ACADIA Pharmaceuticals (ACAD)

$45.22 (As of 02/12/20)

Price Target (6-12 Months): **$48.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 01/30/19) Prior Recommendation: Outperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**3-Hold**
	Zacks Style Scores:	VGM:D
	Value: F | Growth: B | Momentum: F	

Summary

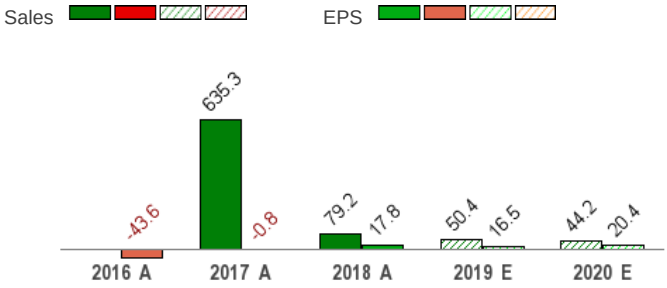
ACADIA's sole marketed drug Nuplazid generated strong sales since its launch. The drug's label expansion program also looks promising with several late-stage studies currently underway targeting different types of neurological and psychiatric disorders. ACADIA plans to meet the FDA authorities to file a supplemental new drug application for pimavanserin to address dementia-related psychosis in the first half of 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. Shares have outperformed the industry in the past year. Loss estimates remains mixed ahead of Q4 earnings. ACADIA has a mixed record of earnings surprises in recent quarters.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$53.70 - $21.56**
20 Day Average Volume (sh)	**1,048,245**
Market Cap	**$7.0 B**
YTD Price Change	**5.7%**
Beta	**2.82**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Biomedical and Genetics**
Zacks Industry Rank	**Top 28% (72 out of 254)**
Last EPS Surprise	**29.3%**
Last Sales Surprise	**6.8%**
EPS F1 Est- 4 week change	**-3.1%**
Expected Report Date	**02/26/2020**
Earnings ESP	**0.0%**
P/E TTM	**NA**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**23.2**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2020	95 E	109 E	116 E	117 E	486 E
2019	63 A	83 A	95 A	96 E	337 E
2018	49 A	57 A	58 A	60 A	224 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2020	-$0.37 E	-$0.33 E	-$0.23 E	-$0.28 E	-$1.29 E
2019	-$0.59 A	-$0.38 A	-$0.29 A	-$0.37 E	-$1.62 E
2018	-$0.44 A	-$0.51 A	-$0.50 A	-$0.50 A	-$1.94 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 02/12/2020. The reports text is as of 02/13/2020.

Overview

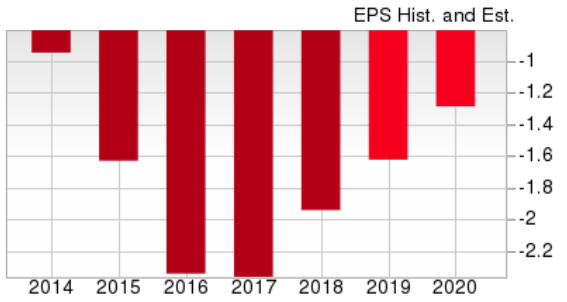
San Diego, CA-based ACADIA Pharmaceuticals Inc. is a biopharmaceutical company focused on developing innovative medicines to address the unmet medical needs in central nervous system (CNS) disorders.

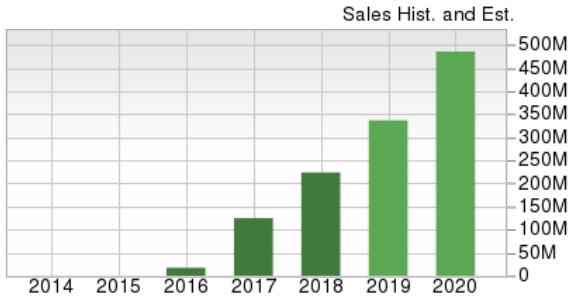
The company's sole marketed drug Nuplazid (pimavanserin) is the first and the only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. The drug was launched in May 2016. ACADIA's top-line consists of only net product sales of Nuplazid in the United States. The drug recorded sales of $233.8 million in 2018.

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 of $233.8 million in 2018 compared with $124.9 million in 2017.





Reasons To Buy:

- **Share Price Performance:** Shares of ACADIA have outperformed the industry in the past year. The stock has skyrocketed 106.2% against the industry's decrease of 2.5%.

- **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 the first nine months of 2019, Nuplazid recorded sales of $240.8 million reflecting a surge of 46.6% year-over-year.

  Given Nuplazid's strong performance, during the third quarter of 2019, the company raised the full year net sales guidance to $330-$340 million from the earlier projection representing 50% increase year-over-year at the midpoint of the range.

> 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.

- **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).

  In September 2019, Nuplazid met the primary endpoint in the phase III HARMONY study by showing statistically significant superiority over placebo in increasing the time-to-relapse of dementia-related psychosis. ACADIA is planning to meet the FDA authorities for discussing a possible submission of a supplemental new drug application for Nupalzid in the first half of 2020.

  Meanwhile in November 2019, 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 goal. The company plans to begin a second pivotal study on pimavanserin (34 mg) dose in the first half of 2020.

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

  Meanwhile, ACADIA initiated a phase III study on its investigational candidate trofinetide in the fourth quarter of 2019 for the treatment of Rett syndrome, a rare neurodevelopmental congenital CNS disorder for treating girls aged between five and 20 years.

- **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.

Reasons To Sell:

- **Overdependence on Nuplazid (pimavanserin):** 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. Moreover, gaining the FDA approval has become more difficult with an increasingly stringent regulatory environment. In such a scenario, any regulatory or developmental setback for Nuplazid will weigh heavily on the stock.

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

- **Stiff Competition:** Competition looms large on ACADIA as many companies are developing treatments to address various CNS disorders. One such company is Axsome 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 is devoid of collaboration contracts for product development/ commercialization, which is alarming. Without future collaboration partners in the United States and other countries, it might not be able to continue with the development of Nuplazid alone.

  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 debacle will affect the stock in the future.

Last Earnings Report

ACADIA Earnings Beat Estimates in Q3, Nuplazid Drives Sales

Quarter Ending	09/2019
Report Date	**Oct 30, 2019**
Sales Surprise	**6.79%**
EPS Surprise	**29.27%**
Quarterly EPS	**-0.29**
Annual EPS (TTM)	**-1.76**

ACADIA reported a loss of 29 cents per share in the third quarter of 2019, narrower than the Zacks Consensus Estimate of a loss of 41 cents. However, the company incurred a wider loss of 50 cents in the year-ago quarter.

Total revenues comprised net sales of Nuplazid and soared 62% year over year to $94.6 million, driven by year-over-year volume growth. The top line also surpassed the Zacks Consensus Estimate of $89 million.

Quarter in Detail

Sales of Nuplazid have grown steadily both year over year and sequentially. On third-quarter 2019 conference call, management stated that the number of patients being treated with Nuplazid continues to grow. Per the company, ACADIA is currently in the mid to high-teens in terms of market penetration, which provides a lot of growth opportunities.

Research and development (R&D) expenses were $62.6 million in the quarter, up 17.9% from the year-ago period owing to higher development costs related to trofinetide and clinical study costs for pimavanserin.

Selling, general and administrative (SG&A) expenses rose 18.9% year over year to $72.7 million due to increased marketing expense and higher advertising and personnel costs.

As of Sep 30, 2019, ACADIA had cash and cash equivalents of $683.8 million compared with $473.5 million as of Dec 31, 2018.

2019 Guidance

ACADIA raised its Nuplazid net sales guidance for 2019 to $330-$340 million, previously expected in the range of $320-$330 million.

Non-adjusted R&D guidance for 2019 was lowered to $240-$250 million from the earlier band of $250-$265 million.

Non-adjusted SG&A guidance for 2019 is now expected in the band of $315-$325 million compared with the previous range of $300-$315 million.

Recent News

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.

Initiates Phase III Study on Trofinetide for Rett Syndrome — Oct 30

ACADIA announced that it has initiated a placebo-controlled phase III study, LAVENDER, to evaluate the efficacy and safety of trofinetide for treating girls and young women with Rett syndrome, a rare neurodevelopmental congenital CNS disorder. The indication currently has no approved therapy.

Valuation

ACADIA's shares are up 5.7% in the year-to-date period and 106.2% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are up 0.8% and 2.4% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 2.5% while the sector is up 3.6%.

The S&P 500 index is up 4.3% in the year-to-date period and up 21.4% in the past year.

The stock is currently trading at 10.11X trailing 12-month book value, which compares to 3.89X for the Zacks sub-industry, 4.64X for the Zacks sector and 4.33X 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 9.31X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $48 price target reflects 10.73X trailing 12-month tangible book value.

Industry Analysis **Zacks Industry Rank:** Top 28% (72 out of 254)

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	-	-	D	C	D
Market Cap	6.97 B	207.62 M	24.53 B	3.13 B	482.26 M	501.23 M
# of Analysts	9	3	13	6	6	8
Dividend Yield	0.00%	0.00%	1.75%	0.00%	0.00%	0.00%
Value Score	F	-	-	C	C	D
Cash/Price	0.11	0.22	0.04	0.01	0.17	0.64
EV/EBITDA	-26.03	-3.62	13.98	-105.57	-11.97	-2.19
PEG Ratio	NA	2.02	2.09	NA	NA	NA
Price/Book (P/B)	10.10	3.94	3.29	457.48	6.18	4.62
Price/Cash Flow (P/CF)	NA	13.81	13.69	NA	NA	NA
P/E (F1)	NA	33.41	19.19	NA	10.06	NA
Price/Sales (P/S)	23.19	14.47	2.68	NA	6.64	6.80
Earnings Yield	-2.85%	-15.07%	5.21%	-1.78%	10.04%	-21.82%
Debt/Equity	0.01	0.02	0.71	2.80	0.01	0.00
Cash Flow ($/share)	-1.94	-1.07	6.92	-1.02	-0.33	-2.71
Growth Score	B	-	-	F	A	B
Hist. EPS Growth (3-5 yrs)	NA%	16.51%	10.85%	NA	NA	NA
Proj. EPS Growth (F1/F0)	20.67%	7.05%	7.30%	9.13%	40.91%	-85.04%
Curr. Cash Flow Growth	-15.41%	19.01%	8.56%	9.92%	84.94%	27.79%
Hist. Cash Flow Growth (3-5 yrs)	NA%	7.72%	8.36%	NA	NA	NA
Current Ratio	10.96	5.09	1.23	2.39	5.04	4.09
Debt/Capital	0.92%	3.97%	42.91%	73.69%	0.92%	0.00%
Net Margin	-82.48%	-209.62%	11.81%	NA	12.99%	-72.64%
Return on Equity	-50.15%	-64.11%	16.92%	-430.09%	15.53%	-57.32%
Sales/Assets	0.53	0.20	0.54	NA	0.98	0.22
Proj. Sales Growth (F1/F0)	44.32%	16.79%	3.96%	NA	43.03%	-40.03%
Momentum Score	F	-	-	C	F	F
Daily Price Chg	3.05%	0.00%	0.64%	-2.27%	1.96%	2.35%
1 Week Price Chg	4.33%	1.53%	2.47%	3.49%	7.06%	17.50%
4 Week Price Chg	-0.40%	-0.92%	1.87%	0.00%	6.61%	-5.52%
12 Week Price Chg	-2.10%	13.04%	6.69%	177.26%	1.52%	-6.82%
52 Week Price Chg	102.69%	-6.68%	16.42%	892.23%	73.98%	26.95%
20 Day Average Volume	1,048,245	196,531	2,019,212	579,008	1,435,365	323,562
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	-3.11%	0.00%	-0.06%	-0.52%	-1.41%	-9.10%
(F1) EPS Est 12 week change	-3.30%	0.00%	-0.19%	-15.00%	-10.29%	-9.50%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	-0.16%	-1.18%	0.00%	0.08%

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	F
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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