occurred during the nine months ended September 29, 2017.

During the three months ended September 28, 2018, the Company initiated a reorganization of its intercompany financing and associated legal entity ownership in response to the changing global tax environment. As a result, the Company recognized current income tax expense of \$1.0 million and a deferred income tax benefit of \$83.3 million with a corresponding reduction to net deferred tax liabilities. The reduction in net deferred tax liabilities is comprised of a \$67.0 million increase in deferred tax assets associated with tax loss and credit carryforwards, a \$58.9 million increase in deferred tax liabilities associated with its investment in partnership, a \$58.9 million decrease in deferred tax liabilities predominately associated with intangible assets and a \$16.3 million decrease related to a change in valuation allowances as a result of the utilization of tax loss and credit carryforwards.

During the nine months ended September 28, 2018, and the fiscal year ended December 29, 2017, the net cash payments for income taxes were \$12.5 million and \$73.4 million, respectively.

The Sucampo Acquisition resulted in a net deferred tax liability increase of \$170.2 million. Significant components of this increase include \$179.3 million of deferred tax liabilities associated with intangible assets and a \$24.1 million deferred tax liability associated with inventories. The increase in deferred tax liabilities is partially offset by \$29.4 million of deferred tax assets associated with tax loss and credit carryforwards, and various other net deferred tax assets of \$3.8 million.

The sale of a portion of the Hemostasis business, inclusive of the PreveLeak and Recothrom products, was completed on March 16, 2018. This divestiture resulted in a net deferred tax liability decrease of \$3.0 million. A significant component of this decrease includes a decrease of \$3.0 million of deferred tax liability associated with inventories. In addition, there was a decrease of \$1.5 million associated with other deferred tax assets, a decrease of \$2.4 million of deferred tax asset associated with tax loss and credit carryforwards, and a decrease of \$4.2 million of deferred tax asset associated with intangible assets, all of which were offset by a reduction in valuation allowance of \$8.1 million.

The Company's unrecognized tax benefits, excluding interest, totaled \$192.3 million at September 28, 2018 and \$182.5 million at December 29, 2017. The net increase of \$9.8 million primarily resulted from a net increase from prior period tax positions, predominately from acquired companies of \$16.6 million, a net decrease from settlements of \$2.0 million, and a net decrease from lapse of statute of limitations of \$4.8 million. If favorably settled, \$179.5 million of unrecognized tax benefits at September 28, 2018 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 related to these obligations was \$18.0 million at September 28, 2018 and \$7.1 million at December 29, 2017.

It is reasonably possible that within the next twelve months, as a result of the resolution of various U.K. and non-U.K. examinations, appeals and litigation and the expiration of various statutes of limitation, that the unrecognized tax benefits will decrease by up to \$34.2 million and the amount of related interest and penalties will decrease by up to \$5.7 million.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the TCJA. The TCJA reduces the U.S. federal corporate statutory rate from 35% to 21%, requires companies to pay a one-time transition tax on certain undistributed earnings of the Company's foreign subsidiaries of U.S. entities and creates new taxes on certain foreign sourced earnings. The Company is applying the guidance in SAB 118 when accounting for the enactment-date effects of the TCJA. At September 28, 2018, the Company has not completed its accounting for all of the tax effects of the TCJA. As discussed below, the Company has recorded provisional estimates for certain provisions where the accounting is incomplete but a reasonable estimate can be made. In other cases, the Company continues to evaluate certain portions of the TCJA and the application of ASC 740 and no adjustments have been made in the unaudited condensed consolidated financial statements. In all cases, the Company will continue to

make and refine its calculations as additional analysis is completed. These estimates may also be affected as the Company gains a more thorough understanding of the tax law.

During fiscal 2017 the Company recorded a deferred tax benefit of \$444.8 million for the provisional estimate of the remeasurement of its net U.S. deferred tax liabilities for the reduction in the U.S. federal corporate statutory tax rate to 21%. The provisional estimate was affected by other analyses related to the TCJA, including, but not limited to, having a U.S. tax return year that straddles the effective date of the statutory rate change and that is different than the Company's financial statement year. During the three and nine months ended September 28, 2018, on the basis of additional analysis related to certain tax calculations, the Company recognized an additional deferred tax benefit of \$9.1 million, impacting the effective tax rate by 41.0 and 4.8 percentage points, respectively.

The one-time transition tax under the TCJA is based upon the amount of post-1986 cumulative undistributed earnings of certain of the Company's subsidiaries which was deferred from U.S. income tax under previous U.S. law. In fiscal 2017, the Company estimated this item would not result in any current or future tax. For the nine months ended September 28, 2018, no adjustments related to this provisional estimate have been made. While the Company is able to make a reasonable estimate of the impact of the one-time transition tax, additional information will continue to be gathered to finalize this conclusion.

Because of the complexity and uncertainties of the new global intangible low-taxed income rules, the Company continues to evaluate this portion of the TCJA and the application of ASC 740. Under GAAP, the Company is allowed to make an accounting policy choice of either (1) treating taxes due on future U.S. inclusions in taxable income related to global intangible low-taxed income as a current-period expense when incurred or (2) factoring such amounts into a company's measurement of its deferred taxes. The Company's selection of an accounting policy with respect to these new tax rules will depend on whether it expects to have future U.S. inclusions in taxable income related to global intangible low-taxed income and, if so, what the tax impact is expected to be. Whether the Company expects to have future U.S. inclusions in taxable income depends on not only the Company's current structure and estimated future results of global operations but also its intent and ability to modify its structure and/or business. While the Company estimates these rules will not have a material tax impact, it is not yet able to finalize the effect of this portion of the TCJA. Therefore, the Company has not made any adjustments related to this item in its unaudited condensed consolidated financial statements and has not made a policy decision regarding whether to record deferred taxes on global intangible low-taxed income.

## 8. Earnings per Share

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

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Basic	83.2	96.7	84.2	99.5
Dilutive impact of restricted share units and share options	1.8	0.3	1.0	0.3
Diluted	85.0	97.0	85.2	99.8

The computation of diluted weighted-average shares outstanding for both the three and nine months ended September 28, 2018 excludes approximately 3.4 million shares of equity awards because the effect would have been anti-dilutive. The computation of diluted weighted-average shares outstanding for the three and nine months ended September 29, 2017 excludes approximately 4.3 million and 3.6 million shares of equity awards, respectively, because the effect would have been anti-dilutive.

## 9. Inventories

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

	September 28, 2018	December 29, 2017
Raw materials and supplies	\$ 22.0	\$ 23.7
Work in process	91.3	61.1
Finished goods	30.1	43.9
	<u>\$ 143.4</u>	<u>\$ 128.7</u>

## 10. Property, Plant and Equipment

The gross carrying amount and accumulated depreciation of property, plant and equipment at the end of each period was as follows:

	September 28, 2018	December 29, 2017
Property, plant and equipment, gross	\$ 620.9	\$ 569.7
Less: accumulated depreciation	(181.6)	(156.5)
Property, plant and equipment, net	<u>\$ 439.3</u>	<u>\$ 413.2</u>

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Depreciation expense	\$ 15.1	\$ 12.0	\$ 38.4	\$ 37.8

## 11. Goodwill and Intangible Assets

The gross carrying amount and accumulated impairment of goodwill at the end of each period was as follows:

	September 28, 2018		December 29, 2017	
	Gross Carrying Amount	Accumulated Impairment	Gross Carrying Amount	Accumulated Impairment
Specialty Brands	\$ 3,675.4	\$ —	\$ 3,482.7	\$ —

During the nine months ended September 28, 2018, the gross carrying value of goodwill within the Specialty Brands segment increased by \$192.7 million. The increase was attributable to the Sucampo Acquisition, which yielded \$244.7 million of goodwill, partially offset by \$51.5 million of goodwill ascribed to the sale of a portion of the Company's Hemostasis business, inclusive of the PreveLeak and Recothrom products. The remaining change in goodwill was related to purchase accounting adjustments during the twelve month measurement period for previous acquisitions.

### *Stannsoporfin*

On May 3, 2018, in a joint meeting, the FDA's Gastrointestinal Drugs Advisory Committee and Pediatric Advisory Committee (the "Advisory Committee") recommended that the risk benefit profile of the Company's stannsoporfin IPR&D product does not support approval for the treatment of newborns  $\geq 35$  weeks of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia (severe jaundice).

On August 9, 2018, the Company received a complete response letter from the FDA related to its new drug application ("NDA") for stannsoporfin. In the letter, the FDA provided guidance regarding areas of further evaluation for resubmitting the stannsoporfin NDA for the treatment of newborns  $\geq 35$  weeks of gestational age with indicators of hemolysis who are at risk of developing

hyperbilirubinemia. While the timing of the development program has shifted outward, the Company continues to have conversations with 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 \$113.5 million included within intangible assets, net on the unaudited condensed consolidated balance sheets as of September 28, 2018 and December 29, 2017. Refer to Note 18 for the associated impact on the Company's contingent consideration liability related to stannosporfin.

#### 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 recently 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 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 September 28, 2018.

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 at the end of each period was as follows:

	September 28, 2018		December 29, 2017	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
<b>Amortizable:</b>				
Completed technology	\$ 10,278.4	\$ 2,656.4	\$ 9,693.0	\$ 2,126.1
Customer relationships	28.7	14.0	29.5	12.2
Trademarks	75.3	13.4	75.5	10.8
Other	8.6	8.6	8.6	8.6
<b>Total</b>	<b>\$ 10,391.0</b>	<b>\$ 2,692.4</b>	<b>\$ 9,806.6</b>	<b>\$ 2,157.7</b>
<b>Non-Amortizable:</b>				
Trademarks	\$ 35.0		\$ 35.0	
In-process research and development	851.6		577.1	
<b>Total</b>	<b>\$ 886.6</b>		<b>\$ 612.1</b>	

Intangible asset amortization expense was as follows:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Amortization expense	\$ 184.2	\$ 169.3	\$ 544.8	\$ 508.4

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

Remainder of Fiscal 2018	\$ 184.2
Fiscal 2019	737.2
Fiscal 2020	736.9
Fiscal 2021	736.6
Fiscal 2022	609.6

## 12. Debt

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

	September 28, 2018		December 29, 2017	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
<b>Current maturities of long-term debt:</b>				
3.50% notes due April 2018	\$ —	\$ —	\$ 300.0	\$ 0.2
Term loan due September 2024	12.3	0.2	14.0	0.3
Term loan due February 2025	4.5	0.1	—	—
ACOA <sup>(1)</sup> loan due December 2028	0.2	—	—	—
Capital lease obligation and vendor financing agreements	—	—	0.2	—
<b>Total current debt</b>	<b>17.0</b>	<b>0.3</b>	<b>314.2</b>	<b>0.5</b>
<b>Long-term debt:</b>				
4.875% notes due April 2020	700.0	3.8	700.0	5.7
Variable-rate receivable securitization due July 2020	225.0	0.5	200.0	0.7
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% notes due August 2022	884.0	8.0	884.0	9.5
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% notes due April 2023	500.2	3.7	526.5	4.5
5.625% notes due October 2023	731.4	8.4	738.0	9.7
Term loan due September 2024	1,601.5	20.7	1,837.2	26.7
Term loan due February 2025	592.5	11.1	—	—
5.50% notes due April 2025	692.1	8.0	692.1	9.0
ACOA loan due December 2028	1.6	—	—	—
Revolving credit facility	300.0	4.9	900.0	5.9
<b>Total long-term debt</b>	<b>6,243.1</b>	<b>69.1</b>	<b>6,492.6</b>	<b>71.7</b>
<b>Total debt</b>	<b>\$ 6,260.1</b>	<b>\$ 69.4</b>	<b>\$ 6,806.8</b>	<b>\$ 72.2</b>

(1) Atlantic Canada Opportunities Agency ("ACOA")

In April 2018, \$300.0 million of the Company's 3.50% unsecured, fixed-rate notes matured and were repaid with cash on hand.

In March 2018, BioVectra entered into an agreement with the ACOA to obtain an interest-free loan of up to \$5.0 million Canadian Dollars ("CAD") in exchange for specified investments in Canada. The loan is repayable in equal monthly installments over 10 years starting in January 2019. The Company has the option of prepaying this loan without any penalties. As of September 28, 2018, the outstanding principal under this agreement was approximately \$1.8 million.

In February 2018, in conjunction with the Sucampo Acquisition, Mallinckrodt International Finance S.A. ("MIFSA") and Mallinckrodt CB LLC ("MCB") issued a \$600.0 million senior secured term loan. The variable-rate loan bears an interest rate of LIBOR plus 300 basis points and was issued with a discount of 25 basis points. The incremental term loan requires quarterly principal amortization payments in an amount equal to 1.00% of the original principal balance of the incremental term loan, and may be reduced by making optional prepayments. The quarterly principal amortization is payable on the last day of each calendar quarter, which commenced on June 30, 2018, with the remaining principal balance due on February 24, 2025. The incremental term loan matures on February 24, 2025 under terms generally consistent with the term loan due September 2024.

In January 2018, the Company made a \$225.0 million prepayment on its term loan due September 2024. In making this payment, the Company 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 September 28, 2018, 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	5.14%	\$ 1,613.8
Term loan due February 2025	5.52%	597.0
Variable-rate receivable securitization	3.16%	225.0
Revolving credit facility	4.64%	300.0

As of September 28, 2018, 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 29, 2017.

### 13. Retirement Plans

The net periodic benefit (credit) cost for the Company's defined benefit pension plans was as follows:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Service cost	\$ 0.1	\$ —	\$ 0.2	\$ 1.3
Interest cost	0.2	0.1	0.5	1.7
Expected return on plan assets	—	—	—	(0.8)
Amortization of net actuarial loss	0.1	—	0.4	1.8
Amortization of prior service cost	—	—	0.1	0.2
Plan settlements	(3.4)	—	(3.4)	69.7
Net periodic benefit (credit) cost	<u>\$ (3.0)</u>	<u>\$ 0.1</u>	<u>\$ (2.2)</u>	<u>\$ 73.9</u>

The net periodic benefit credit for the Company's postretirement benefit plans was approximately \$0.1 million and zero for the three months ended September 28, 2018 and September 29, 2017, respectively, and \$1.1 million and zero for the nine months ended September 28, 2018 and September 29, 2017, respectively.

Of the net periodic benefit (credit) cost for the Company's defined benefit pension plans and postretirement benefit plans, only service costs are included within other employee compensation costs recorded within cost of sales, R&D, and SG&A expenses, while all other components of the net periodic benefit costs are included within other income and expense on the unaudited condensed consolidated statements of income.

#### *Pension Plan Termination*

During the nine months ended September 29, 2017, the Company completed the third-party settlement of the remaining obligations of six defined benefit pension plans that were terminated during fiscal 2016. In conjunction with this final settlement, the Company made a \$61.3 million cash contribution to the terminated plans and recognized a \$69.7 million charge, recorded as other income (expense), net within the unaudited condensed consolidated statement of income. During the three months ended September 28, 2018, the Company received a refund of \$3.4 million of the initial cash contribution, recorded as other income (expense), net within the unaudited condensed consolidated statement of income.



#### 14. Accumulated Other Comprehensive Loss

The following summarizes the change in accumulated other comprehensive loss for the nine months ended September 28, 2018 and September 29, 2017:

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized Loss on Benefit Plans	Unrecognized Gain on Investment <sup>(1)</sup>	Accumulated Other Comprehensive Loss <sup>(1)</sup>
<b>Balance at December 29, 2017</b>	\$ (8.2)	\$ (4.7)	\$ (1.5)	\$ —	\$ (14.4)
Other comprehensive (loss) income before reclassifications	(4.1)	—	4.3	—	0.2
Amounts reclassified from accumulated other comprehensive loss	—	0.7	(5.2)	—	(4.5)
Net current period other comprehensive (loss) income	(4.1)	0.7	(0.9)	—	(4.3)
<b>Balance at September 28, 2018</b>	<b>\$ (12.3)</b>	<b>\$ (4.0)</b>	<b>\$ (2.4)</b>	<b>\$ —</b>	<b>\$ (18.7)</b>

(1) Upon adoption of ASU 2016-01, a reclassification of \$1.5 million relating to the unrealized gain on investment resulted in an increase to beginning retained earnings with an offsetting decrease to accumulated other comprehensive loss. See Note 2 for additional details.

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized Loss on Benefit Plans	Unrecognized Gain on Investment	Accumulated Other Comprehensive Loss
<b>Balance at December 30, 2016</b>	\$ (19.5)	\$ (5.7)	\$ (47.3)	\$ —	\$ (72.5)
Other comprehensive income before reclassifications	17.7	—	5.6	0.1	23.4
Amounts reclassified from accumulated other comprehensive loss	(4.7)	0.9	39.8	—	36.0
Net current period other comprehensive income	13.0	0.9	45.4	0.1	59.4
<b>Balance at September 29, 2017</b>	<b>\$ (6.5)</b>	<b>\$ (4.8)</b>	<b>\$ (1.9)</b>	<b>\$ 0.1</b>	<b>\$ (13.1)</b>

The following summarizes reclassifications from accumulated other comprehensive loss for the nine months ended September 28, 2018 and September 29, 2017:

	Amount Reclassified from Accumulated Other Comprehensive Loss		Line Item in the Unaudited Condensed Consolidated Statement of Income
	Nine Months Ended		
	September 28, 2018	September 29, 2017	
Currency translation	\$ —	\$ (4.7)	Income from discontinued operations, net of income taxes
Amortization and other of unrealized loss on derivatives	0.7	1.1	Interest expense
Income tax provision	—	(0.2)	Income tax benefit
<b>Net of income taxes</b>	<b>0.7</b>	<b>0.9</b>	
Amortization of pension and post-retirement benefit plans:			
Net actuarial loss	0.4	1.8 <sup>(1)</sup>	
Prior service credit	(1.5)	(1.0) <sup>(1)</sup>	
Divestiture of discontinued operations	—	(3.1)	Income from discontinued operations, net of income taxes
Plan settlements	(4.1)	69.7 <sup>(1)</sup>	
Total before tax	(5.2)	67.4	
Income tax provision	—	(27.6)	Income tax benefit
<b>Net of income taxes</b>	<b>(5.2)</b>	<b>39.8</b>	
<b>Total reclassifications for the period</b>	<b>\$ (4.5)</b>	<b>\$ 36.0</b>	

(1) These accumulated other comprehensive loss components are included in the computation of net periodic benefit cost. See Note 13 for additional details.

## 15. Equity

On March 16, 2016, the Company's Board of Directors authorized a \$350.0 million share repurchase program (the "March 2016 Program"), which was completed during the three months ended March 31, 2017. On March 1, 2017, the Company's Board of Directors authorized an additional \$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.

	March 2017 Repurchase Program		March 2016 Repurchase Program	
	Number of Shares	Amount	Number of Shares	Amount
Authorized repurchase amount		\$ 1,000.0		\$ 350.0
Repurchases:				
Transition Period 2016 <sup>(1)</sup>	—	—	1,501,676	84.0
Fiscal 2017	13,490,448	380.6	5,366,741	266.0
Fiscal 2018	3,610,968	55.2	—	—
Remaining amount available		<u>\$ 564.2</u>		<u>\$ —</u>

<sup>(1)</sup> Represents the period from October 1, 2016 through December 30, 2016. The Company historically reported its results based on a "52-53 week" year ending on the last Friday in September. On May 17, 2016, the Board of Directors of the Company approved a change in the Company's fiscal year end to the last Friday in December from the last Friday in September. The change in fiscal year end became effective for the Company's 2017 fiscal year, which began on December 31, 2016 and ended on December 29, 2017. As a result of the change in fiscal year end, the Company filed a Transition Report on Form 10-Q on February 7, 2017 covering the period from October 1, 2016 through December 30, 2016.

The Company also repurchases shares from employees in order to satisfy employee tax withholding requirements in connection with the vesting of restricted shares and share option exercises.

## 16. 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 their ultimate resolutions will not have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemicals business (formerly known as Mallinckrodt Baker) in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on the Company's unaudited condensed consolidated balance sheets as of September 28, 2018 and December 29, 2017 was \$14.3 million and \$14.9 million, respectively, of which \$11.6 million and \$12.1 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 at September 28, 2018 and December 29, 2017. As of September 28, 2018, 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 \$18.5 million and \$18.3 million remained in restricted cash, included in long-term other assets on the unaudited condensed consolidated balance sheets at September 28, 2018 and December 29, 2017, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 17.

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

As of September 28, 2018, the Company had various other letters of credit, guarantees and surety bonds totaling \$22.5 million.

## 17. Commitments and Contingencies

The Company is subject to various legal proceedings and claims, including patent infringement claims, product liability matters, 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 resolutions are not expected to have a material adverse effect on its financial condition, results of operations and cash flows.

### *Governmental Proceedings*

#### *Opioid Related Matters*

*Multidistrict Litigation.* The Company, along with other opioid manufacturers and often, distributors, has been named in lawsuits brought by various counties, cities, Native American tribes, hospitals, health care clinics, Medicaid managed care organizations, and third-party payers. In general, the lawsuits assert claims of public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") or similar state laws, consumer fraud, deceptive trade practices, insurance fraud, unjust enrichment and other common law claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. These lawsuits were originally filed against, or amended to include, the Company in various U.S. District Courts or in state courts with the state court lawsuits subsequently removed to U.S. District Courts. On December 5, 2017, the Judicial Panel in Multidistrict Litigation ("JPML") issued its order establishing a Multidistrict Litigation ("MDL") in the Northern District of Ohio for opioid litigation cases and transferring those cases to the MDL that were originally filed in U.S. District Courts or removed to U.S. District Courts from state court. There are currently 1,275 lawsuits naming the Company that either are in the MDL or are expected to be transferred to the MDL. The Company intends to vigorously defend itself in these matters.

*State Court Lawsuits.* On July 12, 2018, the Commonwealth of Kentucky, through its Attorney General, filed suit in the Madison County Circuit Court in Kentucky against the Company. The lawsuit asserts violations of the Kentucky Consumer Protection Act, Medicaid Fraud Statute and Assistance Program Fraud Statute, asserts claims of public nuisance, fraud, negligence and unjust enrichment, and seeks relief similar to that sought in other state and federal actions.

On May 15, 2018, the State of Florida, through its Attorney General, filed suit in the Circuit Court of the Sixth Judicial Circuit in and for Pasco County in Florida against certain opioid distributors and manufacturers, including the Company. The lawsuit asserts violations of the Florida Deceptive and Unfair Trade Practices and RICO, asserts claims of public nuisance and negligence and seeks relief similar to that sought in other state and federal actions.

On December 20, 2017, the State of New Mexico, through its Attorney General, amended its lawsuit pending in the First Judicial District Court in the County of Santa Fe against certain opioid distributors and manufacturers, to add the Company. The lawsuit asserts violations of public nuisance laws and the New Mexico Unfair Practices, Medicaid Fraud and Racketeering Acts and seeks relief similar to that sought in other state and federal actions.

In addition, the Company is currently named in 88 lawsuits pending in state courts in Alabama (1), Arkansas (1), Connecticut (2), Florida (2), Georgia (1), Illinois (3), Louisiana (2), Maryland (1), Massachusetts (2), Missouri (1), Nevada (1), New Hampshire (8), New York (16), Oklahoma (1), Pennsylvania (10), Tennessee (3), Texas (12), Utah (7), Virginia (12) and West Virginia (2). These state lawsuits are brought on behalf of cities, counties, towns, third party payers, individuals, and hospitals. The lawsuits assert claims and seek damages similar to those sought in the cases pending before the MDL. The Company intends to vigorously defend itself in these state court matters.

*Investigations.* The Company has also received various subpoenas and requests for information related to the distribution, marketing and sale of the Company's opioid products. On July 26, 2017, the Company received a subpoena from the Department of Justice ("DOJ"), on August 24, 2017, the Company received a Civil Investigative Demand ("CID") from the Missouri Attorney General's Office, on September 22, 2017, the Company received a subpoena from the New Hampshire Attorney General's Office, on January 9, 2018, the Company received a subpoena and CID from the Kentucky Attorney General's Office, on January 16, 2018, the Company received a CID from the Attorney General's Office for the State of Washington, on February 5, 2018, the Company received a subpoena from the Attorney General's Office for the State of Alaska, on May 15, 2018, the Company received a CID from the Attorney General's Office for the State of South Carolina, and on September 25, 2018, the Company received a CID from the Attorney General's Office for Puerto Rico.

In addition, 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 Company's distribution, marketing and sale of its oxymorphone generic products.

The Company is in the process of responding to these subpoenas and CIDs.

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 August 2, 2018, Energy and Commerce Committee leaders in the U.S. House of Representatives sent a letter to the Company requesting information about the Company's efforts to monitor its opioid sales for suspicious orders. The Company is in the process of responding to this letter.

The Company intends to cooperate fully in these investigations.

Since these lawsuits and investigations are in early stages, the Company is unable to predict their outcome or estimate a range of reasonably possible losses.

#### Other Matters

*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 Department of Justice 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.

*SEC Subpoena.* In January 2017, the Company received a subpoena from the SEC for documents related to the Company's public statements, filings and other disclosures regarding H.P. Acthar<sup>®</sup> Gel sales, profits, promotion and pricing. The Company has responded to this subpoena, and in February 2018, the SEC notified the Company that it had concluded its investigation and that no enforcement action was recommended against the Company.

*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 is in the process of responding to this subpoena, and the Company intends to cooperate fully in the investigation.

*Texas Pricing Investigation.* In November 2014, the Company received a CID from the Civil Medicaid Fraud Division of the Texas Attorney General's Office. According to the CID, the Attorney General's office is investigating the possibility of false reporting of information by the Company regarding the prices of certain of its drugs used by Texas Medicaid to establish reimbursement rates for pharmacies that dispensed the Company's drugs to Texas Medicaid recipients. The Company has responded to these requests.

*Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America.* In November 2014, the Company filed a Complaint ("the Complaint") in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States for judicial review of what the Company believes is the FDA's inappropriate and unlawful reclassification of the Company's Methylphenidate HCl Extended-Release tablets USP (CII) ("Methylphenidate ER") in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("Orange Book"). The Company also sought a temporary restraining order ("TRO") directing the FDA to reinstate the Orange Book AB rating for the Company's Methylphenidate ER products. The court denied the Company's motion for a TRO and in July 2015, the court granted the FDA's motion to dismiss with respect to three of the five counts in the Complaint and granted summary judgment in favor of the FDA with respect to the two remaining counts. The Company appealed the court's decision to the U.S. Court of Appeals for the Fourth Circuit. 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 United States Court of Appeals for the Fourth Circuit issued an order placing that litigation in abeyance pending the outcome of the withdrawal proceedings. The Company concurrently submitted to the FDA requests for a hearing in the withdrawal proceeding and for an extension of the deadline for submitting documentation supporting the necessity of a hearing. The FDA granted the Company's initial request to extend the deadline, and on February 21, 2017, the FDA suspended the deadline in order to give the Center for Drug Evaluation and Research ("CDER") an opportunity to complete its production of documents. CDER shared an initial set of documents with the Company in June 2017 and a second set of documents in October 2017. Following the Company's receipt of the October tranche of documents from CDER, the Company presented a supplemental document request to CDER to ensure all of its initial document requests were fulfilled, and on February 13, 2018, CDER provided a final set of documents in response to the Company's requests. 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.

*FTC Investigation.* In June 2014, Questcor Pharmaceuticals, Inc. ("Questcor") received a subpoena and CID from the Federal Trade Commission ("FTC") seeking documentary materials and information regarding the FTC's investigation into whether Questcor's acquisition of certain rights to develop, market, manufacture, distribute, sell and commercialize Synacthen Depot<sup>®</sup> from Novartis AG and Novartis Pharma AG (collectively, "Novartis") violates antitrust laws. Subsequently, California, Maryland, Texas, Washington, New York and Alaska (collectively, "the Investigating States") commenced similar investigations focused on whether the transaction

violates state antitrust laws. On January 17, 2017, the FTC, all Investigating States (except California) ("the Settling States") and the Company entered into an agreement to resolve this matter for a one-time cash payment of \$102.0 million and an agreement to license Synacthen Depot to a third party designated by the FTC for possible development in Infantile Spasms ("IS") and Nephrotic Syndrome ("NS") in the U.S. To facilitate that settlement, a complaint was filed on January 18, 2017, in the U.S. District Court for the District of Columbia. The settlement was approved by the court on January 30, 2017. On July 16, 2017, the Company announced the completion of the U.S. license of both the Synacthen trademark and certain intellectual property associated with Synacthen Depot to West Pharmaceuticals to develop and pursue possible FDA approval of the product in IS and NS. The Company retains the right to develop MNK-1411 (the product formerly described as Synacthen Depot) for all other indications in the U.S. and retains rights to the Synacthen trademark outside the U.S.

*Therakos Investigation.* 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<sup>®</sup> 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 is in the process of responding to these requests.

*DEA Investigation.* In November 2011 and October 2012, the Company received subpoenas from the U.S. Drug Enforcement Administration ("DEA") requesting production of documents relating to its suspicious order monitoring program for controlled substances. The USAO for the Eastern District of Michigan investigated the possibility that the Company failed to report suspicious orders of controlled substances during the period 2006-2011 in violation of the Controlled Substances Act and its related regulations. The USAO for the Northern District of New York and Office of Chief Counsel for the U.S. DEA investigated the possibility that the Company failed to maintain appropriate records and security measures with respect to manufacturing of certain controlled substances at its Hobart, New York facility during the period 2012-2013. In July 2017, the Company entered into a final settlement with the DEA and the USAOs for the Eastern District of Michigan and the Northern District of New York to settle these investigations. As part of the agreement, the Company paid \$35.0 million to resolve all potential claims.

*Questcor DOJ Investigation.* 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 H.P. Acthar Gel. Questcor has also been 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 related to H.P. Acthar Gel. 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 H.P. Acthar Gel. The Company intends to cooperate fully in the investigation.

#### **Patent Litigation**

*Amitiza Patent Litigation: Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc..* In October 2018, Sucampo AG, Sucampo Pharmaceuticals, Inc. and Sucampo Pharma LLC, 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.

*Amitiza Patent Litigation: Teva Pharmaceuticals USA, Inc.* In September 2017, Sucampo AG and Sucampo Pharmaceuticals, Inc., subsidiaries of the Company, and Takeda filed suit in the U.S. District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. ("Teva") alleging that Teva infringed U.S. Patent Nos. 6,414,016, 6,982,283, 7,795,312, 8,026,393, 8,071,613, 8,097,653, 8,338,639, 8,389,542 and 8,748,481 following receipt of an August 2017 notice from Teva concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Amitiza. On June 28, 2018, the parties entered into a settlement agreement under which Teva was granted the non-exclusive right to market a competing lubiprostone product in the U.S. under its ANDA on or after January 1, 2023, or earlier under certain circumstances.

*Amitiza Patent Litigation: Amneal Pharmaceuticals, LLC.* In April 2017, Sucampo AG and Sucampo Pharmaceuticals, Inc., subsidiaries of the Company, and Takeda filed suit in the U.S. District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC ("Amneal") alleging that Amneal infringed U.S. Patent Nos. 6,982,283, 8,026,393, 8,097,653, 8,338,639 and 8,389,542 following receipt of a March 2017 notice from Amneal concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Amitiza. On June 28, 2018, the parties entered into a settlement agreement under which Amneal was granted the non-exclusive right to market a competing lubiprostone product in the U.S. under its ANDA on or after January 1, 2023, or earlier under certain circumstances.

*Amitiza Patent Litigation: Par and DRL.* Settlement and License Agreements were entered into with Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") and Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "DRL") to settle Paragraph IV patent litigation with each of Par and DRL. Under the terms of the Par settlement dated September 30, 2014, Par was granted a non-exclusive license and right to market a competing generic of Amitiza on or after January 1, 2021, or earlier under certain circumstances. Under the terms of the DRL settlement dated September 14, 2016, DRL was granted a non-exclusive license and right to market a competing generic of Amitiza on or after January 1, 2023, or earlier under certain circumstances.

*Inomax Patent Litigation: Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair").* In February 2015, INO Therapeutics LLC and Ikaria, Inc., 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. 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 decision by Praxair to launch at-risk prior to the appellate decision) could result in the launch of a generic version of Inomax 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.

*Inomax Patents: IPR Proceedings.* In February 2015 and March 2015, the U.S. Patent and Trademark Office ("USPTO") issued Notices of Filing Dates Accorded to Petitions for IPR petitions filed by Praxair Distribution, Inc. concerning ten patents covering Inomax (i.e., five patents expiring in 2029 and five patents expiring in 2031).

In July 2015 the USPTO Patent Trial and Appeal Board ("PTAB") issued rulings denying the institution of four of the five IPR petitions challenging the five patents expiring in 2029. The PTAB also issued a ruling in July 2015 that instituted the IPR proceeding in the fifth of this group of patents and the PTAB ruled in July 2016 that one claim of this patent survived review and is valid while the remaining claims were unpatentable. The Company believed the claim held valid by the PTAB describes and encompasses a manner in which Inomax is distributed in conjunction with its approved labeling and that Praxair infringes that claim. Praxair filed an appeal and Mallinckrodt filed a cross-appeal of this decision to the Court of Appeals for the Federal Circuit. Oral argument of that appeal occurred in January 2018. The Federal Circuit decision was issued May 16, 2018 and held all claims unpatentable (invalid).

In March 2016, Praxair Distribution, Inc. submitted additional IPR petitions for the five patents expiring in 2029. The PTAB issued non-appealable rulings in August and September 2016 denying institution of all five of these additional IPR petitions.

In September 2015 the USPTO PTAB issued rulings that instituted the IPR proceedings in each of the second set of five patents that expire in 2031. In September 2016 the PTAB ruled that all claims in the five patents expiring in 2031 are patentable.

*Ofirmev Patent Litigation: Aurobindo Pharma U.S.A., Inc.* In December 2017, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP Unlimited Group, subsidiaries of the Company, and New Pharmatop L.P. ("Pharmatop"), the current owner of the two U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against Aurobindo Pharma U.S.A., Inc. ("Aurobindo") alleging that Aurobindo infringed U.S. Patent No. 6,992,218 ("the '218 patent"), U.S. Patent No. 9,399,012 ("the '012 patent") and U.S. Patent No. 9,610,265 ("the '265 patent") following receipt of a November 2017 notice from Aurobindo concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev®. On May 7, 2018 the parties entered into a settlement agreement under which Aurobindo was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its ANDA on or after December 6, 2020, or earlier under certain circumstances.

*Ofirmev Patent Litigation: B. Braun Medical Inc.* In April 2017, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the then owner of the two U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against B. Braun Medical Inc. ("B. Braun") alleging that B. Braun infringed the '218 patent and the '012 patent following receipt of a February 2017 notice from B. Braun concerning its submission of a New Drug Application ("NDA"), containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On October 3, 2018, the parties entered into a settlement agreement under which B. Braun was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its ANDA on or after December 6, 2020, or earlier under certain circumstances.

*Ofirmev Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc.* In September 2014, Cadence Pharmaceuticals, Inc. ("Cadence") and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the then owner of the two U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against InnoPharma Licensing LLC and InnoPharma, Inc. (both are subsidiaries of Pfizer and collectively "InnoPharma") alleging that InnoPharma infringed U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent"). Separately, on December 1, 2016 Mallinckrodt IP Filed suit in the U.S. District Court for the District of Delaware against InnoPharma alleging that InnoPharma infringed the '012 patent. On May 4, 2017 the parties entered into settlement agreements on both suits under which InnoPharma was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its NDA on or after December 6, 2020, or earlier under certain circumstances.

*Ofirmev Patent Litigation: Agila Specialties Private Limited, Inc. (now Mylan Laboratories Ltd.) and Agila Specialties Inc. (a Mylan Inc. Group), (collectively "Agila").* In December 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed the '222 and the '218 patents. Separately, on December 1, 2016 Mallinckrodt IP filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed the '012 patent. On December 31, 2016, the parties entered into settlement agreements on both suits under which Agila was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its NDA on or after December 6, 2020, or earlier under certain circumstances.

The Company has successfully asserted the '222 and '218 patents and maintained their validity in both litigation and proceedings at the USPTO. 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.

*Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Group, Inc.* In March 2007, the Company filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, "Mutual") after Mutual submitted an ANDA to the FDA seeking to sell a generic version of the Company's 7.5 mg RESTORIL™ sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. In March 2017, the parties entered into a settlement agreement regarding the antitrust and unfair competition counterclaims and the case was dismissed.

*Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland v. Mallinckrodt PLC, Mallinckrodt Inc. and Mallinckrodt LLC.* In January 2018, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland (collectively, "Jazz") filed suit in the U.S. District Court for the District of New Jersey against the Company alleging that the Company infringed U.S. Patent Nos. 7,668,730, 7,765,106, 7,765,107, 7,895,059, 8,457,988, 8,589,182, 8,731,963, 8,772,306, 9,050,302, and 9,486,426 following receipt of a November 2017 notice from the Company concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Xyrem. On June 4, 2018, the parties entered into a settlement agreement under which the Company was granted the non-exclusive right to market a competing sodium oxybate product in the U.S. under its ANDA on or after December 31, 2025, or earlier under certain circumstances.

*Shire Development LLC, Shire LLC and Shire US, Inc. v. SpecGx LLC.* In May 2018, Shire Development LLC, Shire LLC and Shire US, Inc. (collectively "Shire") filed suit in the U.S. District Court for the District of Delaware against the Company alleging that the Company infringed U.S. Patent Nos. 6,913,768, 8,846,100, and 9,173,857 following receipt of an April 2018 notice from the Company concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Mydayis. The Company intends to vigorously defend its position.

### **Commercial and Securities Litigation**

*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. Mallinckrodt intends to vigorously defend itself in this matter.

*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. The case is captioned *MSP Recovery Claims, Series II LLC, et al. v. Mallinckrodt ARD, Inc., et al.* The complaint purports to be brought on behalf of two classes: all Medicare Advantage Organizations and related entities in the U.S. who purchased or provided reimbursement for H.P. Acthar Gel pursuant to (i) Medicare Part C contracts (Class 1) and (ii) Medicare Part D contracts (Class 2) since January 1, 2011, with certain exclusions. The complaint alleges that the Company engaged in anticompetitive, unfair, and deceptive acts to artificially raise and maintain the price of H.P. Acthar Gel. To this end, 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 and reaching anti-competitive agreements with the other defendants by selling H.P. Acthar Gel through an exclusive distribution network. The complaint purports to allege claims under federal and state antitrust laws and state unfair competition and unfair trade practice laws. Pursuant to a motion filed by defendants,

this case has been transferred to the U.S. District Court for the Northern District of Illinois. The Company intends to vigorously defend itself in this matter.

**Putative Class Action Litigation.** 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 H.P. Acthar Gel from August 2007 to the present. The lawsuit alleges that the Company engaged in anticompetitive, unfair, and deceptive acts to artificially raise and maintain the price of H.P. 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 Depot; conspired with UBC and violated anti-racketeering laws by selling H.P. Acthar Gel through an exclusive distributor; and committed fraud on consumers by failing to correctly identify H.P. Acthar Gel's active ingredient on package inserts. The Company intends to vigorously defend itself in this matter.

**Employee Stock Purchase Plan Securities Litigation.** On July 20, 2017, a purported purchaser of Mallinckrodt stock through Mallinckrodt's Employee Stock Purchase Plans ("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 Chief Executive Officer Mark C. Trudeau ("CEO"), its Chief Financial Officer Matthew K. Harbaugh ("CFO"), 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 Securities Litigation.** 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 H.P. 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 H.P. Acthar Gel revenues, and the exposure of H.P. 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 and its CEO and 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 CFO, and Executive Vice President, Hugh O'Neill, as defendants, and containing similar claims, but further alleging misstatements regarding payer reimbursement restrictions for H.P. Acthar Gel. On August 30, 2018, Lead Plaintiff voluntarily dismissed the claims against Mr. O'Neill without prejudice. The Company intends to vigorously defend itself in this matter.

### **Pricing Litigation**

**State of Utah v. Apotex Corp., et al.** The Company, along with several other pharmaceutical companies, was a defendant in this matter which was filed in May 2008, in the Third Judicial Circuit of Salt Lake County, Utah. The State of Utah alleged, generally, that the defendants reported false pricing information in connection with certain drugs that were reimbursable under Utah Medicaid, resulting in overpayment by Utah Medicaid for those drugs, and sought monetary damages and attorneys' fees. The Company believes that it had meritorious defenses to these claims and vigorously defended against them. In December 2015, the parties entered into a



binding settlement agreement, under the terms of which the State of Utah agreed to dismiss the litigation with prejudice and the Company agreed to make a one-time cash payment to the State of Utah within the reserve established for this matter.

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

The Company is involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. The Company concluded that, as of September 28, 2018, it was probable that it would incur remedial costs in the range of \$26.7 million to \$67.3 million. The Company also concluded that, as of September 28, 2018, the best estimate within this range was \$52.2 million, of which \$2.4 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the unaudited condensed consolidated balance sheet at September 28, 2018. 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.

*Coldwater Creek, Saint Louis County, Missouri.* The Company is named as a defendant in numerous tort complaints with numerous plaintiffs pending in the U.S. District Court for the Eastern District of Missouri that were filed in or after February 2012. These cases allege personal injury for alleged exposure to radiological substances, including in Coldwater Creek in Missouri, and in the air. Plaintiffs allegedly lived and/or worked in various locations in Saint Louis County, Missouri, near Coldwater Creek. Radiological residues which may have been present in the creek have previously been remediated by the U.S. Army Corps of Engineers ("USACE"). The USACE continues to study and remediate the creek and surrounding areas. The Company believes that it had meritorious defenses to these complaints and vigorously defended against them. Groups of bellwether plaintiffs have been selected by the court and discovery is ongoing. Upon further evaluation of the Company's potential exposure, this matter is no longer considered material.

*Lower Passaic River, New Jersey.* The Company and approximately 70 other companies originally comprised the Lower Passaic Cooperating Parties Group ("the CPG") and 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 Study Area ("the River"). The Company's potential liability stems from former operations at Lodi and Belleville, New Jersey. In June 2007, the EPA issued a draft Focused Feasibility Study ("FFS") that contained interim remedial options for the lower 8-miles of the River, in addition to a "no action" option. As an interim step related to the 2007 AOC, on June 18, 2012 the CPG voluntarily entered into an AOC with the EPA for remediation actions focused solely at mile 10.9 of the River. The Company's estimated costs related to the RI/FS and focused remediation at mile 10.9, based on interim allocations, are immaterial and have been accrued.

In April 2014, the EPA issued its revised 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. 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. The CPG's RI/FS included alternative remedial actions for the entire 17-mile stretch of the River.

On November 20, 2015, the Company withdrew from the CPG, but remains liable for its obligations under the two above-referenced AOCs, as well as potential future liabilities.

On March 4, 2016, the EPA issued the Record of Decision ("ROD") for the lower 8 miles of the River. The EPA's selected remedy for this stretch of the River was a slight modification of the preferred approach it identified in the revised FFS issued in April 2014. The new discounted, estimated cost was \$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. In exchange for this settlement, the Company received, *inter alia*, a covenant not to sue and contribution protection. 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 suit filed on June 30, 2018, by OCC. OCC seeks cost recovery and contribution for past and future costs in response to releases and threatened releases of hazardous substances into the Lower Passaic River ("the River"). The suit relates to 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. The approximately 120 other companies have formed a group to defend against the claims made in the suit. A motion to dismiss several of the claims has been submitted to the court.

*Mallinckrodt Veterinary, Inc., Millsboro, Delaware.* The Company previously operated a facility in Millsboro, Delaware ("the Millsboro Site") where various animal healthcare products were manufactured. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ("TCE") in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. The Company, and another former owner, have assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The companies have entered into two AOCs with the EPA to perform investigations to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site and to conduct an Engineering Evaluation/Cost Analysis ("EE/CA") to characterize the nature and extent of the contamination. In January 2017, the EPA issued its Action Memorandum regarding the EE/CA. The parties have negotiated a third AOC to implement the removal action. The AOC has been fully executed, with an effective date of August 8, 2017. 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.* The Company is a successor in interest to International Minerals and Chemicals Corporation ("IMC"). Between 1967 and 1982, IMC leased portions of the Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the 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 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 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 alleged contamination of soils and groundwater resulting from historic operations, and has threatened to file a contribution claim against the Company and other parties for recovery of its costs incurred in connection with the RI/FS activities being conducted at the AUS Operable Unit. The Company and other PRPs who received demand letters from General Dynamics have explored settlement alternatives, but have not reached settlement to date. General Dynamics has completed the RI and initiated the FS, and the PRPs have reached an agreement to enter into a non-binding mediation process, which has begun. 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 vigorously defend itself in these matters. When appropriate, the Company settles claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of September 28, 2018, there were approximately 11,600 asbestos-related cases pending against the Company.

The Company estimates pending asbestos claims and 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 resolutions 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.

#### ***Acquisition-Related Litigation***

Several putative class actions were filed by purported holders of Questcor common stock in connection with the Company's acquisition of Questcor in 2014 (*Hansen v. Thompson, et al.*, *Heng v. Questcor Pharmaceuticals, Inc., et al.*, *Buck v. Questcor Pharmaceuticals, Inc., et al.*, *Ellerbeck v. Questcor Pharmaceuticals, Inc., et al.*, *Yokem v. Questcor Pharmaceuticals, Inc., et al.*, *Richter v. Questcor Pharmaceuticals, Inc., et al.*, *Tramantano v. Questcor Pharmaceuticals, Inc., et al.*, *Crippen v. Questcor Pharmaceuticals, Inc., et al.*, *Patel v. Questcor Pharmaceuticals, Inc., et al.*, and *Postow v. Questcor Pharmaceuticals, Inc., et al.*). The actions were consolidated on June 3, 2014. The consolidated complaint named as defendants, and generally alleged that, the directors of Questcor breached their fiduciary duties in connection with the acquisition by, among other things, agreeing to sell Questcor for inadequate consideration and pursuant to an inadequate process. The consolidated complaint also alleged that the Questcor directors breached their fiduciary duties by failing to disclose purportedly material information to shareholders in connection with the merger. The consolidated complaint also alleged, among other things, that the Company aided and abetted the purported breaches of fiduciary duty. The lawsuits sought various forms of relief, including but not limited to, rescission of the transaction, damages and attorneys' fees and costs.

On July 29, 2014, the defendants reached an agreement in principle with the plaintiffs in the consolidated actions, and that agreement was reflected in a Memorandum of Understanding ("MOU"). In connection with the settlement contemplated by the MOU, Questcor agreed to make certain additional disclosures related to the proposed transaction with the Company, which are contained in the Company's Current Report on Form 8-K filed with the SEC on July 30, 2014. Additionally, as part of the settlement and pursuant to the MOU, the Company agreed to forbear from exercising certain rights under the merger agreement with Questcor, as follows: the four business day period referenced in Section 5.3(e) of the merger agreement with Questcor was reduced to three business days. Consistent with the terms of the MOU, the parties entered into a formal stipulation of settlement in February 2015 and re-executed the stipulation of settlement on May 7, 2015 (collectively the "Stipulation of Settlement").

The Stipulation of Settlement was subject to customary conditions, including court approval. On May 8, 2015, the California Court denied plaintiffs' Motion for Preliminary Approval of Settlement. On October 23, 2015, the parties submitted a proposed Stipulation and Order re Dismissal With Prejudice dismissing the action with prejudice as to each of the named plaintiffs and without prejudice as to the remainder of the class and, on October 30, 2015, the California Court entered that Order.

#### ***Interest-bearing Deferred Tax Obligation***

As part of the integration of Questcor, the Company entered into an internal installment sale transaction related to certain H.P. 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 31, 2017, the Company sold its Intrathecal Therapy business with a portion of the consideration from the sale being in the form of a note receivable subject to the installment sale provisions described above. During the three months ended March 30, 2018, the Company received payment on the note receivable and settled all installment sale provisions related to its sale of the Intrathecal Therapy business.

As of September 28, 2018, the Company had an aggregate \$537.9 million of interest-bearing U.S. deferred tax liabilities associated with outstanding installment notes. 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 \$6.4 million and \$17.6 million for the three months ended September 28, 2018 and September 29, 2017, respectively, and \$18.1 million and \$53.9 million for the nine months ended September 28, 2018 and September 29, 2017, respectively.

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 \$56.0 million and \$46.0 million as of September 28, 2018 and December 29, 2017, respectively. The balance of this liability is expected to increase over future periods until such uncertainty is resolved. 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.

## 18. Financial Instruments and Fair Value Measurements

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

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

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

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

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

	September 28, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 35.3	\$ 24.5	\$ 10.8	\$ —
Equity securities	—	—	—	—
Foreign exchange forward and option contracts	—	—	—	—
	<u>\$ 35.3</u>	<u>\$ 24.5</u>	<u>\$ 10.8</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities	\$ 41.7	\$ —	\$ 41.7	\$ —
Contingent consideration and acquired contingent liabilities	167.3	—	—	167.3
Foreign exchange forward and option contracts	0.1	0.1	—	—
	<u>\$ 209.1</u>	<u>\$ 0.1</u>	<u>\$ 41.7</u>	<u>\$ 167.3</u>
	December 29, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 35.4	\$ 24.0	\$ 11.4	\$ —
Equity securities	22.7	22.7	—	—
Foreign exchange forward and option contracts	0.1	0.1	—	—
	<u>\$ 58.2</u>	<u>\$ 46.8</u>	<u>\$ 11.4</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities	\$ 42.7	\$ —	\$ 42.7	\$ —
Contingent consideration and acquired contingent liabilities	246.4	—	—	246.4
Foreign exchange forward and option contracts	0.1	0.1	—	—
	<u>\$ 289.2</u>	<u>\$ 0.1</u>	<u>\$ 42.7</u>	<u>\$ 246.4</u>

*Debt and equity securities held in rabbi trusts.* Debt securities held in rabbi trusts primarily consist of U.S. government and agency securities and corporate bonds. When quoted prices are available in an active market, the investments are classified as level 1. When quoted market prices for a security are not available in an active market, they are classified as level 2. Equity securities held in rabbi trusts primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges.

*Equity securities.* Equity securities consist of shares in Mesoblast Limited, for which quoted prices are available in an active market; therefore, the investment is classified as level 1 and is valued based on quoted market prices reported on a nationally recognized securities exchange. During the nine months ended September 28, 2018, the Company's remaining shares were sold for gross proceeds of \$25.5 million resulting in a \$3.4 million gain being recognized within other income (expense), net within the unaudited condensed consolidated statement of income.

*Foreign exchange forward and option contracts.* Foreign currency option and forward contracts are used to economically manage the foreign exchange exposures of operations outside the U.S. Quoted prices are available in an active market; as such, these derivatives are classified as level 1.

*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 the development product MNK-1411. During the nine months ended September 28, 2018, the Company paid the required annual payment of \$25.0 million related to the license of development product MNK-1411 from Novartis. The fair value of the remaining contingent payments was measured based on the net present value of a probability-weighted assessment. As of September 28, 2018, the total remaining payments under the license agreement shall not exceed \$115.0 million. The Company determined the fair value of the contingent consideration associated with the acquisition of Questcor to be \$86.7 million and \$111.8 million as of September 28, 2018 and December 29, 2017, respectively.

As part of the acquisition of a development program from Stratatech in August 2016, 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 of 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 acquisition of Stratatech to be \$56.9 million and \$53.5 million as of September 28, 2018 and December 29, 2017, respectively.

As part of the acquisition of Ocera in December 2017, the Company provided contingent consideration to the prior shareholders of Ocera in the form of both patient enrollment clinical study milestones for MNK-6105 and MNK-6106 (previously referred to collectively as OCR-002), which represent the intravenous ("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 \$23.7 million and \$22.0 million as of September 28, 2018 and December 29, 2017, respectively.

Prior to September 28, 2018, the Company maintained various contingent consideration and acquired contingent liabilities associated with the acquisitions of three commercial stage topical hemostasis drugs from the Medicines Company ("the Hemostasis Acquisition") and InfaCare Pharmaceutical Corporation ("InfaCare").

As part of the Hemostasis Acquisition in February 2016, the Company provided contingent consideration to The Medicines Company in the form of sales based milestones associated with Raplixa and PreveLeak, and acquired contingent liabilities associated with The Medicines Company's prior acquisitions of the aforementioned products. The Company determined the fair value of the contingent consideration and acquired contingent liabilities based on an option pricing model to be \$7.0 million and \$17.1 million at December 29, 2017, respectively. The Company paid \$12.0 million related to the FDA approval of PreveLeak during the three months ended March 30, 2018. On March 16, 2018, the Company sold a portion of the Hemostasis business, inclusive of the Recothrom and PreveLeak products to Baxter and the remaining contingent consideration liability balance of \$12.1 million was transferred upon sale.

As part of the acquisition of InfaCare in September 2017, the Company provided contingent consideration to the prior shareholders of InfaCare in the form of both regulatory approval milestones for full-term and pre-term neonates for stannosporfin and sales-based milestones associated with stannosporfin. Due to recent developments and discussions with the FDA, as discussed

in further detail in Note 11, the timing of the development program is expected to shift outward. During the three and nine months ended September 28, 2018, the Company recognized a \$7.0 million and \$35.0 million fair value adjustment due to this shift in timing and its impact on the achievement of milestones per the purchase agreement. The fair value of the contingent consideration is zero after the aforementioned adjustments as of September 28, 2018. The fair value of the contingent consideration based on an option pricing model was determined to be \$35.0 million as of December 29, 2017.

Of the total fair value of the contingent consideration of \$167.3 million, \$52.8 million was classified as current and \$114.5 million was classified as non-current in the unaudited condensed consolidated balance sheet as of September 28, 2018. The following table summarizes the fiscal 2018 activity for contingent consideration:

Balance at December 29, 2017	\$	246.4
Disposal of business		(12.1)
Payments		(37.0)
Accretion expense		3.3
Fair value adjustments		(33.3)
Balance at September 28, 2018	\$	<u>167.3</u>

### ***Financial Instruments Not Measured at Fair Value***

The following methods and assumptions were used by the Company in estimating fair values for financial instruments not measured at fair value as of September 28, 2018 and December 29, 2017:

- The carrying amounts of cash and cash equivalents, accounts receivable, notes 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 \$18.5 million and \$18.3 million as of September 28, 2018 and December 29, 2017, (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 the nine months ended September 28, 2018. These securities are classified as held-to-maturity and are carried at amortized cost, which approximates fair value, of \$9.0 million at September 28, 2018 (level 3). 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 \$66.1 million and \$67.0 million at September 28, 2018 and December 29, 2017, 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 (level 1). The Company's 3.50%, 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 ACOA loan is based on the present value of future cash flows under the terms of the agreement (level 3) with future cash flows and interest rates as significant assumptions. The following table presents the carrying values and estimated fair values of the Company's debt, excluding capital leases, as of the end of each period:

	September 28, 2018		December 29, 2017	
	Carrying Value	Fair Value	Carrying Value	Fair Value
<b>Level 1</b>				
3.50% notes due April 2018	\$ —	\$ —	\$ 300.0	\$ 299.1
4.875% notes due April 2020	700.0	694.7	700.0	675.2
Variable-rate receivable securitization due July 2020	225.0	225.0	200.0	200.0
5.75% notes due August 2022	884.0	815.9	884.0	804.8
4.75% notes due April 2023	500.2	427.7	526.5	412.4
5.625% notes due October 2023	731.4	648.6	738.0	628.8
5.50% notes due April 2025	692.1	583.9	692.1	564.5
Revolving credit facility	300.0	300.0	900.0	900.0
<b>Level 2</b>				
9.50% debentures due May 2022	10.4	11.0	10.4	10.9
8.00% debentures due March 2023	4.4	4.5	4.4	4.4
Term loan due September 2024	1,613.8	1,605.5	1,851.2	1,848.7
Term loan due February 2025	597.0	596.8	—	—
<b>Level 3</b>				
ACOA loan due December 2028	1.8	1.8	—	—
<b>Total debt</b>	<b>\$ 6,260.1</b>	<b>\$ 5,915.4</b>	<b>\$ 6,806.6</b>	<b>\$ 6,348.8</b>

### 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 does not typically require collateral from customers. A portion of the Company's accounts receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries' national economies.

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
CuraScript, Inc.	44.9%	55.2%	46.1%	55.7%

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

	September 28, 2018	December 29, 2017
CuraScript, Inc.	30.8%	33.8%

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
H.P. Acthar Gel	45.3%	51.4%	44.8%	51.1%
Inomax	20.8%	20.9%	21.9%	21.6%
Ofirmev	13.6%	12.6%	13.8%	12.8%

## 19. Segment Data

The Company's continuing operations are limited to the results of operations from the Specialty Brands segment as the Specialty Generics Disposal Group is reported as a discontinued operation. See Note 4 for further details on the Specialty Generics Disposal Group. Selected information for the reportable segment is as follows:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
<b>Net sales:</b>				
Specialty Brands	\$ 640.0	\$ 600.6	\$ 1,844.3	\$ 1,760.7
<b>Operating income:</b>				
Specialty Brands	\$ 287.8	\$ 314.8	\$ 794.0	\$ 851.8
Unallocated amounts:				
Corporate and unallocated expenses <sup>(1)</sup>	(28.0)	(45.8)	(81.9)	(95.0)
Intangible asset amortization	(184.2)	(169.3)	(544.8)	(508.4)
Restructuring and related charges, net <sup>(2)</sup>	(19.6)	(16.1)	(101.4)	(28.4)
<b>Operating income</b>	<b>\$ 56.0</b>	<b>\$ 83.6</b>	<b>\$ 65.9</b>	<b>\$ 220.0</b>

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

(2) Includes restructuring-related accelerated depreciation.

Net sales by product family within the Company's reportable segment is as follows:

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
H.P. Acthar Gel	\$ 290.1	\$ 308.7	\$ 827.1	\$ 899.9
Inomax	133.2	125.7	404.0	379.6
Ofirmev	87.1	75.4	254.7	224.5
Therakos	60.0	55.3	174.2	157.7
Amitiza <sup>(1)</sup>	48.2	—	119.2	—
BioVectra	13.9	16.0	35.7	36.4
Other	7.5	19.5	29.4	62.6
<b>Net sales</b>	<b>\$ 640.0</b>	<b>\$ 600.6</b>	<b>\$ 1,844.3</b>	<b>\$ 1,760.7</b>

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

## 20. Condensed Consolidating Financial Statements

MIFSA, an indirectly 100%-owned subsidiary of Mallinckrodt plc, is the borrower under the 3.50% notes due April 2018, which were paid in full in April 2018, and the 4.75% notes due April 2023 (collectively, "the 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 Notes, MIFSA as issuer of the Notes and the other subsidiaries. There are no subsidiary guarantees related to the Notes.

Set forth on the following pages are the condensed consolidating financial statements for the three and nine months ended September 28, 2018 and September 29, 2017, and as of September 28, 2018 and December 29, 2017. Eliminations represent adjustments to eliminate investments in subsidiaries and intercompany balances and transactions between or among Mallinckrodt plc, MIFSA and other subsidiaries. Condensed consolidating financial information for Mallinckrodt plc and MIFSA, on a standalone basis, has been presented using the equity method of accounting for subsidiaries.



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

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Assets</b>					
Current Assets:					
Cash and cash equivalents	\$ 0.3	\$ 151.3	\$ 139.1	\$ —	\$ 290.7
Accounts receivable, net	—	—	349.6	—	349.6
Inventories	—	—	143.4	—	143.4
Prepaid expenses and other current assets	3.3	0.2	114.2	—	117.7
Notes receivable	—	—	—	—	—
Current assets held for sale	—	—	1,136.8	—	1,136.8
Intercompany receivables	192.0	52.2	353.5	(597.7)	—
Total current assets	195.6	203.7	2,236.6	(597.7)	2,038.2
Property, plant and equipment, net	—	—	439.3	—	439.3
Goodwill	—	—	3,675.4	—	3,675.4
Intangible assets, net	—	—	8,585.2	—	8,585.2
Investment in subsidiaries	6,194.4	29,157.0	11,964.2	(47,315.6)	—
Intercompany loans receivable	504.0	—	13,073.8	(13,577.8)	—
Other assets	—	—	170.5	—	170.5
<b>Total Assets</b>	<b>\$ 6,894.0</b>	<b>\$ 29,360.7</b>	<b>\$ 40,145.0</b>	<b>\$ (61,491.1)</b>	<b>\$ 14,908.6</b>
<b>Liabilities and Shareholders' Equity</b>					
Current Liabilities:					
Current maturities of long-term debt	\$ —	\$ 16.5	\$ 0.2	\$ —	\$ 16.7
Accounts payable	0.1	0.1	76.4	—	76.6
Accrued payroll and payroll-related costs	—	—	89.0	—	89.0
Accrued interest	—	76.2	0.8	—	77.0
Income taxes payable	—	—	43.4	—	43.4
Accrued and other current liabilities	1.6	0.4	435.5	—	437.5
Current liabilities held for sale	—	—	182.4	—	182.4
Intercompany payables	288.7	19.4	289.6	(597.7)	—
Total current liabilities	290.4	112.6	1,117.3	(597.7)	922.6
Long-term debt	—	3,698.3	2,475.7	—	6,174.0
Pension and postretirement benefits	—	—	65.2	—	65.2
Environmental liabilities	—	—	49.8	—	49.8
Deferred income taxes	—	—	668.9	—	668.9
Other income tax liabilities	—	—	127.6	—	127.6
Intercompany loans payable	—	13,577.8	—	(13,577.8)	—
Other liabilities	—	7.8	289.1	—	296.9
<b>Total Liabilities</b>	<b>290.4</b>	<b>17,396.5</b>	<b>4,793.6</b>	<b>(14,175.5)</b>	<b>8,305.0</b>
Shareholders' Equity	6,603.6	11,964.2	35,351.4	(47,315.6)	6,603.6
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 6,894.0</b>	<b>\$ 29,360.7</b>	<b>\$ 40,145.0</b>	<b>\$ (61,491.1)</b>	<b>\$ 14,908.6</b>

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING BALANCE SHEET**  
As of December 29, 2017  
*(unaudited, in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Assets</b>					
Current Assets:					
Cash and cash equivalents	\$ 0.7	\$ 908.8	\$ 351.4	\$ —	\$ 1,260.9
Accounts receivable, net	—	—	275.4	—	275.4
Inventories	—	—	128.7	—	128.7
Prepaid expenses and other current assets	1.0	0.2	73.5	—	74.7
Notes receivable	—	—	154.0	—	154.0
Current assets held for sale	—	—	391.5	—	391.5
Intercompany receivables	70.0	173.4	831.4	(1,074.8)	—
Total current assets	71.7	1,082.4	2,205.9	(1,074.8)	2,285.2
Property, plant and equipment, net	—	—	413.2	—	413.2
Goodwill	—	—	3,482.7	—	3,482.7
Intangible assets, net	—	—	8,261.0	—	8,261.0
Long-term assets held for sale	—	—	742.7	—	742.7
Investment in subsidiaries	6,551.6	23,217.8	12,356.2	(42,125.6)	—
Intercompany loans receivable	593.1	—	4,664.8	(5,257.9)	—
Other assets	—	—	156.2	—	156.2
<b>Total Assets</b>	<b>\$ 7,216.4</b>	<b>\$ 24,300.2</b>	<b>\$ 32,282.7</b>	<b>\$ (48,458.3)</b>	<b>\$ 15,341.0</b>
<b>Liabilities and Shareholders' Equity</b>					
Current Liabilities:					
Current maturities of long-term debt	\$ —	\$ 313.5	\$ 0.2	\$ —	\$ 313.7
Accounts payable	0.1	—	77.2	—	77.3
Accrued payroll and payroll-related costs	—	—	78.4	—	78.4
Accrued interest	—	53.0	4.0	—	57.0
Income taxes payable	—	—	15.5	—	15.5
Accrued and other current liabilities	0.8	0.4	367.3	—	368.5
Current liabilities held for sale	—	—	140.0	—	140.0
Intercompany payables	693.5	104.6	276.7	(1,074.8)	—
Total current liabilities	694.4	471.5	959.3	(1,074.8)	1,050.4
Long-term debt	—	6,206.8	214.1	—	6,420.9
Pension and postretirement benefits	—	—	67.1	—	67.1
Environmental liabilities	—	—	62.8	—	62.8
Deferred income taxes	—	—	749.1	—	749.1
Other income tax liabilities	—	—	94.1	—	94.1
Long-term liabilities held for sale	—	—	22.6	—	22.6
Intercompany loans payable	—	5,257.9	—	(5,257.9)	—
Other liabilities	—	7.8	344.2	—	352.0
<b>Total Liabilities</b>	<b>694.4</b>	<b>11,944.0</b>	<b>2,513.3</b>	<b>(6,332.7)</b>	<b>8,819.0</b>
Shareholders' Equity	6,522.0	12,356.2	29,769.4	(42,125.6)	6,522.0
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 7,216.4</b>	<b>\$ 24,300.2</b>	<b>\$ 32,282.7</b>	<b>\$ (48,458.3)</b>	<b>\$ 15,341.0</b>

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

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 640.0	\$ —	\$ 640.0
Cost of sales	0.7	—	325.5	—	326.2
<b>Gross (loss) profit</b>	<b>(0.7)</b>	<b>—</b>	<b>314.5</b>	<b>—</b>	<b>313.8</b>
Selling, general and administrative expenses	12.4	0.1	151.5	—	164.0
Research and development expenses	1.6	—	76.9	—	78.5
Restructuring charges, net	—	—	14.7	—	14.7
Losses on divestiture	—	—	0.6	—	0.6
<b>Operating (loss) income</b>	<b>(14.7)</b>	<b>(0.1)</b>	<b>70.8</b>	<b>—</b>	<b>56.0</b>
Interest expense	(1.6)	(112.0)	(257.4)	277.4	(93.6)
Interest income	2.4	249.6	27.4	(277.4)	2.0
Other income (expense), net	2.3	(156.8)	167.9	—	13.4
Intercompany fees	(3.5)	(0.1)	3.6	—	—
Equity in net income of subsidiaries	127.8	238.9	221.9	(588.6)	—
<b>Income (loss) from continuing operations before income taxes</b>	<b>112.7</b>	<b>219.5</b>	<b>234.2</b>	<b>(588.6)</b>	<b>(22.2)</b>
Income tax benefit	(1.1)	(2.4)	(121.7)	—	(125.2)
<b>Income from continuing operations</b>	<b>113.8</b>	<b>221.9</b>	<b>355.9</b>	<b>(588.6)</b>	<b>103.0</b>
Income from discontinued operations, net of income taxes	—	—	10.8	—	10.8
<b>Net income</b>	<b>113.8</b>	<b>221.9</b>	<b>366.7</b>	<b>(588.6)</b>	<b>113.8</b>
Other comprehensive income, net of tax	3.0	3.0	5.8	(8.8)	3.0
<b>Comprehensive income</b>	<b>\$ 116.8</b>	<b>\$ 224.9</b>	<b>\$ 372.5</b>	<b>\$ (597.4)</b>	<b>\$ 116.8</b>

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME**  
For the three months ended September 29, 2017  
*(unaudited, in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 600.6	\$ —	\$ 600.6
Cost of sales	0.9	—	267.1	—	268.0
<b>Gross (loss) profit</b>	(0.9)	—	333.5	—	332.6
Selling, general and administrative expenses	13.4	0.2	172.7	—	186.3
Research and development expenses	1.8	—	45.1	—	46.9
Restructuring charges, net	—	—	15.4	—	15.4
Losses on divestiture	—	—	0.4	—	0.4
<b>Operating (loss) income</b>	(16.1)	(0.2)	99.9	—	83.6
Interest expense	(3.3)	(90.9)	(19.0)	20.6	(92.6)
Interest income	2.2	0.4	19.3	(20.6)	1.3
Other income (expense), net	1.4	1.7	(0.1)	—	3.0
Intercompany fees	(4.3)	—	4.3	—	—
Equity in net income of subsidiaries	82.4	261.8	174.7	(518.9)	—
<b>Income (loss) from continuing operations before income taxes</b>	62.3	172.8	279.1	(518.9)	(4.7)
Income tax benefit	(1.4)	(2.1)	(54.3)	—	(57.8)
<b>Income from continuing operations</b>	63.7	174.9	333.4	(518.9)	53.1
(Loss) income from discontinued operations, net of income taxes	—	(0.2)	10.8	—	10.6
<b>Net income</b>	63.7	174.7	344.2	(518.9)	63.7
Other comprehensive loss, net of tax	(5.1)	(5.1)	(10.5)	15.6	(5.1)
<b>Comprehensive income</b>	\$ 58.6	\$ 169.6	\$ 333.7	\$ (503.3)	\$ 58.6

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

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 1,844.3	\$ —	\$ 1,844.3
Cost of sales	1.6	—	935.1	—	936.7
<b>Gross (loss) profit</b>	(1.6)	—	909.2	—	907.6
Selling, general and administrative expenses	30.1	0.5	490.1	—	520.7
Research and development expenses	3.8	—	220.1	—	223.9
Restructuring charges, net	—	—	96.5	—	96.5
Losses on divestiture	—	—	0.6	—	0.6
<b>Operating (loss) income</b>	(35.5)	(0.5)	101.9	—	65.9
Interest expense	(6.2)	(323.2)	(272.2)	321.5	(280.1)
Interest income	6.8	251.6	69.7	(321.5)	6.6
Other income (expense), net	9.0	(154.0)	162.5	—	17.5
Intercompany fees	(12.0)	(0.1)	12.1	—	—
Equity in net income of subsidiaries	145.9	647.2	425.4	(1,218.5)	—
<b>Income (loss) from continuing operations before income taxes</b>	108.0	421.0	499.4	(1,218.5)	(190.1)
Income tax benefit	(3.4)	(4.4)	(214.2)	—	(222.0)
<b>Income from continuing operations</b>	111.4	425.4	713.6	(1,218.5)	31.9
Income from discontinued operations, net of income taxes	—	—	79.5	—	79.5
<b>Net income</b>	111.4	425.4	793.1	(1,218.5)	111.4
Other comprehensive loss, net of tax	(4.3)	(4.3)	(9.3)	13.6	(4.3)
<b>Comprehensive income</b>	\$ 107.1	\$ 421.1	\$ 783.8	\$ (1,204.9)	\$ 107.1

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME**  
For the nine months ended September 29, 2017  
*(unaudited, in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 1,760.7	\$ —	\$ 1,760.7
Cost of sales	1.8	—	806.5	—	808.3
<b>Gross (loss) profit</b>	(1.8)	—	954.2	—	952.4
Selling, general and administrative expenses	46.7	0.6	571.2	—	618.5
Research and development expenses	3.6	—	140.6	—	144.2
Restructuring charges, net	—	—	26.3	—	26.3
Gains on divestiture	—	—	(56.6)	—	(56.6)
<b>Operating (loss) income</b>	(52.1)	(0.6)	272.7	—	220.0
Interest expense	(10.0)	(264.9)	(57.9)	53.8	(279.0)
Interest income	5.3	1.0	50.3	(53.8)	2.8
Other income (expense), net	19.0	(1.6)	(88.0)	—	(70.6)
Intercompany fees	(13.3)	—	13.3	—	—
Equity in net income of subsidiaries	572.1	1,113.5	848.1	(2,533.7)	—
<b>Income (loss) from continuing operations before income taxes</b>	521.0	847.4	1,038.5	(2,533.7)	(126.8)
Income tax benefit	(4.7)	(2.6)	(146.1)	—	(153.4)
<b>Income from continuing operations</b>	525.7	850.0	1,184.6	(2,533.7)	26.6
(Loss) income from discontinued operations, net of income taxes	—	(1.9)	501.0	—	499.1
<b>Net income</b>	525.7	848.1	1,685.6	(2,533.7)	525.7
Other comprehensive income, net of tax	59.4	59.4	117.9	(177.3)	59.4
<b>Comprehensive income</b>	\$ 585.1	\$ 907.5	\$ 1,803.5	\$ (2,711.0)	\$ 585.1

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

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

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS**  
For the nine months ended September 29, 2017  
*(unaudited, in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Cash Flows From Operating Activities:</b>					
Net cash from operating activities	\$ 1,172.0	\$ 1,233.7	\$ 1,963.0	\$ (3,920.2)	\$ 448.5
<b>Cash Flows From Investing Activities:</b>					
Capital expenditures	—	—	(151.3)	—	(151.3)
Acquisitions, net of cash acquired	—	—	(35.9)	—	(35.9)
Proceeds from divestitures, net of cash	—	—	576.9	—	576.9
Intercompany loan investment, net	(741.3)	—	(920.8)	1,662.1	—
Investment in subsidiary	—	(1,412.5)	—	1,412.5	—
Other	—	—	0.5	—	0.5
Net cash from investing activities	(741.3)	(1,412.5)	(530.6)	3,074.6	390.2
<b>Cash Flows From Financing Activities:</b>					
Issuance of external debt	—	500.0	40.0	—	540.0
Repayment of external debt and capital lease obligation	—	(759.9)	(127.6)	—	(887.5)
Debt financing costs	—	(12.7)	—	—	(12.7)
Proceeds from exercise of share options	4.0	—	—	—	4.0
Repurchase of shares	(437.7)	—	—	—	(437.7)
Intercompany loan borrowings, net	—	1,614.5	47.6	(1,662.1)	—
Intercompany dividends	—	(1,170.0)	(2,750.2)	3,920.2	—
Capital contribution	—	—	1,412.5	(1,412.5)	—
Other	3.2	—	(21.8)	—	(18.6)
Net cash from financing activities	(430.5)	171.9	(1,399.5)	845.6	(812.5)
Effect of currency rate changes on cash	—	—	2.7	—	2.7
<b>Net change in cash, cash equivalents and restricted cash</b>	<b>0.2</b>	<b>(6.9)</b>	<b>35.6</b>	<b>—</b>	<b>28.9</b>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<b>0.5</b>	<b>44.5</b>	<b>316.1</b>	<b>—</b>	<b>361.1</b>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$ 0.7</b>	<b>\$ 37.6</b>	<b>\$ 351.7</b>	<b>\$ —</b>	<b>\$ 390.0</b>
Cash and cash equivalents at end of period	\$ 0.7	\$ 37.6	\$ 333.5	\$ —	\$ 371.8
Restricted Cash, included in other assets at end of period	—	—	18.2	—	18.2
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$ 0.7</b>	<b>\$ 37.6</b>	<b>\$ 351.7</b>	<b>\$ —</b>	<b>\$ 390.0</b>



## **21. Subsequent Events**

### ***Financing Activities***

On October 22, 2018, the Company borrowed an additional \$25.0 million on its receivable securitization, bringing total outstanding borrowings to \$250.0 million for this instrument as of the date of this report.

On October 23, 2018, the Company made an \$80.0 million payment on the revolving credit facility, bringing total outstanding borrowings to \$220.0 million for this instrument as of the date of this report.

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

Certain litigation matters occurred during the nine months ended September 28, 2018 or prior, but had subsequent updates through the issuance of this report. See further discussion in Note 17.

## **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 29, 2017, filed with the United States ("U.S.") Securities and Exchange Commission ("the SEC") on February 27, 2018.

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 <sup>TM</sup> 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 that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies.

On February 22, 2018, our Board of Directors authorized commencement of a process to dispose of (1) our Specialty Generics business comprised of the previously reported Specialty Generics segment, with the exception of BioVectra, Inc. - our wholly-owned subsidiary that operates a contract manufacturing business in Canada ("BioVectra"), (2) certain of our non-promoted brands business, which was previously reflected in the Specialty Brands segment; and (3) our ongoing, post-divestiture supply agreement with the acquirer of the contrast media and delivery systems (CMDS) business, which was previously reflected in the Other non-operating segment (referred to collectively as the "Specialty Generics Disposal Group"). We evaluated the criteria prescribed by U.S. Generally Accepted Accounting Principles ("GAAP") for recording a disposal group as held for sale and discontinued operations. This criteria was met during the three months ended March 30, 2018, and as a result, prior year balances have been recast to present the financial results of the disposal group as a discontinued operation.

As the Specialty Generics Disposal Group is reported as a discontinued operation, our continuing operations are limited to the results of operations from the Specialty Brands segment. Our Specialty Brands segment markets branded pharmaceutical products for autoimmune and rare diseases in the specialty areas of neurology, rheumatology, nephrology, ophthalmology and pulmonology; immunotherapy and neonatal respiratory critical care therapies, analgesics and gastrointestinal products. Our diversified, in-line portfolio of both marketed and development products is focused on patients with significant unmet medical needs.

For further information on our business and products, refer to our Annual Report on Form 10-K for the fiscal year ended December 29, 2017, filed with the SEC on February 27, 2018.

### **Significant Events**

#### *Acquisitions*

On February 13, 2018, the Company acquired Sucampo Pharmaceuticals, Inc. ("Sucampo") through the acquisition of all the outstanding common stock of Sucampo. Consideration for the transaction consisted of approximately \$1.2 billion, including the assumption of Sucampo's third-party debt ("the Sucampo Acquisition"). The acquisition was funded through the issuance of \$600.0 million aggregate principal amount of senior secured notes (as discussed further below), a \$900.0 million borrowing under our revolving credit facility and cash on hand. Sucampo's commercialized products include Amitiza<sup>®</sup> (lubiprostone) ("Amitiza"), a leading global product in the branded constipation market, and Rescula<sup>®</sup> (unoprostone isopropyl ophthalmic solution) 0.15% ("Rescula"), which is indicated for ocular hypertension and open-angle glaucoma, and marketed solely in Japan. Through this acquisition, we acquired VTS-270, a Phase 3 development product for Niemann-Pick Type C, a rare, neurodegenerative, and ultimately fatal disease that can present at any age. Also acquired was an option to exercise a collaborative agreement with Cancer Prevention Pharmaceuticals ("CPP") associated with the development of CPP-1X/sulindac, a Phase 3 development product for Familial Adenomatous Polyposis ("FAP"). For more information on our ongoing development of CPP-1X/sulindac, refer to "Research and Development Investment" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

### ***Discontinued Operations and Divestitures***

As previously mentioned, on February 22, 2018, our Board of Directors authorized commencement of a process to dispose of the Specialty Generics Disposal Group. Refer to Note 4 to the unaudited condensed consolidated financial statements for further information on the Specialty Generics Disposal Group.

On March 16, 2018, we completed the sale of a portion of our Hemostasis business, inclusive of our PreveLeak™ Surgical Sealant ("PreveLeak") and Recothrom® Thrombin topical (Recombinant) ("Recothrom") products to Baxter International, Inc. ("Baxter") for approximately \$185.0 million, with a base payment of \$153.0 million, inclusive of existing inventory and subject to a closing inventory adjustment, with the remainder in potential future milestones. Baxter assumed other expenses, including contingent liabilities associated with PreveLeak. We recorded a pre-tax loss on the sale of \$0.6 million during the three and nine months ended September 28, 2018, which excluded any potential proceeds from the attainment of future milestones and reflected a post-sale closing inventory adjustment of \$13.7 million. The financial results associated with the operations of PreveLeak and Recothrom are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations classification.

### ***Stannosporfin***

On May 3, 2018, in a joint meeting, the Federal Drug Administration's ("FDA") Gastrointestinal Drugs Advisory Committee and Pediatric Advisory Committee (the "Advisory Committee") recommended that the risk benefit profile of our stannosporfin in-process research and development ("IPR&D") product does not support approval for the treatment of newborns  $\geq 35$  weeks of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia (severe jaundice). On August 9, 2018, we received a complete response letter from the FDA related to our new drug application ("NDA") for stannosporfin, which provided guidance regarding areas of further evaluation for resubmitting the stannosporfin NDA. While the timing of the development program has shifted outward, we continue to have conversations with 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 IPR&D asset of \$113.5 million included within intangible assets, net on the unaudited condensed consolidated balance sheets as of September 28, 2018 and December 29, 2017.

As part of the acquisition of InfaCare Pharmaceutical Corporation ("InfaCare") in September 2017, we provided contingent consideration to the prior shareholders of InfaCare in the form of both regulatory approval milestones for full-term and pre-term neonates for stannosporfin and sales-based milestones associated with stannosporfin. Due to recent developments and discussions with the FDA, the timing of the development has shifted outward. During the three and nine months ended September 28, 2018, we recognized a \$7.0 million and \$35.0 million fair value adjustment, respectively, due to this shift in timing and its impact on the achievement of milestones per the purchase agreement. The fair value of the contingent consideration is zero after the aforementioned adjustments as of September 28, 2018.

### ***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 recently 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 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 IPR&D asset of \$274.5 million included within intangible assets, net on the unaudited condensed consolidated balance sheet as of September 28, 2018.

## **Business Factors Influencing the Results of Operations**

### ***Products***

As a result of the Sucampo Acquisition in fiscal 2018, we obtained the sales and marketing rights for Amitiza and Rescula and acquired an arrangement under which we license certain rights to Amitiza to a third party in exchange for royalties on net sales of the product. The addition of these products to our Specialty Brands portfolio contributed to the net sales and operating income within this segment. The aggregate net sales of these products were \$50.7 million and \$124.5 million during the three and nine months ended September 28, 2018, respectively, which includes both royalty revenue and product sales. Our cost of sales for the three and nine months ended September 28, 2018 included \$31.0 million and \$77.5 million of expense recognition associated with the fair value

adjustments of acquired inventory, respectively and \$18.0 million and \$45.0 million of amortization associated with intangibles recognized from this acquisition, respectively. Included within selling, general and administrative expenses ("SG&A") in our unaudited condensed consolidated statement of income was \$0.5 million and \$3.2 million of transaction costs incurred during the three and nine months ended September 28, 2018, respectively, associated with our acquisition.

### ***Restructuring Initiatives***

We continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies.

In July 2016, our Board of Directors approved a \$100.0 million to \$125.0 million restructuring program ("the 2016 Mallinckrodt Program") designed to further improve our cost structure, as we continue to transform our business. The 2016 Mallinckrodt Program is expected to include actions across both the Specialty Brands segment and the Specialty Generics Disposal Group, as well as within corporate functions. There is no specified time period associated with the 2016 Mallinckrodt Program. Through September 28, 2018, we incurred restructuring charges of \$120.9 million under the 2016 Mallinckrodt Program, which are expected to generate savings, primarily within our SG&A expenses. The 2016 Mallinckrodt Program is substantially complete.

In February 2018, our 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. Through September 28, 2018, we incurred restructuring charges of \$5.2 million under the 2018 Mallinckrodt Program, which are expected to generate savings, primarily within our SG&A expenses.

In addition to the 2016 and 2018 Mallinckrodt Programs, we take certain restructuring actions to generate synergies from our acquisitions.

On January 8, 2018 we announced that we would discontinue marketing of Raplix<sup>®</sup> after an evaluation of strategic options. During the nine months ended September 28, 2018, we incurred restructuring expenses of \$48.8 million under the 2016 Mallinckrodt Program, consisting primarily of contract termination costs related to the production of Raplix. Amounts paid in the future may differ from the amount currently recorded.

### ***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 from continuing operations of \$78.5 million and \$223.9 million for the three and nine months ended September 28, 2018, respectively, and \$46.9 million and \$144.2 million for the three and nine months ended September 29, 2017, 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.

On April 5, 2018 (the "Exercise Date"), we exercised the option under our collaborative agreement with CPP to negotiate terms of an exclusive license to develop and commercialize CPP-1X/sulindac in North America. In addition, we provided CPP with a \$10.0 million upfront R&D payment for expenses related to the FAP pivotal trial incurred during the "Negotiation Period", or the period from the Exercise Date through the execution of such license agreement. CPP shall return to us any portion of the R&D payment that is not utilized during the Negotiation Period. Of the \$10.0 million upfront payment, \$7.3 million was utilized during the nine months ended September 28, 2018 and recorded as R&D expense within the unaudited condensed consolidated statement of income. The remaining \$2.7 million was included in prepaid expenses and other current assets on the unaudited condensed consolidated balance sheet as of September 28, 2018.

On August 4, 2018, the license agreement with CPP was executed and the Company paid \$5.0 million upfront with cash on hand and gained exclusive rights to develop and commercialize the product in North America, if approved. The agreement includes additional payments of up to \$185.0 million dependent on developmental, regulatory and sales milestones, subject to reduction up to \$15.0 million related to amounts provided by the Company in advance of entering into this agreement, and provides for both parties' reimbursement of R&D expenses from future profits. Following the commercialization of the product, CPP and the Company will share profits in accordance with the agreement. The Company will manage the development of the product in North America.

## Results of Operations

### Three Months Ended September 28, 2018 Compared with Three Months Ended September 29, 2017

#### Net Sales

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

	Three Months Ended		Percentage Change
	September 28, 2018	September 29, 2017	
U.S.	\$ 576.4	\$ 563.4	2.3%
Europe, Middle East and Africa	36.9	16.0	130.6
Other geographic areas	26.7	21.2	25.9
Net sales	<u>\$ 640.0</u>	<u>\$ 600.6</u>	6.6

Net sales for the three months ended September 28, 2018 increased \$39.4 million, or 6.6%, to \$640.0 million, compared with \$600.6 million for the three months ended September 29, 2017. This increase was primarily driven by net sales of the newly acquired Amitiza product, strength in Ofirmev<sup>®</sup> and Therakos<sup>®</sup> demand, and benefits of Inomax<sup>®</sup> contracting and consumption. These increases were partially offset by decreased net sales of H.P. Acthar<sup>®</sup> Gel driven by the residual impact of previously reported patient withdrawal issues. We have taken a number of steps to address the issue, including engagement with payers, prescribers and patients. 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 three months ended September 28, 2018 decreased \$18.8 million, or 5.7%, to \$313.8 million, compared with \$332.6 million for the three months ended September 29, 2017. Gross profit margin was 49.0% for the three months ended September 28, 2018, compared with 55.4% for the three months ended September 29, 2017. The decrease in gross profit and gross profit margin was primarily attributable to amortization of the Amitiza intangible asset and expense recognition of inventory fair value adjustments associated with the product.

*Selling, general and administrative expenses.* SG&A expenses for the three months ended September 28, 2018 were \$164.0 million, compared with \$186.3 million for the three months ended September 29, 2017, a decrease of \$22.3 million, or 12.0%. The decrease was attributable to various factors, including an \$11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability; a \$7.0 million decrease in fair value of the contingent consideration liability related to stannosporfin; lower legal fees and advertising and promotion expenses; in addition to cost benefits gained from restructuring actions, including lower stock compensation expenses. These changes were partially offset by higher one-time employee compensation costs and professional fees. SG&A expenses were 25.6% of net sales for the three months ended September 28, 2018 and 31.0% of net sales for the three months ended September 29, 2017.

*Research and development expenses.* R&D expenses increased \$31.6 million, or 67.4%, to \$78.5 million for the three months ended September 28, 2018, compared with \$46.9 million for the three months ended September 29, 2017. The increase was primarily attributable to the additional pipeline products that have been acquired within the past year. 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 12.3% and 7.8% for the three months ended September 28, 2018 and September 29, 2017, respectively.

*Restructuring charges, net.* During the three months ended September 28, 2018, we recorded \$19.6 million of restructuring and related charges, net, including \$4.9 million of accelerated depreciation in SG&A and cost of sales, primarily related to employee severance and benefits and exiting certain facilities. During the three months ended September 29, 2017, we recorded \$16.1 million of restructuring and related charges, net, including \$0.7 million of accelerated depreciation in SG&A and cost of sales, primarily related to exiting certain facilities.

*Losses on divestiture.* During the three months ended September 28, 2018, we recorded a \$0.6 million pre-tax loss associated with a post-sale closing inventory adjustment related to the sale of a portion of our Hemostasis business, inclusive of our PreveLeak and Recothrom products. During the three months ended September 29, 2017, we recorded a \$0.4 million pre-tax loss associated with additional transaction costs related to the sale of our Intrathecal Therapy business.

### **Non-Operating Items**

*Interest expense and interest income.* During the three months ended September 28, 2018 and September 29, 2017, net interest expense was \$91.6 million and \$91.3 million, respectively. This increase was attributable to a higher average outstanding debt balance during the three months ended September 28, 2018, following the close of the Sucampo Acquisition, which yielded an increase in interest expense of \$12.2 million over the comparable period. This was partially offset by an \$11.2 million decrease in interest accrued on deferred tax liabilities associated with outstanding installment notes primarily due to our fiscal 2017 legal entity reorganization and the Tax Cut and Jobs Act ("TCJA") that reduced the interest-bearing U.S. deferred tax liabilities balance. In addition, interest income increased to \$2.0 million for the three months ended September 28, 2018, compared with \$1.3 million for the three months ended September 29, 2017 primarily related to higher interest earned on our money market funds.

*Other income, net.* During the three months ended September 28, 2018 and September 29, 2017, we recorded other income, net, of \$13.4 million and \$3.0 million, respectively. The increase is primarily attributable to the receipt of \$8.2 million of royalty income and a refund of \$3.4 million of the initial cash contribution related to the settlement of remaining obligations of six defined benefit pension plans that were terminated during fiscal 2016. The remaining amounts in both fiscal years 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 \$125.2 million on a loss from continuing operations before income taxes of \$22.2 million for the three months ended September 28, 2018, and an income tax benefit of \$57.8 million on a loss from continuing operations before income taxes of \$4.7 million for the three months ended September 29, 2017. This resulted in effective tax rates of 564.0% and 1,229.8% for the three months ended September 28, 2018 and September 29, 2017, respectively. The income tax benefit for the three months ended September 28, 2018 is comprised of \$16.1 million of current tax expense and \$141.3 million of deferred tax benefit which is predominantly related to acquired intangible assets and the generation of net operating losses. The income tax benefit for the three months ended September 29, 2017 is comprised of \$81.4 million of current tax benefit and \$23.6 million of deferred tax expense. The net deferred tax expense of \$23.6 million includes \$50.7 million of deferred tax benefit which is predominantly related to acquired intangible assets offset by \$74.3 million of deferred tax expense related to utilization of tax attributes.

The income tax benefit was \$125.2 million for the three months ended September 28, 2018, compared with a tax benefit of \$57.8 million for the three months ended September 29, 2017. The \$67.4 million net increase in the tax benefit includes an increase of \$82.3 million attributable to the tax benefit from the reorganization of the Company's intercompany financing and associated legal entity ownership which occurred during the three months ended September 28, 2018, an increase of \$17.3 million attributable to tax expense from a reorganization of legal entity ownership which occurred during the three months ended September 29, 2017, an increase of \$9.1 million attributable to the tax benefit from an adjustment to the provisional estimate of the remeasurement of its net U.S. deferred tax liabilities resulting from U.S. Tax Reform, and an increase in tax benefit of \$3.7 million attributable to the impact of acquisitions occurring since September 29, 2017; partially offset by a decrease to tax benefit of \$36.7 million attributable to the reduction in the U.S. federal corporate statutory rate resulting from U.S. Tax Reform, and a decrease in tax benefit of \$8.3 million attributable to changes in the amount and jurisdictional mix of operating income.

*Income from discontinued operations, net of income taxes.* We recorded income from discontinued operations of \$10.8 million and \$10.6 million during the three months ended September 28, 2018 and September 29, 2017, respectively. The income from discontinued operations for the three months ended September 28, 2018 consisted of \$11.2 million of income from operating results, net of tax, associated with the Specialty Generics Disposal Group and a \$0.4 million loss, net of tax, related to various post-sale adjustments associated with our previous divestitures. The income from discontinued operations for the three months ended September 29, 2017 included \$11.2 million of income from operating results, net of tax, associated with the Specialty Generics Disposal Group and a \$0.6 million loss, net of tax, related to various post-sale adjustments associated with our previous divestitures

## Results of Operations

### Nine Months Ended September 28, 2018 Compared with Nine Months Ended September 29, 2017

#### Net Sales

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

	Nine Months Ended		Percentage Change
	September 28, 2018	September 29, 2017	
U.S.	\$ 1,669.0	\$ 1,665.2	0.2%
Europe, Middle East and Africa	101.0	50.5	100.0
Other geographic areas	74.3	45.0	65.1
Net sales	<u>\$ 1,844.3</u>	<u>\$ 1,760.7</u>	4.7

Net sales for the nine months ended September 28, 2018 increased \$83.6 million, or 4.7%, to \$1,844.3 million, compared with \$1,760.7 million for the nine months ended September 29, 2017. This increase was primarily driven by net sales of the newly acquired Amitiza product, strength in Ofirmev and Therakos demand and benefits of Inomax contracting and consumption. These increases were partially offset by decreased net sales of H.P. Acthar Gel driven by the residual impact of previously reported patient withdrawal issues. We have taken a number of steps to address the issue, including engagement with payers, prescribers and patients. In addition, we experienced lower net sales in Other branded products primarily due to the sale of Recothrom in the first quarter of 2018 and our Intrathecal Therapy business in the first quarter of 2017. For further information on changes in our net sales, refer to "Segment Results" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### Operating Income

**Gross profit.** Gross profit for the nine months ended September 28, 2018 decreased \$44.8 million, or 4.7%, to \$907.6 million, compared with \$952.4 million for the nine months ended September 29, 2017. Gross profit margin was 49.2% for the nine months ended September 28, 2018, compared with 54.1% for the nine months ended September 29, 2017. The decrease in gross profit and gross profit margin was primarily attributable to amortization of the Amitiza intangible asset and expense recognition of inventory fair value adjustments associated with the product.

**Selling, general and administrative expenses.** SG&A expenses for the nine months ended September 28, 2018 were \$520.7 million, compared with \$618.5 million for the nine months ended September 29, 2017, a decrease of \$97.8 million, or 15.8%. This decrease was primarily attributable to various factors, including a \$35.0 million decrease in fair value of the contingent consideration liability related to stannosporfin; cost benefits gained from restructuring actions, including lower stock compensation expense and employee compensation costs; an \$11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability; in addition to lower legal fees. SG&A expenses were 28.2% of net sales for the nine months ended September 28, 2018 and 35.1% of net sales for the nine months ended September 29, 2017.

**Research and development expenses.** R&D expenses increased \$79.7 million, or 55.3%, to \$223.9 million for the nine months ended September 28, 2018, compared with \$144.2 million for the nine months ended September 29, 2017. The increase was primarily attributable to the additional pipeline products that have been acquired within the past year. 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 12.1% and 8.2% for the nine months ended September 28, 2018 and September 29, 2017, respectively.

**Restructuring charges, net.** During the nine months ended September 28, 2018 we recorded \$101.4 million of restructuring and related charges, net, including \$4.9 million of accelerated depreciation in SG&A and cost of sales. During the nine months ended September 29, 2017, we recorded \$28.4 million including \$2.1 million of accelerated depreciation, in cost of sales. The increase over the comparable period was primarily attributable to contract termination costs related to the production of Raplixa, as well as employee severance and benefits and the exiting of certain facilities.

**Gains on divestiture.** During the nine months ended September 28, 2018, we sold a portion of our Hemostasis business, inclusive of our PreveLeak and Recothrom products. As a result of this sale, we recorded a pre-tax loss of \$0.6 million. In comparison, during the nine months ended September 29, 2017, we recorded a \$56.6 million pre-tax gain associated with the sale of our Intrathecal Therapy business.

## **Non-Operating Items**

*Interest expense and interest income.* During the nine months ended September 28, 2018 and September 29, 2017, net interest expense was \$273.5 million and \$276.2 million, respectively. Interest accrued on deferred tax liabilities associated with outstanding installment notes decreased \$35.8 million primarily due to our fiscal 2017 legal entity reorganization and the TCJA that reduced the interest-bearing U.S. deferred tax liabilities balance. Also, non-cash interest expense decreased by \$1.2 million over the comparable period. These decreases were partially offset by a higher average outstanding debt balance during the nine months ended September 28, 2018, following the close of the Sucampo Acquisition, which yielded an increase in interest expense of \$38.1 million over the comparable period. During the nine months ended September 28, 2018, we also recognized interest income of \$6.6 million compared to \$2.8 million during the nine months ended September 29, 2017 primarily related to higher interest earned on our money market funds.

*Other income (expense), net.* During the nine months ended September 28, 2018, we recorded other income, net, of \$17.5 million and during the nine months ended September 29, 2017, we recorded other expense, net, of \$70.6 million. The nine months ended September 28, 2018 included royalty income received of \$8.2 million, a gain of \$6.5 million on debt repurchased and a refund of \$3.4 million of the initial cash contribution related to the settlement of remaining obligations of six defined benefit pension plans that were terminated during fiscal 2016. The nine months ended September 29, 2017 included a \$69.7 million charge from the recognition of previously deferred losses on the settlement of obligations associated with the termination of six defined benefit pension plans. This settlement charge was reclassified from SG&A to other income (expense), net as a result of our adoption of Accounting Standards Update 2017-07, "Compensation - Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Post Retirement Benefit Cost," in fiscal 2018, which required retroactive application. In addition, there was a \$10.0 million charge associated with the refinancing of our term loan during the nine months ended September 29, 2017. 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 \$222.0 million on a loss from continuing operations before income taxes of \$190.1 million for the nine months ended September 28, 2018, and an income tax benefit of \$153.4 million on a loss from continuing operations before income taxes of \$126.8 million for the nine months ended September 29, 2017. This resulted in effective tax rates of 116.8% and 121.0% for the nine months ended September 28, 2018 and September 29, 2017, respectively. The income tax benefit for the nine months ended September 28, 2018 is comprised of \$29.2 million of current tax expense and \$251.2 million of deferred tax benefit which is predominantly related to acquired intangible assets and the generation of net operating losses. The income tax benefit for the nine months ended September 29, 2017 is comprised of \$13.6 million of current tax benefit and \$139.8 million of deferred tax benefit. The net deferred tax benefit of \$139.8 million includes \$241.3 million of deferred tax benefit, which is predominantly related to acquired intangible assets offset by \$101.5 million of deferred tax expense related to utilization of tax attributes.

The income tax benefit was \$222.0 million for the nine months ended September 28, 2018, compared with a tax benefit of \$153.4 million for the nine months ended September 29, 2017. The \$68.6 million net increase in the tax benefit includes an increase of \$82.3 million attributable to the tax benefit from reorganization of the Company's intercompany financing and associated legal entity ownership which occurred during the nine months ended September 28, 2018, an increase of \$27.1 million attributable to tax expense from the impact of dispositions predominately occurring during the nine months ended September 29, 2017, an increase of \$17.3 million attributable to tax expense from a reorganization of legal entity ownership which occurred during the nine months ended September 29, 2017, an increase in tax benefit of \$11.8 million attributable to the impact of acquisitions occurring since September 29, 2017, an increase of \$9.1 million attributable to the tax benefit from an adjustment to the provisional estimate of the remeasurement of its net U.S. deferred tax liabilities resulting from U.S. Tax Reform, and an increase in tax benefit of \$9.1 million attributable to changes in the amount and jurisdictional mix of operating income; partially offset by a decrease to tax benefit of \$70.0 million attributable to the reduction in the U.S. federal corporate statutory rate from U.S. Tax Reform, and a decrease of \$18.1 million attributable to tax benefit from the termination of the defined benefit pension plans which occurred during the nine months ended September 29, 2017.

*Income from discontinued operations, net of income taxes.* We recorded income from discontinued operations of \$79.5 million and \$499.1 million during the nine months ended September 28, 2018 and September 29, 2017, respectively. The income from discontinued operations for the nine months ended September 28, 2018 consisted of \$64.6 million of income from operating results, net of tax, associated with the Specialty Generics Disposal Group and \$13.5 million of income, net of tax, from the receipt of contingent consideration related to the sale of the Nuclear Imaging business. The income from discontinued operations for the nine months ended September 29, 2017 included a \$361.7 million gain on divestiture and \$4.1 million of income from operating results, both net of tax, associated with the Nuclear Imaging business and \$137.2 million of income from operating results, net of tax, associated with the Specialty Generics Disposal Group. These were partially offset by various post-sale adjustments associated with our previous divestitures.



## Segment Results

Our continuing operations are limited to the results of operations from the Specialty Brands segment as the Specialty Generics Disposal Group is reported as a discontinued operation. Management measures and evaluates our Specialty Brands segment based on net sales and operating income. Management excludes certain 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 segment excluding such items. These items include intangible asset amortization, impairments and net restructuring and related charges. 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.

### Three Months Ended September 28, 2018 Compared with Three Months Ended September 29, 2017

#### Net Sales

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

	Three Months Ended		Percentage Change
	September 28, 2018	September 29, 2017	
H.P. Acthar Gel	\$ 290.1	\$ 308.7	(6.0)%
Inomax	133.2	125.7	6.0
Ofirmev	87.1	75.4	15.5
Therakos	60.0	55.3	8.5
Amitiza <sup>(1)</sup>	48.2	—	—
BioVectra	13.9	16.0	(13.1)
Other	7.5	19.5	(61.5)
Specialty Brands	<u>\$ 640.0</u>	<u>\$ 600.6</u>	6.6

<sup>(1)</sup> Amitiza consists of both product net sales and royalties. Refer to Note 3 to the unaudited condensed consolidated financial statements for further information on Amitiza's revenue.

*Specialty Brands.* Net sales for the three months ended September 28, 2018 increased \$39.4 million to \$640.0 million, compared with \$600.6 million for the three months ended September 29, 2017. The increase in net sales was primarily driven by net sales of \$48.2 million from the newly acquired Amitiza product and an increase in Ofirmev, Therakos and Inomax net sales compared with the three months ended September 29, 2017 as Ofirmev and Therakos experienced increased demand and Inomax net sales continue to benefit from favorable contracting and consumption. These increases were partially offset by an \$18.6 million or 6.0% decrease in H.P. Acthar Gel net sales driven by the residual impact of previously reported patient withdrawal issues, and a \$12.0 million or 61.5% decrease in Other products compared with the three months ended September 29, 2017. The decrease in Other products net sales is primarily attributable to the sale of Recothrom during the first quarter of 2018, which contributed net sales of \$15.3 million during the three months ended September 29, 2017.

#### Operating Income

Operating income by segment and as a percentage of segment net sales for the three months ended September 28, 2018 and September 29, 2017 is shown in the following table (dollars in millions):

	Three Months Ended	
	September 28, 2018	September 29, 2017
Specialty Brands	\$ 287.8      45.0%	\$ 314.8      52.4%
Unallocated amounts:		
Corporate and allocated expenses	(28.0)	(45.8)
Intangible asset amortization	(184.2)	(169.3)
Restructuring and related charges, net <sup>(1)</sup>	(19.6)	(16.1)
Total operating income	<u>\$ 56.0</u>	<u>\$ 83.6</u>

<sup>(1)</sup> Includes restructuring-related accelerated depreciation.

*Specialty Brands.* Operating income for the three months ended September 28, 2018 decreased \$27.0 million to \$287.8 million, compared with \$314.8 million for the three months ended September 29, 2017. Operating margin decreased to 45.0% for the three months ended September 28, 2018 compared with 52.4% for the three months ended September 29, 2017. The decrease in operating income and margin was primarily due to a \$31.6 million increase in R&D expenses over the comparable period and expense recognition of inventory fair value adjustments associated with Amitiza. These changes were partially offset by a decrease of \$5.4 million in SG&A expenses compared with the three months ended September 29, 2017 primarily due to lower advertising and promotion expenses, legal fees and cost benefits gained from restructuring actions, including stock compensation expenses and employee compensation costs partially offset by increased professional fees.

*Corporate and allocated expenses.* Corporate and allocated expenses were \$28.0 million and \$45.8 million for the three months ended September 28, 2018 and September 29, 2017, respectively. This decrease was primarily driven by an \$11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability and a \$7.0 million decrease in fair value of the contingent consideration liability related to stansoporfin during the three months ended September 28, 2018, partially offset by higher one-time employee compensation costs.

#### ***Nine Months Ended September 28, 2018 Compared with Nine Months Ended September 29, 2017***

##### ***Net Sales***

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

	<b>Nine Months Ended</b>		<b>Percentage Change</b>
	<b>September 28, 2018</b>	<b>September 29, 2017</b>	
H. P. Acthar Gel	\$ 827.1	\$ 899.9	(8.1)%
Inomax	404.0	379.6	6.4
Ofirmev	254.7	224.5	13.5
Therakos	174.2	157.7	10.5
Amitiza <sup>(1)</sup>	119.2	—	—
BioVectra	35.7	36.4	(1.9)
Other	29.4	62.6	(53.0)
Specialty Brands	<u>\$ 1,844.3</u>	<u>\$ 1,760.7</u>	4.7

<sup>(1)</sup> Amitiza consists of both product net sales and royalties. Refer to Note 3 to the unaudited condensed consolidated financial statements for further information on Amitiza's revenue.

*Specialty Brands.* Net sales for the nine months ended September 28, 2018 increased \$83.6 million to \$1,844.3 million, compared with \$1,760.7 million for the nine months ended September 29, 2017. The increase in net sales was primarily driven by net sales of \$119.2 million from the newly acquired Amitiza product and an increase in Ofirmev, Therakos and Inomax net sales compared with the nine months ended September 29, 2017 as Ofirmev and Therakos experienced increased demand and Inomax net sales continue to benefit from favorable contracting and consumption. These increases were partially offset by a \$72.8 million or 8.1% decrease in H.P. Acthar Gel net sales driven by the residual impact of previously reported patient withdrawal issues, and a \$33.2 million or 53.0% decrease in Other products compared with the nine months ended September 29, 2017. The decrease in Other products net sales is primarily attributable to a decrease of \$31.3 million related to the sale of Recothrom during the first quarter of 2018, and the sale of our Intrathecal Therapy business during the first quarter of 2017, which up through the March 17, 2017 divestiture date contributed net sales of \$8.0 million.

## Operating Income

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

	Nine Months Ended					
	September 28, 2018		September 29, 2017			
Specialty Brands	\$	794.0	43.1%	\$	851.8	48.4%
Unallocated amounts:						
Corporate and allocated expenses		(81.9)			(95.0)	
Intangible asset amortization		(544.8)			(508.4)	
Restructuring and related charges, net <sup>(1)</sup>		(101.4)			(28.4)	
Total operating income	\$	<u>65.9</u>		\$	<u>220.0</u>	

(1) Includes restructuring-related accelerated depreciation.

*Specialty Brands.* Operating income for the nine months ended September 28, 2018 decreased \$57.8 million to \$794.0 million, compared with \$851.8 million for the nine months ended September 29, 2017. Operating margin decreased to 43.1% for the nine months ended September 28, 2018, compared with 48.4% for the nine months ended September 29, 2017. The decrease in operating income and margin was primarily due to an \$82.4 million increase in R&D expenses over the comparable period and expense recognition of inventory fair value adjustments associated with Amitiza. These changes were partially offset by a decrease of \$25.6 million in SG&A expenses compared with the nine months ended September 29, 2017 primarily due to cost benefits gained from restructuring actions, including lower employee compensation costs and stock compensation expenses, in addition to lower legal fees.

*Corporate and allocated expenses.* Corporate and allocated expenses were \$81.9 million and \$95.0 million for the nine months ended September 28, 2018 and September 29, 2017, respectively. The nine months ended September 28, 2018 included a \$35.0 million decrease in fair value of the contingent consideration liability related to stannosporfin and an \$11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability. The nine months ended September 29, 2017 included a pre-tax gain of \$56.6 million associated with the sale of our Intrathecal Therapy business. The remaining decrease of \$22.9 million was primarily due to cost benefits gained from restructuring actions including lower stock compensation expenses, in addition to lower legal expenses; all of which are partially offset by an increase in professional fees and acquisition-related costs.

## 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 license 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):

	Nine Months Ended				
	September 28, 2018		September 29, 2017		
<b>Net cash from:</b>					
Operating activities	\$	481.1	\$	448.5	
Investing activities		(451.2)		390.2	
Financing activities		(998.9)		(812.5)	
Effect of currency exchange rate changes on cash and cash equivalents		(0.9)		2.7	
Net decrease in cash and cash equivalents	\$	<u>(969.9)</u>	\$	<u>28.9</u>	

### ***Operating Activities***

Net cash provided by operating activities of \$481.1 million for the nine months ended September 28, 2018, was primarily attributable to income from continuing operations of \$31.9 million and income from discontinued operations of \$79.5 million, adjusted for non-cash items of \$389.1 million driven by depreciation and amortization of \$597.0 million, partially offset by \$232.7 million related to a reduction in our deferred income tax liabilities, and a \$19.4 million outflow from net investment in working capital. Included within this change in working capital were a \$20.1 million net cash outflow related to other assets and liabilities and a \$59.0 million increase in accounts receivable, partially offset by a \$43.1 million decrease in inventory and a \$16.7 million net cash inflow related to income taxes.

Net cash provided by operating activities of \$448.5 million for the nine months ended September 29, 2017 was primarily attributable to income from continuing operations of \$26.6 million and income from discontinued operations of \$499.1 million partially offset by an adjustment for non-cash items of \$146.6 million, in addition to a \$223.8 million outflow from net investment in working capital. Included within this change in working capital were cash payments of \$102.0 million for the FTC settlement, a \$61.3 million contribution to the terminated pension plans that were settled during the nine months ended September 29, 2017, a \$34.7 million increase in accounts receivable and a \$30.2 million decrease in accounts payable, and a \$68.1 million net cash outflow related to income taxes.

The aforementioned cash flows from operating activities include cash flows from the ongoing operations of the Specialty Generics Disposal Group and the Nuclear Imaging business that are included within discontinued operations. Subsequent to the completion of the Nuclear Imaging transaction on January 27, 2017, we no longer generate cash flows from the operation of this business. See further discussion of our discontinued operations in Note 4 of the notes to the unaudited condensed consolidated financial statements.

### ***Investing Activities***

Net cash used in investing activities was \$451.2 million for the nine months ended September 28, 2018, compared with a \$390.2 million net cash inflow for the nine months ended September 29, 2017. The \$841.4 million change primarily resulted from the cash outflows related to the Sucampo Acquisition of \$698.0 million. These cash outflows were partially offset by the inflow of \$159.2 million in proceeds received, net of transaction costs, from the divestiture of a portion of the Hemostasis business, inclusive of the PreveLeak and Recothrom products during the nine months ended September 28, 2018; proceeds received of \$154.0 million related to the note receivable from the purchaser of the Intrathecal Therapy business which was sold during the nine months ended September 29, 2017; and a \$25.5 million cash inflow related to the sale of the remaining portion of our investment in Mesoblast Limited during the nine months ended September 28, 2018. This is compared with \$576.9 million of proceeds received from the divestiture of the Nuclear Imaging and Intrathecal Therapy businesses during the nine months ended September 29, 2017, partially offset by cash outflows of \$21.5 million related to the investment in Mesoblast Limited that was made during the nine months ended September 29, 2017. Additionally, there was a \$58.0 million decrease in capital expenditures, compared to the nine months ended September 29, 2017.

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.

### ***Financing Activities***

Net cash used in financing activities was \$998.9 million for the nine months ended September 28, 2018, compared with \$812.5 million for the nine months ended September 29, 2017. The \$186.4 million increase in cash outflows was attributable to a \$558.7 million increase in debt repayments, net of issuances, offset by a \$380.3 million decrease in shares repurchased. The significant components of our current year debt repayments included \$600.0 million related to our revolving credit facility, a \$225.0 million 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***

At September 28, 2018, the total principal amount of debt was \$6,260.1 million as compared with \$6,806.8 million at December 29, 2017. The total principal amount of debt at September 28, 2018 was comprised of \$3,522.5 million of fixed-rate instruments, \$2,210.8 million of variable-rate term loans, \$300.0 million of borrowings under our revolving credit facility, \$225.0 million of borrowings under a variable-rate securitization program and \$1.8 million of an interest-free loan. 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 original principal amount. As of September 28, 2018, our fixed-rate instruments have a weighted-average interest rate of 5.45% and pay interest at various dates throughout the fiscal year. Our receivable securitization program bears interest based on one-month LIBOR plus a margin of 0.90% and has a capacity of \$250.0 million that may, subject to certain conditions, be increased to \$300.0 million. In addition to the borrowing capacity under our receivable securitization program, we had \$600.0 million available under our \$900.0 million revolving credit facility at September 28, 2018.

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. During the nine months ended September 28, 2018, we repurchased debt that aggregated to a total principal amount of \$33.0 million.

At September 28, 2018, \$17.0 million of our debt principal was classified as current, as these payments are expected to be made within the next twelve months.

In January 2018, we made a \$225.0 million prepayment on our outstanding term loan due September 2024. In making this payment, 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.

In February 2018, in conjunction with the Sucampo Acquisition, the Company entered into a \$600.0 million senior secured term loan. The variable-rate loan bears an interest rate of LIBOR plus 300 basis points and was issued with a discount of 25 basis points. The incremental term loan matures on February 25, 2025 under terms generally consistent with the Company's existing term loan.

Upon completion of the Sucampo Acquisition, Sucampo's 3.25% convertible senior notes due 2021 ("the Sucampo Notes") became eligible to receive increased consideration in conjunction with a make-whole fundamental change, such that each \$1,000 principal face amount of Sucampo Notes could be converted into \$1,221 in cash. As of September 28, 2018, all \$300.0 million of the issued convertible debt was converted and paid in full.

In April 2018, \$300.0 million of the 3.50% unsecured, fixed-rate notes matured and were repaid with cash on hand.

As of September 28, 2018, we were, and expect to remain, in full compliance with the provisions and covenants associated with our debt agreements.

On October 22, 2018, we borrowed an additional \$25.0 million on our receivable securitization, bringing total outstanding borrowings to \$250.0 million for this instrument as of the date of this report.

On October 23, 2018, we made an \$80.0 million payment on the revolving credit facility, bringing total outstanding borrowings to \$220.0 million for this instrument as of the date of this report.

## **Commitments and Contingencies**

### ***Legal Proceedings***

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Note 17 of the notes to the unaudited condensed consolidated financial statements. We believe 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, we believe, unless otherwise indicated in Note 17 of the notes to the unaudited condensed consolidated financial statements, given the information currently available, that their ultimate resolutions are not expected to have a material adverse effect on our financial condition, results of operations and cash flows.

### ***Guarantees***

In disposing of assets or businesses, we have from time to time provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to 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.

In connection with the sale of the Specialty Chemicals business (formerly known as Mallinckrodt Baker) in fiscal 2010, we 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 unaudited condensed consolidated balance sheets as of September 28, 2018 and December 29, 2017 was \$14.3 million and \$14.9 million, respectively, of which \$11.6 million and \$12.1 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 at September 28, 2018 and December 29, 2017. As of September 28, 2018, the maximum future payments we could be required to make under these indemnification obligations were \$70.2 million. We were required to pay \$30.0 million into an escrow account as collateral to the purchaser, of which \$18.5 million and \$18.3 million remained in restricted cash, included in long-term other assets on the unaudited condensed consolidated balance sheets at September 28, 2018 and December 29, 2017, respectively.

We have recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 17 of the notes to the unaudited condensed consolidated financial statements.

We are also liable for product performance; however, we believe, given the information currently available, that the ultimate resolution of any such claims will not have a material adverse effect on our financial condition, results of operations and cash flows.

### ***Off-Balance Sheet Arrangements***

As of September 28, 2018, we had various letters of credit, guarantees and surety bonds totaling \$22.5 million. There has been no change in our off-balance sheet arrangements during the nine months ended September 28, 2018. Refer to the Company's Annual Report filed on Form 10-K for the fiscal year ended December 29, 2017 for further detail on the Company's off-balance sheet arrangements.

### **Critical Accounting Policies and Estimates**

The preparation of our unaudited condensed consolidated financial statements in conformity with 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, goodwill and other intangible assets, acquisitions, contingencies and income taxes are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. During the nine months ended September 28, 2018, 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 29, 2017.

Refer to Note 2 to the unaudited condensed consolidated financial statements for our adoption of ASU 2014-09, "Revenue from Contracts with Customers," and its related amendments, which did not result in a material change to the unaudited condensed consolidated financial statements.

### **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 29, 2017 and within Part II, Item 1A of this Quarterly Report on Form 10-Q could cause our results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business.

These forward-looking statements are made as of the filing date of this Quarterly Report on Form 10-Q. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

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

#### ***Interest Rate Risk***

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of September 28, 2018, our outstanding debt included \$2,210.8 million variable-rate debt on our senior secured term loans, \$300.0 million outstanding borrowings on our senior unsecured revolving credit facility and \$225.0 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 \$6.8 million.

The remaining outstanding debt as of September 28, 2018 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 non-U.S. operations are denominated in the local currency of the respective countries. As such, profits from these subsidiaries may be impacted by fluctuations in the value of these local currencies relative to the U.S. dollar. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain operational and intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations.

The unaudited condensed consolidated statement of income is exposed to currency risk from intercompany financing arrangements, which primarily consist of intercompany debt and intercompany cash pooling, where the denominated currency of the transaction differs from the functional currency of one or more of our subsidiaries. We performed a sensitivity analysis for these arrangements as of September 28, 2018 that measures 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. There is a \$1.3 million aggregate potential unfavorable impact from a hypothetical 10.0% adverse change in foreign exchange rates as of September 28, 2018. 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 non-U.S. operations are translated into U.S. dollars, further exposing us to currency exchange rate fluctuations. We have performed a sensitivity analysis as of September 28, 2018 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 \$14.2 million as of September 28, 2018. 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. Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were effective.

### **Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably 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 patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Note 17 of the notes to the unaudited condensed consolidated financial statements. We believe 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, we believe, unless otherwise indicated in Note 17 of the notes to the unaudited condensed consolidated financial statements, given the information currently available, that their ultimate resolutions are not expected to have a material adverse effect on our financial condition, results of operations and cash flows. For further information on pending legal proceedings, refer to Note 17 of the notes to the unaudited condensed consolidated financial statements.

### **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 29, 2017, filed with the SEC on February 27, 2018.

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

#### **(c) Issuer Purchases of Securities**

The following table summarizes the repurchase activity of our ordinary shares during the three months ended September 28, 2018. 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 16, 2016, the Company's Board of Directors authorized an additional \$350.0 million share repurchase program (the "March 2016 Program") which was completed during the three months ended March 31, 2017. 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.

	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid Per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under Plans or Programs</b>
June 30, 2018 to July 27, 2018	36,282	\$ 18.66	—	\$ 564.2
July 27, 2018 to August 31, 2018	121	22.87	—	564.2
September 1, 2018 to September 28, 2018	169	34.62	—	564.2

### **Item 3. Defaults Upon Senior Securities.**

None.



**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Exhibit</b>
31.1	<a href="#"><u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2	<a href="#"><u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1	<a href="#"><u>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.</u></a>
101	Interactive Data File (Form 10-Q for the quarterly period ended September 28, 2018 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/ Matthew K. Harbaugh

Matthew K. Harbaugh

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

Date: November 6, 2018

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

I, Mark C. Trudeau, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Mallinckrodt plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2018

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

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

I, Matthew K. Harbaugh, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Mallinckrodt plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2018

By: /s/ Matthew K. Harbaugh

**Matthew K. Harbaugh**

*Executive Vice President and Chief*

*Financial Officer*

*(principal financial officer)*

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

The undersigned officers of Mallinckrodt plc ("the Company") hereby certify to their knowledge that the Company's quarterly report on Form 10-Q for the period ended September 28, 2018 ("the Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Mark C. Trudeau

**Mark C. Trudeau**

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

November 6, 2018

By: /s/ Matthew K. Harbaugh

**Matthew K. Harbaugh**

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

November 6, 2018