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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 OR 15(d) of the  
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **April 3, 2015**

**Mallinckrodt public limited company**

(Exact name of registrant as specified in its charter)

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**Ireland**  
(State or other jurisdiction of incorporation)

**001-35803**  
(Commission File Number)

**98-1088325**  
(IRS Employer Identification No.)

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**Damastown, Mulhuddart  
Dublin 15, Ireland**  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **+353 1 880-8180**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

## Item 8.01 Other Events.

Mallinckrodt plc ("the Company") is filing this Current Report on Form 8-K to provide a recast of the presentation of its consolidated and combined financial statements filed with the Securities and Exchange Commission ("the SEC") in the Company's Annual Report on Form 10-K ("the 2014 Form 10-K") for the fiscal year ended September 26, 2014 filed on November 24, 2014 to reflect changes in the Company's reportable segments. As previously disclosed in the Company's Quarterly Report on Form 10-Q for the quarter ended December 26, 2014 filed with the SEC on February 3, 2015, the integration of Questcor Pharmaceuticals, Inc. was substantially completed during the first quarter of fiscal 2015. With this, and given the increased significance of the Specialty Brands business to the Company's results and the expected long-term growth of this business as compared to the Specialty Generics business, the Company has changed its reportable segments. The Company now presents the Specialty Brands and Specialty Generics businesses as reportable segments, along with the continued presentation of Global Medical Imaging as a reportable segment. The Company historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment. These consolidated and combined financial statements and related footnotes, including prior year financial information, are presented to reflect the new reportable segments.

Attached as Exhibit 99.1 are the recast consolidated and combined financial statements and revised notes to the consolidated and combined financial statements, which reflect the change in reportable segments. Only the following notes have been revised and updated from their previous presentation:

- Note 1 - Background and Basis of Presentation
- Note 4 - Discontinued Operations and Divestitures
- Note 5 - Acquisitions and License Agreements
- Note 6 - Restructuring and Related Charges
- Note 11 - Goodwill and Intangible Assets
- Note 20 - Segment and Geographical Data
- Note 23 - Subsequent Events

Additionally, Management's Discussion and Analysis of Financial Condition and Results of Operations and the Business section of the 2014 Form 10-K have been revised and updated from their previous presentation to reflect the change in reportable segments, and are attached as Exhibits 99.2 and 99.3, respectively.

The change in reportable segments had no impact on the Company's historical consolidated and combined financial position, results of operations or cash flows, as reflected in the recast consolidated and combined financial statements contained in Exhibit 99.1 to this Current Report on Form 8-K. The recast consolidated and combined financial statements do not represent a restatement of previously issued consolidated and combined financial statements.

No attempt has been made in this Current Report on Form 8-K to modify or update disclosures presented in the 2014 Form 10-K to reflect events or occurrences after the date of the filing of the 2014 Form 10-K, November 24, 2014. As such, this Current Report on Form 8-K should be read in conjunction with the 2014 Form 10-K and the Company's filings made with the SEC subsequent to the filing of the 2014 Form 10-K, including the Quarterly Report on Form 10-Q for the quarter ended December 26, 2014.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Exhibit</b>
23.1	Consent of Deloitte & Touche LLP.
99.1	Consolidated and Combined Financial Statements from the Company's Annual Report on Form 10-K for the fiscal year ended September 26, 2014, revised solely to reflect the change in segment reporting.
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations from the Company's Annual Report on Form 10-K for the fiscal year ended September 26, 2014, revised solely to reflect the change in segment reporting.
99.3	Business Section from the Company's Annual Report on Form 10-K for the fiscal year ended September 26, 2014, revised solely to reflect the change in segment reporting.
101	The following materials from the Mallinckrodt plc Annual Report on Form 10-K for the fiscal year ended September 26, 2014 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated and Combined Statements of Income, (ii) the Consolidated and Combined Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated and Combined Statements of Cash Flows, (v) the Consolidated and Combined Statements of Shareholders' Equity and (vi) related notes.

**SIGNATURES**

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**MALLINCKRODT PUBLIC LIMITED COMPANY**  
(registrant)

Date: April 3, 2015

By: /s/ Matthew K. Harbaugh

Name: Matthew K. Harbaugh

Title: Senior Vice President and Chief Financial Officer

## EXHIBIT INDEX

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement Nos. 333-189711, 333-189712, 333-189716, and 333-196054 on Form S-8 of our report dated November 24, 2014 (April 3, 2015 as to Footnotes 20 and 23), relating to the consolidated and combined financial statements of Mallinckrodt plc (which report expresses an unqualified opinion and includes an explanatory paragraph related to the fact that Mallinckrodt plc's results for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included within the Mallinckrodt plc's fiscal 2013 results, may not be indicative of the Mallinckrodt plc's future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had it operated as an independent, publicly-traded company for the entirety of the periods presented), appearing in this Form 8-K of Mallinckrodt plc as of April 3, 2015.

/s/ DELOITTE & TOUCHE LLP  
St. Louis, Missouri  
April 3, 2015

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc:

We have audited the accompanying consolidated balance sheets of Mallinckrodt plc and subsidiaries (the "Company") as of September 26, 2014 and September 27, 2013, and the related consolidated and combined statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the three fiscal years in the period ended September 26, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated and combined financial statements present fairly, in all material respects, the financial position of Mallinckrodt plc and subsidiaries as of September 26, 2014 and September 27, 2013, and the results of their operations and their cash flows for each of the three years in the period ended September 26, 2014, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated and combined financial statements, the Company's combined financial statements for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included within the Company's fiscal 2013 results, may not be indicative of the Company's future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had it operated as an independent, publicly-traded company for the entirety of the periods presented.

/s/ DELOITTE & TOUCHE LLP

St. Louis, Missouri

November 24, 2014 (April 3, 2015 as to Footnotes 20 and 23)

**MALLINCKRODT PLC**  
**CONSOLIDATED AND COMBINED STATEMENTS OF INCOME**  
*(in millions, except per share data)*

	Fiscal Year		
	2014	2013	2012
<b>Net sales</b>	\$ 2,540.4	\$ 2,204.5	\$ 2,056.2
Cost of sales	1,337.3	1,179.6	1,091.4
<b>Gross profit</b>	1,203.1	1,024.9	964.8
Selling, general and administrative expenses	842.1	609.9	551.7
Research and development expenses	166.9	165.7	144.1
Separation costs	9.6	74.2	25.5
Restructuring charges, net	128.6	33.2	11.2
Non-restructuring impairment charges	355.6	—	—
Gain on divestiture and license	(15.6)	(2.9)	(2.9)
<b>Operating (loss) income</b>	(284.1)	144.8	235.2
Interest expense	(82.6)	(19.5)	(0.5)
Interest income	1.5	0.3	0.4
Other income, net	1.8	0.8	1.0
<b>Income (loss) from continuing operations before income taxes</b>	(363.4)	126.4	236.1
Provision for (benefit from) income taxes	(44.8)	68.6	94.8
<b>Income (loss) from continuing operations</b>	(318.6)	57.8	141.3
Income (loss) from discontinued operations, net of income taxes	(0.7)	1.0	(6.7)
<b>Net income (loss)</b>	\$ (319.3)	\$ 58.8	\$ 134.6
<b>Basic earnings (loss) per share (Note 8):</b>			
Income (loss) from continuing operations	\$ (4.91)	\$ 1.00	\$ 2.45
Income (loss) from discontinued operations, net of income taxes	(0.01)	0.02	(0.12)
Net income (loss)	(4.92)	1.02	2.33
Basic weighted-average shares outstanding	64.9	57.7	57.7
<b>Diluted earnings (loss) per share (Note 8):</b>			
Income (loss) from continuing operations	\$ (4.91)	\$ 1.00	\$ 2.45
Income (loss) from discontinued operations, net of income taxes	(0.01)	0.02	(0.12)
Net income (loss)	(4.92)	1.02	2.33
Diluted weighted-average shares outstanding	64.9	57.8	57.7

See Notes to Consolidated and Combined Financial Statements.

**MALLINCKRODT PLC**  
**CONSOLIDATED AND COMBINED STATEMENTS OF COMPREHENSIVE INCOME**  
*(in millions)*

	Fiscal Year		
	2014	2013	2012
<b>Net income (loss)</b>	\$ (319.3)	\$ 58.8	\$ 134.6
<b>Other comprehensive income (loss), net of tax</b>			
Currency translation adjustments	(27.6)	1.5	(2.9)
Unrecognized gain (loss) on derivatives, net of \$(0.2), \$- and \$- tax	0.5	(7.3)	—
Unrecognized gain (loss) on benefit plans, net of \$7.3, \$(23.9) and \$4.6 tax	(15.7)	34.2	(10.7)
<b>Total other comprehensive income (loss), net of tax</b>	(42.8)	28.4	(13.6)
<b>Comprehensive income (loss)</b>	\$ (362.1)	\$ 87.2	\$ 121.0

See Notes to Consolidated and Combined Financial Statements.

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

	September 26, 2014	September 27, 2013
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 707.8	\$ 275.5
Accounts receivable, less allowance for doubtful accounts of \$6.6 and \$4.6	545.6	400.8
Inventories	396.6	403.1
Deferred income taxes	165.2	171.1
Prepaid expenses and other current assets	255.8	134.4
Total current assets	2,071.0	1,384.9
Property, plant and equipment, net	949.2	997.4
Goodwill	2,401.9	532.0
Intangible assets, net	7,112.2	422.1
Other assets	330.5	220.2
<b>Total Assets</b>	<b>\$ 12,864.8</b>	<b>\$ 3,556.6</b>
<b>Liabilities and Shareholders' Equity</b>		
Current Liabilities:		
Current maturities of long-term debt	\$ 21.2	\$ 1.5
Accounts payable	128.7	120.9
Accrued payroll and payroll-related costs	125.1	66.5
Accrued royalties	68.0	13.2
Accrued branded rebates	15.1	34.6
Accrued and other current liabilities	546.7	363.5
Total current liabilities	904.8	600.2
Long-term debt	3,951.5	918.3
Pension and postretirement benefits	119.1	108.0
Environmental liabilities	59.9	39.5
Deferred income taxes	2,398.6	310.1
Other income tax liabilities	122.6	153.1
Other liabilities	350.3	171.8
<b>Total Liabilities</b>	<b>7,906.8</b>	<b>2,301.0</b>
Commitments and contingencies (Note 18)		
Shareholders' Equity:		
Preferred shares, \$0.20 par value, 500,000,000 authorized; none issued or outstanding	—	—
Ordinary A shares, €1.00 par value, 40,000 authorized; none issued or outstanding	—	—
Ordinary shares, \$0.20 par value, 500,000,000 authorized; 116,160,353 and 57,713,873 issued; 115,929,588 and 57,713,390 outstanding	23.2	11.5
Ordinary shares held in treasury at cost, 230,765 and 483	(17.5)	—
Additional paid-in capital	5,172.4	1,102.1
Retained earnings	(285.8)	33.5
Accumulated other comprehensive income	65.7	108.5
<b>Total Shareholders' Equity</b>	<b>4,958.0</b>	<b>1,255.6</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 12,864.8</b>	<b>\$ 3,556.6</b>

See Notes to Consolidated and Combined Financial Statements.

**MALLINCKRODT PLC**  
**CONSOLIDATED AND COMBINED STATEMENTS OF CASH FLOWS**  
*(in millions)*

	Fiscal Year		
	2014	2013	2012
<b>Cash Flows From Operating Activities:</b>			
Net income (loss)	\$ (319.3)	\$ 58.8	\$ 134.6
(Income) loss from discontinued operations, net of income taxes	0.7	(1.0)	6.7
Income (loss) from continuing operations	(318.6)	57.8	141.3
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	275.9	139.6	130.9
Share-based compensation	67.7	16.2	10.7
Deferred income taxes	(107.5)	(9.0)	9.0
Non-cash impairment charges	381.2	—	—
Inventory provisions	32.1	15.5	2.7
Other non-cash items	(24.3)	(5.2)	(13.4)
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	(51.3)	(181.2)	(6.8)
Inventories	56.0	27.7	(62.8)
Accounts payable	(32.9)	7.2	(8.3)
Income taxes	(54.8)	60.7	79.4
Accrued and other liabilities	110.5	22.6	(38.7)
Other	39.4	(16.0)	11.8
Net cash provided by operating activities	373.4	135.9	255.8
<b>Cash Flows From Investing Activities:</b>			
Capital expenditures	(127.8)	(147.9)	(144.2)
Acquisitions and intangibles, net of cash acquired	(2,793.8)	(88.1)	(13.2)
Restricted cash	4.1	—	—
Other	26.7	1.3	5.2
Net cash (used in) investing activities	(2,890.8)	(234.7)	(152.2)
<b>Cash Flows From Financing Activities:</b>			
Issuance of external debt	3,043.2	898.1	—
Repayment of external debt and capital leases	(34.8)	(1.3)	(1.3)
Excess tax benefit from share-based compensation	8.9	3.4	1.7
Debt financing costs	(71.7)	(12.0)	—
Net transfers to parent	—	(515.9)	(104.0)
Proceeds from exercise of share options	25.8	0.6	—
Repurchase of shares	(17.5)	—	—
Other	—	0.1	—
Net cash provided by (used in) financing activities	2,953.9	373.0	(103.6)
Effect of currency rate changes on cash	(4.2)	1.3	—
<b>Net increase in cash and cash equivalents</b>	<b>432.3</b>	<b>275.5</b>	<b>—</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>275.5</b>	<b>—</b>	<b>—</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 707.8</b>	<b>\$ 275.5</b>	<b>\$ —</b>
<b>Supplemental Disclosures of Cash Flow Information:</b>			
Cash paid for interest, net	\$ 57.2	\$ 0.8	\$ 0.6
Cash paid for income taxes, net	128.0	15.0	4.9

See Notes to Consolidated and Combined Financial Statements.

**MALLINCKRODT PLC**  
**CONSOLIDATED AND COMBINED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY**  
*(in millions)*

	Ordinary Shares		Treasury Shares		Additional Paid-In Capital	Retained Earnings	Contributed Surplus	Parent Company Investment	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Number	Par Value	Number	Amount						
<b>Balance at September 30, 2011</b>	—	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ 1,690.2	\$ 98.5	\$ 1,788.7
Net income	—	—	—	—	—	—	—	134.6	—	134.6
Currency translation adjustments	—	—	—	—	—	—	—	—	(2.9)	(2.9)
Minimum pension liability, net of tax	—	—	—	—	—	—	—	—	(10.7)	(10.7)
Net transfers to parent	—	—	—	—	—	—	—	(17.8)	—	(17.8)
<b>Balance at September 28, 2012</b>	—	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ 1,807.0	\$ 84.9	\$ 1,891.9
Net income	—	—	—	—	—	33.5	—	25.3	—	58.8
Currency translation adjustments	—	—	—	—	—	—	—	—	1.5	1.5
Change in derivatives, net of tax	—	—	—	—	—	—	—	—	(7.3)	(7.3)
Minimum pension liability, net of tax	—	—	—	—	—	—	—	—	34.2	34.2
Net transfers to parent	—	—	—	—	—	—	—	(515.9)	—	(515.9)
Separation related adjustments	—	—	—	—	—	—	—	(209.9)	(4.8)	(214.7)
Transfer of parent company investment to contributed surplus	—	—	—	—	—	—	1,106.5	(1,106.5)	—	—
Transfer of contributed surplus to distributable reserves	—	—	—	—	1,095.0	—	(1,095.0)	—	—	—
Share options exercised	—	—	—	—	0.6	—	—	—	—	0.6
Share-based compensation	—	—	—	—	6.5	—	—	—	—	6.5
Issuance of ordinary shares	57.7	11.5	—	—	—	—	(11.5)	—	—	—
<b>Balance at September 27, 2013</b>	57.7	\$ 11.5	—	\$ —	\$ 1,102.1	\$ 33.5	\$ —	\$ —	\$ 108.5	\$ 1,255.6
Net loss	—	—	—	—	—	(319.3)	—	—	—	(319.3)
Currency translation adjustments	—	—	—	—	—	—	—	—	(27.6)	(27.6)
Change in derivatives, net of tax	—	—	—	—	—	—	—	—	0.5	0.5
Minimum pension liability, net of tax	—	—	—	—	—	—	—	—	(15.7)	(15.7)
Ordinary shares issued in connection with the Questcor acquisition	57.3	11.4	—	—	3,968.2	—	—	—	—	3,979.6
Share options exercised	0.8	0.2	—	—	25.6	—	—	—	—	25.8
Vesting of restricted shares	0.4	0.1	—	—	(0.1)	—	—	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	8.9	—	—	—	—	8.9
Share-based compensation	—	—	—	—	67.7	—	—	—	—	67.7
Repurchase of ordinary shares	—	—	0.2	(17.5)	—	—	—	—	—	(17.5)
<b>Balance at September 26, 2014</b>	116.2	\$ 23.2	0.2	\$ (17.5)	\$ 5,172.4	\$ (285.8)	\$ —	\$ —	\$ 65.7	\$ 4,958.0

See Notes to Consolidated and Combined Financial Statements.

**MALLINCKRODT PLC**  
**NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS**  
*(dollars in millions, except 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 specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology), along with pain and attention-deficit hyperactivity disorder ("ADHD") for prescription by office- and hospital-based physicians. We also support the diagnosis of disease with nuclear medicine and contrast imaging. Our products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the United States ("U.S.") and we have a commercial presence in approximately 65 countries. The Company believes our experience in the acquisition and management of highly regulated raw materials; deep regulatory expertise; and specialized chemistry, formulation and manufacturing capabilities, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

During the first quarter of fiscal 2015, the integration of Questcor Pharmaceuticals, Inc. ("Questcor") was substantially completed. With this, and given the increased significance of the Specialty Brands business to the Company's results and the expected long-term growth of this business as compared to the Specialty Generics business, the Company has changed its reportable segments. The Company now presents the Specialty Brands and Specialty Generics businesses as reportable segments, along with the continued presentation of Global Medical Imaging as a reportable segment. The Company historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment. Prior year amounts have been recast to conform to current presentation. The three reportable segments are further described below:

- *Specialty Brands* produces and markets branded pharmaceuticals and biopharmaceuticals;
- *Specialty Generics* produces specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- *Global Medical Imaging* manufactures and markets contrast media and delivery systems ("CMDs") and radiopharmaceuticals (nuclear medicine).

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the Pharmaceuticals business of Covidien plc ("Covidien"). On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the Pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing its legal separation from Covidien ("the Separation").

***Basis of Presentation***

The accompanying consolidated and combined financial statements reflect the consolidated financial position of the Company as an independent, publicly-traded company for periods subsequent to June 28, 2013, and as a combined reporting entity of Covidien, including operations relating to Covidien's Pharmaceuticals business, for periods prior to June 28, 2013.

The consolidated and combined financial statements have been prepared in U.S. dollars and in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of the consolidated and combined 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 consolidated and combined financial statements include the accounts of the Company, its wholly-owned subsidiaries and entities in which they own or control more than fifty percent of the voting shares, or have the ability to control through similar rights. The results of entities disposed of are included in the consolidated and combined financial statements up to the date of disposal and, where appropriate, these operations have been reflected as discontinued operations. Divestitures of product lines not representing businesses have been reflected in operating income. All intercompany balances and transactions have been eliminated in consolidation and, in the opinion of management, all normal recurring adjustments necessary for a fair presentation have been included in the results reported.

Certain amounts from prior years have been separately presented to conform to the current year presentation, such as the separate presentation of accrued royalties in the consolidated balance sheets, which had no impact on previously reported net income.

The Company's combined financial statements for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included within the Company's fiscal 2013 results, may not be indicative of its future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had it operated as an independent, publicly-traded company for the entirety of the periods presented, including as a result of changes in the Company's capitalization in connection with the Separation. The combined financial statements for periods prior to June 28, 2013 include expense allocations for certain functions provided by Covidien, including, but not limited to, general corporate expenses related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. These expenses were allocated to the Company on the basis of direct usage when identifiable, with the remainder allocated on the basis of operating expenses, headcount or other measures. The amounts allocated were \$39.6 million and \$49.2 million for fiscal 2013 and 2012, respectively, and were included within selling, general and administrative expenses. Management considers the bases on which the expenses have been allocated to reasonably reflect the utilization of services provided to, or the benefit received by, the Company during the periods presented; however, the allocations may not reflect the expense the Company would have incurred as an independent, publicly-traded company. Actual costs that may have been incurred if the Company had been a standalone company would depend on a number of factors, including organizational structure, what functions were outsourced or performed by employees, and strategic decisions made in areas such as information technology and infrastructure. The Company is unable to determine what those costs would have been had the Company been independent during the applicable periods. Following the Separation, the Company has performed these functions using its own resources or purchased services, certain of which are being provided by Covidien during a transitional period pursuant to a transition services agreement dated June 28, 2013, between Mallinckrodt and Covidien, particularly in relation to areas outside the U.S. The terms and prices on which such services are rendered may not be as favorable as those that were allocated to the Company by Covidien. The Company expects to substantially reduce the level of service provided by Covidien in fiscal 2015 as the Company has substantially completed the implementation of information systems in jurisdictions outside the U.S. and terminated the transition services agreement during the first quarter of fiscal 2015.

The combined balance sheets prior to June 28, 2013 include certain assets and liabilities that have historically been recorded at the Covidien corporate level but are specifically identifiable or otherwise allocable to the Company. Covidien's debt and related interest expense were not allocated to the Company since the Company was not the legal obligor of such debt and Covidien's borrowings were not directly attributable to the Company's business. Debt incurred by the Company directly has been included in the combined financial statements. Intercompany transactions between the Company and Covidien, prior to the Separation, have been included in the combined financial statements and were considered to be effectively settled for cash at the time the transaction was recorded. The total net effect of the settlement of these intercompany transactions was reflected in the combined statements of cash flows as a financing activity and in the combined balance sheet as parent company investment.

Prior to June 28, 2013, Covidien's investment in the Pharmaceuticals business is shown as parent company investment in the combined financial statements. On June 28, 2013, Covidien completed a distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien. Upon completion of the Separation, the Company had 57,694,885 ordinary shares outstanding at a par value of \$0.20 per share. After Separation adjustments were recorded, the remaining parent company investment balance, which included all earnings prior to the Separation, was transferred to contributed surplus.

Under Irish law, the Company can only pay dividends and repurchase shares out of distributable reserves, as discussed further in the Company's information statement filed with the U.S. Securities and Exchange Commission ("SEC") as Exhibit 99.2 to the Company's Current Report on Form 8-K filed on July 1, 2013. Upon completion of the Separation, the Company did not have any distributable reserves. On July 22, 2013, the Company filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of the Company's share premium so that it can be treated as distributable for the purposes of Irish law. On September 9, 2013, the High Court of Ireland approved this petition and the High Court's order and minutes were filed with the Registrar of Companies. Upon this filing, the Company's share premium is treated as distributable reserves and the share premium balance was reclassified into additional paid-in capital within the consolidated balance sheet. Net income subsequent to the Separation has been included in retained earnings and is included in distributable reserves.

### ***Preferred Shares***

Mallinckrodt is authorized to issue 500,000,000 preferred shares, par value of \$0.20 per share, none of which were issued and outstanding at September 26, 2014. Rights as to dividends, return of capital, redemption, conversion, voting and otherwise with respect to these shares may be determined by Mallinckrodt's board of directors on or before the time of issuance. In the event of the liquidation of the Company, the holders of any preferred shares then outstanding would, if issued on such terms that they carry a preferential distribution entitlement on liquidation, be entitled to payment to them of the amount for which the preferred shares were subscribed and any unpaid dividends prior to any payment to the ordinary shareholders.

## ***Fiscal Year***

The Company reports its results based on a "52-53 week" year ending on the last Friday of September. Fiscal 2014, 2013 and 2012 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2014, 2013 and 2012 refer to the Company's fiscal years ended September 26, 2014, September 27, 2013 and September 28, 2012, respectively.

## **2. Summary of Significant Accounting Policies**

### ***Revenue Recognition***

The Company recognizes revenue for product sales when title and risk of loss have transferred from the Company to the buyer, which may be upon shipment or upon delivery to the customer site, based on contract terms or legal requirements in non-U.S. jurisdictions. The Company sells products directly to retail pharmacies and end user customers and through distributors who resell the products to retail pharmacies, institutions and end user customers. Chargebacks and rebates represent credits that are provided to certain distributors and customers for either the difference between the Company's contracted price with a customer and the distributor's invoice price paid to the Company or for contractually agreed volume price discounts. When the Company recognizes net sales, it simultaneously records an adjustment to revenue for estimated chargebacks, rebates, product returns and other sales deductions. These provisions are estimated based upon 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. The Company adjusts these reserves to reflect differences between estimated activity and actual experience. Such adjustments impact the amount of net sales recognized by the Company in the period of adjustment.

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

### ***Shipping and Handling Costs***

Shipping costs, which are costs incurred to physically move product from the Company's premises to the customer's premises, are classified as selling, general and administrative expenses. Handling costs, which are costs incurred to store, move and prepare product for shipment, are classified as cost of sales. Shipping costs included in selling, general and administrative expenses were \$55.8 million, \$56.5 million and \$59.1 million in fiscal 2014, 2013 and 2012, respectively.

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

Internal research and development costs are expensed as incurred. Research and development expenses include salary and benefits, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services and other costs.

Upfront and milestone payments made to third parties under license arrangements are expensed as incurred up to the point of regulatory approval of the product. Milestone payments made to third parties upon or subsequent to regulatory approval are capitalized as an intangible asset and amortized to cost of sales over the estimated useful life of the related product.

### ***Advertising***

Advertising costs are expensed when incurred. Advertising expense was \$7.4 million, \$7.5 million and \$8.8 million in fiscal 2014, 2013 and 2012, respectively, and is included in selling, general and administrative expenses.

### ***Currency Translation***

For the Company's non-U.S. subsidiaries that transact in a functional currency other than U.S. dollars, assets and liabilities are translated into U.S. dollars using fiscal year-end exchange rates. Revenues and expenses are translated at the average exchange rates in effect during the related month. The net effect of these translation adjustments is shown in the consolidated and combined financial statements as a component of accumulated other comprehensive income. For subsidiaries operating in highly inflationary environments or where the functional currency is different from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date the assets and liabilities were acquired or assumed, while monetary assets and liabilities are translated at fiscal year-end exchange rates. Translation adjustments of these subsidiaries are included in net income. Gains and losses resulting from foreign currency transactions are included in net income. During fiscal 2014 and 2013, \$0.6 million of foreign currency gains and \$14.2 million of foreign currency losses, respectively, were included within net income. The Company entered into

derivative instruments to mitigate the exposure of movements in certain of these foreign currency transactions and recognized a \$7.9 million loss in fiscal 2014 and a \$10.5 million gain in fiscal 2013. The impact of foreign currency transactions and derivatives was not material to net income in fiscal 2012.

### **Cash and Cash Equivalents**

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 to the Company of three months or less, as cash and cash equivalents.

### **Accounts Receivable and Allowance for Doubtful Accounts**

Trade accounts receivable are presented net of an allowance for doubtful accounts. The allowance for doubtful accounts reflects an estimate of losses inherent in the Company's accounts receivable portfolio determined on the basis of historical experience, specific allowances for known troubled accounts and other available evidence. Accounts receivable are written off when management determines they are uncollectible. Trade accounts receivable are also presented net of reserves related to chargebacks and non-branded rebates payable to customers for whom we have trade accounts receivable and the right of offset exists.

### **Inventories**

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

### **Property, Plant and Equipment**

Property, plant and equipment are stated at cost. Major renewals and improvements are capitalized, while routine maintenance and repairs are expensed as incurred. Depreciation for property, plant and equipment assets, other than land and construction in process, is generally based upon the following estimated useful lives, using the straight-line method:

Buildings	10	to	45 years
Leasehold improvements	1	to	20 years
Capitalized software	1	to	10 years
Machinery and equipment	1	to	20 years

The Company capitalizes certain computer software and development costs incurred in connection with developing or obtaining software for internal use.

Upon retirement or other disposal of property, plant and equipment, the cost and related amount of accumulated depreciation are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds is included in net income.

The Company assesses the recoverability of assets or asset groups using undiscounted cash flows whenever events or circumstances indicate that the carrying value of an asset or asset group may not be recoverable. If an asset or asset group is found to be impaired, the amount recognized for impairment is equal to the difference between the carrying value of the asset or asset group and its fair value.

### **Acquisitions**

Amounts paid for acquisitions are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The Company then allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets, including purchased research and development. The fair value of identifiable intangible assets is based on detailed valuations. The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

The Company's purchased research and development represents the estimated fair value as of the acquisition date of in-process projects that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval.

The fair value of in-process research and development ("IPR&D") is determined using the discounted cash flow method. In determining the fair value of IPR&D, the Company considers, among other factors, appraisals, the stage of completion of the projects, the technological feasibility of the projects, whether the projects have an alternative future use and the estimated residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used is determined at the time of acquisition and includes a rate of return which accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized.

The fair value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset is charged to expense.

### ***Goodwill and Other Intangible Assets***

Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. The Company tests goodwill for impairment during the fourth quarter of each fiscal year, or more frequently if impairment indicators arise. The impairment tests is comprised of a two-step approach. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units. The Company estimates the fair value of its reporting units through internal analyses and valuation, utilizing an income approach (a level three measurement technique) based on the present value of future cash flows. If the carrying value of a reporting unit exceeds its fair value, the Company will perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. The implied fair value of goodwill is determined in the same manner that the amount of goodwill recognized in a business combination is determined, with the Company allocating the fair value of a reporting unit to all of the assets and liabilities of that unit, including intangible assets, as if the reporting unit had been acquired in a business combination. Any excess of the value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill.

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost. Intangible assets with finite useful lives are subsequently amortized generally using the straight-line method over the following estimated useful lives of the assets, except for customer relationships which are amortized over the estimated pattern of benefit from these relationships:

Completed technology	5	to	25 years
License agreements	8	to	30 years
Trademarks	3	to	30 years
Customer relationships			12 years

Amortization expense related to completed technology and certain other intangible assets is included in cost of sales, while amortization expense related to intangible assets that contribute to the Company's ability to sell, market and distribute products is included in selling, general and administrative expenses.

When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset, or the asset group they are part of, to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets, or the asset group they are part of, with their carrying value. The fair value of the intangible asset, or the asset group they are part of, is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, or the asset group they are part of, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the fair value of the asset. The Company assesses the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. The Company annually tests the indefinite-lived intangible assets for impairment by comparing the fair value of the assets, estimated using an income approach, with their carrying value and records an impairment when the carrying value exceeds the fair value.

## ***Contingencies***

The Company is subject to various patent, product liability, government investigations, environmental liability and other legal proceedings in the ordinary course of business. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company discounts environmental liabilities using a risk-free rate of return when the obligation is fixed or reasonably determinable. The impact of the discount in the consolidated balance sheets was not material in any period presented. Legal fees, other than those pertaining to environmental and asbestos matters, are expensed as incurred. Insurance recoveries related to potential claims are recognized up to the amount of the recorded liability when coverage is confirmed and the estimated recoveries are probable of payment. Assets and liabilities are not netted for financial statement presentation.

## ***Asset Retirement Obligations***

The Company establishes asset retirement obligations for certain assets at the time they are installed. The present value of an asset retirement obligation is recorded as a liability when incurred. The liability is subsequently adjusted in future periods as accretion expense is recorded or as revised estimates of the timing or amount of cash flows required to retire the asset are obtained. The corresponding asset retirement costs are capitalized as part of the carrying value of the related long-lived asset and depreciated over the asset's useful life. The Company's obligations to decommission two facilities upon a cessation of its radiological licensed operations are primarily included on the consolidated balance sheet as other liabilities.

## ***Share-Based Compensation***

The Company recognizes the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards. That cost is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (generally the vesting period). For more information about our share-based awards, refer to Note 14.

## ***Income Taxes***

Income taxes for periods prior to the Separation were calculated on a separate tax return basis (inclusive of certain loss benefits), although the Company's operations had historically been included in Covidien's U.S. federal and state tax returns or the tax returns of non-U.S. jurisdictions. Accordingly, the income taxes presented for periods prior to June 28, 2013 do not necessarily reflect the results that would have occurred as an independent, publicly-traded company. With the exception of certain non-U.S. entities, the Company did not maintain taxes payable to or from Covidien and the Company was deemed to settle the annual current tax balances immediately with the legal tax-paying entities in the respective jurisdictions. These settlements were reflected as changes in parent company investment.

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been reflected in the consolidated and combined financial statements. Deferred tax assets and liabilities are determined based on the differences between the book and tax bases of assets and liabilities and operating loss carryforwards, using tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided to reduce net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not expected to be realized on the uncertain tax position, an income tax liability is established. Interest and penalties on income tax obligations, associated with uncertain tax positions, are included in the provision for income taxes. Interest on transactions treated as installment sales are included within interest expense.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across the Company's global operations. Due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from current estimates of the tax liabilities. If the Company's estimate of tax liabilities proves to be less than the ultimate assessment, an additional charge to expense would result. If payment of these amounts ultimately proves to be less than the recorded amounts, the reversal of the liabilities may result in income tax benefits being recognized in the period when it is determined that the liabilities are no longer necessary. A significant portion of these potential tax liabilities are recorded in other income tax liabilities on the consolidated balance sheets as payment is not expected within one year.

### **Parent Company Investment**

Parent company investment in periods prior to the Separation represents Covidien's historical investment in the Company, the Company's accumulated net earnings after income taxes for periods prior to that date, and the net effect of transactions with and allocations from Covidien.

### **3. Recently Issued Accounting Standards**

The Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-11 in December 2011, "Disclosures about Offsetting Assets and Liabilities," which was clarified in January 2013 by ASU 2013-01 "Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities." This guidance provides new disclosure requirements about instruments and transactions eligible for offset in the statement of financial position, as well as instruments and transactions subject to an agreement similar to a netting agreement, to enable users of financial statements to understand the effects or potential effects of those arrangements on an entity's financial position. The guidance was effective for the Company in the first quarter of fiscal 2014. The adoption did not have a material impact on the Company's financial condition, results of operations and cash flows.

FASB issued ASU 2013-02, "Reporting Amounts Classified out of Accumulated Other Comprehensive Income," in February 2013. This guidance requires an entity to present, either on the face of the statement of income or separately in the notes to the financial statements, the effects on net income of significant amounts reclassified out of each component of accumulated other comprehensive income, if those amounts are required to be reclassified to net income in their entirety in the same reporting period. For other amounts not required to be reclassified to net income in their entirety, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. The guidance was effective for the Company in the first quarter of fiscal 2014. The adoption did not have a material impact on the Company's financial condition, results of operations and cash flows.

FASB issued ASU 2013-04, "Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date," in February 2013. This update provides guidance for the recognition, measurement and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date, except for obligations addressed within existing guidance. An entity is required to measure those obligations as the sum of the amount the entity has agreed to pay on the basis of its arrangement among its co-obligors, and any additional amounts it expects to pay on behalf of its co-obligors. The guidance also requires the entity to disclose the nature and amount of those obligations. The guidance is effective for the Company in the first quarter of fiscal 2015. Based on the assessment to date, the Company does not believe the adoption of this pronouncement will have a material impact to the Company's financial condition, results of operations and cash flows.

FASB issued ASU 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," in July 2013. This update provides guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss or a tax credit carryforward exists, to eliminate diversity in practice in the presentation of unrecognized tax benefits in those instances. Except in certain circumstances, an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward. This guidance is effective for the Company in the first quarter of fiscal 2015. The Company has completed its assessment and does not believe the adoption of this pronouncement will have a material impact to the Company's financial condition, results of operations and cash flows.

FASB issued ASU 2014-08, "Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity," in April 2014. Under the new guidance, only disposals representing a strategic shift in a company's operations and financial results should be reported as discontinued operations, with expanded disclosures. In addition, disclosure of the pre-tax income attributable to a disposal of a significant part of an organization that does not qualify as a discontinued operation is required. This guidance is effective for the Company in the first quarter of fiscal 2016, with early adoption permitted. The Company did not have any recent significant disposals. The Company will assess the impact of the pronouncement to prospective disposals, if applicable, disclosures in future filings and the potential early adoption of the standard.

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 FASB and the International Accounting Standards Board to clarify the principles for recognizing revenue and develop a common revenue standard for U.S. 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; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. The guidance is effective for the Company in the first quarter of fiscal 2018. Early adoption is not permitted for public companies. The Company will assess the impact of the pronouncement.

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

##### ***Discontinued Operations***

During fiscal 2010, the Specialty Chemicals business (formerly known as "Mallinckrodt Baker") was sold because its products and customer bases were not aligned with the Company's long-term strategic objectives. This business met the discontinued operations criteria and, accordingly, was included in discontinued operations for all periods presented. During fiscal 2014, 2013 and 2012, the Company recorded a loss of \$0.7 million, a gain of \$1.0 million, and a loss of \$6.7 million, respectively. These gains and losses were primarily related to the indemnification obligations to the purchaser, which are discussed in Note 17.

##### ***License of Intellectual Property***

The Company was involved in patent disputes with a counterparty relating to certain intellectual property relevant to extended-release oxymorphone. In December 2013, the counterparty agreed to pay the Company an upfront cash payment of \$4.0 million and contractually obligated future payments of \$8.0 million through July 2018, in exchange for the withdrawal of all claims associated with the intellectual property and a license to utilize the Company's intellectual property. The Company has completed the earnings process associated with the agreement and recorded an \$11.7 million gain, included within gains on divestiture and license, during fiscal 2014.

##### ***Divestitures***

During fiscal 2011, the Company sold the rights to market TussiCaps™ extended-release capsules, a cough suppressant, for an upfront cash payment of \$11.5 million. As a result of this transaction, the Company recorded an \$11.1 million gain. The purchaser also may be obligated to make contingent payments to the Company of up to \$11.5 million from December 31, 2011 through September 30, 2015, payable in equal quarterly installments until such time as a new competitive generic product is introduced into the market. In addition, the Company would receive a \$1.0 million contingent payment if certain sales targets are achieved over the same time period. The Company received \$2.9 million of contingent payments during fiscal 2014, 2013 and 2012.

#### **5. Acquisitions and License Agreements**

##### **Business Acquisitions**

##### ***Questcor Pharmaceuticals***

On August 14, 2014, the Company acquired all of the outstanding common stock of Questcor, a biopharmaceutical company, for total consideration of approximately \$5.9 billion, comprised of cash consideration of \$30.00 per share, 0.897 ordinary shares of the Company for each share of Questcor common stock owned and the portion of outstanding equity awards deemed to have been earned as of August 14, 2014 ("the Questcor Acquisition"). The acquisition was funded through an issuance of approximately 57 million common shares, proceeds from the issuance of \$900.0 million aggregate principle of senior unsecured notes, proceeds from the issuance of \$700.0 million senior secured term loan facility, \$150.0 million of cash from a receivable securitization program, as further discussed in Note 12, and cash on hand. H.P. Acthar® Gel (repository corticotropin injection) ("Acthar"), Questcor's primary product, is focused on the treatment of patients with serious, difficult-to-treat autoimmune and rare diseases. Acthar is an injectable drug that is approved by the U.S. Food and Drug Administration ("FDA") for use in 19 indications, including the areas of neurology, rheumatology, nephrology and pulmonology. Questcor also supplies specialty contract manufacturing services to the global pharmaceutical and biotechnology industry through its wholly-owned subsidiary, BioVectra Inc. ("BioVectra")

### ***Cadence Pharmaceuticals***

On March 19, 2014, the Company acquired all of the outstanding common stock of Cadence Pharmaceuticals, Inc. ("Cadence"), a biopharmaceutical company focused on commercializing products principally for use in the hospital setting, for total consideration of \$14.00 per share in cash, or approximately \$1.3 billion ("the Cadence Acquisition"). The acquisition was primarily funded through a \$1.3 billion senior secured term loan credit facility, as further discussed in Note 12. Cadence's sole product, OFIRMEV® (acetaminophen) injection ("Ofirmev"), is a proprietary intravenous formulation of acetaminophen for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. The Cadence Acquisition added a growth product to the Specialty Brands segment and provides the Company an opportunity to expand its reach into the adjacent hospital market, in which Cadence had established a presence.

### ***CNS Therapeutics***

On October 1, 2012, the Company acquired all the outstanding equity of CNS Therapeutics, Inc. ("CNS Therapeutics"), a specialty pharmaceuticals company focused on developing and commercializing intrathecal products for site-specific administration to the central nervous system to treat neurological disorders and intractable chronic pain, for total consideration, net of cash acquired, of \$95.0 million. The total consideration was comprised of an upfront cash payment of \$88.1 million (net of cash acquired of \$3.6 million) and the fair value of contingent consideration of \$6.9 million. This contingent consideration, which could potentially total a maximum of \$9.0 million, is discussed further in Note 19. The acquisition of CNS Therapeutics expanded the Company's branded pharmaceuticals portfolio and supports the Company's strategy of leveraging its therapeutic expertise and core capabilities in manufacturing, regulatory and commercialization to serve patients. With the acquisition, the Company now offers products for use in the management of severe spasticity of cerebral or spinal origin with a research and development pipeline of an additional presentation and concentration of GABLOFEN® (baclofen injection) ("Gablofen"), as well as other investigational pain products for intrathecal administration.

### ***Fair Value Allocation***

The following amounts represent the preliminary allocation of the fair value of the identifiable assets acquired and liabilities assumed for the Cadence Acquisition and Questcor Acquisition and final allocation of the fair value of the identifiable assets acquired and liabilities assumed for CNS Therapeutics acquisition:

	<b>Questcor Pharmaceuticals</b>	<b>Cadence Pharmaceuticals</b>	<b>CNS Therapeutics</b>
Cash	\$ 445.1	\$ 43.2	\$ 3.6
Inventory	67.9	21.0	—
Intangible assets	5,601.1	1,300.0	91.9
Goodwill (non-tax deductible)	1,771.5	318.1	24.5
Other assets, current and non-current	273.9	18.0	9.7
<b>Total assets acquired</b>	<b>8,159.5</b>	<b>1,700.3</b>	<b>129.7</b>
<b>Current liabilities</b>	<b>159.8</b>	<b>60.1</b>	<b>4.0</b>
Unpaid purchase consideration (current)	128.8	—	—
Other liabilities (non-current)	183.7	18.7	—
Deferred tax liabilities, net (non-current)	1,900.7	292.3	27.1
Contingent consideration (non-current)	—	—	6.9
<b>Total liabilities assumed</b>	<b>2,373.0</b>	<b>371.1</b>	<b>38.0</b>
<b>Net assets acquired</b>	<b>\$ 5,786.5</b>	<b>\$ 1,329.2</b>	<b>\$ 91.7</b>

The following reconciles the total consideration to net assets acquired:

	Questcor Pharmaceuticals	Cadence Pharmaceuticals	CNS Therapeutics
Total consideration, net of cash	\$ 5,470.2	\$ 1,286.0	\$ 95.0
Plus: cash assumed in acquisition	445.1	43.2	3.6
Total consideration	5,915.3	1,329.2	98.6
Less: unpaid purchase consideration	(128.8)	—	—
Less: contingent consideration	—	—	(6.9)
Net assets acquired	<u>\$ 5,786.5</u>	<u>\$ 1,329.2</u>	<u>\$ 91.7</u>

Intangible assets acquired consist of the following:

**Questcor Pharmaceuticals**

	Amount	Weighted-Average Amortization Period
Completed technology	\$ 5,343.3	18 years
Trademark	5.2	13 years
Customer relationships	34.3	12 years
In-process research and development	218.3	Non-Amortizable
	<u>\$ 5,601.1</u>	

The completed technology intangible asset relates to Acthar. The trademark and customer relationship intangible assets relate to BioVectra. The in-process research and development relates to the development of Synacthen®, a synthetic pharmaceutical product. The fair value of the intangible assets were determined using the income approach, which is a valuation technique that provides an estimate of the fair value of the asset based on market participant expectations of the cash flows an asset would generate. The cash flows were discounted at various discount rates commensurate with the level of risk associated with each asset or their projected cash flows. Completed technology, customer relationships, trademark and in-process research and development intangibles utilized discount rates of 14.5%, 10.0%, 10.0% and 16.0%, respectively. The in-process research and development discount rate was developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in the 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 the assembled workforce, anticipated synergies and the tax status of the transaction. The goodwill is not deductible for U.S. income tax purposes. The majority of assets acquired are included within the Company's Specialty Brands segment.

**Cadence Pharmaceuticals**

	Amount	Amortization Period
Completed technology	\$ 1,300.0	8 years

The completed technology intangible asset relates to Ofirmev, the rights to which have been in-licensed from Bristol-Myers Squibb Company ("BMS"). The fair value of the intangible asset was determined using the income approach, which is a valuation technique that provides an estimate of the fair value of the asset based on market participant expectations of the cash flows an asset would generate. The cash flows were discounted at a 13.0% rate. For more information on the BMS license agreement, refer to "License Agreement" below. The excess of purchase price over net tangible and intangible assets acquired resulted in goodwill, which represents the assembled workforce, anticipated synergies 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.

**CNS Therapeutics**

	Amount	Weighted-Average Amortization Period
Completed technology	\$ 73.1	13 years
Trademark	0.2	3 years
In-process research and development	18.6	Non-Amortizable
	<u>\$ 91.9</u>	

The in-process research and development projects primarily relate to certain investigational intrathecal pain products. As of the date of acquisition, these pain products were in various stages of development, with further development, testing, clinical trials and regulatory submission required in order to bring them to market. At the acquisition date, the total cost to complete these products was estimated to be approximately \$18.0 million. The Company expects that regulatory approvals will occur between 2015 and 2018. The valuation of the in-process research and development was determined using, among other factors, appraisals primarily based on the discounted cash flow method. The cash flows were discounted at a 35% rate, which was considered commensurate with the risks and stages of development of the pain products. Future residual cash flows that could be generated from the products were determined based upon management's estimate of future revenue and expected profitability of the products. These projected cash flows were then discounted to their present values taking into account management's estimate of future expenses that would be necessary to bring the products to completion. The goodwill is not deductible for U.S. income tax purposes. The majority of assets acquired are included within the Company's Specialty Brands segment.

*Financial Results* - The amount of net sales and earnings included in the Company's fiscal 2014 results for each of the fiscal 2014 acquisitions discussed above were as follows:

<b>Net Sales</b>	
Questcor	\$ 129.2
Cadence	124.4
	<u>\$ 253.6</u>
<b>Operating income (loss)</b>	
Questcor	\$ 17.4
Cadence	(66.9)
	<u>\$ (49.5)</u>

*Acquisition-Related Costs* - Acquisition-related costs incurred in fiscal 2014 for each of the fiscal 2014 acquisitions discussed above were as follows:

Questcor	47.5
Cadence	17.6
	<u>\$ 65.1</u>

*Unaudited Pro Forma Financial Information* - The following unaudited pro forma information presents a summary of the results of operations for the periods indicated as if the Questcor Acquisition and Cadence Acquisition had been completed as of September 29, 2012. The pro forma financial information is based on the historical financial information for Mallinckrodt, Questcor and Cadence, along with certain pro forma adjustments. These pro forma adjustments consist primarily of:

- non-recurring costs related to the step-up in fair value of acquired inventory and transaction costs related to the acquisitions;
- increased amortization expense related to the intangible assets acquired in the acquisitions;
- elimination of direct acquisition transaction costs from the period of acquisition;
- increased interest expense to reflect the variable-rate term loan and revolving credit facility entered into in connection with the acquisition of Cadence (utilizing the interest rate in effect at September 26, 2014 of 3.50%) and the fixed-rate senior unsecured notes and variable-rate term loan entered into in connection with the acquisition of Questcor (utilizing the interest rate in effect at September 26, 2014 of 3.50%), including interest and amortization of deferred financing costs and original issue discount; and
- the related income tax effects.

The following unaudited pro forma information has been prepared for comparative purposes only and is not necessarily indicative of the results of operations as they would have been had the acquisition occurred on the assumed date, nor is it necessarily an indication of future operating results. In addition, the unaudited pro forma information does not reflect the cost of any integration activities, benefits from any synergies that may be derived from the acquisition or revenue growth that may be anticipated.

	2014	2013
Net sales	\$ 3,487.1	\$ 3,015.5
Net income (loss)	(326.8)	(61.5)
Basic earnings (loss) per share	\$ (2.84)	\$ (0.54)
Diluted earnings (loss) per share	(2.84)	(0.54)

The consolidated and combined statement of income for fiscal 2013 contained \$29.2 million of net sales of intrathecal products added to the Company's portfolio from the CNS Therapeutics acquisition. Acquisition and integration costs included in the periods presented were not material. The Company does not believe that the results of operations for the periods presented would have been materially different had the acquisition taken place at the beginning of the first period presented.

## Product Acquisitions

### *Roxicodone*

In August 2012, the Company's Specialty Brands segment paid \$13.2 million under an agreement to acquire all of the rights to Xanodyne Pharmaceuticals, Inc.'s Roxicodone®, which was capitalized as an intangible asset. Roxicodone is an immediate-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. Roxicodone is the Reference Listed Drug for one of the Company's generic products and is important to the Company's product pipeline. Sales of Roxicodone during fiscal 2014 and 2013 were \$13.1 million and \$8.4 million, respectively. There are no ongoing royalty payments under this agreement.

## License Agreements

### *Bristol-Myers Squibb*

As part of the Cadence Acquisition, the Company acquired the exclusive development and commercialization rights to Ofirmev in the U.S. and Canada, as well as the rights to the patents and technology, which were originally in-licensed by Cadence from BMS in March 2006. BMS sublicensed these rights to Cadence under a license agreement with SCR Pharmatop S.A. ("Pharmatop"), and the Company has the right to grant sublicenses to third parties. Under this license agreement, the Company may be obligated to make future milestone payments of up to \$25.0 million upon the achievement of certain levels of net sales, in addition to on-going royalties on the sales of the product. From the date of acquisition to the end of fiscal 2014, the Company paid royalties of \$13.2 million.

### *Exalgo*

In 2009, the Company's Specialty Brands segment acquired the rights to market and distribute the pain management drug EXALGO® (hydromorphone HCl) extended-release tablets (CII) ("Exalgo") in the U.S. Under the license agreement, the Company is obligated to make additional payments of up to \$73.0 million based on the successful completion of specified development and regulatory milestones. Through fiscal 2014, \$65.0 million of additional payments have been made, with \$55.0 million being capitalized as an intangible asset. The amount capitalized related to the FDA approval of the New Drug Application ("NDA") for the 8 mg, 12 mg and 16 mg tablet dosage forms of Exalgo. During fiscal 2012 the Company received FDA approval to market a 32 mg tablet dosage form. The Company is also required to pay royalties on sales of the product. During fiscal 2014, 2013 and 2012, the Company paid royalties of \$22.0 million, \$24.0 million and \$16.1 million, respectively.

In January 2014, the Company purchased royalty rights associated with Exalgo for \$7.2 million, which have been classified as an intangible asset.

## Depomed

In 2009, the Company's Specialty Brands segment licensed worldwide rights to utilize Depomed, Inc.'s ("Depomed") Acuform™ gastric retentive drug delivery technology for the exclusive development of four products. Under this license agreement, the Company may be obligated to pay up to \$64.0 million in development milestone payments. Through fiscal 2014, approximately \$22.0 million of these payments have been made by the Company. During fiscal 2014, upon approval by the FDA for XARTEMIS™ XR (oxycodone HCl and acetaminophen) extended release tablets CII ("Xartemis XR"), the Company made a milestone payment of \$10.0 million, which has been capitalized as an intangible asset. In addition, subsequent to FDA's acceptance of our NDA for MNK-155 in July 2014, the Company made a milestone payment of \$5.0 million, which was expensed as incurred as they were made prior to regulatory approval. During fiscal 2013 and 2012, milestone payments of \$5.0 million and an insignificant amount, respectively, were expensed as incurred as they were also made prior to regulatory approval. In addition, an insignificant amount of royalties have been paid through fiscal 2014.

## Pennsaid

In 2009, the Company's Specialty Brands segment entered into a licensing agreement which granted it rights to market and distribute PENNSAID® 1.5% w/w and PENNSAID® 2% w/w ("Pennsaid") a formulation of diclofenac sodium topical solution which was approved in February 2014 by the FDA and indicated for the treatment of pain associated with osteoarthritis of the knee. The Company was responsible for all future development activities and expenses and were required to make milestone payments of up to \$120.0 million based upon the successful completion of specified regulatory and sales milestones. Through fiscal 2014, \$15.0 million of these payments were made, all of which were capitalized as an intangible asset as the payment related to the fiscal 2010 FDA approval of the Pennsaid NDA. The Company is also required to pay royalties on sales of the products under this agreement. During fiscal 2014, 2013 and 2012, the Company paid royalties of \$4.3 million, \$3.9 million and \$7.5 million, respectively. For further discussion regarding Pennsaid, refer to Note 18.

During the fourth quarter of fiscal 2014, the Company reached an agreement in principle with Nuvo Research Inc. ("Nuvo") to settle various claims associated with our license of Pennsaid obtained from Nuvo. As part of the legal settlement, the Company agreed to return the license to Nuvo, which resulted in the Company recording an impairment of \$11.1 million during the fourth quarter of fiscal 2014. For more information on the Nuvo matter, refer to Note 18.

## 6. Restructuring and Related Charges

During fiscal 2013, the Company launched a restructuring program designed to improve its cost structure ("the 2013 Mallinckrodt Program"). The 2013 Mallinckrodt Program includes actions across all segments, as well as within corporate functions. The Company expects to incur charges of \$100.0 million to \$125.0 million under this program as the specific actions required to execute on these initiatives are identified and approved, most of which are expected to be incurred by the end of fiscal 2016.

Prior to Separation, Covidien initiated restructuring programs, which also applied to its Pharmaceutical business. These programs were substantially completed as of September 26, 2014.

Net restructuring and related charges by segment are as follows:

	Fiscal Year		
	2014	2013	2012
Specialty Brands	\$ 57.0	\$ 5.2	\$ 0.6
Specialty Generics	9.8	11.2	10.7
Global Medical Imaging	60.9	16.4	7.9
Corporate	1.4	3.0	—
Restructuring and related charges, net	129.1	35.8	19.2
Less: accelerated depreciation	(0.5)	(2.6)	(8.0)
Restructuring charges, net	\$ 128.6	\$ 33.2	\$ 11.2

Net restructuring and related charges are comprised of the following:

	Fiscal Year		
	2014	2013	2012
2013 Mallinckrodt Program	\$ 74.5	\$ 14.9	\$ —
Acquisition programs	56.4	—	—
Other programs	(1.8)	20.9	19.2
Total programs	129.1	35.8	19.2
Less: non-cash charges, including impairments and accelerated share based compensation expense	(61.3)	(2.6)	(6.2)
Total charges expected to be settled in cash	<u>\$ 67.8</u>	<u>\$ 33.2</u>	<u>\$ 13.0</u>

Non-cash charges in fiscal 2014 include \$35.1 million of accelerated share based compensation expense related to employee terminations, primarily related to our Questcor acquisition, and \$25.6 million of property, plant and equipment asset impairments. The following table summarizes cash activity for restructuring reserves, substantially all of which related to employee severance and benefits, with the exception of \$8.5 million related to consulting costs associated with restructuring initiatives:

	2013 Mallinckrodt Program	Acquisition Programs	Other Programs	Total
Balance at September 30, 2011	\$ —	\$ —	\$ 7.6	\$ 7.6
Charges	—	—	12.8	12.8
Changes in estimate	—	—	0.2	0.2
Cash payments	—	—	(11.5)	(11.5)
Reclassifications <sup>(1)</sup>	—	—	(0.2)	(0.2)
Balance at September 28, 2012	—	—	8.9	8.9
Charges	14.9	—	20.9	35.8
Changes in estimate	—	—	(2.6)	(2.6)
Cash payments	—	—	(15.1)	(15.1)
Reclassifications <sup>(1)</sup>	—	—	(1.5)	(1.5)
Balance at September 27, 2013	14.9	—	10.6	25.5
Charges	58.2	22.9	2.5	83.6
Changes in estimate	(9.4)	(1.6)	(4.8)	(15.8)
Cash payments	(34.8)	(13.4)	(6.8)	(55.0)
Reclassifications <sup>(1)</sup>	(1.3)	—	(1.0)	(2.3)
Currency translation	(1.0)	—	(0.1)	(1.1)
Balance at September 26, 2014	<u>\$ 26.6</u>	<u>\$ 7.9</u>	<u>\$ 0.4</u>	<u>\$ 34.9</u>

(1) Represents the reclassification of pension and other postretirement benefits from restructuring reserves to pension and postretirement obligations.

Net restructuring and related charges, including associated asset impairments, incurred cumulative to date related to the 2013 Mallinckrodt Program are as follows:

Specialty Brands	\$ 1.1
Specialty Generics	11.5
Global Medical Imaging	71.5
Corporate	5.3
	<u>\$ 89.4</u>

Substantially all of the restructuring reserves are included in accrued and other current liabilities on the Company's consolidated balance sheets.

## 7. Income Taxes

The U.S. and non-U.S. components of income from continuing operations before income taxes were as follows:

	2014	2013	2012
U.S.	\$ (334.7)	\$ 70.0	\$ 174.6
Non-U.S.	(28.7)	56.4	61.5
Total	<u>\$ (363.4)</u>	<u>\$ 126.4</u>	<u>\$ 236.1</u>

Significant components of income taxes related to continuing operations are as follows:

	2014	2013	2012
<b>Current:</b>			
U.S.:			
Federal	\$ 49.8	\$ 45.7	\$ 61.1
State	1.5	9.2	7.2
Non-U.S.	11.4	22.7	17.5
Current income tax provision	<u>62.7</u>	<u>77.6</u>	<u>85.8</u>
<b>Deferred:</b>			
U.S.:			
Federal	(68.3)	(11.7)	5.3
State	(17.0)	(1.2)	2.4
Non-U.S.	(22.2)	3.9	1.3
Deferred income tax (benefit) provision	<u>(107.5)</u>	<u>(9.0)</u>	<u>9.0</u>
	<u>\$ (44.8)</u>	<u>\$ 68.6</u>	<u>\$ 94.8</u>

The fiscal 2014 U.S. federal and state current income tax provisions reflect a utilization of \$221.3 million of net operating losses and \$8.6 million of U.S. Research credits. The net operating loss utilization is comprised of \$187.8 million of net operating losses acquired in conjunction with the acquisition of Cadence and the remainder utilization relating to net operating losses carried forward from fiscal 2013.

The reconciliation between U.S. federal income taxes at the statutory rate and the Company's provision for income taxes on continuing operations is as follows:

	2014	2013	2012
Notional U.S. federal income taxes at the statutory rate	\$ (127.2)	\$ 44.3	\$ 82.6
Adjustments to reconcile to income tax provision:			
U.S. state income tax provision, net <sup>(1)</sup>	(7.9)	4.8	7.1
Rate difference between non-U.S. and U.S. jurisdictions <sup>(2) (3)</sup>	(5.8)	(2.2)	(3.5)
Domestic manufacturing deduction	(4.8)	(2.5)	(3.0)
Valuation allowances, nonrecurring	(2.4)	3.4	—
Adjustments to accrued income tax liabilities and uncertain tax positions <sup>(3)</sup>	(0.5)	8.6	1.2
Interest and penalties on accrued income tax liabilities and uncertain tax positions <sup>(3)</sup>	(8.0)	4.7	1.1
Investment in partnership	20.0	—	—
Credits, principally research <sup>(4)</sup>	(0.7)	(6.2)	(0.8)
Impairments, nondeductible	76.9	—	—
Permanently nondeductible and nontaxable items <sup>(5)</sup>	15.0	12.0	8.1
Other	0.6	1.7	2.0
Provision for income taxes	<u>\$ (44.8)</u>	<u>\$ 68.6</u>	<u>\$ 94.8</u>

- (1) Fiscal 2014 includes approximately \$4.4 million of tax benefit associated with the favorable impact of the Questcor acquisition on the Company's measurement of its net deferred tax liabilities.
- (2) Excludes non-deductible charges and other items which are broken out separately in the statutory rate reconciliation presented. Also includes the impact of certain valuation allowances.
- (3) Fiscal years 2013 and 2012 include impact of items relating to entities retained by Covidien in connection with the Separation.
- (4) Due to the December 31, 2011 tax law expiration, fiscal 2012 includes U.S. Research Credits for only the three months ended December 31, 2011. During fiscal 2013, the legislation was extended, with a retroactive effective date of January 1, 2012. As such, fiscal 2013 includes approximately \$2.3 million of credit related to the period January 1, 2012 through September 28, 2012. Due to the December 31, 2013 tax law expiration, fiscal 2014 includes \$0.7 million for the period September 28, 2013 through December 31, 2013.
- (5) Includes the impact of nondeductible transaction and separation costs.

As of September 26, 2014, September 27, 2013 and September 28, 2012, the amounts of unrecognized tax benefits for which the Company is legally and directly liable and would be required to remit cash if not sustained were \$82.0 million, \$100.1 million and \$13.4 million, respectively. For periods prior to the Separation, the Company's operations had been included in tax returns filed by Covidien or certain of its subsidiaries not included in the Company's historical combined financial statements. As a result, some federal uncertain tax positions related to the Company's operations resulted in unrecognized tax benefits that are obligations of entities not included in the combined financial statements for periods prior to June 28, 2013. Because the activities that gave rise to these unrecognized tax benefits relate to the Company's operations, the impact of these items (presented in the table below) were charged to the income tax provision through parent company investment, which was a component of parent company equity in the combined balance sheets.

The following table summarizes the activity related to the Company's unrecognized tax benefits, excluding interest:

	2014	2013	2012
Balance at beginning of fiscal year	\$ 100.1	\$ 165.5	\$ 168.4
Unrecognized tax benefits retained by Covidien	—	(153.7)	—
Unrecognized tax benefits transferred from Covidien	—	84.2	—
Additions related to current year tax positions	3.2	3.5	1.3
Additions related to prior period tax positions	30.6	6.6	1.6
Reductions related to prior period tax positions	(33.0)	(4.3)	(1.9)
Settlements	(6.9)	(1.6)	(1.7)
Lapse of statute of limitations	(12.0)	(0.1)	(2.2)
Balance at end of fiscal year	82.0	100.1	165.5
Cash advance paid in connection with proposed settlements	—	—	(23.5)
Balance at end of fiscal year, net of cash advance	<u>\$ 82.0</u>	<u>\$ 100.1</u>	<u>\$ 142.0</u>

During fiscal 2011, Covidien made a \$35.1 million advance payment to the U.S. Internal Revenue Service ("IRS") in connection with the proposed settlement of certain tax matters. This payment was comprised of \$23.5 million of tax and \$11.6 million of interest. This asset was retained by Covidien in connection with the Separation. During fiscal 2014, the Company made a \$35.9 million advanced payment to the IRS in connection with the proposed settlement of certain tax matters for 2005 through 2007. This payment was comprised of \$27.3 million of tax and \$8.6 million of interest. As of September 26, 2014, the 2005 through 2007 U.S. federal tax years were considered to have been effectively settled. Therefore, this advance payment, associated unrecognized tax benefits and interest were moved to Accrued and other current liabilities.

Unrecognized tax benefits, excluding interest, are reported in the following consolidated and combined balance sheet captions in the amount shown:

	September 26, 2014	September 27, 2013
Accrued and other current liabilities	\$ 6.5	\$ 23.4
Other income tax liabilities	70.7	76.7
Deferred income taxes (non-current liability)	4.8	—
	<u>\$ 82.0</u>	<u>\$ 100.1</u>

Included within total unrecognized tax benefits at September 26, 2014, September 27, 2013 and September 28, 2012, were \$82.0 million, \$96.3 million and \$144.3 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate. The remaining unrecognized tax benefits for each period would be offset by the write-off of related deferred and other tax assets, if recognized. During fiscal 2014, the Company accrued \$7.0 million of additional interest and released interest of \$24.0 million. During fiscal 2013 and 2012, the Company accrued additional interest of \$2.4 million and \$1.4 million, respectively. The total amount of accrued interest related to uncertain tax positions was \$45.1 million, \$62.1 million and \$33.9 million, respectively. Of the \$33.9 million accrued as of September 28, 2012, \$26.0 million was included within parent company investment on the combined balance sheet. This amount was retained by Covidien in connection with the Separation and \$51.8 million of accrued interest related to unrecognized tax benefits was transferred to the Company.

It is reasonably possible that within the next twelve months, as a result of the resolution of various federal, state and foreign examinations and appeals and the expiration of various statutes of limitation, that the unrecognized tax benefits could decrease by up to \$19.8 million. Interest and penalties could decrease by up to \$13.4 million.

Income taxes payable, including uncertain tax positions and related interest accruals, is reported in the following consolidated and combined balance sheet captions in the amounts shown.

	September 26, 2014	September 27, 2013
Accrued and other current liabilities	\$ 17.7	\$ 28.2
Other income tax liabilities	122.6	153.1
	<u>\$ 140.3</u>	<u>\$ 181.3</u>

Other assets includes \$14.8 million of tax payments associated with non-current deferred intercompany transactions. Prepaid expenses and other current assets includes a receivable of \$60.0 million associated with the Questcor acquisition and tax payments of \$3.6 million associated with current deferred intercompany transactions.

	September 26, 2014	September 27, 2013
Other assets	14.8	—
Prepaid expenses and other current assets	76.6	5.4
	<u>\$ 91.4</u>	<u>\$ 5.4</u>

Covidien continues to be examined by various taxing authorities for periods the Company was included within the consolidated results of Covidien. In connection with the Separation, the Company entered into a tax matters agreement ("the Tax Matters Agreement") with Covidien that generally governs Covidien's and Mallinckrodt's respective rights, responsibilities and obligations after the Separation with respect to certain taxes, including, but not limited to, ordinary course of business taxes. For further information on the Tax Matters Agreement, refer to Note 16.

As of September 26, 2014, tax years that remain subject to examination in the Company's major tax jurisdictions are as follows:

<b>Jurisdiction</b>	<b>Earliest Open Year</b>
U.S. - federal and state	1996
Ireland	2009
Netherlands	2013
Switzerland	2012

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

	<b>September 26, 2014</b>	<b>September 27, 2013</b>
<b>Deferred tax assets:</b>		
Accrued liabilities and reserves	\$ 79.1	\$ 35.5
Inventories	22.1	30.5
Tax loss and credit carryforwards	102.0	53.6
Environmental liabilities	29.5	27.3
Rebate reserves	41.1	43.4
Expired product	38.9	18.4
Postretirement benefits	36.3	31.2
Federal and state benefit of uncertain tax positions and interest	29.6	47.1
Deferred intercompany interest	—	19.2
Share-based compensation	28.0	12.3
Other	31.5	25.6
	<u>438.1</u>	<u>344.1</u>
<b>Deferred tax liabilities:</b>		
Property, plant and equipment	(110.0)	(160.5)
Intangible assets	(2,176.5)	(113.1)
Installment sale	(93.5)	—
Investment in partnership	(191.3)	(173.6)
	<u>(2,571.3)</u>	<u>(447.2)</u>
Net deferred tax (liability) asset before valuation allowances	(2,133.2)	(103.1)
Valuation allowances	(77.5)	(30.0)
Net deferred tax (liability) asset	<u>\$ (2,210.7)</u>	<u>\$ (133.1)</u>

Deferred taxes are reported in the following consolidated and combined balance sheet captions in the amounts shown:

	<b>September 26, 2014</b>	<b>September 27, 2013</b>
Deferred income taxes (current asset)	\$ 165.2	\$ 171.1
Other non-current assets	24.1	7.5
Accrued and other current liabilities	(1.4)	(1.6)
Deferred income taxes (non-current liability)	(2,398.6)	(310.1)
Net deferred tax (liability) asset	<u>\$ (2,210.7)</u>	<u>\$ (133.1)</u>

The Company's current deferred tax asset decreased from \$171.1 million at September 27, 2013 to \$165.2 million at September 26, 2014 primarily due to an increase in deferred tax assets of \$21.4 million as a result of the acquisition of Questcor, offset by the Company's utilization of its U.S. federal net operating losses and the utilization of U.S. Research credits. Additionally, the Company's non-current deferred tax liability increased from \$310.1 million at September 27, 2013 to \$2,398.6 million at September 26, 2014, primarily due to \$292.3 million related to the acquisition of Cadence, \$1,900.7 million related to the acquisition of Questcor, \$20.0 million related to an adjustment to the Company's indefinite lived deferred tax liability on its wholly owned partnership investment resulting from pre-Separation income tax adjustments to Covidien and its predecessor affiliates, \$43.3 million of decreases associated with amortization of intangibles, \$25.7 million of decreases associated with impairments, and increases to operational deferred tax assets due to normal operating activities.

The acquisition of Cadence resulted in a net deferred tax liability increase of \$292.3 million. Significant components of this increase include \$487.2 million of deferred tax liability associated with the Ofirmev intangible asset, \$197.4 million of deferred tax asset associated with U.S. federal and state net operating losses, \$6.4 million of deferred tax assets associated with federal and state tax credits, and a \$12.5 million valuation allowance related to the uncertainty of the utilization of certain deferred tax assets. Following the Cadence Acquisition, the Company entered into an internal installment sale transaction that resulted in a decrease of \$272.7 million to the deferred tax liability associated with the Ofirmev intangible asset, a \$93.6 million increase to the deferred tax liability associated with an installment sale note receivable, and a \$182.7 million decrease to the deferred tax asset associated with the U.S. federal and state net operating losses.

The acquisition of Questcor resulted in a net deferred tax liability increase of \$1,900.7 million. Significant components of this increase include \$1,928.8 million of deferred tax liability associated with the Acthar intangible asset, \$10.8 million of deferred tax liability associated with other intangible assets, \$16.2 million of deferred tax liability associated with inventory, \$34.1 million of deferred tax assets associated with share-based compensation and associated merger cash consideration, and \$18.5 million of deferred tax assets associated with accrued royalties.

At September 26, 2014, the Company had approximately \$50.6 million of net operating loss carryforwards in certain non-U.S. jurisdictions, of which \$41.3 million have no expiration and the remaining \$9.3 million will expire in future years through 2024. The Company had \$33.1 million of U.S. federal and state net operating loss carryforwards and \$3.3 million of primarily U.S. federal capital loss carryforwards at September 26, 2014, which will expire during fiscal 2015 through 2034.

At September 26, 2014 the Company also had \$15.9 million of tax credits available to reduce future income taxes payable, primarily in jurisdictions within the U.S., of which \$5.2 million have no expiration and the remainder expire during fiscal 2015 through 2029.

The deferred tax asset valuation allowances of \$77.5 million and \$30.0 million at September 26, 2014 and September 27, 2013, respectively, relate principally to the uncertainty of the utilization of certain deferred tax assets, primarily non-U.S. net operating losses, certain reserves in non-U.S. jurisdictions and realized and unrealized capital losses in the U.S. The Company believes that it will generate sufficient future taxable income to realize the tax benefits related to the remaining net deferred tax assets.

During fiscal 2014, 2013 and 2012, the Company provided for U.S. and non-U.S. income and withholding taxes in the amount of \$1.4 million, \$0.2 million and \$0.4 million, respectively, on earnings that were or are intended to be repatriated. In general, the remaining earnings of the Company's subsidiaries are considered to be permanently reinvested. Income taxes are not provided on undistributed earnings of U.S. and non-U.S. subsidiaries that are either indefinitely reinvested or can be distributed on a tax-free basis. As of September 26, 2014, the cumulative amount of such undistributed earnings was approximately \$1.1 billion. It is not practicable to determine the cumulative amount of tax liability that would arise if these earnings were remitted.

## **8. Earnings (Loss) per Share**

In fiscal 2014, basic and diluted earnings (loss) per share were computed using the two-class method. The two-class method is an earnings allocation that determines earnings per share for each class of common stock and participating securities according to dividends declared and participation rights in undistributed earnings. The Company's restricted stock awards, issued in conjunction with the Questcor Acquisition in August 2014, are considered participating securities as holders are entitled to receive non-forfeitable dividends during the vesting term. Diluted earnings per share includes securities that could potentially dilute basic earnings per share during a reporting period, for which the Company includes all share based compensation awards other than participating securities. 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.

In periods prior to fiscal 2014, basic earnings (loss) per share was computed by dividing net income by the number of weighted-average shares outstanding during the period. Diluted earnings (loss) per share was computed using the weighted-average shares outstanding and, if dilutive, potential ordinary shares outstanding during the period. Potential ordinary shares represent the incremental ordinary shares issuable for restricted share units and share option exercises. The Company calculated the dilutive effect of outstanding restricted share units and share options on earnings (loss) per share by application of the treasury stock method.

The computations of basic and diluted earnings (loss) per share assumes that the number of shares outstanding for periods prior to June 28, 2013 was equal to the number of ordinary shares of Mallinckrodt outstanding on June 28, 2013, immediately following the distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien. The dilutive effect of the Company's share-based awards that were issued as a result of the conversion of Covidien share-based awards with the Separation, the conversion of Questcor share-based awards with the Questcor Acquisition, the initial equity awards granted to certain of the Company's executives on July 1, 2013 and any other Company grants made since the Separation have been included in the computation of diluted earnings per share for fiscal 2014 and 2013, calculated under the methodologies outlined above, weighted appropriately for the portion of the period they were outstanding.

	2014	2013	2012
Weighted-average shares for basic earnings (loss) per share	64.9	57.7	57.7
Effect of share options and restricted shares	—	0.1	—
Weighted-average shares for diluted earnings (loss) per share	64.9	57.8	57.7

As the Company incurred a net loss in fiscal 2014, there was no allocation of the undistributed loss to participating securities because the effect would have been anti-dilutive to basic and diluted earnings per share. The computation of diluted earnings per share for fiscal 2014 and 2013 excludes approximately 5.7 million and approximately 0.5 million of equity awards because the effect would have been anti-dilutive.

## 9. Inventories

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

	September 26, 2014	September 27, 2013
Raw materials and supplies	\$ 73.6	\$ 68.8
Work in process	212.1	191.5
Finished goods	110.9	142.8
Inventories	<u>\$ 396.6</u>	<u>\$ 403.1</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 26, 2014	September 27, 2013
Land	\$ 59.9	\$ 60.4
Buildings	330.6	316.6
Capitalized software	97.6	76.4
Machinery and equipment	1,202.1	1,226.6
Construction in process	198.2	193.7
	1,888.4	1,873.7
Less: accumulated depreciation	(939.2)	(876.3)
Property, plant and equipment, net	<u>\$ 949.2</u>	<u>\$ 997.4</u>

The amounts above include property under capital leases of \$16.9 million and \$17.8 million at September 26, 2014 and September 27, 2013, respectively, consisting primarily of buildings. Accumulated amortization of capitalized leased assets was \$15.8 million and \$15.8 million at the end of fiscal 2014 and 2013, respectively.

Depreciation expense, including amounts related to capitalized leased assets, was \$113.6 million, \$104.2 million and \$103.6 million for fiscal 2014, 2013 and 2012, respectively. Depreciation expense included depreciation on demonstration equipment of \$4.3 million, \$3.6 million and \$3.4 million for fiscal 2014, 2013 and 2012, respectively. Demonstration equipment was included within other assets on the consolidated balance sheets.

### **Long-Lived Asset Impairment Analysis**

During the fourth quarter of fiscal 2014, the Company received notification that we lost preferred supplier status with a significant group purchasing organization ("GPO") and that a related-party supply contract was terminated by the Company. The Company determined that these events constituted a triggering event with respect to our CMDS asset group within the Global Medical Imaging segment and assessed the recoverability of the CMDS asset group. The Company determined that the undiscounted cash flows of this asset group were less than its net book value. This would require the Company to record an impairment charge if the fair value of the CMDS asset group was less than its net book value.

The Company determined the fair value of the CMDS asset group using the income approach, a level three measurement technique. For purposes of determining fair value the Company made various assumptions regarding estimated future cash flows, discount rates and other factors in determining the fair values of each reporting unit using the income approach. The Company's projections of future cash flows were then discounted based on a weighted-average cost of capital ("WACC") determined from relevant market comparisons, adjusted upward for specific risks (primarily the uncertainty of achieving projected operating cash flows). A terminal value growth rate was applied to the terminal year cash flows, both of which represent the Company's estimate of stable, sustainable growth. The fair value of the asset group represents the sum of the discounted cash flows from the discrete period and the terminal year cash flows.

The Company's projections in the CMDS asset group included long-term net sales and operating income at lower than historical levels. The decrease in net sales and operating income is reflective of the notification of the loss of a significant customer, termination of a supply contract with a related party and increased competition in the marketplace. The Company utilized a WACC of 8.0%, which reflects the lower inherent risk with the decreasing revenue trends. These assumptions resulted in a fair value of the CMDS asset group that was less than its net book value. Therefore, the Company recorded impairment charges of \$65.9 million and \$52.4 million to the property, plant and equipment and long-lived amortizing intangible assets, respectively, included in the CMDS asset group. The Global Medical Imaging reporting unit could be subject to further impairment should the Company experience greater than expected revenue declines, revise our long-term projections downward or utilize higher discount rates.

## **11. Goodwill and Intangible Assets**

The changes in the carrying amount of goodwill by segment were as follows:

	Specialty Brands	Specialty Generics	Global Medical Imaging	Total
Goodwill at September 27, 2013	\$ 105.3	\$ 207.0	\$ 219.7	\$ 532.0
Acquisitions	2,089.6	—	—	2,089.6
Impairment	—	—	(219.7)	(219.7)
Goodwill at September 26, 2014	<u>\$ 2,194.9</u>	<u>\$ 207.0</u>	<u>\$ —</u>	<u>\$ 2,401.9</u>

## Goodwill Impairment Analysis

The Company has identified that the Specialty Brands, Specialty Generics and Global Medical Imaging businesses represent both segments and reporting units. For purposes of assessing impairment and the recoverability of goodwill for each reporting unit the Company makes various assumptions regarding estimated future cash flows, discount rates and other factors in determining the fair values of each reporting unit using the income approach. The Company's projections of future cash flows were then discounted based on a WACC determined from relevant market comparisons, adjusted upward for specific reporting unit risks (primarily the uncertainty of achieving projected operating cash flows). A terminal value growth rate was applied to the terminal year cash flows, both of which represent the Company's estimate of stable, sustainable growth. The fair value of the reporting unit represents the sum of the discounted cash flows from the discrete period and the terminal year cash flows. The fair values of the reporting units were assessed for reasonableness by aggregating the fair values and comparing this to the Company's market capitalization with a control premium.

The Company's projections in our Brands business include long-term revenue and operating income at levels higher than historical levels which is primarily associated with revenue growth for Ofirmev, Xartemis XR and the introduction of MNK-155. The projections also reflect the potential impacts from the future loss of exclusivity related to Ofirmev. The Company utilized a WACC of 10.5%. These assumptions resulted in a fair value of the Brands business in excess of its net book value. The Company does not believe that the Specialty Brands reporting unit is at risk of impairment; however, should it fail to experience growth in the aforementioned products, revise its long-term projections for these products downward or market conditions dictate utilization of higher discount rates, the Specialty Brands reporting unit could be subject to impairment in future periods.

The Company's projections in our Generics and API reporting unit include long-term revenue and operating income at higher than historical levels primarily attributable to long-term, single-digit net sales growth. The Company utilized a WACC of 10.5%. These assumptions resulted in a fair value of the Generics and API reporting unit that was significantly in excess of its net book value. Therefore, the Company does not believe that the Specialty Generics segment is at risk of impairment.

The Company's projections in the Global Medical Imaging reporting unit include long-term net sales and operating income at lower than historical levels. The decrease in net sales and operating income is reflective of the notification that we lost preferred supplier status with a significant GPO, that a related-party supply contract was terminated and increased competition in the marketplace. During the fourth quarter of fiscal 2014, the Company received notification that it lost preferred supplier status with a significant GPO and that a related-party supply contract was terminated by the Company. The Company utilized a WACC of 8.0%, which reflects the Company's risk premium associated with the projected cash flows. These assumptions resulted in a fair value of the Global Medical Imaging segment that was less than its net book value, after recording the impairments to long-lived assets discussed in Note 10. Therefore, the Company recognized a \$219.7 million goodwill impairment in the Global Medical Imaging segment.

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

	September 26, 2014		September 27, 2013	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
<b>Amortizable:</b>				
Completed technology	\$ 7,040.1	\$ 339.7	\$ 449.2	\$ 196.6
Licenses	185.1	87.3	191.1	79.3
Customer relationships	33.8	0.6	—	—
Trademarks	13.0	4.1	7.9	3.8
Other	6.7	5.0	—	—
<b>Total</b>	<b>\$ 7,278.7</b>	<b>\$ 436.7</b>	<b>\$ 648.2</b>	<b>\$ 279.7</b>
<b>Non-Amortizable:</b>				
Trademarks	\$ 35.0		\$ 35.0	
In-process research and development	235.2		18.6	
<b>Total</b>	<b>\$ 270.2</b>		<b>\$ 53.6</b>	

### Long-Lived Asset Impairment Analysis

During the fourth quarter of fiscal 2014, the Company received notification that we lost preferred supplier status with a significant GPO and that a related-party supply contract was terminated by the Company. The Company determined that these events constituted a triggering event with respect to our CMD5 asset group, including a finite-lived intangible asset, within the Global Medical Imaging segment and assessed the recoverability of the CMD5 asset group. As discussed further in Note 10, the Company recorded a \$52.4 million impairment to a finite-lived completed technology intangible asset.

Finite-lived intangible asset amortization expense was \$162.3 million, \$35.4 million and \$27.3 million in fiscal 2014, 2013 and 2012, respectively. The estimated aggregate amortization expense on intangible assets owned by the Company is expected to be as follows:

Fiscal 2015	\$	496.5
Fiscal 2016		494.3
Fiscal 2017		492.4
Fiscal 2018		483.3
Fiscal 2019		483.0

## 12. Debt

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

	September 26, 2014	September 27, 2013
Current maturities of long-term debt:		
2.85% term loan due April 2016	\$ 0.4	\$ —
Term loan due March 2021	18.2	—
4.00% term loan due February 2022	1.2	—
Capital lease obligation	1.4	1.4
Loan payable	—	0.1
Total current debt	21.2	1.5
Long-term debt:		
Variable rate receivable securitization	150.0	—
2.85% term loan due April 2016	2.7	—
3.50% notes due April 2018	300.0	299.9
Term loan due March 2021	1,972.1	—
4.00% term loan due February 2022	9.6	—
9.50% debentures due May 2022	10.4	10.4
5.75% notes due August 2022	900.0	—
8.00% debentures due March 2023	8.0	8.0
4.75% notes due April 2023	598.3	598.2
Capital lease obligation	0.4	1.8
Total long-term debt	3,951.5	918.3
Total debt	\$ 3,972.7	\$ 919.8

In November 2012, Mallinckrodt International Finance S.A. ("MIFSA") was formed as a 100% owned subsidiary of Covidien in connection with the Separation. MIFSA is a holding company established to own, directly or indirectly, substantially all of the operating subsidiaries of the Company, to issue debt securities and to perform treasury operations. At the time of the Separation, MIFSA became a 100% owned subsidiary of the Company.

In March 2013, MIFSA entered into a \$250 million five-year senior unsecured revolving credit facility that was scheduled to mature in June 2018 ("the Credit Facility"). Borrowings under the Credit Facility initially accrued interest at LIBOR plus 1.50% per annum (subject to adjustment pursuant to a ratings-based pricing grid). The Credit Facility was replaced by the Revolver (defined below) in March 2014. There were no borrowings or letters of credit issued under the Credit Facility.

In April 2013, MIFSA issued \$300 million aggregate principal amount of 3.50% senior unsecured notes due April 2018 and \$600 million aggregate principal amount of 4.75% senior unsecured notes due April 2023 (collectively, "the Notes"). Mallinckrodt plc has fully and unconditionally guaranteed the Notes on an unsecured and unsubordinated basis. The Notes are subject to an indenture which contains covenants limiting the ability of MIFSA, its restricted subsidiaries (as defined in the Notes) and Mallinckrodt plc, as guarantor, to incur certain liens or enter into sale and lease-back transactions. It also restricts Mallinckrodt plc and MIFSA's ability to merge or consolidate with any other person or sell or convey all or substantially all of their assets to any one person. MIFSA may redeem all of the Notes at any time, and some of the Notes from time to time, at a redemption price equal to the principal amount of the Notes redeemed plus a make-whole premium. MIFSA will pay interest on the Notes semiannually in arrears on April 15 and October 15 of each year, which commenced on October 15, 2013. The net proceeds to MIFSA from the issuance and sale of the Notes was \$889.3 million, the majority of which was retained by Covidien per the terms of the Separation and Distribution Agreement.

In March 2014, Mallinckrodt International Finance S.A. ("MIFSA") and Mallinckrodt CB LLC ("MCB"), each a wholly-owned subsidiary of the Company, entered into senior secured credit facilities consisting of a \$1.3 billion term loan facility due 2021 ("the Term Loan") and a \$250.0 million revolving credit facility due 2019 ("the Revolver") (collectively, "the Facilities"). The Facilities are fully and unconditionally guaranteed by Mallinckrodt plc, certain of its direct or indirect wholly-owned U.S. subsidiaries and each of its direct or indirect wholly-owned subsidiaries that owns directly or indirectly any such wholly-owned U.S. subsidiary (collectively, "the Guarantors"). The Facilities are secured by a security interest in certain assets of MIFSA, MCB and the Guarantors. The Facilities contain customary affirmative and negative covenants, which include, among other things, restrictions on the Company's ability to declare or pay dividends, create liens, incur additional indebtedness, enter into sale and lease-back transactions, make investments, dispose of assets and merge or consolidate with any other person. In addition, the Revolver contains a financial covenant that may limit the Company's total net leverage ratio, which is defined as the ratio of (i) the Company's consolidated debt, less any unrestricted cash and cash equivalents, to (ii) the Company's adjusted consolidated EBITDA, as defined in the credit agreement. The Facilities bear interest at LIBOR plus a margin based on the Company's total net leverage ratio, and the Term Loan is subject to a minimum LIBOR level of 0.75%. Interest payment dates are variable based on the LIBOR rate utilized, but the Company generally expects interest to be payable every 90 days. The Term Loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal amount of the Term Loan payable on the last day of each calendar quarter, which commenced on June 30, 2014, with the remaining balance payable on the due date, March 19, 2021. The Company incurred an original issue discount of 0.25%, or \$3.3 million, associated with the Term Loan. The Revolver contains a \$150.0 million letter of credit provision, of which none had been issued as of September 26, 2014. Unused commitments on the Revolver are subject to an annual commitment fee determined by reference to the Company's public debt rating, which was 0.375% as of September 26, 2014, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. As of September 26, 2014, the applicable interest rate on outstanding borrowings under the Revolver would have been approximately 3.00%; however, there were no outstanding borrowings.

In July 2014, Mallinckrodt Securitization S.À.R.L. ("Mallinckrodt Securitization"), a wholly-owned special purpose subsidiary of the Company, entered into a \$160.0 million accounts receivable securitization facility that matures in July 2017 ("the Receivable Securitization"). Mallinckrodt Securitization may, from time to time, obtain up to \$160.0 million in third-party borrowings secured by certain receivables. The borrowings under the Receivable Securitization are to be repaid as the secured receivables are collected. Loans under the Receivable Securitization will bear interest (including facility fees) at a rate equal to one month LIBOR rate plus a margin of 0.80%. Unused commitments on the Receivables Securitization are subject to an annual commitment fee of 0.35%. The Receivable Securitization agreements contain customary representations, warranties, and affirmative and negative covenants. The size of the securitization facility may be increased to \$300.0 million upon approval of the third-party lenders subject to certain conditions. As of September 26, 2014, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 0.96% and outstanding borrowings totaled \$150.0 million.

In August 2014, MIFSA and MCB issued \$900 million aggregate principal amount of 5.75% senior unsecured notes due August 1 2022 ("the 2022 Notes"). The 2022 Notes are guaranteed on an unsecured basis by certain of MIFSA's subsidiaries. The 2022 Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the 2022 Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. MIFSA may redeem some or all of the 2022 Notes prior to August 1, 2017 by paying a make-whole premium. MIFSA may redeem some or all of the 2022 Notes on or after August 1, 2017 at specified redemption prices. In addition, prior to August 1, 2017, MIFSA may redeem up to 40% of the aggregate principal amount of the 2022 Notes with the net proceeds of certain equity offerings. The Issuers are obligated to offer to repurchase the 2022 Notes at a price of (a) 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain asset sales. These obligations are subject to certain qualifications and exceptions. MIFSA will pay interest on the 2022 Notes semiannually in arrears on February 1 and August 1 of each year, commencing on February 1, 2015.

In August 2014, MIFSA and MCB entered into a \$700 million senior secured term loan facility ("the New Term Loan"). The New Term Loan is an incremental tranche under the credit agreement governing our existing Term Loan and Revolver, entered into in March 2014, (collectively, with the New Term Loan, represent "the Senior Secured Credit Facilities"). New Term Loan has substantially similar terms to the Term Loan (other than pricing); including the determination of interest rates and quarterly principal amortization payments equal to 0.25% of the original principal amount of the New Term Loan. The quarterly principal payments commence on December 31, 2014, with the remaining balance payable on the due date of March 19, 2021. Mallinckrodt plc and its subsidiaries (other than MIFSA, MCB and the subsidiaries of MIFSA that guarantee the Facilities) will not guarantee the New Term Loan, and the New Term Loan will not be secured by the assets of such entities. The New Term Loan bears interest under the same terms of the Term Loan entered into in March 2014, including the use of LIBOR rates with a minimum floor.

As of September 26, 2014, the applicable interest rate for the Term Loan and New Term Loan was 3.50% and outstanding borrowings under these agreements totaled approximately \$2.0 billion.

As of September 26, 2014, the Company was, and expects to remain, in compliance with the provisions and covenants associated with its Credit Agreement, the Notes, the 2022 Notes and its other debt agreements.

The Company's capital lease obligation relates to a non-U.S. manufacturing facility. This lease expires in December 2015. The aggregate amounts of debt, including the capital lease obligation, maturing during the next five fiscal years are as follows:

Fiscal 2015	\$	21.2
Fiscal 2016		24.3
Fiscal 2017		171.3
Fiscal 2018		321.3
Fiscal 2019		21.5

### 13. Retirement Plans

#### Defined Benefit Plans

The Company sponsors a number of defined benefit retirement plans covering certain of its U.S. employees and non-U.S. employees. As of September 26, 2014, U.S. plans represented 71% of both the Company's total pension plan assets and projected benefit obligation. The Company generally does not provide postretirement benefits other than retirement plan benefits for its employees; however, certain of the Company's U.S. employees participate in postretirement benefit plans that provide medical benefits. These plans are unfunded.

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

	Pension Benefits			Postretirement Benefits		
	Fiscal Year			Fiscal Year		
	2014	2013	2012	2014	2013	2012
Service cost	\$ 5.1	\$ 5.0	\$ 5.0	\$ 0.1	\$ 0.1	\$ 0.1
Interest cost	19.6	18.2	21.2	2.1	2.4	3.1
Expected return on plan assets	(24.6)	(29.6)	(24.5)	—	—	—
Amortization of net actuarial loss	8.1	12.3	11.7	—	0.3	0.2
Amortization of prior service cost	(0.6)	0.6	0.7	(9.3)	(9.1)	(9.2)
Plan settlements loss	3.8	6.8	(0.2)	—	—	—
Net periodic benefit cost (credit)	\$ 11.4	\$ 13.3	\$ 13.9	\$ (7.1)	\$ (6.3)	\$ (5.8)

The following table represents the changes in benefit obligations, plan assets and the net amounts recognized on the consolidated balance sheets for pension and postretirement benefit plans at the end of fiscal 2014 and 2013:

	Pension Benefits		Postretirement Benefits	
	2014	2013	2014	2013
<i>Change in benefit obligation:</i>				
Projected benefit obligations at beginning of year	\$ 501.7	\$ 533.2	\$ 53.2	\$ 80.3
Service cost	5.1	5.0	0.1	0.1
Interest cost	19.6	18.2	2.1	2.4
Employee contributions	0.6	0.3	—	—
Actuarial (gain) loss	60.0	(24.0)	0.5	(9.3)
Benefits and administrative expenses paid	(21.9)	(21.9)	(3.9)	(3.8)
Plan amendments	—	(9.0)	—	(16.5)
Plan settlements	(17.6)	(24.2)	—	—
Plan combinations	—	18.4	—	—
Currency translation	(9.1)	5.7	—	—
Projected benefit obligations at end of year	\$ 538.4	\$ 501.7	\$ 52.0	\$ 53.2
<i>Change in plan assets:</i>				
Fair value of plan assets at beginning of year	\$ 456.0	\$ 432.0	\$ —	\$ —
Actual return on plan assets	59.7	17.3	—	—
Employer contributions	4.9	44.4	3.9	3.8
Employee contributions	0.6	0.3	—	—
Benefits and administrative expenses paid	(21.9)	(21.9)	(3.9)	(3.8)
Plan settlements	(17.6)	(24.2)	—	—
Plan combinations	—	2.3	—	—
Currency translation	(8.1)	5.8	—	—
Fair value of plan assets at end of year	\$ 473.6	\$ 456.0	\$ —	\$ —
Funded status at end of year	\$ (64.8)	\$ (45.7)	\$ (52.0)	\$ (53.2)

	Pension Benefits		Postretirement Benefits	
	2014	2013	2014	2013
<i>Amounts recognized on the consolidated balance sheet:</i>				
Non-current assets	\$ 9.8	\$ 17.1	\$ —	\$ —
Current liabilities	(2.7)	(3.1)	(4.8)	(4.9)
Non-current liabilities	(71.9)	(59.7)	(47.2)	(48.3)
Net amount recognized on the consolidated balance sheet	\$ (64.8)	\$ (45.7)	\$ (52.0)	\$ (53.2)

<i>Amounts recognized in accumulated other comprehensive income consist of:</i>				
Net actuarial loss	\$ (115.1)	\$ (102.9)	\$ (2.9)	\$ (2.4)
Prior service credit (cost)	6.9	7.9	18.8	28.2
Net amount recognized in accumulated other comprehensive income	\$ (108.2)	\$ (95.0)	\$ 15.9	\$ 25.8

The estimated amounts that will be amortized from accumulated other comprehensive income into net periodic benefit cost (credit) in fiscal 2015 are as follows:

	Pension Benefits	Postretirement Benefits
Amortization of net actuarial loss	\$ 9.4	\$ —
Amortization of prior service cost	(0.6)	(3.9)

The accumulated benefit obligation for all pension plans at the end of fiscal 2014 and 2013 was \$533.6 million and \$499.9 million, respectively. Additional information related to pension plans is as follows:

	2014	2013
Pension plans with accumulated benefit obligations in excess of plan assets:		
Accumulated benefit obligation	\$ 394.7	\$ 377.6
Fair value of plan assets	321.6	316.2

The accumulated benefit obligation and fair value of plan assets for pension plans with projected benefit obligations in excess of plan assets do not significantly differ from the amounts in the table above since substantially all of the Company's pension plans are frozen.

### Actuarial Assumptions

Weighted-average assumptions used each fiscal year to determine net periodic benefit cost for the Company's pension plans are as follows:

	U.S. Plans			Non-U.S. Plans		
	2014	2013	2012	2014	2013	2012
Discount rate	4.2%	3.5%	4.4%	3.5%	4.0%	5.2%
Expected return on plan assets	6.5%	7.9%	7.5%	3.1%	3.5%	4.0%
Rate of compensation increase	—%	—%	2.8%	3.5%	3.7%	3.7%

Weighted-average assumptions used each fiscal year to determine benefits obligations for the Company's pension plans are as follows:

	U.S. Plans			Non-U.S. Plans		
	2014	2013	2012	2014	2013	2012
Discount rate	3.9%	4.3%	3.5%	2.5%	3.7%	4.0%
Rate of compensation increase	—%	—%	—%	3.4%	3.5%	3.7%

For the Company's U.S. plans, the discount rate is based on the market rate for a broad population of Moody's AA-rated corporate bonds over \$250 million. For the Company's non-U.S. plans, the discount rate is generally determined by reviewing country and region specific government and corporate bond interest rates.

In determining the expected return on pension plan assets, the Company considers the relative weighting of plan assets by class and individual asset class performance expectations as provided by external advisors in reaching conclusions on appropriate assumptions. The investment strategy for the pension plans is to obtain a long-term return on plan assets that is consistent with the level of investment risk that is considered appropriate. Investment risks and returns are reviewed regularly against benchmarks to ensure objectives are being met.

The weighted-average discount rate used to determine net periodic benefit cost and obligations for the Company's postretirement benefit plans are as follows:

	2014	2013	2012
Net periodic benefit cost	4.0%	3.2%	4.1%
Benefit obligations	3.7%	4.0%	3.2%

Healthcare cost trend assumptions for postretirement benefit plans are as follows:

	2014	2013
Healthcare cost trend rate assumed for next fiscal year	7.1%	7.3%
Rate to which the cost trend rate is assumed to decline	4.5%	4.5%
Fiscal year the ultimate trend rate is achieved	2029	2029

A one-percentage-point change in assumed healthcare cost trend rates would have the following effects:

	One-Percentage-Point Increase	One-Percentage-Point Decrease
Effect on total of service and interest cost	\$ —	\$ —
Effect on postretirement benefit obligation	0.4	(0.3)

### Plan Assets

The Company's U.S. pension plans have a target allocation of 24% equity securities and 76% debt securities. Various asset allocation strategies are in place for non-U.S. pension plans depending upon local law, status, funding level and duration of liabilities, and are 39% equity securities, 55% debt securities and 6% other (primarily cash) for our Japanese pension plan and 10% equity securities, 2% debt securities and 88% other (primarily insurance contracts) for our plan in the Netherlands.

Pension plans have the following weighted-average asset allocations at the end of each fiscal year:

	U.S. Plans		Non-U.S. Plans	
	2014	2013	2014	2013
Equity securities	28%	42%	8%	7%
Debt securities	70	56	2	3
Cash and cash equivalents	1	1	—	—
Other	1	1	90	90
Total	100%	100%	100%	100%

The following tables provide a summary of plan assets held by the Company's pension plans that are measured at fair value on a recurring basis at the end of fiscal 2014 and 2013:

	Fiscal 2014	Basis of Fair Value Measurement		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Equity Securities:</b>				
U.S. small mid cap	\$ 16.6	\$ 16.6	\$ —	\$ —
U.S. large cap	50.2	50.2	—	—
International	39.8	28.7	11.1	—
<b>Debt securities:</b>				
Diversified fixed income funds <sup>(1)</sup>	218.7	216.6	2.1	—
High yield bonds	13.0	13.0	—	—
Emerging market funds	9.5	9.5	—	—
Diversified/commingled funds	—	—	—	—
Insurance contracts	119.8	—	—	119.8
Other	6.0	2.6	3.4	—
Total	\$ 473.6	\$ 337.2	\$ 16.6	\$ 119.8

	Basis of Fair Value Measurement			
	Fiscal 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Equity Securities:</b>				
U.S. small mid cap	\$ 19.3	\$ 19.3	\$ —	\$ —
U.S. large cap	76.9	76.9	—	—
International	52.2	43.9	8.3	—
<b>Debt securities:</b>				
Diversified fixed income funds <sup>(1)</sup>	170.0	166.7	3.3	—
High yield bonds	11.7	11.7	—	—
Emerging market funds	7.9	7.9	—	—
Insurance contracts	112.0	—	—	112.0
Other	6.0	3.1	2.9	—
<b>Total</b>	<b>\$ 456.0</b>	<b>\$ 329.5</b>	<b>\$ 14.5</b>	<b>\$ 112.0</b>

(1) Diversified fixed income funds consist of U.S. Treasury bonds, mortgage-backed securities, corporate bonds, asset-backed securities and U.S. agency bonds.

*Equity securities.* Equity securities primarily consist of mutual funds with underlying investments in foreign equity and domestic equity markets. The fair value of these investments is based on net asset value of the units held in the respective fund, which are determined by obtaining quoted prices on nationally recognized securities exchanges (level 1) or through net asset values provided by the fund administrators that can be corroborated by observable market data (level 2).

*Debt securities.* Debt securities are primarily invested in mutual funds with underlying fixed income investments in U.S. government and corporate debt, U.S. dollar denominated foreign government and corporate debt, asset-backed securities, mortgage-backed securities and U.S. agency bonds. The fair value of these investments is based on the net asset value of the units held in the respective fund which are determined by obtaining quoted prices on nationally recognized securities exchanges.

*Insurance contracts.* Insurance contracts held by the Company are issued primarily by Delta Lloyd, a well-known, highly rated insurance company. The fair value of these insurance contracts is based upon the present value of future cash flows under the terms of the contracts and therefore the fair value of these assets has been classified as level 3 within the fair value hierarchy. Significant assumptions used in determining the fair value of these contracts are the amount and timing of future cash flows and counterparty credit risk. The objective of the insurance contracts is to provide the Company with future cash flows that will match the estimated timing and amount of future pension benefit payments. Delta Lloyd's insurance subsidiaries have a Standard & Poor's credit rating of A.

*Other.* Other includes cash and cash equivalents invested in a money market mutual fund, the fair value of which is determined by obtaining quoted prices on nationally recognized securities exchanges (level 1). In addition, other includes real estate funds, the fair value of which is determined using other inputs, such as net asset values provided by the fund administrators that can be corroborated by observable market data (level 2).

The following table provides a summary of the changes in the fair value measurements that used significant unobservable inputs (level 3) for fiscal 2014 and 2013:

	Insurance Contracts
Balance at September 28, 2012	\$ 105.1
Net unrealized gains	3.3
Net purchases, sales and issuances	(1.8)
Currency translation	5.4
Balance at September 27, 2013	112.0
Net unrealized gains	15.5
Net purchases, sales and issuances	(0.6)
Currency translation	(7.1)
Balance at September 26, 2014	\$ 119.8

Mallinckrodt shares are not a direct investment of the Company's pension funds; however, the pension funds may indirectly include Mallinckrodt shares. The aggregate amount of the Mallinckrodt shares are not material relative to the total pension fund assets.

### **Contributions**

The Company's funding policy is to make contributions in accordance with the laws and customs of the various countries in which the Company operates, as well as to make discretionary voluntary contributions from time to time. In fiscal 2014 and 2013, the Company made \$4.9 million and \$44.4 million in contributions, respectively, to the Company's pension plans, including a voluntary contribution of \$37.5 million made by Covidien prior to the Separation in fiscal 2013. The Company does not anticipate making material involuntary contributions in fiscal 2015, but may elect to make voluntary contributions to its defined pension plans or its postretirement benefit plans during fiscal 2015.

### **Expected Future Benefit Payments**

Benefit payments expected to be paid, reflecting future expected service as appropriate, are as follows:

	<b>Pension Benefits</b>	<b>Postretirement Benefits</b>
Fiscal 2015	\$ 45.8	\$ 4.8
Fiscal 2016	34.9	4.5
Fiscal 2017	33.9	4.2
Fiscal 2018	33.4	4.0
Fiscal 2019	32.7	3.7
Fiscal 2020 - 2024	149.8	16.1

### **Defined Contribution Retirement Plans**

The Company maintains one active tax-qualified 401(k) retirement plan and one active non-qualified deferred compensation plan in the U.S. The 401(k) retirement plan provides for an automatic Company contribution of three percent of an eligible employee's pay, with an additional Company matching contribution generally equal to 50% of each employee's elective contribution to the plan up to six percent of the employee's eligible pay. The deferred compensation plan permits eligible employees to defer a portion of their compensation. Total defined contribution expense related to continuing operations was \$22.5 million, \$22.7 million and \$20.9 million for fiscal 2014, 2013 and 2012, respectively.

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

The Company maintains several rabbi trusts, the assets of which are used to pay retirement benefits. The rabbi trust assets are subject to the claims of the Company's creditors in the event of the Company's insolvency. Plan participants are general creditors of the Company with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in other assets on the consolidated balance sheets. Note 19 provides additional information regarding the debt and equity securities. The carrying value of the 135 life insurance contracts held by these trusts was \$56.3 million and \$54.6 million at September 26, 2014 and September 27, 2013, respectively. These contracts had a total death benefit of \$145.7 million and \$143.1 million at September 26, 2014 and September 27, 2013, respectively. However, there are outstanding loans against the policies amounting to \$38.2 million and \$35.3 million at September 26, 2014 and September 27, 2013, respectively.

The Company has insurance contracts which serve as collateral for certain of the Company's non-U.S. pension plan benefits, which totaled \$12.7 million and \$13.1 million at September 26, 2014 and September 27, 2013, respectively. These amounts were also included in other assets on the consolidated balance sheets.

## 14. Share Plans

Total share-based compensation cost was \$67.7 million, \$16.2 million and \$11.1 million for fiscal 2014, 2013 and 2012, respectively. These amounts are generally included within selling, general and administrative expenses in the consolidated and combined statements of income. In conjunction with the the Questcor Acquisition, Questcor equity awards were converted to Mallinckrodt equity awards resulted in post-combination expense of \$48.2 million in fiscal 2014, included in the above total share-based compensation, of which \$13.1 million is included within selling, general and administrative expenses and \$35.1 million is included within restructuring charges, net. Consistent with the prior fiscal year, the incremental fair value associated with the conversion of Covidien equity awards into Mallinckrodt equity awards is included in separation costs. The Company recognized a related tax benefit associated with this expense of \$24.4 million, \$5.8 million and \$3.8 million in fiscal 2014, 2013 and 2012, respectively.

### *Incentive Equity Awards Converted from Covidien Awards*

Prior to the Separation, all employee incentive equity awards were granted by Covidien. At the time of Separation, the restricted share units and share options granted to Mallinckrodt employees prior to June 28, 2013 were converted into restricted share units and share options, respectively, of Mallinckrodt, and all of the performance share awards granted to Mallinckrodt employees were converted to restricted share units of Mallinckrodt (collectively, "the Conversion"). Mallinckrodt incentive equity awards issued upon completion of the Conversion and the related weighted-average grant date fair value is presented below:

	Awards	Weighted-Average Grant-Date Fair Value
Share options	2,399,822	\$ 7.96
Restricted share units	575,213	38.97

*Share Options.* A summary of the status of the Company's share option awards upon completion of the Conversion on June 28, 2013 is presented below:

	Shares Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 28, 2013	2,399,822	\$ 35.94	8.0	\$ 22.9
Exercisable at June 28, 2013	550,097	30.94	5.9	8.0

The Conversion resulted in a modification of the previously issued share option awards. The Company compared the aggregate fair value of the awards immediately before and immediately after the Separation. The fair value of the awards immediately after the Separation was higher than the awards immediately before, primarily due to the elimination of Covidien's dividend yield assumption and the Company's higher volatility as compared to Covidien. The incremental fair value for vested awards was recognized immediately within separation costs, as the incremental fair value is directly attributable to the Separation, and the incremental fair value for unvested awards will be recognized on a straight-line basis over the remaining vesting period of the applicable awards, also within separation costs.

The weighted-average assumptions used in the Black-Scholes pricing model for determining the fair value of the share option awards immediately before and immediately after the Separation were as follows:

	Pre- Separation	Post- Separation
Expected share price volatility	26%	32%
Risk-free interest rate	0.99%	0.99%
Expected annual dividend per share	1.65%	—
Expected life of options (in years)	3.8	3.8
Fair value per option	\$ 18.04	\$ 16.51
Share option awards	1,745,258	2,399,822

*Restricted share units.* The Conversion resulted in a modification of the previously issued restricted share unit awards ("RSUs"). The Company compared the aggregate fair value of the awards immediately before and immediately after the Separation. The Conversion did not result in incremental fair value.

*Performance share units.* The Conversion resulted in a modification of the previously issued performance share unit awards ("PSUs"). The Company compared the aggregate fair value of the awards immediately before and immediately after the Separation. The fair value of the awards was higher after the Conversion as the performance factor utilized to convert the award was higher than what had previously been estimated. The incremental fair value was recognized immediately within separation costs for the service period to date and the remaining incremental fair value will be recognized over the remaining vesting period within separation costs.

### Stock Compensation Plans

Prior to the Separation, the Company adopted the 2013 Mallinckrodt Pharmaceuticals Stock and Incentive Plan ("the 2013 Plan"). The 2013 Plan provides for the award of share options, share appreciation rights, annual performance bonuses, long-term performance awards, restricted units, restricted shares, deferred share units, promissory shares and other share-based awards (collectively, "Awards"). The 2013 Plan provides for a maximum of 5.7 million common shares to be issued as Awards, subject to adjustment as provided under the terms of the 2013 Plan. As of September 26, 2014, all equity awards held by the Company's employees were either converted from Covidien equity awards at the Separation, converted from Questcor equity awards, or granted under its 2013 Plan.

*Share options.* Share options are granted to purchase the Company's ordinary shares at prices that are equal to the fair market value of the shares on the date the share option is granted. Share options generally vest in equal annual installments over a period of four years and expire ten years after the date of grant. The grant-date fair value of share options, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are estimated based on historical experience.

Share option activity and information is as follows:

	Share Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at September 27, 2013	2,760,231	\$ 37.30		
Granted	675,921	52.63		
Converted from Questcor Acquisition	1,292,736	25.08		
Exercised	(878,330)	30.96		
Expired/Forfeited	(323,769)	41.83		
Outstanding at September 26, 2014	<u>3,526,789</u>	36.84	6.4	\$ 187.5
Vested and unvested expected to vest as of September 26, 2014	<u>3,362,751</u>	36.27	6.5	180.7
Exercisable at September 26, 2014	<u>832,680</u>	31.32	4.7	48.8

As of September 26, 2014, there was \$54.0 million of total unrecognized compensation cost related to unvested share option awards, which is expected to be recognized over a weighted-average period of 1.7 years .

The grant date fair value of share options has been estimated using the Black-Scholes pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The expected volatility assumption is based on the historical and implied volatility of the Company's peer group with similar business models for periods after the Separation, and on Covidien's peer group with similar business models for periods prior to the Separation. The expected life assumption is based on the contractual and vesting term of the share option, employee exercise patterns and employee post-vesting termination behavior. The expected annual dividend per share is based on the Company's current intentions regarding payment of cash dividends, or Covidien's dividend rate on the date of grant. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected life assumed at the date of grant. The weighted-average assumptions used in the Black-Scholes pricing model for share options granted in fiscal 2013 subsequent to the Separation are included within the discussion of modification expense above. The weighted-average assumptions used in the Black-Scholes pricing model for shares granted in fiscal 2014, along with the weighted-average grant-date fair value, were as follows:

	2014
Expected share price volatility	32%
Risk-free interest rate	1.96%
Expected annual dividend per share	—%
Expected life of options (in years)	5.5
Fair value per option	\$ 17.38

In fiscal 2013, subsequent to the Separation, the total intrinsic value of share options exercised and the related tax benefit was not significant. In fiscal 2014, the total intrinsic value of options exercised and related tax benefit was \$34.2 million and \$12.0 million, respectively.

*Restricted share units.* Recipients of RSUs have no voting rights and receive dividend equivalent units which vest upon the vesting of the related shares. RSUs generally vest in equal annual installments over a period of four years. Restrictions on RSUs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSUs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the service period. The fair market value of RSUs granted after the Conversion is determined based on the market value of the Company's shares on the date of grant for periods after the Separation.

RSU activity is as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at June 28, 2013	724,269	\$ 40.62
Granted	229,281	55.40
Converted from Questcor Acquisition	30,747	70.88
Vested	(300,237)	34.77
Forfeited	(94,838)	42.48
Non-vested at September 26, 2014	<u>589,222</u>	47.88

The total fair value of Mallinckrodt restricted share unit awards granted during fiscal 2014 was \$12.7 million. The total fair value of Mallinckrodt restricted share units vested during fiscal 2014 was \$16.5 million. As of September 26, 2014, there was \$20.4 million of total unrecognized compensation cost related to non-vested restricted share units granted. The cost is expected to be recognized over a weighted-average period of 2.4 years.

*Performance share units.* Similar to recipients of RSUs, recipients of PSUs have no voting rights and receive dividend equivalent units. The grant date fair value of PSUs, adjusted for estimated forfeitures, is generally recognized as expense on a straight-line basis from the grant date through the end of the performance period. The vesting of PSUs and related dividend equivalent units is generally based on various performance metrics and relative total shareholder return (total shareholder return for the Company as compared to total shareholder return of the PSU peer group), measured over a three-year performance period. The PSU peer group is comprised of various healthcare companies which replicate the Company's mix of businesses. Depending on Mallinckrodt's relative performance during the performance period, a recipient of the award is entitled to receive a number of ordinary shares equal to a percentage, ranging from 0% to 200%, of the award granted.

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

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 27, 2013	—	\$ —
Granted	79,230	63.40
Performance metric adjustment	—	—
Vested	—	—
Forfeited	(6,490)	62.65
Non-vested at September 26, 2014	<u>72,740</u>	63.46

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

The Company generally uses the Monte Carlo model to estimate the probability of satisfying the performance criteria and the resulting fair value of PSU awards. The assumptions used in the Monte Carlo model for PSUs granted during each year were as follows:

	2014
Expected stock price volatility	28%
Peer group stock price volatility	33%
Correlation of returns	17%

The weighted-average grant-date fair value per share of PSUs granted was \$63.40 in fiscal 2014. As of September 26, 2014, there was \$5.2 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 2.0 years.

*Restricted stock awards.* Recipients of restricted stock awards ("RSAs") pertain solely to converted awards from the Questcor Acquisition, which were converted at identical terms to their original award. The converted RSAs maintain voting rights and a non-forfeitable right to receive dividends. RSAs are subject to accelerated vesting as prescribed by the terms of the original award based on a change in control, and substantially all of which will vest over a thirteen month period of time from the date of the Questcor Acquisition. Restrictions on RSAs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSAs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the service period.

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 27, 2013	—	\$ —
Granted	—	—
Converted from Questcor Acquisition	1,829,164	70.88
Vested	(390,731)	70.88
Forfeited	(6,402)	70.88
Non-vested at September 26, 2014	<u>1,432,031</u>	70.88

The total fair value of Mallinckrodt RSAs converted as part of the Questcor Acquisition was \$129.7 million. The total fair value of Mallinckrodt restricted share awards vested during fiscal 2014 was \$30.8 million. As of September 26, 2014, there was \$61.4 million of total unrecognized compensation cost related to non-vested restricted share units granted. The cost is expected to be recognized over a weighted-average period of 1.2 years.

### Employee Stock Purchase Plans

The Company adopted the Mallinckrodt Employee Stock Purchase Plan ("ESPP") effective October 1, 2013. Substantially all full-time employees of the Company's U.S. subsidiaries and employees of certain qualified non-U.S. subsidiaries are eligible to participate in this ESPP. Eligible employees authorize payroll deductions to be made for the purchase of shares. The Company matches a portion of the employee contribution by contributing an additional 15% (25% in fiscal 2014 and fiscal 2015) of the employee's payroll deduction up to a \$25,000 per employee contribution. All shares purchased under the ESPP are purchased on the open market by a designated broker.

## 15. Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income are as follows:

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized Gain (Loss) on Benefit Plans	Accumulated Other Comprehensive Income
Balance at September 30, 2011	\$ 160.0	\$ —	\$ (61.5)	\$ 98.5
Other comprehensive income (loss), net	(2.9)	—	(10.7)	(13.6)
Balance at September 28, 2012	157.1	—	(72.2)	84.9
Other comprehensive income (loss), net	1.5	(7.3)	29.4	23.6
Balance at September 27, 2013	158.6	(7.3)	(42.8)	108.5
Other comprehensive loss before reclassification	(27.6)	—	(17.1)	(44.7)
Reclassification to other comprehensive income (loss)	—	0.5	1.4	1.9
Balance at September 26, 2014	\$ 131.0	\$ (6.8)	\$ (58.5)	\$ 65.7

The following summarizes reclassifications out of accumulated other comprehensive income for the 2014 fiscal year:

	Amount Reclassified from Accumulated Other Comprehensive Income	Line Item in the Condensed Consolidated Statement of Income
	September 26, 2014	
Amortization of unrealized gain on derivatives	\$ 0.6	Interest expense
Income tax provision	(0.1)	Provision for income taxes
Net of income taxes	0.5	
Amortization of pension and post-retirement benefit plans:		
Net actuarial loss	8.1 <sup>(1)</sup>	
Prior service credit	(9.9) <sup>(1)</sup>	
Plan settlements	3.8 <sup>(1)</sup>	
Total before tax	2.0	
Income tax provision	(0.6)	Provision for income taxes
Net of income taxes	1.4	
Total reclassifications for the period	\$ 1.9	

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

## **16. Transactions with Former Parent Company**

Prior to the completion of the Separation on June 28, 2013, the Company was part of Covidien and, as such, transactions between Covidien and the Company were considered related party transactions. As discussed in Note 1, these intercompany transactions are included in the combined financial statements and were considered to be effectively settled for cash at the time the transaction was recorded. The continuing relationship between Covidien and the Company is primarily governed through agreements entered into as part of the Separation, including a Separation Distribution Agreement, a Tax Matters Agreement and a transition services agreement. These agreements were filed with the SEC as Exhibits 2.1, 10.1 and 10.3, respectively, to the Company's Current Report on Form 8-K filed on July 1, 2013. The following discusses the related party transactions and those agreements.

### ***Sales and Purchases***

During fiscal 2014, 2013 and 2012, the Company sold inventory to Covidien in the amount of \$46.0 million, \$51.2 million and \$54.2 million, respectively, which is included in net sales in the consolidated and combined statements of income. The Company also purchases inventories from Covidien. The Company recognized cost of sales from these inventory purchases of \$28.9 million, \$38.4 million and \$34.7 million during fiscal 2014, 2013 and 2012, respectively.

### ***Allocated Expenses***

As discussed in Note 1, the combined financial statements for periods prior to June 28, 2013 include expense allocations for certain functions provided by Covidien, including, but not limited to, general corporate expenses related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. These expenses were allocated to the Company on the basis of direct usage when identifiable, with the remainder allocated on the basis of operating expenses, headcount or other measures. The amounts allocated were \$39.6 million and \$49.2 million for fiscal 2013 and 2012, respectively, and are included within selling, general and administrative expenses.

### ***Balance Sheet Impacts***

Subsequent to the Separation, the Company and Covidien maintain an ongoing relationship in which each party may provide services to the other party, including the distribution of goods. As a result of these relationships, the consolidated balance sheet as of September 26, 2014 includes \$82.2 million of amounts due to the Company from Covidien, within prepaid expenses and other current assets, and \$84.5 million of amounts the Company owes Covidien, included within accrued and other liabilities.

### ***Separation and Distribution Agreement***

On June 28, 2013, the Company entered into a Separation and Distribution Agreement and other agreements with Covidien to effect the Separation and provide a framework for the Company's relationships with Covidien after the Separation. These agreements govern the relationship between Mallinckrodt and Covidien subsequent to the Separation and provide for the assignment to Mallinckrodt of certain of Covidien's assets, liabilities and obligations attributable to periods prior to the Separation.

In general, each party to the Separation and Distribution Agreement assumed liability for all pending, threatened and unasserted legal matters related to its own business or its assumed or retained liabilities and will indemnify the other party for any liability to the extent arising out of, or resulting from, such assumed or retained legal matters.

The Separation and Distribution Agreement provided for the initial cash capitalization of Mallinckrodt in the amount of approximately \$168 million at June 28, 2013. The Separation and Distribution Agreement also provided for an adjustment payment to compensate either Mallinckrodt or Covidien, as applicable, to the extent that the aggregate of the Company's cash, indebtedness and specified working capital accounts as of June 28, 2013 ("the Distribution Date"), as well as the capital expenditures made with respect to the Company's business during fiscal 2013 through the Distribution Date, deviated from the target. The target was calculated pursuant to a formula set forth in the Separation and Distribution Agreement, which assumed the Distribution Date would be June 28, 2013, that the Pharmaceuticals business was conducted in the ordinary course through that date and that the Company would have approximately \$168 million of cash upon completion of the distribution. The Separation and Distribution Agreement also provided that an adjustment payment would only be payable if the amount of the adjustment payment exceeded \$20 million (in which case the entire amount would be paid). Upon final calculation, no adjustment payment was required by either the Company or Covidien.

### ***Tax Matters Agreement***

In connection with the Separation, Mallinckrodt entered into the Tax Matters Agreement with Covidien that generally will govern Covidien's and Mallinckrodt's respective rights, responsibilities and obligations after the Separation with respect to certain taxes, including ordinary course of business taxes and taxes, if any, incurred as a result of any failure of the distribution of Mallinckrodt shares to qualify as a tax-free distribution for U.S. federal income tax purposes within the meaning of Section 355 of the U.S. Internal Revenue Code, or other applicable tax law, or any failure of certain internal transactions undertaken in anticipation of the distribution to qualify for tax-free or tax-favored treatment under the applicable tax law. The Company expects, with certain exceptions, to be responsible for the payment of all taxes attributable to Mallinckrodt or its subsidiaries for taxable periods beginning on or after September 29, 2012. For periods prior to September 29, 2012, the Company is subject to a \$200 million liability limitation, net of any benefits, as prescribed by the Tax Matters Agreement. The Company has made \$33.0 million of payments, net of benefits, for periods prior to September 29, 2012. To the extent that the Company's liability for such taxes, net of any tax benefits, does not exceed \$200 million, it may be responsible for additional taxes attributable to periods prior to September 29, 2012, taxes related to the Separation and a percentage of any taxes arising from the Separation failing to qualify for tax-free or tax-favored treatment through no fault of Covidien or the Company. The Tax Matters Agreement also assigns rights and responsibilities for administrative matters, such as the filing of returns, payment of taxes due, retention of records, tax reporting practices and conduct of audits, examinations or similar proceedings. In addition, the Tax Matters Agreement provides for cooperation and information sharing with respect to tax matters.

The Tax Matters Agreement also contains restrictions on the Company's ability to take actions without Covidien's consent that could cause the Separation or certain internal transactions undertaken in anticipation of the Separation to fail to qualify as tax-free or tax-favored transactions under applicable tax law. These transactions include, but are not limited to, entering into, approving or allowing any transaction that results in a change in ownership of more than 35% of Mallinckrodt's shares; any merger, consolidation, scheme of arrangement, liquidation or partial liquidation, or any approval or allowance of such transaction with respect to certain of the Company's subsidiaries; the cessation or transfer of certain business activities; the sale, issuance or other disposition of any equity interest in certain of the Company's subsidiaries; a sale or other disposition of a substantial portion of the Company's assets or a substantial portion of the assets of certain of the Company's subsidiaries; extraordinary distributions by or to certain of the Company's subsidiaries; or engaging in certain internal transactions. These restrictions will all apply for the two-year period after the Separation and in some cases will apply for periods as long as five years following the Separation. Any taxes imposed on the other party attributable to certain post-distribution actions taken by or in respect of the responsible party or its shareholders that result in failure of the Separation or internal transactions to qualify as tax-free or tax-favored transactions are the responsibility of the party at fault, regardless of whether the actions occur more than two years after the distribution, or whether Covidien consents to such actions. Any actions of the Company or its shareholders that directly give rise to additional taxes are not subject to the \$200 million threshold noted previously.

### ***Transition Services Agreement***

Mallinckrodt and Covidien entered into a transition services agreement in connection with the Separation pursuant to which Mallinckrodt and Covidien will provide each other, on an interim and transitional basis, various services including, but not limited to, treasury administration, information technology services, non-exclusive distribution and importation services for our products in certain countries outside the U.S., regulatory, general administrative services and other support services. The agreed-upon charges for such services are generally intended to allow the servicing party to recover all out-of-pocket costs and expenses, and include a predetermined profit margin. The Company expects to substantially reduce the level of service provided by Covidien in fiscal 2015 as the Company has substantially completed the implementation of information systems in jurisdictions outside the U.S. and terminated the transition services agreement during the first quarter of fiscal 2015.

## **17. Guarantees**

In disposing of assets or businesses, the Company has historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. 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 resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemical business (formerly known as Mallinckrodt Baker) in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on the Company's consolidated balance sheets at September 26, 2014 and September 27, 2013 was \$16.6 million and \$20.1 million, respectively, of which \$13.9 million and \$17.2 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 26, 2014 and September 27, 2013. As of September 26, 2014, the maximum future payments the Company could be required to make under these indemnification obligations was \$71.4 million. The Company was required to pay \$30.0 million into an escrow account as collateral to the purchaser, of which \$19.4 million and \$23.5 million remained in other assets on the consolidated balance sheets at September 26, 2014 and September 27, 2013, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 18. In addition, the Company is liable for product performance; however the Company believes, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

The Company is required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating its ability to fund the decommissioning of its Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though the Company does not intend to close this facility. The Company has provided this financial assurance in the form of surety bonds totaling \$57.2 million.

In addition, as of September 26, 2014, the Company had a \$21.1 million letter of credit to guarantee decommissioning costs associated with its Saint Louis, Missouri plant. As of September 26, 2014, the Company had various other letters of credit and guarantee and surety bonds totaling \$36.2 million.

In addition, the separation and distribution agreement entered into with Covidien at the Separation provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of the Company's business with the Company and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities.

## 18. Commitments and Contingencies

The Company has purchase obligations related to commitments to purchase certain goods and services. At September 26, 2014, such obligations were as follows:

Fiscal 2015	\$	93.8
Fiscal 2016		63.1
Fiscal 2017		60.2
Fiscal 2018		60.2
Fiscal 2019		3.9

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 resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

### **Governmental Proceedings**

On November 30, 2011 and October 22, 2012, the Company received subpoenas from the U.S. Drug Enforcement Administration requesting production of documents relating to its suspicious order monitoring programs.

On September 24, 2012, Questcor received a subpoena from the United States Attorney's Office ("the USAO") for the Eastern District of Pennsylvania for information relating to its promotional practices. 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 are also participating in the investigation to review Questcor's promotional practices and related matters.

On June 11, 2014, Questcor received a subpoena and Civil Investigative Demand ("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® from Novartis AG and Novartis Pharma AG (collectively, "Novartis") violates the antitrust laws.

We are in the process of responding to each of the subpoenas and the CID and we intend to cooperate fully in each such investigation.

*Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America* The Company filed a Complaint for Declaratory and Injunctive Relief in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States of America on November 17, 2014 for judicial review of what the Company believes is FDA's inappropriate and unlawful reclassification of the Company's methylphenidate hydrochloride extended-release tablets in the Orange Book: Approved Drug Products with Therapeutic Equivalence (Orange Book) on November 13, 2014. In its complaint, the Company has asked the court to: issue an injunction to (a) set aside the FDA's reclassification of the Company's methylphenidate ER products from AB (freely substitutable at the pharmacy level) to BX (presumed to be therapeutically inequivalent) in the Orange Book and (b) prohibit the FDA from reclassifying Mallinckrodt's methylphenidate ER products in the future without following applicable legal requirements; and issue a declaratory judgment that the FDA's action reclassifying Mallinckrodt's methylphenidate ER products in the Orange Book is unlawful. Mallinckrodt concurrently filed a motion with the same court requesting an expedited hearing to issue a temporary restraining order (TRO) directing FDA to reinstate the Orange Book AB rating for the Company's methylphenidate ER drug on a temporary basis.

### **Patent/Antitrust Litigation**

*Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, 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 Abbreviated New Drug Application ("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. On January 18, 2013, the trial court issued an opinion and order granting the Company's motion for summary judgment regarding Mutual's antitrust and unfair competition counterclaims. On May 1, 2013, Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit and on August 6, 2014, the Federal Circuit issued a split decision, affirming the trial court in part and remanding to the trial court certain counterclaims for further proceedings.

*'222 and '218 Patent Litigation: Exela Pharma Sciences, LLC.* In August 2011, Cadence, a subsidiary of the Company, and Pharmatop, the owner of the two U.S. patents licensed exclusively by Cadence, filed suit in the U.S. District Court for the District of Delaware against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc. (collectively, "Exela"), alleging that Exela infringed U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent"), by submitting an ANDA to the FDA seeking to sell a generic version of Ofirmev. The filing of the lawsuit triggered a stay of FDA approval of the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Exela, or such shorter or longer period as the court may order. After a bench trial, the court ruled in favor of Cadence in November 2013 and found that Exela's ANDA infringed the '222 and '218 patents. On December 20, 2013, Exela appealed the decision and oral arguments in the appeal occurred on November 7, 2014. It is not possible at this time to predict the outcome of this appeal.

*'222 and '218 Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc.* In September 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, filed suit in the U.S. District Court for the District of Delaware against InnoPharma Licensing LLC and InnoPharma, Inc. (collectively "InnoPharma") following receipt of an August 2014 notice from InnoPharma concerning its submission of a New Drug Application ("NDA"), containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev.

*'222 and '218 Patent Litigation: Agila Specialties Private Limited, Inc. and Agila Specialties Inc. (a Mylan Inc. Company), (collectively "Agila").* In November 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, received notice from Agila concerning its submission of a NDA containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. The Company is currently evaluating the notice and will be analyzing the Agila submission to make a timely determination regarding potentially filing suit against Agila.

The Company intends to vigorously enforce its intellectual property rights relating to Ofirmev to prevent the marketing of infringing generic or competing products prior to the expiration of the Cadence patents. An adverse outcome in either the Exela or InnoPharma matters ultimately could result in the launch of one or more generic versions of Ofirmev before the expiration of the last of the listed patents on June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect the Company's ability to successfully maximize the value of Ofirmev and have an adverse effect on our financial condition, results of operations and cash flows.

*'222 and '218 Patents: Ex Parte Reexamination.* In September 2012, Exela filed with the U.S. Patent and Trademark Office ("USPTO"), a Request for Ex Parte Reexamination of the '222 patent and the USPTO granted that request. The reexamination process requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. Cadence and Pharmatop have filed, with the USPTO, a patent owner's statement commenting on the reexamination request, and thereafter the parties have made various submissions. In July 2014, a Second Final Office Action was issued by the USPTO in which certain claims were indicated to be allowable and certain claims were rejected. A subsequent amendment was filed in September 2014, but the USPTO did not enter that amendment. In October 2014, Cadence and Pharmatop filed a notice of appeal and petitioned the Commissioner of Patents, requesting that certain claim amendments be entered so that set of claims are of record for consideration in any future appeal.

In addition, in January 2014, an unidentified third party filed, with the USPTO, a Request for Ex Parte Reexamination of the '218 patent. The reexamination request was granted on March 14, 2014. In July 2014, the USPTO issued a Non-Final Office Action in the '218 reexamination in which it rejected certain claims. In September 2014, Cadence and Pharmatop filed an Amendment and Response to the Office Action.

All of the claims of the '222 and '218 patents remain valid and in force during the reexamination proceedings. Because we and Pharmatop believe that the scope and validity of the patent claims in these patents are appropriate and that the USPTO's prior issuances of the patents were correct, the Company, in conjunction with Pharmatop, will vigorously defend these patents. It is not possible, at this time, to determine with certainty whether we will ultimately succeed in maintaining the scope and validity of the claims of these patents during reexamination. If any of the patent claims in these patents ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to Ofirmev could be impaired, which could have a material adverse effect on the Company's financial condition, results of operations and cash flows.

*'218 Patent Litigation: Exela Pharma Sciences, LLC.* In April 2012, Exela filed suit against David J. Kappos and the USPTO in the U.S. District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO's decision not to act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international application for the '218 patent. The lawsuit followed the USPTO's rejection of Exela's petition to the USPTO filed in November 2011, which sought to vacate the April 2003 order. The USPTO determined that Exela lacked standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "unintentional" standard are invalid, and seeks similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Cadence intervened in this lawsuit and in December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the dismissal to the Court of Appeals for the Federal Circuit, oral argument was held in February 2014 and a final decision has not been issued.

*'222 and '218 Patent Litigation Settlement: Fresenius Kabi USA, LLC.* In January 2013, Cadence filed suit in the U.S. District Court for the Southern District of California against Fresenius Kabi USA, LLC ("Fresenius"), alleging that Fresenius infringed the '222 and '218 patents by submitting a NDA to the FDA seeking to sell a competing version of Ofirmev. The filing of the lawsuit triggered a stay of FDA approval of the Fresenius NDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Fresenius, or such shorter or longer period as the court may order. In August 2014, Cadence entered into a settlement agreement and license agreement with Fresenius, dismissing with prejudice the lawsuit and granting to Fresenius the non-exclusive right to market an intravenous acetaminophen product in the U.S. under the Fresenius NDA beginning December 6, 2020, or earlier under certain circumstances. Under a related supply agreement, an affiliate of Fresenius will develop, manufacture and supply commercial quantities of Ofirmev to us if certain regulatory approvals are obtained. As a result of these agreements we recorded an \$11.5 million charge during the third quarter of fiscal 2014.

*Other '222 and '218 Patent Litigation Settlements.* Three other similar cases involving generic versions of Ofirmev have previously settled. In each settlement, the defendant was granted the non-exclusive right to market a generic intravenous acetaminophen product in the U.S. under its respective ANDA after December 6, 2020, or earlier under certain circumstances. In connection with those settlements, one settling party was granted the exclusive right of first refusal to negotiate an agreement with Cadence to market an authorized generic of Ofirmev in the U.S. in the event that Cadence elects to launch an authorized generic version of the product. If that settling party elects not to exercise its right of first refusal, Cadence has agreed to grant a similar right of first refusal to another settling party.

## **Commercial and Securities Litigation**

**Retrophin Litigation.** In January 2014, Retrophin Inc. filed a lawsuit against Questcor in the United States District Court for the Central District of California, alleging a variety of federal and state antitrust violations based on Questcor's acquisition from Novartis of certain rights to develop, market, manufacture, distribute, sell and commercialize Synacthen. Discovery has commenced, and the Court set July 10, 2015, as the deadline for filing dispositive motions. While it is not possible at this time to determine with certainty the outcome of this investigation, the Company believes, given the information currently available, that its ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

**Glenridge Litigation.** In June 2011, Glenridge Pharmaceuticals LLC ("Glenridge"), filed a lawsuit against Questcor in the Superior Court of California, Santa Clara County, alleging that Questcor had underpaid royalties to Glenridge under a royalty agreement related to net sales of Acthar. In August 2012, Questcor filed a separate lawsuit against the three principals of Glenridge, as well as Glenridge, challenging the enforceability of the royalty agreement. In August 2013, the two lawsuits were consolidated into one case in the Superior Court of California, Santa Clara County. On October 29, 2014, the parties entered into a binding term sheet settling the lawsuit. Under the terms of the settlement, the royalty rate payable by Questcor was reduced, royalties were capped instead of being payable for so long as Acthar was sold and Questcor agreed to pay Glenridge a reduced amount in satisfaction of royalties Questcor had withheld in the course of the lawsuit.

**Putative Class Action Securities Litigation.** On September 26, 2012, a putative class action lawsuit was filed against Questcor and certain of its officers and directors in the United States District Court for the Central District of California, captioned *John K. Norton v. Questcor Pharmaceuticals, et al.*, No. SACv12-1623 DMG (FMOx). The complaint purports to be brought on behalf of shareholders who purchased Questcor common stock between April 26, 2011 and September 21, 2012. The complaint generally alleges that Questcor and certain of its officers and directors engaged in various acts to artificially inflate the price of Questcor stock and enable insiders to profit through stock sales. The complaint asserts that Questcor and certain of its officers and directors violated sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, as amended, ("the Exchange Act"), by making allegedly false and/or misleading statements concerning the clinical evidence to support the use of Acthar for indications other than infantile spasms, the promotion of the sale and use of Acthar in the treatment of MS and nephrotic syndrome, reimbursement for Acthar from third-party insurers, and Questcor's outlook and potential market growth for Acthar. The complaint seeks damages in an unspecified amount and equitable relief against the defendants. This lawsuit has been consolidated with four subsequently-filed actions asserting similar claims under the caption: *In re Questcor Securities Litigation*, No. CV 12-01623 DMG (FMOx). On October 1, 2013, the District Court granted in part and denied in part Questcor's motion to dismiss the consolidated amended complaint. On October 29, 2013, Questcor filed an answer to the consolidated amended complaint. Discovery is currently ongoing. The Court set a jury trial for December 1, 2015.

**Federal Shareholder Derivative Litigation.** On October 4, 2012, another alleged shareholder filed a derivative lawsuit in the United States District Court for the Central District of California captioned *Gerald Easton v. Don M Bailey, et al.*, No. SACV12-01716 DOC (JPRx). The suit asserts claims substantially identical to those asserted in the *do Valle* derivative action described below against the same defendants. This lawsuit has been consolidated with five subsequently-filed actions asserting similar claims under the caption: *In re Questcor Shareholder Derivative Litigation*, CV 12- 01716 DMG (FMOx). Following the resolution of the motion to dismiss in the consolidated putative securities class action, the court issued an order staying the federal derivative action until the earlier of: (a) 60 days after the resolution of any motion for summary judgment filed in the putative class action lawsuit, (b) 60 days after the deadline to file a motion for summary judgment in the putative class action lawsuit, if none is filed, or (c) the execution of any settlement agreement (including any partial settlement agreement) to resolve the putative class action lawsuit.

**State Shareholder Derivative Litigation.** On October 2, 2012, an alleged shareholder filed a derivative lawsuit purportedly on behalf of Questcor against certain of its officers and directors in the Superior Court of the State of California, Orange County, captioned *Monika do Valle v. Virgil D. Thompson, et al.*, No. 30-2012-00602258-CU-SL-CXC. The complaint asserted claims for breach of fiduciary duty, abuse of control, mismanagement and waste of corporate assets arising from substantially similar allegations as those contained in the putative securities class action described above, as well as from allegations relating to sales of our common stock by the defendants and repurchases of Questcor common stock. The complaint sought an unspecified sum of damages and equitable relief. On October 24, 2012, another alleged shareholder filed a derivative lawsuit purportedly on behalf of Questcor against certain of its officers and directors in the Superior Court of the State of California, Orange County, captioned *Jones v. Bailey, et al.*, Case No. 30-2012-00608001-CU-MC-CXC. The suit asserted claims substantially identical to those asserted in the *do Valle* derivative action. On February 19, 2013, the court issued an order staying the state derivative actions until the putative federal securities class action and federal derivative actions are resolved. On May 17, 2014, the Court granted plaintiffs' request for dismissal without prejudice of the *Jones* action. On November 18, 2014, the *do Valle* matter was voluntarily dismissed.

**Put Options Securities Action.** In March 2013, individual traders of put options filed a securities complaint in the United States District Court for the Central District of California captioned *David Taban, et al. v. Questcor Pharmaceuticals, Inc.*, No. SACV13-0425. The complaint generally asserts claims against Questcor and certain of its officers and directors for violations of the Exchange Act and for state law fraud and fraudulent concealment based on allegations similar to those asserted in the putative securities class action described above. The complaint seeks compensatory and punitive damages of an unspecified amount. Following the resolution of the motion to dismiss in the consolidated putative securities class action, the court issued an order staying this action until the earlier of: (a) sixty (60) days after the resolution of any motion for summary judgment filed in the putative class action lawsuit, (b) sixty (60) days after the deadline to file a motion for summary judgment in the putative class action lawsuit, if none is filed, or (c) the execution of any settlement agreement (including any partial settlement agreement) to resolve the putative class action lawsuit. The case remains stayed.

### **Pricing Litigation**

**State of Utah v. Actavis US, Inc., et al.** The Company, along with numerous other pharmaceuticals companies, are defendants in this matter which was filed May 8, 2008, and is pending in the Third Judicial Circuit of Salt Lake County, Utah. The State of Utah alleges, generally, that the defendants reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and is seeking monetary damages and attorneys' fees. The Company believes that it has meritorious defenses to these claims and is vigorously defending against them. While it is not possible at this time to determine with certainty the outcome of the case, the Company believes, given the information currently available, that its ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

### **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 26, 2014, it was probable that it would incur remedial costs in the range of \$43.7 million to \$106.9 million. The Company also concluded that, as of September 26, 2014, the best estimate within this range was \$67.1 million, of which \$7.2 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet at September 26, 2014.

**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 U.S. Environmental Protection Agency ("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 remedial investigation and feasibility study ("RI/FS") for the AUS Operable Unit. General Dynamics negotiated an Administrative Order on Consent ("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. The Company and other PRPs are awaiting completion of the RI by General Dynamics before the initiation of formal PRP negotiations to address resolution of these alleged claims. While it is not possible at this time to determine with certainty the ultimate outcome of this case, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

**Mallinckrodt Veterinary, Inc., Millsboro, Delaware.** The Company previously operated a plant in Millsboro, Delaware ("the Millsboro Site") that manufactured various animal healthcare products. 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, assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The Company and another PRP 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 to characterize the nature and extent of the contamination. The Company, along with the other party, continues to conduct the studies and prepare remediation plans

in accordance with the AOCs. 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.

*Coldwater Creek, Saint Louis County, Missouri.* The Company is named as a defendant in numerous tort complaints filed between February 2012 and September 2014 with numerous plaintiffs pending in the U.S. District Court for the Eastern District of Missouri. These cases allege personal injury for alleged exposure to radiological substances present in Coldwater Creek in Missouri. Plaintiffs allegedly lived in various locations in Saint Louis County, Missouri near Coldwater Creek. Radiological residues which may have been present in the creek have been remediated by the U.S. Army Corps of Engineers. The Company believes that it has meritorious defenses to these complaints and is vigorously defending against them. The Company is unable to estimate a range of reasonably possible losses for the following reasons: (i) the proceedings are in early stages; (ii) the Company has not received and reviewed complete information regarding the plaintiffs and their medical conditions; and (iii) there are significant factual issues to be resolved. While it is not possible at this time to determine with certainty the ultimate outcome of these cases, the Company believes, given the information currently available, that the ultimate resolution of all known claims will not have a material adverse effect on its financial condition, results of operations and cash flows.

*Lower Passaic River, New Jersey.* The Company and approximately 70 other companies comprise the Lower Passaic Cooperating Parties Group ("the CPG") and are parties to a May 2007 AOC with the EPA to perform a 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 considered 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, the CPG voluntarily entered into an AOC on June 18, 2012 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.

On April 11, 2014, the EPA issued its revised FFS, with remedial alternatives to address cleanup of the lower 8-mile stretch of the River, which also included a "no action" option. The EPA estimates the cost for the alternatives range from \$365.0 million to \$3.2 billion. The EPA's preferred approach would involve bank-to-bank dredging of the lower 8-mile stretch of the River and installing an engineered cap at a discounted, estimated cost of \$1.7 billion. Based on the issuance of the EPA's revised FFS, the Company recorded a \$23.1 million accrual in fiscal 2014 representing the Company's estimate of its allocable share of the joint and several remediation liability resulting from this matter. Despite the issuance of the revised FFS, there are many uncertainties associated with the final agreed upon remediation 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 is ultimately responsible and will be refined as events in the remediation process occur.

#### ***Products Liability Litigation***

Beginning with lawsuits brought in July 1976, the Company is also named as a defendant in personal injury lawsuits based on alleged exposure to asbestos-containing materials. A majority of the cases involve product liability claims based principally on allegations of past distribution of products containing asbestos. A limited number of the cases allege premises liability based on claims that individuals were exposed to asbestos while on the Company's property. Each case typically names dozens of corporate defendants in addition to the Company. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to products containing asbestos. The Company's involvement in asbestos cases has been limited because it did not mine or produce asbestos. Furthermore, in the Company's experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. The Company has not suffered an adverse verdict in a trial court proceeding related to asbestos claims and intends to continue to defend these lawsuits. When appropriate, the Company settles claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of September 26, 2014, there were approximately 11,900 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 consolidated balance sheets. The Company's estimate of its liability for pending and future claims is based on claims experience over the past five years and covers claims either currently filed or expected to be filed over the next seven years. The Company believes that it has adequate amounts recorded related to these matters. While it is not possible at this time to determine with certainty the ultimate outcome of these asbestos-related proceedings, the Company believes, given the information currently available, that the ultimate resolution of all known and anticipated future claims, after taking into account amounts already accrued, along with recoveries from insurance, will not have a material adverse effect on its financial condition, results of operations and cash flows.

### **Asset Retirement Obligations**

The Company has recorded asset retirement obligations for the estimated future costs primarily associated with legal obligations to decommission facilities within the Global Medical Imaging segment, including the facilities located in Petten, the Netherlands and Maryland Heights, Missouri. Substantially all of these obligations are included in other liabilities on the consolidated balance sheets. The following table provides a summary of the changes in the Company's asset retirement obligations for fiscal 2014 and 2013:

	2014	2013
Balance at beginning of period	\$ 50.6	\$ 46.4
Additions and adjustments	(11.6)	0.4
Accretion expense	3.2	2.9
Payments	—	(0.2)
Currency translation	(1.4)	1.1
Balance at end of period	<u>\$ 40.8</u>	<u>\$ 50.6</u>

The Company believes that any potential payment of such estimated amounts will not have a material adverse effect on its financial condition, results of operations and cash flows.

### **Leases**

The Company has facility, vehicle and equipment leases that expire at various dates. Rental expense under facility, vehicle and equipment operating leases related to continuing operations was \$19.9 million, \$16.9 million and \$15.5 million for fiscal 2014, 2013 and 2012, respectively. The Company also has facility and equipment commitments under capital leases.

The following is a schedule of minimum lease payments for non-cancelable leases as of September 26, 2014:

	Operating Leases	Capital Leases
Fiscal 2015	\$ 21.5	\$ 1.4
Fiscal 2016	16.6	0.4
Fiscal 2017	13.9	—
Fiscal 2018	9.8	—
Fiscal 2019	8.2	—
Thereafter	25.0	—
Total minimum lease payments	<u>\$ 95.0</u>	<u>1.8</u>
Less: interest portion of payments		—
Present value of minimum lease payments		<u>\$ 1.8</u>

The Company exchanged title to \$27.4 million of its plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. The Company also simultaneously leased such assets back from Saint Louis County under a capital lease expiring December 2025, the terms of which provide the Company with the right of offset against the IRBs. The lease also provides an option for the Company to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a ten-year property tax abatement from the date the property is placed in service. Due to right of offset, the capital lease obligation and IRB asset are recorded net in the consolidated balance sheets and excluded from the above table. The Company expects that the right of offset will be applied to payments required under these arrangements.

### **Tax Matters**

The income tax returns of the Company and its subsidiaries are periodically examined by various tax authorities. The resolution of these matters is subject to the conditions set forth in the Tax Matters Agreement between the Company and Covidien. Covidien has the right to administer, control and settle all U.S. income tax audits for periods prior to the Separation. 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 established liabilities are reasonable and that the ultimate resolution of these matters will not have a material adverse effect on its financial condition, results of operations and cash flows.

With respect to certain tax returns filed by predecessor affiliates of the Company and Covidien, the IRS has concluded its field examination for the years 1997 through 2007. The Company considers such uncertain tax positions associated with these years as having been effectively settled. All but one of the matters associated with these audits have been resolved. The unresolved proposed adjustment asserts that substantially all of the predecessor affiliates' intercompany debt originating during the years 1997 through 2000 should not be treated as debt for U.S. federal income tax purposes, and has disallowed interest deductions related to the intercompany debt and certain tax attribute adjustments recognized on the U.S. income tax returns. This matter is subject to the Company's \$200 million liability limitation for periods prior to September 29, 2012, as prescribed in the Tax Matters Agreement. 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 it will not have a material adverse effect on its financial condition, results of operations and cash flows.

### **Acquisition-Related Litigation**

Several purported class action lawsuits have been filed in February 2014 and March 2014 by purported holders of Cadence common stock in connection with the Cadence Acquisition, including in the Delaware Court of Chancery (consolidated under the caption *In re Cadence Pharmaceuticals, Inc. Stockholders Litigation*), and in California State Court, San Diego County (*Denny v. Cadence Pharmaceuticals, Inc., et al., Militello v. Cadence Pharmaceuticals, Inc., et al., and Schuon v. Cadence Pharmaceuticals, Inc., et al.*). The actions bring claims against, and generally allege that, the board of directors of Cadence breached their fiduciary duties in connection with the the Cadence Acquisition by, among other things, failing to maximize shareholder value, and the Delaware and *Schuon* actions further allege that Cadence omitted to disclose allegedly material information in its Schedule 14D-9. The lawsuits also allege, among other things, that the Company aided and abetted the purported breaches of fiduciary duty. The lawsuits seek various forms of relief, including but not limited to, rescission of the transaction, damages and attorneys' fees and costs. On March 7, 2014, following expedited discovery, the parties in the consolidated Delaware action entered into a Memorandum of Understanding ("the MOU"), which sets forth the parties' agreement in principle for a settlement of those actions. The settlement contemplated by the MOU will include, among other things, a release of all claims relating to the Cadence Acquisition as set forth in the MOU. The settlement is subject to a number of conditions, including, among other things, final court approval following notice to the class. There have been no substantive proceedings in any of the California actions. On July 29, 2014, the *Militello* case was voluntarily dismissed without prejudice. On September 8, 2014, the *Denny* case was voluntarily dismissed without prejudice. While it is not possible at this time to determine with certainty the ultimate outcomes of these matters, the Company believes, given the information available to it today, that they will not have a material adverse effect on its financial condition, results of operations and cash flows.

Since the announcement of the merger with Questcor on April 7, 2014, several putative class actions have been filed by purported holders of Questcor common stock in connection with the Company's acquisition of Questcor (*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 names as defendants, and generally alleges 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 alleges 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 alleges, among other things, that we aided and abetted the purported breaches of fiduciary duty. The lawsuit seeks various forms of relief, including but not limited to, rescission of the transaction, damages and attorney's fees and costs.

On July 29, 2014, the defendants reached an agreement in principle with the plaintiffs in the consolidated actions, and that agreement is reflected in a memorandum of understanding. In connection with the settlement contemplated by the memorandum of understanding, 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 memorandum of understanding, 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 will be reduced to three business days. The memorandum of understanding contemplates that the parties will enter into a stipulation of settlement.

The stipulation of settlement will be subject to customary conditions, including court approval. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the California Superior Court will consider the fairness, reasonableness, and adequacy of the settlement. If the settlement is finally approved by the court, it will resolve and release all claims in all actions that were or could have been brought challenging any aspect of the proposed transaction, the Merger Agreement, and any disclosures made in connection therewith, including the definitive joint proxy statement/prospectus relating to the Questcor Acquisition, pursuant to terms that will be disclosed to shareholders prior to final approval of the settlement. In addition, in connection with the settlement, the parties contemplate that they shall negotiate in good faith regarding the amount of attorney's fees and expense that shall be paid to plaintiffs' counsel in connection with the actions. There can be no assurance that the parties will ultimately enter

into a stipulation of settlement or that the California Superior Court will approve the settlement even if the parties were to enter into such stipulation. In such event, the proposed settlement as contemplated by the memorandum of understanding may be terminated.

While it is not possible at this time to determine with certainty the ultimate outcomes of these matters, the Company believes, given the information available to it today, that they will not have a material adverse effect on its financial condition, results of operations and cash flows.

### 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.

## 19. 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 26, 2014	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	\$ 35.7	\$ 22.9	\$ 12.8	\$ —
	<u>\$ 35.7</u>	<u>\$ 22.9</u>	<u>\$ 12.8</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities	\$ 15.0	\$ —	\$ 15.0	\$ —
Contingent consideration and acquired contingent liabilities	202.8	—	—	202.8
Foreign exchange forward and option contracts	0.2	0.2	—	—
	<u>\$ 218.0</u>	<u>\$ 0.2</u>	<u>\$ 15.0</u>	<u>\$ 202.8</u>

	September 27, 2013	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	\$ 22.6	\$ 12.7	\$ —
Foreign exchange forward and option contracts	0.9	0.9	—	—
	<u>\$ 36.2</u>	<u>\$ 23.5</u>	<u>\$ 12.7</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities	\$ 13.5	\$ —	\$ 13.5	\$ —
Contingent consideration	6.9	—	—	6.9
Foreign exchange forward and option contracts	1.4	1.4	—	—
	<u>\$ 21.8</u>	<u>\$ 1.4</u>	<u>\$ 13.5</u>	<u>\$ 6.9</u>

*Debt and equity securities held in rabbi trust.* Debt securities held in the rabbi trust 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 the rabbi trust primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges.

*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.

*Goodwill.* The Company performs an annual goodwill impairment assessment using an income approach based on the present value of future cash flows. See further discussion in Notes 2 and 11.

*Contingent consideration and acquired contingent liabilities.* In October 2012, the Company recorded contingent consideration of \$6.9 million upon the acquisition of CNS Therapeutics. This contingent consideration, which could potentially total a maximum of \$9.0 million, is primarily based on whether the FDA approves another concentration of Gablofen on or before December 31, 2016. The fair value of the contingent payments was measured based on the probability-weighted present value of the consideration expected to be transferred using a discount rate of 1.0%. At September 26, 2014, the fair value of this contingent consideration was \$7.0 million.

In August 2014, the Company recorded acquired contingent liabilities of \$195.4 million from the Questcor Acquisition. The contingent liabilities relate to Questcor's contingent obligations associated with their acquisition of an exclusive, perpetually and irrevocable license to develop, market, manufacture, distribute, sell and commercialize Synacthen and Synacthen Depot (collectively "Synacthen") from Novartis AG and Novartis Pharma AG (collectively "Novartis") and their acquisition of BioVectra. The fair value of these contingent consideration obligations at September 26, 2014 were \$195.8 million.

Under the terms of the license agreement with Novartis, the Company is obligated to make a \$25 million payment in each of fiscal 2015 and 2016, make annual payments of \$25 million subsequent to fiscal 2016 until such time that the Company obtains FDA approval of Synacthen and make a \$25 million payment upon obtaining FDA approval of Synacthen. If FDA approval is obtained, the Company will pay an annual royalty to Novartis based on a percentage of net sales of the products in the U.S. market. As of both, the Questcor Acquisition date and September 26, 2014, the total remaining payments under the license agreement shall not exceed \$215.0 million. The terms of the license agreement do allow the Company to terminate the license agreement at our discretion following the fiscal 2018 payment or upon the occurrence of certain events following the fiscal 2016 payment. The Company measured the fair value of the contingent payments based on a probability-weighted present value of the consideration expected to be transferred using a discount rate of 4.7%. Under the terms of the license agreement, the Company was required to maintain deposits equal to the the fiscal 2015 and 2016 annual \$25 million payments which are included in prepaid expenses and other current assets and other assets in the consolidated balance sheets.

Based on the terms of the acquisition agreement with the former shareholders of BioVectra, the Company may be obligated to pay, as of both the Questcor Acquisition date and September 26, 2014, additional cash consideration of \$45.0 million CAD based on BioVectra's financial results from January 2013 through a portion of fiscal 2016. The Company measured the fair value of the contingent payments based on a probability-weighted present value of the consideration expected to be transferred using a discount rate of 1.3%.

Balance at September 27, 2013	\$	6.9
Acquisition date fair value of acquired contingent liabilities		195.4
Accretion expense		1.1
Effect of currency rate change		(0.6)
Balance at September 26, 2014	\$	<u>202.8</u>

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

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the majority of other current assets and liabilities approximate fair value because of their short-term nature. The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Company of three months or less, as cash and cash equivalents (level 1). The fair value of restricted cash is equivalent to its carrying value of \$69.8 million and \$24.0 million as of September 26, 2014 and September 27, 2013, respectively (level 1), substantially all of which is included in other assets on the 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 \$69.0 million and \$67.7 million at September 26, 2014 and September 27, 2013, respectively. These contracts are included in other assets on the consolidated and combined balances sheets.

The carrying values of the Company's loan payable and variable rate receivable securitization approximate the fair values due to the short-term nature of these instruments. The carrying values of the 2.85% and 4.00% term loans approximate the fair values of these instruments, as calculated using the discounted exit price for each instrument, and are therefore classified as level 3. Since the quoted market prices for the Company's term loans and 8.00% and 9.50% debentures are not available in an active market, they are classified as level 2 for purposes of developing an estimate of fair value. The Company's 3.50%, 4.75%, and 5.75% notes are classified as level 1, as quoted prices are available in an active market for these notes. The following table presents the carrying values and estimated fair values of the Company's long-term debt, excluding capital leases, as of the end of each period:

	September 26, 2014		September 27, 2013	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Loan payable	\$ —	\$ —	\$ 0.1	\$ 0.1
Variable rate receivable securitization	150.0	150.0	—	—
2.85% term loan due April 2016	3.1	3.1	—	—
3.50% notes due April 2018	300.0	290.2	299.9	293.7
Term loans due March 2021	1,990.3	1,970.4	—	—
4.00% term loan due February 2022	10.8	10.8	—	—
9.50% debentures due May 2022	10.4	14.2	10.4	14.3
5.75% notes due August 2022	900.0	907.3	—	—
8.00% debentures due March 2023	8.0	10.2	8.0	10.2
4.75% notes due April 2023	598.3	563.8	598.2	568.5

### **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 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% or more of the Company's total net sales:

	Fiscal Year		
	2014	2013	2012
Cardinal Health, Inc.	18%	18%	19%
McKesson Corporation	17%	15%	14%
Amerisource Bergen Corporation	11%	9%	9%

The following table shows accounts receivable attributable to distributors that accounted for 10% or more of the Company's gross accounts receivable at the end of each period:

	September 26, 2014	September 27, 2013
Cardinal Health, Inc.	17 %	18 %
McKesson Corporation	24 %	22 %
Amerisource Bergen Corporation	13 %	14 %
CuraScript, Inc.	13 %	—

The following table shows net sales attributable to products that accounted for 10% or more of the Company's total net sales:

	Fiscal Year		
	2014	2013	2012
Optiray™ (CMDS)	11%	14%	17%
Acetaminophen products (API)	8%	10%	11%

Molybdenum-99 ("Mo-99") is a key raw material in the Company's Ultra-Technekow™ DTE technetium generators that are sold by its Global Medical Imaging segment. There are only eight suppliers of this raw material worldwide. The Company has agreements to obtain Mo-99 from three nuclear research reactors and relies predominantly upon two of these reactors for its Mo-99 supply. Accordingly, a disruption in the commercial supply or a significant increase in the cost of this material from these sources could have a material adverse effect on the Company's financial condition, results of operations and cash flows.

## 20. Segment and Geographical Data

During the first quarter of fiscal 2015, the integration of Questcor was substantially completed. With this, and given the increased significance of the Specialty Brands business to the Company's results and the expected long-term growth of this business as compared to the Specialty Generics business, the Company has changed its reportable segments. The Company now presents the Specialty Brands and Specialty Generics businesses as reportable segments, along with the continued presentation of Global Medical Imaging as a reportable segment. The Company historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment. Prior year amounts have been recast to conform to current presentation. The three reportable segments are further described below:

- *Specialty Brands* produces and markets branded pharmaceuticals and biopharmaceuticals;
- *Specialty Generics* produces specialty generic pharmaceuticals and API consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- *Global Medical Imaging* manufactures and markets CMDS and radiopharmaceuticals (nuclear medicine).

Management measures and evaluates the Company's operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment operating income because management evaluates the operating results of the segments excluding such items. These items include revenues and expenses associated with sales of products to Covidien, intangible asset amortization, net restructuring and related charges, non-restructuring impairments and separation costs. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated and combined operating income and in the following reconciliations.

Management manages assets on a total company basis, not by operating segment. The chief operating decision maker does not regularly review any asset information by operating segment and, accordingly, the Company does not report asset information by operating segment. Total assets were approximately \$12.9 billion and \$3.6 billion at September 26, 2014 and September 27, 2013, respectively.

Selected information by business segment is as follows:

	Fiscal Year		
	2014	2013	2012
<b>Net sales:</b>			
Specialty Brands	\$ 413.5	\$ 206.4	\$ 156.4
Specialty Generics	1,199.4	1,011.2	848.8
Global Medical Imaging	881.5	935.7	996.8
Net sales of operating segments <sup>(1)</sup>	2,494.4	2,153.3	2,002.0
Other <sup>(2)</sup>	46.0	51.2	54.2
Net sales	<u>\$ 2,540.4</u>	<u>\$ 2,204.5</u>	<u>\$ 2,056.2</u>
<b>Operating income:</b>			
Specialty Brands	\$ (50.6)	\$ (36.2)	\$ (75.0)
Specialty Generics	617.4	347.9	237.8
Global Medical Imaging	47.1	112.3	214.3
Segment operating income	613.9	424.0	377.1
<b>Unallocated amounts:</b>			
Corporate and allocated expenses <sup>(3)</sup>	(241.4)	(133.8)	(69.9)
Intangible asset amortization	(162.3)	(35.4)	(27.3)
Restructuring and related charges, net <sup>(4)</sup>	(129.1)	(35.8)	(19.2)
Non-restructuring impairments	(355.6)	—	—
Separation costs	(9.6)	(74.2)	(25.5)
Operating (loss) income	<u>\$ (284.1)</u>	<u>\$ 144.8</u>	<u>\$ 235.2</u>
<b>Depreciation and amortization <sup>(5)</sup>:</b>			
Specialty Brands	\$ 152.9	\$ 24.9	\$ 16.7
Specialty Generics	77.8	72.7	72.0
Global Medical Imaging	45.2	42.0	42.2
Depreciation and amortization	<u>\$ 275.9</u>	<u>\$ 139.6</u>	<u>\$ 130.9</u>

(1) Amounts represent sales to external customers. There were no intersegment sales.

(2) Represents products that were sold to Covidien, which is discussed in Note 16.

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

(4) Includes restructuring-related accelerated depreciation of \$0.5 million, \$2.6 million and \$8.0 million for fiscal 2014, 2013 and 2012, respectively.

(5) Depreciation for certain shared facilities is allocated based on occupancy percentage.

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

	Fiscal Year		
	2014	2013	2012
Exalgo	\$ 76.1	\$ 126.1	\$ 91.9
Ofirmev	124.4	—	—
Acthar	122.9	—	—
Other	90.1	80.3	64.5
Specialty Brands	413.5	206.4	156.4
Methylphenidate ER	209.6	148.3	—
Oxycodone (API) and oxycodone-containing tablets	155.2	139.0	144.1
Hydrocodone (API) and hydrocodone-containing tablets	99.4	140.0	130.5
Other controlled substances	584.5	443.3	439.5
Other	150.7	140.6	134.7
Specialty Generics	1,199.4	1,011.2	848.8
Optiray	284.0	318.5	352.2
Other	165.8	179.6	189.8
Contrast Media and Delivery Systems	449.8	498.1	542.0
Nuclear Imaging	431.7	437.6	454.8
Global Medical Imaging	881.5	935.7	996.8
Other <sup>(1)</sup>	46.0	51.2	54.2
Net sales	\$ 2,540.4	\$ 2,204.5	\$ 2,056.2

(1) Represents products that were sold to Covidien, which is discussed in Note 16.

Selected information by geographic area is as follows:

	Fiscal Year		
	2014	2013	2012
Net sales <sup>(1)</sup> :			
U.S.	\$ 1,899.8	\$ 1,518.7	\$ 1,350.2
Europe, Middle East and Africa	394.0	404.3	411.0
Other	246.6	281.5	295.0
	\$ 2,540.4	\$ 2,204.5	\$ 2,056.2
Long-lived assets <sup>(2)</sup> :			
U.S.	\$ 854.2	\$ 893.3	\$ 847.7
Europe, Middle East and Africa <sup>(3)</sup>	61.9	81.0	72.2
Other	57.4	51.8	52.1
	\$ 973.5	\$ 1,026.1	\$ 972.0

(1) Net sales are attributed to regions based on the location of the entity that records the transaction, none of which relate to the country of Ireland.

(2) Long-lived assets are primarily composed of property, plant and equipment.

(3) Includes long-lived assets located in Ireland of \$26.9 million, \$48.7 million and \$45.5 million at the end of fiscal 2014, 2013 and 2012, respectively.

## 21. Selected Quarterly Financial Data (Unaudited)

	Fiscal 2014 (by quarter)			
	Q1	Q2	Q3	Q4
Net sales	\$ 540.2	\$ 557.8	\$ 653.1	\$ 789.3
Gross profit	255.6	262.6	284.3	400.6
Income (loss) from continuing operations	46.4	11.7	(24.3)	(352.4)
(Loss) income from discontinued operations	(0.8)	(0.1)	0.2	—
Net income (loss)	45.6	11.6	(24.1)	(352.4)
Basic earnings (loss) per share from continuing operations <sup>(2)</sup>	\$ 0.80	\$ 0.20	\$ (0.42)	\$ (4.14)
Diluted earnings (loss) per share from continuing operations <sup>(2)</sup>	0.79	0.20	(0.42)	(4.14)

	Fiscal 2013 (by quarter)			
	Q1	Q2	Q3 <sup>(1)</sup>	Q4
Net sales	\$ 504.0	\$ 585.3	\$ 570.0	\$ 545.2
Gross profit	233.5	273.5	265.8	252.1
Income (loss) from continuing operations	19.8	34.5	(27.7)	31.2
(Loss) income from discontinued operations	(0.6)	(0.5)	(0.2)	2.3
Net income (loss)	19.2	34.0	(27.9)	33.5
Basic earnings (loss) per share from continuing operations <sup>(2)(3)</sup>	\$ 0.34	\$ 0.60	\$ (0.48)	\$ 0.54
Diluted earnings (loss) per share from continuing operations <sup>(2)(3)</sup>	0.34	0.60	(0.48)	0.54

(1) Operations in the third quarter of fiscal 2013 were impacted by the Separation.

(2) Quarterly and annual computations are prepared independently. Therefore, the sum of each quarter may not necessarily total the fiscal period amounts noted elsewhere within this Annual Report on Form 10-K.

(3) The computation of basic and diluted earnings per share assumes that the number of shares outstanding for the first three quarters of fiscal 2013 was equal to the number of ordinary shares of Mallinckrodt outstanding on June 28, 2013, immediately following the distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien.

## 22. Condensed Consolidating and Combining Financial Statements

In November 2012, MIFSA was formed as a 100%-owned subsidiary of Covidien in connection with the Separation. MIFSA is a holding company established to own, directly or indirectly, substantially all of the operating subsidiaries of the Company, to issue debt securities and to perform treasury operations.

MIFSA is the borrower under the 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 operating companies that represent assets of MIFSA. There are no subsidiary guarantees related to the Notes.

Set forth below are the condensed consolidating financial statements for the as of and for the fiscal years ended September 26, 2014 and September 27, 2013. Eliminations represent adjustments to eliminate investments in subsidiaries and intercompany balances and transactions between or among Mallinckrodt plc, MIFSA and the other subsidiaries. Condensed consolidating and combining financial information for Mallinckrodt plc and MIFSA, on a standalone basis, has been presented using the equity method of accounting for subsidiaries.

Consolidating financial information for Mallinckrodt plc and MIFSA have only been presented for fiscal years 2014 and 2013 as they were formed during fiscal 2013.

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING BALANCE SHEET**  
As of September 26, 2014  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Assets</b>					
Current Assets:					
Cash and cash equivalents	\$ 0.3	\$ 18.5	\$ 689.0	\$ —	\$ 707.8
Accounts receivable, net	—	—	545.6	—	545.6
Inventories	—	—	396.6	—	396.6
Deferred income taxes	—	—	165.2	—	165.2
Prepaid expenses and other current assets	0.5	10.8	244.5	—	255.8
Intercompany receivable	13.5	—	25.7	(39.2)	—
<b>Total current assets</b>	<b>14.3</b>	<b>29.3</b>	<b>2,066.6</b>	<b>(39.2)</b>	<b>2,071.0</b>
Property, plant and equipment, net	—	—	949.2	—	949.2
Goodwill	—	—	2,401.9	—	2,401.9
Intangible assets, net	—	—	7,112.2	—	7,112.2
Investment in subsidiaries	586.8	10,645.7	4,945.1	(16,177.6)	—
Intercompany loan receivable	4,385.0	—	1,941.6	(6,326.6)	—
Other assets	—	76.5	254.0	—	330.5
<b>Total Assets</b>	<b>\$ 4,986.1</b>	<b>\$ 10,751.5</b>	<b>\$ 19,670.6</b>	<b>\$ (22,543.4)</b>	<b>\$ 12,864.8</b>
<b>Liabilities and Shareholders' Equity</b>					
Current Liabilities:					
Current maturities of long-term debt	\$ —	\$ 18.2	\$ 3.0	\$ —	\$ 21.2
Accounts payable	1.2	0.2	127.3	—	128.7
Accrued payroll and payroll-related costs	0.1	—	125.0	—	125.1
Accrued royalties	—	—	68.0	—	68.0
Accrued branded rebates	—	—	15.1	—	15.1
Accrued and other current liabilities	1.1	50.9	494.7	—	546.7
Intercompany payable	25.7	—	13.5	(39.2)	—
<b>Total current liabilities</b>	<b>28.1</b>	<b>69.3</b>	<b>846.6</b>	<b>(39.2)</b>	<b>904.8</b>
Long-term debt	—	3,770.4	181.1	—	3,951.5
Pension and postretirement benefits	—	—	119.1	—	119.1
Environmental liabilities	—	—	59.9	—	59.9
Deferred income taxes	—	—	2,398.6	—	2,398.6
Other income tax liabilities	—	—	122.6	—	122.6
Intercompany loans payable	—	1,966.6	4,360.0	(6,326.6)	—
Other liabilities	—	—	350.3	—	350.3
<b>Total liabilities</b>	<b>28.1</b>	<b>5,806.3</b>	<b>8,438.2</b>	<b>(6,365.8)</b>	<b>7,906.8</b>
Shareholders' equity	4,958.0	4,945.2	11,232.4	(16,177.6)	4,958.0
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 4,986.1</b>	<b>\$ 10,751.5</b>	<b>\$ 19,670.6</b>	<b>\$ (22,543.4)</b>	<b>\$ 12,864.8</b>

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING BALANCE SHEET**  
As of September 27, 2013  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Assets</b>					
Current Assets:					
Cash and cash equivalents	\$ 1.2	\$ 56.5	\$ 217.8	\$ —	\$ 275.5
Accounts receivable, net	—	—	400.8	—	400.8
Inventories	—	—	403.1	—	403.1
Deferred income taxes	—	—	171.1	—	171.1
Prepaid expenses and other current assets	1.0	—	133.4	—	134.4
Intercompany receivable	2.7	—	12.2	(14.9)	—
<b>Total current assets</b>	<b>4.9</b>	<b>56.5</b>	<b>1,338.4</b>	<b>(14.9)</b>	<b>1,384.9</b>
Property, plant and equipment, net	—	—	997.4	—	997.4
Goodwill	—	—	532.0	—	532.0
Intangible assets, net	—	—	422.1	—	422.1
Investment in subsidiaries	1,266.1	2,520.4	—	(3,786.5)	—
Intercompany loan receivable	—	2.4	409.6	(412.0)	—
Other assets	—	11.2	209.0	—	220.2
<b>Total Assets</b>	<b>\$ 1,271.0</b>	<b>\$ 2,590.5</b>	<b>\$ 3,908.5</b>	<b>\$ (4,213.4)</b>	<b>\$ 3,556.6</b>
<b>Liabilities and Shareholders' Equity</b>					
Current Liabilities:					
Current maturities of long-term debt	\$ —	\$ —	\$ 1.5	\$ —	\$ 1.5
Accounts payable	0.1	—	120.8	—	120.9
Accrued payroll and payroll-related costs	0.1	—	66.4	—	66.5
Accrued royalties	—	—	13.2	—	13.2
Accrued branded rebates	—	—	34.6	—	34.6
Accrued and other current liabilities	0.6	18.3	344.6	—	363.5
Intercompany payable	12.2	—	2.7	(14.9)	—
<b>Total current liabilities</b>	<b>13.0</b>	<b>18.3</b>	<b>583.8</b>	<b>(14.9)</b>	<b>600.2</b>
Long-term debt	—	898.1	20.2	—	918.3
Pension and postretirement benefits	—	—	108.0	—	108.0
Environmental liabilities	—	—	39.5	—	39.5
Deferred income taxes	—	—	310.1	—	310.1
Other income tax liabilities	—	—	153.1	—	153.1
Intercompany loans payable	2.4	409.6	—	(412.0)	—
Other liabilities	—	—	171.8	—	171.8
<b>Total liabilities</b>	<b>15.4</b>	<b>1,326.0</b>	<b>1,386.5</b>	<b>(426.9)</b>	<b>2,301.0</b>
Shareholders' equity	1,255.6	1,264.5	2,522.0	(3,786.5)	1,255.6
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 1,271.0</b>	<b>\$ 2,590.5</b>	<b>\$ 3,908.5</b>	<b>\$ (4,213.4)</b>	<b>\$ 3,556.6</b>

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME**  
Fiscal year ended September 26, 2014  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 2,540.4	\$ —	\$ 2,540.4
Cost of sales	—	—	1,337.3	—	1,337.3
<b>Gross profit</b>	—	—	1,203.1	—	1,203.1
Selling, general and administrative expenses	38.6	7.3	796.2	—	842.1
Research and development expenses	—	—	166.9	—	166.9
Separation costs	2.5	—	7.1	—	9.6
Restructuring charges, net	35.3	—	93.3	—	128.6
Non-restructuring impairments	—	—	355.6	—	355.6
Gains on divestiture and license	—	—	(15.6)	—	(15.6)
<b>Operating (loss) income</b>	(76.4)	(7.3)	(200.4)	—	(284.1)
Interest expense	—	(86.3)	—	3.7	(82.6)
Interest income	—	—	5.2	(3.7)	1.5
Other income (expense), net	30.9	—	(29.1)	—	1.8
Intercompany interest and fees	(9.0)	—	9.0	—	—
Equity in net income of subsidiaries	(264.8)	(171.2)	(300.2)	736.2	—
<b>Income (loss) from continuing operations before income taxes</b>	(319.3)	(264.8)	(515.5)	736.2	(363.4)
Income tax expense (benefit)	—	—	(44.8)	—	(44.8)
<b>Income (loss) from continuing operations</b>	(319.3)	(264.8)	(470.7)	736.2	(318.6)
Loss from discontinued operations, net of income taxes	—	—	(0.7)	—	(0.7)
<b>Net income (loss)</b>	(319.3)	(264.8)	(471.4)	736.2	(319.3)
Other comprehensive loss, net of tax	(42.8)	(42.8)	(84.1)	126.9	(42.8)
<b>Comprehensive income (loss)</b>	\$ (362.1)	\$ (307.6)	\$ (555.5)	\$ 863.1	\$ (362.1)

**MALLINCKRODT PLC**  
**CONDENSED COMBINING STATEMENT OF COMPREHENSIVE INCOME**

Fiscal year ended September 27, 2013

(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Combined
<b>Net sales</b>	\$ —	\$ —	\$ 2,204.5	\$ —	\$ 2,204.5
Cost of sales	—	—	1,179.6	—	1,179.6
<b>Gross profit</b>	—	—	1,024.9	—	1,024.9
Selling, general and administrative expenses	5.4	0.1	604.4	—	609.9
Research and development expenses	—	—	165.7	—	165.7
Separation costs	3.2	0.6	70.4	—	74.2
Restructuring charges, net	—	—	33.2	—	33.2
Gains on divestiture and license	—	—	(2.9)	—	(2.9)
<b>Operating (loss) income</b>	(8.6)	(0.7)	154.1	—	144.8
Interest expense	—	(19.6)	0.1	—	(19.5)
Interest income	—	—	0.3	—	0.3
Other income (expense), net	0.2	—	0.6	—	0.8
Intercompany interest and fees	(9.5)	—	9.5	—	—
Equity in net income of subsidiaries	76.4	96.7	—	(173.1)	—
<b>Income from continuing operations before income taxes</b>	58.5	76.4	164.6	(173.1)	126.4
Income tax expense	(0.3)	—	68.9	—	68.6
<b>Income from continuing operations</b>	58.8	76.4	95.7	(173.1)	57.8
Loss from discontinued operations, net of income taxes	—	—	1.0	—	1.0
<b>Net income</b>	58.8	76.4	96.7	(173.1)	58.8
Other comprehensive loss, net of tax	28.4	28.4	35.7	(64.1)	28.4
<b>Comprehensive income</b>	\$ 87.2	\$ 104.8	\$ 132.4	\$ (237.2)	\$ 87.2

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS**  
Fiscal year ended September 26, 2014  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Cash Flows From Operating Activities:</b>					
Net cash (used in) provided by operating activities	\$ 18.2	\$ (65.0)	\$ 420.2	\$ —	\$ 373.4
<b>Cash Flows From Investing Activities:</b>					
Capital expenditures	—	—	(127.8)	—	(127.8)
Acquisitions and intangibles, net of cash acquired	—	—	(2,793.8)	—	(2,793.8)
Intercompany loan investment	(25.0)	(298.1)	(915.8)	1,238.9	—
Subsidiary dividend proceeds	—	300.5	—	(300.5)	—
Investment in subsidiary	—	(3,735.5)	—	3,735.5	—
Restricted cash	—	—	4.1	—	4.1
Other	—	—	26.7	—	26.7
Net cash (used in) provided by investing activities	(25.0)	(3,733.1)	(3,806.6)	4,673.9	(2,890.8)
<b>Cash Flows From Financing Activities:</b>					
Issuance of external debt	—	2,893.3	149.9	—	3,043.2
Repayment of external debt and capital leases	—	(3.3)	(31.5)	—	(34.8)
Excess tax benefit from share-based compensation	—	—	8.9	—	8.9
Debt financing costs	—	(70.7)	(1.0)	—	(71.7)
Net transfers to parent	—	—	—	—	—
Proceeds from exercise of share options	25.8	—	—	—	25.8
Subsidiary dividend payment	—	—	(300.5)	300.5	—
Intercompany loan borrowings	(2.4)	940.8	300.5	(1,238.9)	—
Capital contribution	—	—	3,735.5	(3,735.5)	—
Repurchase of shares	(17.5)	—	—	—	(17.5)
Other	—	—	—	—	—
Net cash provided by (used in) financing activities	5.9	3,760.1	3,861.8	(4,673.9)	2,953.9
Effect of currency rate changes on cash	—	—	(4.2)	—	(4.2)
<b>Net increase in cash and cash equivalents</b>	<b>(0.9)</b>	<b>(38.0)</b>	<b>471.2</b>	<b>—</b>	<b>432.3</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>1.2</b>	<b>56.5</b>	<b>217.8</b>	<b>—</b>	<b>275.5</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 0.3</b>	<b>\$ 18.5</b>	<b>\$ 689.0</b>	<b>\$ —</b>	<b>\$ 707.8</b>

**MALLINCKRODT PLC**  
**CONDENSED COMBINING STATEMENT OF CASH FLOWS**  
Fiscal year ended September 27, 2013  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Combined
<b>Cash Flows From Operating Activities:</b>					
Net cash (used in) provided by operating activities	\$ (1.8)	\$ (8.4)	\$ 146.1	\$ —	\$ 135.9
<b>Cash Flows From Investing Activities:</b>					
Capital expenditures	—	—	(147.9)	—	(147.9)
Acquisitions and intangibles, net of cash acquired	—	—	(88.1)	—	(88.1)
Intercompany loan investment	—	(2.4)	(409.6)	412.0	—
Investment in subsidiary	—	(68.0)	—	68.0	—
Other	—	—	1.3	—	1.3
Net cash (used in) provided by investing activities	—	(70.4)	(644.3)	480.0	(234.7)
<b>Cash Flows From Financing Activities:</b>					
Issuance of external debt	—	898.1	—	—	898.1
Repayment of external debt and capital leases	—	—	(1.3)	—	(1.3)
Excess tax benefit from share-based compensation	—	—	3.4	—	3.4
Debt financing costs	—	(12.0)	—	—	(12.0)
Net transfers to parent	—	(1,160.4)	644.5	—	(515.9)
Proceeds from exercise of share options	0.6	—	—	—	0.6
Intercompany loan borrowings	2.4	409.6	—	(412.0)	—
Capital contribution	—	—	68.0	(68.0)	—
Other	—	—	0.1	—	0.1
Net cash provided by (used in) financing activities	3.0	135.3	714.7	(480.0)	373.0
Effect of currency rate changes on cash	—	—	1.3	—	1.3
<b>Net increase in cash and cash equivalents</b>	<b>1.2</b>	<b>56.5</b>	<b>217.8</b>	<b>—</b>	<b>275.5</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1.2</b>	<b>\$ 56.5</b>	<b>\$ 217.8</b>	<b>\$ —</b>	<b>\$ 275.5</b>

## 23. Subsequent Events

On November 12, 2014, the Company was informed by the FDA that they believe that the Company's Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug. As a result, on November 13, 2014, the FDA reclassified Methylphenidate ER from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX). The FDA has indicated that it has not identified any serious safety concerns with the products. The FDA indicated that its reclassification is attributable to concerns that the products may not produce the same therapeutic benefits for some patients as the reference listed drug. The FDA further indicated that Company's Methylphenidate ER product is still approved and can be prescribed. The FDA has requested that within six months, the Company demonstrate the bioequivalence of its products using the draft guidance for revised bioequivalence standards issued by the FDA on November 6, 2014 or voluntarily withdraw our products from the market. The Company expects that the FDA's action to reclassify our Methylphenidate ER products will significantly impact net sales and operating income unless the FDA revises its decision.

*Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America.* The Company filed a Complaint for Declaratory and Injunctive Relief in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States of America on November 17, 2014 for judicial review of what the Company believes is FDA's inappropriate and unlawful reclassification of the Company's methylphenidate hydrochloride extended-release tablets in the Orange Book: Approved Drug Products with Therapeutic Equivalence (Orange Book) on November 13, 2014. In its complaint, the Company has asked the court to: issue an injunction to (a) set aside the FDA's reclassification of the Company's methylphenidate ER products from AB (freely substitutable at the pharmacy level) to BX (presumed to be therapeutically inequivalent) in the Orange Book and (b) prohibit the FDA from reclassifying Mallinckrodt's methylphenidate ER products in the future without following applicable legal requirements; and issue a declaratory judgment that the FDA's action reclassifying Mallinckrodt's methylphenidate ER products in the Orange Book is unlawful. Mallinckrodt concurrently filed a motion with the same court requesting an expedited hearing to issue a temporary restraining order (TRO) directing FDA to reinstate the Orange Book AB rating for the Company's methylphenidate ER drug on a temporary basis.

During the three months ended March 27, 2015, the Company increased reserves for various legal contingencies, that existed as of September 26, 2014, by approximately \$40 million as a result of changes in estimates regarding the ultimate resolution of certain matters.

## 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 consolidated and combined financial statements and the accompanying notes included Exhibit 99.1 to this Form 8-K. 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 and "Forward-Looking Statements" included within the Annual Report on Form 10-K for the fiscal year ended September 26, 2014, which was filed on November 24, 2014.

### Overview

We are a global specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology), along with pain and attention-deficit hyperactivity disorder ("ADHD") for prescription by office- and hospital-based physicians. We also support the diagnosis of disease with nuclear medicine and contrast imaging. Our products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the United States ("U.S.") and we have a commercial presence in approximately 65 countries. We believe our experience in the acquisition and management of highly regulated raw materials; deep regulatory expertise; and specialized chemistry, formulation and manufacturing capabilities, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

During the first quarter of fiscal 2015, the integration of Questcor Pharmaceuticals, Inc. ("Questcor") was substantially completed. With this, and given the increased significance of the Specialty Brands business to our results and the expected long-term growth of this business as compared to the Specialty Generics business, we have changed our reportable segments. We now present the Specialty Brands and Specialty Generics businesses as reportable segments, along with the continued presentation of Global Medical Imaging as a reportable segment. We historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment. Prior year amounts have been recast to conform to current presentation. The three reportable segments are further described below:

- *Specialty Brands* produces and markets branded pharmaceuticals and biopharmaceuticals;
- *Specialty Generics* produces specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- *Global Medical Imaging* manufactures and markets contrast media and delivery systems ("CMDs") and radiopharmaceuticals (nuclear medicine).

For further information on our business and products, refer to Business included within Exhibit 99.3 to this Form 8-K.

### Significant Events

#### *Separation from Covidien*

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the Pharmaceuticals business of Covidien plc ("Covidien"). On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the Pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing its legal separation from Covidien ("the Separation").

Our consolidated and combined financial statements reflect the consolidated financial position of Mallinckrodt plc and its subsidiaries as an independent publicly-traded company for periods subsequent to June 28, 2013, and as a combined reporting entity of Covidien, including operations relating to Covidien's Pharmaceuticals business, for periods prior to June 28, 2013. Our results for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included with our fiscal 2013 results, may not be indicative of our future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had we operated as an independent, publicly-traded company for the entirety of

the periods presented, including as a result of changes in our capitalization in connection with the Separation. The combined financial statements for periods prior to June 28, 2013 include expense allocations related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. The amounts allocated were \$39.6 million and \$49.2 million in fiscal 2013 and 2012, respectively. Management considers the bases on which the expenses have been allocated to reasonably reflect the utilization of services provided to, or the benefit received by, us during the periods presented; however, the allocations may not reflect the expense we would have incurred as an independent, publicly-traded company. These allocations have not recurred following the completion of the Separation on June 28, 2013, as we have been performing these functions using our own resources or purchased services, certain of which are being provided by Covidien during a transitional period pursuant to a transition services agreement dated June 28, 2013, between us and Covidien, particularly in relation to areas outside the U.S. The terms and prices on which such services are rendered may not be as favorable as those allocated to us by Covidien. We expect to substantially reduce the level of service provided by Covidien in fiscal 2015 as we have substantially completed the implementation of information systems in jurisdictions outside the U.S and terminated the transition services agreement during the first quarter of fiscal 2015.

### **Acquisitions**

In August 2014, we acquired Questcor, a high-growth biopharmaceutical company, for total consideration of approximately \$5.9 billion ("the Questcor Acquisition"). The acquisition was funded through an issuance of approximately 57 million common shares, proceeds from the issuance of \$900.0 million aggregate principal of senior unsecured notes, proceeds from the issuance of \$700.0 million senior secured term loan facility, \$150.0 million of cash from a receivable securitization program and cash on hand. Questcor is focused on the treatment of patients with serious, difficult-to-treat autoimmune and rare diseases. Questcor's primary product, H.P. Acthar® Gel (repository corticotropin injection) ("Acthar"), is an injectable drug that is approved by the U.S. Food and Drug Administration ("FDA") for use in 19 indications, including the areas of neurology, rheumatology, nephrology and pulmonology. Questcor also supplies specialty contract manufacturing services to the global pharmaceutical and biotechnology industry through its wholly-owned subsidiary, BioVectra Inc. The Questcor Acquisition is expected to provide a strong and sustainable platform for future revenue and earnings growth primarily within our Specialty Brands segment. The consolidated statement of income for fiscal 2014 included \$122.9 million of net sales for Acthar.

In March 2014, we acquired Cadence Pharmaceuticals, Inc. ("Cadence"), a biopharmaceutical company focused on commercializing products principally for use in the hospital setting for approximately \$1.3 billion ("the Cadence Acquisition"). The acquisition was primarily funded through a \$1.3 billion senior secured term loan credit facility. Cadence's sole product, OFIRMEV® (acetaminophen) injection ("Ofirmev"), is a proprietary intravenous formulation of acetaminophen for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. The Cadence Acquisition added a growth product to the Specialty Brands product portfolio and provides us with an opportunity to expand its reach into the adjacent hospital market, in which Cadence had established a presence. The consolidated statement of income for fiscal 2014 included \$124.4 million of net sales for Ofirmev.

In October 2012, we acquired CNS Therapeutics, Inc. ("CNS Therapeutics"), a specialty pharmaceutical company focused on developing and commercializing intrathecal products for site-specific administration to the central nervous system to treat neurological disorders and intractable chronic pain, for total consideration, net of cash acquired, of \$95.0 million. Gablofen (baclofen injection), the primary product of CNS Therapeutics, is indicated for use in the management of severe spasticity of cerebral or spinal origin in patients age four years and above. The acquisition of CNS Therapeutics expanded our branded pharmaceuticals portfolio and supports our strategy of leveraging our therapeutic expertise and core capabilities in manufacturing, regulatory and commercialization to serve patients. The consolidated and combined statements of income for fiscal 2014 and 2013 included \$32.9 million and \$29.2 million of net sales, respectively, of intrathecal products added to our portfolio with this acquisition.

### **License of Intellectual Property**

We were involved in patent disputes with a counterparty relating to certain intellectual property relevant to extended-release oxymorphone. In December 2013, the counterparty agreed to pay us an upfront cash payment of \$4.0 million and contractually obligated future payments of \$8.0 million through July 2018, in exchange for the withdrawal of all claims associated with the intellectual property and a license to utilize our intellectual property. We completed the earnings process associated with the agreement and recorded an \$11.7 million gain, included within gain on divestiture and license, during fiscal 2014.

## ***Divestitures***

During fiscal 2011, we sold the rights to market TussiCaps™ extended-release capsules ("TussiCaps"), a cough suppressant, for an upfront cash payment of \$11.5 million. As a result of this transaction, we recorded an \$11.1 million gain. The purchaser also may be obligated to make contingent payments to us of up to \$11.5 million from December 31, 2011 through September 30, 2015, payable in equal quarterly installments until such time as a new competitive generic product is introduced into the market. In addition, we would receive a \$1.0 million contingent payment if certain sales targets are achieved over the same time period. We received \$2.9 million of contingent payments during fiscal 2014, 2013 and 2012.

## ***Royalty and Milestone Payments***

We are required to pay royalties and milestone payments for various product acquisitions and license agreements we entered into with third parties. We incurred royalty expense of \$72.0 million, \$51.6 million and \$48.4 million in fiscal 2014, 2013 and 2012, respectively, under our product acquisitions and license agreements, including those discussed below.

We acquired the exclusive development and commercialization rights to Ofirmev in the U.S. and Canada, as well as the rights to the patents and technology. Under this license agreement, we may be obligated to make future milestone payments of up to \$25.0 million upon the achievement of certain levels of net sales, in addition to on-going royalties on the sales of the product.

For EXALGO® (hydromorphone HCl) ("Exalgo"), we are obligated to make additional payments based on the successful completion of specified development and regulatory milestones payments of up to \$73.0 million based on the successful completion of specified development and regulatory milestones. Through fiscal 2014, \$65.0 million of additional payments have been made, with \$55.0 million being capitalized as an intangible asset. We are also required to pay royalties on sales of the product. In January 2014, we purchased royalty rights associated with Exalgo for \$7.2 million, which have been classified as an intangible asset.

In fiscal 2009, we entered into a licensing agreement to utilize Depomed Inc.'s Acuform™ gastric retentive drug delivery technology for the exclusive development of four products. Under this license agreement, we may be obligated to pay up to \$64.0 million in development milestone payments. Through fiscal 2014, approximately \$22.0 million of these payments have been made by us. During fiscal 2014, upon approval by the FDA for Xartemis XR, we made a milestone payment of \$10.0 million, which was capitalized as an intangible asset. In addition, subsequent to FDA's acceptance of our New Drug Application ("NDA") for MNK-155 in July 2014, we made a milestone payment of \$5.0 million, which was expensed as incurred as it was made prior to regulatory approval. During fiscal 2013 and 2012, milestone payments of \$5.0 million and an insignificant amount, respectively, were expensed as incurred as they were also made prior to regulatory approval. In addition, an insignificant amount of royalties have been paid through fiscal 2014.

In 2009, we also entered into a licensing agreement which granted rights to market and distribute PENNSAID® (diclofenac sodium topical solution 1.5% w/w ("Pennsaid")) and Pennsaid (diclofenac sodium topical solution 2% w/w) ("Pennsaid 2%"). We were responsible for all future development activities and expenses and were required to make milestone payments of up to \$120.0 million based upon the successful completion of specified regulatory and sales milestones. Through fiscal 2014, \$15.0 million of these payments were made, all of which were capitalized as an intangible asset as the payment related to the fiscal 2010 FDA approval of the Pennsaid NDA. We were also required to pay royalties on sales of the products under this agreement. During the fourth quarter of fiscal 2014, we reached an agreement in principle with Nuvo Research Inc. ("Nuvo") to settle various claims associated with our license of Pennsaid. As part of the legal settlement, we agreed to return the license to Nuvo, which resulted in the Company recording an impairment of \$11.1 million during the fourth quarter of fiscal 2014.

## ***Nuclear Imaging***

In November 2012, the High Flux Reactor ("HFR") in the Netherlands, one of two primary reactors we utilize, experienced an unscheduled shutdown. We were able to receive increased target irradiations from the two other reactors and purchased additional molybdenum-99 ("Mo-99") from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The HFR resumed production in June 2013.

In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in the Netherlands also experienced a shutdown. We received increased target irradiations from other reactors, purchased additional Mo-99 from other sources and outsourced Mo-99 processing to continue meeting customer orders; however, the additional Mo-99 and processing services we procured from alternative sources came at a higher than normal cost. The HFR resumed production of medical isotopes and irradiation of materials in February 2014 and the Mo-99 processing facility resumed production in April 2014. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

### ***Lower Passaic River Environmental Reserve***

On April 11, 2014, the U.S. Environmental Protection Agency ("EPA") issued its revised Focused Feasibility Study ("FFS"), with remedial alternatives to address cleanup of the lower 8-mile stretch of the Lower Passaic River Study Area ("the River"), which also included a "no action" option. The EPA estimates the cost for the alternatives range from \$365.0 million to \$3.2 billion. The EPA's preferred approach would involve bank-to-bank dredging of the lower 8-mile stretch of the River and installing an engineered cap at a discounted, estimated cost of \$1.7 billion. Based on the issuance of the EPA's revised FFS, we recorded a \$23.1 million accrual in the second quarter of fiscal 2014 representing our estimate of our allocable share of the joint and several remediation liability resulting from this matter. Despite the issuance of the revised FFS, there are many uncertainties associated with the final agreed upon remediation and our allocable share of the remediation. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which will be ultimately responsible and will be refined as events in the remediation process occur.

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

### ***Products***

In March 2014, the FDA approved our NDA for XARTEMIS™ XR (oxycodone HCl and acetaminophen) Extended-Release Tablets ("Xartemis XR"), for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. Xartemis XR is the first and only extended-release oral combination of oxycodone and acetaminophen. In February 2014, we were granted a patent from the U.S. Patent and Trademark Office ("USPTO"), which contains composition claims directed to unique design, formulation, pharmacokinetic and release characteristics of Xartemis XR. Pursuant to the terms of our licensing agreement, we paid and capitalized as an intangible asset, a \$10.0 million milestone payment to Depomed, Inc., in connection with the FDA approval of Xartemis XR. Xartemis XR received FDA approval and was launched in March 2014.

In December 2012, we received approval from the FDA to manufacture Methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER"), a generic version of the branded CONCERTA® (methylphenidate HCl) Extended -Release Tablets, a registered trademark of Alza Corporation, for the treatment of ADHD in 27 mg, 36 mg and 54 mg dosages. We held a 180-day exclusivity period for each of the 27 mg, 36 mg and 54 mg dosage strengths, which began upon the commercial launch of each dosage strength. We launched the 27 mg dosage strength upon FDA approval during the first quarter of fiscal 2013 and launched the 36 mg and 54 mg dosage strengths during the second quarter of fiscal 2013. In July 2013, a competitor received FDA approval to manufacture all strengths of Methylphenidate ER and entered the marketplace. As our exclusivity has expired, other competitors may also enter the market for Methylphenidate ER. Net sales of Methylphenidate ER were \$209.6 million and \$148.3 million in fiscal 2014 and 2013, respectively. We expects that the FDA's action to reclassify our Methylphenidate ER products will significantly impact net sales and operating income unless the FDA revises its decision.

In August 2012, the FDA approved a 32 mg tablet of Exalgo, which further expanded the patient population that Exalgo can effectively treat with a single daily dose. The 8 mg, 12 mg and 16 mg dosages of Exalgo were approved by the FDA in March 2010 for the treatment of chronic pain in opioid-tolerant patients requiring continuous around-the-clock opioid analgesia for an extended amount of time; and have shown significant prescription growth since launch in April 2010. Exalgo was granted marketing exclusivity in the U.S. as a prescription medicine through March 2013 and is protected by two Orange Book-listed patents for a method of treating moderate to severe pain. In May 2014, we launched an authorized generic version of Exalgo and shortly thereafter a competitor entered the market. Net sales of Exalgo were \$76.1 million, \$126.1 million and \$91.9 million in fiscal 2014, 2013 and 2012, respectively. We expect sales of Exalgo, across both the branded and authorized generic product, to decrease in fiscal 2015 compared with net sales in fiscal 2014.

We completed two acquisitions that added Ofirmev and Acthar to our product portfolio in fiscal 2014. Net sales in fiscal 2014 from these products was \$247.3 million. As a result of these transactions, we increased the value of inventory on-hand at the acquisition dates to its fair value and recorded approximately \$6.9 billion in intangible assets primarily related to the completed technology associated with Ofirmev and Acthar. Our fiscal 2014 cost of sales, includes \$25.7 million of expense recognition associated with the fair value adjustment of acquired inventory and \$121.0 million of amortization associated with these intangible assets. Additionally, we incurred and expensed \$65.1 million of transaction costs in fiscal 2014 associated with these transactions, which are reflected in SG&A in our consolidated statement of income. We expect net sales of these products to increase in fiscal 2015 due to inclusion of the full year of net sales.

### ***Restructuring Initiatives***

Following the Separation, we have focused on realigning our cost structure due to the changing nature of our business and looked for opportunities to achieve operating efficiencies. As such, in July 2013 our board of directors approved a restructuring program in the amount of \$100.0 million to \$125.0 million that is expected to occur over a two to three-year period, from the approval of the program, with a two-year cost recovery period. Through September 26, 2014, we incurred restructuring charges of \$89.4 million under our July 2013 program which are primarily expected to generate savings within our selling, general and administrative expenses. In addition to the July 2013 program, we have taken restructuring actions to generate synergies from our fiscal 2014 acquisitions.

During fiscal 2014, 2013 and 2012, we incurred restructuring and related charges, net, of \$129.1 million, \$35.8 million and \$19.2 million, respectively, which included accelerated depreciation costs of \$0.5 million, \$2.6 million and \$8.0 million, respectively. The restructuring charges incurred during fiscal 2014 primarily related to employee severance and benefits across both our segments, consulting costs and non-cash charges. The non-cash charges included \$25.7 million of asset impairments, most notably associated with the termination of a related-party supply agreement, and \$35.1 million of accelerated share based compensation associated with Questcor unvested equity awards that were converted to Mallinckrodt awards at the date of the Questcor Acquisition. Restructuring charges in fiscal 2013 and 2012 primarily related to severance and employee benefit costs across our segments.

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

We expect to continue to invest in research and development ("R&D") activities, as well as enter into license agreements to supplement our internal R&D initiatives. We intend to focus our R&D investments in the specialty pharmaceuticals area, specifically investments to support our Specialty Brands segment, where we believe there is the greatest opportunity for growth and profitability.

*Specialty Brands.* We devote significant R&D resources for our branded products. A number of our branded products are protected by patents and have enjoyed market exclusivity. Our R&D strategy focuses on the development of extended-release opioid products with abuse deterrent properties and expanding the opportunities for existing products by documenting and publishing clinical experience and evidence that support health economic and patient outcomes. MNK-155 has completed Phase III clinical trials and our NDA filing was accepted for review by the FDA in May 2014. We have received notice of allowance from the USPTO related to composition claims directed to unique design, formulation, pharmacokinetic and release characteristics for MNK-155.

In accordance with a Pediatric Research Equity Act requirement included in the NDA approval for Ofirmev, Cadence began enrolling patients in 2012 in a post-marketing efficacy study of Ofirmev in infants and neonates. The data from this study will be used to satisfy a formal written request Cadence received from the FDA under Section 505A of the U.S. Food, Drug and Cosmetic Act that was made as part of the approval process for Ofirmev. The FDA has agreed to an August 2015 due date for completion of this study. Upon timely completion and acceptance by the FDA of the data from this study, Ofirmev may be eligible for an additional six months of marketing exclusivity in the U.S. The FDA is also currently reviewing a supplemental NDA that Cadence submitted in December 2013, which would enable us to offer Ofirmev in flexible intravenous bags.

*Specialty Generics.* In regard to specialty generic product development, we are focused on controlled substances with difficult-to-replicate pharmacokinetic profiles. As of September 26, we had various Abbreviated New Drug Applications on file with the FDA. In addition, we are focused on process improvements to increase yields and reduce costs.

*Global Medical Imaging.* Our R&D efforts in our Global Medical Imaging segment are focused on driving efficiency and regulatory compliance throughout CMDS and Nuclear Imaging.

## Results of Operations

### Fiscal Year Ended September 26, 2014 Compared with Fiscal Year Ended September 27, 2013

#### Net Sales

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

	Fiscal Year		Percentage Change
	2014	2013	
U.S.	\$ 1,899.8	\$ 1,518.7	25.1 %
Europe, Middle East and Africa	394.0	404.3	(2.5)
Other	246.6	281.5	(12.4)
Net sales	<u>\$ 2,540.4</u>	<u>\$ 2,204.5</u>	15.2

Net sales in fiscal 2014 increased \$335.9 million, or 15.2%, to \$2,540.4 million, compared with \$2,204.5 million in fiscal 2013. This increase was primarily attributable to increased net sales in our Specialty Generics segment, driven by strategic initiatives on certain specialty controlled substance generics and increased Methylphenidate ER net sales. Specialty Brands net sales also contributed to the increase due to net sales of the newly acquired Acthar and Ofirmev. These increases were partially offset by a decrease in CMDS net sales. For further information on changes in our net sales, refer to "Business Segment Results" within this Exhibit.

#### Operating Income

**Gross profit.** Gross profit for fiscal 2014 increased \$178.2 million, or 17.4%, to \$1,203.1 million, compared with \$1,024.9 million in fiscal 2013. The increase in gross profit primarily resulted from increased net sales from strategic initiatives and a further shift in net sales to the higher margin Specialty Brands segment, including the newly acquired Acthar and Ofirmev products. These increases were partially offset by a \$126.9 million increase in amortization primarily associated with Acthar and Ofirmev, \$25.7 million of expense recognition associated with the fair value adjustment of acquired Acthar and Ofirmev inventory, a \$16.7 million increase in inventory provision expense and higher raw material costs in the Global Medical Imaging segment, including the unscheduled shutdowns of our Mo-99 processing facility and the HFR that supplies us with Mo-99. Gross profit margin was 47.4% during fiscal 2014, compared with 46.5% during fiscal 2013. The fiscal 2014 profit margin includes the increased amortization and expense recognition of inventory fair value adjustments.

**Selling, general and administrative expenses.** Selling, general and administrative expenses for fiscal 2014 were \$842.1 million, compared with \$609.9 million for fiscal 2013, an increase of \$232.2 million, or 38.1%. The increase primarily resulted from higher internal and third-party expenses associated with being an independent, publicly-traded company, \$93.0 million from the inclusion of selling, administration and integration costs associated with Acthar and Ofirmev, \$65.1 million of transaction costs associated with our fiscal 2014 acquisitions, a \$23.1 million environmental remediation charge, and \$29.6 million of higher selling expenses in our Specialty Brands segment related to the launch of Xartemis XR and Pennsaid 2%. These increases were partially offset by benefits from restructuring actions and certain prior year costs that did not recur in fiscal 2014. In fiscal 2013, selling, general and administrative expenses included higher legal settlement costs and \$39.6 million of allocations from Covidien for general corporate expenses. These allocations are generally consistent with functions we have developed in our corporate build-out and ceased following the completion of the Separation on June 28, 2013. Selling, general and administrative expenses were 33.1% of net sales for fiscal 2014 and 27.7% of net sales for fiscal 2013.

**Research and development expenses.** R&D expenses increased \$1.2 million, or 0.7%, to \$166.9 million in fiscal 2014, compared with \$165.7 million in fiscal 2013. As products, such as Xartemis XR, Pennsaid 2% and MNK-155, moved toward or through the FDA review process, we devoted additional resources to other potential products in our R&D pipeline and the continued pursuit of abuse-deterrent labeling for Xartemis XR. As a percentage of our net sales, R&D expenses were 6.6% and 7.5% in fiscal 2014 and 2013, respectively.

*Separation costs.* During fiscal 2014 and 2013, we incurred separation costs of \$9.6 million and \$74.2 million, respectively, primarily related to legal, accounting, tax and other professional fees. Separation costs were higher in the prior year period as we approached and completed the Separation on June 28, 2013. We have continued to incur costs related to the Separation as a result of our transition services agreement with Covidien, our costs to implement information and accounting systems, share-based compensation related to the conversion of Covidien awards to Mallinckrodt awards, and other transitional costs; however, these costs are not expected to recur at historical levels.

*Restructuring and related charges, net.* During fiscal 2014, we recorded \$129.1 million of restructuring and related charges, net, of which \$0.5 million related to accelerated depreciation and was included in cost of sales. The remaining \$128.6 million primarily related to severance and benefits across all our segments, consulting costs and non-cash charges. The non-cash charges included \$25.7 million of asset impairments, most notably associated with the termination of a related-party supply agreement, and \$35.1 million of accelerated share based compensation associated with Questcor unvested equity awards that were converted to Mallinckrodt awards at the date of the Questcor Acquisition. During fiscal 2013, we recorded restructuring and related charges, net of \$35.8 million, of which \$2.6 million related to accelerated depreciation and was included in cost of sales. The remaining \$33.2 million primarily related to severance and employee benefits costs incurred across all our segments.

*Non-restructuring impairment charges.* During fiscal 2014, we recorded \$355.6 million of non-restructuring impairment charges. The charges consisted of \$219.7 million associated with impairment of goodwill in the Global Medical Imaging Segment and \$65.9 million and \$52.4 million of property, plant & equipment and intangible asset impairments, respectively, of assets included within our CMDS asset group. These impairment charges are partially the result of receiving notification that we lost preferred supplier status with a significant GPO and that we terminated a related-party supply contract, both of which occurred in the fourth quarter of fiscal 2014. Further, the Company recorded other impairments of \$17.6 million, which primarily relate to the impairment of Pennsaid intangibles upon the return of our product rights to Nuvo as part of a fourth quarter legal settlement.

*Gain on divestiture and license.* During fiscal 2014 and 2013, we recorded gains on divestiture and license of \$15.6 million and \$2.9 million, respectively. The \$15.6 million gain recorded during fiscal 2014 primarily resulted from an \$11.7 million gain from the license of extended-release oxycodone intellectual property to a third-party.

### **Non-Operating Items**

*Interest expense and interest income.* During fiscal 2014 and fiscal 2013, net interest expense was \$81.1 million and \$19.2 million, respectively. Net interest expense is primarily attributable to our \$900.0 million issuance of senior unsecured notes in April 2013, \$1.3 billion of debt associated with our March 2014 acquisition of Cadence and approximately \$1.8 billion of debt associated with our August 2014 acquisition of Questcor. Interest expense during 2014 and 2013 includes \$7.7 million and \$1.1 million, respectively, of non-cash interest expense.

*Other income, net.* During fiscal 2014 and 2013, we recorded other income, net of \$1.8 million and \$0.8 million, respectively, which represents miscellaneous items, including gains and losses on intercompany financing foreign currency transactions and related hedging instruments.

*Provision for income taxes.* In fiscal 2014, we recognized an income tax benefit of \$44.8 million on a loss from continuing operations before income taxes of \$363.4 million. In fiscal 2013, income tax expense was \$68.6 million on income from continuing operations before income taxes of \$126.4 million. Our effective tax rate was 12.3% compared with 54.3% for fiscal 2014 and 2013, respectively. Our effective tax rate for fiscal 2014 was impacted by only receiving a \$17.4 million tax benefit on \$74.7 million of transaction and Separation costs, \$39.4 million of tax benefit associated with \$129.1 million of restructuring costs, \$8.5 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, \$12.4 million of tax benefit associated with the favorable rate difference between non-U.S. and U.S. jurisdictions (excluding impact of below referenced impairments), \$4.8 million of tax benefit associated with the U.S. Domestic Manufacturing Deduction, a \$20.0 million expense associated with an adjustment to the Company's wholly owned partnership investment, and a \$45.3 million tax benefit associated with the \$355.6 million impairment of tangible and intangible assets and goodwill. Our effective tax rate for fiscal 2013 was impacted by only receiving a \$4.2 million tax benefit on \$74.2 million of separation costs due to the tax-free status of the Separation, \$13.3 million of expense associated with uncertain tax positions, \$2.5 million of tax benefit associated with the U.S. Domestic Manufacturing Deduction and \$2.2 million of tax benefit associated with the favorable rate difference between non-U.S. and U.S. jurisdictions, which includes the benefit of intercompany debt transferred to the Company at the Separation.

*Income (loss) from discontinued operations, net of income taxes.* We recorded a \$0.7 million loss and \$1.0 million gain on discontinued operations, net of income taxes, during fiscal 2014 and 2013, respectively. These amounts relate to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

**Fiscal Year Ended September 27, 2013 Compared with Fiscal Year Ended September 28, 2012**

**Net Sales**

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

	Fiscal Year		Percentage Change
	2013	2012	
U.S.	\$ 1,518.7	\$ 1,350.2	12.5 %
Europe, Middle East and Africa	404.3	411.0	(1.6)
Other	281.5	295.0	(4.6)
Net sales	<u>\$ 2,204.5</u>	<u>\$ 2,056.2</u>	7.2

Net sales in fiscal 2013 increased \$148.3 million, or 7.2%, to \$2,204.5 million, compared with \$2,056.2 million in fiscal 2012. This increase was primarily driven by increased sales within our Specialty Brands and Specialty Generics segments resulting from the launch of Methylphenidate ER, increased sales of Exalgo and the addition of GABLOFEN® (baclofen injection) ("Gablofen") to our product portfolio in early fiscal 2013. These increases were partially offset by decreased sales in both our CMDS and Nuclear Imaging businesses. For further information on changes in our net sales, refer to "Business Segment Results" within this Exhibit.

**Operating Income**

*Gross profit.* Gross profit for fiscal 2013 increased \$60.1 million, or 6.2%, to \$1,024.9 million, compared with \$964.8 million in fiscal 2012. The increase in gross profit primarily resulted from higher net sales in the current year period, in addition to a favorable product mix from increased sales of our higher margin pharmaceutical products. These factors were offset by increased manufacturing and raw material costs, primarily attributable to the unscheduled shutdown of the HFR that supplies us with Mo-99. Gross margin was 46.5% in fiscal 2013, compared with 46.9% in fiscal 2012.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for fiscal 2013 were \$609.9 million, compared with \$551.7 million for fiscal 2012, an increase of \$58.2 million, or 10.5%. The increase primarily resulted from \$70.6 million of costs in the current year period related to the build-out of our corporate infrastructure, compared with \$10.7 million in the prior year period. Selling, general and administrative expenses were 27.7% of net sales for fiscal 2013, compared with 26.8% of net sales for fiscal 2012. Selling, general and administrative expenses include allocations from Covidien of \$39.6 million and \$49.2 million in fiscal 2013 and 2012, respectively, for general corporate expenses. These expenses are generally consistent with functions we have developed in our corporate build-out and ceased following the completion of the Separation on June 28, 2013. Fiscal 2013 included minimal launch expenses related to Xartemis XR and Pennsaid 2%.

*Research and development expenses.* R&D expenses increased \$21.6 million, or 15.0%, to \$165.7 million in fiscal 2013, compared with \$144.1 million in fiscal 2012. The increase in R&D expenses is primarily attributable to increased development activities related to our MNK-155, Pennsaid 2% and intrathecal products. The increase in R&D also reflects a \$5.0 million milestone payment related to acceptance of the Xartemis XR NDA for priority review by the FDA. As a percentage of our net sales, R&D expenses were 7.5% and 7.0% fiscal 2013 and 2012, respectively.

*Separation costs.* During fiscal 2013 and 2012, we incurred separation costs of \$74.2 million and \$25.5 million, respectively, primarily related to legal, accounting, tax and other professional fees. Separation costs were higher in fiscal 2013 as we approached and completed the Separation on June 28, 2013.

*Restructuring and related charges, net.* During fiscal 2013, we recorded \$35.8 million of restructuring and related charges, net, of which \$2.6 million related to accelerated depreciation and was included in cost of sales. The remaining \$33.2 million primarily related to severance and employee benefits costs incurred across all our segments. During fiscal 2012, we recorded restructuring and related charges, net of \$19.2 million, of which \$8.0 million related to accelerated depreciation and was included in cost of sales. The remaining \$11.2 million primarily related to severance and employee benefit costs incurred in the Global Medical Imaging segment.

*Gain on divestitures.* During fiscal 2013, we recorded gains of \$2.9 million related to the sale of the rights to market TussiCaps.

### **Non-Operating Items**

*Interest expense and interest income.* During fiscal 2013, net interest expense was \$19.2 million. Net interest expense is primarily attributable to our \$900 million issuance of senior unsecured notes in April 2013. Interest expense during fiscal 2013 includes \$1.1 million non-cash interest expense.

*Other income, net.* During fiscal 2013 and 2012, we recorded other income, net, of \$0.8 million and \$1.0 million, respectively, which represents miscellaneous items, including gains and losses on intercompany financing foreign currency transactions and related hedging instruments.

*Provision for income taxes.* Income tax expense was \$68.6 million and \$94.8 million on income from continuing operations before income taxes of \$126.4 million and \$236.1 million for fiscal 2013 and 2012, respectively. Our effective tax rate was 54.3% and 40.2% for fiscal 2013 and 2012, respectively. Our effective tax rate for fiscal 2013 was impacted by only receiving a \$4.2 million tax benefit on \$74.2 million of separation costs due to the tax-free status of the Separation, \$13.3 million of expense associated with uncertain tax positions, and an \$11.6 million benefit associated with intercompany debt transferred to the Company at the Separation. Our effective tax rate for fiscal 2012 was impacted by only receiving \$1.8 million of tax benefit on \$25.5 million of separation costs due to the tax-free status of the Separation and recognizing \$2.3 million of expense associated with uncertain tax positions.

*Loss from discontinued operations, net of income taxes.* We recorded a \$1.0 million gain and \$6.7 million loss on discontinued operations, net of income taxes, during fiscal 2013 and 2012, respectively. These amounts relate to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

### **Business Segment Results**

The businesses included within our Specialty Brands, our Specialty Generics and our Global Medical Imaging segments are described below:

#### **Specialty Brands**

- includes branded pharmaceuticals drugs, primarily for pain management, and a biopharmaceutical drug for autoimmune and rare diseases.

#### **Specialty Generics**

- produces specialty generic pharmaceuticals and API consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

#### **Global Medical Imaging**

- *Contrast Media and Delivery Systems* develops, manufactures and markets contrast media for diagnostic imaging applications, and power injectors to allow delivery of contrast media.
- *Nuclear Imaging* manufactures and markets radioactive isotopes and associated pharmaceuticals used for the diagnosis and treatment of disease.

Management measures and evaluates our operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment operating income because management evaluates the operating results of the segments excluding such items. These items include revenues and expenses associated with sales of products to Covidien, intangible asset amortization, net restructuring and related charges, non-restructuring impairments and separation costs. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated and combined operating income and in the reconciliations presented below. Selected information by business segment is as follows:

**Fiscal Year Ended September 26, 2014 Compared with Fiscal Year Ended September 27, 2013**

**Net Sales**

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

	Fiscal Year		Percentage Change
	2014	2013	
Specialty Brands	\$ 413.5	\$ 206.4	100.3 %
Specialty Generics	1,199.4	1,011.2	18.6
Global Medical Imaging	881.5	935.7	(5.8)
Net sales of operating segments	2,494.4	2,153.3	15.8
Other <sup>(1)</sup>	46.0	51.2	(10.2)
Net sales	\$ 2,540.4	\$ 2,204.5	15.2

(1) Represents products that were sold to Covidien.

*Specialty Brands.* Net sales for fiscal 2014 increased \$207.1 million, or 100.3%, to \$413.5 million, compared with \$206.4 million for fiscal 2013. The increase in net sales was primarily driven by \$124.4 million of net sales of Ofirmev and \$122.9 million of net sales from Acthar. These increases were partially offset by a \$50.0 million decrease in branded Exalgo as we launched an authorized generic version and a competitor entered the market.

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

	Fiscal Year		Percentage Change
	2014	2013	
U.S.	\$ 413.1	\$ 206.4	100.1%
Europe, Middle East and Africa	0.4	—	—
Other	—	—	—
Net sales	\$ 413.5	\$ 206.4	100.3

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

	Fiscal Year		Percentage Change
	2014	2013	
Exalgo	\$ 76.1	\$ 126.1	(39.7)%
Ofirmev	124.4	—	—
Acthar	122.9	—	—
Other	90.1	80.3	12.2
Specialty Brands	\$ 413.5	\$ 206.4	100.3

*Specialty Generics.* Net sales for fiscal 2014 increased \$188.2 million, or 18.6%, to \$1,199.4 million, compared with \$1,011.2 million for fiscal 2013. The increase in net sales was primarily driven by \$157.4 million of increased net sales from other controlled substances and oxycodone-related products resulting from certain strategic initiatives that offset lower volume and a \$61.3 million increase in Methylphenidate ER from favorable comparisons due to timing of the product launch in fiscal 2013. These increases were partially offset by a \$40.6 million decrease in hydrocodone-related products due to lower pricing from competitive pressures.

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

	Fiscal Year		Percentage Change
	2014	2013	
U.S.	\$ 1,071.9	\$ 891.5	20.2 %
Europe, Middle East and Africa	103.0	104.1	(1.1)
Other	24.5	15.6	57.1
Net sales	<u>\$ 1,199.4</u>	<u>\$ 1,011.2</u>	18.6

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

	Fiscal Year		Percentage Change
	2014	2013	
Methylphenidate ER	\$ 209.6	\$ 148.3	41.3 %
Oxycodone (API) and oxycodone-containing tablets	155.2	139.0	11.7
Hydrocodone (API) and hydrocodone-containing tablets	99.4	140.0	(29.0)
Other controlled substances	584.5	443.3	31.9
Other	150.7	140.6	7.2
Specialty Generics	<u>\$ 1,199.4</u>	<u>\$ 1,011.2</u>	18.6

*Global Medical Imaging.* Net sales for fiscal 2014 decreased \$54.2 million, or 5.8%, to \$881.5 million compared with \$935.7 million for fiscal 2013. The decrease was primarily driven by a \$48.3 million decline in net sales of CMDS products, which were impacted by certain restructuring actions aimed at improving profitability. Nuclear sales decreased only slightly despite supply chain disruptions in the current year. During the fourth quarter of fiscal 2014, we received notification that we lost preferred supplier status with a significant GPO which may negatively impact Global Medical Imaging net sales in fiscal 2015.

Net sales for Global Medical Imaging by geography are as follows (dollars in millions):

	Fiscal Year		Percentage Change
	2014	2013	
U.S.	\$ 414.7	\$ 418.2	(0.8)%
Europe, Middle East and Africa	290.6	300.2	(3.2)
Other	176.2	217.3	(18.9)
Net sales	\$ 881.5	\$ 935.7	(5.8)

Net sales for Global Medical Imaging by key products are as follows (dollars in millions):

	Fiscal Year		Percentage Change
	2014	2013	
Optiray™	\$ 284.0	\$ 318.5	(10.8)%
Other	165.8	179.6	(7.7)
Contrast Media and Delivery Systems	449.8	498.1	(9.7)
Nuclear Imaging	431.7	437.6	(1.3)
Global Medical Imaging	\$ 881.5	\$ 935.7	(5.8)

### Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2014 and 2013 is shown in the following table (dollars in millions):

	Fiscal Year			
	2014		2013	
Specialty Brands	\$ (50.6)	(12.2)%	\$ (36.2)	(17.5)%
Specialty Generics	617.4	51.5	347.9	34.4
Global Medical Imaging	47.1	5.3	112.3	12.0
Segment operating income	613.9	24.6	424.0	19.7
Unallocated amounts:				
Corporate and allocated expenses	(241.4)		(133.8)	
Intangible asset amortization	(162.3)		(35.4)	
Restructuring and related charges, net <sup>(1)</sup>	(129.1)		(35.8)	
Non-restructuring impairment charges	(355.6)		—	
Separation costs	(9.6)		(74.2)	
Total operating (loss) income	\$ (284.1)		\$ 144.8	

(1) Includes restructuring-related accelerated depreciation of \$0.5 million and \$2.6 million for fiscal 2014 and 2013, respectively.

*Specialty Brands.* Operating loss for fiscal 2014 increased \$14.4 million to \$50.6 million, compared with \$36.2 million for fiscal 2013. Our operating margin improved to negative 12.2% for fiscal 2014, compared with negative 17.5% for fiscal 2013. The most significant impact to the Specialty Brands segment was associated with the inclusion of Acthar and Ofirmev, which were acquired in August 2014 and March 2014, respectively. The increased loss was attributable to higher costs of sales attributable to Acthar and Ofirmev, including \$25.7 million of expense recognition associated with the fair value adjustment of acquired Acthar and Ofirmev inventory. The Specialty Brands segment experienced a \$160.9 million increase in selling, general and administrative costs that includes \$91.4 million of costs associated with the inclusion of Acthar and Ofirmev and higher expenses associated with the launch of Xartemis XR. These higher expenses were partially offset by the \$207.1 million increase in Specialty Brands net sales in fiscal 2014 compared with 2013.

*Specialty Generics.* Operating income for fiscal 2014 increased \$269.5 million to \$617.4 million, compared with \$347.9 million for fiscal 2013. Our operating margin increased to 51.5% for fiscal 2014, compared with 34.4% for fiscal 2013. The increase in operating income and margin was primarily due to benefits from strategic initiatives on certain specialty controlled substance generic products. In addition, the Specialty Generics segment recognized an \$11.7 million gain on the license of intellectual property to a third-party.

*Global Medical Imaging.* Operating income for fiscal 2014 decreased \$65.2 million to \$47.1 million, compared with \$112.3 million for fiscal 2013. Our operating margin decreased to 5.3% for fiscal 2014, compared with 12.0% for fiscal 2013. The decrease in operating income was attributable to lower net sales, increased nuclear manufacturing and raw material costs and higher regulatory compliance costs. Our increased nuclear manufacturing and raw material costs were most significantly impacted by the unscheduled shutdowns of our Mo-99 processing facility and the HFR that supplies us with Mo-99, which decreased operating income by approximately \$21.0 million compared to the prior year period. These increases were partially offset by a \$23.1 million decrease in selling, general and administrative expenses primarily attributable to benefits from restructuring actions. Ongoing materials and manufacturing costs and lower net sales will very likely limit our ability to return the Global Medical Imaging segment to historical operating margins.

*Corporate and allocated expenses.* Corporate and allocated expenses were \$241.4 million and \$133.8 million for fiscal 2014 and 2013, respectively. The increase primarily resulted from \$65.1 million of transaction costs associated with our Questcor and Cadence acquisitions, a \$23.1 million environmental remediation charge, increased internal and third-party costs of being an independent publicly-traded company, which was partially offset by certain prior year costs that did not recur in fiscal 2014. We were allocated general corporate expenses of \$39.6 million during fiscal 2013 for certain services provided by Covidien. These allocations ceased in periods following the completion of the Separation on June 28, 2013.

### ***Fiscal Year Ended September 27, 2013 Compared with Fiscal Year Ended September 28, 2012***

#### **Net Sales**

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

	Fiscal Year		Percentage Change
	2013	2012	
Specialty Brands	\$ 206.4	\$ 156.4	32.0 %
Specialty Generics	1,011.2	848.8	19.1
Global Medical Imaging	935.7	996.8	(6.1)
Net sales of operating segments	2,153.3	2,002.0	7.6
Other <sup>(1)</sup>	51.2	54.2	(5.5)
Net sales	\$ 2,204.5	\$ 2,056.2	7.2

(1) Represents products that were sold to Covidien.

*Specialty Brands.* Net sales for fiscal 2013 increased \$50.0 million, or 32.0%, to \$206.4 million, compared with \$156.4 million for fiscal 2012. The increase in net sales was primarily driven by a \$34.2 million increase in net sales of Exalgo, which was aided by the launch of the 32 mg dosage in August 2012.

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

	Fiscal Year		Percentage Change
	2013	2012	
U.S.	\$ 206.4	\$ 156.4	32.0%
Europe, Middle East and Africa	—	—	—
Other	—	—	—
Net sales	\$ 206.4	\$ 156.4	32.0

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

	Fiscal Year		Percentage Change
	2013	2012	
Exalgo	\$ 126.1	\$ 91.9	37.2%
Ofirmev	—	—	—
Acthar	—	—	—
Other	80.3	64.5	24.5
Specialty Brands	\$ 206.4	\$ 156.4	32.0

*Specialty Generics.* Net sales for fiscal 2013 increased \$162.4 million, or 19.1%, to \$1,011.2 million, compared with \$848.8 million for fiscal 2012. The increase in net sales was primarily driven by \$148.3 million of sales from the launch of Methylphenidate ER during fiscal 2013.

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

	Fiscal Year		Percentage Change
	2013	2012	
U.S.	\$ 891.5	\$ 724.2	23.1 %
Europe, Middle East and Africa	104.1	108.7	(4.2)
Other	15.6	15.9	(1.9)
Net sales	\$ 1,011.2	\$ 848.8	19.1

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

	Fiscal Year		Percentage Change
	2013	2012	
Methylphenidate ER	\$ 148.3	\$ —	— %
Oxycodone (API) and oxycodone-containing tablets	139.0	144.1	(3.5)
Hydrocodone (API) and hydrocodone-containing tablets	140.0	130.5	7.3
Other controlled substances	443.3	439.5	0.9
Other	140.6	134.7	4.4
Specialty Generics	\$ 1,011.2	\$ 848.8	19.1

*Global Medical Imaging.* Net sales for fiscal 2013 decreased \$61.1 million, or 6.1%, to \$935.7 million compared with \$996.8 million for fiscal 2012. Net sales of CMDS products decreased \$43.9 million, and were negatively impacted by the effects of commoditization in mature markets. Net sales of nuclear products decreased \$17.2 million, primarily due to additional sales opportunities during fiscal 2012 that resulted from challenges a competitor faced in supplying the market.

Net sales for Global Medical Imaging by geography are as follows (dollars in millions):

	Fiscal Year		Percentage Change
	2013	2012	
U.S.	\$ 418.2	\$ 466.8	(10.4)%
Europe, Middle East and Africa	300.2	302.3	(0.7)
Other	217.3	227.7	(4.6)
Net sales	<u>\$ 935.7</u>	<u>\$ 996.8</u>	(6.1)

Net sales for Global Medical Imaging by key products are as follows (dollars in millions):

	Fiscal Year		Percentage Change
	2013	2012	
Optiray	\$ 318.5	\$ 352.2	(9.6)%
Other	179.6	189.8	(5.4)
Contrast Media and Delivery Systems	498.1	542.0	(8.1)
Nuclear Imaging	437.6	454.8	(3.8)
Global Medical Imaging	<u>\$ 935.7</u>	<u>\$ 996.8</u>	(6.1)

### Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2013 and 2012 is shown in the following table (dollars in millions):

	Fiscal Year			
	2013		2012	
Specialty Brands	\$ (36.2)	(17.5)%	\$ (75.0)	(48.0)%
Specialty Generics	347.9	34.4	237.8	28.0
Global Medical Imaging	112.3	12.0	214.3	21.5
Segment operating income	424.0	19.7	377.1	18.8
Unallocated amounts:				
Corporate and allocated expenses	(133.8)		(69.9)	
Intangible asset amortization	(35.4)		(27.3)	
Restructuring and related charges, net <sup>(1)</sup>	(35.8)		(19.2)	
Separation costs	(74.2)		(25.5)	
Total operating income	<u>\$ 144.8</u>		<u>\$ 235.2</u>	

(1) Includes restructuring-related accelerated depreciation of \$2.6 million and \$8.0 million for fiscal 2013 and 2012, respectively.

*Specialty Brands.* Operating loss for fiscal 2013 decreased \$38.8 million to \$36.2 million, compared with \$75.0 million for fiscal 2012. Our operating margin improved to negative 17.5% for fiscal 2013, compared with negative 48.0% for fiscal 2012. The decrease in operating income and margin improvement was primarily due to increased sales of higher margin products, such as Exalgo.

*Specialty Generics.* Operating income for fiscal 2013 increased \$110.1 million to \$347.9 million, compared with \$237.8 million for fiscal 2012. Our operating margin increased to 34.4% for fiscal 2013, compared with 28.0% for fiscal 2012. The increase in operating income and margin was primarily due to increased sales of higher margin products, such as Methylphenidate ER.

*Global Medical Imaging.* Operating income for fiscal 2013 decreased \$102.0 million to \$112.3 million, compared with \$214.3 million for fiscal 2012. Our operating margin decreased to 12.0% for fiscal 2013, compared with 21.5% for fiscal 2012. The decrease in operating income was attributable to lower net sales, discussed previously, increased manufacturing and raw material costs and the effects of a renegotiated customer contract in the U.S., partially offset by a decrease in selling, general and administrative expenses. Our operating margin was most significantly impacted by higher raw material costs from the unscheduled shutdown of the HFR that supplies us with Mo-99.

*Corporate and allocated expenses.* Corporate and allocated expenses were \$133.8 million and \$69.9 million for fiscal 2013 and 2012, respectively. The increase primarily resulted from \$70.6 million of costs related to the build-out of our corporate infrastructure during the current year period compared with \$10.7 million during the prior year period. In addition to corporate infrastructure build-out costs, we were allocated general corporate expenses of \$39.6 million and \$49.2 million during fiscal 2013 and 2012, respectively, for certain functions provided by Covidien. These allocations ceased in periods following the completion of the Separation on June 28, 2013.

## Liquidity and Capital Resources

Significant factors driving our liquidity position include cash flows generated from operating activities, financing transactions, capital expenditures and cash paid in connection with acquisitions and license agreements. Historically, we have typically generated, and expect to continue to generate, positive cash flow from operations. Through June 28, 2013, as part of Covidien, our cash was swept regularly by Covidien at its discretion. Covidien also funded our operating and investing activities as needed prior to the Separation. The cash and cash equivalents held by Covidien at the corporate level were not specifically identifiable or otherwise allocable to us and, as such, were not reflected on the combined balance sheets for dates prior to June 28, 2013. Cash flows related to financing activities prior to the Separation reflect changes in Covidien's investments in us. Transfers of cash to and from Covidien were reflected as a component of parent company investment within parent company equity on our combined balance sheets through June 28, 2013. Our cash flows for periods prior to June 28, 2013, may not be indicative of our future performance and do not necessarily represent the cash flows that would have been generated had we operated as an independent, publicly-traded company for the entirety of the periods presented.

Effective June 28, 2013, we are no longer participating in cash management and funding arrangements with Covidien and our ability to fund our capital needs is impacted by our ongoing ability to generate cash from operations and access to capital markets. 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.

In fiscal 2015, we expect our total capital expenditures to be in the range of \$130 million to \$150 million. While we intend to fund these capital expenditures with cash generated from operations, we also have an undrawn \$250 million revolving credit facility. At September 26, 2014, we had capital expenditure commitments of \$6.3 million.

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

	Fiscal Year		
	2014	2013	2012
Net cash provided by (used in):			
Operating activities	\$ 373.4	\$ 135.9	\$ 255.8
Investing activities	(2,890.8)	(234.7)	(152.2)
Financing activities	2,953.9	373.0	(103.6)
Effect of currency exchange rate changes on cash and cash equivalents	(4.2)	1.3	—
Net increase in cash and cash equivalents	\$ 432.3	\$ 275.5	\$ —

### ***Operating Activities***

Net cash provided by operating activities was \$373.4 million for fiscal 2014 was primarily attributable to income from continuing operations, as adjusted for non-cash items, and a \$66.9 million inflow from net investment in working capital. The working capital inflow was primarily driven by a \$56.0 million decrease in inventory as we reduced inventory levels in fiscal 2014 and a \$110.5 million increase in other accrued liabilities. The increase in other accrued liabilities includes higher incentive compensation reserves, current year accruals for unpaid legal settlements and higher accrued interest balances reflecting our fiscal 2014 financing transactions, all of which were offset by declines in accrued branded rebates following the introduction of generic alternatives to Exalgo. These increases were offset by \$54.8 million in payments to taxing authorities, a \$51.3 million increase in accounts receivable driven by increased net sales and a \$32.9 million decrease in accounts payable after completing our fiscal 2014 acquisitions.

Net cash provided by operating activities of \$135.9 million for fiscal 2013 was primarily attributable to income from continuing operations, as adjusted for non-cash items, partially offset by a \$79.0 million outflow from net investment in working capital. The working capital outflow was primarily driven by a \$181.2 million increase in accounts receivable and a \$16.0 million outflow in other working capital accounts, partially offset by a \$60.7 million increase in income taxes payable, which was substantially settled through parent company investment, a \$27.7 million decrease in inventory and a \$22.6 million increase in accrued and other liabilities. The increase in accounts receivable was primarily attributable to the fact that \$95.6 million of accounts receivable in certain jurisdictions outside the U.S. were retained by Covidien through parent company investment, which is included within the financing section of the consolidated and combined statement of cash flows.

Net cash provided by operating activities of \$255.8 million for fiscal 2012 was primarily attributable to income from continuing operations, as adjusted for non-cash items, partially offset by a \$25.4 million outflow from net investments in working capital. The working capital outflow was primarily driven by a \$62.8 million increase in inventory and a \$38.7 million decrease in accrued and other liabilities, partially offset by a \$79.4 million increase in income taxes payable, the latter of which was recorded in parent company investment. A build-up of inventory in advance of a planned plant closure contributed to the increase in inventory, while environmental payments contributed to the decrease in accrued and other liabilities.

### ***Investing Activities***

Net cash used in investing activities increased \$2,656.1 million to \$2,890.8 million for fiscal 2014, compared with \$234.7 million for fiscal 2013. The increase primarily resulted from fiscal 2014 payments, net of cash acquired, of \$1,490.5 million and \$1,286.0 million related to the acquisition of Questcor and Cadence, respectively, and \$17.3 million for the acquisition of other intangible assets; compared with an \$88.1 million payment made during fiscal 2013 to acquire CNS Therapeutics. This net increase was partially offset by a \$29.5 million increase in other cash inflows, which include proceeds from the sale of investments and assets, and a \$20.1 million decrease in capital expenditures in fiscal 2014 compared with fiscal 2013.

Net cash used in investing activities increased \$82.5 million to \$234.7 million for fiscal 2013, compared with \$152.2 million for fiscal 2012. This increase primarily resulted from an \$88.1 million payment made during fiscal 2013 to acquire CNS Therapeutics and a \$3.7 million increase in capital expenditures. These increases were partially offset by a \$13.2 million payment in fiscal 2013 to acquire rights to Roxicodeone.

### ***Financing Activities***

Net cash provided by financing activities was \$2,953.9 million for fiscal 2014, compared with net cash provided by financing activities of \$373.0 million for fiscal 2013. The \$2,580.9 million increase in cash provided by financing activities resulted from the receipt of \$2,971.5 million of cash proceeds from the issuance of external debt used to fund the Cadence and Questcor acquisitions, net of debt financing costs, compared with \$886.1 million from the issuance of debt in the prior year. This net increase was partially offset by a \$33.5 million increase in debt and capital lease repayments, primarily related to debt assumed in the Cadence acquisition, and prior year net transfers to Covidien of \$515.9 million, which reflected the remittance of the net proceeds from the issuance of debt partially offset by funding of the CNS Therapeutics, Inc. acquisition and funding of capital expenditures.

Net cash provided by financing activities was \$373.0 million for fiscal 2013, compared with net cash used in financing activities of \$103.6 million for fiscal 2012. The \$476.6 million increase in cash provided by financing activities resulted from the receipt of \$886.1 million of cash proceeds from the issuance of debt, net of debt financing costs, partially offset by a \$411.9 million increase in net transfers to Covidien. This increase was attributable to remitting the net proceeds from the issuance of debt partially offset by the initial cash capitalization, funding of higher capital expenditures and funding of the CNS Therapeutics acquisition.

## ***Inflation***

Inflationary pressures have had an adverse effect on us through higher raw material and fuel costs, primarily in our Global Medical Imaging segment as noted previously. We have entered into commodity swap contracts in the past to mitigate the impact of rising prices and may do so in the future. If these contracts are not effective or we are not able to achieve price increases on our products, we may continue to be impacted by these increased costs.

## ***Foreign Currency***

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

## ***Concentration of Credit and Other Risks***

Financial instruments that potentially subject us to concentrations of credit risk primarily consist of accounts receivable. We generally do not require collateral from customers. A portion of our 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.

## ***Debt and Capitalization***

At September 26, 2014, total debt was \$3,972.7 million compared with total debt at September 27, 2013 of \$919.8 million. The increase in total debt resulted from financing transactions to fund our fiscal 2014 acquisitions. The total debt at September 26, 2014 is comprised of \$1,990.3 million of variable rate term loans, \$1,830.6 million of fixed rate instruments, \$150.0 million of borrowings under a variable rate receivable securitization program and \$1.8 million of capital lease obligations. The variable rate term loan interest rates are based on LIBOR, subject to 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 26, 2014 our fixed rate instruments have a weighted-average interest rate of 5.07% and pay interest at various dates throughout the fiscal year. Our receivable securitization program bears interest based on one month LIBOR plus a rate margin of 0.80% and has a capacity of \$160.0 million that may, subject to certain conditions, be increased to \$300.0 million.

At September 26, 2014, \$21.2 million of our total debt is classified as current as these payments are expected to be made within the next fiscal year.

In addition to the additional borrowing capacity under our receivable securitization program, we have a \$250.0 million revolving credit facility. At September 26, 2014, we had no borrowings or letters of credit outstanding against our revolving credit facility. As such the entire \$250.0 million under the revolving credit facility is available for borrowing.

As of September 26, 2014, we were, and expect to remain, in compliance with the provisions and covenants associated with our Credit Agreement, the Notes and our other debt agreements.

Additional discussion of the related to our debt is presented in Note 12 of Notes to the Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K.

## ***Capitalization***

Shareholders' equity was \$4,958.0 million, at September 26, 2014, compared with \$1,255.6 million, at September 27, 2013. The increase in shareholder's equity is primarily attributable to the issuance of approximately 57 million shares to the former shareholders of Questcor, which increased shareholders' equity by \$3,979.6 million. The remaining differences are comprised of share-based compensation, share option exercises, fiscal year 2014 net loss and changes in accumulated other comprehensive income.

## ***Dividends***

We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance R&D, acquisitions and the operation and expansion of our business. The recommendation, declaration and payment of dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay dividends in the future, there can be no assurance that we will continue to pay such dividends.

## Commitments and Contingencies

### Contractual Obligations

The following table summarizes our contractual obligations as of September 26, 2014 (in millions):

	Payments Due By Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt obligations	\$ 3,970.9	\$ 19.8	\$ 195.2	\$ 342.8	\$ 3,413.1
Interest on long-term debt obligations <sup>(1)</sup>	1,185.9	161.0	325.6	309.2	390.1
Capital lease obligations <sup>(1)</sup>	1.8	1.4	0.4	—	—
Operating lease obligations	95.0	21.5	30.5	18.0	25.0
Purchase obligations <sup>(2)</sup>	281.2	93.8	123.3	64.1	—
Total contractual obligations	\$ 5,534.8	\$ 297.5	\$ 675.0	\$ 734.1	\$ 3,828.2

(1) Interest on debt and capital lease obligations are projected for future periods using interest rates in effect as of September 26, 2014. Certain of these projected interest payments may differ in the future based on changes in market interest rates.

(2) Purchase obligations consist of commitments for purchases of goods and services made in the normal course of business to meet operational and capital requirements.

The preceding table does not include other liabilities of \$651.9 million, primarily consisting of obligations under our pension and postretirement benefit plans, unrecognized tax benefits for uncertain tax positions and related accrued interest and penalties, environmental liabilities and asset retirement obligations, because the timing of their future cash outflow is uncertain. The most significant of these liabilities are discussed below.

Non-current income taxes payable, primarily related to unrecognized tax benefits, is included within other income tax liabilities on the consolidated and combined balances sheet and, as of September 26, 2014, was \$122.6 million. Payment of these liabilities is uncertain and, even if payments are determined to be necessary, they are subject to the timing of rulings by the Internal Revenue Service of tax positions we take. For further information on income tax related matters, refer to Note 7 of Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K.

As of September 26, 2014, we had net unfunded pension and postretirement benefit obligations of \$64.8 million and \$52.0 million, respectively. The timing and amounts of long-term funding requirements for pension and postretirement obligations are uncertain. The Company does not anticipate making material involuntary contributions in fiscal 2015, but may elect to make voluntary contributions to its defined pension plans or its postretirement benefit plans during fiscal 2015.

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites. These projects relate to a variety of activities, including decontamination and decommissioning of radioactive materials and removal of solvents, metals and other hazardous substances from soil and groundwater. The ultimate cost of cleanup and timing of future cash outlays is difficult to predict given uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. As of September 26, 2014, we believe that it is probable that we will incur investigation and remedial costs of approximately \$67.1 million, of which \$7.2 million is included in accrued and other current liabilities on our consolidated balance sheet at September 26, 2014. Note 18 of Notes to Consolidated and Combined Financial Statements, included within Exhibit 99.1 to this Form 8-K, provides additional information regarding environmental matters, including asset retirement obligations.

### 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 18 of the Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K. Although it is not feasible to predict the outcome of these matters, management believes that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

### **Guarantees**

In disposing of assets or businesses, we have historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. We assess the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. We have no reason to believe that these uncertainties would 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, 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 our consolidated balance sheet at September 26, 2014 was \$16.6 million, of which \$13.9 million 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 26, 2014. As of September 26, 2014, the maximum future payments we could be required to make under these indemnification obligations was \$71.4 million. We were required to pay \$30.0 million into an escrow account as collateral to the purchaser, of which \$19.4 million remained in other assets on the consolidated balance sheet at September 26, 2014.

We have recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 18 of Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K. In addition, we are liable for product performance; however, in the opinion of management, such obligations will not have a material adverse effect on our financial condition, results of operations and cash flows.

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

We are required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating our ability to fund the decommissioning of our Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though we do not intend to close this facility. We have provided this financial assurance in the form of surety bonds totaling \$57.2 million.

In addition, as of September 26, 2014, we had a \$21.1 million letter of credit to guarantee decommissioning costs associated with our Saint Louis, Missouri plant upon closure, though we do not intend to close this facility. As of September 26, 2014, we had various other letters of credit and guarantee and surety bonds totaling \$36.2 million.

We exchanged title to \$27.4 million of our plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. We also simultaneously leased such assets back from Saint Louis County under a capital lease expiring December 2022, the terms of which provide us with the right of offset against the IRBs. The lease also provides an option for us to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a property tax abatement ten years from the date the property is placed in service. Due to right of offset, the capital lease obligation and IRB asset are recorded net in the consolidated balance sheets. The Company expects that the right of offset will be applied to payments required under these arrangements.

In addition, the Separation and Distribution Agreement provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities.

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

The consolidated and combined financial statements have been prepared in U.S. dollars and in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of the consolidated and combined 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. The following accounting policies are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. Management's estimates are based on the relevant information available at the end of each period.

### Revenue Recognition

We recognize revenue for product sales when title and risk of loss have transferred from us to the buyer, which may be upon shipment or upon delivery to the customer site, based on contract terms or legal requirements in non-U.S. jurisdictions. We sell products direct to retail pharmacies and end user customers and through distributors who resell the products to retail pharmacies, institutions and end user customers. We establish contracts with wholesalers, chain stores, government agencies, institutions, managed care organizations and group purchasing organizations that provide for rebates, sales incentives, distribution service agreements ("DSAs") fees, fees for services and administration fees. Direct rebates and fees are paid based on direct customer's purchases from us, including DSA fees paid to wholesalers under our DSAs. Indirect rebates and fees are paid based on products purchased from a wholesaler under a contract with us. We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may enter into agreements with wholesalers at a contract price to offer our products to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback.

When we recognize net sales, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, product returns and other sales deductions. These provisions are estimated based upon historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of our products and other competitive factors. We adjust reserves for rebates and chargebacks, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of sales we recognize in the period of adjustment.

Sales return reserves for new products are estimated and primarily based on our historical sales return experience with similar products, such as those within the same product line or those within the same or similar therapeutic category. In limited circumstances, where the new product is not an extension of an existing product line or where we have no historical experience with products in a similar therapeutic category (such that we cannot reliably estimate expected returns), we would defer recognition of revenue until the right of return no longer exists or until we have developed sufficient historical experience to estimate sales returns. When establishing sales return reserves for new products, we also consider estimated levels of inventory in the distribution channel and projected demand. The following table reflects activity in our sales reserve accounts (dollars in millions):

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
Balance at September 30, 2011	\$ 224.0	\$ 33.9	\$ 13.3	\$ 271.2
Provisions	1,085.9	30.0	41.9	1,157.8
Payments or credits	(1,077.7)	(29.2)	(42.3)	(1,149.2)
Balance at September 28, 2012	232.2	34.7	12.9	279.8
Provisions	1,219.8	37.1	60.0	1,316.9
Payments or credits	(1,194.9)	(21.7)	(57.2)	(1,273.8)
Balance at September 27, 2013	257.1	50.1	15.7	322.9
Provisions	1,668.6	84.5	93.7	1,846.8
Payments or credits	(1,642.5)	(31.3)	(96.0)	(1,769.8)
Acquisitions	30.1	0.5	—	30.6
Balance at September 26, 2014	\$ 313.3	\$ 103.8	\$ 13.4	\$ 430.5

## ***Inventory***

Inventories are recorded at the lower of cost or market value, primarily using the first-in, first-out convention. We reduce the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors. If market conditions and actual demands are less favorable than projected, additional inventory write-downs may be required.

## ***Goodwill and Other Intangible Assets***

In performing goodwill assessments, management relies on a number of factors including operating results, business plans, economic projections, anticipated future cash flows, transactions and market place data. There are inherent uncertainties related to these factors and judgment in applying them to the analysis of goodwill impairment. Since judgment is involved in performing goodwill valuation analyses, there is risk that the carrying value of our goodwill may be overstated or understated. We calculate our goodwill valuations using an income approach based on the present value of future cash flows of each reporting unit. This approach incorporates many assumptions including future growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in goodwill impairment in future periods.

We test goodwill during the fourth quarter of each year for impairment, or more frequently if certain indicators are present or changes in circumstances suggest that impairment may exist. We utilize a two-step approach. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units. We estimate the fair value of our reporting units through internal analyses and valuation, using an income approach based on the present value of future cash flows. If the carrying value of a reporting unit exceeds its fair value, we will perform the second step of the goodwill impairment to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. To determine the implied fair value of goodwill, we allocate the fair value of a reporting unit to all of the assets and liabilities of that unit, including intangible assets, as if the reporting unit had been acquired in a business combination. Any excess of the value of a reporting unit over the amounts assigned to its assets and liabilities represents the implied fair value of goodwill. The results of our annual goodwill impairment test for fiscal 2014 showed that the fair value of our Specialty Brands and Specialty Generics reporting units exceeded their respective carrying values. The fair value of our Global Medical Imaging reporting unit was less than the carrying value of the reporting unit and we recorded a \$219.7 million goodwill impairment. The impairment of Global Medical Imaging goodwill was primarily attributable to the fourth quarter of fiscal 2014, as we received notification that we lost preferred supplier status with a significant GPO and that we terminated a related-party supply contract.

For further information our goodwill impairment analysis, refer to Notes 2 and 11 of the Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K.

Intangible assets include completed technology, licenses, trademarks and in-process research and development. We record intangible assets at cost and amortize finite-lived intangible assets, generally using the straight-line method over three to thirty years. When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets with their carrying value. The fair value of the intangible asset is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the present value of future cash flows. We assess the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. We considered the fourth quarter 2014 loss of preferred supplier status with a significant GPO and termination of a related-party supply contract to be a triggering event for the CMDS asset group, including an intangible asset. The undiscounted cash flows were less than the carrying value of the CMDS asset group. Therefore, we compared the fair value of the CMDS asset group to its carrying value and recorded impairment charges of \$65.9 million and \$52.4 million to the property, plant and equipment and long-lived amortizing intangible assets, respectively, included in the CMDS asset group. In the fourth quarter of each year, we test the indefinite-lived intangible assets for impairment by comparing the fair value of the assets, estimated using an income approach, with their carrying value and record an impairment when the carrying value exceeds the fair value.

## ***Contingencies***

We are involved, both as a plaintiff and a defendant, in various legal proceedings that arise in the ordinary course of business, including, without limitation, patent infringement, product liability and environmental matters, as further discussed in Note 18 of Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K. Accruals recorded for various contingencies, including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provisions are recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

## ***Pension and Postretirement Benefits***

Our pension expense and obligations are developed from actuarial valuations. Two critical assumptions in determining pension expense and obligations are the discount rate and expected long-term return on plan assets. We evaluate these assumptions at least annually. Other assumptions reflect demographic factors such as retirement, mortality and turnover and are evaluated periodically and updated to reflect our actual experience. Actual results may differ from actuarial assumptions. The discount rate is used to calculate the present value of the expected future cash flows for benefit obligations under our pension plans. For our U.S. plans, we use a broad population of Moody's AA-rated corporate bonds to determine the discount rate assumption. All bonds are non-callable, denominated in U.S. dollars and have a minimum amount outstanding of \$250 million. This population of bonds was used to generate a yield curve and associated spot rate curve, to discount the projected benefit payments for the U.S. plans. The discount rate is the single level rate that produces the same result as the spot rate curve. For our non-U.S. plans, the discount rate is generally determined by reviewing country- and region-specific government and corporate bond interest rates. A decrease in the discount rate increases the present value of pension benefit obligations and increases pension expense. A 50 basis point decrease in the discount rate would increase our present value of pension obligations by approximately \$34.7 million.

We consider the current and expected asset allocations of our pension plans, as well as historical and expected long-term rates of return on those types of plan assets, in determining the expected long-term return on plan assets. In determining the expected return on pension plan assets, we consider the relative weighting of plan assets by class and individual asset class performance expectations as provided by external advisors in reaching our conclusions on appropriate assumptions. Our overall investment objective is to obtain a long-term return on plan assets that is consistent with the level of investment risk that is considered appropriate. Investment risks and returns are reviewed regularly against benchmarks to ensure objectives are being met. A 50 basis point decrease in the expected long-term return on plan assets would increase our annual pension expense by approximately \$2.2 million.

## ***Share-Based Compensation***

Share-based compensation cost is measured at the grant or modification date based on the value of the award and is recognized as expense over the vesting period for awards expected to vest. Determining the fair value of share-based awards at the grant date requires judgment, including estimating the expected term, expected stock price volatility, risk-free interest rate and expected dividends. Additionally, judgment is required in estimating the amount of share-based awards that are expected to be forfeited before vesting. The original estimate of the grant date fair value is not subsequently revised unless the awards are modified, but the estimate of expected forfeitures is revised throughout the vesting period and the cumulative share-based compensation cost recognized is adjusted accordingly. For more information about our share-based awards, refer to Note 14 of Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K.

## ***Income Taxes***

In determining income for financial statement purposes, we must make certain estimates and judgments. These estimates and judgments affect the calculation of certain tax liabilities and the determination of the recoverability of certain of the deferred tax assets, which arise from temporary differences between the tax and financial statement recognition of revenue and expense.

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of cumulative losses in the most recent years and our forecast of future taxable income. In estimating future taxable income, we develop assumptions including the amount of future state, federal and international pre-tax operating income, the reversal of temporary differences, and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates we use to manage the underlying businesses.

We determine whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not realized on the uncertain tax position, an income tax liability is established. We adjust these liabilities as a result of changing facts and circumstances; however, due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. A significant portion of our potential tax liabilities are recorded in non-current income taxes payable, which is included in other liabilities on our consolidated balance sheets, as payment is not expected within one year.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across our global operations. Changes in tax laws and rates could affect recorded deferred tax assets and liabilities in the future. Management is not aware of any such changes, however, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We believe that we will generate sufficient future taxable income in the appropriate jurisdictions to realize the tax benefits related to the net deferred tax assets on our consolidated balance sheets. However, any reduction in future taxable income, including any future restructuring activities, may require that we record an additional valuation allowance against our deferred tax assets. An increase in the valuation allowance would result in additional income tax expense in such period and could have a significant impact on our future earnings. Our income tax expense recorded in the future may also be reduced to the extent of decreases in our valuation allowances.

## ***Recently Issued Accounting Standards***

Refer to Note 3 of Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K for a discussion regarding recently issued accounting standards and their estimated impact on our financial condition, results of operations and cash flows.

## Business

### Overview

We are a global specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology), along with pain and attention-deficit hyperactivity disorder ("ADHD") for prescription by office- and hospital-based physicians. We also support the diagnosis of disease with nuclear medicine and contrast imaging. Our products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the United States ("U.S.") and we have a commercial presence in approximately 65 countries. We believe our experience in the acquisition and management of highly regulated raw materials; deep regulatory expertise; and specialized chemistry, formulation and manufacturing capabilities, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

During the first quarter of fiscal 2015, the integration of Questcor Pharmaceuticals, Inc. ("Questcor") was substantially completed. With this, and given the increased significance of the Specialty Brands business to our results and the expected long-term growth of this business as compared to the Specialty Generics business, we have changed our reportable segments. We now present the Specialty Brands and Specialty Generics businesses as reportable segments, along with the continued presentation of Global Medical Imaging as a reportable segment. We historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment. Prior year amounts have been recast to conform to current presentation. The three reportable segments are further described below:

- *Specialty Brands* produces and markets branded pharmaceuticals and biopharmaceuticals;
- *Specialty Generics* produces specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- *Global Medical Imaging* manufactures and markets contrast media and delivery systems ("CMDS") and radiopharmaceuticals (nuclear medicine).

For further information on our products and segments, refer to "Our Businesses and Product Strategies" within this Exhibit.

### History and Development

Our Specialty Generics segment can trace its development from the founding of G. Mallinckrodt & Co. in 1867 (predecessor of today's API business). We expanded from the controlled substance API business into controlled substance generics and branded specialty pharmaceuticals. Our Global Medical Imaging segment traces its start from a series of innovations, including the introduction of barium in 1916, and now includes our CMDS business, including products for computed tomography ("CT") imaging and magnetic resonance imaging ("MRI"). We entered the nuclear imaging business in 1966 with technetium generators, and have subsequently expanded into "cold" kits and other radioisotopes.

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the Pharmaceuticals business of Covidien plc ("Covidien"). On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the Pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing our legal separation from Covidien ("the Separation").

Fiscal 2014 was a transformational year for Mallinckrodt and today we provide a broad range of solutions to patients that will drive growth, improve profitability and deliver value to our shareholders. This was partially accomplished through the expansion of our portfolio of branded products with the acquisitions of H.P. Acthar<sup>®</sup> Gel ("Acthar"), for the treatment of autoimmune and rare diseases, and OFIRMEV<sup>®</sup> (acetaminophen) injection ("Ofirmev"), for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. We believe these acquisitions have created a foundation and framework for future growth. In addition to product expansion, we also implemented significant actions under our 2013 restructuring program intended to improve our long-term gross profit margins and yield efficiencies from our spending on selling, general and administrative expenses ("SG&A").

Our principal executive offices are located at Damastown, Mulhuddart, Dublin 15, Ireland. Our telephone number at this location is +353 (1) 880-8180. Our U.S. headquarters is located at 675 James S. McDonnell Boulevard, Hazelwood, Missouri 63042. Our telephone number at this location is (314) 654-2000.

## Our Competitive Strengths

We believe we have the following strengths:

- *Ability to successfully execute strategies to drive growth.* We became an independent public company in June 2013. In March 2014, we acquired Cadence Pharmaceuticals, Inc. ("Cadence"), a biopharmaceutical company focused on commercializing products principally for use in the hospital setting, for total consideration of approximately \$1.3 billion ("the Cadence Acquisition"). In August 2014, we acquired Questcor, a high-growth biopharmaceutical company, for total consideration of approximately \$5.9 billion ("the Questcor Acquisition"). Over the same period, we successfully completed the integration of Cadence, commenced the integration of Questcor and took restructuring actions, all of which are expected to drive efficiencies. These actions further diversified Mallinckrodt, significantly increasing our scale, revenues, profitability and cash flow.
- *Expertise in highly regulated raw materials and strong regulatory relationships.* We have expertise in the acquisition and importation of highly regulated raw materials, such as opioids, other controlled substances and radioisotopes. For example, in calendar 2013, we estimated we received approximately 26% of the U.S. Drug Enforcement Administration's ("DEA") total annual quota for controlled substances that we manufacture. Based on IMS Health data for the same period, our Generics business had an approximately 30% market share of DEA Schedules II and III opioid and oral solid dose medications. The acquisition of certain raw materials and the processing of them into finished products requires a close collaboration with a wide variety of regulatory authorities including the DEA, U.S. Food and Drug Administration ("FDA"), U.S. Department of Agriculture ("USDA"), U.S. Nuclear Regulatory Commission ("NRC"), European Medicines Agency and Irish Medicines Board, among many others. We have a long history of working closely with regulatory agencies to ensure ongoing, reliable access to these highly regulated materials.
- *Specialized chemistry, development and formulation expertise which supports our operations.* We have specialized chemistry expertise in the formulation of new drug combinations, reformulation of existing drugs, and manufacture of controlled substances into a wide range of products, such as tablets, capsules, oral liquids, injectable and intrathecal products.
- *Distinctive high-quality manufacturing and distribution skills with vertical integration where there are competitive advantages.* We have expertise in the manufacturing of complex substances including those that come from naturally derived sources. Our manufacturing and supply chain capabilities enable highly efficient controlled substance tableting, packaging and distribution. We own one of the world's largest DEA Schedule C-II vault storage capacities for raw materials, intermediates and finished dosages. In our Global Medical Imaging segment, we have the capability to process Mo-99 for use in our Ultra-Technekow DTE generators and to manufacture cyclotron-derived isotopes such as thallium-201, indium-111, gallium-67, germanium-68 and iodine-123. In addition, we produce the large-volume terminally sterilized pre-filled plastic syringes that fit into our power injectors. Where appropriate, we have also pursued selective vertical integration initiatives to ensure our manufacturing and supply chain benefit from cost and productivity efficiencies, such as using several of our API products to provide the raw materials for some of our generic products.
- *Diversified business model with increasing shift towards high-margin pharmaceuticals business with high cash flow conversion.* We have a diverse portfolio across our three different reporting segments, Specialty Brands, Specialty Generics and Global Medical Imaging. In the fourth quarter of fiscal 2014, combined net sales from our Specialty Brands and Specialty Generics segments represented 72.6% of net sales, excluding sales to our former parent, compared with 57.1% in the fourth quarter of fiscal 2013. We expect this percentage to increase in fiscal 2015 due to the inclusion of full year results from our fiscal 2014 acquisitions. These acquisitions have also increased the combined segment operating income from 25.3% in the fourth quarter of fiscal 2013 to 39.4% in the fourth quarter of fiscal 2014. The increased revenues and segment operating income positions us for strong cash flow generation, enabling us to potentially decrease leverage over time.

- *An extensive portfolio of generic products and controlled substance API for pain.* Our Specialty Generics segment has a strong position in the controlled substance generics market. Our generics products are focused on pain and ADHD while our APIs are for a broad range of products. We believe this segment offers the broadest product line of opioid and other controlled substances available (primarily DEA Schedules II and III), and we focus in a number of therapeutic areas with high technical barriers, limited competition and long product life-cycles.

While we have set forth our competitive strengths above, our business involves numerous risks and uncertainties which may prevent us from executing our strategies. These risks include, among others, risks relating to: DEA regulation of the availability of API controlled substances, drug products under development and marketed drug products; the highly exacting and complex nature of our manufacturing processes; the limited global supply of fission-produced Mo-99 for use in our Ultra-Technekow DTE generators and the aging global infrastructure of nuclear reactors; our customer concentration; cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations; developing or commercializing new products; expanding commercial opportunities for existing products; adapting to a changing technology and diagnostic treatment landscape; protecting our intellectual property rights or being subject to claims that we infringe on the intellectual property rights of others; and significant competition. For a more complete description of the risks associated with our business, see Item 1A. Risk Factors and "Forward-Looking Statements" included within the Annual Report on Form 10-K for the fiscal year ended September 26, 2014, which was filed on November 24, 2014.

## **Our Businesses and Product Strategies**

We manage our business in three reportable segments: Specialty Brands, Specialty Generics and Global Medical Imaging. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion. Financial information regarding each of our reportable segments, as well as other geographical information, is included in Management's Discussion and Analysis of Financial Condition and Results of Operations, included in Exhibit 99.2 to this Form 8-K, and in Note 20 of Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K.

### **Specialty Brands**

Our Specialty Brands segment markets branded pharmaceutical and biopharmaceutical drugs for pain management and autoimmune and rare diseases (including in the areas of neurology, rheumatology, nephrology and pulmonology). In fiscal 2014, our Specialty Brands segment accounted for 16.6% of net sales from our operating segments. We expect this segment will represent a larger percentage of our net sales in fiscal 2015 and beyond.

We started our Brands product portfolio in 2001 and shifted our focus to pain management with the 2010 launch of EXALGO® (hydromorphone HCl) extended-release tablets (CII) ("Exalgo"). Our exclusivity period for Exalgo expired and generic competition entered the market beginning in May 2014. In fiscal 2014, we significantly expanded our Brands product portfolio, with the March 2014 acquisition of Ofirmev and August 2014 acquisition of Acthar. Also in March 2014, the FDA approved our New Drug Application ("NDA") for XARTEMIS™ XR (oxycodone HCl and acetaminophen) extended-release tablets (CII) ("Xartemis XR"), which we launched shortly thereafter. Our development pipeline includes MNK-155, a hydrocodone combination product, which was accepted for review by the FDA in May 2014. Our long-term strategy is to increase patient access and utilization of our existing products, advance pipeline products and bring them to market, develop new and follow-on formulations for recently acquired products and selectively acquire or license products that are strategically aligned with our product portfolio to expand the size and profitability of our Brands business.

We promote our branded products directly to physicians in their offices, hospitals and ambulatory surgical centers (including pain specialists, anesthesiologists, pulmonologists, autoimmune specialists and primary care physicians) with our own direct sales force of over 400 sales representatives as of September 26, 2014. Our products are purchased by wholesale drug distributors, specialty pharmaceutical distributors and retail pharmacy chains, among others, and are eventually dispensed by prescription to patients. We also market our branded products directly to managed care organizations to gain access to drug formularies and allow patients access to these medications.

The following is a description of select products in our Brands product portfolio:

- *Acthar* is an injectable biopharmaceutical drug approved by the FDA for use in 19 indications. The product currently generates substantially all of its net sales from nine of the on-label indications including the treatment of proteinuria in nephrotic syndrome of the idiopathic type ("NS"); the treatment of acute exacerbations of multiple sclerosis ("MS") in adults; the treatment of infantile spasms ("IS"), in infants and children under two years of age; and the treatment of certain rheumatology related conditions, including the treatment of the rare and closely related neuromuscular disorders, dermatomyositis and polymyositis. We may initiate commercial efforts for other on-label indications where there is high unmet medical need. The currently approved indications of Acthar are not subject to patent or other exclusivity, with the exception of IS which was granted orphan drug status from the FDA upon its approval in October 2010.
- *Ofirmev* is a proprietary intravenous formulation of acetaminophen indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. This product is marketed to hospitals and ambulatory surgical centers and provides us with an expanded presence in these channels. Ofirmev is protected by two Orange Book-listed patents that expire in August 2017 and June 2021 and we have the potential to obtain an additional six months of exclusivity for each patent if the FDA grants pediatric exclusivity. Settlement agreements have been reached in association with certain challenges to these patents, which allow for generic competitors to Ofirmev in December 2020, or earlier under certain circumstances.
- *Xartemis XR* is the first and only extended-release oral combination of oxycodone and acetaminophen. Xartemis XR is approved for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. In February 2014, we were granted a patent from the USPTO, which contains composition claims directed to unique design, formulation, pharmacokinetic and release characteristics of Xartemis XR. Xartemis XR received FDA approval and was launched in March 2014.
- *Exalgo*, which was acquired in June 2009, is the only branded long-acting, once-daily form of hydromorphone in the U.S. market. In August 2012, the FDA approved a 32 mg tablet of Exalgo, which further expanded the patient population that Exalgo can effectively treat with a single daily dose. The 8 mg, 12 mg and 16 mg dosages of Exalgo were approved by the FDA in March 2010 for the treatment of chronic pain in opioid-tolerant patients requiring continuous around-the-clock opioid analgesia for an extended amount of time, and have shown significant prescription growth since launch in April 2010. Our exclusivity period for Exalgo has expired and generic competition entered the market beginning in May 2014. In anticipation of this loss of exclusivity, we launched a generic form of Exalgo in May 2014. We expect sales of Exalgo, across both the branded and authorized generic product, to decrease in fiscal 2015 compared with net sales in fiscal 2014.

### Specialty Generics

Our Specialty Generics segment markets drugs that include a variety of product formulations containing hydrocodone, oxycodone and several other controlled substances. We have a pipeline of controlled substance products either in development or awaiting approval from the FDA. Our API business provides bulk API products, including opioids and acetaminophen, to a wide variety of pharmaceutical companies, many of which are direct competitors of our Brands and Generics businesses. In addition, we use our API for internal manufacturing of our finished dosage products. In fiscal 2014, our Specialty Generics segment accounted for 48.1% of net sales from our operating segments.

We market our API products to other pharmaceutical companies around the world, many of which are competitors of our Brands and Generics businesses. Additionally, we use our API for internal manufacturing of our finished dosage products. We are among the largest manufacturers of bulk acetaminophen in the world and the only producer of acetaminophen outside of Asia. We manufacture controlled substances under DEA quota restrictions and in calendar 2013 we believe we received approximately 26% of the total DEA quota provided to the U.S. market for the controlled substances we manufacture. We believe that our strong market position in the API business and allocation of opioid raw materials from the DEA is a competitive advantage for our API business and, in turn, for our Generics and Brands businesses. The strategy for our API business is based on manufacturing large volumes of high-quality product and customized product offerings, responsive technical services and timely delivery to our customers.

We believe our Generics and API businesses represent the broadest product line of opioid and other controlled substances (primarily DEA Schedules II and III) currently available from a single manufacturer. Our Generics and API businesses have a strong position in the controlled substance generics market with products, including hydrocodone, hydrocodone-containing tablets, oxycodone and oxycodone-containing tablets, all of which are significant products in the overall pain products industry, as well as other controlled substance products. Historically, our primary competition has been other U.S. participants due to importation restrictions on controlled substance API and finished products. Our commitment to investment in our R&D infrastructure and capabilities has resulted in a pipeline of generic controlled substances, many of which are long-acting or hard to formulate products, which are under development or pending approval by the FDA.

We market our generic products principally through drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, food store chains with pharmacies, pharmaceutical benefit managers that have mail order pharmacies and hospital buying groups.

The following is a list of significant products and product families in our Generics and API product portfolio:

- hydrocodone (API) and hydrocodone-containing tablets;
- oxycodone (API) and oxycodone-containing tablets;
- methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER") and;
- other controlled substances, including acetaminophen (API) products.

On November 12, 2014, the Company was informed by the FDA that they believe that the Company's Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug. As a result, on November 13, 2014, the FDA reclassified Methylphenidate ER from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX). The FDA has indicated that it has not identified any serious safety concerns with the products. The FDA indicated that its reclassification is attributable to concerns that the products may not produce the same therapeutic benefits for some patients as the reference listed drug. The FDA further indicated that Company's Methylphenidate ER product is still approved and can be prescribed. The FDA has requested that within six months, the Company demonstrate the bioequivalence of its products using the draft guidance for revised bioequivalence standards issued by the FDA on November 6, 2014 or voluntarily withdraw our products from the market. The Company expects that the FDA's action to reclassify our Methylphenidate ER products will significantly impact net sales and operating income unless the FDA revises its decision.

## **Global Medical Imaging**

Our Global Medical Imaging segment develops, manufactures and markets products in two areas: CMDS, used in CT and MRI imaging, and Nuclear Imaging, which provides radiopharmaceuticals used in single photon emission computed tomography ("SPECT") imaging for myocardial perfusion cardiac imaging and bone scans. In fiscal 2014, our Global Medical Imaging segment accounted for 35.3% of net sales from our operating segments. We are focused on driving operating efficiencies in the Global Medical Imaging segment to maximize operating margins and cash flow.

## ***Contrast Media and Delivery Systems***

Our contrast media include the brands Optiray for CT and Optimark™ for MRI, which are packaged in pre-filled syringes, vials and bottles. Our delivery systems include power injectors to allow delivery of contrast media into the patient, coordination of the timing of the injection with the CT or MRI scanner and delivery of the contrast media at a specific rate and volume. Our CMDS product strategy is based on differentiating our Optiray and Optimark brands with pre-filled syringes as opposed to vials or bulk containers that must be transferred to a syringe for injection. Pre-filled syringes offer a safer alternative to self-filled doses and offer risk reduction benefits that address The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) and U.S. Pharmacopeia <797> guidelines. In addition, our pre-filled syringes are color coded and pre-labeled for easier medication management. Our delivery systems are marketed under the brand Optivantage™ Dual-Head ("Optivantage DH") for CT, Optistar™ for MRI and Illumena™ for cardiac catheterization laboratories. All of our injectors can accept both pre-filled syringes and our disposable syringes for use with saline and contrast media. We sell our CMDS products primarily to hospitals and imaging centers through group purchasing organizations ("GPOs").

The following are significant products in our CMDS product portfolio:

- *Optiray* (ioversol injection) is a low osmolar, lower viscosity and non-ionic organically bound solution of iodine with a broad range of indications in CT imaging procedures, including peripheral and coronary arteriography, angiography and venography. Optiray is available in a Radio Frequency Identification ("RFID")-enabled Ultraject pre-filled syringe that, when combined with a RFID-enabled Optivantage DH CT Contrast Delivery System (a medical device used to synchronize the injection of contrast media with the CT scanner), provides a safer and more efficient method of delivering contrast media. Sales of our Optiray product represent 11%, 14% and 17% of our total net sales in fiscal 2014, 2013 and 2012, respectively. Optiray has been on the market for over 25 years. The high capital intensity in manufacturing API for Optiray products and our significant scale have contributed to the longevity of this product.
- *Optimark* (gadoversetamide injection) is a non-ionic extracellular Gadolinium-Based Contrast Agent ("GBCA") indicated for use with MRI in patients where abnormal vascularity of the brain or liver is suspected. It is the only GBCA approved by the FDA for administration by power injector and is available in pre-filled syringes to help reduce medication errors and improve patient safety.

### ***Nuclear Imaging***

Our Nuclear Imaging business manufactures radioactive isotopes for the diagnosis and treatment of disease. Our nuclear radiopharmaceutical product offering includes both "hot" radioisotopes (primarily Tc-99m, used in approximately 80% of nuclear medicine imaging procedures) and "cold" kits (tagging agents that are paired with "hot" radioisotopes for diagnostic procedures). We have significant expertise in managing the highly regulated radioactive materials used to manufacture the isotope generators and in dealing with products (isotopes) with an extremely short half-life, which precludes stockpiling and requires exacting execution along all aspects of the supply chain. We believe that our investment in Tc-99m generators in North America and Europe, our own Mo-99 processing facility in The Netherlands and a very well-coordinated logistics network provides us with a competitive advantage. Our strategy for our Nuclear Imaging business is focused on bolstering the Tc-99m/Mo-99 supply chain through supplier diversification and driving efficiencies to maximize operating margins and cash flow. We have entered into agreements to obtain Mo-99 from the Maria nuclear research reactor in Poland, the High Flux Reactor in the Netherlands and the BR2 reactor in Belgium, and are also able to purchase finished Mo-99 from other suppliers in the marketplace, with whom we do not have long-term supply agreements. Going forward, we will continue to seek further diversification of our supplier base.

In 2004, the U.S. National Security Administration established its Global Threat Initiative to, as quickly as possible, identify, secure and remove or facilitate the disposition of vulnerable, high-risk nuclear and radiological materials around the world. Included as one of the stated initiatives is the conversion by research reactors and isotope production facilities to us of low enriched uranium ("LEU") from highly enriched uranium ("HEU"). We currently use HEU targets for the production of Mo-99, but ultimately intend to eliminate the use of HEU in favor of using LEU and have begun the process of converting our Mo-99 production operation in the Netherlands to LEU targets. For a discussion of how Mo-99 is used in our business, refer to "Raw Materials" within Exhibit and Item 1A. Risk Factors and "Forward-Looking Statements" included within the Annual Report on Form 10-K for the fiscal year ended September 26, 2014, which was filed on November 24, 2014. We primarily market our nuclear radiopharmaceutical products to nuclear radiopharmacies in the U.S. and to hospitals in Europe.

The following are significant products in our Nuclear Imaging product portfolio:

- *Ultra-Technekow DTE* is a dry-ship, top eluting Tc-99m radioisotope generator that provides an on-site isotope source of Tc-99m solution that is combined by a nuclear pharmacist with various "cold" kit targeting agents to prepare an individualized radiopharmaceutical dose. The prepared Tc-99m radiopharmaceutical is used in procedures using SPECT. SPECT radiopharmaceutical scans account for approximately 80% of all radiopharmaceutical scans and are used in a number of applications, including myocardial perfusion imaging and bone scans. Tc-99m is a decay product of Mo-99, the parent isotope contained in the Tc-99m generator. We are one of only a limited number of manufacturers of Tc-99m generators in North America and Europe, and the only one on either continent that has its own Mo-99 processing facility, which provides cost and raw material supply advantages.
- *Octreoscan*<sup>™</sup> (kit for the preparation of indium In-111 pentetreotide) is a unique molecular imaging agent used for the localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors. The product was approved by the FDA in June 1994 and is sold primarily in the U.S. and Europe. There are three Orange Book-listed patents for the drug product and usage in detection of neuroendocrine tumors. The last patent expires in September 2017.

## **Industry Overview and Trends**

We believe our businesses are well positioned in attractive markets based on a global broadening of access to healthcare, increased demand for pharmaceutical products from emerging markets and the medical industry's continued focus on diagnostic imaging for the early diagnosis of diseases.

We expect that the specialty pharmaceuticals market in the U.S. will likely grow in the low-to-mid single digits in the near-term. With respect to branded drugs, most disease areas are addressed by products of a small group of companies that can create extensions of existing brands. Pain management represents the largest therapeutic prescription market in the U.S., with pain medications accounting for approximately one out of every ten dispensed prescriptions. Pain management is a time-tested therapeutic area, and pain products have been available on the U.S. market since the 1920s.

We believe our experience in satisfying the regulatory requirements relating to raw materials for nuclear radiopharmaceuticals provides competitive advantages versus other potential competitors. Currently, nuclear imaging tends to be concentrated in developed markets due to its high capital-intensity requirements. However, there are opportunities for growth in emerging markets as governments build out their healthcare infrastructure.

## **Competition**

### ***Specialty Brands and Specialty Generics***

Our pharmaceuticals products compete with products manufactured by many other companies in highly competitive markets, primarily throughout the U.S. Our competitors vary depending upon therapeutic and product categories. Major competitors of our pharmaceuticals products include Actavis, Inc., Endo Health Solutions Inc., Johnson & Johnson (including its Noramco, Inc. subsidiary), Johnson Matthey plc, Mylan Inc., Pfizer Inc., Purdue Pharma L.P. and Teva Pharmaceutical Industries Ltd., among others. Acthar, a biopharmaceutical product, has limited direct competition due to the unique nature of the product; however, it generally is prescribed by physicians when alternative treatments have not yielded favorable outcomes for patients. Our secure sources of raw opioid material, vertically integrated manufacturing capabilities, broad offerings of API controlled substances and acetaminophen, comprehensive generic controlled substance product line and established relationships with retail pharmacies enable us to compete effectively with larger generics manufacturers. In addition, we believe that our experience with the FDA, DEA and Risk Evaluation and Mitigation Strategies ("REMS") provides us the knowledge to successfully operate in this highly competitive and highly regulated environment.

The competitive landscape in the acquisition and in-licensing of pharmaceutical products has intensified in recent years, reflecting both a reduction in the number of compounds available and an increase in the number of companies and the collective resources bidding on available assets. The ability to effectively compete in product development, acquisitions and in-licensing is important to our long-term growth strategy. In addition to product development and acquisitions, other competitive factors in the pharmaceutical industry include product efficacy, safety, ease of use, price, demonstrated cost-effectiveness, third-party reimbursement, marketing effectiveness, customer service, reliability of supply, reputation and access to technical information.

The highly competitive environment of our Specialty Brands segment requires us to continually seek out new products to treat diseases and conditions in areas of high unmet medical needs, create technological innovations and to market our products effectively. Most new products that we introduce must compete with other products already on the market, as well as other products that are later developed by competitors. For our branded products, we may be granted market exclusivity either through the FDA, the U.S. Patent Office or similar agencies internationally. Regulatory exclusivity is granted by the FDA for new innovations, such as new clinical data, a new chemical entity or orphan drugs, and patents are issued for inventions, such as composition of matter or method of use. While patents offer a longer period of exclusivity, there are more bases to challenge patent-conferred exclusivity than with regulatory exclusivity. Once market exclusivity expires on our branded products, competition will likely intensify as generic forms of the product are launched. Products which do not benefit from regulatory or patent exclusivity must rely on other competitive advantages, such as confidentiality agreements or product formulation trade secrets for difficult to replicate products.

Manufacturers of generic pharmaceuticals typically invest far less in R&D than research-based pharmaceutical companies, allowing generic versions to typically be significantly less expensive than the related branded products. The generic form of a drug may also enjoy a preferred position relative to the branded version under third-party reimbursement programs, or be routinely dispensed in substitution for the branded form by pharmacies. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions, decreased sales volume or both. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our branded products offer not only superior health outcomes but also cost advantages, as compared with other forms of care. Certain of our branded products are specialized pharmaceuticals or biopharmaceuticals, for example Acthar, that may not be prescribed unless a clear benefit in efficacy or safety is demonstrated or until lower-cost alternatives have failed to provide positive patient outcomes or are not well tolerated by the patient.

In our Specialty Generics segment, we face intense competition from other generic drug manufacturers, brand-name pharmaceutical companies marketing authorized generics, existing branded equivalents and manufacturers of therapeutically similar drugs. The competition varies depending on the specific product category and dosage strength, and we believe that our competitive advantages include our ability to introduce new generic versions of brand-name drug products, our formulation expertise and drug delivery technology, our access to controlled substance API, our quality and cost-effective production, our customer service and the breadth of our generic product line. Among the large generic controlled substance providers, we are the only generic manufacturer that has its own controlled substance API manufacturing capability, and we believe the vertical integration and production of our own API confers certain competitive advantages that might not be available to other pharmaceutical companies. New drugs and future developments in improved or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to products we market. The maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and timely launch new generic products, to manufacture such new products in a cost efficient, high-quality manner and implement and maintain pricing actions.

As a result of consolidation among wholesale distributors and rapid growth of large retail drug store chains, a small number of large wholesale distributors and retail drug store chains control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. This has resulted in customers gaining more purchasing power. Consequently, there is heightened competition among generic drug producers for the business of this smaller and more selective customer base.

In our API business, we believe that our competitive advantages include our manufacturing capabilities in controlled substances that enable high-speed, high-volume tableting, packaging and distribution. Additionally, we believe we offer customers reliability of supply and broad-based technical customer service.

### ***Global Medical Imaging***

In Global Medical Imaging, we compete primarily on the ability of our products to capture market share. While we believe that the number of procedures using contrast media will grow in emerging markets, due in part to increasing access to healthcare, we expect that our ability to effectively compete with other providers of contrast media will be impacted by ongoing pricing pressures. We believe that our key product characteristics, such as proven efficacy, reliability and safety, coupled with our core competencies such as our efficient manufacturing processes and established distribution network, are important factors that may distinguish us from our competitors.

The market for imaging agents is highly competitive. Major competitors in our Global Medical Imaging segment include, among others:

- for contrast imaging agents: GE Healthcare, a division of General Electric Company, Bracco Imaging S.p.A., Bayer AG and Guerbet Group;
- for delivery systems: Nemoto & Co, Ltd.;
- for CMDS: Bayer AG and Bracco Imaging S.p.A.;
- for radiopharmaceutical generators sold in the U.S.: Lantheus Medical Imaging, Inc.;
- for radiopharmaceutical generators sold in Europe: GE Healthcare, IBA Group, and POLATOM; and
- for radiopharmaceutical SPECT "cold" kits: Lantheus Medical Imaging, Inc., GE Healthcare, Bracco Imaging S.p.A. and IBA Group.

Unlike some of our competition, we offer a full line of CMDS and radiopharmaceutical products. Our broad product portfolio allows us to be a complete source for most imaging agent needs.

Our current or future products could be rendered obsolete or uneconomical as a result of the competition described above and the factors described in "Intellectual Property" included within this Exhibit, as well as any of the risk factors described in Item 1A. Risk Factors and "Forward-Looking Statements" included within the Annual Report on Form 10-K for the fiscal year ended September 26, 2014, which was filed on November 24, 2014. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

## **Intellectual Property**

We own or license a number of patents in the U.S. and other countries covering certain products and have also developed brand names and trademarks for other products. Generally, our Specialty Brands segment relies upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks and license rights to be of material value and act to protect these rights from infringement. However, our business is not materially dependent upon any single patent, trademark or license or any group of patents, trademarks or licenses.

The majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the branded pharmaceutical industry, an innovator product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovator is entitled. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there often are very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have some market viability based upon the goodwill of the product name, which typically benefits from trademark protection or is based on the difficulties associated with replicating the product formulation or bioavailability. Acthar is not subject to patent or other exclusivity, with the exception of IS which was granted orphan drug status from the FDA upon its approval in October 2010. Acthar's commercial durability therefore relies partially upon product formulation trade secrets, confidentiality agreements and trademark and copyright laws. These items may not prevent our competitors from independently developing similar technology or duplicating our product.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the product. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms, and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Many developed countries provide certain non-patent incentives for the development of pharmaceuticals. For example, the U.S., European Union ("E.U.") and Japan each provide for a minimum period of time after the approval of certain new drugs during which the regulatory agency may not rely upon the innovator's data to approve a competitor's generic copy. Regulatory exclusivity is also available in certain markets as incentives for research on new indications, orphan drugs (drugs that demonstrate promise for the diagnosis or treatment of rare diseases or conditions) and medicines that may be useful in treating pediatric patients. Regulatory exclusivity is independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory exclusivity on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of our branded products because of the complex interaction between patent and regulatory forms of exclusivity, the relative success or lack thereof by potential competitors' experience in product development and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registrations of such trademarks are for fixed terms and subject to renewal as provided by the laws of the particular country.

## Research and Development

We devote significant resources to the research and development of products and proprietary drug delivery technologies. We incurred R&D expenses of \$166.9 million, \$165.7 million and \$144.1 million in fiscal 2014, 2013 and 2012, respectively. We expect to continue to invest in R&D activities, as well as enter into license agreements and business development opportunities to supplement our internal R&D initiatives. We intend to focus our R&D investments in the specialty pharmaceuticals area, specifically investments to support our Specialty Brands segment, where we believe there is the greatest opportunity for growth and profitability.

*Specialty Brands.* We devote significant R&D resources for our branded products. A number of our branded products are protected by patents and have enjoyed market exclusivity. Our R&D strategy focuses on the development of extended-release opioid products with abuse deterrent properties and expanding the opportunities for existing products by documenting and publishing clinical experience and evidence that support health economic and patient outcomes. MNK-155 has completed Phase III clinical trials and our NDA filing was accepted for review by the FDA in May 2014. We have received notice of allowance from the USPTO related to composition claims directed to unique design, formulation, pharmacokinetic and release characteristics for MNK-155.

In accordance with a Pediatric Research Equity Act requirement included in the NDA approval for Ofirmev, Cadence began enrolling patients in 2012 in a post-marketing efficacy study of Ofirmev in infants and neonates. The data from this study will be used to satisfy a formal written request Cadence received from the FDA under Section 505A of the U.S. Food, Drug and Cosmetic Act that was made as part of the approval process for Ofirmev. The FDA has agreed to an August 2015 due date for completion of this study. Upon timely completion and the acceptance by the FDA of the data from this study, Ofirmev may be eligible for an additional six months of marketing exclusivity in the U.S. The FDA is also currently reviewing a supplemental NDA that Cadence submitted in December 2013, which would enable us to offer Ofirmev in flexible intravenous bags.

*Specialty Generics.* In regard to specialty generic product development, we are focused on controlled substances with difficult-to-replicate pharmacokinetic profiles. As of September 26, 2014, we had various ANDAs on file with the FDA. In addition, we are focused on process improvements to increase yields and reduce costs.

*Global Medical Imaging.* Our R&D efforts in our Global Medical Imaging segment are focused on driving efficiency and regulatory compliance throughout CMDS and Nuclear Imaging.

## Regulatory Matters

### Quality Assurance Requirements

The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging and holding of drugs and medical devices conform to current good manufacturing practice ("cGMP"). The cGMP regulations that the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, and are designed to ensure that the finished products meet all the required identity, strength, quality and purity characteristics. The cGMP regulations for devices, called the Quality System Regulations, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the U.S. Federal Food, Drug and Cosmetic Act ("the FDCA"). Other regulatory authorities have their own cGMP rules. Ensuring compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packaging, testing and holding of the drugs subject to NDAs and ANDAs. If the FDA concludes that the facilities to be used do not or did not meet cGMP, good laboratory practice ("GLP") or good clinical practice ("GCP") requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and API used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The FDA also conducts periodic inspections of drug and device facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could materially adversely affect our business, results of operations, financial condition and cash flows. Additionally, imported API and other components needed to manufacture products could be rejected by U.S. Customs and Border Protection, usually after conferring with the FDA. In the case of domestic facilities, the FDA could initiate product seizures or, in some instances, require product recalls and seek to enjoin a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an "unacceptable supplier," thereby disqualifying that company from selling products to federal agencies.

### **United States**

In general, drug manufacturers operate in a highly regulated environment. In the U.S., we must comply with laws, regulations, guidance documents and standards promulgated by the FDA, the Department of Health and Human Services ("DHHS"), the DEA, the Environmental Protection Agency ("EPA"), the NRC, the Customs Service and state boards of pharmacy.

The FDA's authority to regulate the safety and efficacy of pharmaceuticals comes from the FDCA. In addition to reviewing NDAs, for branded drugs, and ANDAs, for generic drugs, the FDA has the authority to ensure that pharmaceutical products introduced into interstate commerce are neither "adulterated" nor "misbranded." Adulterated means that the product may cause or has caused injury to patients when used as intended because it fails to comply with cGMP. Misbranded means that the labels of, or promotional materials for, the product contain false or misleading information. Failure to comply with applicable FDA and other federal and state regulations could result in product recalls or seizures, partial or complete suspension of manufacturing or distribution, refusal to approve pending NDAs or ANDAs, monetary fines, civil penalties or criminal prosecution.

In order to market and sell a new prescription drug product in the U.S., a drug manufacturer must file with the FDA a NDA that shows the safety and effectiveness of (a) a new chemical entity that serves as the API, known as a 505(b)(1) NDA; or (b) a product that has significant differences from an already approved one, known as a 505(b)(2) NDA. Alternatively, in order to market and sell a generic version of an already approved drug product, a drug manufacturer must file an ANDA that shows that the generic version is "therapeutically equivalent," or behaves almost the same when taken by a patient to the branded drug product and, therefore, is substitutable.

For all pharmaceuticals sold in the U.S., the FDA also regulates sales and marketing to ensure that drug product claims made by manufacturers are neither false nor misleading. Manufacturers are required to file copies of all product-specific promotional materials to the FDA's Office of Prescription Drug Promotion prior to their first use. In general, such advertising does not require FDA prior approval. Failure to implement a robust internal company review process and comply with FDA regulations regarding advertising and promotion increases the risk of enforcement action by either the FDA or the U.S. Department of Justice.

For both NDAs and ANDAs, the manufacture, marketing and selling of certain drug products may be limited by quota grants for controlled substances by the DEA. Refer to "Drug Enforcement Administration" within this Exhibit for further information.

*NDA Process.* The path leading to FDA approval of a NDA for a new chemical entity begins when the drug product is merely a chemical formulation in the laboratory. In general, the process involves the following steps:

- Completion of formulation, laboratory and animal testing in accordance with GLP that fully characterizes the drug product from a pre-clinical perspective and provides preliminary evidence that the drug product is safe to test in human beings;
- Filing with the FDA an Investigational New Drug Application that will permit the conduct of clinical trials (testing in human beings under adequate and well-controlled conditions);
- Designing and conducting clinical trials to show the safety and efficacy of the drug product in accordance with GCP;
- Submitting the NDA for FDA review, which provides a complete characterization of the drug product;
- Satisfactory completion of FDA pre-approval inspections regarding the conduct of the clinical trials and the manufacturing processes at the designated facility in accordance with cGMP;

- If applicable, satisfactory completion of a FDA Advisory Committee meeting in which the Agency requests help from outside experts in evaluating the NDA;
- Final FDA approval of the full prescribing information, labeling and packaging of the drug product; and
- Ongoing monitoring and reporting of adverse events related to the drug product, implementation of a REMS program, if applicable, and conduct of any required Phase IV studies.
- Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:
  - Phase I trials are typically small (less than 100 healthy volunteers) and are designed to determine the toxicity and maximum safe dose of the drug product.
  - Phase II trials usually involve 100 to 300 participants and are designed to determine whether the drug product produces any clinically significant effects in patients with the intended disease or condition. If the results of these trials show promise, then a larger Phase III trial may be conducted.
  - Phase III trials are often multi-institution studies that involve a large number of participants and are designed to show efficacy. Phase III (and some Phase II) trials are designed to be pivotal, or confirmatory trials. The goal of a pivotal trial is to establish the safety and efficacy of a drug product by eliminating biases and increasing statistical power.
- In some cases, the FDA requires Phase IV trials, which are usually performed after the NDA has been approved. Such post-marketing surveillance is intended to obtain more information about the risks of harm, benefits and optimal use of the drug product by observing the results of the drug product in a large number of patients.

A drug manufacturer may conduct clinical trials either in the U.S. or outside the U.S., but in all cases must comply with GCP, which includes (a) a legally effective informed consent process when enrolling participants; (b) an independent review by an Institutional Review Board to minimize and manage the risks of harm to participants; and (c) ongoing monitoring and reporting of adverse events related to the drug product.

In addition, a drug manufacturer may decide to conduct a clinical trial of a drug product on pediatric patients in order to obtain a form of marketing exclusivity as permitted under the Best Pharmaceuticals for Children Act ("BPCA"). Alternatively, the FDA may require a drug manufacturer, using its authority under the Pediatric Research Equity Act, to conduct a pediatric clinical trial. The goal of conducting pediatric clinical trials is to gather data on how drug products should best be administered to this patient population.

The path leading to FDA approval of a NDA for a drug product that has significant differences from an already approved one is somewhat shorter. The FDA requires a drug manufacturer to submit data from either already published reports or newly conducted studies that show the safety and efficacy of those differences. Significant differences include different dosage strengths or route of administration.

Under the U.S. Prescription Drug User Fee Act, the FDA has the authority to collect fees from drug manufacturers who submit NDAs for review and approval. These user fees help the FDA fund the drug approval process. For fiscal 2015, the user fee rate has been set at \$2,335,200 for a 505(b)(1) NDA and \$1,167,600 for a NDA not requiring a complete clinical data package, generally a 505(b)(2) NDA. We expense these fees as they are incurred. The average review time for a NDA is approximately six months for priority review and ten months for standard review.

*ANDA Process.* The path leading to FDA approval of an ANDA is much different from that of a NDA. By statute, the FDA waives the requirement for a drug manufacturer to complete pre-clinical studies and clinical trials and instead focuses on data from bioequivalence studies. Bioequivalence studies generally involve comparing the absorption rate and concentration levels of a generic drug in the human body to that of the branded drug or Reference Listed Drug ("RLD"). In the event that the generic drug behaves in the same manner in the human body as the RLD, the two drug products are considered bioequivalent. The FDA considers a generic drug therapeutically equivalent, and therefore substitutable, if it also contains the same active ingredients, dosage form, route of administration and strength.

In 2010, U.S. Congress passed into law the Generic Drug User Fee Act to address the FDA's backlog, which at the time was over 2,000 ANDAs. This legislation granted the FDA authority to collect, for the first time, user fees from generic drug manufacturers who submit ANDAs for review and approval, and the fees collected will help the FDA fund the drug approval process. For fiscal 2015, the user fee rate is set at \$58,730 for an ANDA and \$29,370 for a prior approval supplement to an ANDA. These fees are expensed as incurred. In August 2013, it was reported that the average review time for an ANDA was about 35 months. The FDA anticipates that the approval process timeframe will begin to improve in fiscal 2015 with a target of approving 60% of ANDA submissions within 15 months of submission.

Aside from the backlog described above, the timing of FDA approval of ANDAs depends on other factors, including whether an ANDA holder has challenged any listed patents to the RLD and whether the RLD is entitled to one or more periods of marketing exclusivity under the FFDCA (such as pediatric exclusivity under the BPCA). In general, the FDA will not approve (but will continue to review) an ANDA in which the RLD holder has sued, within 45 days of receiving notice of the ANDA filing, the ANDA holder for patent infringement until either the litigation has been resolved or 30 months has elapsed, whichever is later.

*Patent and Non-Patent Exclusivity Periods.* A sponsor of a NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files a Section 505(b)(2) NDA, the type of NDA that relies upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of a previous drug, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless the generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the RLD of the bases upon which the patents are challenged, and the holder of the RLD does not sue the later applicant for patent infringement within 45 days of receipt of notice. If an infringement suit is filed, the FDA may not approve the later application until the earliest of: (a) 30 months after receipt of the notice by the holder of the NDA for the RLD; (b) entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; (c) such time as the court may order; or (d) the expiration of the patent.

One of the key motivators for challenging patents is the 180-day market exclusivity period ("generic exclusivity") granted to the developer of a generic version of a product that is the first to make a Paragraph IV certification and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s) or is not sued. For a variety of reasons, there are situations in which a company may not be able to take advantage of an award of generic exclusivity. The determination of when generic exclusivity begins and ends is very complicated.

The holder of the NDA for the RLD may also be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b)(2) NDA product. Generally, if the RLD is a new chemical entity, the FDA may not accept for filing any application that references the innovator's NDA for five years from the approval of the innovator's NDA. However, this five-year period is shortened to four years where a filer's ANDA includes a Paragraph IV certification. In other cases, where the innovator has provided certain clinical study information, the FDA may accept for filing, but may not approve, an application that references the innovator's NDA for a period of three years from the approval of the innovator's NDA.

Certain additional periods of exclusivity may be available if the RLD is indicated for use in a rare disease or condition or is studied for pediatric indications.

*Risk Evaluation and Mitigation Strategies ("REMS").* For certain drug products or classes, such as transmucosal immediate-release fentanyl products and extended-release and long-acting opioids, the FDA has the authority to require the manufacturer to provide a REMS that is intended to ensure that the benefits of a drug product (or class of drug products) outweigh the risks of harm. The FDA may require that a REMS include elements to ensure safe use to mitigate a specific serious risk of harm, such as requiring that prescriber have particular training or experience or that the drug product is dispensed in certain healthcare settings. The FDA has the authority to impose civil penalties on or take other enforcement action against any drug manufacturer who fails to properly implement an approved REMS program. Separately, a drug manufacturer cannot use an approved REMS program to delay generic competition.

In December 2011, the FDA approved a single, class-wide REMS program for transmucosal immediate-release fentanyl ("TIRF") products (called "the TIRF REMS Access Program") in order to ease the burden on the healthcare system. TIRF products are opioids used to manage pain in adults with cancer who routinely take other opioid pain medicines around-the-clock. We were part of the original industry working group that collaborated to develop and implement the TIRF REMS Access Program. The goals of this program are to ensure patient access to important medications and mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by: (a) prescribing and dispensing only to appropriate patients, including use only in opioid-tolerant patients; (b) preventing inappropriate conversion between fentanyl products; (c) preventing accidental exposure to children and others for whom such products were not prescribed; and (d) educating prescribers, pharmacists and patients on the potential for misuse, abuse, addiction and overdose. This program started in March 2012 and requires manufacturers, distributors, prescribers, dispensers and patients to enroll in a real-time database that maintains a closed-distribution system.

In February 2009, the FDA requested that drug manufacturers help develop a single, shared REMS for extended-release and long-acting opioid products that contain fentanyl, hydromorphone, methadone, morphine, oxycodone and oxymorphone. In April 2009, the FDA announced that the "REMS would be intended to ensure that the benefits of these drugs continue to outweigh the risks associated with: (1) use of high doses of long-acting opioids and extended-release opioid products in non-opioid-tolerant and inappropriately selected individuals; (2) abuse; (3) misuse; and (4) overdose, both accidental and intentional." We were part of the original industry working group that collaborated to develop and implement this REMS program. In July 2012, the FDA approved a class-wide REMS program (called "the Extended-Release and Long-Acting Opioid Analgesics REMS") that affected more than 30 extended-release and long-acting opioid analgesics (both branded and generic products). This REMS program requires drug manufacturers to make available training on appropriate prescribing practices for healthcare professionals who prescribe these opioid analgesics and to distribute educational materials on their safe use to prescribers and patients.

We are committed to responsible prescribing, dispensing, use and storage of opioid analgesics to avoid misuse, abuse, addiction, diversion and overdose. In 2010, we started the Collaborating & Acting Responsibly to Ensure Safety Alliance ("the C.A.R.E.S. Alliance"), which offers free non-branded tools and materials to patients, pharmacists and physicians to foster the safe use of opioid pain medications. The C.A.R.E.S. Alliance sponsors drug take back programs among other initiatives. We also founded and provided the regulatory framework for Risk Evaluation and Mitigation Strategies - An Employer-Driven Continuing Medical Education Initiative for Efficacy and Safety ("REMEDIES"). The purpose of the REMEDIES initiative is to train prescribers on evidence-based approaches to optimize the evaluation, treatment and management of chronic pain. In addition to educational efforts, we work closely with our major distributors to monitor suspicious controlled substance orders and take active steps to limit potential diversion.

*Drug Enforcement Administration.* The DEA is the federal agency responsible for domestic enforcement of the Controlled Substances Act of 1970 ("CSA"). The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Opioids, such as oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are either Schedule II or III controlled substances. Consequently, the manufacture, storage, distribution and sale of these substances are highly regulated.

The DEA regulates the availability of API, products under development and marketed drug products that are Schedule II or III by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our commercial and R&D needs. To date in calendar 2014, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. During calendar 2012, the initial hydrocodone manufacturing and procurement quota grants we received from the DEA were below the amounts requested and were therefore insufficient to meet customer demand. While we were granted additional quota, these shortfalls did result in lost sales of hydrocodone products, the amount of which was not significant. Future delay or refusal by the DEA to grant, in whole or in part, our quota requests could delay or result in stopping the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials.

In October 2013, the FDA announced its recommendation that the DEA reschedule hydrocodone combination products (such as Vicodin® (registered trademark of AbbVie Inc.) and our developmental product MNK-155) from Schedule III to Schedule II, thereby increasing regulatory controls on these drug products. On August 22, 2014, the DEA issued its final rule to reschedule hydrocodone combination products from Schedule III to Schedule II, which was effective on October 6, 2014. In accordance with the final rule, we have discontinued sales of Schedule III labeled products and launched Schedule II labeled products. The effects of the rescheduling resulted in increased returns of Schedule III labeled product, which did not have a material impact to our financial condition, results of operations and cash flows.

DEA regulations make it extremely difficult for a manufacturer in the U.S. to import finished dosage forms of controlled substances manufactured outside the U.S. These rules reflect a broader enforcement approach by the DEA to regulate the manufacture, distribution and dispensing of legally produced controlled substances. Accordingly, drug manufacturers who market and sell finished dosage forms of controlled substances in the U.S. typically manufacture or have them manufactured in the U.S.

The DEA also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring ("SOM") system includes well-defined due diligence, "know your customer" efforts and order monitoring.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. The facilities must have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action that could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also regulate controlled substances, and we, as well as our third-party API suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of these products.

We and, to our knowledge, our third-party API suppliers, dosage form manufacturers, distributors and researchers have all necessary registrations, and we believe all registrants operate in conformity with applicable registration requirements, under controlled substance laws.

*Government Benefit Programs.* Statutory and regulatory requirements for Medicaid, Medicare, Tricare and other government healthcare programs govern provider reimbursement levels, including requiring that all pharmaceutical companies pay rebates to individual states based on a percentage of their net sales arising from Medicaid program-reimbursed products. The federal and state governments may continue to enact measures in the future aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. We cannot predict the nature of such measures, which could have material adverse consequences for the pharmaceutical industry as a whole and, consequently, also for us. However, we believe we have provided for our best estimate of potential refunds based on current information available.

From time to time, legislative changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 created a new prescription drug coverage program for people with Medicare through a new system of private market drug benefit plans. This law provides a prescription drug benefit to seniors and individuals with disabilities in the Medicare program ("Medicare Part D"). Congress continues to examine various Medicare policy proposals that may result in pressure on the prices of prescription drugs in the Medicare program.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, "the Healthcare Reform Act") provided for major changes to the U.S. healthcare system, which impacted the delivery and payment for healthcare services in the U.S. Several provisions of the Healthcare Reform Act have already taken effect, including the elimination of lifetime caps and no rescission of policies or denial of coverage due to preexisting conditions, improving patients' ability to obtain and maintain health insurance. While significant components of the Healthcare Reform Act have been implemented, various other aspects are ongoing and there may still be challenges and uncertainties ahead. Such a comprehensive reform measure requires expanded implementation efforts on the part of federal and state agencies embarking on rule-making to develop the specific components of their new authority. We continue to closely monitor the implementation of the Healthcare Reform Act and related legislative and regulatory developments. To date our business has been most notably impacted by changes in the Medicare Part D coverage gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers and increased rebates in the Medicaid Fee-For-Service Program and Medicaid Managed Care plans. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator average manufacturers' price for new formulations and the expansion of 340B pricing to new entities.

### ***Healthcare Fraud and Abuse Laws***

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the U.S., there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations, including the U.S. Anti-Kickback Statute and similar state statutes, the False Claims Act and the Health Insurance Portability and Accountability Act of 1996. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws apply to hospitals, physicians and other potential purchasers of our products and are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs. In addition, some states in the U.S. have enacted compliance and reporting requirements aimed at drug manufacturers.

We are also subject to the Foreign Corrupt Practices Act of 1977 and similar worldwide anti-bribery laws in non-U.S. jurisdictions, such as the United Kingdom ("U.K.") Bribery Act of 2010, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents.

### ***Compliance Programs***

In order to systematically and comprehensively mitigate the risks of non-compliance with regulatory requirements described within this Exhibit. Business, we have developed what we believe to be a robust compliance program based on the April 2003 Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, the U.S. Federal Sentencing Guidelines, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, the Code of Ethics of the Advanced Medical Technology Association, the U.K. Anti-Bribery guidance, and other relevant guidance from government and national or regional industry codes of behavior. We conduct ongoing compliance training programs for all employees and maintain a 24-hour ethics and compliance reporting hotline with a strict policy of non-retaliation. We further demonstrated our commitment to our compliance programs by the addition of a Chief Compliance Officer that reports directly to the Chief Executive Officer and the Compliance Committee of our Board of Directors. The Compliance function is an independent of the manufacturing and commercial operations functions and is responsible for implementing our compliance programs.

As part of our compliance program, we have implemented internal cross-functional processes to review and approve product-specific promotional materials, presentations and external communications to address the risk of misbranding or mislabeling our products through our promotional efforts. For example, we have established programs to monitor promotional speaker activities and field sales representatives, which includes a "ride along" program for field sales representatives similar to those included in recent Corporate Integrity Agreements from the OIG in order to obtain first-hand observations of how these approved materials are used, as well as monitoring of sales representative expenses. We have also implemented a comprehensive controlled substances compliance program, including anti-diversion efforts that go beyond the DEA's SOM requirements and we regularly assist federal, state and local law enforcement and prosecutors in the U.S. by providing information and testimony on our products and placebos for use by the DEA and other law enforcement agencies in investigations and at trial. As part of this program, we also work with some of our customers to help develop and implement what we believe are best practices for SOM and other anti-diversion activities.

We believe our compliance program design also addresses our FDA, healthcare anti-kickback and anti-fraud, and anti-bribery-related risks. We believe we have complied with reporting obligations of the U.S. Federal Physician Payment Sunshine Act and relevant state disclosure laws and have implemented a program across the Company to track and report data per Centers for Medicare & Medicaid Services ("CMS") guidance and state disclosure requirements.

### ***Outside the United States***

Outside the U.S., we must comply with laws, guidelines and standards promulgated by other regulatory authorities that regulate the development, testing, manufacturing, marketing and selling of pharmaceuticals, including, but not limited to, Health Canada, the Medicines and Healthcare Products Regulatory Agency in the U.K., the Irish Medicines Board, the European Medicines Agency and member states of the E.U., the State Food and Drug Administration in China, the Therapeutic Goods Administration in Australia, the New Zealand Medicines and Medical Devices Safety Authority, the Ministry of Health and Welfare in Japan, the European Pharmacopoeia of the Council of Europe and the International Conference on Harmonization. Although international harmonization efforts continue, many laws, guidelines and standards differ by region or country.

We currently market our products in Canada, in various countries in the E.U., and in the Latin American, Middle Eastern, African and Asia-Pacific regions. The approval requirements and process vary by country, and the time required to obtain marketing authorization may vary from that required for FDA approval. Certain drug products and variations in drug product lines also must meet country-specific and other local regulatory requirements. The following discussion highlights some of the differences in the approval process in other regions or countries outside the U.S.

*European Union.* Marketing authorizations are obtained either pursuant to a centralized or decentralized procedure. The centralized procedure, which provides for a single marketing authorization valid for all E.U. member states, is mandatory for the approval of certain drug products and is optional for novel drug products that are in the interest of patient health. Under the centralized procedure, a single marketing authorization application is submitted for review to the European Medicines Agency, which makes a recommendation on the application to the European Commission, who determines whether or not to approve the application. The decentralized procedure provides for concurrent mutual recognition of national approval decisions, and is available for products that are not subject to the centralized procedure.

The E.U. has also adopted directives and other laws that govern the labeling, marketing, advertising, supply, distribution and drug safety monitoring and reporting of drug products. Such directives set regulatory standards throughout the E.U. and permit member states to supplement such standards with additional requirements.

European governments also regulate drug prices through the control of national healthcare systems that fund a large part of such costs to patients. Many regulate the pricing of a new drug product at launch through direct price controls or reference pricing and, recently, some have also imposed additional cost-containment measures on drug products. Such differences in national pricing regimes may create price differentials between E.U. member states. Many European governments also advocate generic substitution by requiring or permitting prescribers or pharmacists to substitute a different company's generic version of a brand drug product that was prescribed, and patients are unlikely to take a drug product that is not reimbursed by their government.

*Emerging Markets.* Many emerging markets continue to evolve their regulatory review and oversight processes. At present, such countries typically require prior regulatory approval or marketing authorization from large, developed markets (such as the U.S.) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorization. Many emerging markets continue to implement measures to control drug product prices, such as implementing direct price controls or advocating the prescribing and use of generic drugs.

## **Environmental**

Our operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, we are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations. We cannot provide assurance that we have been or will be in full compliance with environmental, health and safety laws and regulations at all times. Certain environmental laws assess strict (i.e., can be imposed regardless of fault) and joint and several liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. We have, from time to time, received notification from the EPA and from state environmental agencies in the U.S. that conditions at a number of sites where the disposal of hazardous substances requires investigation, cleanup and other possible remedial actions. These agencies may require that we reimburse the government for costs incurred at these sites or otherwise pay for the cost of investigation and cleanup of these sites including compensation for damage to natural resources. We have projects underway at a number of current and former manufacturing facilities to investigate and remediate environmental contamination resulting from past operations, as further described in Note 18 to Notes to Consolidated and Combined Financial Statements included within Exhibit 99.1 to this Form 8-K.

Environmental laws are complex, change frequently and generally have become more stringent over time. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations, and have planned for future capital and operating expenditures to comply with these laws and to address liabilities arising from past or future releases of, or exposures to, hazardous substances. However, we cannot provide assurance that our costs of complying with current or future environmental protection, health and safety laws and regulations will not exceed our estimates or have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Further, we cannot provide assurance that we will not be subject to additional environmental claims for personal injury or cleanup in the future based on our past, present or future business activities. While it is not feasible to predict the outcome of all pending environmental matters, it is reasonably possible that there will be a need for future provisions for environmental costs that, in management's opinion, are not likely to have a material adverse effect on our financial condition, but could be material to the results of operations in any one accounting period.

Certain radiological licenses at certain manufacturing sites owned by us require the establishment of decommissioning programs which will require remediation in accordance with regulatory requirements upon cessation of operations at these sites.

## **Raw Materials**

We contract with various third-party manufacturers and suppliers to provide us with raw materials used in our products, finished goods and certain services. If, for any reason, we are unable to obtain sufficient quantities of any of the raw materials or components required for our products, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The active ingredients in the majority of our current pharmaceutical products and products in development, including oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are listed by the DEA as Schedule II or III substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation and the DEA limits both the availability of these active ingredients and the production of these products. As discussed in "Regulatory Matters" within this Exhibit, we must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. The DEA has complete discretion to adjust these quotas from time to time during the calendar year and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or to conduct bioequivalence studies and clinical trials. Any delay or refusal by the DEA in granting, in whole or in part, our quota requests for controlled substances could delay or result in the stoppage of the manufacture of our pharmaceutical products, our clinical trials or product launches and could require us to allocate product among our customers.

Our radiopharmaceutical product offering includes "hot" radioisotopes including Mo-99, a critical ingredient of our Ultra-Technekow DTE Tc-99m generators. Mo-99 is produced in nuclear research reactors utilizing HEU or LEU targets. These targets, either tubular or flat and of varying sizes, are fabricated from HEU or LEU and, in either case, aluminum. The targets are placed in or near the core of the nuclear reactor where fission reactions occur resulting in the production of Mo-99 and other isotopes. This process, which takes approximately six days, is known as target irradiation. There are currently eight reactors around the world producing the global supply of Mo-99. We have agreements to obtain Mo-99 from three of these reactors and we rely predominantly on two of these reactors for our Mo-99 supply. These reactors are subject to scheduled and unscheduled shutdowns which can have a significant impact on the amount of Mo-99 available for processing. Mo-99 produced at these reactors is then finished at one of five processing sites located throughout the world, including our processing facility located in the Netherlands. At the processing facility, the targets are dissolved and chemically separated. In this process, the Mo-99 is isolated as a radiochemical. We transport finished Mo-99 from our processing facility in the Netherlands to our facility in Maryland Heights, Missouri, where it, together with Mo-99 received from other third-party processors, is loaded into our Tc-99m generators. Mo-99 has a 66 hour half-life and degrades into, among other things, Tc-99m, which has a half-life of only six hours. The radiopharmacies or hospitals prepare dosages from the Tc-99m generators for use in SPECT imaging medical procedures.

In November 2012, the High Flux Reactor ("HFR") in the Netherlands, one of two primary reactors we utilize, experienced an unscheduled shutdown. We were able to receive increased target irradiations from the two other reactors and purchased additional Mo-99 from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The HFR resumed production in June 2013.

In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in the Netherlands also experienced a shutdown. We received increased target irradiations from other reactors, purchased additional Mo-99 from other sources and outsourced Mo-99 processing to continue meeting customer orders; however, the additional Mo-99 and processing services we procured from alternative sources came at a higher than normal cost. The HFR resumed production of medical isotopes and irradiation of materials in February 2014 and the Mo-99 processing facility resumed production in April 2014. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

## **Sales, Marketing and Customers**

### ***Sales and Marketing***

We market our branded, generic and CMDS products to physicians, pharmacists, pharmacy buyers, specialty pharmacies, radiologists and radiology technicians. We distribute these products to major drug wholesalers, retail pharmacy chains, specialty pharmaceutical distributors, hospital networks, ambulatory surgical centers and governmental agencies. In addition, we contract with GPOs and managed care organizations to improve access to our products. We sell and distribute API directly or through distributors to other pharmaceutical companies. In the U.S., we market and distribute our nuclear imaging products to radiopharmacies which, in turn, supply hospitals and standalone imaging centers with patient-customized doses. Outside the U.S., we market and distribute our nuclear imaging products to hospitals.

We often negotiate with parties that enter into supply contracts for the benefit of their member facilities, including GPOs, integrated delivery networks, large and medium size retail pharmacy chains, nuclear pharmacy chains, wholesalers and, solely outside the U.S., with governments through a tender process. In September 2014, we were notified by Premier U.S., Inc. ("Premier"), that we were no longer a preferred supplier of CMDS products after a 19 year relationship. While individual members of the Premier GPO may purchase our products, we expect the loss of preferred supplier status to negatively impact net sales for CMDS products.

For further information on our sales and marketing strategies, refer to "Our Businesses and Product Strategies" included within this Exhibit.

## Customers

Net sales to distributors that accounted for more than 10% of our total net sales in fiscal 2014, 2013 and 2012 were as follows:

	Fiscal Year		
	2014	2013	2012
Cardinal Health, Inc.	18%	18%	19%
McKesson Corporation	17%	15%	14%
Amerisource Bergen Corporation	11%	9%	9%

No other customer accounted for 10% or more of our net sales in the past three fiscal years. CuraScript Specialty Distributor distributes Acthar and is expected to account for more than 10% of our total net sales in fiscal 2015.

## Manufacturing and Distribution

We presently have eleven manufacturing sites, including seven located in the U.S., as well as sites in Canada, Ireland and the Netherlands, which handle production, assembly, quality assurance testing, packaging and sterilization of our products. We estimate that our manufacturing production by region in fiscal 2014 (as measured by cost of production) was as follows:

U.S.	78%
Europe	13%
Canada	9%

We maintain distribution centers in 18 countries. In addition, in certain countries outside the U.S. we utilize third-party distribution centers. Products generally are delivered to these distribution centers from our manufacturing facilities and then subsequently delivered to the customer. In some instances, product, such as nuclear medicine, is delivered directly from our manufacturing facility to the customer. We contract with a wide range of transport providers to deliver our products by road, rail, sea and air.

We utilize contract manufacturing organizations ("CMOs") to manufacture certain of our finished goods that are available for resale. We most frequently utilize CMOs in the manufacture of our Brands products, including Acthar (for finish and filling of the product), Ofirmev and Xartemis XR.

## Backlog

At September 26, 2014, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of September 26, 2014 will be shipped during fiscal 2015.

## Seasonality

We have historically experienced fluctuations in our business resulting from seasonality. DEA quotas for raw materials and final dosage products are allocated in each calendar year to companies and may impact our sales until the DEA grants additional quotas, if any. Impacts from quota limitations are most commonly experienced during the third and fourth calendar quarters, which represent our fourth and first fiscal quarters, respectively. As a result, net sales of DEA controlled products have historically been higher during the second and third fiscal quarters as compared with the first and fourth fiscal quarters. Acthar has experienced lower net sales during the first calendar quarter, our second fiscal quarter, which we believe is partially attributable to certain medical conditions being exacerbated by warm temperatures and effects of annual insurance deductibles. Lastly, we have experienced lower operating cash flows during our first fiscal quarter as we pay annual employee compensation and have experienced lower net sales in DEA controlled products. While we have experienced these fluctuations in the past, they may not be indicative of what we will experience in the future.

## Employees

At September 26, 2014, we had approximately 5,500 employees, approximately 4,100 of which are based in the U.S. Certain of these employees are represented by unions or work councils. We believe that we generally have a good relationship with our employees, and with the unions and work councils that represent certain employees.

## Executive Officers

Set forth below are the names, ages as of November 1, 2014, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	53	President, Chief Executive Officer and Director
Matthew Harbaugh	44	Senior Vice President and Chief Financial Officer
Peter Edwards	53	Senior Vice President and General Counsel
Meredith Fischer	61	Senior Vice President, Communications and Public Affairs
Raymond Furey	46	Senior Vice President and Chief Compliance Officer
Sandra Hatten	57	Senior Vice President, Quality and Regulatory Compliance
Hugh O'Neill	51	Senior Vice President and President of Specialty Pharmaceuticals
Gary Phillips	48	Senior Vice President and President of Autoimmune and Rare Diseases
Mario Saltarelli	54	Senior Vice President and Chief Science Officer
Frank Scholz	45	Senior Vice President, Global Operations
Ian Watkins	52	Senior Vice President and Chief Human Resources Officer

Set forth below is a brief description of the position and business experience of each of our executive officers.

*Mark Trudeau* is our President and Chief Executive Officer, and also serves on our board of directors. In anticipation of the Separation, Mr. Trudeau joined Covidien in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. He joined Covidien from Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer. He simultaneously served as President of Bayer HealthCare Pharmaceuticals, the U.S. organization of Bayer's global pharmaceuticals business. In addition, he served as Interim President of the global specialty medicine business unit from January to August 2010. Prior to joining Bayer in 2009, Mr. Trudeau headed the Immunoscience Division at Bristol-Myers Squibb. During his 10-plus years at Bristol-Myers Squibb, he served in multiple senior roles, including President of the Asia/Pacific region, President and General Manager of Canada and General Manager/Managing Director in the United Kingdom. Mr. Trudeau was also with Abbott Laboratories, serving in a variety of executive positions, from 1988 to 1998. Mr. Trudeau holds a Bachelor's degree in chemical engineering and a M.B.A., both from the University of Michigan.

*Matthew Harbaugh* is our Senior Vice President and Chief Financial Officer. Mr. Harbaugh previously served as Vice President, Finance of Covidien's Pharmaceuticals business, a position he had held from July 2008 until June 2013, when Mallinckrodt became an independent public company. He also served as Interim President of Covidien's Pharmaceuticals business from November 2010 to January 2012. Mr. Harbaugh joined Covidien's Pharmaceuticals business in August 2007 as its Vice President and Controller, Global Finance for the Global Medical Imaging business. Mr. Harbaugh was a Lead Finance Executive with Cerberus Capital Management, L.P. from April 2007 until August 2007. Mr. Harbaugh worked for Monsanto from 1997 to 2007 serving in senior U.S. roles in treasury, investor relations, financial planning and analysis and strategy, in addition to two international assignments in Canada and Argentina.

*Peter Edwards* is our Senior Vice President and General Counsel. Mr. Edwards served as Vice President and General Counsel of Covidien's Pharmaceuticals business from May 2010 until June 2013, when Mallinckrodt became an independent public company. Mr. Edwards previously served as Executive Vice President and General Counsel for the Solvay Group in Brussels, Belgium from June 2007 until April 2010 and previous to that, held positions of increasing responsibility with Eli Lilly and Company.

*Meredith Fischer* is our Senior Vice President, Communications and Public Affairs. In anticipation of our spin transaction with Covidien plc Ms. Fischer joined Covidien in February 2013 as Vice President, Communications and Public Affairs for its Pharmaceuticals business. Ms. Fischer was employed by Bayer Corporation from 2001 until February 2013, where she served as Vice President of Communications and Public Policy for Bayer HealthCare and Bayer HealthCare Pharmaceuticals, North America. In that role, Ms. Fischer supported Bayer HealthCare's U.S. pharmaceutical and animal health divisions and the company's global medical care and consumer care businesses. She was also Vice President of Marketing and Communications at Pitney Bowes, where she was responsible for product marketing, sales communications and the establishment of professional best practices.

*Raymond Furey* is our Senior Vice President and Chief Compliance Officer, a role he assumed in August 2014. Previously, Mr. Furey served Questcor Pharmaceuticals, Inc. as Chief Compliance Officer since October 2011 and as its Senior Vice President since May 23, 2013. Mr. Furey has over 20 years of experience in the pharmaceutical industry. Prior to joining Questcor, Mr. Furey served as the Corporate Compliance Officer for OSI Pharmaceuticals and prior to OSI, he served 17 years in various capacities for Genentech, including healthcare compliance, commercial operations, finance, regulatory compliance and manufacturing.

*Sandra Hatten* is our Senior Vice President, Quality. Ms. Hatten joined Covidien's Pharmaceuticals business in October 2010 as its Director of Quality and in 2011, became a Senior Director of Quality-API Operations. In September 2012 she was appointed interim Vice President of Quality and became Vice President of Quality in February 2013. She was promoted to her current position in February 2014. Ms. Hatten was Vice President of Quality Assurance for KV Pharmaceuticals from August 2007 until August 2010. She was Director of Site Quality and Compliance for Catalent Pharmaceutical Solutions from March 2006 until August 2007. Previously, Ms. Hatten served as Director of Quality from December 2000 to March 2006 for Perrigo Company plc. Ms. Hatten has more than 30 years of experience in the pharmaceutical industry.

*Hugh O'Neill* is our Senior Vice President and President of U.S. Specialty Pharmaceuticals. Prior to joining Mallinckrodt in September 2013, Mr. O'Neill worked at Sanofi-Aventis for ten years where he held various commercial leadership positions including Vice President of Commercial Excellence from June 2012 to July 2013, General Manager, President of Sanofi-Aventis Canada from June 2009 to May 2012, and Vice President Market Access and Business Development from 2006 to 2009. Mr. O'Neill joined Sanofi in 2003 as its Vice President, United States Managed Markets. Mr. O'Neill previously served in a variety of positions of increasing responsibility for Sandoz Pharmaceuticals, Forest Laboratories, Novartis Pharmaceuticals and Pfizer.

*Gary Phillips, M.D.* is our Senior Vice President and President of our Autoimmune and Rare Disease business. Dr. Phillips joined Mallinckrodt in October 2013 and served as Senior Vice President and Chief Strategy Officer until he was appointed to his current position in August 2014. Before joining Mallinckrodt, Dr. Phillips served as head of Global Health and Healthcare Industries for the World Economic Forum in Geneva, Switzerland from January 2012 to September 2013. Previously, Dr. Phillips served as President of Reckitt Benckiser Pharmaceuticals North America from 2011 to 2012, as Head, Portfolio Strategy, Business Intelligence and Innovation at Merck Serono from 2008 to 2011, and as President of US Pharmaceuticals and Surgical and Bausch & Lomb from 2002 to 2008. Dr. Phillips has also held positions of leadership at Novartis Pharmaceuticals, Wyeth-Ayerst and Gensia Pharmaceuticals.

*Mario Saltarelli, M.D., Ph.D.* is our Senior Vice President and Chief Science Officer. Prior to joining Mallinckrodt in October 2013, Dr. Saltarelli served as Senior Vice President, R&D for Shire plc since September 2012 and as its Senior Vice President Clinical Development and Medical Affairs from January 2011 to September 2012. From 2004 to 2011, Dr. Saltarelli served as Divisional Vice President of Abbott Laboratories. From 1997 to 2004, he held positions of increasing responsibility at Pfizer, and, prior to that, academic posts in the Department of Neurology at the Emory University School of Medicine in Atlanta.

*Frank Scholz* is our Senior Vice President of Global Operations. He joined Mallinckrodt in March 2014. His responsibilities include global manufacturing operations, procurement and supply chain, in addition to leading the global operations transformation. Prior to joining Mallinckrodt, Dr. Scholz was a partner with McKinsey & Co, a global management consulting firm first in its Hamburg, Germany office and then in its Chicago, Illinois office. Dr. Scholz was a leader in McKinsey's global pharmaceutical and operations practices. He joined McKinsey in 1997. Prior to joining McKinsey, Dr. Scholz was a research assistant at the Institute for Management and Accounting at the University of Hanover, Germany.

*Ian Watkins* is our Senior Vice President and Chief Human Resources Officer. Mr. Watkins joined Covidien's Pharmaceuticals business in September 2012 as the Chief Human Resources Officer. Mr. Watkins served as Vice President, Global Human Resources at Synthes, Inc. from June 2007 to September 2012, which was recently acquired by Johnson & Johnson. Mr. Watkins served as Senior Vice President, Human Resources from 2003 to 2006 for Andrx Corporation, which is now part of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.).

#### **Available Information**

Our website address is [www.mallinckrodt.com](http://www.mallinckrodt.com). We are not including the information contained on our website as part of, or incorporating it by reference into, this filing. We make available to the public on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after such material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission ("SEC"). Our reports filed with, or furnished to, the SEC may be read and copied at the SEC's Public Reference Room at 100 F Street, N.E. Washington, DC 20549. Investors may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. These filings are also available on the SEC's website at [www.sec.gov](http://www.sec.gov).