

Amarin Corporation

Amarin Reports Third Quarter 2019 Financial Results and Provides Update on Operations

November 5, 2019

Record Revenue Levels and Preparations On-Track for Further Expansion

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

DUBLIN, Ireland and BRIDGEWATER, N.J., Nov. 05, 2019 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on improving cardiovascular health, today announced financial results for the three and nine months ended September 30, 2019 and provided an update on company operations.

Key Amarin achievements since its last quarterly report include:

- **Record total revenue:** Reported total revenue of \$112.4 million and \$286.5 million for the three and nine months ended September 30, 2019, respectively, representing increases of 103% and 89%, respectively, over the corresponding periods of the prior year. The total revenue reported for the first nine months of 2019 exceeded the full-year results reported for 2018.
- **Record prescriptions:** Growth in net product revenue was supported by increased prescription levels of *Vascepa*® (icosapent ethyl) capsules. The increased prescription levels reflect both a higher number of *Vascepa* prescribers and an increase in the average prescriptions per prescriber.
- **Preparing for anticipated label expansion:** Assuming that, on or before the previously announced December 28, 2019 PDUFA date, *Vascepa*'s label will be expanded to reflect cardiovascular risk reduction as demonstrated in the REDUCE-IT® cardiovascular outcomes study, Amarin is taking broad steps to prepare for commercialization of *Vascepa* as the first therapy to address this important unmet medical need, including preparation for increased education of healthcare professionals and patients. Furthermore, to support FDA's approval of *Vascepa* for this expanded indication, Amarin has prepared for, and looks forward to, the FDA's advisory committee meeting scheduled for November 14, 2019.
- **International regulatory activities on track:** Amarin continues to target making its submission, before the end of 2019, seeking regulatory approval of *Vascepa* in Europe. Regulatory review of *Vascepa* in Canada continues to progress through Amarin's commercial partner in Canada with approval anticipated near the end of 2019 (late 2019 or early 2020).
- **Scientific advancement continues:** Thus far in 2019, Amarin has supported more than 40 scientific manuscripts or scientific publications with additional presentations anticipated before year-end, including multiple presentations later this month at the American Heart Associations' Annual Scientific Sessions.
- **Medical community support for using *Vascepa* to help patients:** Following the American Diabetes Association (ADA) new medical guidelines issued in March 2019, leading cardiology, endocrinology and lipidology societies have updated their clinical guidelines or provided varying other forms of advisories that reflect the results of the REDUCE-IT study for patients who despite well-controlled LDL-cholesterol have elevated triglyceride levels (≥ 135 mg/dL) and other cardiovascular risk factors. In Amarin's view, it is extraordinary to witness this broad level of medical society support prior to FDA approval for this important medical indication. These societies include the National Lipid Association, American Heart Association, European Society of Cardiology and the European Atherosclerosis Society. Separately, an independent drug pricing watchdog group concluded that *Vascepa* is cost effective for cardiovascular risk reduction even under the most stringent standards of that group, which is rarely achieved in their analysis.

"Our aim is to help as many patients as possible with *Vascepa*. Accordingly, we are pleased to witness the growth in *Vascepa* usage as reported in the third quarter. These recent results are laying the foundation for our future growth as we seek to make *Vascepa* a new standard of care for use in appropriate at-risk patient populations based on REDUCE-IT," stated John F. Thero, president and chief executive officer. "We are appreciative of the many patients and health care professionals who have reached out to us expressing support for approval of *Vascepa* for the expanded indication being sought. We are working with leading physicians to ensure that the results of the landmark REDUCE-IT study are well understood by regulatory authorities and their advisors. We recognize that much work remains following the anticipated approval of *Vascepa*. We remain guided by science and highly motivated by the unmet medical need that we believe *Vascepa* can address."

Prescription Growth

Based on monthly compilations of data provided by third parties, Symphony Health and IQVIA, the estimated number of normalized total *Vascepa* prescriptions for the three months ended September 30, 2019 were approximately 865,000 and 787,000, respectively, compared to 458,000 and 417,000, respectively, in the three months ended September 30, 2018. These estimates reflect increases of 89% in the third quarter of 2019 over the

same period of 2018.

The increase in prescriptions occurred broadly across the United States with the fastest percentage growth reported to come from cardiologists and endocrinologists and with the largest overall volume growth coming from general practitioners as there are many more general practitioners than specialists in the United States. The growth came from areas supported by Amarin's legacy sales representatives and from faster than expected productivity of new sales representatives added in early 2019. It is this increased productivity of new sales representatives, together with feedback from physicians, that convinced Amarin that the size of its sales force should be doubled from 400 sales representatives (the level at which the company has operated for most of 2019) to 800 sales representatives in preparation for the launch of *Vascepa* for cardiovascular risk reduction at the start of 2020, assuming FDA approval.

Regulatory Schedule in the United States

December 28, 2019 is the Prescription Drug User Fee Act (PDUFA) target date for action on Amarin's supplemental New Drug Application (sNDA) seeking approval of *Vascepa* as the first drug approved for cardiovascular risk reduction in the patient population studied in REDUCE-IT. An FDA advisory committee meeting pertaining to the sNDA for *Vascepa* is scheduled to be held on November 14, 2019 at the FDA's offices in White Oak, Maryland. The FDA makes information available regarding this advisory meeting at <https://www.fda.gov/advisory-committees/november-14-2019-meeting-endocrinologic-and-metabolic-drugs-advisory-committee-meeting-announcement>. Holding an advisory committee meeting in conjunction with its evaluation of a new drug is not uncommon for the FDA, particularly when the indication being sought is first in class for a potentially large patient population as is true for the sNDA under review for *Vascepa*.

As is the usual protocol, briefing books will be used for preparation of advisory committee panel members with information related to *Vascepa*, the related science and questions that the advisory committee panel members will be asked to vote on at the meeting. The briefing books typically are made public two days before the commencement of the advisory committee meeting. We expect this process to be no different for the *Vascepa*-related advisory committee meeting on November 14, 2019. Advisory committee panel members may ask their own questions regardless of whether such questions are covered in the briefing books or not.

The results of the REDUCE-IT study have been published in *The New England Journal of Medicine* and the *Journal of the American College of Cardiology*. And, as noted above, leading medical societies and other groups support the use of *Vascepa* to cost effectively address cardiovascular risk in studied at risk patients beyond statin therapy. Based on data, if all patients in the United States who have risk profiles similar to what was studied in REDUCE-IT were to take *Vascepa*, this could lower the number of major adverse cardiovascular events in the United States by approximately 150,000 to 450,000 per year.

Amarin looks forward to the advisory committee meeting on November 14, 2019 as an opportunity to further illuminate the results of the REDUCE-IT study and to provide further education on why *Vascepa* is a unique drug that should be approved for cardiovascular risk reduction which would position the drug to potentially help millions of patients. Amarin is appreciative of the approximately 100 letters which have been sent to the FDA from health care professionals, patients and others in support of prompt approval of *Vascepa* for cardiovascular risk reduction. The letters can be viewed with this link: <https://bit.ly/36ypKev>.

Commercial Growth

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

One important element of the robust launch Amarin is planning is an expanded sales team. The nucleus of Amarin's sales team is experienced and productive and has experienced limited turnover. Amarin's sales representatives enjoy helping healthcare professionals learn about new treatment options for their patients. As noted above, Amarin intends to increase the size of the Amarin direct sales team to approximately 800 sales representatives for the start of 2020. Amarin has received over 10,000 resumes for the 400 sales representatives Amarin seeks to hire. While Amarin has hired some additional sales representatives, Amarin's plan is to hire most of the additional sales representatives near the end of this year to support a launch of *Vascepa*, if approved, after the December 28, 2019 PDUFA date. The larger sales team is expected to educate a larger number of healthcare professionals and have more frequent interactions with targeted healthcare professionals. The increased sales force size is expected to reach approximately 70,000 to 80,000 healthcare professionals. Most of the sales management needed to support this expansion has been hired or internally promoted and support systems are in place with ample capacity to support this expansion.

Amarin reiterates its net revenue guidance for 2019 of \$380 million to \$420 million. Amarin does not plan to issue quantified 2020 guidance until after it knows the details of the label for *Vascepa* following the PDUFA date.

Financial Update

Amarin recorded net product revenue of \$112.3 million and \$285.3 million during the three and nine months ended September 30, 2019, respectively, compared to \$55.0 million and \$151.3 million in the corresponding periods of 2018, respectively, representing increases of 104% and 89%, respectively. This increase in net product revenue was driven primarily by an increase in estimated normalized total *Vascepa* prescriptions in the United States.

Net pricing of *Vascepa* in the third quarter of 2019 was relatively consistent with the prior year and channel inventory levels were in the ordinary range at the beginning and end of the period.

Licensing revenue during the nine months ended September 30, 2019 and 2018 were \$1.1 million and \$0.6 million, respectively.

Gross margin on net product revenue for the three and nine months ended September 30, 2019 were 77% compared to 75% and 76%, respectively, in the same periods of 2018.

Selling, general and administrative (SG&A) expense for the three and nine months ended September 30, 2019 were \$82.6 million and \$227.6 million, respectively, compared to \$50.0 million and \$147.3 million, respectively, in the corresponding periods of 2018, representing increases of 65% and 55%. These increases in SG&A expense were due primarily to increased commercial and other promotional costs for expansion following successful REDUCE-IT results (announced on September 24, 2018), including sales force expansion costs, partially offset by agreeing not to extend beyond

December 31, 2018 the company's previous co-promotion agreement for *Vascepa*.

Research and development (R&D) expense for the three and nine months ended September 30, 2019 were \$8.9 million and \$23.3 million, respectively, compared to \$14.1 million and \$44.0 million, respectively, in the corresponding periods of 2018, representing decreases of 37% and 47%, respectively. These decreases in R&D expense is attributed to the decline in REDUCE-IT related costs following presentation of such results in November 2018.

Under U.S. GAAP, Amarin reported net losses of \$3.5 million and \$29.7 million in the three and nine months ended September 30, 2019, or basic and diluted loss per share of \$0.01 and \$0.09, respectively, compared to net losses of \$24.5 million and \$82.8 million in the corresponding periods of 2018, or basic and diluted per share of \$0.08 and \$0.28, respectively. The net losses included \$8.0 million and \$22.7 million in non-cash stock-based compensation expense in the three and nine months ended September 30, 2019 compared to \$6.7 million and \$14.0 million in the corresponding periods of 2018.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$4.5 million and non-GAAP adjusted net loss was \$7.0 million for the three and nine months ended September 30, 2019, respectively, or non-GAAP adjusted basic and diluted earnings per share of \$0.01 and loss per share of \$0.02, respectively, compared to non-GAAP adjusted net loss of \$17.8 million and \$68.7 million for the corresponding periods of 2018, respectively, or non-GAAP adjusted basic and diluted loss per share of \$0.06 and \$0.24, respectively.

Cash and cash equivalents were \$673.2 million as of September 30, 2019. Net accounts receivable were \$103.6 million (\$133.5 million in gross accounts receivable before allowances and reserves) as of September 30, 2019.

Net cash flows, excluding net proceeds from the equity offering completed in the third quarter of 2019, was positive \$11.3 million and negative \$16.1 million for the three and nine month periods ended September 30, 2019, respectively.

As of September 30, 2019, Amarin had approximately 357.2 million American Depository Shares (ADSs) and ordinary shares outstanding, 28.9 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 16.3 million equivalent shares underlying stock options at a weighted-average exercise price of \$6.21, as well as 9.4 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, November 5, 2019. The call will be webcast live with slides and accessible through the investor relations section of the company's website at www.amarincorp.com. The call can also be heard via telephone by dialing 877-407-8033. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010 (inside the United States) or 919-882-2331 (outside the United States). A replay of the call will also be available through the company's website shortly after the call. For both dial-in numbers please use conference ID 55910.

Use of Non-GAAP Adjusted Financial Information

Included in this press release are non-GAAP adjusted financial information as defined by U.S. Securities and Exchange Commission Regulation G. The GAAP financial measure most directly comparable to each non-GAAP adjusted financial measure used or discussed, and a reconciliation of the differences between each non-GAAP adjusted financial measure and the comparable GAAP financial measure, is included in this press release after the condensed consolidated financial statements.

Non-GAAP adjusted net loss was derived by taking GAAP net loss and adjusting it for non-cash stock-based compensation expense. Management uses these non-GAAP adjusted financial measures for internal reporting and forecasting purposes, when publicly providing its business outlook, to evaluate the company's performance and to evaluate and compensate the company's executives. The company has provided these non-GAAP financial measures in addition to GAAP financial results because it believes that these non-GAAP adjusted financial measures provide investors with a better understanding of the company's historical results from its core business operations.

While management believes that these non-GAAP adjusted financial measures provide useful supplemental information to investors regarding the underlying performance of the company's business operations, investors are reminded to consider these non-GAAP measures in addition to, and not as a substitute for, financial performance measures prepared in accordance with GAAP. Non-GAAP measures have limitations in that they do not reflect all of the amounts associated with the company's results of operations as determined in accordance with GAAP. In addition, it should be noted that these non-GAAP financial measures may be different from non-GAAP measures used by other companies, and management may utilize other measures to illustrate performance in the future.

About Amarin

Amarin Corporation plc. is a rapidly growing, innovative pharmaceutical company focused on developing therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in polyunsaturated fatty acids and lipid science. *Vascepa* (icosapent ethyl) is Amarin's first FDA-approved drug and is available by prescription in the United States, Lebanon and the United Arab Emirates. Amarin's commercial partners are pursuing additional regulatory approvals for *Vascepa* in Canada, China and the Middle East. For more information about Amarin, visit www.amarincorp.com.

REDUCE-IT® Study

REDUCE-IT, an 8,179-patient cardiovascular outcomes study, was completed in 2018.¹ REDUCE-IT was the first multinational cardiovascular outcomes study that evaluated the effect of prescription pure EPA therapy as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, had elevated triglyceride levels (at least 135 mg/dL). A large portion of the male and female patients enrolled in this outcomes study were diagnosed with type 2 diabetes.

More information on the REDUCE-IT study results can be found at www.amarincorp.com.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths – one

death approximately every 38 seconds – with annual treatment cost in excess of \$500 billion.^{1, 2}

Multiple primary and secondary prevention trials have shown a significant reduction of 25% to 35% in the risk of cardiovascular events with statin therapy, leaving significant persistent residual risk despite the achievement of target LDL-C levels.³

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.^{4, 5, 6, 7}

About VASCEPA® (icosapent ethyl) Capsules

Vascepa (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. *Vascepa* is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient from degradation. *Vascepa*, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. Amarin has been issued multiple patents internationally based on the unique clinical profile of *Vascepa*, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

The FDA has not completed its review and made a final determination on a supplemental new drug application related to REDUCE IT. FDA has not reviewed the information herein or determined whether to approve *Vascepa* for use to reduce the risk of major adverse cardiovascular events in the REDUCE-IT patient population.

Indication and Usage Based on Current FDA-Approved Label (not including REDUCE-IT results)

- *Vascepa* (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
- The effect of *Vascepa* on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for *Vascepa* Based on Current FDA-Approved Label (not including REDUCE-IT results) (Includes Data from Two 12-Week Studies (n=622) (MARINE and ANCHOR) of Patients with Triglycerides Values of 200 to 2000 mg/dL)

- *Vascepa* is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to *Vascepa* or any of its components.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence $>2\%$ and greater than placebo) was arthralgia (2.3% for *Vascepa*, 1.0% for placebo). There was no reported adverse reaction $>3\%$ and greater than placebo.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088. Patients receiving treatment with *Vascepa* and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- Patients should be advised to swallow *Vascepa* capsules whole; not to break open, crush, dissolve, or chew *Vascepa*.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

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

- Excluding the major adverse cardiovascular events (MACE) results described above, overall adverse event rates in REDUCE-IT were similar across the statin plus *Vascepa* and the statin plus placebo treatment groups.
- There were no significant differences between treatments in the overall rate of treatment emergent adverse events or serious adverse events leading to withdrawal of study drug.
- There was no serious adverse event (SAE) occurring at a frequency of $>2\%$ which occurred at a numerically higher rate in the statin plus *Vascepa* treatment group than in the statin plus placebo treatment group.
- Adverse events (AEs) occurring in 5% or greater of patients and more frequently with *Vascepa* than placebo were:
 - peripheral edema (6.5% *Vascepa* patients versus 5.0% placebo patients), although there was no increase in the rate of heart failure in *Vascepa* patients

- constipation (5.4% *Vascepa* patients versus 3.6% placebo patients), although mineral oil, as used as placebo, is known to lower constipation, and
- atrial fibrillation (5.3% *Vascepa* patients versus 3.9% placebo patients), although there were *reductions* in rates of cardiac arrest, sudden death and myocardial infarctions observed in *Vascepa* patients
- There were numerically more SAEs related to bleeding in the statin plus *Vascepa* treatment group although overall rates were low with no fatal bleeding observed in either group and no significant difference in adjudicated hemorrhagic stroke or serious central nervous system or gastrointestinal bleeding events between treatments.
- In summary, *Vascepa* was well tolerated with a safety profile generally consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling of such products.

Important Cautionary Information About These Data

Further REDUCE-IT data assessment and data release is expected to yield additional useful information to inform greater understanding of the trial outcome. For example, detailed data assessment by regulatory authorities, such as the FDA and Health Canada, will continue and take time to complete and announce. The FDA advisory committee process and the final evaluation by regulatory authorities of the totality of efficacy and safety data from REDUCE-IT is anticipated to include some or all of the following, as well as other considerations: new information or analyses affecting the degree of treatment benefit on studied endpoints; study conduct and data robustness, quality, integrity and consistency; additional safety data considerations and risk/benefit considerations; and consideration of REDUCE-IT results in the context of other clinical studies. More detailed presentation of such considerations is set forth in the risk factors section of Amarin's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission. Because regulatory reviews are typically fluid and not definitive interactions between sponsor and agency on individual elements of an application and related information, Amarin does not plan to update investors further on ongoing communications with regulatory authorities. Amarin plans to announce the final outcome of such regulatory reviews when appropriate.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the use of *Vascepa* to potentially help millions of patients, commercial expansion plans and anticipated regulatory reviews and related timing. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 submissions, reviews and approvals; the risk that data interpretations or other information from third parties, the regulatory review process, regulatory authorities and in connection with an advisory committee could be made public that are negative or may delay approval or limit *Vascepa's* marketability; the risk that special protocol assessment (SPA) agreements with the FDA are not a guarantee that FDA will approve a product candidate; the risk associated with the FDA's rescinding the REDUCE-IT SPA agreement; the risk related to FDA advisory committee meetings; and the risk that the FDA may not complete its review of the REDUCE-IT sNDA within the timing expected. 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 <http://www.amarincorp.com/>), the 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 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.

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

	September 30, 2019	December 31, 2018
(in thousands)		
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 673,207	\$ 249,227
Restricted cash	3,904	1,500
Accounts receivable, net	103,583	66,523
Inventory	54,557	57,802
Deferred tax assets, current	—	—
Prepaid and other current assets	12,859	2,945
Total current assets	848,110	377,997
Property, plant and equipment, net	2,124	63
Operating lease right-of-use asset	8,633	- 0
Other long-term assets	1,074	174
Intangible asset, net	6,996	7,480
TOTAL ASSETS	\$ 866,937	\$ 385,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 42,042	\$ 37,632
Accrued expenses and other current liabilities	134,542	84,171
Current portion of long-term debt from royalty-bearing instrument	51,166	34,240
Deferred revenue, current	1,962	1,220
Total current liabilities	229,712	157,263
Long-Term Liabilities:		
Long-term debt from royalty-bearing instrument	8,878	46,108
Deferred revenue, long-term	17,617	19,490
Long-term operating lease liability	9,432	- 0
Other long-term liabilities	5,402	10,523
Total liabilities	271,041	233,384
Stockholders' Equity:		
Preferred stock	21,850	21,850
Common stock	266,878	246,663
Additional paid-in capital	1,745,946	1,282,762
Treasury stock	(20,533)	(10,413)
Accumulated deficit	(1,418,245)	(1,388,532)

Total stockholders' equity	595,896	152,330
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 866,937	\$ 385,714

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

	Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30, (in thousands, except per share amounts)	
	2019	2018	2019	2018
Product revenue, net	\$ 112,250	\$ 54,973	\$ 285,347	\$ 151,286
Licensing revenue	158	350	1,131	598
Total revenue, net	112,408	55,323	286,478	151,884
Less: Cost of goods sold	25,444	13,541	65,354	37,035
Gross margin	86,964	41,782	221,124	114,849
Operating expenses:				
Selling, general and administrative (1)	82,559	49,960	227,598	147,310
Research and development (1)	8,923	14,072	23,295	43,993
Total operating expenses	91,482	64,032	250,893	191,303
Operating loss	(4,518)	(22,250)	(29,769)	(76,454)
Interest income (expense), net	1,146	(2,163)	238	(6,188)
Other expense, net	(90)	(58)	(182)	(134)
Loss from operations before taxes	(3,462)	(24,471)	(29,713)	(82,776)
(Provision for) benefit from income taxes	—	—	—	—
Net loss	\$ (3,462)	\$ (24,471)	\$ (29,713)	\$ (82,776)
Loss per share:				
Basic	\$ (0.01)	\$ (0.08)	\$ (0.09)	\$ (0.28)
Diluted	\$ (0.01)	\$ (0.08)	\$ (0.09)	\$ (0.28)
Weighted average shares:				
Basic	350,994	295,595	336,938	291,526
Diluted	350,994	295,595	336,938	291,526

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$75,803 and \$44,357 for the three months ended September 30, 2019 and 2018, respectively, and research and development expenses were \$7,716 and \$13,024, 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 \$75,803 and \$33,200 for the three months ended September 30, 2019 and 2018, respectively.

RECONCILIATION OF NON-GAAP NET INCOME (LOSS)
Unaudited

Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30 (in thousands, except per share amounts)	
2019	2018	2019	2018

Net loss for EPS1 - GAAP	\$	(3,462)	\$	(24,471)	\$	(29,713)	\$	(82,776)
Non-cash stock-based compensation expense		7,963		6,651		22,729		14,032
Adjusted net income (loss) for EPS1 - non-GAAP	\$	4,501	\$	(17,820)	\$	(6,984)	\$	(68,744)
1basic and diluted								
Earnings (loss) per share:								
Basic - non-GAAP	\$	0.01	\$	(0.06)	\$	(0.02)	\$	(0.24)
Diluted - non-GAAP		0.01		(0.06)		(0.02)		(0.24)
Weighted average shares:								
Basic		350,994		295,595		336,938		291,526
Diluted		379,926		295,595		336,938		291,526

References

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