ACADIA Pharmaceuticals (ACAD)

$38.00 (As of 08/24/20)

Price Target (6-12 Months): **$40.00**

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: D | Growth: C | Momentum: B	

Summary

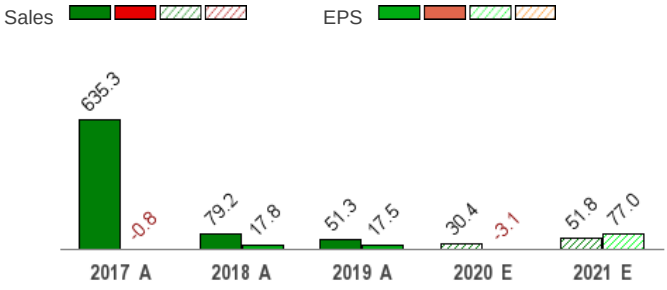
ACADIA beat on both earnings and revenues in the second quarter. The company's sole marketed drug Nuplazid recorded strong sales since its launch. The drug's label expansion program also looks promising with several studies targeting various CNS disorders currently being underway. A regulatory application seeking an approval of Nuplazid for dementia-related psychosis is under review with the FDA. The decision is expected on Apr 3, 2021. If approved, not only the drug's eligible patient population will be expanded but sales will be driven higher as well. However, a heavy dependence on Nuplazid for revenues remains a concern. Any regulatory and developmental setback will too hurt the stock severely. Moreover, an acute competition remains a woe. Shares of the company have underperformed the industry year to date.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$58.72 - $23.77**
20 Day Average Volume (sh)	**1,590,811**
Market Cap	**$6.0 B**
YTD Price Change	**-11.2%**
Beta	**1.68**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Biomedical and Genetics**
Zacks Industry Rank	**Bottom 29% (180 out of 252)**
Last EPS Surprise	**38.6%**
Last Sales Surprise	**4.2%**
EPS F1 Est- 4 week change	**13.3%**
Expected Report Date	**11/04/2020**
Earnings ESP	**4.0%**
P/E TTM	**NA**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**15.2**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021					671 E
2020	90 A	110 A	117 E	124 E	442 E
2019	63 A	83 A	95 A	98 A	339 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021					-$0.38 E
2020	-$0.57 A	-$0.27 A	-$0.39 E	-$0.44 E	-$1.65 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 08/24/2020. The reports text is as of 08/25/2020.

Overview

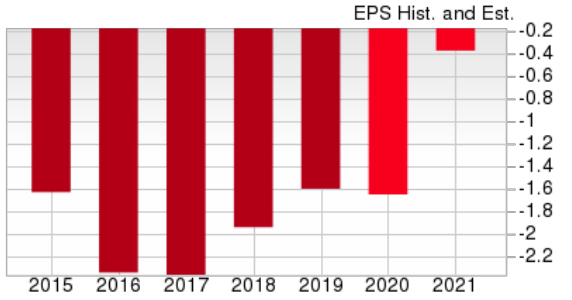
San Diego, CA-based ACADIA Pharmaceuticals Inc. is a biopharmaceutical company focused on developing innovative medicines to address the unmet medical needs in central nervous system (CNS) disorders.

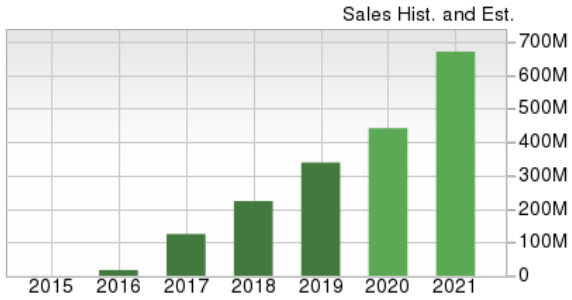
The company's sole marketed drug Nuplazid (pimavanserin) is the first and the only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. The drug was launched in May 2016. ACADIA's top-line consists of only net product sales of Nuplazid in the United States.

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 dementia-related psychosis, 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.

- **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 $430-$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 an approval for Nupalzid to treat hallucinations and delusions associated with DRP. In July, the FDA accepted the sNDA for Nuplazid and set an action date of Apr 3, 2021. 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 recently initiated a second pivotal study, ADVANCE-2, on Nupalzid for treating the negative symptoms of schizophrenia. Currently, there is no FDA-approved treatment option for the given condition. 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:** ACADIA is evaluating its investigational candidate trofinetide in the phase III LAVENDER study for the treatment of Rett syndrome, a rare neurodevelopmental congenital CNS disorder for girls aged between five and 20 years. Top-line outcomes from the same are expected in the second half of 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 Jun 30, 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 $659 million at June-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 June end has remained flat quarter-over-quarter.

Reasons To Sell:

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

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

- **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.

- **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. Also, in July 2020, ACADIA announced top-line results from the phase III CLARITY study evaluating Nuplazid for the adjunctive treatment of major depressive disorder. The study did not achieve any statistical significance in relation to the primary endpoint. Such setbacks are detrimental to the company and can affect the stock in the future.

Last Earnings Report

ACADIA Beat Earnings Estimates in Q2, Nuplazid Drives Sales

Quarter Ending	06/2020
Report Date	**Aug 05, 2020**
Sales Surprise	**4.22%**
EPS Surprise	**38.64%**
Quarterly EPS	**-0.27**
Annual EPS (TTM)	**-1.47**

ACADIA reported second-quarter 2020 loss of 27 cents per share, narrower than the Zacks Consensus Estimate of a loss of 44 cents as well as the year-ago loss of 38 cents.

Total revenues comprising net sales of the company's sole marketed drug Nuplazid soared 32% year over year to $110.1 million in the second quarter. The top line also surpassed the Zacks Consensus Estimate of $106 million.

Quarter in Detail

Sales of Nuplazid grew steadily both year over year and sequentially. driven by a strong commercial execution. The drug saw a solid uptake ever since its launch in 2016.

Research and development (R&D) expenses were $64.3 million in the quarter, down 4.4% from the year-ago period owing to lower development costs of Nuplazid for additional indications.

Selling, general and administrative (SG&A) expenses rose 23.9% year over year to $84.3 million due to increased advertising and promotional costs, and higher personnel costs.

As of Jun 30, 2020, ACADIA had cash, cash equivalents and investments worth $658.6 million compared with $651.4 million as of Mar 31, 2020.

2020 Guidance

Owing to the strong adoption of Nuplazid, ACADIA raised the lower end of its net sales guidance for the drug. The company now expects total revenues in the range of $430-$450 million for the full year, tightened from the previous guidance of $420-$450 million.

Meanwhile, the R&D expenses are now expected within $265-$280 million, down from the previous guided range of $270-$285 million. SG&A expenses are projected in the band of $400-$420 million, lower than the earlier forecast of $425-$445 million

Recent News

Acquires CerSci Therapeutics to Boost Pain Portfolio – Aug 25

ACADIA announced that it has acquired CerSci Therapeutics and worldwide rights to a portfolio of novel compounds developed for neurological conditions, including non-opioid therapies for acute and chronic pain.

FDA Accepts sNDA for Nuplazid — Jul 20

ACADIA announced that the FDA accepted the sNDA for Nuplazid to treat hallucinations and delusions associated with dementia-related psychosis (DRP). The regulatory body set an action date of Apr 3, 2021. If approved, Nuplazid will get a potential second indication on its label and become the first and the only treatment indicated for DRP.

Posts Top-line Results From MDD Study on Nuplazid — Jul 20

ACADIA announced top-line results from the phase III CLARITY study evaluating Nuplazid for the adjunctive treatment of major depressive disorder (MDD). The study did not achieve any statistical significance in relation to the primary endpoint. However, positive results were observed pertaining to the key secondary endpoint.

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.

Valuation

ACADIA's shares are down 11.2% in the year-to-date period and up 36.6% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are flat and down 0.2% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is up 13.3% and the sector is up 8.8%.

The S&P 500 index is up 6.5% in the year-to-date period and up 19.5% in the past year.

The stock is currently trading at 9.04X trailing 12-month book value, which compares to 3.01X for the Zacks sub-industry, 3.82X for the Zacks sector and 4.64X 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 $40.00 price target reflects 9.51X trailing 12-month tangible book value.

Industry Analysis **Zacks Industry Rank:** Bottom 29% (180 out of 252)

Top Peers

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

Industry Comparison Industry: Medical - Biomedical And Genetics

	ACAD	X Industry	S&P 500	AXSM	CPRX	VYGR
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	3	3	3
VGM Score	D	-	-	C	A	C
Market Cap	5.99 B	270.20 M	23.81 B	2.87 B	345.57 M	467.14 M
# of Analysts	10	3	14	6	6	9
Dividend Yield	0.00%	0.00%	1.64%	0.00%	0.00%	0.00%
Value Score	D	-	-	C	A	C
Cash/Price	0.11	0.23	0.07	0.07	0.32	0.51
EV/EBITDA	-22.70	-3.92	13.37	-40.58	6.84	-5.35
PEG Ratio	NA	1.74	3.02	NA	NA	NA
Price/Book (P/B)	9.04	4.02	3.17	18.52	3.11	6.04
Price/Cash Flow (P/CF)	NA	18.69	12.77	NA	10.70	NA
P/E (F1)	NA	25.78	21.72	NA	8.38	NA
Price/Sales (P/S)	15.24	15.30	2.48	NA	2.89	4.68
Earnings Yield	-4.34%	-12.77%	4.44%	-3.36%	11.98%	-12.90%
Debt/Equity	0.01	0.02	0.76	0.09	0.00	0.00
Cash Flow ($/share)	-1.53	-1.08	6.93	-1.96	0.31	-1.20
Growth Score	C	-	-	C	A	D
Hist. EPS Growth (3-5 yrs)	NA%	19.03%	10.41%	NA	NA	NA
Proj. EPS Growth (F1/F0)	-3.13%	15.73%	-5.05%	-28.69%	32.78%	-33.06%
Curr. Cash Flow Growth	-2.74%	13.92%	5.20%	121.54%	-194.72%	-49.72%
Hist. Cash Flow Growth (3-5 yrs)	NA%	7.73%	8.50%	NA	33.37%	NA
Current Ratio	8.51	5.99	1.33	8.30	6.49	3.65
Debt/Capital	0.85%	3.39%	44.50%	8.18%	0.00%	0.00%
Net Margin	-57.29%	-199.98%	10.13%	NA	34.87%	-60.61%
Return on Equity	-33.49%	-59.07%	14.66%	-76.42%	44.37%	-66.46%
Sales/Assets	0.51	0.19	0.51	NA	1.05	0.30
Proj. Sales Growth (F1/F0)	30.29%	1.00%	-1.45%	NA	22.07%	9.06%
Momentum Score	B	-	-	A	B	B
Daily Price Chg	-0.84%	-1.44%	1.32%	-0.70%	-3.75%	4.52%
1 Week Price Chg	-2.62%	0.00%	-1.45%	-1.81%	0.00%	5.94%
4 Week Price Chg	-14.28%	-3.60%	3.38%	-0.19%	-31.13%	1.88%
12 Week Price Chg	-22.27%	-1.36%	7.69%	0.05%	-25.28%	2.04%
52 Week Price Chg	36.59%	7.36%	3.85%	206.28%	-42.61%	-36.36%
20 Day Average Volume	1,590,811	314,687	1,873,293	356,006	2,821,672	228,761
(F1) EPS Est 1 week change	0.27%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	13.31%	0.00%	1.00%	6.45%	6.22%	40.88%
(F1) EPS Est 12 week change	13.56%	1.34%	3.40%	6.17%	6.22%	40.88%
(Q1) EPS Est Mthly Chg	15.64%	0.00%	0.00%	0.89%	6.98%	83.21%

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	D
Growth Score	C
Momentum Score	B
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.

Disclosures

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