Amarin Corporation

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

May 1, 2019

Total Revenue Increased 67% to $73.3 Million in First Quarter 2019 Compared to Prior Year

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

BEDMINSTER, N.J., and DUBLIN, Ireland, May 01, 2019 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on improving cardiovascular health, today announced financial results for the quarter ended March 31, 2019 (Q1 2019) and provided an update on company operations.

Key Amarin achievements in Q1 2019 include:

- Revenue growth: Net total revenue of $73.3 million in Q1 2019 as compared to $43.9 in Q1 2018, an increase of approximately 67% primarily reflecting increased Vascepa prescription growth.
- sNDA submission: On March 28, 2019, Amarin submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking an expanded indication for Vascepa® (icosapent ethyl) capsules, based on the positive results of the landmark REDUCE-IT™ cardiovascular outcomes study which, assuming approval, will facilitate considerably broader promotion of Vascepa in the United States.
- Total events analysis presented from REDUCE-IT study: New data presented in March 2019 at the American College of Cardiology 68th Annual Scientific Session showed that Vascepa provided a statistically significant 30% risk reduction in total (first and subsequent) cardiovascular events compared to placebo in the statin-treated patient population studied in REDUCE-IT demonstrating approximately one fewer major adverse cardiovascular events (MACE) per six patients treated with Vascepa (or 159 fewer MACE per 1000 patients) over a five year period. This new data was concurrently published in the *Journal of the American College of Cardiology*[1].
- American Diabetes Association® guidelines updated: The American Diabetes Association (ADA) updated its *2019 Standards of Medical Care in Diabetes*[2] to incorporate findings from REDUCE-IT recommending that "in patients with ASCVD (atherosclerotic cardiovascular disease) or other cardiac risk factors on a statin with controlled low-density cholesterol (LDL-C), but elevated triglycerides (135-499), the addition of icosapent ethyl should be considered to reduce cardiovascular risk."

"Initial reaction from the medical community to REDUCE-IT results has been very encouraging, including the updated guidelines from the ADA. Our expanded sales team is off to a good start and we are optimistic regarding the potential results of pharmacoeconomic analysis expected later this year," commented John Thero, Amarin's president and chief executive officer. "We remain very early in the process of introducing Vascepa to healthcare professionals and we remain limited in what we can say about Vascepa, particularly to consumers, until the label for Vascepa is expanded. We are confident in the robust results of the REDUCE-IT study and we look forward to interacting with regulatory authorities in their review of these Vascepa clinical results in conjunction with the expanded labeling we seek for Vascepa."

Commercialization Progressing Well in Second Phase of Four Phase Plan

Following positive clinical results from the REDUCE-IT cardiovascular outcomes study, Amarin commenced what it described previously as the second of four phases of its commercial evolution. In this second phase, Amarin more than doubled the size of its U.S. sales force to begin 2019 with approximately 400 sales representatives plus their managers in the U.S. while in parallel not renewing its prior co-promotion agreement for Vascepa. The new sales representatives were fully trained and deployed by mid-January 2019. Amarin also significantly expanded the number of healthcare professionals it calls on for Vascepa education to approximately 55,000 healthcare professionals and expanded various other marketing and medical education programs.

Amarin reported that there was encouraging evidence of commercial progress in the first quarter despite the majority of Amarin's sales representatives being new and despite the label for Vascepa not referencing the results of the REDUCE-IT study. During the first quarter of 2019, shipments of Vascepa to customers increased, driven by increased levels of Vascepa prescriptions. Such increased prescriptions were derived from both past prescribers and new prescribers of Vascepa. Many of the new sales representatives hired by Amarin have already demonstrated positive contributions.

As an industry benchmark, it is generally accepted that it requires at least 5 sales calls before most physicians change prescribing behaviors. For Vascepa, this may require fewer visits to some doctors due to the robustly positive REDUCE-IT results and the lack of an alternative proven treatment option to address the risk evaluated in REDUCE-IT. Conversely, it may also take more visits to some doctors for them to begin prescribing Vascepa as the label for Vascepa has not yet expanded, and because prescribers have not had a practice changing new therapy for preventative cardiovascular care in many years beyond cholesterol management and diabetes therapies. As of the end of March 2019, consistent with previously communicated projections, Amarin sales representatives called on approximately 75% of our target physicians two or more times with the published results of the REDUCE-IT study. However, only slightly greater than half of these physicians had been called on three or more times.

The first quarter of each year historically was difficult for Vascepa prescription growth due to seasonal factors such as beginning of the year deductibles under patient insurance coverages. These factors are independent of Vascepa. In the first quarter of 2019, such seasonal factors, which curtail patient refill prescriptions, were largely offset by new prescriptions. Based on data from Symphony Health, new prescriptions (NRx) of Vascepa

increased by approximately 80% in the first quarter of 2019 compared to the same period of the prior year. In addition, refill prescription rates were approximately 3% to 5% higher in the first quarter of 2019 compared to the same period of the prior year. These increases in the first quarter of 2019 were partially offset by a decline in Vascepa inventory levels reported by independent commercial wholesalers. Such channel inventory levels at wholesalers were in the normal industry range. Calculated on a days-of-sales outstanding basis, channel inventory levels also declined in the first quarter of 2018.

Prescription Growth

Normalized prescriptions for Vascepa (prescription of 120 grams of Vascepa representing a one-month supply) increased by approximately 58% and 55% in Q1 2019 compared to Q1 2018 based on data from Symphony Health and IQVIA, respectively. Estimated normalized Vascepa prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 618,000 and 553,000 in the first quarter of 2019.

As described more fully in Amarin's Quarterly Report on Form 10-Q, Amarin recognizes product revenue when its customers, consisting mostly of independent commercial distributors, take possession of the product which they order from us and we ship to them. Amarin revenue is not recognized when individual patients fill prescriptions. In each of the three months ended March 31, 2019 and 2018, based on product shipment information available to Amarin, it appears that Symphony Health and IQVIA may have understated the rate of growth in Vascepa prescription levels.

Symphony Health and IQVIA collect and report estimates of prescription information. There is a limited amount of information available to such companies to determine the actual number of total prescriptions for prescription products like Vascepa during such periods. Data reported by Symphony Health and IQVIA is rarely identical. Their estimates are based on a combination of data received from pharmacies and other distributors, and historical data when actual data is unavailable. Their calculations of changes in prescription levels between periods can be significantly affected by lags in data reporting from various sources or by changes in how pharmacies and other distributors provide data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. These inaccuracies have historically been most prevalent and pronounced during periods of time of inflections upward or downward in rates of use and less prevalent and pronounced over longer periods of time such as annually. As such, the resulting conclusions from such sources should be viewed with caution. Amarin cites such third-party information as a courtesy to its investors and because Amarin does not have direct access to prescription information.

The prescription levels and changes in prescription levels reported above are based on information made available to us from third-party resources and may be subject to adjustment and may overstate or understate actual prescriptions. For example, it is Amarin's understanding that in March and April 2019 Symphony Health had been working to fill gaps in data sources and that they may issue "corrected" data at some point in the near future. Amarin is not directly aware of the details related to such source issues, or the precise timeline for corrective data or the degree to which estimated Vascepa prescriptions, as reported by Symphony Health, may change upward or downward if such corrections are implemented.

Regulatory Update

On March 28, 2019 Amarin submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking an expanded indication for Vascepa® (icosapent ethyl) capsules, based on the positive results of the REDUCE-IT™ cardiovascular outcomes study. The FDA has a 60-day review period to determine whether the sNDA is complete and acceptable for filing. Pending such acceptance for filing, Amarin, unless and until it learns otherwise in communications from the FDA, is operating under the assumption that the sNDA will be reviewed on a standard review clock of ten months resulting in a PDUFA date near the end of January 2020. While Amarin is not relying on priority review for the sNDA, if the FDA were to decide that the sNDA will be subject to priority review this would typically be communicated within 60 to 74 days of the FDA's receipt of the sNDA.

Amarin continues to expect that there will be an Advisory Committee (AdCom) meeting organized by the FDA in conjunction with its review of the expanded label for Vascepa sought in its sNDA, reflecting that Vascepa is positioned to become the first drug approved to treat the large patient population studied in the REDUCE-IT trial. However, the FDA determination as to whether or not there will be an AdCom has not yet been communicated to Amarin. Typically, the FDA does not communicate such a decision until it has had the opportunity to substantially review the sNDA.

In the event that Amarin receives a definitive communication from FDA regarding the scheduling of a PDUFA date for the sNDA or the scheduling of an AdCom, Amarin will seek to provide public update on such matters.

Health Canada has communicated to Amarin's Canadian partner that priority review status was granted for its New Drug Submission (NDS) for Vascepa in Canada. The NDS for Vascepa was submitted to Health Canada on April 26, 2019 seeking approval to market and sell Vascepa in Canada to reduce the risk of ischemic cardiovascular events in statin-treated patients with elevated triglycerides and other risk factors. The FDA operates independently of Health Canada.

Financial Update

Net product revenue, the largest component of net total revenue, for the three months ended March 31, 2019 and 2018 was approximately $72.7 million and $43.8 million, respectively, primarily reflecting increased Vascepa prescriptions in the United States. The net selling price of Vascepa declined modestly in this period of 2019 compared to 2018 primarily due to an increased portion of Vascepa prescriptions in 2019 derived from prescriptions to patients with lower net paying Medicare insurance coverage.

In addition, Amarin recognized licensing revenue of approximately $0.5 million and $0.1 million for the quarters ended March 31, 2019 and 2018, respectively, under agreements for the commercialization of Vascepa outside the U.S.

Cost of goods sold for the three months ended March 31, 2019 and 2018 was $17.1 million and $10.6 million, respectively. Gross margin on net product revenue was 76% for each of the three months ended March 31, 2019 and 2018.

Selling, general and administrative (SG&A) expenses in the three months ended March 31, 2019 and 2018 were $71.6 million and $43.4 million, respectively. This increase is due primarily to increased promotional activities, including commercial spend for expansion, including increased sales force expansion following successful REDUCE-IT results, partially offset by elimination of expenses associated with the company's prior co-promotion partner. This 65% increase in SG&A expenses supported a 67% increase in net total revenue and is intended to help support future revenue growth consistent with the company's previously expressed guidance that 2019 revenue levels will grow at least 50% over 2018 levels to approximately $350 million in 2019.

Research and development expenses in the three months ended March 31, 2019 and 2018 were $7.2 and $11.8 million, respectively. This decrease in expense was primarily driven by a decline in REDUCE-IT related costs after the successful completion of the REDUCE-IT study. Following the reporting of REDUCE-IT results, R&D costs consisted primarily of clinical trial wrap-up activities, costs related to scientific publications and preparing for sNDA submission based on the results of the study, which occurred in March 2019.

Under U.S. GAAP, Amarin reported a net loss of $24.4 million in the first quarter of 2019, or basic and diluted loss per share of $0.07. This net loss included $6.9 million in non-cash stock-based compensation expense. Amarin reported a net loss of $24.1 million in the first quarter of 2018, or basic and diluted loss per share of $0.08. This net loss included $3.8 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net loss was $17.5 million for the first quarter of 2019, or non-GAAP adjusted basic and diluted loss per share of $0.05, compared to non-GAAP adjusted net loss of $20.3 million for the first quarter of 2018, or non-GAAP adjusted basic and diluted loss per share of $0.07.

As of March 31, 2019, Amarin reported cash and cash equivalents of $211.1 million, $79.5 million in net accounts receivable ($104.0 million in gross accounts receivable before allowances and reserves) and $57.9 million in inventory. In connection with the recently adopted lease standard, ASC 842, the company recorded an operating lease right-of-use asset and corresponding operating lease liability of approximately $9.0 million.

As of March 31, 2019, Amarin had approximately 330.6 million American Depository Shares (ADSs) and ordinary shares outstanding, 28.9 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 16.8 million equivalent shares underlying stock options at a weighted-average exercise price of $5.51, as well as 9.3 million equivalent shares underlying restricted or deferred stock units.

Conference Call and Webcast Information

The conference call can be heard live on the investor relations section of the company's website at www.amarincorp.com, or via telephone by dialing 877-407-8033 within the United States or 201-689-8033 from outside the United States. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010, PIN: 46060. A replay of the call will also be available through the company's website shortly after the call.

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.

About REDUCE-IT

REDUCE-IT[3], an 8,179-patient cardiovascular outcomes study, was completed in 2018. 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.[4, 5]

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. [6]

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. [7-10]

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.

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*[3] 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.

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. FDA has not reviewed and opined 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 MACE. 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.

Important Cautionary Information About These Data

Further REDUCE-IT data assessment and data release could yield additional useful information to inform greater understanding of the trial outcome. Further detailed data assessment by Amarin and regulatory authorities will continue and take several months to complete and record. The final evaluation of the totality of the efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations: new information 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; consideration of REDUCE-IT results in the context of other clinical studies.

Recurrent event analyses for the total primary endpoint events and for the total key secondary endpoint in REDUCE-IT as published in the *Journal of*

the American College of Cardiology[9] were conducted using a series of statistical models. These analyses were tertiary or exploratory endpoints; most of the models used were prespecified and one was post hoc. Each recurrent event statistical model has inherent strengths and weaknesses, with no single model considered definitive or outperforming the other models, and this is an evolving field of science. Nonetheless, results from the total primary and total key secondary endpoint events analyses are consistent across the various recurrent event statistical models and are also consistent with the original primary and secondary endpoint results. Together, the REDUCE-IT recurrent event analyses and the original primary and key secondary endpoint analyses support the robustness of the clinical benefit of Vascepa therapy in reducing cardiovascular risk.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding regulatory review and related timing thereof; and expectations regarding further advancement, commercial expansion and revenue growth. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In addition, Amarin's ability to effectively 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, its ability to obtain an expanded indication for Vascepa in the United States, to achieve 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 sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may not be upheld in patent litigation and applications may not result in issued patents sufficient to protect the Vascepa franchise. 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.

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Amarin Contact Information

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

Lee M. Stern
Solebury Trout
In U.S.: +1 (646) 378-2992
lstern@soleburytrout.com

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

	March 31, 2019	December 31, 2018
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 211,089	$ 249,227
Restricted cash	1,502	1,500
Accounts receivable, net	79,485	66,523
Inventory	57,909	57,802
Prepaid and other current assets	5,334	2,945
Total current assets	355,319	377,997
Property, plant and equipment, net	57	63
Operating lease right-of-use asset	8,900	—
Other long-term assets	643	174
Intangible asset, net	7,319	7,480
TOTAL ASSETS	$ 372,238	$ 385,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 26,776	$ 37,632
Accrued expenses and other current liabilities	94,170	84,171
Current portion of long-term debt from royalty-bearing instrument	38,960	34,240
Deferred revenue, current	1,898	1,220
Total current liabilities	161,804	157,263
Long-Term Liabilities:		
Long-term debt from royalty-bearing instrument	35,338	46,108
Deferred revenue, long-term	18,265	19,490
Long-term operating lease liability	7,930	—
Other long-term liabilities	8,030	10,523
Total liabilities	231,367	233,384
Stockholders' Equity:		
Preferred Stock	21,850	21,850
Common stock	250,088	246,663
Additional paid-in capital	1,301,389	1,282,762
Treasury stock	(19,493)	(10,413)
Accumulated deficit	(1,412,963)	(1,388,532)
Total stockholders' equity	140,871	152,330
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 372,238	$ 385,714

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

	Three months ended March 31, (in thousands, except per share amounts)	
	2019	2018
Product revenue, net	$ 72,731	$ 43,777
Licensing revenue	547	142

Total revenue, net	73,278	43,919
Less: Cost of goods sold	17,140	10,648
Gross margin	56,138	33,271
Operating expenses:		
Selling, general and administrative (1)	71,633	43,407
Research and development (1)	7,242	11,762
Total operating expenses	78,875	55,169
Operating loss	(22,737)	(21,898)
Interest expense, net	(1,697)	(2,252)
Other income, net	3	55
Loss from operations before taxes	(24,431)	(24,095)
(Provision for) benefit from income taxes	—	—
Net loss	$ (24,431)	$ (24,095)
Loss per share:		
Basic	$ (0.07)	$ (0.08)
Diluted	$ (0.07)	$ (0.08)
Weighted average shares:		
Basic	328,712	285,207
Diluted	328,712	285,207

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were $66,027 and $40,205 for the three months ended March 31, 2019 and 2018, respectively, and research and development expenses were $5,964 and $11,202, respectively, for the same periods.

RECONCILIATION OF NON-GAAP NET LOSS
Unaudited

	Three months ended March 31, (in thousands, except per share amounts)	
	2019	**2018**
Net loss for EPS[1] - GAAP	$ (24,431)	$ (24,095)
Non-cash stock-based compensation expense	6,884	3,762
Adjusted net loss for EPS[1] - non-GAAP	$ (17,547)	$ (20,333)
[1]basic and diluted		
Loss per share:		
Basic and diluted - non-GAAP	$ (0.05)	$ (0.07)
Weighted average shares:		
Basic and diluted	328,712	285,207