

AMARIN CORP PLC\UK

FORM 8-K (Current report filing)

Filed 02/28/17 for the Period Ending 02/28/17

Telephone	353 1 6699 020
CIK	0000897448
Symbol	AMRN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): February 28, 2017

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.)

**2 Pembroke House, Upper Pembroke Street 28-32,
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))
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Item 2.02. Results of Operations and Financial Condition.

On February 28, 2017, Amarin Corporation plc issued a press release announcing its financial results for the three and twelve months ended December 31, 2016 (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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated February 28, 2017

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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: February 28, 2017

Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated February 28, 2017



**Amarin Reports Record Fourth Quarter and Full Year 2016 Financial Results
and Provides Update on Operations**

*\$130.1 Million and \$38.7 Million Total Revenue for Full Year and Fourth Quarter 2016 Reflect Increases
of 59% and 45% Compared to Corresponding Periods in 2015*

*REDUCE-IT Cardiovascular Outcomes Study Remains on Schedule to Reach Onset of Final Target
Event Near the End of 2017*

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

BEDMINSTER, N.J., and DUBLIN, Ireland, February 28, 2017 — Amarin Corporation plc (NASDAQ: AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced financial results for the quarter and year ended December 31, 2016, and provided an update on company operations.

Key Amarin achievements in 2016 include:

- **Revenue growth**: Recognized total revenue of \$130.1 million for 2016 comprised of \$129.0 million in net product revenue from U.S. sales of Vascepa® (icosapent ethyl) and \$1.1 million in licensing revenue in connection with collaborations for the commercialization of Vascepa outside the United States. Both the total revenue and net product revenue for 2016 represent increases of 59% over 2015. Included in annual revenue was \$38.7 million in total revenue recognized in the fourth quarter of 2016, comprised of \$38.4 million in net product revenue and \$0.3 million in licensing revenue. Both the total revenue and net product revenue in the fourth quarter of 2016 increased 45% over corresponding amounts recognized in the fourth quarter of 2015. As previously reported, Amarin has guided that 2017 net product revenue from sales of Vascepa in the United States are anticipated to be between \$155 million and \$165 million.
- **Prescription growth**: Increased normalized prescriptions, based on data from Symphony Health Solutions and IMS Health, by approximately 50% or more for 2016 and for each of its quarters. Additionally, there are now more than 100,000 patients using Vascepa.
- **Gross margins**: Increased gross margin on product sales to 73% in 2016, versus 66% in 2015, driven by improvements in product related costs.
- **R&D progress**: REDUCE-IT cardiovascular outcomes study continues to track towards achieving, near the end of 2017, the onset of the targeted 1,612 aggregate primary cardiovascular events for completion of the study. The previously described pre-specified interim efficacy and safety analysis to be completed by the independent data monitoring committee (DMC) at approximately 80% of the total primary cardiovascular events is on schedule to be completed in or about the end of Q3 2017. Amarin remains blinded to the results of this study and anticipates that the

recommendation of the DMC based on this interim analysis will be to continue the study to completion, in which scenario final REDUCE-IT results are expected to be available to report in 2018.

- **Strengthened balance sheet** : Through transactions in 2016 and early 2017, reduced Amarin's debt burden from face value in exchangeable debt of \$165 million to \$30 million and moved the earliest scheduled put date for the remaining debt to 2022. Amarin's cash balance at December 31, 2016 was \$98.3 million. On a pro forma basis, reflecting the aforementioned debt transaction in January 2017, Amarin began 2017 with a cash balance of approximately \$112 million.
- **Cash flow improving** : Over the last nine months of 2016, Amarin was cash flow neutral, excluding financing, interest, royalty and research and development costs. On a similar basis, as previously guided, Amarin anticipates being cash flow positive in 2017. In 2017, Amarin anticipates spending approximately \$50 million to \$60 million for research and development, with the majority of this spending for the REDUCE-IT trial, and also increasing purchases of supply for Vascepa both to support anticipated growth in 2017 and to prepare for REDUCE-IT success.

"2016 was another exceptional year of progress for Amarin both commercially and operationally," commented John F. Thero, president and chief executive officer. "We begin 2017 with a strong team of motivated people, a product in Vascepa that has a positively differentiated efficacy and safety profile, and managed care coverage for Vascepa that was broad at the start of 2016 and expanded further over the past year. We are pleased to observe key opinion leaders increasing their attention to the potential impacts on public health and the practice of medicine if REDUCE-IT achieves the results we seek and we, of course, look forward to learning the results of this landmark study."

Commercial Update

During the fourth quarter, Amarin continued to see substantial prescription growth and steady increases in prescription omega-3 and non-statin market share, particularly among detailed physicians. Vascepa growth continues to be driven by focused message delivery, compelling supportive data and improved managed care coverage.

Amarin reported a 45% increase in net product revenue during Q4 2016 compared to Q4 2015, which was mostly driven by prescription growth as the net price of Vascepa has remained relatively flat. The majority of this prescription growth has come from physicians called upon and educated about Vascepa by our sales force. Based on data provided by Symphony Health Solutions and IMS Health, estimated normalized Vascepa prescriptions totaled approximately 286,000 and 312,000, respectively, for the three months ended December 31, 2016. These prescription levels represent growth of approximately 50% and 54%, respectively, from levels in the corresponding prior year periods.

REDUCE-IT Trial Progressing on Schedule

The REDUCE-IT cardiovascular outcomes trial continues to progress on schedule. Amarin expects the onset of the final primary cardiovascular event to occur near the end of 2017 with report of top-line results and publications anticipated in 2018. The projected timing of available data from which we can report top-line results should be easier to estimate after the interim look which, as discussed below, is

scheduled for Q3 2017. Currently we estimate that results of the trial will become available to Amarin and be publicly communicated in mid-2018. This estimated timing reflects our assumptions of the time necessary to collect vital data from all patients in the study, compile the results, and subject the results to scrutiny of the independent review committees and the REDUCE-IT operational team.

The 8,175-patient outcomes study is evaluating whether treatment with Vascepa reduces cardiovascular events in patients who despite stabilized statin therapy have elevated triglyceride levels and other cardiovascular risk factors. The results of this important trial, if successful, could lead to improved medical care for tens of millions of patients. Amarin is positioned to be the first company to complete an outcomes study in the population of patients being studied in REDUCE-IT.

The primary endpoint of this global, double-blind study is the time to the first occurrence of a composite of major adverse cardiovascular events (MACE). Results will be compared between the Vascepa and placebo groups. The study is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

A second pre-specified interim efficacy and safety analysis of REDUCE-IT is scheduled to be conducted by the independent DMC at approximately 80% of the total 1,612 primary cardiovascular events targeted for completion of the study. Amarin anticipates that the onset of 80% of the target primary events will be reached in the first half of 2017 and that the interim analysis will be conducted before the end of Q3 2017. Consistent with the trial design, Amarin continues to believe that the REDUCE-IT study is most likely to continue to completion of 100% of the target events. This is the case because the efficacy requirements detailed to the DMC for early study stoppage after the 80% interim assessment are high and include robustness thresholds for underlying data that go beyond the assessment for statistical significance on the analysis of the primary endpoint after the expected completion of the study at 100% of planned events.

Amarin will remain blinded to results of the REDUCE-IT study until after the study is stopped and the database is locked at either the 80% interim analysis or at the final analysis.

Financial Update

Net product revenue for the three months ended December 31, 2016 and 2015 was \$38.4 million and \$26.4 million, respectively. Net product revenue for the years ended December 31, 2016 and 2015 was \$129.0 million and \$81.0 million, respectively. These increases in net product revenue were primarily attributable to increases both in new and recurring prescriptions of Vascepa driven by increased sales productivity.

In addition, Amarin recognized licensing revenue of \$1.1 million and \$0.8 million for the years ended December 31, 2016 and 2015, respectively, related to agreements for the commercialization of Vascepa outside the United States. Amarin's partners for China and for the Middle East and North Africa are working towards regulatory approval of Vascepa in their respective territories.

Cost of goods sold for the three months ended December 31, 2016 and 2015 was \$10.2 million and \$8.4 million, respectively. Cost of goods sold for the years ended December 31, 2016 and 2015 was \$34.4 million and \$27.9 million, respectively. Gross margin on product sales improved to 74% and 73% in the

quarter and year ended December 31, 2016, respectively, as compared to 68% and 66% in the quarter and year ended December 31, 2015, respectively. The improvement in gross margin on product sales was primarily driven by lower active pharmaceutical ingredient cost.

Selling, general and administrative (SG&A) expenses for the three months ended December 31, 2016 and 2015 were \$31.2 million and \$23.5 million, respectively. SG&A expenses in the years ended December 31, 2016 and 2015 were \$111.4 million and \$101.0 million, respectively. The increase in SG&A expenses primarily reflects an increase in sales and marketing expenses and co-promotion fees payable to Kowa Pharmaceuticals America, Inc.

Research and development expenses for the three months ended December 31, 2016 and 2015 were \$10.2 million and \$13.3 million, respectively. Research and development expenses in the years ended December 31, 2016 and 2015 were \$50.0 million and \$51.1 million, respectively. This slight decrease was primarily driven by a decrease in overhead costs and non-cash stock based compensation.

Amarin reported a net loss applicable to common shareholders of \$27.5 million in the fourth quarter of 2016, or basic and diluted loss per share of \$0.10. This net loss included \$3.2 million in non-cash stock-based compensation expense and a provision for income taxes of \$12.3 million, the majority of which is non-cash. Amarin reported a net loss applicable to common shareholders of \$21.9 million in the fourth quarter of 2015, or basic and diluted loss per share of \$0.12. This net loss included \$3.7 million in non-cash stock-based compensation expense, a \$0.7 million non-cash loss on the change in fair value of derivatives, a \$1.3 million non-cash gain on extinguishment of debt, and a benefit from income taxes of \$1.5 million.

Amarin reported a net loss applicable to common shareholders of \$86.4 million in the year ended December 31, 2016, or basic and diluted loss per share of \$0.41. This net loss included \$13.6 million in non-cash stock-based compensation expense, an \$8.2 million non-cash gain on the change in fair value of derivatives, and a provision for income taxes of \$10.0 million, the majority of which is non-cash. For the year ended December 31, 2015, Amarin reported a net loss applicable to common shareholders of \$149.1 million, or basic and diluted loss per share of \$0.83. This net loss included \$13.9 million in non-cash stock-based compensation expense, a \$1.1 million non-cash loss on the change in fair value of derivatives, a \$1.3 million non-cash gain on extinguishment of debt, \$33.9 million in charges for non-cash deemed dividends for accounting purposes, and a benefit from income taxes of \$3.1 million.

Amarin reported cash and cash equivalents of \$98.3 million at December 31, 2016. The cash balance includes \$64.6 million in net proceeds from an equity financing completed in August. The primary purpose of that financing was to fund REDUCE-IT to completion. During the quarter ended December 31, 2016, net cash used in operating activities, including research and development costs, was \$19.3 million, or approximately \$3.3 million excluding research and development costs, interest and royalties. At December 31, 2016, the company had \$20.0 million in net accounts receivable (\$24.1 million in gross accounts receivable before allowances and reserves) and \$20.5 million in inventory.

In January 2017, Amarin issued \$30.0 million in aggregate principal amount of 3.50% Exchangeable Senior Notes due 2047 (the "2017 Notes"), and purchased approximately \$15.0 million aggregate principal amount of 3.50% Exchangeable Senior Notes due 2032 that were issued in 2012 (the "2012

Notes”). Amarin was required by the terms of the indenture governing the 2012 Notes to purchase all 2012 Notes surrendered to it on January 19, 2017. Amarin has initiated the process to redeem the remaining \$0.1 million of outstanding principal amount of 2012 Notes not surrendered, which is expected to be completed in the first quarter of 2017. The remainder of the net proceeds from the 2017 Notes will be used for general corporate and working capital purposes. Pursuant to this January 2017 debt restructuring, on a pro forma basis as of December 31, 2016, Amarin had approximately \$112 million in cash and cash equivalents and \$30.1 million in exchangeable debt outstanding.

As of December 31, 2016, Amarin had approximately 269.4 million American Depositary Shares (ADSs) and ordinary shares outstanding, 32.8 million share equivalents Series A Convertible Preferred Shares outstanding, approximately 21.2 million equivalent shares underlying stock options at a weighted-average exercise price of \$3.37, and 10.1 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, February 28, 2017. The call will be webcast live with slides and accessible through 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 the replay, dial 877-481-4010 (inside the United States) or 919-882-2331 (outside the United States) and use replay ID 10260.

About Amarin

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin’s product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin’s clinical program includes a commitment to an ongoing outcomes study. Vascepa[®] (icosapent ethyl), Amarin’s first FDA approved product, is a highly-pure, omega-3 fatty acid product available by prescription. For more information about Vascepa visit www.vascepa.com. For more information about Amarin visit www.amarincorp.com.

About VASCEPA[®] (icosapent ethyl) capsules

VASCEPA[®] (icosapent ethyl) capsules are a single-molecule prescription product consisting of 1-gram or 0.5-gram 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. Vascepa is known in scientific literature as AMR101.

FDA-approved Indication and Usage

- 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

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- 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.
- Patients receiving treatment with VASCEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow VASCEPA capsules whole; not to break open, crush, dissolve, or chew VASCEPA.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

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. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. 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 statements about the future commercialization of Vascepa; expectations regarding planned research and development expenses and increased supply purchases; expectations regarding Vascepa sales, revenue, costs and other financial metrics; expectations related to Amarin's anticipated financial performance; expectations for event rates, interim data reviews, results and related announcements with respect to Amarin's REDUCE-IT cardiovascular outcomes study; expectations related to the interim and final outcome of the REDUCE-IT study and the anticipated successful completion of the REDUCE-IT study; and statements regarding the potential efficacy, safety and therapeutic benefits of Vascepa. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in filings with the U.S. Securities and Exchange Commission, these risks and uncertainties include the following: Amarin's ability to commercialize Vascepa in line with company expectations will depend in part on its ability to continue to create market demand for Vascepa through education, marketing and sales activities, to achieve continued market acceptance of Vascepa, to continue to receive adequate levels of reimbursement from third-party payers, to continue 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 historical REDUCE-IT clinical trial event rates may not be predictive of future results and related cost may increase beyond expectations; the risk that Vascepa may not show

clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be upheld in patent litigation and applications may not result in issued patents. 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 and upcoming 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.

Important information regarding prescription data and product revenue

The historical prescription data provided in this press release is based on data published by third parties. References to normalized prescriptions equate to one month's supply of 1-gram (120 count) and 0.5-gram (240 count) Vascepa capsules. Although Amarin believes these data are prepared on a period to period basis in a manner that is generally consistent and that such results are indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. These data may overstate or understate actual prescriptions. Based on other data available to Amarin and the history of such third-party prescription estimates in similar stages of launch of other pharmaceutical products, Amarin believes that the trends provided by this information can be useful to gauge current prescription levels. There is a limited amount of information available to determine the actual number of total prescriptions for prescription products like Vascepa. Amarin believes that investors should view these data with caution, as data for this single and limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales may affect future prescription trends of Vascepa on a monthly and quarterly basis, for example, as could changes in prescriber sentiment and other factors. Amarin believes investors should consider its results during this quarter together with its results over several future quarters, or longer, and in light of seasonal fluctuations before making an assessment about potential future performance. The commercialization and co-promotion of a new pharmaceutical product are complex undertakings, and Amarin's ability to effectively and profitably commercialize Vascepa will depend in part on its ability to continue to generate market demand for Vascepa through education, marketing and sales activities, its ability to achieve market acceptance of Vascepa, its ability to generate product revenue and its ability to receive adequate levels of reimbursement from third-party payers and its ability to benefit from continued contributions of its Vascepa co-promotion partner, Kowa Pharmaceuticals America, Inc. See "Risk Factors—Risks Related to the Commercialization and Development of Vascepa" included in Part I, Item 1A. Risk Factors in Amarin's most recent Annual Report on Form 10-K.

Availability of other information about Amarin

Investors and others should note that we communicate with our investors and the public using our company website (www.amarincorp.com), our 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 we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information

that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

Amarin contact information:

Investor Relations:

Elisabeth Schwartz
Investor Relations and Corporate Communications
Amarin Corporation plc
In U.S.: +1 (908) 719-1315
investor.relations@amarincorp.com

Lee M. Stern
Trout Group
In U.S.: +1 (646) 378-2992
lsfern@troutgroup.com

Media Inquiries:

Kristie Kuhl
Finn Partners
In U.S.: +1 (212) 583-2791
Kristie.kuhl@finnpartners.com

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

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 98,251	\$ 106,961
Restricted cash	600	600
Accounts receivable, net	19,985	13,826
Inventory	20,507	18,985
Prepaid and other current assets	6,983	3,152
Total current assets	<u>146,326</u>	<u>143,524</u>
Property, plant and equipment, net	78	243
Deferred tax assets	11,082	19,872
Other long-term assets	741	174
Intangible asset, net	8,772	9,417
TOTAL ASSETS	<u>\$ 166,999</u>	<u>\$ 173,230</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	\$ 6,062	\$ 10,832
Accrued expenses and other current liabilities	37,720	24,226
Current portion of exchangeable senior notes, net of discount	15,351	2,266
Current portion of long-term debt from royalty-bearing instrument	15,944	12,476
Deferred revenue, current	1,172	923
Total current liabilities	<u>76,249</u>	<u>50,723</u>
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	—	136,734
Long-term debt from royalty-bearing instrument	85,155	91,512
Long-term debt derivative liabilities	—	8,170
Deferred revenue, long-term	13,943	13,308
Other long-term liabilities	710	335
Total liabilities	<u>176,057</u>	<u>300,782</u>
Stockholders' Deficit:		
Preferred stock	24,364	24,364
Common stock	207,166	149,978
Additional paid-in capital	964,914	816,171
Treasury stock	(1,498)	(411)
Accumulated deficit	(1,204,004)	(1,117,654)
Total stockholders' deficit	<u>(9,058)</u>	<u>(127,552)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 166,999</u>	<u>\$ 173,230</u>

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

	Three months ended December 31, (in thousands, except per share amounts)		Twelve months ended December 31, (in thousands, except per share amounts)	
	2016	2015	2016	2015
Product revenue, net	\$ 38,403	\$ 26,402	\$ 128,966	\$ 80,987
Licensing revenue	293	231	1,118	769
Total revenue, net	38,696	26,633	130,084	81,756
Less: Cost of goods sold	10,155	8,389	34,363	27,875
Gross margin	28,541	18,244	95,721	53,881
Operating expenses:				
Selling, general and administrative (1)	31,225	23,519	111,372	101,041
Research and development (1)	10,177	13,347	49,975	51,062
Total operating expenses	41,402	36,866	161,347	152,103
Operating loss	(12,861)	(18,622)	(65,626)	(98,222)
Gain (loss) on change in fair value of derivative liabilities (2)	—	(740)	8,170	(1,106)
Gain on extinguishment of debt	—	1,314	—	1,314
Interest expense, net	(2,190)	(5,295)	(18,443)	(20,048)
Other expense, net	(101)	(93)	(482)	(228)
Loss from operations before taxes	(15,152)	(23,436)	(76,381)	(118,290)
(Provision for) benefit from income taxes	(12,301)	1,545	(9,969)	3,086
Net loss	(27,453)	(21,891)	(86,350)	(115,204)
Preferred stock purchase option	—	—	—	(868)
Preferred stock beneficial conversion features	—	—	—	(32,987)
Net loss applicable to common shareholders	\$ (27,453)	\$ (21,891)	\$ (86,350)	\$ (149,059)
Loss per share:				
Basic	\$ (0.10)	\$ (0.12)	\$ (0.41)	\$ (0.83)
Diluted	\$ (0.10)	\$ (0.12)	\$ (0.41)	\$ (0.83)
Weighted average shares:				
Basic	269,223	183,313	211,874	180,654
Diluted	269,223	183,313	211,874	180,654

- (1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$100,011 and \$90,441 for 2016 and 2015, respectively, and research and development expenses were \$47,723 and \$47,782, respectively, for the same periods. Excluding non-cash stock-based compensation as well as co-promotion fees paid to our U.S. co-promotion partner, selling, general and administrative expenses were \$82,042 and \$82,474 for 2016 and 2015, respectively.
- (2) Non-cash gains and losses result from changes in the fair value of a warrant derivative liability, long-term debt derivative liabilities, and a preferred stock purchase option derivative liability.