

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of Earliest Event Reported): August 3, 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.)

77 Sir John Rogerson's Quay, Block C,
Grand Canal Docklands, 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 August 3, 2022, Amarin Corporation plc (“Amarin”) issued a press release announcing its financial results for the three and six months ended June 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 August 3, 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: August 3, 2022

Amarin Corporation plc

By: /s/ Karim Mikhail

Karim Mikhail

President and Chief Executive Officer



Amarin Reports Second Quarter 2022 Financial Results and Provides Business Update

Company Received Final Positive Reimbursement Decision for VAZKEPA® by UK's NICE in England & Wales

Market Access Negotiations and Launch Preparations for VAZKEPA Underway Across Multiple European Markets

*Initiated Comprehensive Cost Reduction Plan in June to Address Market Dynamics in the U.S. with Expected Savings of \$100 Million Over 12 Months**

Plans On Track for Regulatory Filings for Approval of VASCEPA® (icosapent ethyl) in Several Additional Countries in 2022

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

DUBLIN, Ireland and BRIDGEWATER, N.J., August 3, 2022 -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the quarter ended June 30, 2022 and provided an update on company operations.

"In the second quarter of 2022, we made important progress on our long-term growth strategy. Our achievements give us confidence in the direction of and opportunities for Amarin during the remainder of 2022 and into 2023," said Karim Mikhail, president and chief executive officer of Amarin.

"In Europe, we are pleased with our progress in several major markets as we secured three favorable reimbursement decisions for VAZKEPA so far this year. We received our first reimbursement in Sweden, individual reimbursement in Denmark and announced final guidance for reimbursement by the National Institute for Health and Care Excellence (NICE) in England and Wales, our first positive decision in an EU5 country. These advances mark the transition to the next phase of our geographic expansion strategy. We also made important progress in a second major market, Spain, where we were able to accelerate into pricing discussions during the second quarter. In addition, we previously received a positive reimbursement assessment from Haute Autorité de Santé (HAS), the French National Authority for Health, and we continue to make progress on price negotiations in that market.

"Market and macroeconomic conditions remain difficult in Germany. That said, we continue to engage in price negotiations and have taken prudent steps to ensure our financial investments match the risk profile of the market. These actions include a suspension of our contracted primary care field force, and we remain committed to our presence in Germany pending the outcome of price negotiations with the payer.

"We remain on track to deliver on our commitment to obtain reimbursement status in up to eight European markets and launch in up to six key European markets this year and remain confident in our greater than \$1 billion revenue opportunity in Europe.

"In the U.S, while we are experiencing additional pressure from the first full quarter with a third generic entrant on the market and we are addressing these challenges with our cost reduction program, I am pleased that our second quarter revenue level was consistent with the first quarter of 2022. In June, we implemented our comprehensive cost savings plan,

with anticipated cost savings of \$100 million over the next 12 months to address the U.S. market dynamics. And internationally, we continue to advance filings and hold active partnership discussions in key territories.

“We remain steadfast in our conviction on the depth and breadth of our clinical data based on REDUCE-IT, the definitive, large, long-term outcomes study of icosapent ethyl with gold standard cardiovascular clinical endpoints. Further, we remain committed to maximizing the value of VASCEPA/VAZKEPA by maintaining our strong presence at future medical meetings and supporting potential publications, which will continue to highlight the strength of this data and impact for patients. 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 look forward, our progress in the quarter and the first half of 2022, as well as our conviction in our robust science and clinical data, gives us confidence that our long-term strategy will allow us to execute against a BOLD vision to stop heart disease from being the leading cause of death, worldwide,” concluded Mr. Mikhail.

Europe

- Achieved final reimbursement decision for VAZKEPA from the United Kingdom’s NICE for England and Wales.
- Launch activities are underway in Sweden, and England & Wales to drive formulary access and education in those markets.
- Initiated the fourth round of price negotiations in Germany, while we continue to receive temporary reimbursement for VAZKEPA. Based on the status of negotiations and current market conditions, we have suspended our contracted primary care field force.
- Clinical and Health Technology Assessment processes and reimbursement discussions are progressing across all of the targeted markets in Europe where Amarin has submitted market access dossiers, including Norway, Finland, France, Italy, Spain, Portugal, Austria, Switzerland, Israel and the Netherlands:
 - o Price negotiations have begun with Spain’s Ministry of Health, which could allow for a possible pricing and reimbursement decision before the end of 2022.
 - o As a reminder, we received a positive reimbursement assessment from HAS – the French National Authority for Health – and price negotiations continue to progress.
 - o New dossiers were submitted and accepted in Portugal, Austria and Switzerland and are now in pricing and reimbursement negotiations.

United States

U.S. product net revenue was \$90.6 million in the second quarter of 2022, a decline of \$2.8 million versus the first quarter of 2022. Importantly, the second quarter was the first full quarter where three generic entrants were in the market versus only one generic entrant in the prior year period.

U.S. commercial operations continue to maintain a strong core sales force to support branded VASCEPA sales targeting the top prescribers and continue to focus on secondary prevention. This business 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.

In the U.S., the company continues to focus on positive contribution margin to support the growth and expansion of VASCEPA/VAZKEPA globally.

International

Amarin continues to gain traction with its goal to unlock the potential of VASCEPA internationally. The company is in the process of filing regulatory submissions for approval of VASCEPA in 20 additional countries to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA. In addition, Amarin continues to make meaningful progress in these efforts with our partners.

- Amarin received acceptances of the regulatory reviews of VASCEPA market authorization submissions in Australia and New Zealand, with the filings advancing as per local protocols.
- In Canada, HLS Therapeutics, Inc. completed negotiations with Canada's pan-Canadian Pharmaceutical Alliance (pCPA) for the terms and conditions under which VASCEPA would qualify for public market reimbursement in Canada and has received approval from the provinces of Quebec, Ontario, New Brunswick and Northwest Territories, Saskatchewan, as well as the NIHB program for First Nations and Inuit peoples, expanding reimbursement of VASCEPA across the country.
- Biologix, Amarin's partner in the Middle East and North Africa (MENA), received the official registration certificate for VASCEPA from the Kingdom of Saudi Arabia (KSA) regulatory authority for the treatment of severe hypertriglyceridemia. This first approval in KSA enables the preparation and submission of a variation to seek review and approval for the CV risk reduction indication.
- Eddingpharm (Asia) Macao Commercial Offshore Limited (Edding), Amarin's partner in China, received approval for VASCEPA in Hong Kong and is planning for commercial launch by the end of the year. In addition, Edding continues to expect to receive approval for VASCEPA in Mainland China this year.

Financial Update

Total net revenue for the three months ended June 30, 2022 was \$94.4 million, compared to \$154.5 million in the corresponding period of 2021, a decrease of 39%. Net product revenue for the three months ended June 30, 2022 was \$93.8 million, compared to \$153.8 million in the corresponding period of 2021, a decrease of 39%. 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 June 30, 2022 there were three generic competitors in the U.S. market as compared to one generic competitor in the U.S. market during the three months ended June 30, 2021.

Amarin recognized licensing and royalty revenue of approximately \$0.6 million and \$0.7 million during the three months ended June 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 June 30, 2022 was \$50.8 million, compared to \$32.2 million in the corresponding period of 2021. Amarin's overall gross margin on net product revenue for the three months ended June 30, 2022 was 46%, compared with 79% for the corresponding period of 2021. During the three months ended June 30, 2022, Amarin has taken steps to amend supplier agreements to align supply arrangements with current and future market demand resulting in a charge of \$15.0 million and had a charge of \$9.6 million related to unsellable inventory not related to product dating. Excluding the impact of these two items, gross margin was 72% for the three months ended June 30, 2022.

Selling, general and administrative expenses for the three months ended June 30, 2022 was \$86.9 million, compared to \$107.2 million in the corresponding period of the prior year. This decrease was primarily due to a decrease in U.S. commercial costs and was partially offset by investments to support commercial operations in Europe.

Research and development expenses for the three months ended June 30, 2022 were \$9.4 million, compared to \$6.4 million in the corresponding period of the prior year. This increase was primarily driven by costs incurred related to the development of a fixed-dose combination of VASCEPA with a statin.

In June, the company implemented a comprehensive cost reduction plan in response to the market dynamics experienced in the U.S. with the third generic entrant launching in the first quarter of 2022. The Company will reduce its total operational expenditure by approximately \$100.0 million over 12 months* while continuing its investments in European expansion. The cost reduction plan included a significant workforce reduction across the Company's U.S. field force and corporate positions reductions and reallocations in overall selling, general and administrative (SG&A) expenses as well as savings related to refining the Company's R&D strategy to a more focused, stepwise approach for its FDC program. As a result of these cost savings efforts, the company incurred a total of \$25.2 million in restructuring charges during the second quarter 2022, \$10.2 million relating to restructuring charges and \$15.0 million relating to the steps taken to amend supplier agreements to align supply arrangements with current and future market demand.

Under U.S. GAAP, Amarin reported a net loss of \$70.0 million for the second quarter ended June 30, 2022, or basic and diluted loss per share of \$0.18. This net loss includes \$9.1 million in non-cash stock-based compensation and \$25.2 million in restructuring expenses. For the second quarter ended June 30, 2021, Amarin reported a net income of \$7.8 million, or basic and diluted earnings per share of \$0.02. This net income included \$2.5 million in non-cash stock-based compensation expense. Excluding non-cash stock-based compensation expense and restructuring expense, non-GAAP adjusted net loss was \$35.6 million for the second quarter ended June 30, 2022 or non-GAAP adjusted basic and diluted loss per share of \$0.09, compared with non-GAAP adjusted net income of \$10.3 million for the second quarter ended June 30, 2021, or non-GAAP adjusted basic and diluted earnings per share of \$0.03. As of June 30, 2022, Amarin reported aggregate cash and investments of \$324.6 million.

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

2022 Financial Outlook

Given the ongoing global impact of COVID-19, as well as the uncertainty resulting from the impact of generic IPE availability in the U.S. and challenges for most drugs seeking market access in Europe, Amarin will continue to suspend 2022 revenue guidance.

Amarin reiterates its belief that current cash and investments and other assets are adequate to support continued operations, including European launch activities for at least the next twelve months.

Conference Call and Webcast Information:

Amarin will host a conference call on August 3, 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 316813. 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 45865. 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 VAZKEPA.

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

	June 30, 2022	December 31, 2021
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 228,001	\$ 219,454
Restricted cash	3,918	3,918
Short-term investments	85,232	234,674
Accounts receivable, net	143,942	163,653
Inventory	225,772	234,676
Prepaid and other current assets	32,259	22,352
Total current assets	719,124	878,727
Property, plant and equipment, net	1,137	1,425
Long-term investments	11,395	34,996
Long-term inventory	210,252	121,254
Operating lease right-of-use asset	8,599	7,660
Other long-term assets	456	456
Intangible asset, net	22,274	23,547
TOTAL ASSETS	\$ 973,237	\$ 1,068,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 116,312	\$ 114,922
Accrued expenses and other current liabilities	243,064	253,111
Current deferred revenue	2,198	2,649
Total current liabilities	361,574	370,682
Long-Term Liabilities:		
Long-term deferred revenue	13,810	14,060
Long-term operating lease liability	10,174	8,576
Other long-term liabilities	7,636	7,648
Total liabilities	393,194	400,966
Stockholders' Equity:		
Common stock	294,659	294,027
Additional paid-in capital	1,869,770	1,855,246
Treasury stock	(61,419)	(60,726)
Accumulated deficit	(1,522,967)	(1,421,448)
Total stockholders' equity	580,043	667,099
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 973,237	\$ 1,068,065

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

	Three months ended June 30,		Six months ended June 30,	
	(in thousands, except per share amounts)		(in thousands, except per share amounts)	
	2022	2021	2022	2021
Product revenue, net	\$ 93,796	\$ 153,773	\$ 187,782	\$ 295,156
Licensing and royalty revenue	644	715	1,288	1,502
Total revenue, net	94,440	154,488	189,070	296,658
Less: Cost of goods sold	35,810	32,155	58,049	60,481
Less: Cost of goods sold - restructuring inventory	15,000	-	15,000	-
Gross margin	43,630	122,333	116,021	236,177
Operating expenses:				
Selling, general and administrative (1)	86,893	107,203	177,540	213,001
Research and development (1)	9,356	6,357	19,407	15,734
Restructuring	10,213	—	10,213	—
Total operating expenses	106,462	113,560	207,160	228,735
Operating (loss) income	(62,832)	8,773	(91,139)	7,442
Interest income, net	288	285	491	756
Other expense, net	(2,255)	(191)	(2,501)	(333)
(Loss) income from operations before taxes	(64,799)	8,867	(93,149)	7,865
Income tax provision	(5,157)	(1,059)	(8,370)	(1,683)
Net (loss) income	<u>\$ (69,956)</u>	<u>\$ 7,808</u>	<u>\$ (101,519)</u>	<u>\$ 6,182</u>
(Loss) earnings per share:				
Basic	\$ (0.18)	\$ 0.02	\$ (0.26)	\$ 0.02
Diluted	\$ (0.18)	\$ 0.02	\$ (0.26)	\$ 0.02
Weighted average shares:				
Basic	398,187	395,899	397,997	395,272
Diluted	398,187	401,767	397,997	402,778

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$79,244 and \$104,550 for the three months ended June 30, 2022 and 2021, respectively, and research and development expenses were \$7,905 and \$6,531, respectively, for the same periods.

RECONCILIATION OF NON-GAAP NET (LOSS) INCOME
Unaudited

	Three months ended June 30, (in thousands, except per share amounts)		Six months ended June 30, (in thousands, except per share amounts)	
	2022	2021	2022	2021
Net (loss) income for EPS ¹ - GAAP	(69,956)	7,808	(101,519)	6,182
Non-cash stock-based compensation expense	9,100	2,479	15,178	16,403
Restructuring inventory	15,000	—	15,000	—
Restructuring expense	10,213	—	10,213	—
Adjusted net (loss) income for EPS ¹ - non-GAAP	\$ (35,643)	\$ 10,287	\$ (61,128)	\$ 22,585
¹ basic and diluted				
(Loss) earnings per share:				
Basic - non-GAAP	\$ (0.09)	\$ 0.03	\$ (0.15)	\$ 0.06
Diluted - non-GAAP	\$ (0.09)	\$ 0.03	\$ (0.15)	\$ 0.06
Weighted average shares:				
Basic	398,187	395,899	397,997	395,272
Diluted	398,187	401,767	397,997	402,778

