

Alkermes plc (ALKS)

\$20.84 (As of 03/02/20)

Price Target (6-12 Months): **\$22.00**

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: A

Momentum: F

Summary

Alkermes reported impressive fourth-quarter results wherein both earnings and sales beat estimates. 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 the and a potential approval will be a significant boost for the company and 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 in the past year.

Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$37.75 - \$16.65
20 Day Average Volume (sh)	2,214,001
Market Cap	\$3.4 B
YTD Price Change	4.1%
Beta	1.56
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 40% (102 out of 255)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	25.8%
Last Sales Surprise	1.1%
EPS F1 Est- 4 week change	-200.0%
Expected Report Date	04/23/2020
Earnings ESP	0.0%
P/E TTM	29.9
P/E F1	63.2
PEG F1	2.7
P/S TTM	2.9

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	253 E	300 E	300 E	320 E	1,186 E
2020	225 E	269 E	266 E	285 E	1,043 E
2019	223 A	280 A	255 A	413 A	1,171 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.04 E	\$0.11 E	\$0.11 E	\$0.14 E	\$0.60 E
2020	-\$0.09 E	\$0.12 E	\$0.10 E	\$0.17 E	\$0.33 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 03/02/2020. The reports text is as of 03/03/2020.

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.

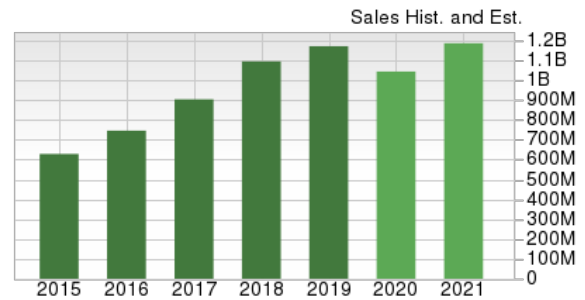
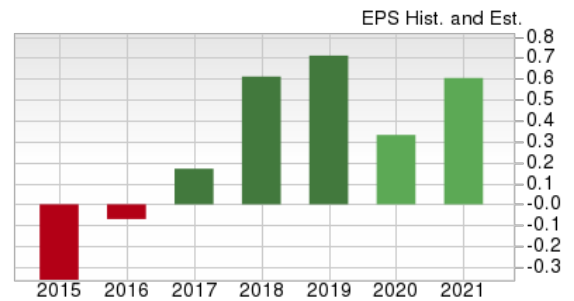
Alkermes derives revenues on net sales of its proprietary products – Vivitrol (alcohol and opioid dependence) and Aristada (schizophrenia), and manufacturing and/or royalty revenues on net sales of products commercialized by the company's partners. These include Risperdal Consta (schizophrenia and bipolar 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% and 16%, respectively, of the total revenues in 2018. 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. In 2020, the company expects a new stream of royalty revenues from Vumerity. 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. On Jul 2, 2018, the FDA approved Aristada Initio (aripiprazole lauroxil) extended-release product for the treatment of schizophrenia in adults. 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. In November 2019, the company submitted a new drug application (NDA) to the FDA seeking approval of ALKS 3831 for the treatment of schizophrenia and bipolar I disorder. Alkermes is seeking approval of fixed dosage strengths of ALKS 3831 composed of 10 mg of samidorphan co-formulated with 5 mg, 10 mg, 15 mg or 20 mg of Zyprexa. In July, after a pre-NDA meeting with the FDA, the company announced its plans to expand the NDA for the candidate to include the treatment of bipolar I disorder in addition to that for schizophrenia. Approval of the additional indication will help Alkermes gain access to a broader section of patients. In Jan 2020, the FDA accepted the company's NDA for the same and set an 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.

- ▲ **Restructuring Initiative to Save Costs:** In October, Alkermes announced a restructuring plan to reduce costs, improve cost structure and focus on growth opportunities. The company stated that the plan will likely result in cost savings of approximately \$150 million. It will cut 160 jobs as part of the plan.

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.

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.

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

Last Earnings Report

Alkermes' Earnings and Revenues Beat Estimates in Q4

Alkermes reported adjusted earnings of 83 cents per share in the fourth quarter of 2019 compared with earnings of 34 cents in the year-ago quarter. Earnings beat the Zacks Consensus Estimate of 66 cents.

The company's revenues of \$412.7 million in the quarter increased 30.7% from the year-ago quarter. The top line beat the Zacks Consensus Estimate of \$408 million. The company's proprietary products — Vivitrol and Aristada — drove revenues.

Quarter Ending **12/2019**

Report Date	Feb 13, 2020
Sales Surprise	1.14%
EPS Surprise	25.76%
Quarterly EPS	0.83
Annual EPS (TTM)	0.71

Factors Impacting Q4

Manufacturing and royalty revenues from J&J's drugs — Risperdal Consta, Invega Sustenna/Xeplion and InvegaTrinza/Trevicta — were \$107.3 million, down 35.9% year over year. Total revenues also included a \$150-million milestone payment from Biogen related to the FDA approval of Vumerity, of which \$144.8 million were recorded as license revenues and \$5.2 million were recorded as research and development revenues.

Vivitrol sales improved about 10.7% year over year to \$92.8 million.

Aristada sales came in at \$56.7 million, up 16.3% year over year.

Research and development (R&D) expenses were \$198.2 million, up 81.8% year over year.

Selling, general and administrative (SG&A) expenses were \$154.5 million, up 9.4% year over year.

2019 Results

The company recorded earnings of 71 cents per share compared with 63 cents in 2018.

The company's revenues increased 7% year over year to \$1.17 billion.

Restructuring Update

During the quarter, Alkermes implemented a strategic restructuring to reduce cost structure and, in turn, accelerate and drive sustained profitability. The company implemented a restructuring design to deliver savings of about \$150 million in 2020 with about one-third related to R&D and two-thirds driven by SG&A.

2020 Guidance

The company expects total revenues of \$1.03-\$1.08 billion. The midpoint of the guided range is \$1.06 billion, which is below the Zacks Consensus Estimate of \$1.07 billion.

Alkermes expects Vivitrol net sales of \$340-\$355 million and Aristada net sales of \$220-\$235 million.

The company expects R&D expenses of \$405-\$430 million. SG&A expenses are expected to be \$535-\$560 million.

The company expects adjusted earnings per share of \$25-\$43 cents, based on a weighted average share count of approximately 161 million shares outstanding. The Zacks Consensus Estimate for 2020 earnings is pegged at 45 cents.

Pipeline Update

The company submitted a new drug application to the FDA for ALKS 3831 for the treatment of schizophrenia and bipolar I disorder. The NDA was also accepted by the FDA.

During the quarter, the company acquired Rodin Therapeutics, building on its experience in CNS diseases and expanding its development efforts to a wide range of neurodegenerative disorders.

Recent News

Alkermes' NDA for ALKS 3831 Accepted by FDA for Review-Jan 28

Alkermes new drug application (NDA) seeking approval of ALKS 3831 (olanzapine/samidorphan) for the treatment of schizophrenia and for the treatment of bipolar I disorder has been accepted by the FDA for review. The NDA has been given an action date of Nov 15, 2020.

Schizophrenia is a chronic, severe and disabling brain disorder. Bipolar disorder is a brain disorder that causes unusual shifts in a person's mood, energy and ability to function.

The NDA for ALKS 3831 includes data from the completed ENLIGHTEN clinical development program in patients with schizophrenia and the pharmacokinetic (PK) bridging data comparing ALKS 3831 with Eli Lilly & Co.'s Zyprexa (olanzapine).

The NDA includes data to support the treatment of manic or mixed episodes associated with bipolar I disorder, with ALKS 3831 as a monotherapy, or adjunct to lithium or valproate, and the maintenance treatment of bipolar I disorder.

Approval of the additional indication will help Alkermes gain access to a broader patient population.

We remind investors that in July 2019, after a pre-NDA meeting with the FDA, Alkermes planned to expand the NDA for ALKS 3831 to include the treatment of bipolar I disorder in addition to that of schizophrenia. In November 2019, the company submitted an NDA to the FDA seeking approval of the candidate for the treatment of both diseases. Alkermes is seeking approval of fixed dosage strengths of ALKS 3831 composed of 10 mg of samidorphan co-formulated with 5 mg, 10 mg, 15 mg or 20 mg of Zyprexa.

Completes the Acquisition of Rodin Therapeutics-Nov 25

Alkermes announced that it has completed its previously announced acquisition of Rodin Therapeutics, Inc. , a privately held biopharmaceutical company. 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.

At the closing of the transaction, Alkermes made an upfront cash payment of \$100 million (subject to customary adjustments) to Rodin's former security holders.

Under the terms of the definitive agreement between Alkermes and Rodin, and subject to the conditions and adjustments set forth therein, Rodin's former security holders are eligible to receive future payments of up to \$850 million upon achievement by Rodin's development candidates of certain specified clinical and regulatory milestones, and attainment of certain sales thresholds.

Announces Receipt of \$150 Million Milestone Payment from Biogen-Nov 12

Alkermes announced the receipt of a \$150 million milestone payment from Biogen triggered by the recent FDA approval of Vumerity (dioxime fumarate), a novel oral fumarate with a distinct chemical structure, for the treatment of relapsing forms of multiple sclerosis, and Alkermes' transfer to Biogen Inc. of the new drug application and other regulatory documentation related to Vumerity. Alkermes' financial expectations for 2019, provided on Oct. 23, 2019, reflect this milestone payment. The company will record substantially all of the milestone payment as license revenue in the fourth quarter of 2019.

Valuation

Alkermes' shares are up 4.1% in the year-to-date period and down 37.2% over the trailing 12-month period. Stocks in the Zacks sub-industry are down 4.4% and stocks in the Zacks Medical sector are down 3.9% in the year-to-date period. Over the past year, the Zacks sub-industry is down 6.9% while the sector is down 2.2%.

The S&P 500 index is down 3.8% in the year-to-date period and up 11.9% in the past year.

The stock is currently trading at 2.86X trailing 12-month sales per share, which compares to 2.79X for the Zacks sub-industry, 3.02X for the Zacks sector and 3.33X for the S&P 500 index.

Over the past five years, the stock has traded as high as 18.99X and as low as 2.31X, with a 5-year median of 9.71X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$22.00 price target reflects 2.96X forward 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	2.86	2.79	3.02	3.33
	5-Year High	18.99	5.04	4.17	3.65
	5-Year Low	2.31	2.13	2.73	2.48
	5-Year Median	9.71	2.66	3.27	3.15
	Current	3.08	3.85	4.39	4.14
P/B TTM	5-Year High	9.06	5.8	5.05	4.54

P/D Ratio	5-Year High	3.00	3.0	3.03	4.34
	5-Year Low	2.49	2.44	3.44	2.85
	5-Year Median	6.06	3.28	4.32	3.62

As of 03/02/2020

Industry Analysis Zacks Industry Rank: Top 40% (102 out of 255)



Top Peers

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

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	ALKS Neutral	X Industry	S&P 500	BIIB Neutral	LLY Neutral	RHHBY Neutral
VGM Score	B	-	-	A	C	A
Market Cap	3.35 B	191.13 M	22.14 B	57.07 B	127.05 B	282.16 B
# of Analysts	8	3	13	27	6	4
Dividend Yield	0.00%	0.00%	1.98%	0.00%	2.23%	1.65%
Value Score	C	-	-	A	C	B
Cash/Price	0.16	0.23	0.05	0.08	0.02	0.04
EV/EBITDA	-29.99	-3.29	12.79	7.36	21.38	12.84
PEG Ratio	2.72	1.78	1.92	1.22	1.66	2.48
Price/Book (P/B)	3.08	3.87	3.00	4.44	47.25	7.82
Price/Cash Flow (P/CF)	36.53	12.42	11.97	8.49	18.75	12.89
P/E (F1)	62.97	33.44	17.43	10.02	19.62	15.52
Price/Sales (P/S)	2.86	13.62	2.48	3.97	5.69	NA
Earnings Yield	1.55%	-16.19%	5.74%	9.98%	5.10%	6.43%
Debt/Equity	0.25	0.02	0.70	0.37	5.30	0.35
Cash Flow (\$/share)	0.58	-1.09	6.94	38.63	7.08	3.20
Growth Score	A	-	-	B	C	A
Hist. EPS Growth (3-5 yrs)	NA%	18.12%	10.85%	16.51%	16.64%	NA
Proj. EPS Growth (F1/F0)	-53.35%	4.61%	6.48%	-2.54%	12.09%	4.53%
Curr. Cash Flow Growth	-4.72%	14.26%	6.03%	9.02%	-7.51%	11.61%
Hist. Cash Flow Growth (3-5 yrs)	-0.32%	8.17%	8.52%	11.97%	9.27%	9.89%
Current Ratio	2.46	4.92	1.23	1.72	1.16	1.30
Debt/Capital	20.17%	4.29%	42.57%	26.75%	84.13%	26.10%
Net Margin	-16.79%	-227.76%	11.57%	40.96%	37.27%	NA
Return on Equity	1.58%	-67.18%	16.66%	46.51%	192.27%	NA
Sales/Assets	0.66	0.21	0.54	0.54	0.58	NA
Proj. Sales Growth (F1/F0)	-10.27%	14.10%	4.07%	-1.78%	7.94%	7.01%
Momentum Score	F	-	-	A	B	A
Daily Price Chg	1.92%	2.09%	3.82%	6.32%	5.32%	3.28%
1 Week Price Chg	2.96%	-9.92%	-12.06%	-8.41%	-11.20%	-9.40%
4 Week Price Chg	22.56%	-3.56%	-6.43%	20.23%	-5.79%	-1.60%
12 Week Price Chg	-2.30%	0.50%	-5.15%	10.94%	10.48%	7.31%
52 Week Price Chg	-37.25%	-17.61%	4.77%	0.19%	4.22%	18.42%
20 Day Average Volume	2,214,001	200,250	2,363,047	2,132,815	3,767,009	1,926,389
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.07%	0.00%	0.00%
(F1) EPS Est 4 week change	-200.00%	0.00%	-0.04%	0.47%	0.20%	0.00%
(F1) EPS Est 12 week change	-257.14%	0.00%	-0.33%	-0.86%	2.94%	1.63%
(Q1) EPS Est Mthly Chg	-566.67%	0.00%	-0.38%	-0.38%	-0.61%	NA

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	A
Momentum Score	F
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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