

Mallinckrodt plc (MNK)

\$2.23 (As of 03/27/20)

Price Target (6-12 Months): **\$3.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 04/29/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:A

Value: A

Growth: B

Momentum: D

Summary

Mallinckrodt's proposed settlement agreement for lawsuits related to opioid crisis comes as a relief for investors. A final execution will be great relief for the company. Mallinckrodt's lead drug, Acthar, continues to face reimbursement pressures as payers challenge longer duration prescriptions for certain indications. This, in turn, has affected sales and the trend is likely to continue in the near term. While the company's hospital portfolio maintains momentum on solid performance of Ofirmev and Inomax, it is facing tough business conditions due to the opioid litigations. Its high debt levels make matters worse. Its shares have underperformed the industry in the past year.

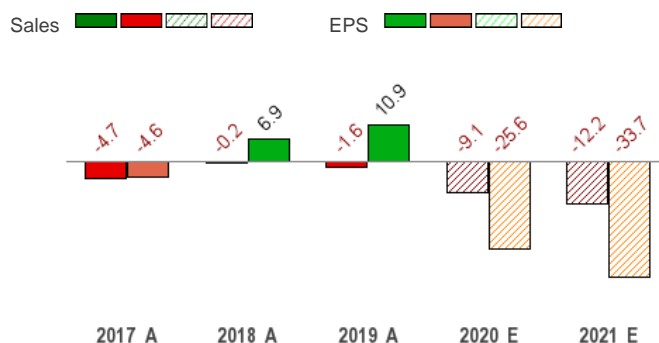
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$23.90 - \$1.00
20 Day Average Volume (sh)	8,656,188
Market Cap	\$187.8 M
YTD Price Change	-36.1%
Beta	2.40
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Generic Drugs
Zacks Industry Rank	Top 19% (49 out of 254)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	17.1%
Last Sales Surprise	4.0%
EPS F1 Est- 4 week change	-3.2%
Expected Report Date	05/05/2020
Earnings ESP	-2.4%

P/E TTM	0.3
P/E F1	0.3
PEG F1	0.0
P/S TTM	0.1

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	591 E	627 E	574 E	624 E	2,524 E
2020	708 E	731 E	698 E	739 E	2,876 E
2019	791 A	823 A	744 A	805 A	3,163 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.68 E	\$0.99 E	\$0.69 E	\$0.98 E	\$4.38 E
2020	\$1.64 E	\$1.69 E	\$1.52 E	\$1.72 E	\$6.61 E
2019	\$1.94 A	\$2.53 A	\$2.07 A	\$2.40 A	\$8.88 A

*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 03/27/2020. The reports text is as of 03/30/2020.

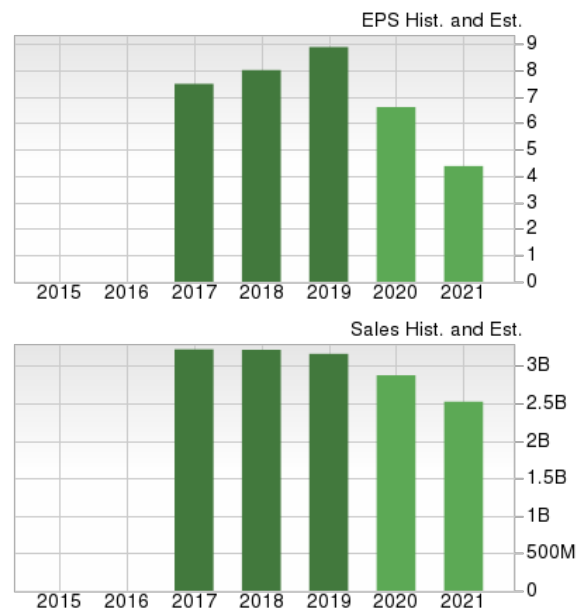
Overview

Dublin, Ireland-based Mallinckrodt is a specialty biopharmaceutical with a worldwide presence. The company develops, manufactures, markets and distributes branded and generic specialty pharmaceutical and biopharmaceutical products and therapies as well as nuclear medicine products.

Mallinckrodt operates under two segments — Specialty Brands and Specialty Generics. Specialty Brands produces and markets branded pharmaceutical products, like Acthar and Ofirmev, 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. In December 2018, the company announced that it intends to spin-off the Specialty Generics business into a new company. However, based on current market conditions and developments, including increasing uncertainties regarding the opioid litigation, the company has shelved this plan for now. Mallinckrodt continues to evaluate a range of options for the separation of the Specialty Generics business. The company has also inked a definitive agreement to sell its wholly-owned subsidiary, BioVectra Inc., to an affiliate of H.I.G. Capital for approximately \$250 million.

Mallinckrodt's key acquisitions include Cadence Pharmaceuticals in March 2014, Questcor Pharmaceuticals in August 2014, Ikaria in April 2015, Therakos in September 2015 and three commercial-stage topical hemostasis drugs from The Medicines Company in February 2016. The company also acquired Sucampo in February 2018. Meanwhile, the company sold its contrast media and delivery systems (CMDs) business in November 2015. Mallinckrodt sold its Nuclear Imaging business to IBA Molecular and Intrathecal Therapy business to Piramal Enterprises Limited.

Net sales came in at \$3.16 billion in 2019.



Reasons To Buy:

▲ **Untapped Potential in Acthar Gel:** Acthar Gel, which became part of the company's portfolio following the Questcor acquisition, continues to drive growth. Performance of the drug has been impressive aided by solid demand in rheumatology, pulmonology, ophthalmology and nephrology indications, and expanded access in more recently promoted indications such as lupus and sarcoidosis, and mature indications such as infantile spasms and nephrotic syndrome.

Inomax and Acthar hold significant potential. The company continues to work on boosting presence of these drugs in the hospital segment.

▲ **Strong Hospital Portfolio:** Mallinckrodt's hospital portfolio is now its largest and fastest growing platform in terms of sales. The acquisition of critical-care company, Ikaria added Inomax (a vasodilator used in conjunction with ventilatory support and other appropriate agents) to the company's portfolio. The acquisition broadened Mallinckrodt's footprint in hospitals and expanded its presence to include critical-care respiratory therapies in neonatal intensive care units. Growth continues to be driven by sustained, consistent demand and contract renewals fueled by the product's differentiated total service model.

Also, the Cadence acquisition added Ofirmev to the company's specialty pharmaceuticals portfolio, expanding its pain management franchise. With Ofirmev, Mallinckrodt targets the adjacent acute-care hospital market. Penetration rates on available surgical procedures are relatively low and hospitals continue to develop recovery standards after surgery protocols, which should drive the sale of products like Ofirmev and enable patients to recover quicker after surgery. Growth of the drug is expected to be driven by strong demand, as customers focus on non-opioid or multimodal pain management.

▲ **Promising Candidates in The Pipeline:** Mallinckrodt is striving hard to diversify its portfolio. Two late-phase programs — terlipressin and StrataGraft — in the pipeline promise potential. Patients are being enrolled in the ongoing phase III trial on pipeline candidate, terlipressin for the treatment of Hepatorenal Syndrome type 1. Mallinckrodt announced positive top-line results from its phase III CONFIRM study evaluating the efficacy and safety of terlipressin in 300 adults with hepatorenal syndrome type 1 (HRS-1). The study met its primary endpoint of verified HRS-1 reversal. The company has already submitted a New Drug Application to the FDA.

StrataGraft is in phase III development for the treatment of deep partial thickness burns and phase II development for full thickness burns. The company recently reported positive top-line results from its pivotal phase III study of StrataGraft regenerative tissue. The study, which met both primary endpoints, evaluated the efficacy and safety of a single application of the candidate for the treatment of deep partial-thickness thermal burns. Mallinckrodt plans to submit a Biologics License Application for the same to the FDA in the first half of 2020.

Reasons To Sell:

- ▼ **Share Price Performance:** Mallinckrodt has underperformed the industry in the past year. Shares have plummeted due to pricing pressure in the generic segment and the rising menace of penalties regarding litigations. There were reports that the company may file for bankruptcy to limit its liabilities related to the pending opioid litigations, which resulted in a significant decline in the share price. Per the report, Mallinckrodt hired restructuring advisers to explore options that could help avoid the multidistrict litigation scheduled in October. Moreover, its high-debt levels will make matters worse if a settlement is reached or a penalty is imposed by the court. The company may also divest its generic business, which includes opioid drugs. We expect the ongoing litigations to weigh on the shares.

Pricing pressure in the generic segment and the rising menace of penalties regarding opioid litigations are a concern.

Previously, there were allegations against Acthar's previous owner, Questcor, for conducting illegal sales and marketing activities related to the drug. Per the company, the original action was filed in 2012, prior to Mallinckrodt's ownership of Acthar Gel, which consisted of two complaints filed by former Questcor employees. The company reached an agreement in principle with the U.S. Department of Justice (DOJ) in relation with the Questcor litigation. Mallinckrodt will pay \$15.4 million related to legacy Questcor activities, per the civil False Claims Act settlement.

- ▼ **Pipeline Setbacks:** The company suffered a setback when the FDA's Gastrointestinal Drugs Advisory Committee and Pediatric Advisory Committee recommended in a vote of 21 to 3 that the risk-benefit profile of stannsoporfin does not support approval for the treatment of newborns aging 35 weeks or more of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia (severe jaundice). The FDA has issued a complete response letter to its new drug application (NDA) for stannsoporfin. The letter provides guidance on areas of further evaluation for resubmitting the NDA. Similar setbacks will adversely impact the stock.
- ▼ **Acthar Under Pressure:** Acthar continues to face reimbursement pressures because payers challenge longer duration prescriptions for certain indications. Consequently, sales have been declining for the last few quarters. Competition is also increasing for Amitiza in the United States.
- ▼ **Separation of Generics Business on Hold:** In December 2018, the company announced that it intends to spin-off the Specialty Generics business into a new company. However, based on current market conditions and developments, including increasing uncertainties regarding the opioid litigation, the company has shelved this plan for now. Mallinckrodt continues to evaluate a range of options for the separation of the Specialty Generics business, which further adds to uncertainty. The company's high level of debt will make its worse for the company to counter menace of penalties regarding litigations.
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Last Earnings Report

Mallinckrodt Beats on Q4 Earnings

The company reported adjusted earnings of \$2.40 per share in the fourth quarter, handily beating the Zacks Consensus Estimate of \$2.05. The figure came in higher than the year-ago quarter's \$2.18. Net sales in the quarter came in at \$804.9 million, decreasing 3.6% year over year. The revenue figure also beat the Zacks Consensus Estimate of \$774 million.

Quarter in Detail

The company now operates two reportable segments aligned with the previously-announced separation — the Specialty Brands and the Specialty Generics.

Specialty Brands sales came in at \$611.4 million, down 6.3% year over year.

Acthar, Mallinckrodt's largest product, generated sales of \$232.6 million, down 17.8% year on year, primarily due to continued reimbursement challenges impacting new and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending.

Inomax, the company's second largest product, generated sales of \$143.8 million, up 3.7% year over year, driven by strong customer demand for INOmax, partially offset by heightened competition in the market.

Ofirmev sales increased 28.2% year over year to \$111.8 million, owing to typical quarter-to-quarter order variability.

Sales of the Therakos immunology platform came in at \$63.3 million, up 11.1% primarily owing to the capture of new patients and the conversion to the Cellex device.

Amitza net sales were \$50.9 million, down 21.2% due to lower royalties in the United States thanks to an increasingly competitive landscape.

Specialty Generics sales amounted to \$193.5 million, up 6%.

Adjusted selling, general and administrative expenses were \$191.6 million, down from the year-ago quarter's \$212.2 million. Research and development expenses decreased to \$81.4 million from \$100.4 million due to the completion of certain development programs.

2019 Results

Sales came in at \$3.16 billion, down from \$3.22 billion in 2018 due to weakness in Acthar product. Earnings per share came in at \$8.88 compared with \$8.01 in 2018.

Guidance

The company did not provide any guidance for 2020.

Opioid Settlement

Concurrently, Mallinckrodt announced that the company and its specialty generics-focused subsidiaries Mallinckrodt LLC, SpecGx LLC, and certain other affiliates have reached an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against the company, Specialty Generics, and other subsidiaries.

The agreement in principle has been reached with a court-appointed plaintiff's executive committee representing the interests of thousands of plaintiffs in the opioid multidistrict litigation, and is supported by a broad-based group of 47 states and U.S. Territory Attorneys General.

Mallinckrodt expects that Specialty Generics, which manufactures certain generic opioid products, among other products, will file voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code in the coming months. The settlement terms include structured payments of \$1.6 billion over eight years and warrants for 19.99% of company's outstanding shares.

Quarter Ending **12/2019**

Report Date	Feb 25, 2020
Sales Surprise	3.99%
EPS Surprise	17.07%
Quarterly EPS	2.40
Annual EPS (TTM)	8.94

Recent News

Completes Rolling Submission For Terlipressin - Mar 17

Mallinckrodt announced that it has completed the rolling submission of the new drug application ("NDA") seeking approval for its pipeline candidate, terlipressin, as a treatment for hepatorenal syndrome type 1 (HRS-1). The life-threatening syndrome involves acute kidney failure in cirrhosis patients. The company initiated the rolling submission last month. The company stated that the NDA submission is considered as a Class 2 resubmission.

Per the FDA guidelines, the review of a Class 2 resubmission is completed within six months of acceptance. The FDA's acceptance of the terlipressin NDA is yet to be announced.

Update on Lawsuit – Mar 16

Mallinckrodt received a decision from the U.S. District Court For The District Of Columbia in its suit against HHS and CMS (or the Agency) regarding the company's calculation of Medicaid drug rebates for Acthar. The District Court upheld CMS' decision to reverse its previous determination of the base date average manufacturer price (AMP) used to calculate Acthar Gel rebates. Mallinckrodt will pay roughly \$650 million as charges.

Potential Role for Inhaled Nitric Oxide to Treat COVID-19 – Mar 12

Mallinckrodt announced that it is currently evaluating the limited published evidence suggesting a potential role for inhaled nitric oxide ("iNO") as a supportive measure in treating those patients infected with coronavirus (SARS-CoV-2) and having associated pulmonary complications.

Update on Proposed Global Opioid Settlement – Mar 11

Mallinckrodt announced that New York State Attorney General Letitia James has joined 47 other state and U.S. Territory Attorneys General in supporting the previously-announced proposed global opioid settlement with Mallinckrodt and related entities. The motion to remove Mallinckrodt LLC and SpecGx LLC from the New York State trial related to opioid-abuse is currently pending before the Supreme Court of New York.

Valuation

Mallinckrodt's shares are down 33.3% in the year-to-date period and 89.5% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 18.1% and 16.6% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 19.7% while the sector is down 16.1%.

The stock is currently trading at 0.37X forward 12-month earnings per share, which compares to 7.49X for the Zacks sub-industry, 17.32X for the Zacks sector and 15.48X for the S&P 500 index.

Over the past five years, the stock has traded as high as 16.59X and as low as 0.17X, with a 5-year median of 4.56X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$3 price target reflects 0.49X forward 12-month earnings per share.

The table below shows summary valuation data for MNK

Valuation Multiples - MNK					
		Stock	Sub-Industry	Sector	S&P 500
P/E F 12M	Current	0.37	7.49	17.32	15.48
	5-Year High	16.59	16.2	21.09	19.34
	5-Year Low	0.17	6.54	15.81	15.18
	5-Year Median	4.56	9.42	18.76	17.42
P/S F12M	Current	0.07	1.31	2.33	2.76
	5-Year High	3.98	4.35	3.84	3.43
	5-Year Low	0.03	1.19	2.33	2.54
	5-Year Median	1.07	1.97	2.97	3
P/B TTM	Current	0.1	1	3.21	3.42
	5-Year High	2.98	3.64	5.05	4.55
	5-Year Low	0.04	0.87	2.84	2.85
	5-Year Median	0.69	1.32	4.3	3.63

As of 03/27/2020

Industry Analysis Zacks Industry Rank: Top 19% (49 out of 254)



Top Peers

Allergan plc (AGN)	Neutral
Bausch Health Cos Inc. (BHC)	Neutral
Endo International plc (ENDP)	Neutral
Mylan N.V. (MYL)	Neutral
Novartis AG (NVS)	Neutral
Pacira Pharmaceuticals, Inc. (PCRX)	Neutral
Dr. Reddys Laboratories Ltd (RDY)	Neutral
Teva Pharmaceutical Industries Ltd. (TEVA)	Neutral

Industry Comparison Industry: Medical - Generic Drugs				Industry Peers		
	MNK Neutral	X Industry	S&P 500	MYL Neutral	RDY Neutral	TEVA Neutral
VGM Score	A	-	-	A	A	B
Market Cap	187.78 M	267.49 M	17.63 B	7.68 B	6.40 B	8.26 B
# of Analysts	8	3.5	13	9	2	13
Dividend Yield	0.00%	0.00%	2.41%	0.00%	0.68%	0.00%
Value Score	A	-	-	A	B	A
Cash/Price	5.94	0.42	0.07	0.06	0.05	0.25
EV/EBITDA	-12.49	-0.84	10.81	6.84	11.83	67.49
PEG Ratio	0.03	0.65	1.69	1.27	NA	0.65
Price/Book (P/B)	0.10	1.77	2.35	0.65	3.07	0.55
Price/Cash Flow (P/CF)	0.11	3.20	9.47	1.79	14.30	1.94
P/E (F1)	0.36	6.06	14.74	3.39	27.18	3.10
Price/Sales (P/S)	0.06	2.30	1.89	0.67	2.63	0.48
Earnings Yield	296.41%	-13.57%	6.73%	29.50%	3.68%	32.28%
Debt/Equity	2.44	0.04	0.70	0.94	0.01	1.63
Cash Flow (\$/share)	20.20	-0.23	7.01	8.33	2.70	3.89
Growth Score	B	-	-	C	B	D
Hist. EPS Growth (3-5 yrs)	2.51%	2.46%	10.85%	2.42%	-0.76%	-18.67%
Proj. EPS Growth (F1/F0)	-25.56%	2.78%	2.89%	-0.60%	-13.41%	1.54%
Curr. Cash Flow Growth	10.71%	-3.68%	5.93%	-3.91%	29.21%	-9.67%
Hist. Cash Flow Growth (3-5 yrs)	10.87%	9.76%	8.55%	16.74%	-0.91%	-6.21%
Current Ratio	1.28	2.82	1.23	1.21	1.81	0.98
Debt/Capital	70.96%	8.59%	42.57%	48.55%	0.81%	61.99%
Net Margin	-31.51%	-33.23%	11.64%	0.15%	9.62%	-5.75%
Return on Equity	27.05%	-41.94%	16.74%	19.35%	18.08%	16.57%
Sales/Assets	0.31	0.31	0.54	0.37	0.75	0.30
Proj. Sales Growth (F1/F0)	-9.05%	0.00%	2.37%	9.48%	8.93%	-3.45%
Momentum Score	D	-	-	C	B	C
Daily Price Chg	-3.88%	-2.48%	-3.35%	-4.25%	-4.41%	-4.30%
1 Week Price Chg	-48.03%	-6.38%	-16.96%	1.33%	-5.17%	-13.45%
4 Week Price Chg	-44.39%	-17.50%	-18.79%	-20.34%	-8.32%	-38.08%
12 Week Price Chg	-35.73%	-29.12%	-25.68%	-27.94%	-4.65%	-20.92%
52 Week Price Chg	-89.80%	-30.91%	-17.12%	-47.31%	-2.89%	-51.48%
20 Day Average Volume	8,656,188	367,405	4,286,768	10,884,368	236,164	24,106,082
(F1) EPS Est 1 week change	0.00%	0.00%	-0.15%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	-3.17%	-0.11%	-2.28%	-1.63%	0.00%	-0.23%
(F1) EPS Est 12 week change	-2.98%	-2.98%	-3.22%	-0.85%	-5.96%	-2.19%
(Q1) EPS Est Mthly Chg	-2.02%	-1.21%	-1.60%	-2.13%	NA	0.00%

Zacks Style Scores

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

Value Score	A
Growth Score	B
Momentum Score	D
VGM Score	A

As an investor, you want to buy stocks with the highest probability of success. That means buying stocks with a Zacks Recommendation of Outperform, which also has a Style Score of an A or a B.

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