
**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): August 1, 2018

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))

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 August 1, 2018, Amarin Corporation plc issued a press release announcing its financial results for the three and six months ended June 30, 2018 (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 August 1, 2018

* * *

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: August 1, 2018

Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero
President and Chief Executive Officer



Amarin Reports Second Quarter 2018 Financial Results and Provides Update on Operations

REDUCE-IT™ Study On-Track for Reporting Top-Line Results by the End of September 2018

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

BEDMINSTER, N.J., and DUBLIN, Ireland, August 1, 2018 -- 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 and six months ended June 30, 2018, and provided an update on company operations.

Key Amarin achievements since its last quarterly report include:

- **R&D progress:** The Vascepa cardiovascular outcomes study, REDUCE-IT™, is designed to provide data to support a significantly expanded market opportunity for Vascepa® (icosapent ethyl). The company announced that, as expected, it is making progress towards completion of this important study. The company reiterated that it anticipates reporting top-line results from REDUCE-IT before the end of September 2018.
- **U.S. revenue growth:** Recognized \$52.5 million in net product revenue from Vascepa sales in Q2 2018 compared to \$44.9 million in Q2 2017, an increase of 17%.
- **U.S. prescription growth:** Increased normalized prescriptions for Vascepa by 22% and 24% compared to Q2 2017 based on data from Symphony Health Solutions and IQVIA, respectively.
- **International development:** Announced regulatory approval for Vascepa in the United Arab Emirates. Announced a strategic collaboration with Mochida Pharmaceutical Co., Ltd. to further develop preventative healthcare solutions on a worldwide basis through continued innovation, research and development of product opportunities based on the unique properties of eicosapentaenoic acid (EPA).
- **Intellectual property:** Announced a settlement agreement with Teva Pharmaceuticals USA, Inc. that resolves Amarin's previously reported Vascepa patent litigation as it relates to Teva's abbreviated new drug application seeking U.S. Food and Drug Administration approval of generic forms of Vascepa capsules.
- **Cash balance:** As of June 30, 2018, Amarin had a cash balance of \$102.3 million.

"There is an urgent need to help more patients, and it is becoming increasingly evident that lowering cholesterol is not enough," stated John F. Thero, president and chief executive officer. "After decades of decline in the death rate from cardiovascular disease, the number of deaths from cardiovascular disease is rising again in spite of increased statin use and increased focus on other LDL-lowering therapies.¹ Vascepa could potentially be used for tens of millions of at-risk patients. We look forward with excitement to very soon having the results of the landmark REDUCE-IT study to report."

REDUCE-IT Cardiovascular Outcomes Study

The Vascepa cardiovascular outcomes study, REDUCE-IT, is progressing closer to completion with top-line results from the study anticipated to be reported before the end of September 2018. Amarin commented that final vital status data now has been secured for more than 99.5% of the 8,175 patients enrolled in the study. Consistent with late stage activities for large outcomes studies, efforts remain ongoing to adjudicate reported events, including major adverse cardiovascular events (MACE) within the primary endpoint that could not be adjudicated until after the last patient visits occurred. Efforts are also underway to complete the review of data for consistency and completeness across the more than 35,000 patient years in the trial, with emphasis on resolving remaining data queries to contribute to a robust and accurate database.

Amarin continues to be intentionally blinded to the results of the study and will remain blinded to such results until after the study is completed and the database is locked. Furthermore, all parties associated with the REDUCE-IT study, including the contract research organizations, independent review committees, clinical sites and patients, remain blinded to the final results of the study. As previously stated, once the REDUCE-IT database is locked, consistent with other outcomes studies, the company and a team of experts plan to confidentially review and analyze the data and promptly announce top-line results publicly. Broader reporting of results is targeted for a scientific conference in Q4 2018. The time between locking the database and reporting top-line results is intended to be as brief as is

possible to support both timely and accurate reporting of the results. Consistent with the practices of most other companies, Amarin does not plan to separately announce the date the database is locked. Rather, the company will focus on reporting the top-line results promptly after top-line results are known following database lock. Amarin's anticipation of reporting top-line results before the end of September 2018 is consistent with the end of study wind-down timing periods observed for other large outcomes studies.

Company Preparations for REDUCE-IT Conclusion

Amarin continues to prepare its commercial infrastructure for the announcement of the results of the REDUCE-IT study, including recent promotion of three high performing district sales managers to newly defined roles as regional directors in preparation for potential rapid sales force expansion and increasing levels of available Vascepa inventory. As previously stated, during 2018 we anticipate incremental inventory increases prior to REDUCE-IT results of up to approximately \$10 million. As of June 30, 2018, we had increased inventory levels during 2018 by approximately half of the target increase amount with the balance of the increase scheduled for coming months.

Financial Update

Net product revenue for the three months ended June 30, 2018 and 2017 was \$52.5 million and \$44.9 million, respectively. Net product revenue for the six months ended June 30, 2018 and 2017 was \$96.3 million and \$79.3 million, respectively. The increase in net product revenue was primarily attributable to increases in new and recurring prescriptions of Vascepa.

During the second quarter, based on data from Symphony Health Solutions and IQVIA, Amarin experienced continued prescription growth and increase in Vascepa market share, particularly among detailed physicians. These sources both reported estimated normalized total Vascepa prescriptions of approximately 430,000 for the three months ended June 30, 2018, representing growth of approximately 22% and 24%, respectively, over levels estimated by these sources for the same three months of the prior year.

Despite record levels of estimated Vascepa prescriptions reported by these third-party sources for the second quarter of 2018 and record levels of physicians reported to have prescribed Vascepa during the same period, Vascepa growth during this period appears to have been limited by patients lost to therapy during the first quarter of 2018 who did not resume filling Vascepa prescriptions during the second quarter of 2018. As previously described, beginning of the year insurance deductibles increased in 2018 under various health insurance plans. This industry-wide phenomenon, which is particularly impactful to prescriptions for therapies addressing asymptomatic medical conditions, resulted in some patients not filling prescriptions early in 2018. Once patients cease filling prescriptions, they become less prone, or unable, to resume filling prescriptions until they again visit their doctors. Net pricing of Vascepa in the second quarter of 2018 is relatively consistent with the prior year and channel inventory levels remain in the ordinary range.

Licensing revenues recognized by the company were \$0.2 million and \$0.6 million in the six months ended June 30, 2018 and 2017, 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, 2018 and 2017 was \$12.8 million and \$11.4 million, respectively. Cost of goods sold for the six months ended June 30, 2018 and 2017 was \$23.5 million and \$19.6 million, respectively. Gross margin on net product revenue for the three and six months ended June 30, 2018 and 2017 was 76% and 75%, respectively.

Selling, general and administrative (SG&A) expenses in the six months ended June 30, 2018 and 2017 were \$97.4 million and \$65.7 million, respectively, an increase of 48%. This increase is due primarily to increased promotional activities, including commercial spend for anticipated expansion following successful REDUCE-IT results, and increased co-promotion fees calculated on increased gross profit resulting from higher net product revenue, including an accrual of \$6.8 million for co-promotion tail payments. The tail co-promotion fees, which are calculated as a percentage of the 2018 co-promotion fee, are payable in 2019 through 2021. SG&A expenses for the six months ended June 30, 2018 also include \$2.0 million related to the settlement agreement with Teva Pharmaceuticals USA, Inc. which resolved Amarin's previously reported Vascepa patent litigation related to Teva's abbreviated new drug application (ANDA) seeking U.S. Food and Drug Administration approval of generic forms of Vascepa capsules. As previously disclosed, ANDA-related patent litigation continues in the United States District Court for the District of Nevada with West-Ward Pharmaceuticals Corp. and Dr. Reddy's Laboratories, Inc. and their affiliated entities.

Research and development (R&D) expenses in the six months ended June 30, 2018 and 2017 were \$29.9 million and \$24.5 million, respectively, an increase of 22%. This increase in expense is primarily driven by the timing of REDUCE-IT and related costs and the recording of \$2.7 million in expense related to the company's previously announced strategic collaboration with Mochida Pharmaceutical Co., Ltd. We continue to anticipate that our level of spending on R&D will decline after completion of the REDUCE-IT and initial publication of results from this important study.

Under U.S. GAAP, Amarin reported a net loss of \$34.2 million in the three months ended June 30, 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. Amarin reported a net loss of \$13.6 million in the second quarter of 2017, or basic and diluted loss per share of \$0.05. This net loss included \$3.6 million in non-cash stock-based compensation expense.

Under GAAP, Amarin reported a net loss of \$58.3 million in the six months ended June 30, 2018, or basic and diluted loss per share of \$0.20. This net loss included \$7.4 million in non-cash stock-based compensation expense. For the six months ended June 30, 2017, Amarin reported a net loss of \$34.6 million, or basic and diluted loss per share of \$0.13. This net loss included \$7.0 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net loss was \$30.6 million for the second quarter of 2018, or non-GAAP adjusted basic and diluted loss per share of \$0.10, compared to non-GAAP adjusted net loss of \$10.0 million for the second quarter of 2017, or non-GAAP adjusted basic and diluted loss per share of \$0.04.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net loss was \$50.9 million for the six months ended June 30, 2018, or non-GAAP adjusted basic and diluted loss per share of \$0.18, compared to non-GAAP adjusted net loss of \$27.6 million for the six months ended June 30, 2017, or non-GAAP adjusted basic and diluted loss per share of \$0.10.

Amarin reported cash and cash equivalents of \$102.3 million as of June 30, 2018. Net cash flows for the six months ended June 30, 2018, excluding the \$70.0 million in net proceeds from the equity offering completed in the first quarter, was negative \$41.4 million. Net cash flows for the same period was positive \$9.3 million excluding cash outflows associated with financing and REDUCE-IT. More specifically, net cash flow was positive for this period excluding finance related proceeds and expenses (interest and royalty), excluding research and development payments (most of which relates to the REDUCE-IT study), excluding payments made in preparation for expansion upon positive REDUCE-IT results, and excluding the one-time payment made related to the settlement agreement with Teva Pharmaceuticals USA, Inc.

As of June 30, 2018, the company had \$50.3 million in net accounts receivable (\$67.0 million in gross accounts receivable before allowances and reserves) and \$40.1 million in inventory.

As of June 30, 2018, Amarin had approximately 293.9 million American Depository Shares (ADSs) and ordinary shares outstanding, 32.8 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 25.3 million equivalent shares underlying stock options at a weighted-average exercise price of \$3.35, as well as 12.2 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, August 1, 2018. 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 34827.

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 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. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, EPA 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 REDUCE-IT

Amarin's clinical development program for Vascepa includes a trial known as the REDUCE-IT cardiovascular outcomes study, an 8,175-patient study commenced in 2011. REDUCE-IT is the first multinational cardiovascular outcomes study evaluating the effect of prescription pure EPA therapy, or any triglyceride-lowering therapy, as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, have elevated triglyceride levels (150-499 mg/dL). A large portion of the male and female patients enrolled in this outcomes study are anticipated to also be diagnosed with type 2 diabetes. As reported previously, Amarin expects to announce top-line results of this important study before the end of Q3 2018. The REDUCE-IT trial is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration.

Additional information on clinical studies of Vascepa can be found at www.clinicaltrials.gov.

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. 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.

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. 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.

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.^{1, 2}

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.^{3, 4, 5, 6}

Leading clinical investigations seeking to address cardiovascular risk reduction beyond lowering LDL-C focus on interrupting the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting other lipid, lipoprotein and inflammation biomarkers and cellular functions thought to be related to atherosclerosis and cardiovascular events.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding adjudication of MACE events, results and related timing and announcements with respect to Amarin's REDUCE-IT cardiovascular outcomes study; expectations related to the 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 related cost may increase beyond expectations; 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 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 American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.

² American Heart Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.

³ Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. *Am J Cardiol.* 2016;118:138-145.

4 Toth PP, Granowitz C, Hull M, et al. High triglycerides increase cardiovascular events, medical costs, and resource utilization in a real-world analysis of statin-treated patients with high cardiovascular risk and well-controlled low-density lipoprotein cholesterol [abstract]. *Circulation*. 2017;136(suppl 1):A15187.

5 Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. *Circ Res*. 2016;118:547-563.

6 Nordestgaard BG, Varbo A. Triglycerides and cardiovascular disease. *Lancet*. 2014; 384: 626–635.

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

	June 30, 2018	December 31, 2017
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 102,257	\$ 73,637
Restricted cash	600	600
Accounts receivable, net	50,309	45,318
Inventory, net	40,093	30,260
Prepaid and other current assets	2,878	3,455
Total current assets	<u>196,137</u>	<u>153,270</u>
Property, plant and equipment, net	17	28
Other long-term assets	174	174
Intangible asset, net	7,803	8,126
TOTAL ASSETS	<u>\$ 204,131</u>	<u>\$ 161,598</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	\$ 34,471	\$ 25,155
Accrued expenses and other current liabilities	73,753	58,902
Current portion of exchangeable senior notes, net of discount	481	481
Current portion of long-term debt from royalty-bearing instrument	27,876	22,348
Deferred revenue, current	1,056	1,644
Total current liabilities	<u>137,637</u>	<u>108,530</u>
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	29,103	28,992
Long-term debt from royalty-bearing instrument	59,564	70,834
Deferred revenue, long-term	17,750	17,192
Other long-term liabilities	6,764	1,150
Total liabilities	<u>250,818</u>	<u>226,698</u>
Stockholders' Deficit:		
Preferred Stock	24,364	24,364
Common stock	225,507	208,768
Additional paid-in capital	1,040,743	977,866
Treasury stock	(6,909)	(4,229)
Accumulated deficit	(1,330,392)	(1,271,869)
Total stockholders' deficit	<u>(46,687)</u>	<u>(65,100)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 204,131</u>	<u>\$ 161,598</u>

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)	
	2018	2017	2018	2017
Product revenue, net	\$ 52,537	\$ 44,948	\$ 96,313	\$ 79,292
Licensing revenue	106	293	248	586
Total revenue, net	52,643	45,241	96,561	79,878
Less: Cost of goods sold	12,846	11,401	23,494	19,599
Gross margin	39,797	33,840	73,067	60,279
Operating expenses:				
Selling, general and administrative (1)	53,944	31,545	97,350	65,716
Research and development (1)	18,159	13,694	29,921	24,517
Total operating expenses	72,103	45,239	127,271	90,233
Operating loss	(32,306)	(11,399)	(54,204)	(29,954)
Interest expense, net	(1,773)	(2,315)	(4,025)	(4,696)
Other (expense) income, net	(131)	80	(76)	75
Loss from operations before taxes	(34,210)	(13,634)	(58,305)	(34,575)
(Provision for) benefit from income taxes	—	—	—	—
Net loss	\$ (34,210)	\$ (13,634)	\$ (58,305)	\$ (34,575)
Loss per share:				
Basic	\$ (0.12)	\$ (0.05)	\$ (0.20)	\$ (0.13)
Diluted	\$ (0.12)	\$ (0.05)	\$ (0.20)	\$ (0.13)
Weighted average shares outstanding:				
Basic	293,662	270,725	289,458	270,445
Diluted	293,662	270,725	289,458	270,445

- (1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$50,878 and \$28,478 for the three months ended June 30, 2018 and 2017, respectively, and research and development expenses were \$17,607 and \$13,136, 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 \$40,594 and \$23,909 for the three months ended June 30, 2018 and 2017, respectively.

RECONCILIATION OF NON-GAAP NET LOSS
Unaudited

	Three months ended June 30, (in thousands, except per share amounts)		Six months ended June 30, (in thousands, except per share amounts)	
	2018	2017	2018	2017
Net loss for EPS ¹ - GAAP	\$ (34,210)	\$ (13,634)	\$ (58,305)	\$ (34,575)
Non-cash stock-based compensation expense	3,618	3,625	7,381	6,976
Adjusted net loss for EPS ¹ - non-GAAP	\$ (30,592)	\$ (10,009)	\$ (50,924)	\$ (27,599)
Basic and diluted				
Loss per share:				
Basic and diluted - non-GAAP	\$ (0.10)	\$ (0.04)	\$ (0.18)	\$ (0.10)
Weighted average shares:				
Basic and diluted	293,662	270,725	289,458	270,445