

Mallinckrodt plc (MNK)

\$2.43 (As of 07/02/20)

Price Target (6-12 Months): **\$2.50**

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: A

Momentum: A

Summary

Mallinckrodt's pipeline progress has been encouraging with promising products like StrataGraft and terlipressin, and probable approvals in the near future should boost the top line. However, most of its lead products registered a decline in the first quarter due to the ongoing pandemic and the impact will be magnified in the second quarter. The company warned that the next few quarters will be challenging due to the impact of the COVID-19 outbreak, as some of its products are sensitive to reduced numbers of surgical procedures and doctor visits. Meanwhile, Mallinckrodt is embroiled in litigations with the U.S. Department of Health and Human Services and CMS related to the calculation of Medicaid drug rebates for lead drug, Acthar. The huge level of debt is also a concern. Its shares have underperformed the industry in the past year.

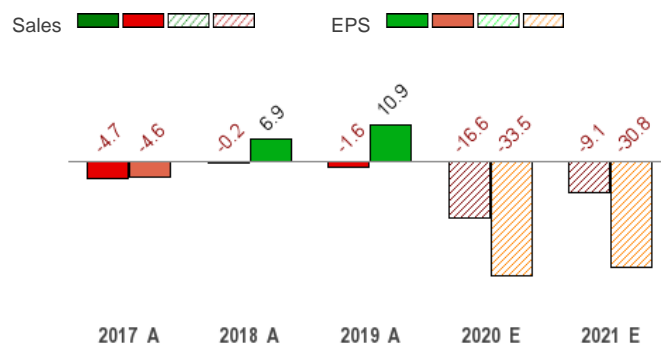
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$9.19 - \$1.00
20 Day Average Volume (sh)	3,610,774
Market Cap	\$205.2 M
YTD Price Change	-30.4%
Beta	3.42
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Generic Drugs
Zacks Industry Rank	Top 22% (56 out of 252)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	16.3%
Last Sales Surprise	-2.2%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	08/04/2020
Earnings ESP	0.0%
P/E TTM	0.3
P/E F1	0.4
PEG F1	0.0
P/S TTM	0.1

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	570 E	602 E	590 E	604 E	2,398 E
2020	666 A	628 E	650 E	694 E	2,638 E
2019	791 A	823 A	744 A	805 A	3,163 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.73 E	\$0.94 E	\$0.81 E	\$1.07 E	\$4.09 E
2020	\$1.64 A	\$1.22 E	\$1.42 E	\$1.66 E	\$5.91 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 07/02/2020. The reports text is as of 07/03/2020.

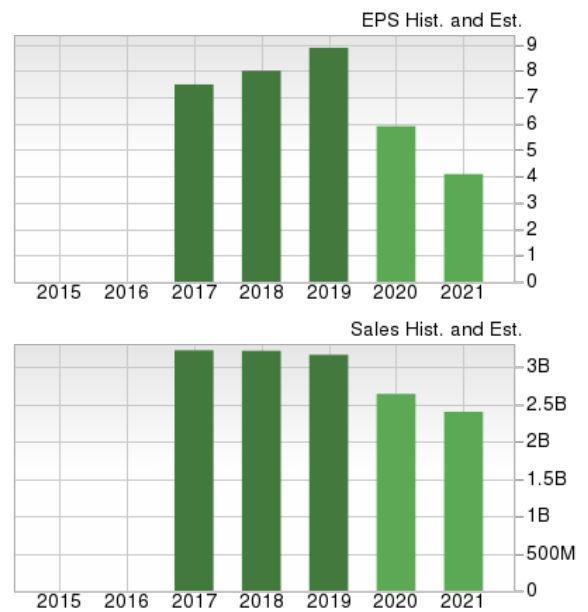
Overview

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. 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.

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:

▲ **Opioid Settlement A Relief:** Mallinckrodt recently announced that the company and its specialty generics-focused subsidiaries Mallinckrodt LLC and 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.

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

▲ **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.

▲ **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 and 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 recently initiated the rolling submission of a biologics license application (BLA) to the FDA for StrataGraft regenerative skin tissue, to treat adults with deep partial-thickness thermal burns.

Reasons To Sell:

▼ **Share Price Performance:** Mallinckrodt has underperformed the industry in the past year. The COVID-19 pandemic will adversely impact the company's business due to the stay-at-home orders, reduction of elective surgeries and a drop in overall patient procedures. The performance of Acthar gel, Therakos and Ofirmev will be more significant as these products are the most sensitive to the restrictions.

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

In March, the U.S. Attorney's office in Massachusetts announced its intervention in a lawsuit filed against the company alleging violations of the False Claims Act relating to the method to calculate Medicaid drug rebates for Acthar. Thereafter, the U.S. District Court for the District of Columbia ruled against Mallinckrodt in its lawsuit against the U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services (CMS) regarding the company's calculation of Medicaid drug rebates for Acthar.

▼ **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 stannosporfin 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 stannosporfin. 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.

▼ **High Debt Ratio:** As of Mar 31, 2020, Mallinckrodt's total debt-to-total capital ratio stood at 73.9X, which compares unfavorably with the industry's 45.6X. A higher debt ratio indicates higher financial risk and vice versa. Moreover, the company has cash, equivalents and marketable securities of \$808 million against long-term debt of \$4.8 billion. The huge levels of debt are concerning, as the company will not be able to pay this debt in case of insolvency.

Last Earnings Report

Mallinckrodt Q1 Earnings Beat Estimates, Sales Miss

Mallinckrodt reported adjusted earnings of \$1.64 per share in the first quarter, beating the Zacks Consensus Estimate of \$1.41 but decreasing from the year-ago quarter's \$1.94.

Net sales in the quarter came in at \$665.8 million, decreasing 15.8% year over year and missing the Zacks Consensus Estimate of \$678 million.

Quarter Ending **03/2020**

Report Date	May 05, 2020
Sales Surprise	-2.15%
EPS Surprise	16.31%
Quarterly EPS	1.64
Annual EPS (TTM)	8.64

Quarter in Detail

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

Specialty Brands' sales came in at \$490.6 million, down 18.8% year over year.

Acthar, Mallinckrodt's largest product, generated sales of \$167.6 million, down 25.1% year on year, primarily due to continued reimbursement challenges affecting new and returning patients, continued payer scrutiny on overall specialty pharmaceutical spending, and reduced patient demand due to the COVID-19 stay-at-home order.

Inomax, the company's second-largest product, generated sales of \$141.7 million, down 6.2% year over year due to increased competition for inhaled nitric oxide.

Ofirmev sales decreased 21.7% year over year to \$74.9 million due to significant quarter-to-quarter order variability and a reduction in elective surgeries due to public health orders and institutions focusing on responding to the COVID-19 pandemic.

Sales of the Therakos immunology platform came in at \$63.7 million, up 3.1%.

Amitza net sales were \$41.1 million, down 22.5% due to increased competition in the United States and the biennial price reduction in Japan.

Specialty Generics' sales amounted to \$175.2 million, down 6%.

Adjusted selling, general and administrative expenses were \$187.2 million, down from the year-ago quarter's \$211.4 million. Research and development expenses decreased to \$77.4 million from \$85.3 million owing to the completion of two phase III clinical trials in late 2019.

Guidance

Reduced patient demand due to the COVID-19 stay-at-home order started affecting the business toward the end of the first quarter and the company expects this impact to be more significant in the second quarter at least.

Litigation Update

In February 2020, Mallinckrodt announced an agreement in principle for a global resolution to its opioid litigation, subject to certain conditions. 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.

In March, the U.S. Attorney's office in Massachusetts announced its intervention in a lawsuit filed against the company alleging violations of the False Claims Act relating to the method to calculate Medicaid drug rebates for Acthar. Thereafter, the U.S. District Court for the District of Columbia ruled against Mallinckrodt in its lawsuit against the U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services (CMS) regarding the company's calculation of Medicaid drug rebates for Acthar.

Recent News

Update on Ongoing Acthar Litigation - Jun 15

Mallinckrodt received a setback in the ongoing litigation for Acthar. The U.S. Court of Appeals For The District Of Columbia has denied the company's request for a temporary injunction preventing the U.S. Centers For Medicare And Medicaid Services (CMS) from enforcing a change in Medicaid drug rebate calculation for Acthar (repository corticotropin injection). Mallinckrodt had asked for the temporary injunction as it appeals a lower court ruling that allowed CMS to reset the base date average manufacturer price (AMP).

As a result of today's appeals court ruling, Mallinckrodt will change the base date AMP for Acthar Gel, as directed by CMS. The effect of the change is an immediate recognition of retroactive non-recurring charges (estimated at approximately \$650 million through mid-June) and the prospective loss of Acthar Medicaid net sales, which has historically contributed to Acthar Gel net sales of \$90-\$100 million annually.

Completes Rolling Submission of BLA for StrataGraft – Jun 9

Mallinckrodt completed its rolling submission of a Biologics License Application ("BLA") to the FDA for StrataGraft, a regenerative skin tissue therapy in the development for the treatment of adult patients with deep partial-thickness thermal burns. The rolling submission was initiated in April. StrataGraft skin tissue is an investigational product, and its safety and effectiveness have not yet been established by the FDA.

Valuation

Mallinckrodt's shares are down 30.4% in the year-to-date period and down 73% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 8% but up 0.5% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 5.9% while the sector is up 4.1%.

The stock is currently trading at 0.49X forward 12-month earnings per share, which compares to 7.41X for the Zacks sub-industry, 22.81X for the Zacks sector and 22.24X for the S&P 500 index.

Over the past five years, the stock has traded as high as 15.22X and as low as 0.17X, with a 5-year median of 3.95X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$2.5 price target reflects 0.50X 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	0.49	7.41	22.81	22.24
	5-Year High	15.22	15.68	23.15	22.24
	5-Year Low	0.17	5.77	15.93	15.25
	5-Year Median	3.95	7.81	18.94	17.52
P/S F12M	Current	0.08	0.87	2.81	3.49
	5-Year High	3.71	3.9	3.74	3.49
	5-Year Low	0.03	0.72	2.21	2.53
	5-Year Median	0.92	1.22	2.9	3.02
P/B TTM	Current	0.11	1.1	4.33	4.29
	5-Year High	2.79	3.9	5.06	4.56
	5-Year Low	0.04	0.73	2.93	2.83
	5-Year Median	0.61	1.29	4.28	3.69

As of 07/02/2020

Industry Analysis Zacks Industry Rank: Top 22% (56 out of 252)



Top Peers

Company (Ticker)	Rec	Rank
Supernus Pharmaceuticals, Inc. (SUPN)	Outperform	2
Amphastar Pharmaceuticals, Inc. (AMPH)	Neutral	3
ASPEN PHARMACR (APNHY)	Neutral	2
Bausch Health Cos Inc. (BHC)	Neutral	3
Endo International plc (ENDP)	Neutral	3
Personalis, Inc. (PSNL)	Neutral	4
Dr. Reddys Laboratories Ltd (RDY)	Neutral	2
Voyager Therapeutics, Inc. (VYGR)	Neutral	2

Industry Comparison Industry: Medical - Generic Drugs				Industry Peers		
	MNK	X Industry	S&P 500	APNHY	ENDP	RDY
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	2	3	2
VGM Score	A	-	-	A	A	B
Market Cap	205.23 M	348.71 M	21.98 B	3.85 B	801.67 M	8.76 B
# of Analysts	8	4	14	1	9	2
Dividend Yield	0.00%	0.00%	1.91%	0.00%	0.00%	0.50%
Value Score	A	-	-	A	A	C
Cash/Price	3.45	0.31	0.07	NA	2.19	0.04
EV/EBITDA	-12.48	-2.83	12.74	NA	9.06	20.20
PEG Ratio	0.03	0.62	2.89	NA	NA	NA
Price/Book (P/B)	0.11	3.04	2.98	1.01	NA	4.26
Price/Cash Flow (P/CF)	0.12	2.92	11.75	7.06	0.67	13.94
P/E (F1)	0.41	6.95	21.41	8.98	1.55	28.82
Price/Sales (P/S)	0.07	2.69	2.30	NA	0.27	3.59
Earnings Yield	243.21%	-11.94%	4.42%	11.14%	64.47%	3.48%
Debt/Equity	2.50	0.01	0.76	NA	-11.38	0.01
Cash Flow (\$/share)	20.20	-0.31	6.94	1.19	5.21	3.79
Growth Score	A	-	-	B	A	B
Hist. EPS Growth (3-5 yrs)	1.99%	1.99%	10.93%	NA	-14.71%	4.60%
Proj. EPS Growth (F1/F0)	-33.50%	-2.35%	-9.56%	6.82%	-5.32%	-34.23%
Curr. Cash Flow Growth	10.71%	3.14%	5.51%	-19.79%	-15.98%	40.31%
Hist. Cash Flow Growth (3-5 yrs)	10.87%	6.59%	8.62%	NA	2.66%	5.28%
Current Ratio	1.46	2.86	1.30	NA	2.03	1.79
Debt/Capital	71.43%	6.05%	44.46%	NA	NA	0.82%
Net Margin	-39.56%	-40.08%	10.62%	NA	-9.09%	11.15%
Return on Equity	29.14%	-43.33%	15.75%	NA	-91.00%	19.83%
Sales/Assets	0.30	0.33	0.55	NA	0.31	0.77
Proj. Sales Growth (F1/F0)	-16.59%	0.13%	-2.54%	-0.17%	-3.12%	0.25%
Momentum Score	A	-	-	C	D	C
Daily Price Chg	-2.80%	-0.43%	0.47%	0.24%	-0.57%	1.11%
1 Week Price Chg	7.36%	-0.54%	-3.90%	0.72%	-1.71%	-1.86%
4 Week Price Chg	-13.52%	-0.17%	-3.77%	-0.94%	-12.31%	-0.17%
12 Week Price Chg	-33.61%	12.27%	8.02%	41.37%	-6.68%	12.82%
52 Week Price Chg	-72.97%	-2.91%	-7.59%	15.93%	-24.30%	39.78%
20 Day Average Volume	3,610,774	330,742	2,649,865	5,755	6,181,447	198,700
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 12 week change	-8.95%	-3.44%	-9.53%	9.94%	-1.93%	-5.17%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	0.00%	NA	0.00%	NA

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	A
Momentum Score	A
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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