

Mallinckrodt plc Reports Strong Fourth Quarter and 2019 Results

February 25, 2020

- Fourth quarter net sales of \$804.9 million and 2019 net sales of \$3.163 billion, with strong performance across hospital products and the Specialty Generics segment, offset by declines in Acthar® Gel
- Diluted loss per share of \$13.76 in the fourth quarter and \$11.88 in fiscal 2019; adjusted diluted earnings per share (EPS) of \$2.40 in the fourth quarter and \$8.88 in fiscal 2019
- Fourth quarter operating cash flow of \$208.8 million and free cash flow of \$184.5 million; fiscal 2019 operating cash flow of \$742.9 million and free cash flow of \$609.9 million
- Principal debt reduced by \$733.9 million in fiscal 2019, with net debt reduced by \$1.176 billion, reflecting strong cash-generation,
 debt repurchased at a discount and the debt exchange offer completed in the fourth quarter
- As separately announced today, reached an agreement in principle for a global settlement with a broad-based group of plaintiffs that would resolve all opioid-related claims against the company and its subsidiaries, and taking actions to address near-term maturities to strengthen capital structure

STAINES-UPON-THAMES, United Kingdom, Feb. 25, 2020 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, today reported results for the three months and fiscal year ended Dec. 27, 2019. Unless otherwise noted, the three months and fiscal year comparisons are to the prior year comparable period ended Dec. 28, 2018.

Net sales were \$804.9 million in the quarter with diluted loss per share of \$13.76, primarily driven by \$1.643 billion in expense associated with the agreement in principle pertaining to a global opioid resolution, partially offset by a \$377.4 million gain on debt extinguishment. Adjusted diluted EPS was \$2.40 versus \$2.18, an increase of 10.1%

"We are pleased with the operating strength of the business as we finished 2019," said **Mark Trudeau, President and Chief Executive Officer of Mallinckrodt**. "Our hospital products had an exceptional fourth quarter, as we anticipated, and the Specialty Generics segment finished the year strong, marking its fourth consecutive quarter of growth. Acthar[®] Gel performed largely in line with our expectations given a challenging payer environment. We remain focused on executing our long-term strategy for this product by generating clinically meaningful data and exploring opportunities to drive greater access for patients. At the same time, we continue to advance our pipeline, including preparing for approval submissions for terlipressin and StrataGraft[®] in the coming months."

Trudeau continued, "Over the past year, it has been one of our top priorities to remove three uncertainties impacting our business - opioid litigation, near-term debt maturities and the Acthar CMS¹ matter. We are pleased that we now have what we believe to be a clear path forward for resolving two of those: reaching an agreement in principle on the terms of a comprehensive global opioid resolution, and taking steps to strengthen our capital structure by addressing near term maturities. While managing these uncertainties, we remain focused on achieving our long-term vision of becoming an innovation-driven biopharmaceutical company focused on improving outcomes for underserved patients with severe and critical conditions."

COMPANY FINANCIAL RESULTS

Fourth Quarter 2019 Results

Gross profit was \$373.1 million with gross profit as a percentage of net sales of 46.4%, compared with 43.5%, driven by inventory step-up expense in the prior period and product mix. Adjusted gross profit was \$575.9 million, compared with \$608.0 million, with adjusted gross profit as a percentage of net sales of 71.5%, compared with 72.8%, driven primarily by product mix.

Selling, general and administrative (SG&A) expenses were \$169.2 million or 21.0% of net sales, as compared to \$239.6 million, or 28.7%, driven primarily by legal settlement expenses in the prior period and the change in the fair value of contingent consideration. Adjusted SG&A expenses were \$191.6 million or 23.8% of net sales, compared with \$212.2 million or 25.4%. Adjusted SG&A expenses decreased due to ongoing focused efforts on SG&A reductions.

Research and development expenses were \$81.4 million or 10.1% of net sales, as compared to \$100.4 million or 12.0%, due to the completion of certain development programs.

As a result of the agreement in principle for a global opioid resolution, the company recorded a \$1.643 billion expense attributed to the anticipated structured cash payments under the settlement agreement and the anticipated warrants to purchase ordinary shares at \$3.15 per share representing approximately 19.99% of the company's fully diluted outstanding shares, including after giving effect to the exercise of the warrants.

The company recorded \$274.5 million in non-recurring impairments in the quarter, related to its VTS-270 in-process research and development intangible asset; as compared to \$3.891 billion in the prior year, which was primarily attributed to the goodwill impairment.

Interest expense was \$77.2 million as compared to \$90.1 million, a reduction of 14.3%, driven by our continued focus on deleveraging.

Income tax benefit was \$327.7 million, for an effective tax rate of 22.0%. The adjusted effective tax rate was 15.5%.

Fiscal Year 2019 Results

Net sales were \$3.163 billion, compared with \$3.216 billion. The decrease was primarily attributed to Acthar[®] Gel (repository corticotropin injection), partially offset by strength in the hospital products, AMITIZA[®] (lubiprostone) and the Specialty Generics segment.

On a GAAP² basis, net loss was \$996.5 million, compared with \$3.607 billion, with diluted loss per share of \$11.88 compared to \$42.94, both periods impacted by significant one-time items with the opioid agreement in principle liability in 2019 and the goodwill impairment in 2018.

Adjusted net income was \$747.5 million, compared with \$682.2 million. Adjusted diluted EPS was \$8.88 compared with \$8.01, an increase of 10.9%.

BUSINESS SEGMENT RESULTS

Specialty Brands Segment

Net sales for the segment in the fourth quarter 2019 were \$611.4 million.

- Acthar[®] Gel net sales were \$232.6 million, a 17.8% decrease, primarily driven by continued reimbursement challenges impacting new
 and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending.
- INOMAX® (nitric oxide) gas, for inhalation net sales were \$143.8 million, an increase of 3.7%, or 3.8% on a constant-currency basis, driven by strong customer demand for INOmax, partially offset by increased competition in the market.
- OFIRMEV[®] (acetaminophen) injection net sales were \$111.8 million, an increase of 28.2%, primarily due to significant quarter-to-quarter order variability that is expected to continue until loss of exclusivity.
- Therakos[®] immunology platform net sales were \$63.3 million, an increase of 11.1%, or 11.3% on a constant-currency basis, primarily due
 to the capture of new patients, and the conversion to the Cellex device.
- AMITIZA net sales were \$50.9 million, down 21.2% due to lower royalties in the U.S. due to an increasingly competitive landscape.

Specialty Generics Segment

The segment reported fourth quarter net sales in 2019 of \$193.5 million, an increase of 6.0%.

LIQUIDITY

Cash provided by operating activities in the fourth quarter was \$208.8 million, with free cash flow of \$184.5 million. For the year, operating cash flow was \$742.9 million and free cash flow \$609.9 million.

The cash balance at the end of the year was \$790.9 million, and the revolving credit facility was fully drawn. During the fourth quarter, the company executed a debt exchange offer, which reduced total debt by \$383.2 million. With this exchange offer, cash generated from operations, and debt repurchased at a discount earlier in the year, the company reduced net debt by \$1.176 billion in 2019, and ended the year with net debt of \$4.632 billion.

In conjunction with announcing the agreement in principle for a global opioid resolution, the company also announced that it has entered into certain agreements relating to potential financing and debt exchange transactions, which if implemented, will address near-term debt maturities of the company.

CONFERENCE CALL AND WEBCAST

Mallinckrodt will hold a conference call today at 8:30 a.m. U.S. Eastern Time. This call can be accessed in three ways:

- At the Mallinckrodt website: http://www.mallinckrodt.com/investors.
- By telephone: For both listen-only participants and those who wish to take part in the question-and-answer portion of the call, the telephone dial-in number in the U.S. is (877) 359-9508. For participants outside the U.S., the dial-in number is (224) 357-2393. Callers will need to provide the Conference ID of 4168459.
- Through an audio replay: A replay of the call will be available beginning at 11:30 a.m. Eastern Time on Tuesday, Feb. 25, 2020, and ending at 11:30 a.m. Eastern Time on Tuesday, March 10, 2020. Dial-in numbers for U.S.-based participants are (855) 859-2056 or (800) 585-8367. Participants outside the U.S. should use the replay dial-in number of (404) 537-3406. All callers will be required to provide the Conference ID of 4168459.

ABOUT MALLINCKRODT

Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

NON-GAAP FINANCIAL MEASURES

This press release contains financial measures, including adjusted net income, adjusted diluted earnings per share, adjusted gross profit, adjusted SG&A, net sales growth on a constant-currency basis, adjusted effective tax rate, net debt and free cash flow, which are considered "non-GAAP" financial measures under applicable SEC rules and regulations.

Adjusted net income, adjusted gross profit and adjusted SG&A represent amounts prepared in accordance with accounting principles generally accepted in the U.S. (GAAP) and adjusted for certain items that management believes are not reflective of the operational performance of the business. The adjustments for these items are on a pre-tax basis for adjusted gross profit and adjusted SG&A and on an after-tax basis for adjusted net income. Adjustments to GAAP amounts include, as applicable to each measure, amortization and non-restructuring impairment charges; restructuring and related charges, net; inventory step-up expenses; discontinued operations; changes in fair value of contingent consideration obligations; acquisition-related expenses; significant legal and environmental charges; losses on divestiture; unrealized gain on equity investment; gains on debt extinguishment, net; separation costs; research and development upfront payments; tax effects of aforementioned adjustments, changes in related uncertain tax positions, as well as impacts from certain transactions, such as acquisitions or reorganizations; and other items identified by the company. Adjusted diluted earnings per share represent adjusted net income divided by the number of diluted shares.

The adjusted effective tax rate is calculated as the income tax effects on continuing and discontinued operations plus the income tax impact included in Mallinckrodt's reconciliation of net loss, divided by loss from continuing and income from discontinued operations plus the pre-tax, non-income, tax-related adjustments included in its reconciliation of adjusted net income (excluding dilutive share impact). The income tax adjustment included in the reconciliation of adjusted net income primarily represents the tax impact of adjustments between net loss and adjusted net income, changes in related uncertain tax positions, as well as tax impacts from certain transactions, such as acquisitions or reorganizations.

Net sales growth on a constant-currency basis measures the change in net sales between current- and prior-year periods using a constant currency, the exchange rate in effect during the applicable prior-year period.

Free cash flow for the fourth quarter represents net cash provided by operating activities of \$208.8 million less capital expenditures of \$24.3 million, each as prepared in accordance with GAAP.

Free cash flow for the fiscal year represents net cash provided by operating activities of \$742.9 million less capital expenditures of \$133.0 million, each as prepared in accordance with GAAP.

Net debt as of Dec. 27, 2019 represents the total principal debt outstanding of \$5.423 billion less unrestricted cash of \$790.9 million, each as prepared in accordance with GAAP

Net debt as of Dec. 28, 2018 represents the total principal debt outstanding of \$6.157 billion less unrestricted cash of \$348.9 million, each as prepared in accordance with GAAP.

The company has provided these adjusted financial measures because they are used by management, along with financial measures in accordance with GAAP, to evaluate the company's operating performance. In addition, the company believes that they will be used by certain investors to measure Mallinckrodt's operating results. Management believes that presenting these adjusted measures provides useful information about the company's performance across reporting periods on a consistent basis by excluding items that the company does not believe are indicative of its core operating performance.

These adjusted measures should be considered supplemental to and not a substitute for financial information prepared in accordance with GAAP. The company's definition of these adjusted measures may differ from similarly titled measures used by others.

Because adjusted financial measures exclude the effect of items that will increase or decrease the company's reported results of operations, management strongly encourages investors to review the company's consolidated financial statements and publicly filed reports in their entirety. A reconciliation of certain of these historical adjusted financial measures to the most directly comparable GAAP financial measures is included in the tables accompanying this release.

Further information regarding non-GAAP financial measures can be found on the Investor Relations page of the company's website.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, legal, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's businesses, and any other statements regarding events or developments the company believes or anticipates will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties.

There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: governmental investigations and inquiries, regulatory actions and lawsuits brought against Mallinckrodt by government agencies and private parties with respect to its historical commercialization of opioids, including the non-binding agreement in principle regarding terms and conditions of a global settlement to resolve all current and future opioid-related claims; scrutiny from governments, legislative bodies and enforcement agencies related to sales, marketing and pricing practices; pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs; the reimbursement practices of governmental health administration authorities, private health coverage insurers and other third-party payers; complex reporting and payment obligations under the Medicare and Medicaid rebate programs and other governmental purchasing and rebate programs; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations; changes in or failure to comply with relevant laws and regulations; Mallinckrodt's and its partners' ability to successfully develop or commercialize new products or expand commercial opportunities; Mallinckrodt's ability to navigate price fluctuations; competition; Mallinckrodt's and its partners' ability to protect intellectual property rights; limited clinical trial data for Acthar Gel; clinical studies and related regulatory processes; product liability losses and other litigation liability; material health, safety and environmental liabilities; potential indemnification liabilities to Covidien pursuant to the separation and distribution agreement; business development activities; retention of key personnel; the effectiveness of information technology infrastructure including cybersecurity and data leakage risks; customer concentration; Mallinckrodt's reliance on certain individual products that are material to its financial performance; Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; complex manufacturing processes; conducting business internationally; Mallinckrodt's ability to achieve expected benefits from restructuring activities; Mallinckrodt's significant levels of intangible assets and related impairment testing; labor and employment laws and regulations; natural disasters or other catastrophic events; Mallinckrodt's substantial indebtedness and its ability to generate sufficient cash to reduce its indebtedness; the proposed refinancing of certain near-term debt maturities; future changes to U.S. and foreign tax laws or the impact of disputes with governmental tax authorities; and the impact of Irish laws.

These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended December 27, 2019, which the company expects to file later today. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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- ¹ Centers for Medicare & Medicaid Services
- ² Generally accepted accounting principles in the United States

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		Three Months Ended							
		December 27,	Percen	t of	D	ecember 28,	Percent of		
		2019	Net sal	es		2018	Net sa	les	
Net sales	\$	804.9	100.0	%	\$	834.9	100.0	%	
Cost of sales		431.8	53.6			471.6	56.5		
Gross profit		373.1	46.4			363.3	43.5		
Selling, general and administrative expenses		169.2	21.0			239.6	28.7		
Research and development expenses		81.4	10.1			100.4	12.0		
Restructuring charges, net		(12.9)	(1.6)			1.2	0.1		
Non-restructuring impairment charges		274.5	34.1			3,891.1	466.1		
Losses on divestiture		33.5	4.2			0.2	_		
Opioid-related litigation settlement charge		1,643.4	204.2			_			
Operating loss		(1,816.0)	(225.6)			(3,869.2)	(463.4)		
Interest expense		(77.2)	(9.6)			(90.1)	(10.8)		
Interest income		2.9	0.4			1.6	0.2		
Gain on debt extinguishment, net		377.4	46.9			5.7	0.7		
Other income, net		24.2	3.0			7.4	0.9		
Loss from continuing operations before income taxes		(1,488.7)	(185.0)			(3,944.6)	(472.5)		
Income tax benefit		(327.7)	(40.7)			(226.2)	(27.1)		
Loss from continuing operations		(1,161.0)	(144.2)			(3,718.4)	(445.4)		
Income from discontinued operations, net of income taxes		3.9	0.5			_			
Net loss	\$	(1,157.1)	(143.8)	%	\$	(3,718.4)	(445.4)	%	
Basic (loss) earnings per share:									
Loss from continuing operations	\$	(13.80)			\$	(44.64)			
Income from discontinued operations	Φ	0.05			Φ	(44.04)			
Net loss		(13.76)				(44.64)			
Diluted (loss) earnings per share:		(13.70)				(44.04)			
Loss from continuing operations	\$	(13.80)			\$	(44.64)			
Income from discontinued operations	Ψ	0.05			Ψ	(+4.04)			
Net loss		(13.76)				(44.64)			
Weighted-average number of shares outstanding:		(10.70)				(0-1)			
Basic		84.1				83.3			
Diluted		84.1				83.3			
Bildiod		04.1				00.0			

MALLINCKRODT PLC NON-GAAP MEASURES

(unaudited, in millions except per share data)

					Three Mo	onths Ended							
		Dece	embe	r 27, 2019					Dece	mbe	28, 2018		
	Gross profit	SG&A		Net (loss)	Diluted net (loss) income per share ⁽¹⁾		Gross profit		SG&A		Net (loss)		Diluted net (loss) income per share ⁽¹⁾
GAAP	\$ 373.1	\$ 169.2	\$	(1,157.1)	\$ (13.76)	\$	363.3	\$	239.6	\$	(3,718.4)	\$	(44.64)
Adjustments: Intangible asset				,	, ,						, ,		, ,
amortization Restructuring and related charges,	202.8	(0.8)		203.6	2.42		192.0		(1.7)		193.7		2.28
net ⁽²⁾ Inventory step-up	_	_		(12.9)	(0.15)		_		(0.3)		1.5		0.02
expense Income from discontinued	_	_		_	_		41.3		_		41.3		0.49
operations Change in contingent consideration fair	_	_		(3.9)	(0.05)		_		_		_		_
value Acquisition related	_	36.7		(36.7)	(0.44)		_		16.9		(16.9)		(0.20)
expenses Non-restructuring impairment	_	_		_	_		_		(2.0)		2.0		0.02
charges ⁽³⁾ Significant legal and environmental	_	_		274.5	3.26		_		_		3,891.1		45.83
charges ⁽⁴⁾	_	_		1,643.4	19.52		_		(31.5)		31.5		0.37
Divestitures	_	_		33.5	0.40		_		-		0.2		_
Separation costs	_	(13.5)		13.5	0.16		_		(6.0)		6.0		0.07

Gains on debt								
extinguishment,								
net	_	_	(377.4)	(4	.48) —		(6.2)	(0.07)
Unrealized gain								
on equity								
investment (5)	_	_	(13.7)	(0	.16) —		_	_
Legal entity and								
intercompany								
financing								
organization	_	_	(26.0)	(0	.31) –		(173.7)	(2.05)
U.S. Tax Reform	_	_	_				0.6	0.01
Income taxes (6)	_	_	(338.7)	(4	.02) —		(81.6)	(0.96)
Depreciation								
catch up (7)	_	_	_			(2.8)	13.7	0.16
As adjusted	\$ 575.9	\$ 191.6	\$ 202.1	\$ 2	2.40 \$ 608.0	\$ 212.2	\$ 184.8	\$ 2.18
5	74.5	.,	0/ 07.4	0.4	70.4		00.4	0/
Percent of net sales	71.5	% 23.8	% 25.1	%	72.8	8 % 25.4	% 22.1	%

- (1) In periods where losses from continuing operations are incurred, potential ordinary shares outstanding are excluded from the calculation of diluted earnings per share, prepared in accordance with GAAP, as they would be anti-dilutive. These dilutive shares are included in the calculation of adjusted diluted earnings per share if dilutive to adjusted net income. As a result, the adjusted diluted earnings per share utilized a weighted average share count of 84.2 and 84.9 shares for the three months ended December 27, 2019 and December 28, 2018, respectively.
- (2) Includes pre-tax accelerated depreciation.
- (3) The three months ended December 27, 2019 includes an in-process research and development ("IPR&D") intangible asset impairment of \$274.5 million related to VTS-270. The three months ended December 28, 2018 includes the goodwill impairment of \$3,672.8 million and an IPR&D intangible asset impairment of \$218.3 million related to MNK-1411.
- (4) Includes the opioid-related litigation settlement charge of \$1.643 billion.
- (5) Represents an unrealized gain related to the company's equity investment in Silence Therapeutics plc ("Silence").
- (6) Includes tax effects of above adjustments (unless otherwise separately stated), changes in related uncertain tax positions, as well as certain installment sale transactions and other intercompany transactions.
- (7) During the three months ended December 28, 2018, "the Specialty Generics Disposal Group" was reclassified to held and used after being classified as held-for-sale since February 2018. In accordance with GAAP, depreciation and amortization are not recorded during the period in which a disposal group is classified as held-for-sale. When the disposal group was reclassified to held and used, it was measured at its carrying amount before it was classified as held-for-sale, adjusted for depreciation and amortization expense that would have been recognized had the disposal group been continuously classified as held and used. The effect of the required adjustment has been reflected in loss from continuing operations during the fourth quarter of 2018, the period in which the held-for-sale criteria was no longer met.

This adjustment represents \$17.7 million of depreciation expense, net of tax of \$4.0 million, recorded during the three months ended December 28, 2018 that would have been recognized during the first three quarters of fiscal 2018 had the Specialty Generics Disposal Group been continuously classified as held and used. This will not be reflected in the fiscal 2018 non-GAAP measures table as the catch-up in the three months ended December 28, 2018 results in an accurate depiction of total depreciation expense for fiscal 2018. Consistent with historical periods, intangible asset amortization is a non-GAAP adjustment and is therefore not called out separately as a result in the change in classification of the disposal group.

MALLINCKRODT PLC SEGMENT NET SALES AND CONSTANT-CURRENCY GROWTH

(unaudited, in millions)

Three Months Ended

		Three Wo	ntns E	naea				
	Dec	cember 27, 2019	De	cember 28, 2018	Perc char		Currency impact	Constant- currency growth
Specialty Brands	\$	611.4	\$	652.4	(6.3)	%	— %	(6.3) %
Specialty Generics ⁽¹⁾		193.5		182.5	6.0		_	6.0
Net sales	\$	804.9	\$	834.9	(3.6)		_	(3.6)

(1) Includes net sales from the post-divestiture supply agreement with the acquirer of the contrast media and delivery systems ("CMDS") business.

MALLINCKRODT PLC SELECT PRODUCT LINE NET SALES

(unaudited, in millions)

Three Mon	ths Ended			
	_			Constant-
December 27,	December 28,	Percent	Currency	currency
2019	2018	change	impact	growth

Acthar Gel	\$ 232.6	\$ 283.0	(17.8)	%	— %	(17.8)	%
INOmax	143.8	138.7	3.7		(0.1)	3.8	
Ofirmev	111.8	87.2	28.2		_	28.2	
Therakos	63.3	57.0	11.1		(0.2)	11.3	
Amitiza	50.9	64.6	(21.2)		_	(21.2)	
BioVectra (1)	3.3	17.4	(81.0)		(0.2)	(80.8)	
Other	5.7	 4.5	_ 26.7		(0.4)	27.1	
Specialty Brands Total	\$ 611.4	\$ 652.4	(6.3)	%	— %	(6.3)	%
Specialty Generics							
Hydrocodone (API) and hydrocodone-containing tablets	\$ 25.1	\$ 19.6	28.1	%	— %	28.1	%
Oxycodone (API) and oxycodone-containing tablets (2)	21.6	22.8	(5.3)		_	(5.3)	
Acetaminophen (API) (2)	46.8	43.7	7.1		_	7.1	
Other controlled substances (2)	86.8	85.8	1.2		_	1.2	
Other ⁽²⁾	13.2	 10.6	24.5		_	24.5	
Specialty Generics Total	\$ 193.5	\$ 182.5	6.0	%	— %	6.0	%

⁽¹⁾ In November 2019, the company completed its sale of the BioVectra business.

MALLINCKRODT PLC SEGMENT OPERATING INCOME

(unaudited, in millions)

	Three Months Ended							
	De	ecember 27, 2019		December 28, 2018				
Specialty Brands (1)	\$	310.3	\$	298.7				
Specialty Generics (2)		28.0		(5.4)				
Segment operating income		338.3		293.3				
Unallocated amounts:								
Corporate and allocated expenses (3)		(32.2)		(70.1)				
Intangible asset amortization		(203.6)		(193.7)				
Restructuring and related charges, net (4)		12.9		(1.6)				
Non-restructuring impairments		(274.5)		(3,891.1)				
Separation costs		(13.5)		(6.0)				
Opioid-related litigation settlement charge		(1,643.4)	_	_				
Operating loss	\$	(1,816.0)	\$	(3,869.2)				

⁽¹⁾ The three months ended December 28, 2018 includes \$41.3 million of inventory fair-value step up expense related to Amitiza.

MALLINCKRODT PLC CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, in millions, except per share data)

	Fiscal Year									
	2019	Percent of Net sales	2018	Percent of Net sales						
Net sales	\$ 3,162.5	100.0 %	\$ 3,215.6	100.0 %						
Cost of sales	1,741.1	55.1	1,744.4	54.2						
Gross profit	1,421.4	44.9	1,471.2	45.8						
Selling, general and administrative expenses	831.0	26.3	834.1	25.9						
Research and development expenses	349.4	11.0	361.1	11.2						
Restructuring charges, net	(1.7)	(0.1)	103.0	3.2						
Non-restructuring impairment charges	388.0	12.3	3,893.1	121.1						
Losses on divestiture	33.5	1.1	0.8	_						
Opioid-related litigation settlement charge	1,643.4	52.0								
Operating loss	(1,822.2)	(57.6)	(3,720.9)	(115.7)						
Interest expense	(309.0)	(9.8)	(370.2)	(11.5)						
Interest income	9.5	0.3	8.2	0.3						
Gain on debt extinguishment, net	466.6	14.8	8.5	0.3						
Other income, net	63.6	2.0	22.4	0.7						

⁽²⁾ Prior period amounts have been reclassified to conform to current period presentation.

⁽²⁾ During the fourth quarter of 2018, the Specialty Generics Disposal Group was reclassified to held-and-used and measured at its carrying amount before it was classified as held-for-sale, adjusted for depreciation and amortization expense that would have been recognized had the disposal group been continuously classified as held and used. The total depreciation adjustment of \$17.7 million was reflected in the Specialty Generics segment operating income during the fourth quarter of 2018, the period in which the held-for-sale criteria were no longer met.

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

⁽⁴⁾ Includes restructuring-related accelerated depreciation.

Loss from continuing operations before income taxes Income tax benefit Loss from continuing operations Income from discontinued operations, net of income taxes	(1,591.5) (584.3) (1,007.2) 10.7	(50.3) (18.5) (31.8) 0.3		 (4,052.0) (430.1) (3,621.9) 14.9	(126.0) (13.4) (112.6) 0.5	
Net loss	\$ (996.5)	(31.5)	%	\$ (3,607.0)	(112.2)	%
Basic (loss) earnings per share: Loss from continuing operations Income from discontinued operations Net loss	\$ (12.00) 0.13 (11.88)			\$ (43.12) 0.18 (42.94)		
Diluted (loss) earnings per share: Loss from continuing operations Income from discontinued operations Net loss	\$ (12.00) 0.13 (11.88)			\$ (43.12) 0.18 (42.94)		
Weighted-average number of shares outstanding: Basic Diluted	83.9 83.9			84.0 84.0		

MALLINCKRODT PLC NON-GAAP MEASURES

(unaudited, in millions except per share data)

				Fis	cal Year				
			2019				2018		
	Gross profit	SG&A	Net (loss) income	Diluted net (loss) income per share ⁽¹⁾	Gross profit	SG&A	Net (loss) income	Diluted net (loss income per share ⁽¹⁾	
GAAP	\$ 1,421.4	\$ 831.0	\$ (996.5)	\$ (11.88)	\$ 1,471.2	\$ 834.1	\$ (3,607.0)	\$ (42.94)	
Adjustments: Intangible asset amortization Restructuring and related	847.9	(5.5)	853.4	10.14	733.6	(6.6)	740.2	8.69	
charges, net ⁽²⁾ Inventory step-up	_	_	(1.7)	(0.02)	3.0	(2.2)	108.2	1.27	
expense Income from discontinued	10.0	_	10.0	0.12	120.8	_	120.8	1.42	
operations Change in contingent consideration fair	_	_	(10.7)	(0.13)	_	_	(14.9)	(0.17)	
value Acquisition	_	60.2	(60.2)	(0.71)	_	50.2	(50.2)	(0.59)	
related expenses Non-restructuring impairment	_	_	_	_	_	(5.8)	5.8	0.07	
charges ⁽³⁾ Significant legal and environmental	_	_	388.0	4.61	_	_	3,893.1	45.69	
charges (4)	_	(28.2)	1,671.6	19.85	_	(19.7)	19.7	0.23	
Divestitures R&D upfront	_	(20.2)	33.5	0.40	_	(13.7) —	0.8	0.01	
payment	_		20.0	0.24	_	_	_	_	
Separation costs Gains on debt extinguishment,	Ξ	(63.9)	63.9	0.76	=	(6.0)	6.0	0.07	
net Unrealized gain on equity	_	_	(466.6)	(5.54)	_	_	(12.7)	(0.15)	
investment ⁽⁵⁾ Legal entity and intercompany financing	_	_	(20.2)	(0.24)	_	_	_		
organization	_	_	(212.8)	(2.53)	_	_	(256.0)	(3.00)	
U.S. Tax Reform	_	_	· <u> </u>	` _	_	_	(8.5)	(0.10)	
Income taxes (6)		_	(524.2)	(6.23)		_	(263.1)	(3.09)	
s adjusted	\$ 2,279.3	\$ 793.6	\$ 747.5	\$ 8.88	\$ 2,328.6	\$ 844.0	\$ 682.2	\$ 8.01	

- (1) In periods where losses from continuing operations are incurred, potential ordinary shares outstanding are excluded from the calculation of diluted earnings per share, prepared in accordance with GAAP, as they would be anti-dilutive. These dilutive shares are included in the calculation of adjusted diluted earnings per share if dilutive to adjusted net income. As a result, the adjusted diluted earnings per share utilized a weighted average share count of 84.2 and 85.2 shares for fiscal 2019 and 2018, respectively.
- (2) Includes pre-tax accelerated depreciation.
- (3) Fiscal 2019 includes IPR&D intangible asset impairments of \$274.5 and \$113.5 million related to VTS-270 and stannsoporfin, respectively. Fiscal 2018 includes the goodwill impairment of \$3,672.8 million and an IPR&D intangible asset impairment of \$218.3 million related to MNK-1411.
- (4) Includes the opioid-related litigation settlement charge of \$1.643 billion.

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- (5) Represents an unrealized gain related to the company's equity investment in Silence. Fiscal 2019 includes an unrealized gain of \$6.5 million and \$13.7 million for the three months ended September 27, 2019 and the three months ended December 27, 2019, respectively.
- (6) Includes tax effects of above adjustments (unless otherwise separately stated), changes in related uncertain tax positions, as well as certain installment sale transactions and other intercompany transactions.

MALLINCKRODT PLC SEGMENT NET SALES AND CONSTANT-CURRENCY GROWTH

(unaudited, in millions)

	FISCAI YEAR					_					
	2019				2018		Percent change		ency	Cons curre grov	ency
Specialty Brands	\$	2,423.8		\$	2,496.7	_	(2.9) %	(0.2) %	(2.7)	
Specialty Generics ⁽¹⁾		738.7	_		718.9		2.8	(0.1)	2.9	
Net sales	\$	3,162.5	_	\$	3,215.6		(1.7)	(0.2	:)	(1.5)	

(1) Includes net sales from the post-divestiture supply agreement with the acquirer of the CMDS business.

MALLINCKRODT PLC SELECT PRODUCT LINE NET SALES

(unaudited, in millions)

	Fiscal Year				_					
		2019		2018	Perce chan			ncy	Consta curren grow	псу
Specialty Brands										
Acthar Gel	\$	952.7	\$	1,110.1	(14.2)	%	_	%	(14.2)	%
INOmax		571.4		542.7	5.3		(0.1)		5.4	
Ofirmev		384.0		341.9	12.3		_		12.3	
Therakos		246.9		231.2	6.8		(1.5)		8.3	
Amitiza		208.5		183.8	13.4		_		13.4	
BioVectra ⁽¹⁾		40.1		53.1	(24.5)		(2.3)		(22.2)	
Other		20.2		33.9	(40.4)		(1.0)		(39.4)	
Specialty Brands Total	\$	2,423.8	\$	2,496.7	(2.9)	%	(0.2)	%	(2.7)	%
Specialty Generics										
Hydrocodone (API) and hydrocodone-containing tablets	\$	76.3	\$	65.9	15.8	%	_	%	15.8	%
Oxycodone (API) and oxycodone-containing tablets (2)		74.9		66.1	13.3		_		13.3	
Acetaminophen (API) (2)		189.9		192.7	(1.5)		_		(1.5)	
Other controlled substances (2)		352.5		343.8	2.5		(0.1)		2.6	
Other (2)		45.1		50.4	(10.5)		_		(10.5)	
Specialty Generics Total	\$	738.7	\$	718.9	2.8	%	(0.1)	%	2.9	%

⁽¹⁾ In November 2019, the company completed its sale of the BioVectra business.

MALLINCKRODT PLC SEGMENT OPERATING INCOME

(unaudited, in millions)

	Fiscal Year			
	2019		2018	
Specialty Brands (1)	\$ 1,174.5	\$	1,093.1	
Specialty Generics	108.1		89.3	

⁽²⁾ Prior period amounts have been reclassified to conform to current period presentation.

Segment operating income Unallocated amounts:	1,282.6	1,182.4
Corporate and allocated expenses (2) Intangible asset amortization	(137.8) (853.4)	(155.8) (740.2)
Restructuring and related charges, net (3)	1.7	(108.2)
Non-restructuring impairment charges	(388.0)	(3,893.1)
Separation costs	(63.9)	(6.0)
R&D upfront payment (4)	(20.0)	_
Opioid-related litigation settlement charge	(1,643.4)	
Operating loss	\$ (1,822.2)	\$ (3,720.9)

⁽¹⁾ Includes \$10.0 million and \$118.8 million of inventory fair-value step up expense, primarily related to Amitiza during fiscal 2019 and 2018, respectively.

MALLINCKRODT PLC CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in millions)

	December 27, 2019	December 28, 2018	
Assets			
Current Assets:			
Cash and cash equivalents	\$ 790.9	\$ 348.9	
Accounts receivable, net	577.5	623.3	
Inventories	312.1	322.3	
Prepaid expenses and other current assets	150.2	132.7	
Total current assets	1,830.7	1,427.2	
Property, plant and equipment, net	896.5	982.0	
Intangible assets, net	7,018.0	8,282.8	
Other assets	593.7	185.3	
Total Assets	\$ 10,338.9	\$ 10,877.3	
Liabilities and Shareholders' Equity Current Liabilities:			
Current maturities of long-term debt	\$ 633.6	\$ 22.4	
Accounts payable	139.8	147.5	
Accrued payroll and payroll-related costs	105.2	124.0	
Accrued interest	62.9	77.6	
Accrued and other current liabilities	485.4	572.2	
Total current liabilities	1,426.9	943.7	
Long-term debt	4,741.2	6,069.2	
Opioid-related litigation settlement liability	1,643.4	_	
Pension and postretirement benefits	62.4	60.5	
Environmental liabilities	60.0	59.7	
Deferred income taxes	11.0	324.3	
Other income tax liabilities	227.1	228.0	
Other liabilities	226.2	304.6	
Total Liabilities	8,398.2	7,990.0	
Shareholders' Equity:			
Preferred shares	_	_	
Ordinary shares	18.7	18.5	
Ordinary shares held in treasury at cost	(1,615.7)	(1,617.4)	
Additional paid-in capital	5,562.5	5,528.2	
Retained deficit	(2,016.9)	(1,017.7)	
Accumulated other comprehensive loss	(7.9)	(24.3)	
Total Shareholders' Equity	1,940.7	2,887.3	
Total Liabilities and Shareholders' Equity	\$ 10,338.9	\$ 10,877.3	

MALLINCKRODT PLC CONDENSED CONSOLIDATED AND COMBINED STATEMENTS OF CASH FLOWS

(unaudited, in millions)

	 Fiscal Year		
	2019		2018
Cash Flows From Operating Activities:	 		
Net Loss	\$ (996.5)	\$	(3,607.0)
Adjustments to reconcile net cash from operating activities:			

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

⁽³⁾ Includes restructuring-related accelerated depreciation.

⁽⁴⁾ Represents R&D expense incurred related to an upfront payment made to Silence in connection with the license and collaboration agreement entered into in July 2019.

Depreciation and amortization	951.1	852.1
Share-based compensation	33.8	34.6
Deferred income taxes	(604.3)	(541.5)
Non-cash impairment charges	388.0	3,893.1
Inventory provisions	18.0	37.9
Losses on divestiture	33.5	0.8
Gain on debt extinguishment, net	(466.6)	(8.5)
Other non-cash items	(65.7)	(42.4)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	31.6	(145.8)
Inventories	(23.1)	63.1
Accounts payable	6.7	24.6
Income taxes	(2.1)	99.0
Opioid-related litigation settlement liability	1,600.0	_
Other	(161.5)	5.5
Net cash from operating activities	742.9	665.5
Cash Flows From Investing Activities:		
Capital expenditures	(133.0)	(127.0)
Acquisitions, net of cash	· —	(699.9)
Proceeds from divestiture, net of cash	95.1	313.0
Other	29.6	33.6
Net cash from investing activities	(8.3)	(480.3)
Cash Flows From Financing Activities:		
Issuance of external debt	695.0	690.3
Repayment of external debt	(945.1)	(1,693.6)
Debt financing costs	(10.1)	(12.1)
Proceeds from exercise of share options	0.6	1.0
Repurchase of shares	(2.6)	(57.5)
Other	(17.9)	(23.1)
Net cash from financing activities	(280.1)	(1,095.0)
Effect of currency rate changes on cash	0.6	(1.8)
Net change in cash, cash equivalents and restricted cash	455.1	(911.6)
Cash, cash equivalents and restricted cash at beginning of period	367.5	1,279.1
Cash, cash equivalents and restricted cash at end of period	\$ 822.6	\$ 367.5
•		
Cash and cash equivalents at end of period	\$ 790.9	\$ 348.9
Restricted cash included in other long-term assets at end of period	31.7	18.6
Cash, cash equivalents and restricted cash at end of period	\$ 822.6	\$ 367.5
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