

**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): October 27, 2022

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.)

**Iconic Offices, The Greenway, Block C Ardilaun Court,
112 – 114 St Stephens Green, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	AMRN	NASDAQ Stock Market LLC

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 October 27, 2022, Amarin Corporation plc (“Amarin”) issued a press release announcing its financial results for the three and nine months ended September 30, 2022 and 2021 (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 (the “Securities Act”), 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 (results of operations), dated October 27, 2022 (furnished herewith)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* * *

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: October 27, 2022

Amarin Corporation plc

By: /s/ Karim Mikhail

Karim Mikhail

President and Chief Executive Officer



Amarin Reports Third Quarter 2022 Financial Results and Provides Business Update

-- U.S. Business Trends Stabilize and Progress on Operational Initiatives Result in Extended Cash Runway --

-- Commenced Launch of VAZKEPA® (icosapent ethyl) in England & Wales Mid-October As Planned --

-- Achieved Positive National Reimbursement in Finland & Obtained Positive Scientific Assessment for Reimbursement in Italy and the Netherlands --

--Ongoing Market Access Negotiations for VAZKEPA Underway Across Multiple Major European Markets Including Final Price Negotiations in Spain --

-- Company to Host Conference Call Today at 8:00 a.m. EDT --

DUBLIN, Ireland and BRIDGEWATER, N.J., October 27, 2022 -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the quarter ended September 30, 2022 and provided an update on the Company's operations.

"In the third quarter of 2022, Amarin made important progress on meeting its key priorities and long-term growth strategy highlighted by improvement in the Company's cash position, reporting a cash positive quarter excluding restructuring charges. We remain confident in the opportunities that lie ahead and our direction for the remainder of 2022 and into 2023," said Karim Mikhail, President and Chief Executive Officer of Amarin.

In Europe, we are on-track to deliver on our commitment to obtain pricing and reimbursement approval in up to eight European markets and to launch in up to six European markets this year, and we remain confident in our \$1 billion plus revenue opportunity across the region. We are pleased with the progress we are making in key markets, and in the third quarter of 2022, we were successful in securing overall pricing and reimbursement in Finland, as well as individual pricing and reimbursement in Austria. This adds to the reimbursements obtained in England & Wales, Northern Ireland and Sweden, the individual reimbursement in Denmark, and the positive scientific assessments in France, Italy and the Netherlands. We also expect potential reimbursement decisions by year end and into early 2023 in Spain, Italy, Norway, the Netherlands and France.

In the U.S., we are pleased with the continuing stabilization of our VASCEPA® business and our performance in the market. This represents our third consecutive quarter where we have seen stable U.S. revenues, which have been achieved through our team's focus on branded promotion of VASCEPA. In the U.S., steps were also taken earlier in 2022 to reduce our costs and improve our cash position. The implementation of a comprehensive cost savings plan began to materialize in the third quarter and is on track to deliver \$100 million in cost savings* through mid-2023. In addition, we continued to make progress on renegotiating our supply purchase agreements.

We also continue our efforts to expand awareness and understanding around the science behind VASCEPA/VAZKEPA, and the tremendous clinical value that our product provides in reducing cardiovascular (CV) risk in high and very high-risk patients. With respect to thought leadership, we are actively establishing a presence and educating the healthcare

community at key cardiovascular meetings and congresses across the world, including a major presence at the European Society of Cardiology Congress in August, the Canadian Cardiovascular Congress in October and American Heart Association Scientific Sessions coming up in November. We also continue to make progress on the development of our fixed-dose combination of VASCEPA with a statin and enhance and expand our leadership team to support the company's long-term strategy.

As we consider our achievements in the third quarter and move into the fourth quarter of the year, we remain steadfast and confident in our long-term strategy and the opportunities ahead to execute against a BOLD vision to stop heart disease from being the leading cause of death for patients worldwide," concluded Mr. Mikhail.

Europe

Amarin has commenced the launch of VAZKEPA in the U.K. To date, Amarin is making excellent progress securing VAZKEPA patient access through local formulary negotiations, and those negotiations will continue to progress throughout the remainder of 2022 and into 2023. Launch activities also continue to progress in Sweden.

- Secured pricing and reimbursement for VAZKEPA in Finland and Northern Ireland, with broad access to patients, similar to England/Wales and Sweden.

In addition, Amarin obtained individual reimbursement for VAZKEPA in Austria, adding to the individual reimbursement in Denmark obtained earlier this year; the Company plans to resubmit for broader pricing and reimbursement access in those countries in the months ahead. Clinical and Health Technology Assessment processes and reimbursement discussions are progressing across all targeted markets in Europe where Amarin has submitted market access dossiers, including Spain, France, Italy, Norway, the Netherlands, Portugal, Scotland, Switzerland and Israel.

- Price negotiations are nearing conclusion with Spain's Ministry of Health, which could allow for a possible pricing and reimbursement decision before the end of 2022.
- In Italy, our dossier has advanced from the scientific assessment phase of negotiations into the pricing and reimbursement phase of discussions with the regulators in that market.
- In the Netherlands we received a positive recommendation by the National Health Care Institute (ZIN) for reimbursement and expect to begin pricing negotiations with the Dutch Ministry of Health.
- As a reminder, Amarin received a positive reimbursement assessment from HAS – the French National Authority for Health – and price negotiations continue to progress.

United States

U.S. product net revenue was \$87.9 million in the third quarter of 2022, a decrease of \$2.8 million versus the second quarter of 2022, reflecting minimal impact on price and volume. The Company continues to maintain more than 60% market share of the IPE molecule despite generic competition as the U.S. commercial organization continues to maintain targeted support of branded VASCEPA. This revenue continues to support investments in Europe and expansion into new markets.

Amarin continues to actively monitor key performance indicators in the U.S. market to support its strategy moving forward.

International

Amarin continues to advance towards its goal to unlock the potential of VASCEPA internationally. The company is in the process of filing regulatory submissions for approval in 20 additional countries to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA. Amarin's marketing authorization submissions for VASCEPA in Australia and New Zealand are continuing to advance per local procedures.

In addition, Amarin continues to make progress in these efforts with our partners, including:

- Eddingpharm (Asia) Macao Commercial Offshore Limited (Edding), Amarin's partner in China, recently received confirmation that the Chinese government has completed product testing and has initiated the final review period prior to approval. Our partner has communicated that they still anticipate an approval could be achieved before year end.
- In Canada, HLS Therapeutics, Inc. has obtained reimbursement from all major public payors and continues to launch in the public sector.

Financial Update

Total net revenue for the three months ended September 30, 2022 was \$89.9 million, compared to \$142.0 million in the corresponding period of 2021, a decrease of 37%. Net product revenue for the three months ended September 30, 2022 was \$89.2 million, compared to \$141.4 million in the corresponding period of 2021, a decrease of 37%. This decrease was driven by a decline in volume and net selling price due to the impact of an increase in generic competition in the U.S. As a reminder, during the three months ended September 30, 2022 there were three or more generic competitors in the U.S. market as compared to two generic competitors in the U.S. market during the three months ended September 30, 2021.

Amarin recognized licensing and royalty revenue of approximately \$0.7 million and \$0.6 million during the three months ended September 30, 2022 and 2021, respectively, from VASCEPA-related commercial sales from our partners in Canada, the China region and the Middle East.

Cost of goods sold for the three months ended September 30, 2022 was \$27.0 million, compared to \$30.2 million in the corresponding period of 2021. Amarin's overall gross margin on net product revenue for the three months ended September 30, 2022 was 70%, compared with 79% for the corresponding period of 2021. During the three months ended September 30, 2022, Amarin took steps to amend supplier agreements to align supply arrangements with current and future market demand resulting in a charge of \$3.1 million. Excluding the impact of this item, gross margin was 73% for the three months ended September 30, 2022.

Selling, general and administrative expenses for the three months ended September 30, 2022 was \$58.7 million, compared to \$103.0 million in the corresponding period of the prior year. This decrease was primarily due to the implementation of our cost reduction plan announced in June and was partially offset by investments to support commercial operations in Europe.

Research and development expenses for the three months ended September 30, 2022 were \$5.8 million, compared to \$7.8 million in the corresponding period of the prior year. This decrease was primarily driven by the implementation of our cost reduction plan announced in June and was partially offset by costs incurred related to the development of a fixed-dose combination of VASCEPA with a statin.

In August 2022, the company announced the discontinuation of the German operations as a result of not being able to reach a viable agreement on the reimbursement price of VASKEPA in Germany. As a result, the company incurred a total of \$4.4 million in restructuring charges, substantially all of which were cash expenditures incurred during the third quarter 2022.

Under U.S. GAAP, Amarin reported a net loss of \$5.1 million for the third quarter ended September 30, 2022, or basic and diluted loss per share of \$0.01. This net loss includes \$5.0 million in non-cash stock-based compensation and \$6.6 million in restructuring expenses. For the third quarter ended September 30, 2021, Amarin reported a net loss of \$13.2 million, or basic and diluted loss per share of \$0.03. This net loss included \$10.4 million in non-cash stock-based compensation expense and \$14.1 million in restructuring expenses. Excluding non-cash stock-based compensation expense and

restructuring expense, non-GAAP adjusted net income was \$6.4 million for the third quarter ended September 30, 2022 or non-GAAP adjusted basic and diluted earnings per share of \$0.02, compared with non-GAAP adjusted net income of \$11.4 million for the third quarter ended September 30, 2021, or non-GAAP adjusted basic and diluted earnings per share of \$0.03. As of September 30, 2022, Amarin reported aggregate cash and investments of \$306.0 million.

**Compared to 2021 full year GAAP operating expenses and excludes restructuring charges.*

2022 Financial Outlook

Given the uncertainty resulting from the impact of generic IPE in the U.S. and challenges for most drugs seeking market access in Europe, Amarin will continue to suspend 2022 revenue guidance.

The stabilization of the U.S. business revenues and recent cash preservation initiatives have resulted in extended cash runway for the Company. Amarin believes the current cash and investments and other assets are adequate to support continued operations, including European launch activities.

Conference Call and Webcast Information:

Amarin will host a conference call on October 27, 2022, at 8:00 a.m. ET to discuss this information. The conference call can be accessed on the investor relations section of the company's website at www.amarincorp.com, or via telephone by dialing 888-506-0062 within the United States, 973-528-0011 from outside the United States, and referencing conference ID 367970. A replay of the call will be made available for a period of two weeks following the conference call. To listen to a replay of the call, dial 877-481-4010 from within the United States and 919-882-2331 from outside of the United States, and reference conference ID 46629. 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) income was derived by taking GAAP net loss and adjusting it for non-cash stock-based compensation expense and restructuring 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 is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our scientific research foundation to our focus on clinical trials, and now our global commercial expansion, we are evolving and growing rapidly. Amarin has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, Zug in Switzerland, and other countries in Europe as well as commercial partners and suppliers around the world. We are committed to rethinking cardiovascular risk through the advancement of scientific understanding of the impact on society of significant residual risk that exists beyond traditional therapies, such as statins for cholesterol management.

About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was launched in the United States in January 2020 as the first and only drug approved by the U.S. FDA for treatment of the studied high-risk patients with persistent cardiovascular risk after statin therapy. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over ten million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, VASCEPA is approved and sold in Canada, Lebanon and the United Arab Emirates. In Europe, in March 2021 marketing authorization was granted to icosapent ethyl in the European Union for the reduction of risk of cardiovascular events in patients at high cardiovascular risk, under the brand name VASKEPA.

Indications and Limitation of Use (in the United States)

VASCEPA is indicated:

1. As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
 - established cardiovascular disease or
 - diabetes mellitus and two or more additional risk factors for cardiovascular disease.
2. As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information

3. VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
 4. VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
 5. It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.
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6. VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
7. Common adverse reactions in the cardiovascular outcomes trial (incidence $\geq 3\%$ and $\geq 1\%$ more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%).
8. Common adverse reactions in the hypertriglyceridemia trials (incidence $\geq 1\%$ more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
9. Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
10. Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding.

FULL U.S. FDA-APPROVED VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Forward-Looking Statements

This press release contains forward-looking statements, within the meaning of U.S. securities laws, including, but not limited to, including beliefs about the world-wide market potential for VASCEPA; expectations regarding financial metrics and performance such as prescription growth, revenue growth, operating expenses, inventory purchases, and managed care coverage for VASCEPA, including the impact of the COVID-19 pandemic, the disappointing outcome of patent litigation and the launch of generic competition on these metrics; beliefs that Amarin is well positioned to deliver on its goals to grow VASCEPA in the U.S. and beyond; beliefs about patient needs for VASCEPA; effects of the COVID-19 pandemic on Amarin's operations and on the healthcare industry more broadly, which effects continue to be fluid; beliefs that Amarin's strategy for reducing the effects of cardiovascular disease is sound and that Amarin is efficiently reaching physicians, payors, pharmacists and patients; the timing and outcome of regulatory filings and reviews, recommendations and approvals and related reimbursement decisions and commercial launches in Europe, the China region and elsewhere; plans for Amarin's expected launch of VASCEPA directly in major markets in Europe, directly and indirectly; beliefs about the cardioprotective and other benefits of VASCEPA; beliefs about the strength of data in market access dossiers and other reports; expectations for the timing, effectiveness and outcome of promotional activities, including patient-oriented campaigns, conference and posted presentations and education of healthcare professionals; commercial and international expansion, prescription growth and revenue growth and future revenue levels, including the contributions of sales representatives and the new leadership team; beliefs that Amarin's current resources are sufficient to fund projected operations; and the impact of the COVID-19 pandemic on all of the foregoing. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Amarin's ability to effectively commercialize VASCEPA and maintain or grow market share will depend in part on Amarin's ability to continue to effectively finance its business, VASCEPA approval in geographies outside the U.S., efforts of third parties, Amarin's ability to create and increase market demand for VASCEPA through education, marketing and sales activities, to achieve broad 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 secure, maintain and defend its patent protection for VASCEPA. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: the possibility that VASCEPA may not receive regulatory approval in the China region or other geographies on the expected timelines or at all; the risk that additional generic versions of VASCEPA will enter the market and that generic versions of VASCEPA will achieve greater market share and more commercial supply than anticipated, particularly in light of the disappointing outcome of Amarin's litigation against two generic drug companies and subsequent requests for appeal; the risk that the scope and duration of the COVID-19 pandemic will continue to impact access to and sales of VASCEPA; the risk that Amarin has overestimated the market potential for VASCEPA in the U.S., Europe and other geographies; risks associated with Amarin's expanded enterprise; 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; and the risk that patents may be determined to not be infringed or not be valid 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 Amarin's annual report on Form 10-K for the year ended December 31, 2021, and quarterly report on Form 10-Q for the quarter ended September 30, 2022. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Amarin undertakes no obligation to update or revise the information contained in its forward-looking statements, whether as a result of new information, future events or circumstances or otherwise. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, dispositions, joint ventures or any material agreements that Amarin may enter into, amend or terminate.

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, U.S. 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.

Amarin Contact Information

Investor Inquiries:

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Media Inquiries:

Mark Marmur
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-Tables to Follow-

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

	September 30, 2022	December 31, 2021
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 240,498	\$ 219,454
Restricted cash	3,920	3,918
Short-term investments	63,203	234,674
Accounts receivable, net	123,379	163,653
Inventory	227,606	234,676
Prepaid and other current assets	27,914	22,352
Total current assets	686,520	878,727
Property, plant and equipment, net	999	1,425
Long-term investments	2,264	34,996
Long-term inventory	187,964	121,254
Operating lease right-of-use asset	8,462	7,660
Other long-term assets	456	456
Intangible asset, net	21,638	23,547
TOTAL ASSETS	\$ 908,303	\$ 1,068,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 93,157	\$ 114,922
Accrued expenses and other current liabilities	192,001	253,111
Current deferred revenue	2,198	2,649
Total current liabilities	287,356	370,682
Long-Term Liabilities:		
Long-term deferred revenue	13,499	14,060
Long-term operating lease liability	9,924	8,576
Other long-term liabilities	9,697	7,648
Total liabilities	320,476	400,966
Stockholders' Equity:		
Common stock	298,596	294,027
Additional paid-in capital	1,878,923	1,855,246
Treasury stock	(61,585)	(60,726)
Accumulated deficit	(1,528,107)	(1,421,448)
Total stockholders' equity	587,827	667,099
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 908,303	\$ 1,068,065

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

	Three months ended September 30,		Nine months ended September 30,	
	(in thousands, except per share amounts)		(in thousands, except per share amounts)	
	2022	2021	2022	2021
Product revenue, net	\$ 89,222	\$ 141,442	\$ 277,004	\$ 436,598
Licensing and royalty revenue	656	596	1,944	2,098
Total revenue, net	89,878	142,038	278,948	438,696
Less: Cost of goods sold	23,941	30,211	81,990	90,692
Less: Cost of goods sold - restructuring inventory	3,078	—	18,078	—
Gross margin	62,859	111,827	178,880	348,004
Operating expenses:				
Selling, general and administrative (1)	58,745	102,965	236,285	315,966
Research and development (1)	5,765	7,820	25,172	23,554
Restructuring	3,493	14,115	13,706	14,115
Total operating expenses	68,003	124,900	275,163	353,635
Operating loss	(5,144)	(13,073)	(96,283)	(5,631)
Interest income, net	750	163	1,241	919
Other income (expense), net	511	(57)	(1,990)	(390)
Loss from operations before taxes	(3,883)	(12,967)	(97,032)	(5,102)
Income tax provision	(1,257)	(184)	(9,627)	(1,867)
Net loss	<u>\$ (5,140)</u>	<u>\$ (13,151)</u>	<u>\$ (106,659)</u>	<u>\$ (6,969)</u>
Loss per share:				
Basic	\$ (0.01)	\$ (0.03)	\$ (0.27)	\$ (0.02)
Diluted	\$ (0.01)	\$ (0.03)	\$ (0.27)	\$ (0.02)
Weighted average shares:				
Basic	404,614	396,618	399,944	395,681
Diluted	404,614	396,618	399,944	395,681

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$54,358 and \$93,723 for the three months ended September 30, 2022 and 2021, respectively, and research and development expenses were \$5,138 and \$6,630, respectively, for the same periods.

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)	
	2022	2021	2022	2021
Net loss for EPS ¹ - GAAP	(5,140)	(13,151)	(106,659)	(6,969)
Non-cash stock-based compensation expense	5,015	10,432	20,192	26,836
Restructuring inventory	3,078	—	18,078	—
Restructuring expense	3,493	14,115	13,706	14,115
Adjusted net income (loss) for EPS ¹ - non-GAAP	\$ 6,446	\$ 11,396	\$ (54,683)	\$ 33,982
¹ basic and diluted				
Earnings (loss) per share:				
Basic - non-GAAP	\$ 0.02	\$ 0.03	\$ (0.14)	\$ 0.09
Diluted - non-GAAP	\$ 0.02	\$ 0.03	\$ (0.14)	\$ 0.08
Weighted average shares:				
Basic	404,614	396,618	399,944	395,681
Diluted	405,541	402,657	399,944	402,657

