

Amarin Corporation (AMRN)

\$6.70 (As of 06/26/20)

Price Target (6-12 Months): **\$7.25**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 01/01/20)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:C

Value: D

Growth: B

Momentum: F

Summary

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 started 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 growth. The company anticipates adverse impact on sales due to COVID-19 in 2020. Moreover, potential generic competition remains a concern. Shares have underperformed the industry so far this year.

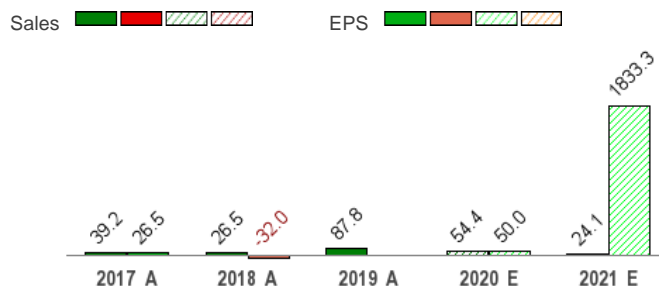
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$26.12 - \$3.95
20 Day Average Volume (sh)	6,895,756
Market Cap	\$2.6 B
YTD Price Change	-68.8%
Beta	2.71
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 20% (51 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	0.0%
Last Sales Surprise	7.5%
EPS F1 Est- 4 week change	-7.1%
Expected Report Date	07/29/2020
Earnings ESP	0.0%
P/E TTM	167.5
P/E F1	223.3
PEG F1	NA
P/S TTM	5.1

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021					824 E
2020	155 A	147 E	169 E	187 E	664 E
2019	73 A	101 A	112 A	143 A	430 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021					\$0.58 E
2020	-\$0.03 A	-\$0.04 E	\$0.03 E	\$0.06 E	\$0.03 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 06/26/2020. The reports text is as of 06/29/2020.

Overview

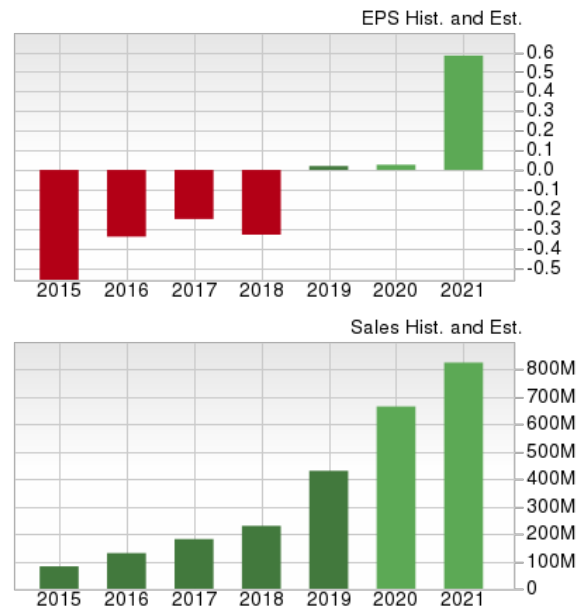
Dublin, Ireland based Amarin Corporation plc is a commercial-stage pharmaceutical company focused on developing therapies, especially based on omega-3 fatty acid, for treating cardiovascular diseases.

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.

The has several initiatives to boost Vascepa sales. It has initiated various promotional activities and direct-to-consumer programs as well as expanded its salesforce to support promotion of Vascepa's expanded label.

However, Amarin is currently facing district court ruled in favor of generic companies seeking approval for generic version of Vascepa for treating hypertriglyceridemia. The company has appealed against the ruling. Meanwhile, the company has signed settlement agreement with Teva and Apotex related to patent litigation for generic version of Vascepa.

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 more than 100% growth in the first quarter of 2020. 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 increased its sales team to 800 in early 2020 and has started promoting the expanded label of the drug among physicians. The company has initiated various promotional activities and direct-to-consumer 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 like 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.

▲ **Favorable Debt Profile:** Amarin has a favorable debt profile. As of Mar 31, 2020, the company's debt to total capital stood at 5.9%, which compared favorably with 7.6% at the end of fourth quarter 2019. A lower ratio indicates lower financial risk. Moreover, the company brought down its debt (current + long-term) significantly in the past five quarters to \$37 million as of Mar 31, 2020 from \$80.3 million at 2018 end. This sharply reduced its debt-to-capital ratio from 34.5% at 2018 end. Also, Amarin's long-term debt level was zero as of March end. The company's cash, cash equivalents, and marketable securities of approximately \$546 million at the end of March 2020 should be sufficient to pay the debt in case of insolvency.

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. It has appealed against the ruling. Meanwhile, the FDA approved Hikma's generic version of Vascepa in May 2020. An unfavorable outcome of the appeal will significantly dent the company's prospects, as it will allow generics to be launched which can erode Vascepa's sales.

Amarin stated on its first-quarter earnings call that reports of COVID-19 infection are most pronounced in areas where the company was relying for sales growth in 2020. Moreover, the company witnessed a decline in the rate of new prescriptions for Vascepa as it suspended in-person sales calls due to COVID-19 social distancing priorities. These developments will likely affect the drug's sales in the remainder of 2020.

▼ **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 Q1 Loss In Line With Estimates, Sales Beat

Amarin reported first-quarter 2020 adjusted loss of 3 cents (excluding stock-based compensation) per American depositary share, in line with the Zacks Consensus Estimate. The company had recorded adjusted loss of 5 cents in the year-ago period.

Revenues, primarily from Vascepa, were up almost 111.5% year over year to \$155 million in the quarter, beating the Zacks Consensus Estimate of \$144.13 million.

Quarter Ending **03/2020**

Report Date	Apr 30, 2020
Sales Surprise	7.54%
EPS Surprise	0.00%
Quarterly EPS	-0.03
Annual EPS (TTM)	0.04

Quarter in Details

Product revenues, entirely from Vascepa, were \$152.2 million, up 109.3% year over year. Sales were up 7.2% sequentially. Strong demand for the drug continues to drive sales. Sales in ex-U.S. market, solely from Canada, were \$6.7 million.

Per IQVIA, normalized prescriptions for Vascepa increased approximately 74% year over year to 962,000 in the United States.

Licensing revenues were \$2.8 million in the first quarter compared with \$0.5 million in the year-ago period.

Adjusted selling, general and administrative expenses were up 89.2% to \$124.9 million due to rise in commercial and other promotional costs to support launch of Vascepa in expanded label.

Adjusted research & development expenses surged 45.9% to \$8.7 million driven by costs related to further analysis of samples collected from REDUCE-IT patients and certain milestones payments made to Mochida as part of a strategic collaboration agreement.

The company ended the quarter with \$623.7 million in cash and investments, compared with \$644.6 million as of Dec 31, 2019.

Recent News

Settles Patent Litigation With Apotex – Jun 16

Amarin announced that it has entered into a settlement agreement with Apotex resolving patent litigation related to Vascepa. Apotex has previously filed an abbreviated NDA seeking approval for a generic version of Vascepa.

The agreement will allow Apotex to market a generic version of Vascepa not earlier than Aug 9, 2029.

Supports Study to Evaluate Vascepa in COVID-19 patients – May 21

Amarin announced that it will support a clinical study to evaluate Vascepa in COVID-19 patients for inflammatory biomarkers and other patient outcomes. The study is sponsored by the Canadian Medical and Surgical Knowledge Translation Research Group.

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 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 68.7% in the year-to-date period and 65.2% over the trailing 12-month period. Stocks in the Zacks sub-industry are up 10.5% while stocks in the Zacks sector are down 3.7% in the year-to-date period. Over the past year, stocks in the sub-industry and the sector are up 12.9% and 0.1%, respectively.

The S&P 500 Index is down 6.6% in the year-to-date period but up 2.1% in the past year.

The stock is currently trading at 4.73X trailing 12-month sales per share which compares to 4.48X for the Zacks sub-industry, 4.18X for the Zacks sector and 4.12X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 33.02X and as low as 2.82X, with a 5-year median of 5.82X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our \$7.25 price target reflects 5.12X trailing 12-month sales per share.

Industry Analysis Zacks Industry Rank: Top 20% (51 out of 253)



Top Peers

Company (Ticker)	Rec	Rank
Eli Lilly and Company (LLY)	Outperform	2
Acasti Pharma, Inc. (ACST)	Neutral	3
Alnylam Pharmaceuticals, Inc. (ALNY)	Neutral	3
Amgen Inc. (AMGN)	Neutral	3
AstraZeneca PLC (AZN)	Neutral	2
Ionis Pharmaceuticals, Inc. (IONS)	Neutral	3
Regeneron Pharmaceuticals, Inc. (REGN)	Neutral	2
Sanofi (SNY)	Neutral	3

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	AMRN	X Industry	S&P 500	ACST	AZN	IONS
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	3	2	3
VGM Score	C	-	-	F	C	F
Market Cap	2.58 B	251.10 M	21.00 B	50.80 M	138.30 B	8.37 B
# of Analysts	3	3	14	3	5	10
Dividend Yield	0.00%	0.00%	2%	0.00%	3.53%	0.00%
Value Score	D	-	-	F	B	D
Cash/Price	0.21	0.22	0.07	0.29	0.03	0.29
EV/EBITDA	-154.17	-3.81	12.28	-0.97	22.28	15.30
PEG Ratio	NA	2.01	2.80	NA	1.57	NA
Price/Book (P/B)	4.30	4.25	2.88	NA	11.32	5.33
Price/Cash Flow (P/CF)	NA	16.12	11.08	NA	16.64	24.73
P/E (F1)	225.33	30.50	20.57	NA	25.99	NA
Price/Sales (P/S)	5.05	17.36	2.14	NA	5.48	8.73
Earnings Yield	0.45%	-12.25%	4.62%	-73.21%	3.85%	-0.80%
Debt/Equity	0.00	0.02	0.77	0.00	1.32	0.51
Cash Flow (\$/share)	-0.06	-1.08	7.01	-0.47	3.17	2.43
Growth Score	B	-	-	D	D	F
Hist. EPS Growth (3-5 yrs)	NA%	16.29%	10.84%	NA	-2.89%	NA
Proj. EPS Growth (F1/F0)	33.34%	10.20%	-10.73%	31.67%	15.89%	-123.03%
Curr. Cash Flow Growth	-82.27%	14.86%	5.46%	501.31%	2.12%	-22.36%
Hist. Cash Flow Growth (3-5 yrs)	12.50%	7.75%	8.55%	NA	-0.86%	126.64%
Current Ratio	2.63	5.14	1.29	2.07	0.75	9.91
Debt/Capital	0.00%	4.38%	45.14%	NA	56.87%	33.60%
Net Margin	-3.67%	-204.33%	10.53%	NA	5.94%	16.79%
Return on Equity	-4.05%	-63.41%	16.06%	-2,168.55%	33.97%	12.50%
Sales/Assets	0.67	0.19	0.55	NA	0.42	0.32
Proj. Sales Growth (F1/F0)	54.57%	0.22%	-2.70%	628.28%	9.48%	-34.75%
Momentum Score	F	-	-	C	C	D
Daily Price Chg	-3.18%	-2.64%	-1.90%	-7.19%	-0.58%	-1.57%
1 Week Price Chg	4.86%	4.94%	0.92%	2.80%	3.01%	0.99%
4 Week Price Chg	-1.90%	2.45%	-3.33%	-13.74%	-1.50%	6.47%
12 Week Price Chg	28.35%	39.54%	19.31%	60.87%	20.43%	22.61%
52 Week Price Chg	-64.21%	1.14%	-9.84%	-49.08%	28.57%	-7.11%
20 Day Average Volume	6,895,756	374,945	2,782,477	4,037,039	5,776,788	855,028
(F1) EPS Est 1 week change	-19.74%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	-7.06%	0.00%	0.00%	0.00%	0.70%	0.00%
(F1) EPS Est 12 week change	-26.39%	1.33%	-12.23%	-30.16%	1.00%	-273.69%
(Q1) EPS Est Mthly Chg	-8.57%	0.00%	0.00%	0.00%	-1.14%	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	D
Growth Score	B
Momentum Score	F
VGM Score	C

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

This report contains independent commentary to be used for informational purposes only. The analysts contributing to this report do not hold any shares of this stock. The analysts contributing to this report do not serve on the board of the company that issued this stock. The EPS and revenue forecasts are the Zacks Consensus estimates, unless indicated otherwise on the reports first page. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts personal views as to the subject securities and issuers. ZIR certifies that no part of the analysts compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report.

Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Any opinions expressed herein are subject to change.

ZIR is not an investment advisor and the report should not be construed as advice designed to meet the particular investment needs of any investor. Prior to making any investment decision, you are advised to consult with your broker, investment advisor, or other appropriate tax or financial professional to determine the suitability of any investment. This report and others like it are published regularly and not in response to episodic market activity or events affecting the securities industry.

This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. ZIR or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time. ZIR is not a broker-dealer. ZIR may enter into arms-length agreements with broker-dealers to provide this research to their clients. Zacks and its staff are not involved in investment banking activities for the stock issuer covered in this report.

ZIR uses the following rating system for the securities it covers. **Outperform-** ZIR expects that the subject company will outperform the broader U.S. equities markets over the next six to twelve months. **Neutral-** ZIR expects that the company will perform in line with the broader U.S. equities markets over the next six to twelve months. **Underperform-** ZIR expects the company will underperform the broader U.S. equities markets over the next six to twelve months.

No part of this report can be reprinted, republished or transmitted electronically without the prior written authorization of ZIR.