

# AMARIN CORP PLC\UK

## **FORM 8-K** (Current report filing)

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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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

**Date of Report (Date of Earliest Event Reported): May 3, 2017**

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**Amarin Corporation plc**

(Exact name of registrant as specified in its charter)

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**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

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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))

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.

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**Item 2.02. Results of Operations and Financial Condition.**

On May 3, 2017, Amarin Corporation plc issued a press release announcing its financial results for the three months ended March 31, 2017 (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 May 3, 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: May 3, 2017

Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer

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**Exhibit Index**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 3, 2017



**Amarin Reports First Quarter 2017 Financial Results  
and Provides Update on Operations**

*Prescription Growth Up >50%; Outcomes Study Beyond 80% Complete*

*Re-affirms Guidance on Full Year Net Product Revenues of between \$155 and \$165 Million*

*Management to Host Conference Call at 8:00 a.m. ET Today*

BEDMINSTER, N.J., and DUBLIN, Ireland, May 3, 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 three months ended March 31, 2017, and provided an update on company operations.

Key Amarin achievements through March 31, 2017 include:

- **U.S. revenue growth**: Recognized \$34.3 million in net product revenue from Vascepa® (icosapent ethyl) sales in Q1 2017 compared to \$25.3 million in Q1 2016, an increase of 36%.
- **U.S. prescription growth**: Increased normalized prescriptions for Vascepa by 52% and 58% compared to Q1 2016 based on data from Symphony Health Solutions and IMS Health, respectively.
- **International development**: China regulatory authorities approved the Vascepa clinical trial application (CTA) from Amarin's partner, Eddingpharm, paving the way for Eddingpharm to commence a clinical trial of Vascepa in China before the end of 2017.
- **R&D progress**: Our REDUCE-IT cardiovascular outcomes study, designed to provide data to support a significantly expanded market opportunity for Vascepa, is progressing as planned. Our statistical models indicate that in March 2017, the study reached the onset of approximately 80% of the target aggregate number of primary cardiovascular events. The onset of the target final primary cardiovascular event will likely be reached near the end of 2017 in this 8,175 patient study that commenced in 2011.
- **Cash flow**: Net cash outflow from operations during Q1 2017 was less than \$1.5 million, excluding costs for R&D, interest and royalty. The company aims to be net cash flow positive on this basis for the full year with continued quarterly variability.
- **Cash balance**: As of March 31, 2017, Amarin had a cash balance of \$96.1 million compared to \$98.3 million at December 31, 2016. The March 31<sup>st</sup> cash balance includes approximately \$13.7 million in net cash proceeds from the January 2017 redemption of debt and simultaneous issuance of \$30.0 million face value of new debt long-term.

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“Historically, Q1 has been our most challenging quarter for revenue growth due to seasonal factors. We are pleased that both revenues and prescriptions for Vascepa grew significantly in Q1, as prescription growth exceeded our internal projections. We are on-track to achieve our full year 2017 product revenue guidance of \$155 to \$165 million,” stated John F. Thero, president and chief executive officer. “Our expectations are that REDUCE-IT study results will be reported in mid-2018, and we are actively planning for expanded promotion based on anticipated positive results from this study. There is a large unmet medical need that we are seeking to address through demonstration of positive results in REDUCE-IT. We believe the efficacy, safety, oral administration and affordable cost of Vascepa position the product for substantial growth, assuming that REDUCE-IT results are positive.”

#### ***Increases in New and Recurring Prescriptions Drive Steady Commercial Growth***

During the first quarter, Amarin again experienced substantial prescription growth and continued increase in Vascepa market share, particularly among detailed physicians. Overall, approximately 150,000 patients received prescriptions for Vascepa during the quarter, with new prescriptions growing to approximately 5% of the non-statin lipid modifying market and approaching 30% of the prescription omega-3 market. Strong Vascepa growth is driven by positive physician experience in conjunction with our focused message delivery, compelling efficacy and safety data, and improved managed care coverage.

Estimated normalized total Vascepa prescriptions, based on data from Symphony Health Solutions and IMS Health, totaled approximately 305,000 and 335,000, respectively, for the three months ended March 31, 2017. These prescription levels represent growth of approximately 52% and 58%, respectively, from prior year levels.

During the first quarter of 2017, overall wholesaler inventory levels decreased from year-end 2016 levels calculated based on estimated days of Vascepa sales on hand. Consequently, we estimate that this decrease in wholesaler inventory levels adversely impacted net product revenue by approximately \$2.8 million to \$3.1 million for the first quarter of 2017. During the first quarter of 2016, wholesaler inventory levels adversely impacted net product revenue by approximately \$1.2 million to \$1.5 million. We believe that changes in channel inventory at these independent wholesalers and retail pharmacies are common and impacted by numerous factors, including holiday timing and recent order trends. We also deduce, based on information available to us, that channel inventory levels at the end of the first quarters of 2017 and 2016 are within ordinary ranges, and that such levels will continue to vary from quarter to quarter.

#### ***REDUCE-IT Cardiovascular Outcomes Study***

The REDUCE-IT cardiovascular outcomes trial continues to progress on schedule. Amarin anticipates the onset of the final primary cardiovascular event to occur near the end of 2017, with report of top-line results and publications 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 to complete in Q3 2017. We currently estimate that we will report results of REDUCE-IT in mid-2018, assuming the study goes to completion. These estimates reflect our assumptions of the necessary time needed 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.

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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.

Preparations are underway for a second pre-specified interim efficacy and safety analysis of REDUCE-IT by the independent DMC, since we believe that approximately 80% of the primary cardiovascular events occurred in the mid-March timeframe. The ensuing analysis should be completed 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. We surmise this because the efficacy requirements detailed to the DMC for early study stoppage after the 80% interim assessment are high. Unlike the data analysis at the end of the study, the interim analysis and review by the DMC also includes robustness thresholds for certain secondary endpoints. There are potential statistical advantages for the study to run to its full term.

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.

### ***International Development of Vascepa***

Our international initiatives are progressing positively. Our partner for China, Eddingpharm, submitted the clinical trial application (CTA) to the Chinese regulatory authorities in 2016. This CTA was recently approved, enables Eddingpharm to progress into the clinical testing phase, and potentially positions Vascepa to be the first prescription grade EPA product to receive drug approval in China. We believe the commercial opportunity in China is large based on the prevalence of hypertriglyceridemia, which is estimated to affect 11.9% of the adult Chinese population. Our partner in China is responsible for the conduct and cost of the clinical studies in China. Amarin will provide the clinical trial material for this study.

### ***Financial Update***

Net product revenue for the three months ended March 31, 2017 and 2016 was \$34.3 million and \$25.3 million, respectively. This increase in net product revenue was primarily attributable to increases both in new and recurring prescriptions of Vascepa driven by increased sales productivity and supported by expanded managed care coverage.

In addition, Amarin recognized licensing revenue of \$0.3 million and \$0.2 million in the three months ended March 31, 2017 and 2016, respectively, related to agreements for the commercialization of Vascepa outside the United States. Based upon current estimates, Amarin anticipates approximately \$1.2 million in licensing revenue to be recognized in aggregate during 2017 from existing agreements.

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Cost of goods sold for the three months ended March 31, 2017 and 2016 was \$8.2 million and \$6.9 million, respectively. Gross margin on product sales improved to 76% in the quarter ended March 31, 2017 compared to 73% in the quarter ended March 31, 2016. The improvement in gross margin on product sales was primarily driven by lower active pharmaceutical ingredient cost.

Selling, general and administrative (SG&A) expenses in the three months ended March 31, 2017 and 2016 were \$34.2 million and \$28.0 million, respectively. The increase in SG&A expenses primarily reflects a \$1.7 million increase in co-promotion fees accrued under our contract with Kowa Pharmaceuticals America, Inc., increased promotional activities, and increased legal costs. The co-promotion fee is calculated based on gross margin on Vascepa product sales. The increase in co-promotion fees primarily reflects an increase during Q1 2017 compared to Q1 2016 in gross margin on product sales.

Research and development expenses in the three months ended March 31, 2017 and 2016 were \$10.8 million and \$13.7 million, respectively. This decrease in expense was primarily driven by the timing of REDUCE-IT expenses.

Under GAAP, Amarin reported a net loss of \$20.9 million in the first quarter of 2017, or basic and diluted loss per share of \$0.08. This net loss included \$3.4 million in non-cash stock-based compensation expense. Amarin reported a net loss of \$29.8 million in the first quarter of 2016, or basic and diluted loss per share of \$0.16. This net loss included \$3.6 million in non-cash stock-based compensation expense, a \$1.3 million non-cash loss on the change in fair value of derivatives.

Amarin reported cash and cash equivalents of \$96.1 million at March 31, 2017. Excluding cash flow related to research and development and financing, net cash outflows in the quarter ended March 31, 2017 were approximately \$1.4 million. Cash outflows relating to research and development in Q1 2017 were approximately \$10.4 million. Cash flow from financing-type activities included approximately \$13.7 million in net cash proceeds from the previously announced January 2017 redemption of debt and simultaneous issuance of \$30.0 million face value of new debt long-term. Cash paid for interest and royalties in Q1 2017 was approximately \$4.1 million in aggregate.

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As of March 31, 2017, the company had \$29.5 million in net accounts receivable (\$34.5 million in gross accounts receivable before allowances and reserves) and \$23.9 million in inventory.

As of March 31, 2017, Amarin had approximately 270.7 million American Depository Shares (ADSs) and ordinary shares outstanding, 32.8 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 23.5 million equivalent shares underlying stock options at a weighted-average exercise price of \$3.25, as well as 9.8 million equivalent shares underlying restricted or deferred stock units.

**Conference call and webcast information**

Amarin will host a conference call at 8:00 a.m. ET today, May 3, 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](http://www.amarincorp.com). The call can also be heard via telephone by dialing 877-407-8033 within the United States or 201-689-8033 from outside the United States. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010 (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 10316.

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## 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<sup>®</sup> (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](http://www.vascepa.com). For more information about Amarin visit [www.amarincorp.com](http://www.amarincorp.com).

## About VASCEPA<sup>®</sup> (icosapent ethyl) capsules

VASCEPA<sup>®</sup> (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. 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 ( $\geq 500$  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](http://WWW.VASCEPA.COM).

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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 ( $\geq 500$  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 expectations for continued event rates, interim data review, results and related timing and announcements with respect to Amarin's REDUCE-IT cardiovascular outcomes study; expectations related to the interim and final outcomes of the REDUCE-IT study and the anticipated successful completion of the REDUCE-IT study; and statements regarding the potential 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, Amarin's ability to effectively develop and commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve increased market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that historical REDUCE-IT event rates may not be predictive of future results and related cost may increase beyond expectations; the risk that regulatory reviews may impact the current design of the REDUCE-IT study or cause a change in strategic direction with respect to continuation of the study; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; 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 anticipated patent litigation. 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 we communicate with our investors and the public using our company website ([www.amarincorp.com](http://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

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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:**

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

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
	(in thousands)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 96,076	\$ 98,251
Restricted cash	600	600
Accounts receivable, net	29,450	19,985
Inventory	23,879	20,507
Prepaid and other current assets	4,785	6,983
Total current assets	<u>154,790</u>	<u>146,326</u>
Property, plant and equipment, net	69	78
Deferred tax assets	11,082	11,082
Other long-term assets	652	741
Intangible asset, net	8,610	8,772
<b>TOTAL ASSETS</b>	<u>\$ 175,203</u>	<u>\$ 166,999</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 15,117	\$ 6,062
Accrued expenses and other current liabilities	44,434	37,720
Current portion of exchangeable senior notes, net of discount	192	15,351
Current portion of long-term debt from royalty-bearing instrument	17,004	15,944
Deferred revenue, current	1,197	1,172
Total current liabilities	<u>77,944</u>	<u>76,249</u>
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	28,831	—
Long-term debt from royalty-bearing instrument	82,405	85,155
Deferred revenue, long-term	13,625	13,943
Other long-term liabilities	1,167	710
Total liabilities	<u>203,972</u>	<u>176,057</u>
Stockholders' Deficit:		
Preferred stock	24,364	24,364
Common stock	208,465	207,166
Additional paid-in capital	967,073	964,914
Treasury stock	(3,726)	(1,498)
Accumulated deficit	(1,224,945)	(1,204,004)
Total stockholders' deficit	<u>(28,769)</u>	<u>(9,058)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<u>\$ 175,203</u>	<u>\$ 166,999</u>

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

	<b>Three Months Ended March 31,</b>	
	<b>(in thousands, except per share amounts)</b>	
	<b>2017</b>	<b>2016</b>
Product revenue, net	\$ 34,344	\$ 25,307
Licensing revenue	293	236
Total revenue, net	34,637	25,543
Less: Cost of goods sold	8,198	6,896
Gross margin	26,439	18,647
Operating expenses:		
Selling, general and administrative (1)	34,171	28,020
Research and development (1)	10,823	13,730
Total operating expenses	44,994	41,750
Operating loss	(18,555)	(23,103)
Loss on change in fair value of derivative liabilities (2)	—	(1,250)
Interest expense, net	(2,381)	(5,586)
Other expense, net	(5)	(121)
Loss from operations before taxes	(20,941)	(30,060)
Benefit from income taxes	—	289
Net loss	\$ (20,941)	\$ (29,771)
Loss per share:		
Basic	\$ (0.08)	\$ (0.16)
Diluted	\$ (0.08)	\$ (0.16)
Weighted average shares:		
Basic	270,163	184,052
Diluted	270,163	184,052

- (1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$31,343 and \$25,136 for the three months ended March 31, 2017 and 2016, respectively, and research and development expenses were \$10,300 and \$13,017, 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 \$26,111 and \$21,638 for the three months ended March 31, 2017 and 2016, 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.