

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): July 31, 2019

Amarin Corporation plc
(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction
of incorporation)

0-21392
(Commission
File Number)

Not applicable
(I.R.S. Employer
Identification No.)

**77 Sir John Rogerson's Quay, Block C,
Grand Canal Docklands, Dublin 2, Ireland**
(Address of principal executive offices)

Not applicable
(Zip Code)

Registrant's telephone number, including area code: +353 1 6699 020

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	AMRN	NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On July 31, 2019, Amarin Corporation plc issued a press release announcing its financial results for the three and six months ended June 30, 2019 (the “Press Release”). A copy of the Press Release is furnished herewith as Exhibit 99.1.

The information in this report furnished pursuant to Item 2.02 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated July 31, 2019
	* * *

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 31, 2019

Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer



Amarin Reports Second Quarter 2019 Financial Results and Operational Update

Record Total Revenue of \$100.8 Million Achieved in Q2 2019

Commercial Expansion Plans on Track in Anticipation of September 28, 2019 PDUFA Date for Vascepa®

If Approved, Vascepa to Become First Prescription Therapy to Treat Patients with Underlying Cardiovascular Risk Beyond Cholesterol Management as Demonstrated in the REDUCE-IT™ Cardiovascular Outcomes Study

Millions of Patients in the U.S. Have Underlying Cardiovascular Risk Beyond Cholesterol Management

Increased Cash Balance to More Than \$600 Million on a Proforma Basis to Ensure Robust Promotion and Education for Vascepa

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

BEDMINSTER, N.J., and DUBLIN, Ireland, July 31, 2019 -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced financial results for the three and six months ended June 30, 2019, and provided an update on company operations.

Key Amarin achievements since its last quarterly report include:

- U.S. regulatory review progressing: The Priority Review of Amarin's supplemental new drug application (sNDA) seeking to expand the indication for Vascepa® (icosapent ethyl) appears to be progressing in an orderly and timely manner toward the September 28, 2019 PDUFA goal date.
- Second quarter net product revenue growth increased by 91%: Recognized \$100.8 million in total revenue and \$100.4 million in net product revenue from Vascepa sales in Q2 2019 compared to \$52.5 million in Q2 2018, an increase of 91%. The total revenue result is at the upper end of the company's previously estimated revenue of between \$97 and \$101 million announced on July 2, 2019.
- U.S. prescriptions grew by more than 70%: Increased normalized prescriptions for Vascepa by 76% and 73% compared to Q2 2018 based on data from Symphony Health Solutions and IQVIA, respectively.
- Commercial expansion preparation under way: Actively hiring additional sales managers and sales representatives to double the size of Amarin's U.S. sales force to approximately 800 sales representatives by October 2019, while also executing on other plans to effectively educate healthcare professionals and consumers regarding the cardiovascular risk reduction profile of Vascepa and the significant unmet need for this disease, following an anticipated label expansion in late September.
- International plans on track: Progressing through Amarin's licensee, HLS Therapeutics Inc. (TSX:HLS), towards anticipated approval of Vascepa in Canada in the fourth quarter of 2019. As previously disclosed, the application for Vascepa was granted a priority review designation by Health Canada. Other international progress is continuing, including Amarin's plans to submit an application seeking approval for Vascepa in Europe before the end of 2019.
- Increased cash balance to ensure robust launch of Vascepa: As of June 30, 2019, Amarin had a cash balance of \$221.8 million. In July 2019, Amarin completed a \$460.0 million equity offering resulting in an increase in Amarin's cash balance to more than \$600 million on a pro forma basis.

"Amarin made tremendous progress in the first half of 2019, including achieving \$100 million in quarterly revenue which is a record for Vascepa sales," stated John F. Thero, president and chief executive officer, Amarin. "We believe this is just the start of realizing the significant commercial opportunity for Vascepa, which will be driven by our passion to potentially help millions of at-risk patients and our ability to broadly communicate to healthcare professionals and patients the cost-effective value of Vascepa based on the FDA-

approved expanded indication we’re anticipating in September. Our focus right now is ensuring we are prepared to robustly launch *Vascepa* based on that expanded indication.”

Regulatory Update

As previously announced, Amarin submitted a sNDA to the FDA on March 28, 2019, seeking to expand the indication for *Vascepa*. The sNDA was based on the positive results of the landmark REDUCE-IT™ cardiovascular outcomes study. If approved, the expanded label is anticipated to allow for considerably broader promotion of *Vascepa* in the United States. As announced in May 2019, the FDA accepted the sNDA for filing and granted Priority Review designation with an assigned PDUFA goal date of September 28, 2019.

To date, the FDA has not informed Amarin as to whether it plans to convene an Advisory Committee (AdCom) to review the sNDA. The FDA is not required to inform sponsor companies that it does not intend to hold an AdCom. While it remains possible that the FDA may elect to convene an AdCom, with less than two months remaining prior to the PDUFA date Amarin is now assuming that an AdCom is unlikely. If Amarin is informed definitively that there will or will not be an AdCom, the company plans to update investors accordingly.

Label negotiations in the sNDA process could commence as early as one month prior to the PDUFA date under FDA’s typical processes. As such, a final version of the updated *Vascepa* label is not available at this time. It would therefore be unproductive for Amarin to speculate on the wording of such a label before a final determination by the FDA except to express that Amarin is seeking a cardiovascular risk reduction label for *Vascepa* which is consistent with the results of the REDUCE-IT study.

Prescription Growth

Vascepa prescription growth in Q2 2019 stemmed from both prior prescribers and new prescribers. Normalized prescriptions for *Vascepa* (prescription of 120 grams of *Vascepa* representing a one-month supply) increased by approximately 76% and 73% in Q2 2019 compared to Q2 2018 based on data from Symphony Health and IQVIA, respectively. Estimated normalized *Vascepa* prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 756,000 and 683,000 in the second quarter of 2019.

As there has been a trend of an increasing number of 90-day prescriptions (or scripts) vs. 30-day prescriptions, reporting from Symphony and IQVIA on prescription counts may not reflect the true demand for the product. Script counts from these services do not account for whether a script is for 90 days or 30 days as both are counted as one script. Accordingly, Amarin believes that pill counts reported as extended units by Symphony and IQVIA show a more accurate reflection of the demand for *Vascepa*. Normalized prescriptions, as referenced above, take this into account by using the extended unit number and dividing by the pill count in the bottle. Nonetheless, even when normalized, estimates from these independent sources for *Vascepa* and other drugs have historically been most accurate over longer periods of time, such as annually, while directionally informative over shorter periods of time.

As described more fully in Amarin’s Quarterly Report on Form 10-Q, Amarin recognizes product revenue when its customers, consisting mostly of independent commercial distributors, take possession of the product they order and Amarin ships to them. Amarin revenue is not recognized when individual patients fill prescriptions.

Commercial Update

Upon FDA approval of an expanded indication for *Vascepa*, Amarin’s goal is to be ready to launch a robust educational and promotional campaign aimed at healthcare professionals and consumers on the efficacy and safety profile of *Vascepa* as well as on the significant unmet need to help patients with underlying cardiovascular risks beyond cholesterol management.

When physicians become knowledgeable about the results of the REDUCE-IT study, it has been Amarin’s experience that they appreciate the importance of *Vascepa* and how it can be used to help the health of their patients. However, the vast majority of healthcare professionals have little knowledge of *Vascepa*. Amarin views this as an opportunity to be improved through expanded *Vascepa* promotion supported by an expanded label.

With the benefit of funds from recent financing, the company plans to create “surround sound” in its promotion of *Vascepa*. This surround sound will include more sales representatives, various forms of digital outreach, medical education, scientific presentations at industry meetings, direct-to-consumer advertising and other means of effective and responsible communications.

Most of the sales representatives hired at the start of 2019 are performing well and showing promise for greater contribution in the future. Their progress, together with the anticipated value of the expanded label for *Vascepa*, gives Amarin the confidence to double the size of its sales force.

To date, Amarin has hired most of the additional sales managers required for this expansion and is confident that it will have approximately 400 new sales representatives hired, trained and in the field promoting *Vascepa* by early October.

While the expanded sales team will reach a larger number of healthcare professionals, it is equally important to achieve more frequent interactions with targeted healthcare professionals. The current sales team calls on approximately 50,000 healthcare professionals. With the doubling of the sales force, Amarin expects to reach approximately 70,000 to 80,000 healthcare professionals. As of the end of June 2019, consistent with previously communicated projections, Amarin sales representatives called on approximately half of its current target physicians five or more times with the published results of the REDUCE-IT study.

Direct-to-consumer (DTC) promotion is likely to be a phased process. Upon label expansion, Amarin plans to increase promotion through more placement of *Vascepa* advertisement in platforms currently used. In parallel, new messaging for branded promotion based on the anticipated expanded label for *Vascepa* will be submitted to the FDA for review. Such submission for promotional review cannot be made until after the label is expanded. Subject to FDA review, Amarin anticipates launching that DTC campaign in the second quarter of 2020.

Managed care coverage for *Vascepa* continues to be favorable overall. Amarin anticipates marginal further improvement to such coverage in Q3 2019, prior to label expansion, and plans to pursue even broader managed care coverage following assumed label expansion.

The Institute for Clinical and Economic Review (ICER), an independent non-profit organization, released its draft evidence report regarding clinical effectiveness and economic impacts of *Vascepa* on July 24, 2019. ICER's draft report concluded that *Vascepa* is cost effectiveness across all the non-profit organization's analyses, based on its quality-adjusted life year (QALY) metrics. Despite the draft report's positive conclusion regarding cost effectiveness, Amarin believes that ICER understates the value of *Vascepa*. For example, the ICER base-case analyses reflect only the costs of heart attack, stroke and cardiovascular death and appear to exclude high costs associated with other cardiovascular events that were demonstrated to be lowered by *Vascepa* in the REDUCE-IT cardiovascular outcomes study (e.g., revascularization procedures and hospitalizations for unstable angina). Amarin believes this draft report, while not perfect in its value assessment, provides additional support for why medical insurance should broadly cover *Vascepa* for the population of patients studied in REDUCE-IT. While many payors already broadly cover *Vascepa*, upon anticipated label expansion, Amarin plans to use the results of the REDUCE-IT study, pharmaco-economic analysis, such as presented by ICER, and other medical information and data in negotiations with payers seeking expanded *Vascepa* insurance coverage.

Financial Update

Total revenue for the three months ended June 30, 2019 and 2018 was \$100.8 million and \$52.6 million, respectively. Net product revenue for the three months ended June 30, 2019 and 2018 was \$100.4 million and \$52.5 million, respectively. Total revenue for the six months ended June 30, 2019 and 2018, was \$174.1 million and \$96.6 million, respectively. Net product revenue for the six months ended June 30, 2019 and 2018 was \$173.1 million and \$96.3 million, respectively. The increase in net product revenue was primarily attributable to increases in new and recurring prescriptions of *Vascepa* as net selling price remained relatively unchanged for the six months ended June 30, 2019 as compared to the same period in 2018.

During the second quarter, based on data from Symphony Health Solutions and IQVIA, Amarin experienced continued prescription growth and an increase in *Vascepa* market share, particularly among physicians called on by Amarin's sales professionals. Symphony Health Solutions and IQVIA reported estimated normalized total *Vascepa* prescriptions of approximately 756,000 and 683,000, respectfully, for the three months ended June 30, 2019, representing growth of approximately 76% and 73%, respectively, over levels estimated by these sources for the same three months of the prior year.

Licensing revenues recognized by the company were \$1.0 million and \$0.2 million in the six months ended June 30, 2019 and 2018, respectively, related to timing of milestones and other factors impacting revenue recognition for licensing fees under agreements for the commercialization of *Vascepa* outside the United States.

Cost of goods sold for the three months ended June 30, 2019 and 2018 was \$22.8 million and \$12.8 million, respectively. Cost of goods sold for the six months ended June 30, 2019 and 2018 was \$39.9 million and \$23.5 million, respectively. Gross margin on net product revenue for the three and six months ended June 30, 2019 and 2018 was 77% and 76%, respectively.

Selling, general and administrative (SG&A) expenses in the six months ended June 30, 2019 and 2018 were \$145.0 and \$97.4 million, respectively, an increase of 49%. This increase is due primarily to increased promotional activities, including commercial spend for expansion following successful REDUCE-IT results, as well as costs for sales force expansion, partially offset by elimination of expenses associated with the company's prior co-promotion partner. As previously disclosed, the level of anticipated SG&A spending

will increase as Amarin doubles the size of its sales force and increases its promotional and educational spending for *Vascepa* in conjunction with the anticipated label expansion.

Research and development (R&D) expenses in the six months ended June 30, 2019 and 2018 were \$14.4 and \$29.9 million, respectively, a decrease of 52%. This decrease in expense is primarily driven by a decline in REDUCE-IT related costs. Following the completion of the REDUCE-IT trial, costs consisted primarily of the clinical study's wrap-up activities, regulatory support and publications. As previously disclosed, Amarin anticipates the level of spending on R&D will continue to decline as it has completed the REDUCE-IT study and initial publication of results from this important study.

Under U.S. GAAP, Amarin reported a net loss of \$1.8 million in the three months ended June 30, 2019, or basic and diluted loss per share of \$0.01. This net loss included \$7.9 million in non-cash stock-based compensation expense. Amarin reported a net loss of \$34.2 million in the second quarter of 2018, or basic and diluted loss per share of \$0.12. This net loss included \$3.6 million in non-cash stock-based compensation expense.

Under GAAP, Amarin reported a net loss of \$26.3 million in the six months ended June 30, 2019, or basic and diluted loss per share of \$0.08. This net loss included \$14.8 million in non-cash stock-based compensation expense. For the six months ended June 30, 2018, Amarin reported a net loss of \$58.3 million, or basic and diluted loss per share of \$0.20. This net loss included \$7.4 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$6.1 million for the second quarter of 2019, or non-GAAP adjusted basic and diluted earnings per share of \$0.02, compared to non-GAAP adjusted net loss of \$30.6 million for the second quarter of 2018, or non-GAAP adjusted basic and diluted loss per share of \$0.10.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net loss was \$11.5 million for the six months ended June 30, 2019, or non-GAAP adjusted basic and diluted loss per share of \$0.03, compared to non-GAAP adjusted net loss of \$50.9 million for the six months ended June 30, 2018, or non-GAAP adjusted basic and diluted loss per share of \$0.18.

As of June 30, 2019, Amarin reported cash and cash equivalents of \$221.8 million, \$95.4 million in net accounts receivable (\$116.3 million in gross accounts receivable before allowances and reserves) and \$46.3 million in inventory. As noted above, the company completed an equity offering in July 2019 for gross proceeds of approximately \$460.0 million and issued approximately 25.5 million ADSs, including the full exercise of the underwriters' 30-day over-allotment option to purchase up to an additional 15% of the ADSs issued in the offering. Net proceeds after fees and expenses from this financing were approximately \$439.5 million. While Amarin was net cash flow positive in the three months ended June 30, 2019, the company expects net cash flow to be negative in the second half of 2019 reflecting planning increased spending for *Vascepa* promotion and anticipated increased purchases of *Vascepa* inventory.

As of June 30, 2019, prior to the above described financing, Amarin had approximately 331.3 million American Depositary Shares (ADSs) and ordinary shares outstanding, 28.9 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 16.6 million equivalent shares underlying stock options at a weighted-average exercise price of \$5.86, as well as 9.3 million equivalent shares underlying restricted or deferred stock units.

Conference Call and Webcast Information

Amarin will host a conference call at 7:30 a.m. ET today, July 31, 2019. The call will be webcast live with slides and accessible through the investor relations section of the company's website at www.amarincorp.com. The call can also be heard via telephone by dialing 877-407-8033. 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 (inside the United States) or 919-882-2331 (outside the United States). A replay of the call will also be available through the company's website shortly after the call. For both dial-in numbers please use conference ID 51652.

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 REDUCE-IT™

REDUCE-IT¹ was an 8,179-patient multinational cardiovascular outcomes study completed in 2018. REDUCE-IT evaluated the effect of prescription pure EPA therapy as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, had elevated triglyceride levels (at least 135 mg/dL). A large portion of the male and female patients enrolled in this outcomes study were diagnosed with type 2 diabetes.

More information on the REDUCE-IT study results can be found at 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.⁵⁻⁸

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.

Important Safety Information for *Vascepa* based on REDUCE-IT, as previously reported in The New England Journal of Medicine¹ publication of the primary results of the REDUCE-IT study:

- Excluding the major adverse cardiovascular events (MACE) results described above, overall adverse event rates in REDUCE-IT were similar across the statin plus *Vascepa* and the statin plus placebo treatment groups.
- There were no significant differences between treatments in the overall rate of treatment emergent adverse events or serious adverse events leading to withdrawal of study drug.
- There was no serious adverse event (SAE) occurring at a frequency of >2% which occurred at a numerically higher rate in the statin plus *Vascepa* treatment group than in the statin plus placebo treatment group.
- Adverse events (AEs) occurring in 5% or greater of patients and more frequently with *Vascepa* than placebo were:
 - peripheral edema (6.5% *Vascepa* patients versus 5.0% placebo patients), although there was no increase in the rate of heart failure in *Vascepa* patients
 - constipation (5.4% *Vascepa* patients versus 3.6% placebo patients), although mineral oil, as used as placebo, is known to lower constipation, and
 - atrial fibrillation (5.3% *Vascepa* patients versus 3.9% placebo patients), although there were reductions in rates of cardiac arrest, sudden death and myocardial infarctions observed in *Vascepa* patients.
- There were numerically more SAEs related to bleeding in the statin plus *Vascepa* treatment group although overall rates were low with no fatal bleeding observed in either group and no significant difference in adjudicated hemorrhagic stroke or serious central nervous system or gastrointestinal bleeding events between treatments.
- In summary, *Vascepa* was well tolerated with a safety profile generally consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling of such products.

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. FDA has not reviewed and opined on a supplemental new drug application related to REDUCE-IT. FDA has not reviewed the information herein or determined whether to approve *Vascepa* for use to reduce the risk of MACE. 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.

Important Cautionary Information About These Data

Further REDUCE-IT data assessment and data release could yield additional useful information to inform greater understanding of the trial outcome. For example, detailed data assessment by regulatory authorities, such as the FDA and Health Canada, will continue and take several months to complete and announce. The final evaluation by regulatory authorities of the totality of efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations: new information or analyses affecting the

degree of treatment benefit on studied endpoints; study conduct and data robustness, quality, integrity and consistency; additional safety data considerations and risk/benefit considerations; and consideration of REDUCE-IT results in the context of other clinical studies. Because regulatory reviews are typically fluid and not definitive interactions between sponsor and agency on individual elements of an application and related information, Amarin does not plan to update investors on ongoing communications with regulatory authorities. Amarin plans to announce the final outcome of such regulatory reviews when appropriate.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding revenue and prescription growth, including updated revenue guidance for 2019; sales force expansion and marketing initiatives expected in 2019 and beyond; FDA regulatory review, including the timing and outcome of such review; the applicability and reliability of REDUCE-IT results; the cost-effectiveness of *Vascepa*; the likelihood that physicians will prescribe *Vascepa* after learning about the REDUCE-IT results; and the expected outcome and timing of review elements and market dynamics for *Vascepa*. 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 gain regulatory approvals, create market demand for *Vascepa* through education, marketing and sales activities, 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 reviews and 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 quarterly report on Form 10-Q. 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 (www.amarincorp.com), the investor relations website (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

- 1 Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. *N Engl J Med* 2019;380:11-22.
- 2 American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.
- 3 American Heart Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.
- 4 Ganda OP, Bhatt DL, Mason RP, et al. Unmet need for adjunctive dyslipidemia therapy in hypertriglyceridemia management. *J Am Coll Cardiol*. 2018;72(3):330-343.
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- 6 Toth PP, Granowitz C, Hull M, et al. High triglycerides are associated with increased cardiovascular events, medical costs, and resource use: A real-world administrative claims analysis of statin-treated patients with high residual cardiovascular risk. *J Am Heart Assoc*. 2018;7(15):e008740.
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CONSOLIDATED BALANCE SHEET DATA
(U.S. GAAP)
Unaudited

	June 30, 2019	December 31, 2018
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 221,771	\$ 249,227
Restricted cash	1,503	1,500
Accounts receivable, net	95,398	66,523
Inventory	46,268	57,802
Prepaid and other current assets	7,103	2,945
Total current assets	372,043	377,997
Property, plant and equipment, net	858	63
Operating lease right-of-use asset	8,762	—
Other long-term assets	1,102	174
Intangible asset, net	7,157	7,480
TOTAL ASSETS	\$ 389,922	\$ 385,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 34,018	\$ 37,632
Accrued expenses and other current liabilities	103,495	84,171
Current portion of long-term debt from royalty-bearing instrument	45,410	34,240
Deferred revenue, current	1,962	1,220
Total current liabilities	184,885	157,263
Long-Term Liabilities:		
Long-term debt from royalty-bearing instrument	23,202	46,108
Deferred revenue, long-term	17,775	19,490
Long-term operating lease liability	8,160	—
Other long-term liabilities	6,813	10,523
Total liabilities	240,835	233,384
Stockholders' Equity:		
Preferred Stock	21,850	21,850
Common stock	250,588	246,663
Additional paid-in capital	1,311,965	1,282,762
Treasury stock	(20,533)	(10,413)
Accumulated deficit	(1,414,783)	(1,388,532)
Total stockholders' equity	149,087	152,330
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 389,922	\$ 385,714

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

	Three months ended June 30, (in thousands, except per share amounts)		Six months ended June 30, (in thousands, except per share amounts)	
	2019	2018	2019	2018
Product revenue, net	\$ 100,366	\$ 52,537	\$ 173,097	\$ 96,313
Licensing revenue	426	106	973	248
Total revenue, net	100,792	52,643	174,070	96,561
Less: Cost of goods sold	22,770	12,846	39,910	23,494
Gross margin	78,022	39,797	134,160	73,067
Operating expenses:				
Selling, general and administrative (1)	73,406	53,944	145,039	97,350
Research and development (1)	7,130	18,159	14,372	29,921
Total operating expenses	80,536	72,103	159,411	127,271
Operating loss	(2,514)	(32,306)	(25,251)	(54,204)
Interest income (expense), net	789	(1,773)	(908)	(4,025)
Other expense, net	(95)	(131)	(92)	(76)
Loss from operations before taxes	(1,820)	(34,210)	(26,251)	(58,305)
(Provision for) benefit from income taxes	—	—	—	—
Net loss	\$ (1,820)	\$ (34,210)	\$ (26,251)	\$ (58,305)
Loss per share:				
Basic	\$ (0.01)	\$ (0.12)	\$ (0.08)	\$ (0.20)
Diluted	\$ (0.01)	\$ (0.12)	\$ (0.08)	\$ (0.20)
Weighted average shares:				
Basic	330,863	293,662	329,793	289,458
Diluted	330,863	293,662	329,793	289,458

- (1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$66,564 and \$50,878 for the three months ended June 30, 2019 and 2018, respectively, and research and development expenses were \$6,089 and \$17,607, 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 \$66,564 and \$40,594 for the three months ended June 30, 2019 and 2018, respectively.

RECONCILIATION OF NON-GAAP NET INCOME (LOSS)
Unaudited

	Three months ended June 30, (in thousands, except per share amounts)		Six months ended June 30, (in thousands, except per share amounts)	
	2019	2018	2019	2018
Net loss for EPS ¹ - GAAP	\$ (1,820)	\$ (34,210)	\$ (26,251)	\$ (58,305)
Non-cash stock-based compensation expense	7,883	3,618	14,766	7,381
Adjusted net income (loss) for EPS ¹ - non-GAAP	\$ 6,063	\$ (30,592)	\$ (11,485)	\$ (50,924)
¹ basic and diluted				
Earnings (loss) per share:				
Basic - non-GAAP	\$ 0.02	\$ (0.10)	\$ (0.03)	\$ (0.18)
Diluted - non-GAAP	0.02	(0.10)	(0.03)	(0.18)
Weighted average shares:				
Basic	330,863	293,662	329,793	289,458
Diluted	373,238	293,662	329,793	289,458