

ACADIA Pharmaceuticals (ACAD)

\$48.90 (As of 04/17/20)

Price Target (6-12 Months): **\$53.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 01/30/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:D

Value: F

Growth: B

Momentum: C

Summary

ACADIA's sole marketed drug Nuplazid has recorded strong sales since its launch and has grown steadily in 2019. The drug's label expansion program also looks promising with several studies currently underway targeting various CNS disorders. ACADIA plans to file a supplemental new drug application for pimavanserin to address dementia-related psychosis later in 2020. If approved, it will expand the drug's eligible patient population and drive sales higher in the future. However, sole dependence on Nuplazid for revenues remains a concern. Any regulatory and developmental setback will hurt the stock severely. Moreover, lack of collaboration contracts remains a woe. Shares have outperformed the industry year to date. Loss estimates have widened ahead of Q1 earnings. ACADIA has a mixed record of earnings surprises in the recent quarters.

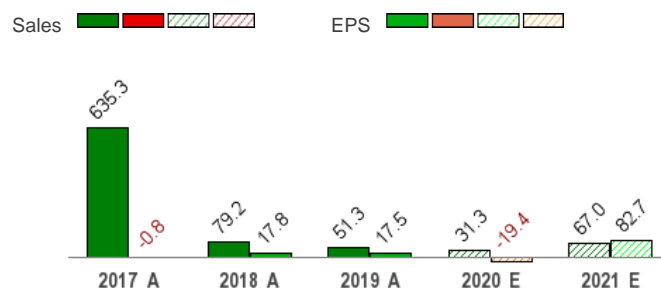
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$53.70 - \$21.56
20 Day Average Volume (sh)	1,218,604
Market Cap	\$7.6 B
YTD Price Change	14.3%
Beta	1.95
Dividend / Div Yld	\$0.00 / 0.0%
Industry	<u>Medical - Biomedical and Genetics</u>
Zacks Industry Rank	Top 4% (11 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	8.1%
Last Sales Surprise	2.6%
EPS F1 Est- 4 week change	-2.7%
Expected Report Date	05/07/2020
Earnings ESP	-10.6%
P/E TTM	NA
P/E F1	NA
PEG F1	NA
P/S TTM	22.4

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	110 E	152 E	186 E	195 E	743 E
2020	92 E	106 E	119 E	127 E	445 E
2019	63 A	83 A	95 A	98 A	339 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	-\$0.37 E	-\$0.22 E	-\$0.14 E	-\$0.17 E	-\$0.33 E
2020	-\$0.45 E	-\$0.44 E	-\$0.47 E	-\$0.59 E	-\$1.91 E
2019	-\$0.59 A	-\$0.38 A	-\$0.29 A	-\$0.34 A	-\$1.60 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 04/17/2020. The reports text is as of 04/20/2020.

Overview

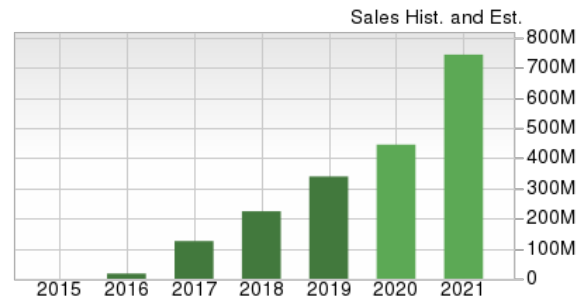
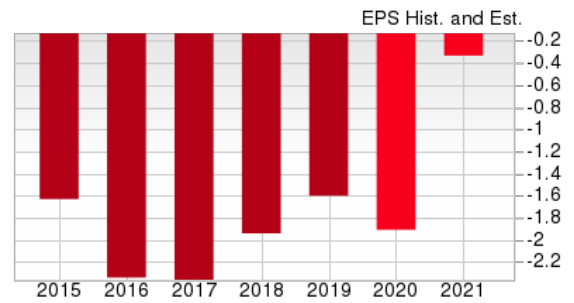
San Diego, CA-based ACADIA Pharmaceuticals Inc. is a biopharmaceutical company focused on developing innovative medicines to address the unmet medical needs in central nervous system (CNS) disorders.

The company's sole marketed drug Nuplazid (pimavanserin) is the first and the only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. The drug was launched in May 2016. ACADIA's top-line consists of only net product sales of Nuplazid in the United States.

Notably, several additional studies on pimavanserin targeting different CNS indications, such as schizophrenia inadequate response, schizophrenia negative symptoms and as an adjunctive treatment of major depressive disorder are currently underway.

Meanwhile, in August 2018, ACADIA entered into a license agreement with Australian biopharmaceutical company Neuren Pharmaceuticals Limited and obtained exclusive North American rights to develop and commercialize trofinetide for Rett syndrome and other indications.

ACADIA's top line mainly comprises U.S. sales of Nuplazid. The company recognized revenues worth \$339.1 million in 2019 compared with \$223.8 million in 2018.



Reasons To Buy:

▲ **Share Price Performance:** Shares of ACADIA have outperformed the industry in the year so far.

▲ **Nuplazid Spurs Sales Growth:** The FDA approval of Nuplazid for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis has been a huge boost to the company. Sales of the drug have improved steadily since its launch in May 2016. In 2019, Nuplazid recorded sales of \$339.1 million reflecting a surge of 52% year-over-year.

Given Nuplazid's strong performance in 2019, the company now expects total net sales from the drug in the range of \$440-\$470 million for 2020.

▲ **Nuplazid's (pimavanserin) Label Expansion Program Looks Promising:** Several additional studies on pimavanserin targeting different types of neurological and psychiatric disorders are presently ongoing.

Pimavanserin is being evaluated in the phase III HARMONY study for treating dementia-related psychosis (DRP). Other studies on pimavanserin include schizophrenia inadequate response (phase III ENHANCE study), schizophrenia negative symptoms (phase II ADVANCE study) and as an adjunctive treatment of major depressive disorder (phase III CLARITY study).

ACADIA is planning to file a supplemental new drug application seeking approval of Nuplazid to treat DRP later in the summer of 2020.

Meanwhile, in April 2019, ACADIA initiated the phase III CLARITY program, which consisted of two phase III studies, namely CLARITY-2 (U.S.-based study) and CLARITY-3 (international study), evaluating pimavanserin as an adjunctive treatment for MDD. The company plans to report top-line results from CLARITY-2 study in the fourth quarter of 2020 while the same from CLARITY-3 is expected in the first quarter of 2021.

In November 2019, ACADIA's phase II ADVANCE study on pimavanserin met the primary endpoint. The company plans to initiate a second pivotal study, ADVANCE-2, on pimavanserin later in 2020 for treating negative symptoms of schizophrenia. Per the company, this is a potential fourth indication for Nuplazid while MDD is a potential third indication for Nuplazid.

A potential approval for any of the above indications will be a significant boost to the company.

▲ **Trofinetide Studies Progressing Well:** In October 2019, the company initiated the phase III LAVENDER study on trofinetide for the treatment of Rett syndrome, a serious and rare neurological disorder for treating girls aged between five and 20 years. Top-line results from the same are expected in 2021. Currently, there are no approved medicines for the treatment of Rett syndrome.

▲ **Target Market Holds Potential:** Nuplazid is the first and the only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. ACADIA believes that the drug has the potential to address important unmet medical needs and rare diseases in neurological and psychiatric disorders in addition to PD Psychosis. Given the way Nuplazid is growing along with probable label expansions, the company expects it to become a blockbuster product as the target market has immense commercial potential.

ACADIA's only marketed drug Nuplazid has been generating steady sales since its launch in 2016 in the United States. Its label expansion studies also look promising.

Reasons To Sell:

- ▼ **Overdependence on Nuplazid:** ACADIA has no approved product in its portfolio other than Nuplazid at the moment. Hence, due to the lack of a strong pipeline, the company is totally reliant on Nuplazid for growth, which does not bode well.
- ▼ **Stiff Competition:** Competition looms large on ACADIA as many companies are developing treatments to address various CNS disorders. One such company is Axxome Therapeutics, which has four core CNS product candidates, namely AXS-05, AXS-07, AXS-09 and AXS-12 that are being developed for multiple CNS indications. A prospective approval for any of these candidates will induce acute competition for ACADIA and its products.
- ▼ **Lack of Collaborations/Pipeline Setbacks:** ACADIA's portfolio is devoid of collaboration contracts for product development/commercialization, which is a concern. In absence of future collaboration partners in the United States and other countries, it might not be able to realize the full value of Nuplazid alone.

ACADIA's sole dependence on Nuplazid for growth is a concern. Stiff competition in the target market is another woe.

Meanwhile, in July 2019, ACADIA suffered a major downfall when Nuplazid failed in a phase III study evaluating it as an adjunctive treatment of schizophrenia patients with inadequate response to existing therapies. In the study, Nuplazid did not achieve any statistical significance in terms of either the primary endpoint or the key secondary endpoint. A similar setback will affect the stock in the future.

Last Earnings Report

ACADIA Q4 Earnings Surpass, Nuplazid Drives Sales

ACADIA reported fourth-quarter 2019 loss of 34 cents per share, narrower than the Zacks Consensus Estimate of a loss of 37 cents as well as the year-ago loss of 50 cents.

Total revenues comprising net sales of the sole marketed drug Nuplazid (pimavanserin) soared 65% year over year to \$98.3 million in the fourth quarter. The top line also surpassed the Zacks Consensus Estimate of \$96 million.

Quarter Ending **12/2019**

Report Date	Feb 26, 2020
Sales Surprise	2.57%
EPS Surprise	8.11%
Quarterly EPS	-0.34
Annual EPS (TTM)	-1.60

Quarter in Detail

Sales of Nuplazid have grown steadily both year over year and sequentially. On fourth-quarter conference call, management stated that the number of patients being treated with Nuplazid continues to grow. Demand for the drug remains strong across both the specialty pharmacy and the specialty distribution channels.

Research and development (R&D) expenses were \$57.5 million in the quarter, up 19.3% from the year-ago period due to higher development costs related to the company's pipeline candidate trofinetide and label expansion studies on Nuplazid.

Selling, general and administrative (SG&A) expenses rose 23.7% year over year to \$91.9 million due to increased marketing expense and higher advertising and personnel costs.

As of Dec31, 2019, ACADIA had cash, cash equivalents and investments of \$697.4 million compared with \$683.8 million as of Sep 30, 2019.

2020 Guidance

ACADIA expects total revenues in the range of \$440-\$470 million for the full year.

Recent News

Gets Rare Pediatric Disease Tag for Trofinetide — Mar 3

ACADIA along with Australia's Neuren Pharmaceuticals announced that the FDA has granted Rare Pediatric Disease designation to trofinetide, which is being developed for the treatment of Rett syndrome.

Top-Line Results From ADVANCE Study on Pimavanserin — Nov 25

ACADIA announced positive top-line results from the phase II ADVANCE study, which evaluated the efficacy and safety of adjunctive pimavanserin in patients with predominantly negative symptoms of schizophrenia who achieved adequate control of positive symptoms with their existing antipsychotic treatment. The study met the primary endpoint as pimavanserin demonstrated a statistically significant improvement in the study's primary endpoint compared to placebo.

The primary goal was the change from baseline to week 26 on the Negative Symptom Assessment-16 total score. Notably, 53.8% of patients who were given the highest dose of pimavanserin experienced a greater improvement in the NSA-16 total score compared to placebo. The company plans to begin a second pivotal study on pimavanserin (34 mg) dose in the first half of 2020.

Valuation

ACADIA's shares are up 14.3% in the year-to-date period and 105.9% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are up 1.8% and down 4% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is up 6.5% and the sector is up 4.1%.

The S&P 500 index is down 10.9% in the year-to-date period and down 1.7% in the past year.

The stock is currently trading at 10.87X trailing 12-month book value, which compares to 3.97X for the Zacks sub-industry, 3.71X for the Zacks sector and 3.80X for the S&P 500 index.

Over the past five years, the stock has traded as high as 19.85X and as low as 4.22X, with a 5-year median of 9.23X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$53 price target reflects 11.78X trailing 12-month tangible book value.

Industry Analysis Zacks Industry Rank: Top 4% (11 out of 253)



Top Peers

Axsome Therapeutics, Inc. (AXSM)	Neutral
Biogen Inc. (BIIB)	Neutral
Catalyst Pharmaceuticals, Inc. (CPRX)	Neutral
Intra-Cellular Therapies Inc. (ITCI)	Neutral
Minerva Neurosciences, Inc (NERV)	Neutral
Sage Therapeutics, Inc. (SAGE)	Neutral
Vanda Pharmaceuticals Inc. (VNDA)	Neutral
Voyager Therapeutics, Inc. (VYGR)	Neutral

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	ACAD Neutral	X Industry	S&P 500	AXSM Neutral	CPRX Neutral	VYGR Neutral
VGM Score	D	-	-	F	B	D
Market Cap	7.60 B	177.17 M	19.60 B	2.57 B	473.61 M	378.96 M
# of Analysts	10	3	14	6	6	8
Dividend Yield	0.00%	0.00%	2.17%	0.00%	0.00%	0.00%
Value Score	F	-	-	C	C	F
Cash/Price	0.10	0.26	0.06	0.11	0.21	0.73
EV/EBITDA	-29.35	-2.75	11.73	-35.67	11.27	-2.19
PEG Ratio	NA	1.82	2.19	NA	NA	NA
Price/Book (P/B)	10.77	3.25	2.67	13.39	5.39	3.80
Price/Cash Flow (P/CF)	NA	14.73	10.55	NA	14.67	NA
P/E (F1)	NA	28.37	18.18	NA	11.69	NA
Price/Sales (P/S)	22.40	13.66	2.08	NA	4.63	3.63
Earnings Yield	-3.91%	-18.16%	5.38%	-3.47%	8.52%	-27.94%
Debt/Equity	0.01	0.02	0.70	0.10	0.01	0.00
Cash Flow (\$/share)	-1.53	-1.04	7.01	-1.96	0.31	-1.20
Growth Score	B	-	-	F	B	D
Hist. EPS Growth (3-5 yrs)	NA%	18.12%	10.92%	NA	NA	NA
Proj. EPS Growth (F1/F0)	-19.25%	4.64%	-3.36%	-19.99%	30.56%	-135.84%
Curr. Cash Flow Growth	-2.74%	13.18%	5.93%	121.54%	-194.72%	-49.72%
Hist. Cash Flow Growth (3-5 yrs)	NA%	8.03%	8.55%	NA	33.37%	NA
Current Ratio	10.16	4.72	1.24	9.00	4.62	4.01
Debt/Capital	0.90%	4.35%	42.78%	8.84%	0.73%	0.00%
Net Margin	-69.38%	-229.34%	11.64%	NA	31.16%	-41.76%
Return on Equity	-42.86%	-65.95%	16.74%	-120.33%	45.52%	-40.86%
Sales/Assets	0.54	0.20	0.54	NA	1.17	0.27
Proj. Sales Growth (F1/F0)	31.16%	5.91%	-0.14%	NA	39.07%	-42.70%
Momentum Score	C	-	-	D	C	B
Daily Price Chg	5.05%	2.17%	4.04%	8.17%	3.85%	6.47%
1 Week Price Chg	7.46%	10.01%	16.01%	2.05%	24.93%	26.81%
4 Week Price Chg	40.68%	24.76%	18.93%	49.26%	58.48%	34.92%
12 Week Price Chg	19.88%	-17.22%	-19.39%	-20.97%	9.05%	-20.12%
52 Week Price Chg	107.38%	-25.66%	-11.34%	362.09%	-13.75%	-46.82%
20 Day Average Volume	1,218,604	227,526	3,220,598	1,037,642	2,002,346	387,311
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	-2.74%	0.00%	-7.09%	-3.06%	-20.47%	-0.04%
(F1) EPS Est 12 week change	-53.47%	-1.01%	-9.32%	-50.57%	-16.96%	-5.45%
(Q1) EPS Est Mthly Chg	-8.71%	0.00%	-10.68%	0.47%	-3.64%	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	F
Growth Score	B
Momentum Score	C
VGM Score	D

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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