

# AMARIN CORP PLC\UK

## **FORM 8-K** (Current report filing)

Filed 08/02/17 for the Period Ending 08/02/17

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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 2, 2017**

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**Amarin Corporation plc**

(Exact name of registrant as specified in its charter)

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England and Wales  
(State or other jurisdiction  
of incorporation)

0-21392  
(Commission  
File Number)

Not applicable  
(I.R.S. Employer  
Identification No.)

2 Pembroke House, Upper Pembroke Street 28-32,  
Dublin 2, Ireland  
(Address of principal executive offices)

Not applicable  
(Zip Code)

Registrant's telephone number, including area code: +353 1 6699 020

Not Applicable  
Former name or former address, if changed since last report

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02. Results of Operations and Financial Condition.**

On August 2, 2017, Amarin Corporation plc issued a press release announcing its financial results for the three and six months ended June 30, 2017 (the “Press Release”). A copy of the Press Release is furnished herewith as Exhibit 99.1.

*The information in this report furnished pursuant to Item 2.02 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.*

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 2, 2017

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**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 2, 2017

Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer

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## Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated August 2, 2017



**Amarin Reports Second Quarter 2017 Financial Results  
and Provides Update on Operations**

*Record-High Net Product Revenue of \$44.9 Million in Second Quarter*

*Increasing Guidance on Full Year Net Product Revenue to \$165-175 Million*

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

BEDMINSTER, N.J., and DUBLIN, Ireland, August 2, 2017 -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced financial results for the three and six months ended June 30, 2017, and provided an update on company operations.

Key Amarin achievements since March 31, 2017 include:

- **Product revenue growth**: Recognized \$44.9 million in U.S. net product revenue from Vascepa® (icosapent ethyl) sales in Q2 2017 compared to \$32.8 million in Q2 2016, an increase of 37%.
- **U.S. prescription growth**: Increased normalized prescriptions for Vascepa by 50% and 52% compared to Q2 2016 based on data from Symphony Health Solutions and IMS Health, respectively.
- **R&D progress**: Landmark long-term cardiovascular outcomes study, REDUCE-IT, nearing completion with results expected to be reported in Q2 or Q3 of 2018.
- **Cash flow**: Net cash flow was modestly positive from operations during three and six months ended June 30, 2017, excluding cash flow related to R&D and finance (i.e., excluding cash inflows/outflows from debt-related transactions reported in Q1 2017, interest and royalty).
- **Cash balance**: As of June 30, 2017, Amarin had a cash balance of \$85.5 million.

“We believe evidence continues to mount supporting the potential success of the REDUCE-IT cardiovascular outcomes study and that Amarin is at the forefront of what could become a new era in preventative cardiovascular care. We have also seen increased interest in addressing residual cardiovascular risk beyond controlling LDL-cholesterol, and a greater focus on finding treatments that can help address this risk,” stated John F. Thero, president and chief executive officer. “This is an exciting time for Amarin both with respect to growing current revenues and contemplation of the broader positive effect that Vascepa could have on improving patient care if REDUCE-IT study results, expected approximately a year from now, are consistent with expectations. We will continue to focus on positive execution.”

Dr. Craig Granowitz, chief medical officer, noted, “Recent studies of add-ons to statin therapy illuminate the need to address the significant residual cardiovascular risk beyond managing LDL-cholesterol.” Dr. Granowitz continued, “While multiple new therapies are in development to address the various medical needs of patients at-risk for cardiovascular disease, if REDUCE-IT is successful in its studied population, we see several practical advantages favoring increased Vascepa use following successful outcomes study results. Vascepa already has years of post-approval market experience that support its favorable safety and tolerability profile. It also has a convenient oral dosage form, an affordable price and broad managed care coverage. These attributes position Vascepa well to help more patients and potentially become a standard of care therapy following positive REDUCE-IT results.”

***Substantial commercial growth continues***

Our commercial team again drove new and recurring Vascepa prescription growth in the second quarter of 2017. This growth, which was aided by expanded managed care coverage at the start of 2017, reflects further productivity improvement from our U.S. sales team, the size of which has remained consistent since the end of 2013.

Estimated normalized total Vascepa prescriptions, based on data from Symphony Health Solutions and IMS Health, totaled approximately 344,000 and 372,000, respectively, for the three months ended June 30, 2017. These prescription levels represent growth of approximately 50% and 52%, respectively, from prior year levels.

### ***REDUCE-IT trial status***

The REDUCE-IT cardiovascular outcomes trial continues to progress towards reported results in Q2 or Q3 of 2018, assuming the trial is not stopped early. Based on historical event rates, Amarin anticipates the study reaching in early 2018 the onset of 100% of the targeted cumulative total of 1,612 primary major adverse cardiovascular events (MACE). Reaching this events target will be followed by final patient visits to clinical sites, accumulation of final data, including on any primary or other categories of MACE that have been documented and adjudicated, and final efficacy and safety data review by the independent review committees and the REDUCE-IT operational team. After Amarin is unblinded and learns the results of the study, the results will be publicly communicated. Amarin believes that the results of this landmark trial, if successful, could lead to improved preventative medical care for tens of millions of patients and could contribute to significantly lower costs for treating these patients.

REDUCE-IT is the first prospectively conducted, multi-national, double-blinded study to evaluate the effects of treating patients who despite well-controlled LDL-cholesterol have high triglycerides and other risk factors associated with cardiovascular disease. This 8,175-patient study, which commenced in late 2011, has accumulated over 30,000 years of study of treated patients. Amarin seeks to determine whether the potentially broad clinical effects of an intentionally high daily dose (4 grams per day) of Vascepa translate into fewer cardiovascular events for at-risk patients. If successful in demonstrating positive cardiovascular outcomes results, Amarin believes that Vascepa is well-positioned to be prescribed for treatment of at-risk patients due to the efficacy, tolerability, ease of administration and affordable price of Vascepa.

Later in the current quarter (Q3 2017), Amarin anticipates receiving the recommendation of the independent data monitoring committee (DMC) regarding its pre-scheduled interim efficacy and safety analysis. In this analysis, the DMC will review data available from the preparations triggered by the onset of approximately 80% of targeted primary MACE. As is typical in cardiovascular outcomes studies, Amarin expects the DMC to recommend that this important study should continue to completion which, as planned, is expected to provide a more robust result based on the larger number of MACE at the end of the trial. The thresholds for early trial stoppage due to overwhelming efficacy are intentionally high with respect to both quantitative and qualitative measures. Amarin is operating with the expectation that the trial will continue to completion.

Amarin will remain blinded to the interim and ongoing results of the REDUCE-IT study as well as to any interim p-values and other statistical information until after the study is ready to be stopped and the database is locked, either at the interim analysis or at the final analysis.

### ***Financial update***

Net product revenue for the three months ended June 30, 2017 and 2016 was \$44.9 million and \$32.8 million, respectively. Net product revenue for the six months ended June 30, 2017 and 2016 was \$79.3 million and \$58.1 million, respectively. As reported in conjunction with results from Q2 2016, an increase in wholesaler inventory levels, calculated on a days-on-hand basis, resulted in a net overall increase in product revenues of approximately \$2.9 million to \$3.2 million. During Q2 2017, wholesaler inventory levels decreased modestly calculated on the same basis. On a pro forma basis, adjusting for the impact of the change in wholesaler inventory levels, net product revenue growth in Q2 2017 as compared to Q2 2016 would have been consistent with reported total prescription (TRx) growth. At the end of Q2 2017, inventory levels at these independent wholesalers are believed to be within a normal range for the industry.

Based on year-to-date results and anticipated trends, Amarin is increasing its guidance estimate for total 2017 net product revenue to \$165.0 million to \$175.0 million. Amarin expects continued TRx growth to drive increased full-year 2017 revenue despite the potential impact of periodic fluctuations in wholesaler inventory levels.

Licensing revenue, which relates to agreements for the commercialization of Vascepa outside the United States, during the six months ended June 30, 2017 and 2016 was \$0.6 million and \$0.5 million, respectively. The amount of licensing revenue recorded may be variable from period to period based on changes in estimates of the timing and level of support required.

Our gross margin on product sales for the three and six months ended June 30, 2017 and 2016 was 75% and 73%, respectively. This improvement was primarily driven by lower unit cost API purchases.

Selling, general and administrative expense for the six months ended June 30, 2017 and 2016 was \$65.7 million and \$54.1 million, respectively, an increase of \$11.6 million, or 22%. The increase is due primarily to increased co-promotion fees resulting from increased sales, increased promotional activities and increased legal costs, which are subject to quarterly variability.

Research and development expense for the six months ended June 30, 2017 and 2016 was \$24.5 million and \$26.3 million, respectively, a decrease of \$1.8 million, or 7%. The decrease in research and development expenses for the six months ended June 30, 2017, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

Under GAAP, Amarin reported a net loss of \$13.6 million in the three months ended June 30, 2017, or basic and diluted loss per share of \$0.05. This net loss included \$3.6 million in non-cash stock-based compensation expense. Amarin reported a net loss of \$13.4 million in the three months ended June 30, 2016, or basic and diluted loss per share of \$0.07. This net loss included \$3.4 million in non-cash stock-based compensation expense and a \$5.8 million non-cash gain on the change in fair value of derivatives.

Under GAAP, Amarin reported a net loss of \$34.6 million in the six months ended June 30, 2017, or basic and diluted loss per share of \$0.13. This net loss included \$7.0 million in non-cash stock-based compensation expense. For the six months ended June 30, 2016, Amarin reported a net loss of \$43.1 million, or basic and diluted loss per share of \$0.23. This net loss included \$7.0 million in non-cash stock-based compensation expense and a \$4.6 million non-cash gain on the change in fair value of derivatives.

Amarin reported cash and cash equivalents of \$85.5 million at June 30, 2017. Net cash flow from operations, excluding debt restructuring, interest and royalties, and R&D costs, in the three and six months ended June 30, 2017 was modestly positive. On this basis, the company anticipates that net cash flow for 2017 will be positive; however, the company expects continued variability due to the timing of certain items, including purchases of API. For the six months ended June 30, 2017, cash outflows relating to research and development were approximately \$20.8 million and cash paid for interest and royalties, in aggregate, was approximately \$7.5 million.

As of June 30, 2017, the company had \$37.5 million in net accounts receivable (\$48.4 million in gross accounts receivable before allowances and reserves), which are current and \$24.8 million in inventory. As of June 30, 2017, the company had accounts payable and accrued expenses of \$65.6 million which increased from \$43.8 million at December 31, 2016 primarily due to the timing of rebate and certain supplier payments.

As of June 30, 2017, Amarin had approximately 270.8 million American Depository Shares (ADSs) and ordinary shares outstanding, 32.8 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 23.7 million equivalent shares underlying stock options at a weighted-average exercise price of \$3.25, as well as 12.1 million equivalent shares underlying restricted or deferred stock units.

#### **Conference call and webcast information**

Amarin will host a conference call at 8:00 a.m. ET today, August 2, 2017. The call will be webcast live with slides and accessible through the investor relations section of the company's website at [www.amarincorp.com](http://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 (inside the United States) or 919-882-2331 (outside the United States). A replay of the call will also be available through the company's website shortly after the call. For both dial-in numbers please use PIN: 16156.

#### **About Amarin**

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to an ongoing outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA approved product, is a highly-pure, omega-3 fatty acid product available by prescription. 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. For more information about Vascepa visit [www.vascepa.com](http://www.vascepa.com). For more information about Amarin visit [www.amarincorp.com](http://www.amarincorp.com).

#### **About Vascepa® (icosapent ethyl) capsules**

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa is known in scientific literature as AMR101.

#### FDA-Approved Indication and Usage

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

### Important Safety Information for Vascepa

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

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. 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.

### **Forward-looking statements**

This press release contains forward-looking statements, including expectations regarding revenue growth, spending levels and cash flow as well as REDUCE-IT related expectations for continued event rates, interim data review, results and related timing and announcements; expectations related to the final outcomes of the REDUCE-IT study and the anticipated successful completion of the REDUCE-IT study; and statements regarding the potential and therapeutic benefits of Vascepa. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively develop and commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve increased market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that historical REDUCE-IT event rates may not be predictive of future results and related cost may increase beyond expectations; the risk that regulatory reviews may alter current expectations related thereto; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be upheld in patent litigation. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

### **Availability of other information about Amarin**

Investors and others should note that we communicate with our investors and the public using our company website ([www.amarincorp.com](http://www.amarincorp.com)), our investor relations website (<http://investor.amarincorp.com>), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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

	June 30, 2017	December 31, 2016
	(in thousands)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 85,464	\$ 98,251
Restricted cash	600	600
Accounts receivable, net	37,475	19,985
Inventory	24,814	20,507
Prepaid and other current assets	2,076	6,983
Total current assets	<u>150,429</u>	<u>146,326</u>
Property, plant and equipment, net	52	78
Deferred tax assets	11,082	11,082
Other long-term assets	173	741
Intangible asset, net	8,449	8,772
<b>TOTAL ASSETS</b>	<u><u>\$ 170,185</u></u>	<u><u>\$ 166,999</u></u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 16,455	\$ 6,062
Accrued expenses and other current liabilities	49,102	37,720
Current portion of exchangeable senior notes, net of discount	455	15,351
Current portion of long-term debt from royalty-bearing instrument	18,833	15,944
Deferred revenue, current	1,447	1,172
Total current liabilities	<u>86,292</u>	<u>76,249</u>
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	28,884	—
Long-term debt from royalty-bearing instrument	79,283	85,155
Deferred revenue, long-term	13,332	13,943
Other long-term liabilities	1,158	710
Total liabilities	<u>208,949</u>	<u>176,057</u>
Stockholders' Deficit:		
Preferred Stock	24,364	24,364
Common stock	208,556	207,166
Additional paid-in capital	970,797	964,914
Treasury stock	(3,902)	(1,498)
Accumulated deficit	(1,238,579)	(1,204,004)
Total stockholders' deficit	<u>(38,764)</u>	<u>(9,058)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<u><u>\$ 170,185</u></u>	<u><u>\$ 166,999</u></u>

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

	Three months ended June 30, (in thousands, except per share amounts)		Six months ended June 30, (in thousands, except per share amounts)	
	2017	2016	2017	2016
Product revenue, net	\$ 44,948	\$ 32,815	\$ 79,292	\$ 58,122
Licensing revenue	293	296	586	532
Total revenue, net	45,241	33,111	79,878	58,654
Less: Cost of goods sold	11,401	8,861	19,599	15,757
Gross margin	33,840	24,250	60,279	42,897
Operating expenses:				
Selling, general and administrative (1)	31,545	26,066	65,716	54,086
Research and development (1)	13,694	12,578	24,517	26,308
Total operating expenses	45,239	38,644	90,233	80,394
Operating loss	(11,399)	(14,394)	(29,954)	(37,497)
Gain on change in fair value of derivative liabilities (2)	—	5,810	—	4,560
Interest expense, net	(2,315)	(5,616)	(4,696)	(11,202)
Other income (expense), net	80	(182)	75	(303)
Loss from operations before taxes	(13,634)	(14,382)	(34,575)	(44,442)
Benefit from income taxes	—	1,028	—	1,317
Net loss	\$ (13,634)	\$ (13,354)	\$ (34,575)	\$ (43,125)
Loss per share:				
Basic	\$ (0.05)	\$ (0.07)	\$ (0.13)	\$ (0.23)
Diluted	\$ (0.05)	\$ (0.07)	\$ (0.13)	\$ (0.23)
Weighted average shares:				
Basic	270,725	184,471	270,445	184,262
Diluted	270,725	184,471	270,445	184,262

- (1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$28,478 and \$23,173 for the three months ended June 30, 2017 and 2016, respectively, and research and development expenses were \$13,136 and \$12,106, respectively, for the same periods. Excluding non-cash stock-based compensation as well as co-promotion fees paid to our U.S. co-promotion partner, selling, general and administrative expenses were \$23,909 and \$18,622 for the three months ended June 30, 2017 and 2016, respectively.
- (2) Non-cash gains and losses result from changes in the fair value of long-term debt derivative liabilities.

**Amarin contact information:**

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