ACADIA Pharmaceuticals (ACAD)

$55.13 (As of 07/15/20)

Price Target (6-12 Months): **$58.00**

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:F
	Value: F | Growth: C | Momentum: F	

Summary

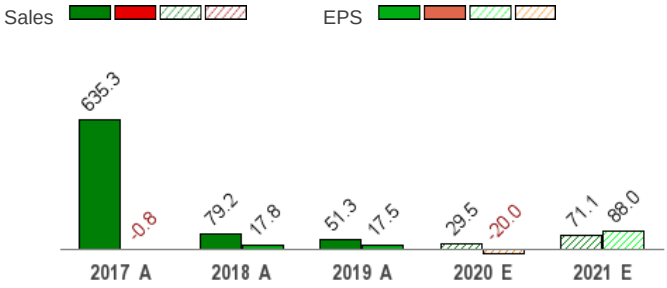
ACADIA's sole marketed drug Nuplazid recorded strong sales since its launch. The drug's label expansion program also looks promising with several studies currently underway, targeting various CNS disorders. In June, ACADIA filed a supplemental new drug application seeking approval of Nuplazid for dementia-related psychosis, a potential second indication for the drug. If approved, the drug's eligible patient population will be expanded and sales driven higher in the future as well. However, sole dependence on Nuplazid for revenues remains a concern. Any regulatory and developmental setback for the drug will hurt the stock severely. Moreover, acute competition remains a woe. Shares of the company have outperformed the industry year to date.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$58.72 - $21.56**
20 Day Average Volume (sh)	**2,397,454**
Market Cap	**$8.6 B**
YTD Price Change	**28.9%**
Beta	**1.80**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Biomedical and Genetics**
Zacks Industry Rank	**Top 30% (75 out of 251)**
Last EPS Surprise	**-23.9%**
Last Sales Surprise	**-3.4%**
EPS F1 Est- 4 week change	**-0.4%**
Expected Report Date	**07/29/2020**
Earnings ESP	**8.1%**
P/E TTM	**NA**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**23.5**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021					751 E
2020	90 A	105 E	117 E	127 E	439 E
2019	63 A	83 A	95 A	98 A	339 A

EPS Estimates

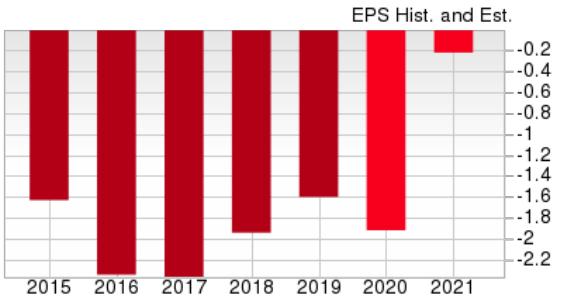
	Q1	Q2	Q3	Q4	Annual*
2021					-$0.23 E
2020	-$0.57 A	-$0.45 E	-$0.47 E	-$0.45 E	-$1.92 E
2019	-$0.59 A	-$0.38 A	-$0.29 A	-$0.34 A	-$1.60 A

*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 07/15/2020. The reports text is as of 07/16/2020.

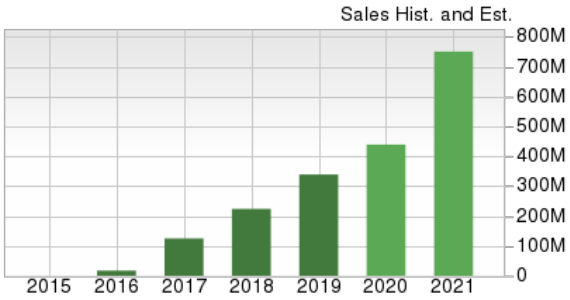
Overview

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.

A supplemental new drug application seeking approval of Nuplazid for dementia-related psychosis has been filed in the United States.



Notably, several additional studies on Nuplazid n targeting different CNS indications, such as schizophrenia inadequate response, schizophrenia negative symptoms and as an adjunctive treatment of major depressive disorder (MDD) 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:

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.

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

- **Nuplazid Spurs Sales Growth:** The FDA approval of Nuplazid was 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 $420-$450 million for 2020.

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

  Nuplazid is being evaluated in the phase III HARMONY study for treating dementia-related psychosis (DRP). Other studies on Nuplazid 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 June 2020, the company submitted a supplemental new drug application to the FDA seeking approval of Nupalzid to treat DRP. If approved, this will be a potential second indication for Nuplazid.

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

  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 study are expected in 2021. Currently, there are no approved medicines for the treatment of Rett syndrome. In March 2020, the FDA granted Rare Pediatric Disease designation to trofinetide for the given indication. Notably, this tag is granted by the FDA in case of serious or life-threatening diseases, which affect less than 200,000 people in the United States, primarily individuals aged 18 years and below.

- **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.

- **Favorable Debt Profile:** ACADIA has a favorable debt profile. As of Mar 31, 2020, the company's total debt (current and long-term debt) was approximately $6 million. The company's cash, cash equivalents and marketable securities worth approximately $651 million at March-end should be sufficient to meet its debt obligations in case of insolvency. Meanwhile, the company's total debt to total capital of 0.9% as of March end has remained flat quarter-over-quarter.

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 Axsome Therapeutics, which has five core CNS product candidates, namely AXS-05, AXS-07, AXS-09, AXS-12 and AXS-14 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.

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

- **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.

  Meanwhile, in July 2019, ACADIA suffered a major pipeline setback when Nuplazid failed in the phase III ENHANCE 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's Q1 Earnings and Revenues Fall Shy of Estimates

Quarter Ending	03/2020
Report Date	**May 07, 2020**
Sales Surprise	**-3.36%**
EPS Surprise	**-23.91%**
Quarterly EPS	**-0.57**
Annual EPS (TTM)	**-1.58**

ACADIA reported first-quarter 2020 loss of 57 cents per share, wider than the Zacks Consensus Estimate of a loss of 46 cents but narrower than the year-ago loss of 59 cents.

Total revenues comprising net sales of the company's sole marketed drug Nuplazid surged 43% year over year to $90.1 million in the first quarter. However, the top line missed the Zacks Consensus Estimate of $93 million.

Quarter in Detail

Sales of Nuplazid grew steadily both year over year and sequentially. On first-quarter conference call, management stated that a strong base of patients is continuing treatment with Nuplazid. However, the current environment can pose a short-term challenge to the rate of new patient growth.

Research and development (R&D) expenses were $72.6 million in the quarter, up 37.2% from the year-ago period due to higher development costs for the pipeline candidate trofinetide and an upfront payment made to Vanderbilt University.

Selling, general and administrative (SG&A) expenses rose 9.6% year over year to $102 million due to increased medical expense and higher personnel costs.

As of Mar 31, 2020, ACADIA had cash, cash equivalents and investments worth $651.4million compared with $697.4 million as of Dec31, 2019.

2020 Guidance

Prompted by the plaguing COVID-19 pandemic, ACADIA lowered its 2020 revenue guidance by approximately 5%.

The company now expects total Nuplazid revenues in the range of $420-$450 million for the full year compared with the previous guidance of $440-$470 million.

Recent News

Files sNDA for Nuplazid in Dementia-Related Psychosis – Jun 15

ACADIA announced that it has submitted a supplemental new drug application (sNDA) to the FDA seeking approval for its marketed drug Nuplazid to treat hallucinations and delusions associated with dementia-related psychosis (DRP). If approved, this will be a potential second indication for Nuplazid.

To Merge Two Phase III Studies on Nuplazid for MDD – May 26

ACADIA announced that it plans to combine the two-phase III studies namely, CLARITY-2 and CLARITY-3 on Nuplazid (pimavanserin) for the adjunctive treatment of major depressive disorder (MDD). Following a positive feedback from the FDA, the company decided to combine the two above-mentioned identically-designed studies into one with a pre-specified statistical analysis plan.Top-line data from the combined study is expected in the third quarter of 2020.

Inks Deal With Vanderbilt University — May 7

ACADIA announced that it has entered into an exclusive licensing and collaboration agreement with Vanderbilt University to develop/commercialize novel drug candidates targeting the muscarinic M1 receptor with the potential to treat a range of CNS disorders.

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.

Valuation

ACADIA's shares are up 28.9% in the year-to-date period and 115.7% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are up 9.4% and down 0.7% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is up 20.5% and the sector is up 4.9%.

The S&P 500 index is down 0.5% in the year-to-date period but up 7.9% in the past year.

The stock is currently trading at 13.46X trailing 12-month book value, which compares to 3.07X for the Zacks sub-industry, 4.41X for the Zacks sector and 4.38X 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 $58.00 price target reflects 14.16X trailing 12-month tangible book value.

Industry Analysis **Zacks Industry Rank:** Top 30% (75 out of 251)

Top Peers

Company (Ticker)	Rec	Rank
Voyager Therapeutics, Inc. **(VYGR)**	Outperform	3
Axsome Therapeutics, Inc. **(AXSM)**	Neutral	4
Biogen Inc. **(BIIB)**	Neutral	3
Catalyst Pharmaceuticals, Inc. **(CPRX)**	Neutral	3
Exelixis, Inc. **(EXEL)**	Neutral	3
IntraCellular Therapies Inc. **(ITCI)**	Neutral	4
Minerva Neurosciences, Inc **(NERV)**	Neutral	3
Sage Therapeutics, Inc. **(SAGE)**	Neutral	2

Industry Comparison Industry: Medical - Biomedical And Genetics

Industry Peers

	ACAD	X Industry	S&P 500	AXSM	CPRX	VYGR
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Outperform
Zacks Rank (Short Term)	3	-	-	4	3	3
VGM Score	F	-	-	D	A	B
Market Cap	8.59 B	235.48 M	22.66 B	3.04 B	525.35 M	511.37 M
# of Analysts	9	3	14	6	6	9
Dividend Yield	0.00%	0.00%	1.83%	0.00%	0.00%	0.00%
Value Score	F	-	-	C	B	C
Cash/Price	0.08	0.22	0.07	0.06	0.20	0.52
EV/EBITDA	-33.79	-3.69	12.99	-43.09	12.58	-5.86
PEG Ratio	NA	1.78	2.97	NA	NA	NA
Price/Book (P/B)	13.46	4.25	3.12	19.49	5.27	6.41
Price/Cash Flow (P/CF)	NA	16.91	12.14	NA	16.27	NA
P/E (F1)	NA	29.85	22.04	NA	13.55	NA
Price/Sales (P/S)	23.47	16.90	2.38	NA	4.41	4.36
Earnings Yield	-3.48%	-12.68%	4.32%	-3.37%	7.48%	-19.78%
Debt/Equity	0.01	0.02	0.76	0.10	0.01	0.00
Cash Flow ($/share)	-1.53	-1.08	6.94	-1.96	0.31	-1.20
Growth Score	C	-	-	F	A	B
Hist. EPS Growth (3-5 yrs)	NA%	17.18%	10.85%	NA	NA	NA
Proj. EPS Growth (F1/F0)	-19.79%	11.61%	-9.64%	-37.56%	25.00%	-125.07%
Curr. Cash Flow Growth	-2.74%	14.86%	5.51%	121.54%	-194.72%	-49.72%
Hist. Cash Flow Growth (3-5 yrs)	NA%	7.73%	8.55%	NA	33.37%	NA
Current Ratio	7.26	5.52	1.30	7.57	6.63	3.76
Debt/Capital	0.94%	4.34%	44.46%	9.05%	0.57%	0.00%
Net Margin	-64.99%	-203.22%	10.59%	NA	36.09%	-34.70%
Return on Equity	-39.41%	-61.83%	15.75%	-98.57%	52.28%	-40.11%
Sales/Assets	0.53	0.19	0.54	NA	1.17	0.33
Proj. Sales Growth (F1/F0)	29.55%	4.12%	-2.52%	NA	22.15%	-26.30%
Momentum Score	F	-	-	C	C	A
Daily Price Chg	2.62%	2.25%	1.91%	3.36%	2.42%	7.25%
1 Week Price Chg	7.44%	-0.65%	-0.41%	2.56%	2.70%	0.08%
4 Week Price Chg	17.00%	0.00%	1.88%	10.06%	12.76%	6.01%
12 Week Price Chg	11.58%	18.00%	16.37%	17.47%	6.05%	27.08%
52 Week Price Chg	115.60%	2.25%	-4.22%	228.10%	20.38%	-42.59%
20 Day Average Volume	2,397,454	394,052	2,266,132	612,352	1,559,443	330,658
(F1) EPS Est 1 week change	-0.41%	0.00%	0.00%	-0.30%	0.00%	0.00%
(F1) EPS Est 4 week change	-0.41%	0.00%	0.00%	-0.30%	0.00%	0.00%
(F1) EPS Est 12 week change	-0.45%	1.06%	-5.76%	-14.65%	-4.26%	4.56%
(Q1) EPS Est Mthly Chg	-0.36%	0.00%	0.00%	0.00%	0.00%	0.00%

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	F
Growth Score	C
Momentum Score	F
VGM Score	F

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.

Disclosures

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