

Amarin Corporation (AMRN)

\$5.81 (As of 04/08/20)

Price Target (6-12 Months): **\$6.25**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 01/01/20)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

2-Buy

Zacks Style Scores:

VGM:F

Value: D

Growth: D

Momentum: F

Summary

Amarin reported encouraging fourth-quarter results, wherein both earnings and sales beat estimates. Amarin's sole marketed drug Vascepa has been on a strong growth trajectory for the last four years. The drug's recent label expansion for cardiovascular indication looks promising. The growth trend for Vascepa is expected to continue in 2020. The company is expanding its sales force and start promotional programs to create awareness for Vascepa's expanded label. These initiatives are likely to drive sales higher. The company is looking to get approval for the drug in additional countries. However, Amarin is over-dependent on Vascepa for its growth. Any setback to its commercialization plans will have an unfavorable impact. Competition is also rising in the targeted market. Shares have underperformed the industry in the past year.

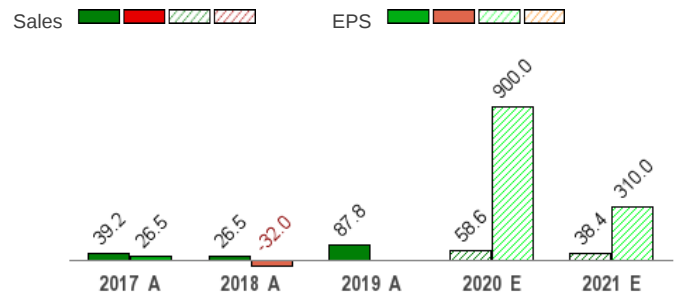
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$26.12 - \$3.95
20 Day Average Volume (sh)	26,686,928
Market Cap	\$2.1 B
YTD Price Change	-72.9%
Beta	2.18
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 9% (24 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	300.0%
Last Sales Surprise	6.6%
EPS F1 Est- 4 week change	-13.9%
Expected Report Date	05/06/2020
Earnings ESP	30.8%
P/E TTM	290.5
P/E F1	29.1
PEG F1	NA
P/S TTM	4.8

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021					944 E
2020	136 E	158 E	180 E	206 E	682 E
2019	73 A	101 A	112 A	143 A	430 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021					\$0.82 E
2020	-\$0.04 E	\$0.02 E	\$0.09 E	\$0.13 E	\$0.20 E
2019	-\$0.05 A	\$0.02 A	\$0.01 A	\$0.04 A	\$0.02 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 04/08/2020. The reports text is as of 04/09/2020.

Overview

Dublin, Ireland based Amarin Corporation plc is a commercial-stage pharmaceutical company focused on developing therapies, especially based on omega-3 fatty acid, for treating cardiovascular diseases.

The company's sole marketed drug, Vascepa (icosapent ethyl) is approved in the United States as an adjunct to diet for treating severe hypertriglyceridemia or elevated triglyceride (TG) levels (≥ 500 mg/dL). In December 2019, the FDA approved Vascepa to reduce cardiovascular risk in patients with persistent elevated triglycerides on statin therapy for LDL-C. The drug is under review in Europe for the cardiovascular indication.

Amarin derives revenues primarily from the sale of Vascepa in the United States. The drug recorded sales of \$427.4 million in 2019. Amarin generated sales of \$429.8 million in 2019 compared with \$229.2 million in 2018.



Reasons To Buy:

▲ **Vascepa Sales Growth Impressive:** Amarin started commercialization of Vascepa in 2013 following its FDA approval. Sales of the drug have recorded strong year-over-year growth in the last four years. Sales registered 87% growth in 2019. Sales from the drug in 2020 are expected to be between \$650 million and \$700 million, suggesting another strong year of growth. The company believes Vascepa has multi-billion dollar potential.

▲ **Efforts to Boost Vascepa Sales:** Amarin is planning several initiatives to boost Vascepa sales. The company is expanding its salesforce to support promotion of Vascepa's expanded label, which was approved based on REDUCE-IT cardiovascular outcome study in December 2019. The company remains on track to increase its sales team to 800 in early 2020 and start branded direct-to-consumer promotion of Vascepa for cardiovascular risk reduction indication by mid-2020. Apart from the planned DTC program, the company has various programs to increase awareness about Vascepa. The company is also actively engaged in improving payer coverage for the drug.

Apart from promotional programs in the United States, Amarin is looking to get approval for Vascepa in additional countries. In December 2019, the drug was approved in Canada and it is under review in Europe. An approval in Europe is expected by the end of 2020. Moreover, the company is actively looking to sign partnership/licensing deals for commercialization of Vascepa in ex-U.S. markets. It already has partnership/licensing deals to commercialize Vascepa in certain ex-U.S. markets which include the Middle East, China and Canada. These deals reduce commercialization costs, and provide additional funds in upfront and milestone payments and access to established marketing networks of partners in concerned territories.

▲ **Lucrative Cardiovascular Market:** Amarin's Vascepa targets patients with high TG levels who are at risk of cardiovascular events, including heart attacks and stroke, which represents a significant opportunity. Costs related to cardiovascular disease in the United States are more than \$500 billion each year, per American Heart Association. Approximately 121 million adults in the United States have a cardiovascular disease with an estimated 1 million new or recurrent coronary events and 795,000 new or recurrent strokes occur each year. It is estimated that more than 50 million adults in the United States have elevated triglyceride level. In Europe, it is estimated that 80 million people have cardiovascular disease and 11 million new cases are added each year. The drug reduces the risk of cardiovascular events by lowering TG levels in patients with controlled LDL-C (bad cholesterol) levels through maximally tolerated statins. Controlled LDL-C levels reduce the risk of cardiovascular events by 25-35%, which leaves a significant opportunity for Vascepa. It is estimated that there are more than 50 million people with elevated TG levels (≥ 150 mg/dL). Vascepa is also the only FDA-approved drug for reducing cardiovascular risk beyond cholesterol lowering therapy in high-risk patients.

Amarin's only marketed drug Vascepa has been generating strong sales over the last four years in the United States. Its label expansion approval is encouraging.

Reasons To Sell:

- ▼ **Overdependence on Vascepa:** Amarin has no approved product in its portfolio other than Vascepa at the moment. The company is completely dependent on the drug for revenues and future growth. Any commercial setback or rise in competition will be a setback for the company. In March 2020, the company received a setback when Nevada district court ruled in favor of generic companies seeking approval for generic version of Vascepa for treating hypertriglyceridemia. Although there are no FDA-approved Vascepa generic and the company plans to appeal against the ruling, an unfavourable will significantly dent the company's prospect.
- ▼ **Competition in Targeted Market:** Although Vascepa reduces risk of cardiovascular events by lowering TG levels, it may face competition from LDL-C lowering drugs and statins. Moreover, AstraZeneca also has an omega-3 based drug, Epanova, approved as an adjunct to diet to reduce triglyceride levels in adults with severe hypertriglyceridemia. Acasti Pharma is also developing its omega-3 based candidate, CaPre, for treating severe hypertriglyceridemia and also has potential to treat patients with mild-to-moderate TG levels. Matinas BioPharma is also developing a candidate targeting hypertriglyceridemia and mixed dyslipidemia. Successful development will increase competition for Vascepa. Other drugs, which may provide competition to Vascepa, include generic version of Tricor, Trilipix and Lovaza.
- ▼ **Pipeline Setback:** Gaining approval for pipeline candidates has become more difficult with an increasingly stringent regulatory environment. Any unfavorable outcome on the regulatory front or in future development programs will have an adverse impact on the shares. We note that Amarin is no stranger to regulatory setbacks. In 2015, the company had received a complete response letter to a label expansion application for Vascepa seeking approval in patients with mixed dyslipidemia, based on data from the ANCHOR study.

Amarin's sole dependence on Vascepa for growth is a concern. Any setback to Vascepa will have an unfavorable impact. Lack of pipeline candidates is another woe.

Last Earnings Report

Amarin's Q4 Earnings and Sales Surpass Estimates

Amarin reported fourth-quarter 2019 adjusted earnings of 4 cents (excluding stock based compensation) per American depositary share, beating the Zacks Consensus Estimate of 1 cent. The company had recorded an adjusted loss of 9 cents in the year-ago period.

Revenues, primarily from its sole marketed drug Vascepa, were up almost 85.3% year over year to \$143.3 million in the quarter, beating the Zacks Consensus Estimate of \$134.44 million.

Quarter Ending **12/2019**

Report Date	Feb 25, 2020
Sales Surprise	6.58%
EPS Surprise	300.00%
Quarterly EPS	0.04
Annual EPS (TTM)	0.02

Quarter in Details

Product revenues, entirely from Vascepa, were \$142 million, up 84.3% year over year. Sales were up 26.4% sequentially. Strong demand for the drug continues to drive sales higher. Per IQVIA, normalized prescriptions for Vascepa increased approximately 85% year over year to 909,000.

Licensing revenues were \$1.2 million in the fourth quarter compared with \$0.24 million in the year-ago period.

Selling, general and administrative expenses were up 20.5% to \$96 million due to rise in commercial and other promotional costs to support launch of Vascepa in expanded label.

Research & development expenses decreased 6.8% to \$11.1 million due to a decline in costs, following completion of REDUCE-IT study.

The company ended the quarter with \$664.6 million in cash and cash equivalents, compared with \$673.2 million as of Sep 30, 2019.

Full-Year Results

Amarin reported revenues of \$429.8 million, up 87.5% year over year. The company's adjusted earnings for 2019 were 2 cents per share against a loss of 33 cents in the year-ago period.

Revenues for the full year as well as the reported quarter were at the highest level recorded by the company.

2020 Guidance

Amarin had provided guidance for revenues and operating expenses with its preliminary results announced in January 2020. It maintained the view on its fourth-quarter earnings call.

The company continues to expect revenues for 2020 to be in the range of \$650-\$700 million, primarily from Vascepa sales, indicating growth of 57% year over year at the mid-point of the range. The company remains on track to increase its sales team to approximately 800 in early 2020. It expects its operating expense to increase approximately to \$200 to \$250 million from expenses incurred in 2019, especially to support its increased sales team and various promotional programs related to Vascepa.

The company had announced in its preliminary results that it anticipates cash flow to remain negative in the beginning of 2020. Meanwhile, the company stated that it has sufficient funds to maintain projected operations and to achieve positive cash flow following the commercial launch of Vascepa in the expanded label.

Recent News

Plans to Appeal Against Unfavorable Patent Ruling Related to Vascepa – Mar 30

Amarin has strongly opposed a ruling from the United States District Court for the District of Nevada in favor of the generic companies related to patent litigation against Vascepa's hypertriglyceridemia. Generic companies — Dr. Reddy's Laboratories and West-Ward Pharmaceuticals, a subsidiary of Hikma Pharmaceuticals — have filed ANDAs seeking approval for generic version of 0.5mg and 1mg dosage of Vascepa as a treatment of hypertriglyceridemia. The court stated that all patent claims made by Amarin in the litigations were "obvious" and thus invalid.

The company plans to appeal against it and will file an injunction against generic companies, restricting them from launching a generic version of Vascepa until a decision related to its appeal is obtained.

The patent litigations do not include Vascepa's expanded label based on REDUCE-IT study

Announces 2019 Preliminary Results – Jan 7

Amarin reported preliminary results for 2019 and issued expense guidance for 2020.

2019 Preliminary Results

For 2019, the company's preliminary results indicate total revenues at the upper end of \$410-\$425 million range or slightly above it. The Zacks Consensus Estimate for the fourth quarter and full year stands at \$131.08 million and \$419 million, respectively.

The estimated full-year sales indicate growth of nearly 85% from the year-ago period, driven by strong demand for Vascepa. Meanwhile, the company ended 2019 with approximately \$645 million in cash. Amarin also ended the year with no outstanding debt except for remaining balance on its royalty-bearing instrument.

2020 Outlook

Amarin provided revenue guidance for 2020 following the FDA approval for the cardiovascular indication in December. The company continues to expect revenues for 2020 to be in the range of \$650-\$710 million, primarily from Vascepa sales. This indicates growth of more than 50% year over year. The company also remains on track to almost double its sales team to 800 in early 2020 to support promotion of Vascepa's expanded label. It also remains committed to start branded direct-to-consumer promotion of Vascepa for cardiovascular risk reduction, which is subject to FDA approval.

The Zacks Consensus Estimate of \$698.99 million for 2020 lies within the guided range. Although Amarin did not provide any revenue estimates beyond 2020, it expects Vascepa sales to reach billions of dollars.

However, the company expects its operating expenses to increase significantly in 2020 due to increase in its sales team and various promotional programs related to Vascepa. It expects its operating expense to increase approximately to \$200 to \$250 million from expenses incurred in 2019. In the first nine months of 2019, the company's operating expenses were \$250.9 million while in 2018, expenses totaled \$282.9 million.

The company also anticipates cash flow to remain negative in the beginning of 2020.

Announces Approval for Vascepa in Canada – Jan 2

Amarin announced that Health Canada approved Vascepa to reduce the risk of cardiovascular events in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor. Vascepa becomes the first drug to receive approval in the country for the indication.

The drug is expected to be launched in Canada in mid-February by the company's partner, HLS Therapeutics. Amarin will receive \$2.5 million from HLS Therapeutics related to Vascepa's Canadian approval.

FDA Approval of Vascepa Label Expansion – Dec 13

Amarin announced that the FDA approved a label expansion for Vascepa to include REDUCE-IT study data. Vascepa is now approved to reduce cardiovascular risk in patients with persistent elevated triglycerides on statin therapy for LDL-C.

Announced Acceptance of Vascepa MAA for Heart Risk Indication in EU – Dec 2

Amarin announced that the European Medicines Agency has validated and accepted its marketing authorization application ("MAA") for Vascepa (icosapent ethyl). The MAA seeks approval for the drug in Europe as a treatment to reduce the risk of cardiovascular events in high-risk patients with cholesterol levels controlled with statin treatment but elevated triglycerides and other cardiovascular risk factors.

The regulatory application includes data from previously completed REDUCE-IT cardiovascular outcomes study. The review of the MAA is expected to be completed before the end of 2020.

Valuation

Amarin's shares are down 72.9% in the year-to-date period and 70.1% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 7.1% and 10.5% in the year-to-date period. Over the past year, stocks in the sub-industry and the sector are down 11.1% and 9.3%, respectively.

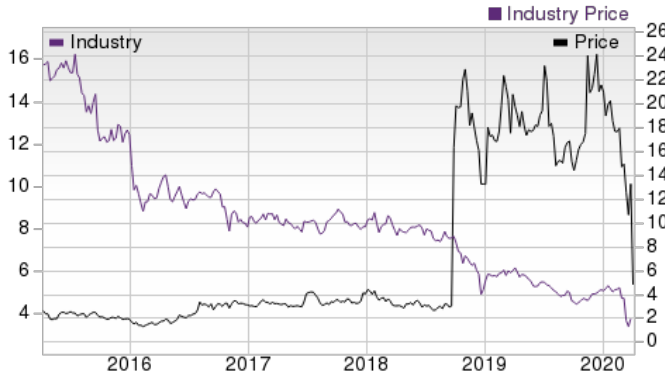
The S&P 500 Index is down 17.3% in the year-to-date period and 8.1% in the past year.

The stock is currently trading at 5.42X trailing 12-month sales per share which compares to 2.99X for the Zacks sub-industry, 2.81X for the Zacks

sector and 2.98X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 33.02X and as low as 2.85X, with a 5-year median of 5.98X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our \$6.25 price target reflects 5.83X trailing 12-month sales per share.

Industry Analysis Zacks Industry Rank: Top 9% (24 out of 253)



Top Peers

Eli Lilly and Company (LLY)	Outperform
Acasti Pharma, Inc. (ACST)	Neutral
Alnylam Pharmaceuticals, Inc. (ALNY)	Neutral
Amgen Inc. (AMGN)	Neutral
AstraZeneca PLC (AZN)	Neutral
Ionis Pharmaceuticals, Inc. (IONS)	Neutral
Regeneron Pharmaceuticals, Inc. (REGN)	Neutral
Sanofi (SNY)	Neutral

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	AMRN Neutral	X Industry	S&P 500	ACST Neutral	AZN Neutral	IONS Neutral
VGM Score	F	-	-	F	C	D
Market Cap	2.08 B	161.87 M	19.05 B	33.48 M	115.08 B	7.31 B
# of Analysts	3	3	13	3	5	11
Dividend Yield	0.00%	0.00%	2.23%	0.00%	4.24%	0.00%
Value Score	D	-	-	F	C	C
Cash/Price	0.38	0.31	0.06	0.65	0.05	0.37
EV/EBITDA	-108.51	-2.13	11.47	-0.44	18.55	12.62
PEG Ratio	NA	1.72	2.00	NA	1.37	NA
Price/Book (P/B)	3.54	3.03	2.56	NA	7.88	4.38
Price/Cash Flow (P/CF)	NA	13.87	10.14	NA	13.84	21.61
P/E (F1)	29.05	28.40	16.97	NA	21.71	NA
Price/Sales (P/S)	4.83	12.55	2.01	NA	4.72	6.51
Earnings Yield	3.44%	-19.78%	5.81%	-86.49%	4.61%	-0.25%
Debt/Equity	0.00	0.02	0.70	0.00	1.11	0.47
Cash Flow (\$/share)	-0.06	-1.03	7.01	-0.47	3.17	2.43
Growth Score	D	-	-	F	D	D
Hist. EPS Growth (3-5 yrs)	NA%	18.12%	10.92%	NA	-2.79%	NA
Proj. EPS Growth (F1/F0)	883.35%	5.73%	-0.64%	47.50%	15.43%	-106.16%
Curr. Cash Flow Growth	-82.27%	13.26%	5.93%	501.31%	2.12%	-22.36%
Hist. Cash Flow Growth (3-5 yrs)	12.50%	8.18%	8.55%	NA	-0.86%	126.64%
Current Ratio	3.53	4.82	1.24	2.07	0.86	9.97
Debt/Capital	0.00%	4.33%	42.36%	NA	52.63%	31.80%
Net Margin	-5.27%	-229.34%	11.64%	NA	5.38%	26.09%
Return on Equity	-6.44%	-65.95%	16.74%	-2,168.55%	32.24%	22.23%
Sales/Assets	0.68	0.20	0.54	NA	0.40	0.38
Proj. Sales Growth (F1/F0)	58.59%	8.07%	0.61%	521.21%	9.61%	-30.83%
Momentum Score	F	-	-	D	A	D
Daily Price Chg	15.28%	2.69%	4.33%	4.04%	1.74%	4.85%
1 Week Price Chg	-63.90%	-3.64%	-4.40%	-16.77%	3.51%	-1.82%
4 Week Price Chg	-53.74%	-3.76%	-1.70%	-3.59%	-1.64%	6.84%
12 Week Price Chg	-70.05%	-25.90%	-20.64%	-56.34%	-13.68%	-15.40%
52 Week Price Chg	-70.14%	-33.49%	-12.97%	-60.94%	8.16%	-38.68%
20 Day Average Volume	26,686,928	254,972	4,016,075	910,401	6,607,548	1,154,172
(F1) EPS Est 1 week change	11.83%	0.00%	-0.26%	0.00%	0.10%	0.00%
(F1) EPS Est 4 week change	-13.89%	0.00%	-5.64%	-11.70%	0.10%	-2.55%
(F1) EPS Est 12 week change	-78.26%	-1.79%	-7.49%	-43.18%	-2.88%	-162.67%
(Q1) EPS Est Mthly Chg	-55.56%	0.00%	-9.90%	0.00%	0.00%	5.41%

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	D
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.

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