

Alkermes plc (ALKS)

\$18.58 (As of 08/10/20)

Price Target (6-12 Months): **\$20.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 12/31/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:B

Value: C

Growth: B

Momentum: A

Summary

Alkermes reported better-than-expected sales in the second quarter. The company remains focused on the commercial execution of its proprietary products — Vivitrol and Aristada. The FDA also accepted the NDA for ALKS 3831 for both schizophrenia and bipolar I disorder indications and set an action date of Nov 15, 2020. A potential approval and the launch of ALKS 3831 will be a significant boost for the company. The company aims to maximize the opportunities for both Aristada and Vivitrol and is preparing to leverage its commercial infrastructure with the potential launch of ALKS 3831. The company also plans to advance the development of ALKS 4230. However, Alkermes is highly dependent on manufacturing and/or royalty revenues from partners, which is a concern. Shares have underperformed the industry year to date.

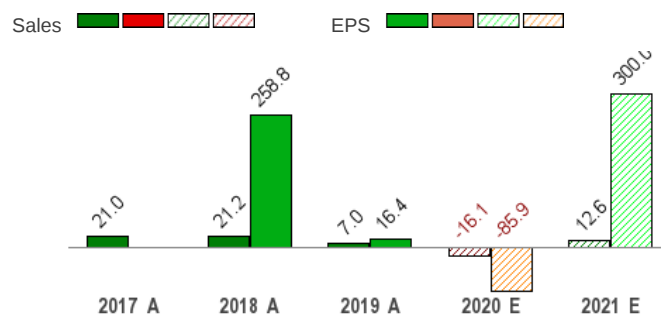
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$23.22 - \$11.98
20 Day Average Volume (sh)	1,535,045
Market Cap	\$3.0 B
YTD Price Change	-9.0%
Beta	1.43
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 48% (122 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	700.0%
Last Sales Surprise	3.6%
EPS F1 Est- 4 week change	50.5%
Expected Report Date	10/28/2020
Earnings ESP	-185.7%
P/E TTM	21.6
P/E F1	185.8
PEG F1	8.0
P/S TTM	2.5

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	256 E	262 E	279 E	274 E	1,106 E
2020	246 A	248 A	240 E	252 E	982 E
2019	223 A	280 A	255 A	413 A	1,171 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.02 E	\$0.04 E	\$0.07 E	\$0.05 E	\$0.40 E
2020	\$0.01 A	\$0.06 A	-\$0.01 E	\$0.04 E	\$0.10 E
2019	-\$0.17 A	\$0.09 A	-\$0.04 A	\$0.83 A	\$0.71 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 08/10/2020. The reports text is as of 08/11/2020.

Overview

Dublin, Ireland-based Alkermes plc was formed by the Sep 2011 merger of Waltham, MA-based Alkermes, Inc. and Elan Drug Technologies (EDT), the drug delivery unit of Elan Corporation, plc. Elan was acquired by Perrigo in 2013. The combined entity is a fully integrated global biopharmaceutical company that utilizes proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products to address unmet medical needs of patients in major therapeutic areas. Alkermes holds a diversified product portfolio and a promising pipeline of candidates targeting major central nervous system (CNS) disorders including schizophrenia, depression, addiction and multiple sclerosis.

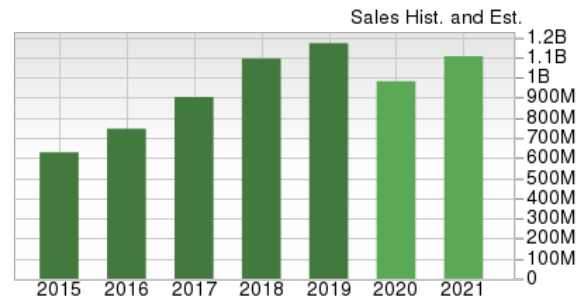
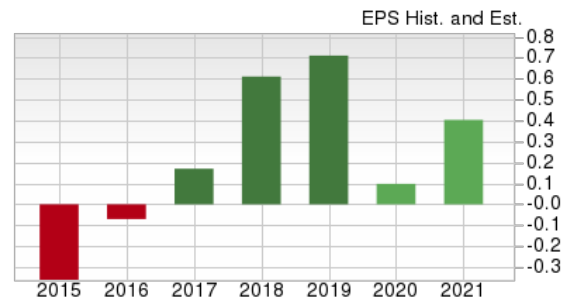
Alkermes derives revenues on net sales of its proprietary products – Vivitrol (alcohol and opioid dependence) and Aristada (schizophrenia), and manufacturing and/or royalty revenues on net sales of products commercialized by the company's partners. These include Risperdal Consta (schizophrenia and bipolar I disorder), Invega Sustenna (schizophrenia and schizoaffective disorder)/Xeplion (schizophrenia), Invega Trinza/Trevicta (schizophrenia), Ampyra/Fampyra (to improve walking in patients with multiple sclerosis) and Bydureon (type II diabetes).

In October 2019, the FDA granted approval to Vumerity (dioximel fumarate), being developed in collaboration with Biogen to treat relapsing forms of multiple sclerosis (MS).

Further, Alkermes has a robust pipeline. Interesting late-stage candidates in the company's pipeline include ALKS 5461 (major depressive disorder/MDD), and ALKS 3831 (schizophrenia).

The company's proprietary drugs – Vivitrol and Aristada – generated more than 28.6% and 16.2%, respectively, of the total revenues in 2019. Vivitrol posted sales of \$335.4 million, up 9.8%. Sales of Aristada increased 28% to 189.1 million in 2019.

In 2019, Alkermes reported total revenues of \$1.17 billion, up 7% year over year.



Reasons To Buy:

▲ **Strong Product Portfolio:** Alkermes' revenues are being driven by its proprietary products, Vivitrol and Aristada, and the some partnered products – Risperdal Consta, Invega Sustenna/Xeplion, Invega Trinza/Trevicta, and Ampyra/Fampyra. We expect these products to continue contributing to the company's top-line growth in the coming quarters. Vumerity (diroximel fumarate) is being developed in collaboration with Biogen to treat relapsing forms of multiple sclerosis (MS). In October 2019, the FDA granted approval to Vumerity, positioning Biogen for potential commercial launch in early 2020. Alkermes received a \$150 million milestone payment from Biogen following the FDA approval of the NDA for the same. The company may also receive a mid-teens percentage royalty on worldwide net sales. Further, Alkermes is also conducting the EVOLVE-MS-2 study, a five-week, head-to-head gastrointestinal (GI) tolerability study evaluating Vumerity versus dimethyl fumarate.

Alkermes' strong product portfolio and pipeline progress have been impressive. Divestment and restructuring initiatives are also a positive for the company.

Alkermes continues to witness robust sales of Vivitrol in both the Medicaid and commercial setting. The company expects Vivitrol to be the primary growth driver.

On the other hand, Aristada is growing impressively in a long-acting injectable (LAI) market. The United States LAI market could cross \$4 billion in 2020.. The approval of Aristada Initio makes Aristada the first and only long-acting atypical antipsychotic that can be initiated on day one, which plays a significant role to treat a complex disease like schizophrenia. The launch of Aristada Initio continues to gain traction as payers and providers recognize the value proposition of this important new offering, particularly in combination with the Aristada two-month dose that provides the unique ability to fully dose a patient on day one for up to two months.

▲ **Promising Pipeline:** Alkermes' pipeline has expanded significantly following the acquisition of the EDT unit. The company's progress with pipeline candidates targeting major CNS disorders, such as schizophrenia, addiction, depression and multiple sclerosis, has been impressive. An important pipeline candidate is ALKS 5461 being developed for the treatment of MDD. In January 2018, a new drug application (NDA) was submitted to the FDA for ALKS 5461 and the same was accepted for review by the FDA in April 2018. If approved, this would be the first therapeutic option for patients with depression with a novel mechanism of action. Other interesting candidates include ALKS 3831. The ALKS 3831 NDA for schizophrenia and bipolar I disorder is currently under review with the FDA with a target action date of Nov 15, 2020.

Another important candidate in Alkermes' pipeline is cancer immunotherapy ALKS 4230, which is being evaluated under ARTISTRY Clinical Development Program in patients with advanced solid tumors. The company is developing ALKS 4230 in three distinct stage under ARTISTRY-1 program, an ongoing monotherapy dose-escalation stage, a monotherapy expansion stage and an ongoing combination therapy stage with the Merck's PD-1 inhibitor Keytruda (pembrolizumab) – in patients with select advanced solid tumors. The ARTISTRY-2 program has two phase I/II studies evaluating subcutaneous administration of ALKS 4230 as monotherapy and in combination with Merck's Keytruda in patients with advanced solid tumors. In February 2019, Alkermes signed a collaboration to evaluate ALKS 4230 in combination with Clovis Oncology's PARP inhibitor Rubraca (rucaparib), and lucitanib across multiple tumor types. In November 2019, Alkermes presented preliminary clinical data from the ARTISTRY-1 phase I/II study investigating intravenous administration of ALKS 4230 and preliminary safety data from the ARTISTRY-2 phase I/II study.

Successful development and subsequent commercialization of these candidates would be a huge boost for the company.

▲ **Acquisition of Rodin Therapeutics, a Boost:** Alkermes acquired Rodin Therapeutics, Inc., a privately held biopharmaceutical company in November 2019. This transaction builds on Alkermes' experience in central nervous system (CNS) diseases and expands Alkermes' CNS development efforts into a wide range of neurodegenerative disorders.

Alkermes plans to advance investigational new drug (IND)-enabling activities for lead preclinical assets in the Rodin development candidate portfolio. Alkermes also intends to continue Rodin's preclinical research program focused on the subset of frontotemporal dementia patients with an inherited mutation of the progranulin gene (FTD-GRN) and exploratory work in hematological disorders and oncology.

▲ **Favorable Debt Profile:** Alkermes has a favorable debt profile. As of June 30, 2020, the company's debt to total capital stood at 21.5, slightly lower than 21.6 at the end of March 31, 2020. A lower ratio indicates lower financial risk. The company's total debt (current and long-term debt) was approximately \$291 million as of June end. The company's cash, cash equivalents, and marketable securities of approximately \$533 million at the end of June 2020 should be sufficient to pay the debt in case of insolvency.

Reasons To Sell:

▼ **Pipeline Setbacks:** Gaining approval for pipeline candidates has become difficult with an increasingly stringent regulatory environment. Any unfavorable outcome on the regulatory front or the ongoing development programs would have an adverse impact on the shares. Alkermes is no stranger to pipeline setbacks.

Alkermes' heavy dependence on partners for revenues is concerning. Pipeline setbacks are also matters for concern.

In February 2019, the FDA issued a Complete Response Letter ("CRL") related to its new drug application ("NDA") for ALKS 5461. The NDA sought approval for the candidate as an adjunctive treatment of major depressive disorder ("MDD"). The regulatory authority refused approval, due to a lack of evidence supporting efficacy of the oral medication. The CRL is likely to delay or result in a missed opportunity for the company.

The FDA requested for additional clinical data to demonstrate substantial evidence of effectiveness of ALKS 5461 for the proposed indication. The company is planning to meet with the FDA to discuss the issues raised in the CRL and future steps related to the development of the candidate.

On Apr 16, 2018, the FDA accepted for review the NDA for ALKS 5461. The FDA had initially issued a Refusal to File letter on Mar 30 for the candidate, stating that the NDA did not have enough evidence for the oral medication to work. The FDA suggested that additional studies might be required to demonstrate the drug's overall effectiveness for the proposed indication.

▼ **High Dependence on Partners:** Alkermes is highly dependent on manufacturing and/or royalty revenues on sales of products that are commercialized by the company's partners. For instance, Johnson and Johnson's Janssen is responsible for the commercialization of Risperdal Consta, Invega Sustenna/Xeplon, Invega Trinza and Vivitrol in Russia and certain Commonwealth of Independent States countries, while Ampyra is marketed by Acorda Therapeutics in the United States and Biogen in the ex-United States' markets. On the other hand, AstraZeneca is responsible for the commercialization of Bydureon. Partnership-related setbacks may weigh heavily on the company. Particularly, any significant negative development related to these products, or to the company's licensing agreements, could have a material adverse effect on its top-line growth. For instance, manufacturing and royalty business recorded a year-over-over decline in third-quarter 2016 due to lower sales of Risperdal Consta, Ampyra and Bydureon by the company's partners.

Last Earnings Report

Alkermes' Q2 Earnings & Revenues Surpass Estimates

Alkermes reported adjusted earnings of 6 cents per share in the second quarter of 2020, lower than earnings of 9 cents reported in the year-ago quarter. The Zacks Consensus Estimate was pegged at a loss of a cent.

The company's revenues of \$247.5 million in the quarter decreased 13.1% from the year-ago quarter. The top line beat the Zacks Consensus Estimate of \$239 million. During the second quarter, the performance of the Aristada product family, together with disciplined management of expenses, partially offset the negative impact on Vivitrol net sales that resulted from COVID-19-related decreases in patient visits to healthcare providers and treatment centers.

Quarter Ending 06/2020

Report Date	Jul 29, 2020
Sales Surprise	3.61%
EPS Surprise	700.00%
Quarterly EPS	0.06
Annual EPS (TTM)	0.86

Quarter Details

Total manufacturing and royalty revenues were up 9.8% year over year to \$116.5 million. Manufacturing and royalty revenues from J&J's (JNJ) drugs — Risperdal Consta, Invega Sustenna/Xeplion and Invega Trinza/Trevicta — were \$83.1 million, down 9.6% year over year.

Vivitrol sales decreased about 19% year over year to \$71.6 million. The decline resulted from reduced new patient starts and more restricted access to healthcare providers due to COVID-19-related disruptions.

Aristada sales came in at \$58.8 million, up 21% year over year, driven primarily by increased breadth of the Aristada provider base and growth in the drug's two-month dose.

Research and development (R&D) expenses were \$94.2 million, down 9.8% year over year.

Selling, general and administrative (SG&A) expenses were \$132 million, down 17.5% year over year.

2020 Guidance

The expectations for 2020 reflect the anticipated net impacts of the COVID-19 pandemic on Alkermes' operating and financial results. The company expects that the negative impact of COVID-19 on Vivitrol net sales will be partially offset by a decrease in operating expenses, notably within R&D.

The company now expects total revenues of \$965-\$1,005 million, down from the previous expectation of \$1,030-\$1,080 million. It expects Vivitrol net sales of \$270-\$300 million, down from the prior expectations of \$340-\$355 million. Aristada net sales are expected to be \$220-\$235 million, same as the prior expectation.

Earnings are expected between break-even and 19 cents, down from the earlier expectation of 25 cents- 43 cents per share.

Recent News

Publishes Data from Alkermes' ALPINE Study in Patients with Schizophrenia-May 20

Alkermes announced that data from its phase IIb ALPINE study were published in the *Journal of Clinical Psychiatry*. ALPINE was a six-month study evaluating the efficacy and safety of the Aristada Initio (aripiprazole lauroxil) one-day initiation regimen, consisting of Aristada Initio and one single dose of 30 mg of oral aripiprazole, together with the Aristada two-month dose in patients experiencing an acute exacerbation of schizophrenia. Positive topline data were first reported in April 2019. Results from the study provide evidence to support the use of the Aristada Initio one-day regimen together with Aristada for treatment of an acute exacerbation of schizophrenia, started in the hospital setting and continued through the critical transition to outpatient care.

Valuation

Alkermes' shares were down 9.06% in the year-to-date period and were down 13.8% over the trailing 12-month period. Stocks in the Zacks sub-industry are up 5.3% while stocks in the Zacks sector are up 0.6% in the year-to-date period. Over the past year, stocks in the sub-industry and the sector are up 18.5% and up 8.6%, respectively.

The S&P 500 Index is up 4.1% in the year-to-date period and up 16.7% in the past year.

The stock is currently trading at 2.54X trailing 12-month sales per share, which compares to 3.43X for the Zacks sub-industry, 3.09X for the Zacks sector and 3.76X for the S&P 500 index.

Over the past five years, the stock has traded as high as 18.99X and as low as 1.76X, with a 5-year median of 8.14X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$20.00 price target reflects 2.73X trailing 12-month sales per share.

The table below shows summary valuation data for ALKS.

Valuation Multiples - ALKS					
		Stock	Sub-Industry	Sector	S&P 500
P/S TTM	Current	2.54	3.43	3.09	3.76
	5-Year High	18.99	4.98	3.99	3.76
	5-Year Low	1.76	2.24	2.29	2.43
	5-Year Median	8.14	3.21	3.19	3.21
P/B TTM	Current	2.78	2.89	4.39	4.68
	5-Year High	9.06	6.01	5.07	4.68
	5-Year Low	1.9	2.06	2.94	2.83
	5-Year Median	5.7	3.87	4.3	3.74

As of 08/10/2020

Industry Analysis Zacks Industry Rank: Top 48% (122 out of 253)



Top Peers

Company (Ticker)	Rec	Rank
Bayer Aktiengesellschaft (BAYRY)	Neutral	3
Biogen Inc. (BIIB)	Neutral	3
Bristol Myers Squibb Company (BMY)	Neutral	3
Eli Lilly and Company (LLY)	Neutral	3
Novartis AG (NVS)	Neutral	3
Pfizer Inc. (PFE)	Neutral	3
Roche Holding AG (RHHBY)	Neutral	2
Sanofi (SNY)	Neutral	3

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	ALKS	X Industry	S&P 500	BIIB	LLY	RHHBY
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	3	3	2
VGM Score	B	-	-	A	A	A
Market Cap	2.95 B	274.23 M	23.56 B	47.54 B	146.34 B	293.12 B
# of Analysts	9	3	14	27	6	4
Dividend Yield	0.00%	0.00%	1.71%	0.00%	1.93%	1.68%
Value Score	C	-	-	A	B	B
Cash/Price	0.18	0.22	0.07	0.09	0.02	0.04
EV/EBITDA	-26.15	-3.99	13.39	6.54	24.47	13.34
PEG Ratio	7.93	1.97	2.92	0.85	1.39	2.84
Price/Book (P/B)	2.78	4.20	3.18	4.21	34.26	8.12
Price/Cash Flow (P/CF)	31.94	17.48	12.69	7.77	21.60	13.39
P/E (F1)	183.50	28.59	22.16	8.46	21.71	15.95
Price/Sales (P/S)	2.54	16.56	2.55	3.28	6.38	NA
Earnings Yield	0.54%	-12.91%	4.33%	11.83%	4.61%	6.26%
Debt/Equity	0.26	0.01	0.77	0.69	3.53	0.35
Cash Flow (\$/share)	0.58	-1.07	6.94	38.63	7.08	3.20
Growth Score	B	-	-	A	A	A
Hist. EPS Growth (3-5 yrs)	NA%	17.80%	10.41%	17.80%	17.69%	NA
Proj. EPS Growth (F1/F0)	-86.23%	14.59%	-6.51%	5.78%	16.67%	5.61%
Curr. Cash Flow Growth	-4.72%	14.86%	5.26%	9.02%	-7.51%	11.61%
Hist. Cash Flow Growth (3-5 yrs)	-0.32%	7.73%	8.55%	11.97%	9.27%	9.89%
Current Ratio	2.95	5.72	1.34	2.46	1.22	1.30
Debt/Capital	20.46%	3.40%	44.59%	40.98%	77.91%	26.10%
Net Margin	-10.87%	-201.60%	10.13%	40.91%	24.48%	NA
Return on Equity	4.47%	-60.39%	14.59%	50.10%	183.80%	NA
Sales/Assets	0.65	0.19	0.51	0.54	0.57	NA
Proj. Sales Growth (F1/F0)	-15.19%	6.99%	-1.54%	-2.52%	6.61%	8.33%
Momentum Score	A	-	-	B	B	B
Daily Price Chg	-0.64%	0.25%	0.91%	-1.78%	0.05%	-0.49%
1 Week Price Chg	3.80%	3.55%	2.30%	11.29%	1.76%	-0.21%
4 Week Price Chg	-2.39%	3.84%	8.54%	8.59%	-5.60%	-3.15%
12 Week Price Chg	12.78%	5.03%	13.68%	-4.95%	-3.14%	-5.16%
52 Week Price Chg	-13.85%	12.67%	3.71%	30.00%	34.78%	22.67%
20 Day Average Volume	1,535,045	338,637	2,015,804	1,219,254	2,788,418	1,106,343
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	50.53%	0.00%	1.67%	7.01%	7.17%	2.29%
(F1) EPS Est 12 week change	50.53%	0.55%	2.27%	7.18%	7.27%	3.37%
(Q1) EPS Est Mthly Chg	62.70%	0.00%	0.67%	1.19%	-0.19%	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	C
Growth Score	B
Momentum Score	A
VGM Score	B

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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