Amarin Corporation

Amarin Reports Record Fourth Quarter and Full Year 2018 Financial Results and Provides Update on Operations

February 27, 2019

Record Revenue of $229.2 Million and $77.3 Million for Full Year and Fourth Quarter 2018

REDUCE-IT™ sNDA Submission Remains on Schedule to be Filed Before the End of Q1 2019

Management to Host Conference Call at 7:30 a.m. ET Today

BEDMINSTER, N.J., and DUBLIN, Ireland, Feb. 27, 2019 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on improving cardiovascular health, today announced financial results for the quarter and year ended December 31, 2018 and provided an update on company operations.

Key Amarin achievements in 2018 include:

- Unprecedented positive clinical trial: Results of the REDUCE-IT™ cardiovascular outcomes study of Vascepa® demonstrated, compared to placebo, a 25% reduction in major adverse cardiovascular events, with a number needed to treat of 21, and including a 20% reduction in cardiovascular death.[1] These results are the largest shown as an add-on to statin therapy by any therapy in any studied patient population. This important result, recognized by the Journal Watch Cardiology section of *The New England Journal of Medicine* as the top story of 2018, positions Vascepa to potentially help millions of patients.

- Revenue growth: Net total revenue, the majority of which was recorded prior to REDUCE-IT results, reached a record level of $229.2 million in 2018, including net total revenue of $77.3 million in the fourth quarter of 2018. The results represent increases of approximately 27% and 44% for full year and fourth quarter of 2018 over the corresponding periods of 2017, respectively, primarily reflecting Vascepa prescription growth.

- Commercialization evolution: Amarin began its transition from a U.S. sales presence with a relatively small specialty sales team reliant on a co-promotion partner promoting Vascepa based on biomarker data to a broader direct sales model with more sales representatives, more physician targets and promotion which includes reference to cardiovascular outcomes study results. Further promotional expansion, particularly consumer-based promotion, is anticipated following label expansion for Vascepa based on the REDUCE-IT study results.

- Strengthened balance sheet: At December 31, 2018, Amarin had $249.2 million of cash and cash equivalents.

“The tremendous progress Amarin made in 2018 helps position us for further significant achievement and accelerated revenue growth in the future,” commented John Thero, Amarin’s president and chief executive officer. “Our excitement regarding the REDUCE-IT study results is being reinforced by feedback from healthcare professionals as they begin to understand these unprecedented results and the positive impact it could have on patient care.”

Guidance Reaffirmed

Amarin provided financial guidance for 2019 in its press release on January 4, 2019. Amarin today reaffirms that such earlier guidance has not changed, including its guidance regarding its planned sNDA and expected 2019 revenue as follows:

- sNDA Submission: Based on the unprecedented results from the REDUCE-IT cardiovascular outcomes study, Amarin intends to submit a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking labeling for Vascepa which reflects the cardiovascular risk reduction results demonstrated in this landmark study. Amarin remains on-track to submit this sNDA before the end of the first quarter of 2019 (i.e. before the end of March 2019) with a normal 10-month regulatory review period assumed prior to a PDUFA date. While priority review for this sNDA is not currently assumed, after the sNDA is submitted, consistent with FDA practices, Amarin will seek to clarify whether priority review by the FDA is possible for this important submission. Amarin’s sNDA will consist of over 200,000 pages of data, all of which is undergoing extensive medical, statistical and quality review.

- 2019 Revenue: Net total revenue for 2019 is anticipated to increase by more than 50% over 2018 to approximately $350 million, mostly from U.S. sales of Vascepa. Amarin believes that continued quarterly variability in revenues is likely. This guidance assumes that the timing of the expanded label for Vascepa which Amarin is seeking, subject to FDA approval, will not be available until late 2019 or early 2020 such that the expanded label has little or no impact on revenue growth in 2019.

Prescription Growth

Normalized prescriptions for Vascepa (prescription of 120 grams of Vascepa representing a one-month supply) increased by 25% and 27% in 2018 compared to 2017 based on data from Symphony Health and IQVIA, respectively, and increased by 33% and 32% in the fourth quarter of 2018 compared to the same period in 2017, respectively. Estimated normalized Vascepa prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 539,000 and 538,000 in the fourth quarter of 2018. Since Vascepa was made commercially available in 2013, more than five million estimated normalized total prescriptions of Vascepa have been reported by Symphony Health.

Sales Force Expansion

Prior to topline results from the REDUCE-IT study which became available in September 2018, Amarin's U.S. sales force consisted of approximately 150 sales representatives plus their managers. Upon learning the positive REDUCE-IT results, Amarin proceeded to hire and train additional sales representatives such that it currently has approximately 400 sales representatives plus their managers in the U.S. The majority of this increase in the U.S. sales force for Vascepa promotion occurred during the late part of 2018 or early in 2019. Corresponding to the increase in the size of its direct sales force, Amarin also significantly expanded the number of healthcare professionals it plans to call on for Vascepa education to approximately 54,000 healthcare professionals and expanded various other marketing and medical education programs. In parallel, as previously described and intended, the company's co-promotion arrangement for Vascepa reached its scheduled conclusion on December 31, 2018 such that Amarin's prior co-promotion partner is no longer promoting Vascepa. Amarin believes that, while there may be some transition period required for new sales representatives to become productive, Vascepa revenue growth will be most cost-effectively achieved by having this expanded Amarin sales team giving priority to Vascepa promotion.

Scientific Publication

During 2018, Amarin supported 40 scientific publications and presentations, up from 25 Amarin supported scientific publications and presentations in 2017. These included results of the REDUCE-IT study, as published in *The New England Journal of Medicine* online in November 2018, which became available in its print edition in early 2019, as well as real-world evidence data, evaluation of multiple mechanisms of action for the active ingredient in Vascepa and various demographic information pertaining to cardiovascular disease.

Results from Amarin's earlier phase 3 studies of Vascepa, the MARINE and ANCHOR studies, resulted in multiple years of scientific publications. Similarly, Amarin continues to analyze the REDUCE-IT data to further assess additional scientific results. We anticipate further scientific publication and presentation to result from this analysis that potentially progress the understanding of cardiovascular disease and the use of Vascepa to further reduce the risk of major adverse cardiovascular events in an at-risk patient population.

In early 2019, we already witnessed additional publication of scientific study of the mechanism of action of Vascepa and the acceptance of various scientific posters for presentation at the upcoming American College of Cardiology's (ACC) 68 th Annual Scientific Session on March 18, 2019 in New Orleans, LA (ACC scientific session). This includes, as previously announced, presentation as late-breaking clinical trial data of new data on the reduction of total major adverse cardiovascular (i.e., ischemic) events shown in REDUCE-IT. Amarin looks forward to all such data being presented at ACC and intends to issue one or more press releases describing the data once it is public.

Financial Update

Net product revenue for the years ended December 31, 2018 and 2017 was $228.4 million and $179.8 million, respectively. Net product revenue for the three months ended December 31, 2018 and 2017 was $77.1 million and $53.5 million, respectively. Increased revenue is mainly attributed to increased Vascepa prescriptions in the U.S.

In addition, Amarin recognized licensing revenue of $0.8 million and $1.3 million for the years ended December 31, 2018 and 2017, respectively, under agreements for the commercialization of Vascepa outside the U.S.

Cost of goods sold for the three months ended December 31, 2018 and 2017 was $17.5 million and $13.4 million, respectively. Cost of goods sold for the years ended December 31, 2018 and 2017 was $54.5 million and $45.0 million, respectively. Gross margin on product sales was approximately 77% and approximately 76% in the quarter and year ended December 31, 2018, as compared to approximately 75% in the quarter and year ended December 31, 2017, respectively.

Selling, general and administrative expenses for the years ended December 31, 2018 and 2017 were $227.0 million and $134.5 million, respectively. This increase is due primarily to increased promotional activities, including commercial spend in preparation for and following the successful REDUCE-IT results (announced on September 24, 2018), including pilot consumer promotion, and increased co-promotion fees calculated on increased gross profit resulting from higher net product revenue plus an accrual of $16.4 million for co-promotion tail payments. The tail co-promotion fees, which were calculated as a percentage of the 2018 co-promotion fee, are payable in 2019 through 2021. No further expense from this prior co-promotion arrangement is anticipated beyond 2018.

Research and development expenses for the years ended December 31, 2018 and 2017 were $55.9 million and $47.2 million, respectively. This increase is primarily due to the REDUCE-IT trial and related costs and the recording of $2.7 million in expense related to the company's previously announced strategic collaboration with Mochida Pharmaceutical Co., Ltd.

Under U.S. GAAP, Amarin reported a net loss of $33.7 million in the three months ended December 31, 2018, or basic and diluted loss per share of $0.11. This net loss included $4.8 million in non-cash stock-based compensation expense. Amarin reported a net loss of $22.5 million in the fourth quarter of 2017, or basic and diluted loss per share of $0.08. This net loss included $3.5 million in non-cash stock-based compensation expense.

Under U.S. GAAP, Amarin reported a net loss of $116.4 million for the year ended December 31, 2018, or basic and diluted loss per share of $0.39. This net loss included $18.8 million in non-cash stock-based compensation expense. For the year ended December 31, 2017, Amarin reported a net loss of $67.9 million, or basic and diluted loss per share of $0.25. This net loss included $14.0 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net loss was $28.9 million for the fourth quarter of 2018, or non-GAAP adjusted basic and diluted loss per share of $0.09, compared to non-GAAP adjusted net loss of $19.0 million for the fourth quarter of 2017, or non-GAAP adjusted basic and diluted loss per share of $0.07.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net loss was $97.6 million for the year ended December 31, 2018, or non-GAAP adjusted basic and diluted loss per share of $0.33, compared to non-GAAP adjusted net loss of $53.9 million for the year ended December 31, 2017, or non-GAAP adjusted basic and diluted loss per share of $0.20.

As of December 31, 2018, the company had $66.5 million in net accounts receivable ($86.1 million in gross accounts receivable before allowances and reserves), which are current, and $57.8 million in inventory. As of December 31, 2018, the company had accounts payable and accrued expenses of $121.8 million which increased from $84.1 million at December 31, 2017 primarily due to the company's growth, including supplier payments associated with the increased levels of Vascepa inventory associated with supporting increased revenue and the magnitude and timing of rebates.

As of December 31, 2018, Amarin had approximately 325.9 million ADSs and ordinary shares outstanding, 28.9 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 19.3 million equivalent shares underlying stock options at a weighted-average exercise price of $4.29, as well as 9.6 million equivalent shares underlying restricted or deferred stock units.

Conference Call and Webcast Information

The conference call can be heard live on the investor relations section of the company's website at www.amarincorp.com, or via telephone by dialing 877-407-8033 within the United States or 201-689-8033 from outside the United States. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010, PIN: 43356. A replay of the call will also be available through the company's website shortly after the call.

Use of Non-GAAP Adjusted Financial Information

Included in this press release are non-GAAP adjusted financial information as defined by U.S. Securities and Exchange Commission Regulation G. The GAAP financial measure most directly comparable to each non-GAAP adjusted financial measure used or discussed, and a reconciliation of the differences between each non-GAAP adjusted financial measure and the comparable GAAP financial measure, is included in this press release after the condensed consolidated financial statements.

Non-GAAP adjusted net loss was derived by taking GAAP net loss and adjusting it for non-cash stock-based compensation expense. Management uses these non-GAAP adjusted financial measures for internal reporting and forecasting purposes, when publicly providing its business outlook, to evaluate the company's performance and to evaluate and compensate the company's executives. The company has provided these non-GAAP financial measures in addition to GAAP financial results because it believes that these non-GAAP adjusted financial measures provide investors with a better understanding of the company's historical results from its core business operations.

While management believes that these non-GAAP adjusted financial measures provide useful supplemental information to investors regarding the underlying performance of the company's business operations, investors are reminded to consider these non-GAAP measures in addition to, and not as a substitute for, financial performance measures prepared in accordance with GAAP. Non-GAAP measures have limitations in that they do not reflect all of the amounts associated with the company's results of operations as determined in accordance with GAAP. In addition, it should be noted that these non-GAAP financial measures may be different from non-GAAP measures used by other companies, and management may utilize other measures to illustrate performance in the future.

About Amarin

Amarin Corporation plc is a rapidly growing, innovative pharmaceutical company focused on developing therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in polyunsaturated fatty acids and lipid science. Vascepa® (icosapent ethyl) is Amarin's first FDA-approved drug and is available by prescription in the United States, Lebanon and the United Arab Emirates. Amarin's commercial partners are pursuing additional regulatory approvals for Vascepa in Canada, China and the Middle East. For more information about Amarin, visit www.amarincorp.com.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths – one death approximately every 38 seconds – with annual treatment cost in excess of $500 billion.[2, 3]

Multiple primary and secondary prevention trials have shown a significant reduction of 25% to 35% in the risk of cardiovascular events with statin therapy, leaving significant persistent residual risk despite the achievement of target LDL-C levels.[4]

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease. [5, 6, 7, 8]

About VASCEPA® (icosapent ethyl) Capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient from degradation. Vascepa, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

Indication and Usage Based on Current FDA-Approved Label (not including REDUCE-IT results)

- Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.
- The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for Vascepa Based on Current FDA-Approved Label (not including REDUCE-IT results) (Includes Data from Two 12-Week Studies (n=622) (MARINE and ANCHOR) of Patients with Triglycerides Values of 200 to 2000 mg/dL)

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence >2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction >3% and greater than placebo.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding planned scientific presentation, publication, regulatory review and related timing thereof, including plans to submit an sNDA before the end of March 2019 seeking an expanded indication for Vascepa in the United States; and expectations regarding further advancement, commercial expansion and revenue growth. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In addition, Amarin's ability to effectively commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, its ability to obtain an expanded indication for Vascepa in the United States, to achieve market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may not be upheld in patent litigation and applications may not result in issued patents sufficient to protect the Vascepa franchise. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent annual report on Form 10-K. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Availability of Other Information About Amarin

Investors and others should note that Amarin communicates with its investors and the public using the company website (http://www.amarincorp.com/), the investor relations website (http://investor.amarincorp.com/), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

References

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CONSOLIDATED BALANCE SHEET DATA
(U.S. GAAP)
Unaudited*

	December 31, 2018	December 31, 2017
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 249,227	$ 73,637
Restricted cash	1,500	600
Accounts receivable, net	66,523	45,318
Inventory	57,802	30,260
Prepaid and other current assets	2,945	3,455
Total current assets	377,997	153,270
Property, plant and equipment, net	63	28
Other long-term assets	174	174
Intangible asset, net	7,480	8,126
TOTAL ASSETS	$ 385,714	$ 161,598
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 37,632	$ 25,155
Accrued expenses and other current liabilities	84,171	58,902
Current portion of exchangeable senior notes, net of discount	—	481
Current portion of long-term debt from royalty-bearing instrument	34,240	22,348
Deferred revenue, current	1,220	1,644
Total current liabilities	157,263	108,530
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	—	28,992
Long-term debt from royalty-bearing instrument	46,108	70,834
Deferred revenue, long-term	19,490	17,192
Other long-term liabilities	10,523	1,150
Total liabilities	233,384	226,698
Stockholders' Equity (Deficit):		
Preferred Stock	21,850	24,364
Common stock	246,663	208,768
Additional paid-in capital	1,282,762	977,866
Treasury stock	(10,413)	(4,229)
Accumulated deficit	(1,388,532)	(1,271,869)
Total stockholders' equity (deficit)	152,330	(65,100)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 385,714	$ 161,598

* Unaudited as standalone schedule; copied from consolidated financial statements.

CONSOLIDATED STATEMENTS OF OPERATIONS DATA
(U.S. GAAP)

	Unaudited Three months ended December 31, (in thousands, except per share amounts)		Unaudited* Twelve months ended December 31, (in thousands, except per share amounts)	
	2018	**2017**	**2018**	**2017**
Product revenue, net	$ 77,085	$ 53,482	$ 228,371	$ 179,825
Licensing revenue	245	384	843	1,279
Total revenue, net	77,330	53,866	229,214	181,104
Less: Cost of goods sold	17,509	13,432	54,543	44,952
Gross margin	59,821	40,434	174,671	136,152
Operating expenses:				
Selling, general and administrative (1)	79,686	35,639	226,996	134,549
Research and development (1)	11,906	11,947	55,900	47,158
Total operating expenses	91,592	47,586	282,896	181,707
Operating loss	(31,771)	(7,152)	(108,225)	(45,555)
Interest expense, net	(1,611)	(2,240)	(7,798)	(9,337)
Other (expense) income, net	(192)	(26)	(326)	74
Loss from operations before taxes	(33,574)	(9,418)	(116,349)	(54,818)
Provision for income taxes (2)	(96)	(13,047)	(96)	(13,047)
Net loss	$ (33,670)	$ (22,465)	$ (116,445)	$ (67,865)
Loss per share:				
Basic	$ (0.11)	$ (0.08)	$ (0.39)	$ (0.25)
Diluted	$ (0.11)	$ (0.08)	$ (0.39)	$ (0.25)
Weighted average shares outstanding:				
Basic	314,183	270,906	297,237	270,652
Diluted	314,183	270,906	297,237	270,652

* Unaudited as standalone schedule; copied from consolidated financial statements.

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were $211,088 and $122,711 for 2018 and 2017, respectively, and research and development expenses were $53,002 and $45,036, respectively, for the same periods. Excluding non-cash stock-based compensation as well as co-promotion fees paid to the company's U.S. co-promotion partner, selling, general and administrative expenses were $164,267 and $100,204 for 2018 and 2017, respectively.

(2) Included in the provision for the year ended December 31, 2017 is non-cash tax expense related to increases in our valuation allowance against deferred tax assets.

RECONCILIATION OF NON-GAAP NET LOSS
Unaudited

	Three months ended December 31, (in thousands, except per share amounts)		Twelve months ended December 31, (in thousands, except per share amounts)	
	2018	**2017**	**2018**	**2017**
Net loss for EPS[1] - GAAP	$ (33,670)	$ (22,465)	$ (116,445)	$ (67,865)
Non-cash stock-based compensation expense	4,775	3,489	18,806	13,960
Adjusted net loss for EPS[1] - non-GAAP	$ (28,895)	$ (18,976)	$ (97,639)	$ (53,905)
[1]basic and diluted				
Loss per share:				
Basic and diluted - non-GAAP	$ (0.09)	$ (0.07)	$ (0.33)	$ (0.20)
Weighted average shares:				

Basic and diluted	314,183	270,906	297,237	270,652

Source: Amarin Corporation plc