



Mallinckrodt plc Reports Earnings for the Second Quarter 2020 and Highlights Pipeline Advancements

August 4, 2020

DUBLIN, Aug. 4, 2020 /PRNewswire/ --



- Second quarter net sales of \$166.5 million net of the retrospective one-time Acthar[®] Gel Medicaid liability; adjusted net sales of \$700.9 million, a decline of 14.9%, due primarily to demand impacts related to COVID-19 and competitive and payer pressures on certain products
- Diluted loss per share of \$11.04 with adjusted diluted earnings per share (EPS) of \$1.89, a decline of 25.3%
- Operating cash flows of \$170.9 million in the quarter with free cash flow of \$159.5 million
- Key pipeline advancements include:
 - A positive vote by the U.S. Food and Drug Administration (FDA) advisory committee for terlipressin
 - Completion of a rolling submission of a Biologics License Application (BLA) to the FDA for StrataGraft[®] regenerative skin tissue
- Company continues to work to resolve outstanding issues related to opioids, Acthar Gel, and other risks, as well as address overall debt levels, and is considering with its external advisors all options to address legal and financial challenges. While no final determination has been made, it is possible that Mallinckrodt plc and most of its subsidiaries could file for Chapter 11 reorganization in the near term

[Mallinckrodt plc](#) (NYSE: MNK), a global biopharmaceutical company, today reported results for the three- and six-months ended June 26, 2020. Unless otherwise noted, the quarter comparisons are to the prior year comparable three- and six-months ended June 28, 2019.

Net sales were \$166.5 million in the second quarter and adjusted net sales, following the adjustment for the retrospective one-time Acthar[®] Gel (repository corticotropin injection) Medicaid rebate liability, were \$700.9 million, with diluted loss per share of \$11.04 compared to diluted earnings per share of \$0.08, following the \$639.7 million impact from the retrospective Acthar Gel Medicaid rebate liability and a \$63.5 million non-restructuring impairment of the OFIRMEV[®] (acetaminophen) injection intangible asset. Adjusted diluted EPS were \$1.89 versus \$2.53, a decrease of 25.3%, on lower net sales in second quarter 2020, partially offset by non-operational favorability from adjusted income tax expense and interest expense.

"Our reported GAAP net sales were impacted by the retrospective one-time Acthar Gel Medicaid liability, and our normalized operating results also displayed a contraction this quarter due to the COVID-19 health crisis along with increased competitive and payer pressures on certain products. Amidst these challenges, we continued to operate well, which is a testament to our employees' hard work and commitment to our business, patients and customers," said **Mark Trudeau, President and Chief Executive Officer of Mallinckrodt**. "We also continue to execute on our strategic priorities – making important progress in advancing our pipeline, including a positive outcome of the recent advisory committee meeting on terlipressin and completion of a rolling submission of a Biologics License Application (BLA) to the FDA for StrataGraft[®] regenerative skin tissue."

Trudeau continued, "Looking ahead, we expect our current challenges to continue in the back half of the year. We remain committed to ensuring patients have uninterrupted access to our medicines throughout the COVID-19 health crisis. We continue to be highly focused in the near term on addressing all legal and financial challenges impacting the business."

COMPANY FINANCIAL RESULTS

Second Quarter 2020 Results

Gross loss was \$220.2 million as compared to gross profit of \$388.9 million, driven in part by the retrospective one-time Acthar Gel Medicaid liability coupled with declines in overall net sales. Adjusted gross profit was \$505.0 million, compared with \$603.9 million, due primarily to the decline in net sales. Adjusted gross profit as a percentage of adjusted net sales was 72.1%, compared with 73.4%, due primarily to changes in product mix.

Selling, general and administrative (SG&A) expenses were \$231.3 million or 138.9% of net sales, as compared to \$225.9 million, or 27.4%, primarily impacted by legal expenses and separation costs. Adjusted SG&A expenses were \$197.5 million or 28.2% of adjusted net sales, compared with \$208.6 million or 25.3%. The decline in adjusted SG&A expense reflects the Company's ongoing efforts to reduce SG&A, while the percentage of net sales and adjusted net sales were impacted by lower net sales in the second quarter 2020.

Research and development expenses were \$82.9 million, or 49.8% of net sales, as compared to \$79.6 million, or 9.7%. Research and development as a percentage of adjusted net sales was 11.8% versus 9.7%.

Interest expense was \$64.2 million as compared to \$71.5 million, a reduction of 10.2%, driven by lower aggregate debt in 2020, a reduction in floating interest costs, and the reversal of deferred interest associated with the interest-bearing deferred tax obligations.

Income tax expense was \$161.3 million, for an effective tax rate of negative 20.4%. The adjusted effective tax rate was 4.6% in the second quarter.

Six-Month Fiscal 2020 Results

Net sales were \$832.3 million and adjusted net sales were \$1,366.7 million, down 15.3% compared with \$1,613.9 million. The adjusted net sales decrease is primarily attributed to the retrospective one-time Acthar Gel Medicaid liability, increased competition on certain products and the impact of the COVID-19 pandemic.

Net loss was \$983.3 million, compared to net income of \$161.7 million. Diluted loss per share was \$11.66, compared to diluted earnings per share of \$1.92, with adjusted diluted earnings per share of \$3.53 versus \$4.48.

BUSINESS SEGMENT RESULTS

Specialty Brands Segment

Net sales for the segment in the second quarter 2020 were \$522.8 million.

- Acthar Gel net sales were \$213.7 million, a 19.8% decrease, primarily driven by continued reimbursement challenges impacting new and returning patients; continued reduction in new patients as a result of COVID-19 pandemic, which is anticipated to impact results in the second half of the year; continued payer scrutiny on overall specialty pharmaceutical spending; and, to a partial extent, the change in the Medicaid rebate calculation.
- INOMAX[®] (nitric oxide) gas, for inhalation, net sales were \$154.9 million, an increase of 10.9%, or 11.0% on a constant-currency basis, driven by an overall increased consumption of nitric oxide by the Company's customers, including strong utilization within COVID-19 patients. The INOMax Total Care service offering remains a differentiating feature among competition.

- OFIRMEV[®] net sales were \$52.4 million, a decrease of 42.1%, impacted by the overall reduction in elective surgeries due to public health orders and institutions being focused on responding to the COVID-19 pandemic.
- Therakos[®] immunology platform net sales were \$47.8 million, a decrease of 21.5%, or 20.7% on a constant-currency basis, driven largely by COVID-19 stay-at-home directives impacting patients' abilities to receive treatment in hospitals or apheresis centers.
- AMITIZA[®] (lubiprostone) net sales were \$49.4 million, down 5.0% due to continued impact of competition in the U.S. and the biennial price reduction in Japan.

Specialty Generics Segment

Net sales for the segment in the second quarter were \$178.1 million, as expected, with slight sequential increase from the first quarter 2020.

LIQUIDITY

Cash provided by operating activities in the second quarter was \$170.9 million, with free cash flow of \$159.5 million. For the six-month period, operating cash flows were \$224.6 million, with free cash flows of \$193.3 million.

The cash balance at the end of the second quarter was \$818.3 million, and the revolving credit facility was fully drawn. Total principal debt outstanding at the end of the second quarter was \$5.293 billion, with net debt of \$4.475 billion.

BUSINESS AND LITIGATION UPDATE

The Company has identified several negative conditions and events impacting the business as of June 26, 2020. Due to pressures from the Acthar Gel Medicaid matter, the ongoing opioid litigation and the Company's existing debts and the related risk of non-compliance with its financial debt covenant over the next twelve months, the Company has been working with external advisors to explore a range of options and engage in dialogue with financial creditors and litigation claimants and their advisors, including the possibility of a filing for reorganization in bankruptcy under Chapter 11 by Mallinckrodt plc and most of its subsidiaries in the near-term. However, these plans have not yet been finalized nor are they fully within the Company's control. Further disclosure regarding this matter will be included within the Form 10-Q expected to be filed later today.

CONFERENCE CALL AND WEBCAST

Mallinckrodt will hold a conference call on Tuesday, Aug. 4, 2020, beginning 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/events-calendar/>.
- 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 5970869. Dial-in 15 minutes in advance of the call is encouraged to avoid connection delays.
- Through an audio replay: A replay of the call will be available beginning at 11:30 a.m. Eastern Time on Tuesday, Aug. 4, 2020, and ending at 11:30 a.m. Eastern Time on Tuesday, Aug. 18, 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 5970869.

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 net sales, 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 net sales, 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 net sales, 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; restructuring and related charges, net; inventory step-up expense; discontinued operations; changes in fair value of contingent consideration obligations; significant legal and environmental charges (inclusive of the CMS retrospective liability); losses on divestiture; unrealized gain on equity investment; gains on debt extinguishment, net; separation costs; tax effects of aforementioned adjustments, changes in uncertain tax positions, tax impacts related to substantial doubt about the Company's ability to continue as a going concern, legislative changes and tax 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 uncertain tax positions, tax impacts related to the substantial doubt about the Company's ability to continue as a going concern, tax impacts of legislative changes and tax impacts from certain transactions, such as acquisitions or reorganizations.

Segment net sales growth on a constant-currency basis measures the change in segment 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 second quarter represents net cash provided by operating activities of \$170.9 million less capital expenditures of \$11.4 million, each as prepared in accordance with GAAP.

Free cash flow for the year to date represents net cash provided by operating activities of \$224.6 million less capital expenditures of \$31.3 million, each as prepared in accordance with GAAP.

Net debt as of June 26, 2020 represents the total principal debt outstanding of \$5.293 billion less cash of \$818.3 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: the dispute between Mallinckrodt, HHS and CMS, including the

lawsuit filed by Mallinckrodt and any related appeals, as well as the time and expense of litigating this dispute; the impact of this dispute on Mallinckrodt's expectations for performance, as well as the financial impact of the retrospective one-time Acthar Gel Medicaid liability on Mallinckrodt or any other related impacts; the impact of the outbreak of the COVID-19 coronavirus; the possibility that Mallinckrodt plc and/or certain of its subsidiaries will file for Chapter 11 and the potential effects of such a filing and resulting bankruptcy process on Mallinckrodt's liquidity, results of operations and business; 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; 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 and Form 10-Q for the fiscal quarter ended March 27, 2020. 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.

CONTACTS

Investor Relations

Daniel J. Speciale

Vice President, Finance and Investor Relations Officer

314-654-3638

daniel.speciale@mnk.com

Media

Michael Freitag / Aaron Palash / Aura Reinhard

Joele Frank, Wilkinson Brimmer Katcher

(212) 355-4449

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

	Three Months Ended			
	June 26, 2020	Percent of Net sales	June 28, 2019	Percent of Net sales
Net sales (includes a retrospective one-time charge of \$534.4 million related to the Medicaid lawsuit for the three months ended June 26, 2020)	\$ 166.5	100.0 %	\$ 823.3	100.0 %
Cost of sales	386.7	232.3	434.4	52.8
Gross (loss) profit	(220.2)	(132.3)	388.9	47.2
Selling, general and administrative expenses	231.3	138.9	225.9	27.4
Research and development expenses	82.9	49.8	79.6	9.7
Restructuring charges, net	14.4	8.6	(0.2)	—
Non-restructuring impairment charges	63.5	38.1	113.5	13.8
Gains on divestiture	(0.6)	(0.4)	—	—
Opioid-related litigation settlement	8.5	5.1	—	—
Medicaid lawsuit	105.3	63.2	—	—
Operating loss	(725.5)	(435.7)	(29.9)	(3.6)
Interest expense	(64.2)	(38.6)	(71.5)	(8.7)
Interest income	1.0	0.6	2.2	0.3
Other (expense) income, net	(0.6)	(0.4)	74.4	9.0
Loss from continuing operations before income taxes	(789.3)	(474.1)	(24.8)	(3.0)
Income tax expense (benefit)	161.3	96.9	(24.3)	(3.0)
Loss from continuing operations	(950.6)	(570.9)	(0.5)	(0.1)
Income from discontinued operations, net of income taxes	17.5	10.5	7.3	0.9
Net (loss) income	\$ (933.1)	(560.4) %	\$ 6.8	0.8 %
Basic (loss) earnings per share:				
Loss from continuing operations	\$ (11.25)		\$ (0.01)	
Income from discontinued operations	0.21		0.09	
Net (loss) income	\$ (11.04)		\$ 0.08	
Diluted (loss) earnings per share:				
Loss from continuing operations	\$ (11.25)		\$ (0.01)	
Income from discontinued operations	0.21		0.09	
Net (loss) income	\$ (11.04)		\$ 0.08	
Weighted-average number of shares outstanding				
Basic weighted-average shares outstanding	84.5		83.8	
Diluted weighted-average shares outstanding	84.5		83.8	

MALLINCKRODT PLC NON-GAAP MEASURES *(unaudited, in millions except per share data)*

	Three Months Ended				
	June 26, 2020			June 28, 2019	
	Net sales	Gross (loss) profit	Net (loss) income	Diluted net (loss) income per share ⁽¹⁾	Diluted net income per share ⁽¹⁾
	SG&A	income	share ⁽¹⁾	Net sales	Gross profit
	SG&A	income	share ⁽¹⁾	SG&A	Net income

GAAP	\$ 166.5	\$ (220.2)	\$ 231.3	\$ (933.1)	\$ (11.04)	\$ 823.3	\$ 388.9	\$ 225.9	\$ 6.8	\$ 0.08
Adjustments:										
Intangible asset amortization	—	190.8	(0.8)	191.6	2.26	—	215.0	(1.6)	216.6	2.58
Restructuring and related charges, net	—	—	—	14.4	0.17	—	—	—	(0.2)	—
Non-restructuring impairment charge	—	—	—	63.5	0.75	—	—	—	113.5	1.35
Income from discontinued operations	—	—	—	(17.5)	(0.21)	—	—	—	(7.3)	(0.09)
Change in contingent consideration fair value	—	—	4.9	(4.9)	(0.06)	—	—	3.2	(3.2)	(0.04)
Significant legal and environmental charges ⁽²⁾	534.4	534.4	(17.2)	665.4	7.86	—	—	—	—	—
Divestitures	—	—	—	(0.6)	(0.01)	—	—	—	—	—
Separation costs	—	—	(20.7)	20.7	0.24	—	—	(18.9)	18.9	0.22
Gains on debt extinguishment, net	—	—	—	—	—	—	—	—	(62.3)	(0.74)
Unrealized loss on equity investment	—	—	—	2.4	0.03	—	—	—	—	—
R&D upfront payment ⁽³⁾	—	—	—	5.0	0.06	—	—	—	—	—
Legal entity and intercompany financing reorganization	—	—	—	(6.3)	(0.07)	—	—	—	3.0	0.04
Income taxes ⁽⁴⁾	—	—	—	159.9	1.89	—	—	—	(72.8)	(0.87)
As adjusted	<u>\$ 700.9</u>	<u>\$ 505.0</u>	<u>\$ 197.5</u>	<u>\$ 160.5</u>	<u>\$ 1.89</u>	<u>\$ 823.3</u>	<u>\$ 603.9</u>	<u>\$ 208.6</u>	<u>\$ 213.0</u>	<u>\$ 2.53</u>
Percent of adjusted net sales	100.0 %	72.1 %	28.2 %	22.9 %		100.0 %	73.4 %	25.3 %	25.9 %	

- (1) In periods where the Company reports a net loss from continuing operations, 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 potentially dilutive shares are included in the calculation of adjusted diluted earnings per share when dilutive. As a result, the adjusted diluted earnings per share utilized a weighted average share count of 84.7 shares and 84.1 shares for the three months ended June 26, 2020 and June 28, 2019, respectively.
- (2) Effective June 15, 2020, the Company was forced under protest to change the base date average manufacturer price ("AMP") for Acthar Gel, as directed by CMS. While the Company continues to pursue its appeal of the March 16, 2020 ruling by the U.S. District Court for the District of Columbia that upheld CMS' position, the Company incurred a retrospective one-time charge of \$639.7 million, of which \$534.4 million and \$105.3 million have been reflected as a component of net sales and operating expenses, respectively, in the unaudited condensed consolidated statement of operations. The \$105.3 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the retrospective liability that arose from sales of Acthar Gel prior to the Company's acquisition of Questcor Pharmaceuticals Inc. in August 2014. Of the \$534.4 million recorded as a component of net sales, \$12.3 million represents the impact of the Medicaid rebate calculation through June 14, 2020 for the three months ended June 26, 2020. Also includes \$17.2 million in opioid defense costs and an \$8.5 million increase in the fair value of the opioid settlement warrants. Opioid defense costs are considered to be non-recurring as a result of the opioid-related litigation settlement announced during the three months ended March 27, 2020; therefore, such costs are included as an adjustment to net income on a go-forward basis until effectuation of the opioid-related litigation settlement.
- (3) Represents research and development ("R&D") expense incurred related to an upfront payment made in June 2020 to acquire product rights for terlipressin in Japan.
- (4) Includes tax effects of above adjustments (unless otherwise separately stated), changes in uncertain tax positions, tax impacts related to the substantial doubt about the Company's ability to continue as a going concern, legislative changes and certain intercompany transactions.

MALLINCKRODT PLC
SEGMENT NET SALES AND CONSTANT-CURRENCY GROWTH
(unaudited, in millions)

	<u>Three Months Ended</u>		Percent change	Currency impact	Constant-currency growth
	June 26, 2020	June 28, 2019			
Specialty Brands ⁽¹⁾	\$ 522.8	\$ 627.8	(16.7) %	(0.1) %	(16.6) %
Specialty Generics	178.1	195.5	(8.9)	(0.1)	(8.8)
Segment net sales	\$ 700.9	\$ 823.3	(14.9) %	(0.1) %	(14.8) %
Medicaid lawsuit	(534.4)	—	*	*	*
Net sales	<u>\$ 166.5</u>	<u>\$ 823.3</u>	(79.8) %	(0.1) %	(79.7) %

*Not meaningful

- (1) The three months ended June 26, 2020 includes the prospective change to the Medicaid rebate calculation of \$8.6 million for the period from June 15, 2020 through June 26, 2020, of which \$6.8 million represents the channel impact.

MALLINCKRODT PLC
SELECT PRODUCT LINE NET SALES AND CONSTANT-CURRENCY GROWTH
(unaudited, in millions)

	<u>Three Months Ended</u>		Percent change	Currency impact	Constant-currency growth
	June 26, 2020	June 28, 2019			
Specialty Brands					
Acthar Gel ⁽¹⁾	\$ 213.7	\$ 266.4	(19.8) %	— %	(19.8) %
INOMax	154.9	139.7	10.9	(0.1)	11.0

Ofirmev	52.4	90.5	(42.1)	—	(42.1)
Therakos	47.8	60.9	(21.5)	(0.8)	(20.7)
Amitiza	49.4	52.0	(5.0)	—	(5.0)
Other (2)	4.6	18.3	(74.9)	—	(74.9)
Specialty Brands Total	<u>\$ 522.8</u>	<u>\$ 627.8</u>	(16.7) %	(0.1) %	(16.6) %
Specialty Generics					
Hydrocodone (API) and hydrocodone-containing tablets	\$ 25.4	\$ 18.1	40.3 %	— %	40.3 %
Oxycodone (API) and oxycodone-containing tablets	15.0	19.6	(23.5)	—	(23.5)
Acetaminophen (API)	55.5	48.4	14.7	—	14.7
Other controlled substances	77.8	98.6	(21.1)	(0.1)	(21.0)
Other	4.4	10.8	(59.3)	—	(59.3)
Specialty Generics Total	<u>\$ 178.1</u>	<u>\$ 195.5</u>	(8.9) %	(0.1) %	(8.8) %
Segment net sales	\$ 700.9	\$ 823.3	(14.9) %	(0.1) %	(14.8) %
Medicaid lawsuit	\$ (534.4)	\$ —	*	*	*
Net sales	<u>\$ 166.5</u>	<u>\$ 823.3</u>	(79.8) %	(0.1) %	(79.7) %

*Not meaningful

- (1) The three months ended June 26, 2020 includes the prospective change to the Medicaid rebate calculation of \$8.6 million for the period from June 15, 2020 through June 26, 2020, of which \$6.8 million represents the channel impact.
- (2) The three months ended June 28, 2019 includes \$13.9 million of net sales related to BioVectra prior to the completion of the sale of this business in November 2019.

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

	Six Months Ended			
	June 26, 2020	Percent of Net sales	June 28, 2019	Percent of Net sales
Net sales (Includes a retrospective one-time charge of \$534.4 million related to the Medicaid lawsuit for the six months ended June 26, 2020)	\$ 832.3	100.0 %	\$ 1,613.9	100.0 %
Cost of sales	768.7	92.4	889.9	55.1
Gross profit	63.6	7.6	724.0	44.9
Selling, general and administrative expenses	462.4	55.6	456.1	28.3
Research and development expenses	160.3	19.3	164.9	10.2
Restructuring charges, net	12.6	1.5	4.0	0.2
Non-restructuring impairment charges	63.5	7.6	113.5	7.0
Gains on divestiture	(0.4)	—	—	—
Opioid-related litigation settlement	(8.3)	(1.0)	—	—
Medicaid lawsuit	105.3	12.7	—	—
Operating loss	(731.8)	(87.9)	(14.5)	(0.9)
Interest expense	(138.7)	(16.7)	(154.2)	(9.6)
Interest income	4.5	0.5	3.7	0.2
Other income, net	1.1	0.1	90.7	5.6
Loss from continuing operations before income taxes	(864.9)	(103.9)	(74.3)	(4.6)
Income tax expense (benefit)	142.4	17.1	(229.0)	(14.2)
(Loss) income from continuing operations	(1,007.3)	(121.0)	154.7	9.6
Income from discontinued operations, net of income taxes	24.0	2.9	7.0	0.4
Net (loss) income	<u>\$ (983.3)</u>	(118.1) %	<u>\$ 161.7</u>	10.0 %
Basic (loss) earnings per share:				
(Loss) income from continuing operations	\$ (11.95)		\$ 1.85	
Income from discontinued operations	0.28		0.08	
Net (loss) income	(11.66)		1.93	
Diluted (loss) earnings per share:				
(Loss) income from continuing operations	\$ (11.95)		\$ 1.84	
Income from discontinued operations	0.28		0.08	
Net (loss) income	(11.66)		1.92	
Weighted-average number of shares outstanding:				
Basic	84.3		83.7	
Diluted	84.3		84.3	

MALLINCKRODT PLC
NON-GAAP MEASURES
(unaudited, in millions except per share data)

	Six Months Ended									
	June 26, 2020					June 28, 2019				
	Net sales	Gross profit	SG&A	Net (loss) income	Diluted net (loss) income per share (1)	Net sales	Gross profit	SG&A	Net income	Diluted net income per share
GAAP	\$ 832.3	\$ 63.6	\$ 462.4	\$ (983.3)	\$ (11.66)	\$ 1,613.9	\$ 724.0	\$ 456.1	\$ 161.7	\$ 1.92
Adjustments:										
Intangible asset amortization	—	387.5	(1.7)	389.2	4.60	—	436.2	(3.2)	439.4	5.21
Restructuring and related charges, net	—	—	—	12.6	0.15	—	—	—	4.0	0.05
Non-restructuring impairment charge	—	—	—	63.5	0.75	—	—	—	113.5	1.35

Inventory step-up expense	—	—	—	—	—	—	10.0	—	10.0	0.12
Income from discontinued operations	—	—	—	(24.0)	(0.28)	—	—	—	(7.0)	(0.08)
Change in contingent consideration fair value	—	—	5.7	(5.7)	(0.07)	—	—	(2.3)	2.3	0.03
Significant legal and environmental charges ⁽²⁾	534.4	534.4	(39.7)	671.1	7.92	—	—	—	—	—
Divestitures	—	—	—	(0.4)	—	—	—	—	—	—
Separation costs	—	—	(42.0)	42.0	0.50	—	—	(30.6)	30.6	0.36
Gain on debt extinguishment, net	—	—	—	—	—	—	—	—	(71.3)	(0.85)
Unrealized gain on equity investment	—	—	—	(3.0)	(0.04)	—	—	—	—	—
R&D upfront payment ⁽³⁾	—	—	—	5.0	0.06	—	—	—	—	—
Reorganization of legal entity ownership	—	—	—	(6.3)	(0.07)	—	—	—	(189.8)	(2.25)
Income taxes ⁽⁴⁾	—	—	—	138.1	1.63	—	—	—	(116.0)	(1.38)
As adjusted	<u>\$ 1,366.7</u>	<u>\$ 985.5</u>	<u>\$ 384.7</u>	<u>\$ 298.8</u>	<u>\$ 3.53</u>	<u>\$ 1,613.9</u>	<u>\$ 1,170.2</u>	<u>\$ 420.0</u>	<u>\$ 377.4</u>	<u>\$ 4.48</u>
Percent of adjusted net sales	100.0 %	72.1 %	28.1 %	21.9 %		100.0 %	72.5 %	26.0 %	23.4 %	

- (1) In periods where the Company reports a net loss from continuing operations, 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 potentially dilutive shares are included in the calculation of adjusted diluted earnings per share when dilutive. As a result, the adjusted diluted earnings per share utilized a weighted average share count of 84.7 shares for the six months ended June 26, 2020.
- (2) Effective June 15, 2020, the Company was forced under protest to change the base date AMP for Acthar Gel, as directed by CMS. While the Company continues to pursue its appeal of the March 16, 2020 ruling by the U.S. District Court for the District of Columbia that upheld CMS' position, the Company incurred a retrospective one-time charge of \$639.7 million, of which \$534.4 million and \$105.3 million have been reflected as a component of net sales and operating expenses, respectively, in the unaudited condensed consolidated statement of operations. The \$105.3 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the retrospective liability that arose from sales of Acthar Gel prior to the Company's acquisition of Questcor Pharmaceuticals Inc. in August 2014. Of the \$534.4 million recorded as a component of net sales, \$27.6 million represents the impact of the Medicaid rebate calculation through June 14, 2020 for the six months ended June 26, 2020. Also includes \$39.7 million in opioid defense costs which are considered to be non-recurring as a result of the opioid-related litigation settlement announced during the three months ended March 27, 2020; therefore, such costs are included as an adjustment to net income on a go-forward basis until effectuation of the opioid-related litigation settlement. These costs were partially offset by a \$8.3 million decrease in the fair value of the opioid settlement warrants.
- (3) Represents R&D expense incurred related to an upfront payment made in June 2020 to acquire product rights for terlipressin in Japan.
- (4) Includes tax effects of above adjustments (unless otherwise separately stated), changes in uncertain tax positions, tax impacts related to the substantial doubt about the Company's ability to continue as a going concern, legislative changes and certain intercompany transactions. The six months ended June 28, 2019 also includes certain installment sale transactions.

MALLINCKRODT PLC
SEGMENT NET SALES AND CONSTANT-CURRENCY GROWTH
(unaudited, in millions)

	<u>Six Months Ended</u>				
	<u>June 26, 2020</u>	<u>June 28, 2019</u>	<u>Percent change</u>	<u>Currency impact</u>	<u>Constant-currency growth</u>
Specialty Brands ⁽¹⁾	\$ 1,013.4	\$ 1,232.0	(17.7) %	(0.1) %	(17.6) %
Specialty Generics	353.3	381.9	(7.5) %	—	(7.5) %
Segment net sales	\$ 1,366.7	\$ 1,613.9	(15.3) %	(0.1) %	(15.2) %
Medicaid lawsuit	(534.4)	—	*	*	*
Net sales	<u>\$ 832.3</u>	<u>\$ 1,613.9</u>	(48.4) %	(0.1) %	(48.3) %

*Not meaningful

- (1) The six months ended June 26, 2020 includes the prospective change to the Medicaid rebate calculation of \$8.6 million for the period from June 15, 2020 through June 26, 2020, of which \$6.8 million represents the channel impact.

MALLINCKRODT PLC
SELECT PRODUCT LINE NET SALES
(unaudited, in millions)

	<u>Six Months Ended</u>				
	<u>June 26, 2020</u>	<u>June 28, 2019</u>	<u>Percent change</u>	<u>Currency impact</u>	<u>Constant-currency growth</u>
Specialty Brands					
Acthar ⁽¹⁾	\$ 381.3	\$ 490.3	(22.2) %	— %	(22.2)
Inomax	296.6	290.8	2.0	(0.1)	2.1
Ofirmev	127.3	186.1	(31.6)	—	(31.6)
Therakos	111.5	122.7	(9.1)	(0.6)	(8.5)
Amitiza	90.5	105.0	(13.8)	—	(13.8)
Other ⁽²⁾	6.2	37.1	(83.3)	—	(83.3)

Specialty Brands Total	\$ 1,013.4	\$ 1,232.0	(17.7) %	(0.1) %	(17.6) %
Specialty Generics					
Hydrocodone (API) and hydrocodone-containing tablets	\$ 51.9	\$ 35.5	46.2 %	— %	46.2
Oxycodone (API) and oxycodone-containing tablets	31.9	36.1	(11.6)	—	(11.6)
Acetaminophen (API)	99.6	94.6	5.3	—	5.3
Other controlled substances	161.4	192.8	(16.3)	(0.1)	(16.2)
Other	8.5	22.9	(62.9)	—	(62.9)
Specialty Generics Total	\$ 353.3	\$ 381.9	(7.5) %	— %	(7.5) %
Segment net sales	1,366.7	1,613.9	(15.3)	(0.1)	(15.2)
Medicaid lawsuit	(534.4)	—	*	*	*
Net sales	\$ 832.3	\$ 1,613.9	(48.4) %	(0.1) %	(48.3) %

*Not meaningful

(1) The six months ended June 26, 2020 includes the prospective change to the Medicaid rebate calculation of \$8.6 million for the period from June 15, 2020 through June 26, 2020, of which \$6.8 million represents the channel impact.

(2) The six months ended June 28, 2019 includes \$26.3 million of net sales related to BioVectra prior to the completion of the sale of this business in November 2019.

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

	June 26, 2020	December 27, 2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 818.3	\$ 790.9
Accounts receivable, net	493.3	577.5
Inventories	333.0	312.1
Prepaid expenses and other current assets	310.2	150.2
Total current assets	1,954.8	1,830.7
Property, plant and equipment, net	864.7	896.5
Intangible assets, net	6,566.5	7,018.0
Other assets	304.1	593.7
Total Assets	\$ 9,690.1	\$ 10,338.9

Liabilities and Shareholders' Equity

Current Liabilities:		
Current maturities of long-term debt	\$ 19.5	\$ 633.6
Accounts payable	86.5	139.8
Accrued payroll and payroll-related costs	132.5	105.2
Accrued interest	67.2	62.9
Medicaid lawsuit	639.7	—
Accrued and other current liabilities	375.5	485.4
Total current liabilities	1,320.9	1,426.9
Long-term debt	5,223.4	4,741.2
Opioid-related litigation settlement liability	1,635.1	1,643.4
Pension and postretirement benefits	61.4	62.4
Environmental liabilities	60.3	60.0
Other income tax liabilities	220.9	227.1
Other liabilities	198.6	237.2
Total Liabilities	8,720.6	8,398.2
Shareholders' Equity:		
Preferred shares	—	—
Ordinary shares	18.8	18.7
Ordinary shares held in treasury at cost	(1,616.0)	(1,615.7)
Additional paid-in capital	5,575.7	5,562.5
Retained deficit	(3,000.2)	(2,016.9)
Accumulated other comprehensive loss	(8.8)	(7.9)
Total Shareholders' Equity	969.5	1,940.7
Total Liabilities and Shareholders' Equity	\$ 9,690.1	\$ 10,338.9

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

	Six Months Ended	
	June 26, 2020	June 28, 2019
Cash Flows From Operating Activities:		
Net (loss) income	\$ (983.3)	\$ 161.7
Adjustments to reconcile net cash from operating activities:		
Depreciation and amortization	439.4	488.6
Share-based compensation	13.3	22.8
Deferred income taxes	314.1	(271.2)
Non-cash impairment charges	63.5	113.5
Gains on divestitures	(0.4)	—
Other non-cash items	(12.5)	(76.0)
Changes in assets and liabilities:		
Accounts receivable, net	83.6	95.5
Inventories	(27.2)	(23.8)
Accounts payable	(45.7)	7.2
Income taxes	(219.8)	22.4
Medicaid lawsuit	639.7	—
Other	(40.1)	(73.3)

Net cash from operating activities	224.6	467.4
Cash Flows From Investing Activities:		
Capital expenditures	(31.3)	(77.6)
Proceeds from divestiture, net of cash	(3.5)	—
Other	6.0	8.2
Net cash from investing activities	(28.8)	(69.4)
Cash Flows From Financing Activities:		
Issuance of external debt	—	200.0
Repayment of external debt	(129.6)	(685.9)
Debt financing costs	(9.1)	—
Repurchase of shares	(0.3)	(2.5)
Other	(19.2)	(18.0)
Net cash from financing activities	(158.2)	(506.4)
Effect of currency rate changes on cash	(0.5)	0.8
Net change in cash, cash equivalents and restricted cash	37.1	(107.6)
Cash, cash equivalents and restricted cash at beginning of period	822.6	367.5
Cash, cash equivalents and restricted cash at end of period	\$ 859.7	\$ 259.9
Cash and cash equivalents at end of period	\$ 818.3	\$ 241.1
Restricted cash included in other assets at end of period	41.4	18.8
Cash, cash equivalents and restricted cash at end of period	\$ 859.7	\$ 259.9

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