

Mallinckrodt plc (MNK)

\$5.20 (As of 01/17/20)

Price Target (6-12 Months): **\$5.50**

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: B

Summary

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 of the company 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 lately due to the ongoing opioid litigations. While Mallinckrodt reached a settlement in principle with Cuyahoga and Summit Counties in Ohio concerning lawsuits pending in multidistrict opioid litigations, it still has a long way to get back on growth trajectory. Its high debt levels make matters worse. Shares have underperformed the industry in the past year. The ongoing litigations will remain a major overhang on the shares.

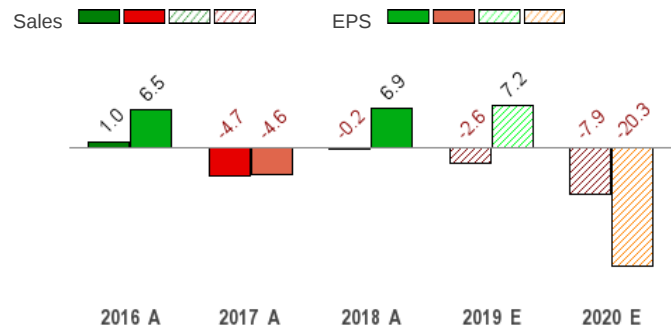
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$27.33 - \$1.43
20 Day Average Volume (sh)	6,486,251
Market Cap	\$437.3 M
YTD Price Change	49.0%
Beta	2.59
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Generic Drugs
Zacks Industry Rank	Top 43% (110 out of 254)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	4.6%
Last Sales Surprise	-3.7%
EPS F1 Est- 4 week change	0.5%
Expected Report Date	02/25/2020
Earnings ESP	-2.4%

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2020	731 E	754 E	689 E	724 E	2,886 E
2019	791 A	823 A	744 A	776 E	3,133 E
2018	573 A	632 A	640 A	835 A	3,216 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2020	\$1.67 E	\$1.87 E	\$1.45 E	\$1.65 E	\$6.85 E
2019	\$1.94 A	\$2.53 A	\$2.07 A	\$2.05 E	\$8.59 E
2018	\$1.31 A	\$1.78 A	\$2.10 A	\$2.18 A	\$8.01 A

*Quarterly figures may not add up to annual.

P/E TTM	0.6
P/E F1	0.8
PEG F1	0.1
P/S TTM	0.1

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 01/17/2020. The reports text is as of 01/20/2020.

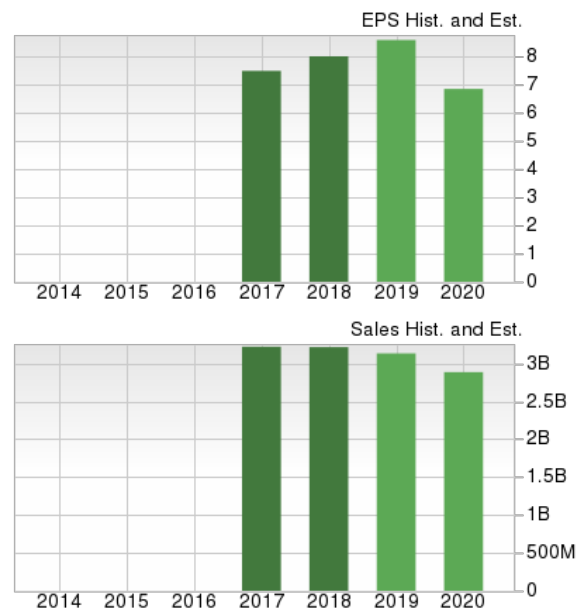
Overview

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. The segment contributed 71.7% of total sales in 2018. Specialty Generics produces specialty generic pharmaceuticals and active pharmaceutical ingredients (API) consisting of biologics, medicinal opioids, synthetic-controlled substances, acetaminophen and other active ingredients. The segment contributed 28.3% of total sales in 2018. 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 \$3.21 billion in 2018.



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 so far, propelled 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. It plans to submit a New Drug Application to the FDA in early 2020.

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 year so far. 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 Q3 Earnings Beat, Sales Miss

Mallinckrodt reported adjusted earnings of \$2.07 per share in the quarter, declining from the year-ago quarter's \$2.25 but easily beating the Zacks Consensus Estimate of \$1.98.

Net sales in the quarter came in at \$743.7 million, decreasing 7.1% year over year and falling short of the Zacks Consensus Estimate of \$772.4 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 \$580.4 million, down 9.3% year over year.

Acthar, Mallinckrodt's largest product, generated sales of \$229.8 million, down 20.8% year over year primarily due to persistent 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 \$136.8 million, up 2.7% year over year, driven by continued demand and significant utilization in multi-year, unlimited use contracts.

Ofirmev sales decreased 1.1% year over year to \$86.1 million, due to lower demand and typical quarter-to-quarter order variability.

Sales of the Therakos immunology platform were \$60.9 million, up 1.5% on growth in the United States.

Amitza net sales were \$52.6 million, up 9.1% owing to consistent strong utilization in Japan, partially offset by an increasingly competitive landscape in the United States.

Specialty Generics sales amounted to \$163.3 million, up 2.1% on share recapture across the business.

Adjusted selling, general and administrative expenses were \$182 million, down from \$205.2 million in the year-ago quarter. Research and development expenses increased to \$103.1 million from \$86.1 million, primarily owing to the \$20-million up-front payment for collaboration with Silence Therapeutics concerning the RNAi technology platform for complement-mediated diseases.

Guidance Update

Earnings per share are now projected to be \$8.50-\$8.70, up from the previous guidance of \$8.40-\$8.70. The hospital business continues to perform well and the company expects the portfolio to see high-single-digit growth for the full year.

Pipeline Update

In September, Mallinckrodt reported positive top-line results for its phase III study demonstrating the benefit of StrataGraft regenerative skin tissue in patients with deep partial-thickness burns. The company plans to submit a BLA for StrataGraft tissue to the FDA in the first half of 2020.

Meanwhile, the CONFIRM study, which evaluated the efficacy and safety of pipeline candidate terlipressin in adults with HRS type I, met its primary endpoint. The company is planning to submit an NDA for the same to the FDA in early 2020.

Quarter Ending 09/2019

Report Date	Nov 05, 2019
Sales Surprise	-3.71%
EPS Surprise	4.55%
Quarterly EPS	2.07
Annual EPS (TTM)	8.72

Recent News

Positive Phase III Results on Terlipressin – Nov 11

Mallinckrodt announced results from its pivotal Phase 3 CONFIRM study to assess the efficacy and safety of its investigational agent, terlipressin, in adults with hepatorenal syndrome type 1 (HRS-1) at the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston. The study showed that a statistically significant number of patients on terlipressin achieved the primary endpoint of Verified HRS Reversal vs placebo.

Completes Sale of BioVectra Inc. – Nov 4

Mallinckrodt announced that it has completed the sale of its wholly-owned subsidiary, BioVectra Inc., to an affiliate of H.I.G. Capital, a leading global private equity investment firm. The terms of the transaction were updated since the initial announcement, with total consideration of up to \$250 million, including an upfront payment of \$135 million and contingent consideration of \$115 million based on the long-term performance of the business.

Finalizes Settlement to Resolve "Track 1" Opioid Cases with the Ohio Counties – Sep 30

Mallinckrodt announced that it has executed a definitive settlement agreement and release (the Settlement Agreement) with Cuyahoga and Summit Counties in Ohio in connection with lawsuits pending in MDL in the U.S. District Court for the Northern District of Ohio. The settlement fully resolves the Track 1 Cases against all named Mallinckrodt entities that were scheduled to go to trial in October 2019 in the MDL. The Track 1 Cases assert various claims related to the opioid business operated by SpecGx LLC.

Per the agreement, Mallinckrodt will pay \$24 million in cash and provide \$6 million in generic products, including addiction treatment products. It also will pay \$500,000 in two years in recognition of the counties' time and expenses.

Valuation

Mallinckrodt's shares are down 74.8% in the over the trailing 12-month period. Over the past year, the Zacks sub-industry is down 6.9% while the sector is up 4.5%. The S&P 500 index is up 23.8% in the past year.

The stock is currently trading at 0.77X forward 12-month earnings per share, which compares to 8.99X for the Zacks sub-industry, 21.79X for the Zacks sector and 19.2X for the S&P 500 index.

Over the past five years, the stock has traded as high as 17.23X and as low as 0.24X, with a 5-year median of 5.21X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$5.5 price target reflects 0.81X 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 F12M	Current	0.77	8.99	21.79	19.2
	5-Year High	17.23	16.24	21.79	19.34
	5-Year Low	0.24	6.55	15.85	15.17
	5-Year Median	5.21	9.87	18.91	17.44
P/S F12M	Current	0.15	1.59	2.88	3.57
	5-Year High	4.06	4.31	3.82	3.57
	5-Year Low	0.05	1.14	2.43	2.54
	5-Year Median	1.22	1.93	2.94	3
P/B TTM	Current	0.14	1.32	4.61	4.55
	5-Year High	3.04	3.7	5.02	4.55
	5-Year Low	0.05	0.86	3.48	2.9
	5-Year Median	0.84	1.31	4.27	3.62

As of 01/17/2020

Industry Analysis Zacks Industry Rank: Top 43% (110 out of 254)



Top Peers

Pacira Pharmaceuticals, Inc. (PCRX)	Outperform
Allergan plc (AGN)	Neutral
Bausch Health Cos Inc. (BHC)	Neutral
Endo International plc (ENDP)	Neutral
Mylan N.V. (MYL)	Neutral
Novartis AG (NVS)	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	-	-	B	B	B
Market Cap	437.28 M	386.32 M	24.65 B	11.18 B	7.03 B	11.14 B
# of Analysts	9	4	13	9	1	13
Dividend Yield	0.00%	0.00%	1.73%	0.00%	0.62%	0.00%
Value Score	A	-	-	A	C	A
Cash/Price	1.87	0.18	0.04	0.03	0.06	0.13
EV/EBITDA	-1.76	-1.46	14.11	8.20	13.20	-45.23
PEG Ratio	0.06	0.98	2.08	1.11	NA	0.98
Price/Book (P/B)	0.14	2.96	3.39	0.97	3.23	0.75
Price/Cash Flow (P/CF)	0.28	4.57	13.81	2.50	15.73	2.20
P/E (F1)	0.76	7.78	19.19	4.83	30.54	4.07
Price/Sales (P/S)	0.14	3.07	2.69	0.98	2.99	0.64
Earnings Yield	131.73%	-8.28%	5.21%	20.73%	3.27%	24.61%
Debt/Equity	1.64	0.08	0.72	1.17	0.10	1.62
Cash Flow (\$/share)	18.42	-0.17	6.94	8.68	2.70	4.63
Growth Score	B	-	-	D	A	D
Hist. EPS Growth (3-5 yrs)	3.37%	3.58%	10.56%	3.79%	-5.32%	-17.10%
Proj. EPS Growth (F1/F0)	-20.23%	2.24%	7.57%	4.05%	-15.24%	4.99%
Curr. Cash Flow Growth	-0.48%	-0.81%	14.73%	5.27%	29.21%	-26.03%
Hist. Cash Flow Growth (3-5 yrs)	36.60%	4.21%	9.00%	22.00%	-0.91%	-4.41%
Current Ratio	1.07	2.91	1.24	1.43	1.96	0.89
Debt/Capital	62.11%	8.22%	42.99%	53.87%	9.03%	61.86%
Net Margin	-111.44%	-56.06%	11.14%	0.42%	16.20%	-22.88%
Return on Equity	24.36%	-42.85%	17.16%	18.80%	18.44%	15.41%
Sales/Assets	0.30	0.29	0.55	0.36	0.72	0.29
Proj. Sales Growth (F1/F0)	-7.88%	2.73%	4.16%	3.94%	9.63%	-1.01%
Momentum Score	B	-	-	B	C	C
Daily Price Chg	-0.76%	-0.59%	0.27%	-1.41%	2.88%	-3.95%
1 Week Price Chg	-5.65%	0.00%	0.39%	3.22%	1.99%	-0.88%
4 Week Price Chg	37.20%	2.34%	2.95%	11.76%	4.61%	2.31%
12 Week Price Chg	72.19%	14.36%	7.76%	18.69%	8.40%	25.00%
52 Week Price Chg	-73.87%	-19.05%	22.29%	-26.70%	13.81%	-45.63%
20 Day Average Volume	6,486,251	481,489	1,536,375	6,294,218	135,648	13,784,133
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.52%	0.00%	0.00%	0.29%	-7.95%	0.00%
(F1) EPS Est 12 week change	-5.29%	-4.57%	-0.40%	0.29%	-32.52%	0.37%
(Q1) EPS Est Mthly Chg	4.44%	0.00%	0.00%	5.75%	NA	0.00%

Zacks Stock Rating System

We offer two rating systems that take into account investors' holding horizons: Zacks Rank and Zacks Recommendation. Each provides valuable insights into the future profitability of the stock and can be used separately or in combination with each other depending on your investment style.

Zacks Recommendation

The Zacks Recommendation aims to predict performance over the next 6 to 12 months. The foundation for the quantitatively determined Zacks Recommendation is trends in the company's estimate revisions and earnings outlook. The Zacks Recommendation is broken down into 3 Levels; Outperform, Neutral and Underperform. Unlike many Wall Street firms, we have an excellent balance between the number of Outperform and Neutral recommendations. Our team of 70 analysts are fully versed in the benefits of earnings estimate revisions and how that is harnessed through the Zacks quantitative rating system. But we have given our analysts the ability to override the Zacks Recommendation for the 1200 stocks that they follow. The reason for the analyst over-rides is that there are often factors such as valuation, industry conditions and management effectiveness that a trained investment professional can spot better than a quantitative model.

Zacks Rank

The Zacks Rank is our short-term rating system that is most effective over the one- to three-month holding horizon. The underlying driver for the quantitatively-determined Zacks Rank is the same as the Zacks Recommendation, and reflects trends in earnings estimate revisions.

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	B
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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