AMARIN CORP PLC\UK
Form 10-Q
May 09, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2014

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 000-21392

Amarin Corporation plc

(Exact Name of Registrant as Specified in its Charter)

England and Wales	**Not applicable**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**Identification No.)**

2 Pembroke House, Upper Pembroke Street 28-32	**Dublin 2, Ireland**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant s telephone number, including area code: +353 (0) 1 6699 020

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ¨ NO x

172,440,450 shares held as American Depository Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 465,613 ordinary shares, were outstanding as of May 1, 2014.

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PART I

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands, except share amounts)

	March 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 164,278	$ 191,514
Restricted cash	600	1,000
Accounts receivable	4,025	3,645
Inventory, current	21,830	21,209
Deferred tax asset	471	471
Other current assets	2,943	1,563
Total current assets	194,147	219,402
Property, plant and equipment, net	523	579
Inventory, long-term		5,482
Deferred tax asset	11,968	11,944
Other non-current assets	3,021	4,360
Intangible asset, net	10,548	10,709
TOTAL ASSETS	220,207	252,476
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable	4,823	6,375
Accrued interest payable	12,569	12,974
Warrant derivative liability	5,929	6,894
Deferred revenue		1,703
Accrued expenses and other liabilities	8,041	9,594
Total current liabilities	31,362	37,540
Long-Term Liabilities:		
Exchangeable senior notes	150,000	149,317
Long-term debt	88,207	87,717
Long-term debt redemption feature	7,600	11,100

Other long-term liabilities	632	658
Total liabilities	277,801	286,332
Commitments and contingencies (Note 7)		
Stockholders Deficit:		
Common stock, £0.50 par, unlimited authorized; 172,906,063 issued, 172,885,984 outstanding at March 31, 2014; 172,691,063 issued, 172,670,984 outstanding at December 31, 2013	141,654	141,477
Additional paid-in capital	740,819	738,754
Treasury stock; 20,079 shares at March 31, 2014 and December 31, 2013	(217)	(217)
Accumulated deficit	(939,850)	(913,870)
Total stockholders deficit	(57,594)	(33,856)
TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT	$ 220,207	$ 252,476

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in thousands, except per share amounts)

	Three months ended March 31,	
	2014	**2013**
Product revenues	$ 10,967	$ 2,341
Less: Cost of goods sold	4,246	1,287
Gross margin	6,721	1,054
Operating expenses:		
Selling, general and administrative	20,585	39,267
Research and development	11,707	21,838
Total operating expenses	32,292	61,105
Operating loss	(25,571)	(60,051)
Gain on change in fair value of derivative liabilities	4,393	3,620
Interest expense, net	(4,393)	(8,860)
Other income (expense), net	16	(124)
Loss from operations before taxes	(25,555)	(65,415)
(Provision for) benefit from income taxes	(425)	3,257
Net loss	$ (25,980)	$ (62,158)
Loss per share:		
Basic	$ (0.15)	$ (0.41)
Diluted	$ (0.15)	$ (0.43)
Weighted average shares:		
Basic	172,872	150,430
Diluted	174,431	157,073

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN DEFICIT

(Unaudited, in thousands, except share amounts)

	Common Shares	Common Stock	Additional Paid-in Capital	Treasury Shares	Accumulated Deficit	Total
At December 31, 2013	**172,691,063**	**$ 141,477**	**$ 738,754**	**$ (217)**	**$ (913,870)**	**$ (33,856)**
Exercise of stock options	215,000	177	107			284
Tax benefits realized from stock-based compensation			1			1
Stock-based compensation			1,957			1,957
Loss for the period					(25,980)	(25,980)
At March 31, 2014	**172,906,063**	**$ 141,654**	**$ 740,819**	**$ (217)**	**$ (939,850)**	**$ (57,594)**

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in thousands)

	Three Months Ended March 31,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (25,980)	$ (62,158)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	56	59
Stock-based compensation	1,957	4,874
Stock-based compensation warrants	(72)	(451)
Excess tax provision (benefit) from stock-based awards	1	(678)
Accrued interest payable	(405)	2,124
Amortization of debt discount and debt issuance costs	1,173	4,204
Amortization of intangible asset	161	161
Gain on changes in fair value of derivative liabilities	(4,393)	(3,620)
Deferred income taxes	(24)	(3,949)
Shares issued for services		8
Change in lease liability		(7)
Changes in assets and liabilities:		
Restricted cash	400	(1,400)
Accounts receivable	(380)	(3,441)
Inventories	4,861	(6,173)
Other current assets	(1,380)	(3,798)
Other non-current assets	1,339	(383)
Deferred revenue	(1,703)	2,865
Accounts payable and other liabilities	(3,105)	12,128
Net cash used in operating activities	(27,494)	(59,635)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment		(14)
Net cash used in investing activities		(14)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options, net of transaction costs	285	439
Proceeds from exercise of warrants, net of transaction costs		70
Excess tax (provision) benefit from stock-based awards	(1)	678
Payments under capital leases	(26)	

Net cash provided by financing activities	258	1,187
NET DECREASE IN CASH AND CASH EQUIVALENTS	(27,236)	(58,462)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	191,514	260,242
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 164,278	$ 201,780
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$ 3,636	$ 2,625
Income taxes	$ 33	$ 563

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For purposes of this Quarterly Report on Form 10-Q, our ordinary shares may also be referred to as common shares or common stock.

(1) Nature of Business and Basis of Presentation

Nature of Business

Amarin Corporation plc, Amarin or the Company is a biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

The Company s lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG ≥500mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. The Company began selling and marketing Vascepa in the United States in January 2013. The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and health care providers. The Company markets Vascepa through its sales force of approximately 150 sales professionals, including sales representatives and their managers. The Company also recently entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. (Kowa Pharmaceuticals America) under which approximately 250 Kowa Pharmaceuticals America sales representatives are expected to devote a substantial portion of their time to promoting Vascepa starting in May 2014. The Company operates in one business segment.

Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 40 million adults in the United States have elevated triglyceride levels (TG ≥200mg/dL) and approximately 4.0 million people in the United States have severely high triglyceride levels (TG ≥500mg/dL), commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides also provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as good cholesterol), and elevated levels of LDL-C (often referred to as bad cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA approved, these trials showed favorable clinical results in their respective patient populations in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these trials, the most commonly reported adverse reaction (incidence >2%

and greater than placebo) in Vascepa-treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

The Company is also developing Vascepa for the treatment of patients with high (TG ³ 200 mg/dL and <500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which the Company refers to as mixed dyslipidemia. The Company refers to this second proposed indication for Vascepa as the ANCHOR indication. The FDA has stated that it views the proposed ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. In addition, in December 2011, Amarin announced commencement of patient dosing in a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy.

The Company has a pending supplemental new drug application, or sNDA, with the FDA that seeks marketing approval of Vascepa for use in the ANCHOR indication. On October 16, 2013, the FDA convened an advisory committee to review the sNDA. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory committee was asked whether Vascepa has been demonstrated to improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study, the first prospective study of cardiovascular outcomes in patients who have high triglyceride levels despite statin therapy. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA considers the recommendation of the advisory committee, but final decisions on the approval of new drug applications are made by the FDA. On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee, the Company implemented a worldwide reduction in force of approximately 50% of its staff positions, including sales positions.

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The ANCHOR clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. A SPA agreement is generally binding upon the FDA, except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. As a basis for this determination, the FDA communicated that it determined that the cumulative results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that while information the Company submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. In November 2013, the Company submitted to the FDA a request for reconsideration of its decision to rescind the ANCHOR SPA agreement. On January 17, 2014, the Company was notified by the FDA that it does not intend to reinstate the ANCHOR SPA agreement. The Company appealed to the next level within the FDA and was informed in late April 2014 that that level determined to uphold the rescission determination. The Company currently plans to appeal the rescission decision to the next level within the FDA in accordance with FDA dispute resolution guidance.

The FDA did not take action on the ANCHOR sNDA by the Prescription Drug User Fee Act, or PDUFA, goal date for completion of FDA s review, December 20, 2013. Instead, the FDA notified the Company on December 19, 2013 that it would first consider the appeal of the ANCHOR SPA agreement rescission. No new PDUFA goal date for the ANCHOR sNDA was established. Based on information available, the Company does not expect a determination on the ANCHOR sNDA while the Company s appeal of the January 17, 2014 FDA decision to uphold the ANCHOR SPA rescission is pending. The Company is also continuing its efforts toward a positive determination on the pending ANCHOR sNDA. There can be no assurance that the FDA will not communicate the results of its review of the ANCHOR sNDA prior to the timing expected.

Based on the Company s communications with the FDA, the Company currently expects that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa. There can be no assurance that the Company will be successful in its efforts to reinstate the ANCHOR SPA agreement or obtain a label expansion reflecting the ANCHOR clinical trial. Such label expansion could include FDA approval of the addition of an ANCHOR indication statement and/or the addition of the ANCHOR clinical trial data to the currently approved labeling. If the FDA does not approve the ANCHOR indication, it could have a material impact on the Company s future results of operations and financial condition.

Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States of America (the U.S. or the United States) and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Certain information in the footnote disclosures of the financial statements has been condensed or omitted where it substantially duplicates information provided in the Company s latest audited consolidated financial statements, in

accordance with the rules and regulations of the SEC. These condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC (the 2013 Form 10-K). The balance sheet amounts at December 31, 2013 in this report were derived from the Company s audited 2013 consolidated financial statements included in the 2013 Form 10-K.

The condensed consolidated financial statements reflect all adjustments that, in the opinion of management, are necessary to present fairly the Company s financial position, results of operations and cash flows for the periods indicated. The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts and classifications of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The results of operations for the three months ended March 31, 2014 and March 31, 2013, respectively, are not necessarily indicative of the results for the entire fiscal year or any future period.

The accompanying consolidated financial statements of the Company and subsidiaries have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and

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commitments in the normal course of business. The Company s business operations are focused on the commercialization and development of Vascepa, which received approval from the FDA in 2012 and for which the Company commenced marketing and sales in 2013.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

At March 31, 2014, the Company had cash and cash equivalents of $164.3 million. The Company s consolidated balance sheet also includes derivative liabilities (see Note 5 Warrants and Warrant Derivative Liability) as well as long term debt and exchangeable senior notes (see Note 6 Debt). The warrant derivative liability reflects the fair value of outstanding warrants to purchase shares of the Company s common stock. The long term debt is not puttable except upon a change in control. The Exchangeable Senior Notes may be redeemed on or after January 19, 2017 at the option of the holders. The Notes are exchangeable under certain circumstances into cash, American Depository Shares, or ADSs, or a combination of cash and ADSs, at the Company s election. Accordingly, the warrant derivative liability, long term debt and Exchangeable Senior Notes do not present a short term claim on the liquid assets of the Company.

The Company believes its cash and cash equivalents will be sufficient to fund its projected operations for at least the next twelve months.

(2) Significant Accounting Policies

Use of Estimates

The preparation of the Company s consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Actual results could differ from those estimates.

Revenue Recognition

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and health care providers. Patients are required to have a prescription in order to purchase Vascepa. In accordance with GAAP, the Company s revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between the Company and the Distributor, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable.

The Company commenced its commercial launch in the United States in January 2013. Prior to 2013, the Company recognized no revenue from Vascepa sales. In accordance with GAAP, until the Company had the ability to reliably estimate returns of Vascepa from its Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from the Company to such Distributors.