



First Quarter 2018 Financial and Operational Results
Slides to Accompany Investor Conference Call

August 1, 2018

NASDAQ: AMRN



# Forward-Looking Statements and Disclaimer



#### Forward-looking statements

This presentation contains forward-looking statements, such as those relating to the commercial potential of Vascepa®, Amarin's product development, clinical and regulatory efforts and timelines, potential FDA approvals, intellectual property, cash flow, and other statements that are predictive in nature and that depend upon or refer to future events or conditions, including financial guidance and milestones. These statements involve known and unknown risks, uncertainties and other factors that can cause actual results to differ materially. Investors should not place undue reliance on forward-looking statements, which speak only as of the presentation date of this presentation. Please refer to the "Risk Factors" section in Amarin's most recent Annual Report on Form 10-K and the Quarterly Report on Form 10-Q filed with the SEC for a more complete description of risks of an investment in Amarin.

#### <u>Presentation is for investors (not drug promotion)</u>

This presentation is intended for communication with investors only.

Nothing in this presentation should be construed as promoting the use of Amarin's product or product candidates.

## REDUCE-IT Top Line Results Expected By End of September



# **Timing Guidance Unchanged**

- Top line results anticipated by end of September
- Publication and presentation at scientific congress targeted for Q4 2018 followed by sNDA

#### **Status**

- Final patient visits completed
- >99.5% of final vital status data confirmed
- Open data queries diminishing; goal to complete data cleaning before or near end of August
- Adjudication of MACE events in late stages of completion, including focus on adjudication of events which could not be done until after final patient visits

# Currently Blinded to Results to Protect Data Integrity

• Until the database is locked, everyone (including Amarin) is blinded to the study results

## **Preparing for Success**

- Potential for Vascepa to provide preventative cardiovascular care for millions of patients if REDUCE-IT results are positive
- Increasing inventory levels, preparing to hire expanded sales force and expand promotion

## Q2 2018 Financial Highlights



#### **U.S. Commercial Results**

- Net product revenue of \$52.5 million in Q2 2018, an increase of 17% over Q2 2017
- Record prescription levels in Q2 2018
- Record total Vascepa® prescriptions of 430,000 in Q2 2018 per Symphony Health Solutions

#### International

Regulatory approval for Vascepa received in the United Arab Emirates

#### Collaboration

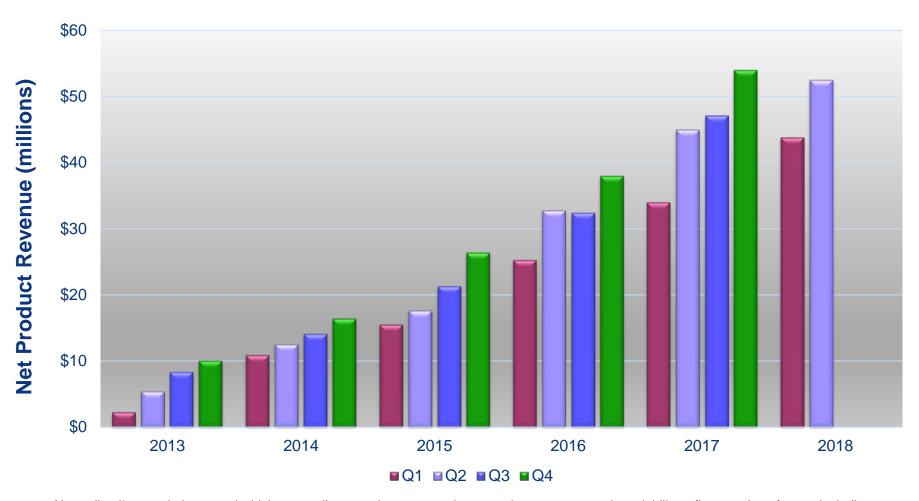
 Entered strategic collaboration with Mochida Pharmaceutical Co., Ltd. to advance early stage development opportunities

#### Cash Position and Cash Flow

Ended quarter with \$102.3 million cash and cash equivalents

## Vascepa Quarterly Net Product Revenue History

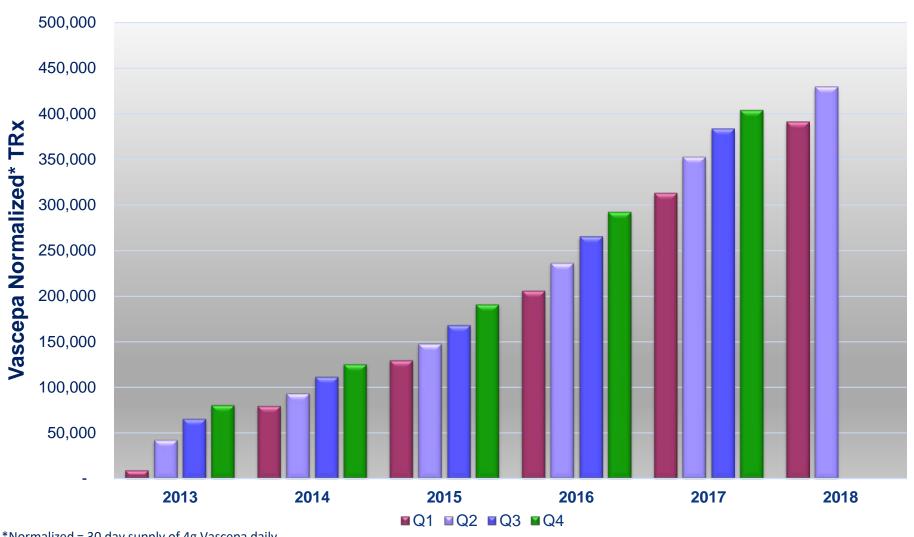




- Normalized\* prescription growth driving overall net product revenue increase, however, quarterly variability reflects various factors including changes in inventory levels maintained by independent wholesalers
- Seasonal factors, particularly in Q1 of each year, impact prescription levels; year over year comparisons may be most representative
- \* Normalized = 30 day supply of 4g Vascepa daily

# Vascepa Quarterly TRx History



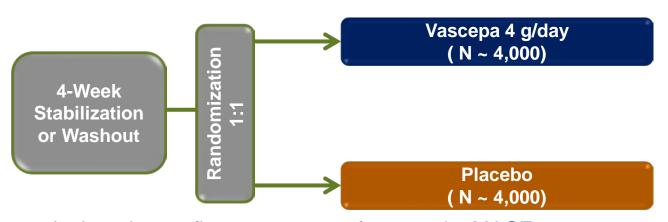


<sup>\*</sup>Normalized = 30 day supply of 4g Vascepa daily

# REDUCE-IT: Blinded Events Based Outcomes Assessment of CV Risk Reduction vs. Placebo



#### 8,175 Patients (enrollment complete)



#### Primary endpoint - time to first occurrence of composite MACE

- MACE (major adverse cardiovascular events): CV death; non-fatal MI; non-fatal stroke; coronary revascularization; and hospitalization for unstable angina (caused by myocardial ischemia, determined by invasive or non-invasive testing)
- All events adjudicated by independent, blinded, Clinical Endpoint Committee
- >30 pre-specified secondary and tertiary endpoints

#### Designed under Special Protocol Assessment (SPA) agreement

#### Study designed for 90% power to detect 15% relative risk reduction

- Assumes 1,612 primary endpoint events across a 4-5 year median patient follow-up period
- As with other long-term outcomes trials, actual study power may be higher or lower driven by typical factors such as the relative risk reduction observed between the treatment groups, the number of events observed at study completion and the aggregate time over which patients are studied

# Data Supporting Potential for Vascepa Outcomes Benefit Goes Well Beyond TG Lowering and Prior Phase 3 Trial Successes



#### **TG Lowering Data Examples**

Lower TG levels correlated with lower CHD risk when LDL-C is well controlled

 PROVE-IT (Lipitor/Pravachol): Analysis of all patients well controlled for LDL (<70 mg/dL) in which patients with TG</li>
 <200 mg/dL were associated with 40% lower risk of recurrent CHD events vs. TG> 200 mg/dL

Subset of patients in clinical outcomes studies evaluating therapies that lower TG levels showed benefit in subset populations with baseline elevated TG, despite failed trials

- ACCORD (fenofibrate): Subgroup TG>204 mg/dL and HDL-C <34 mg/dL; MACE relative risk reduction 31%</li>
- AIM-HIGH (Niacin ER); Subgroup TG>200 mg/dL and HDL-C <32 mg/dL; MACE relative risk reduction 36%</li>

Multiple recent large genetic studies suggest TG and LDL-C levels are similar predictors of CHD

As summarized in recent reviews (e.g. Noordestgaard<sup>3</sup>)

#### **Benefits Beyond TG Lowering Examples**

Mechanistic effects of EPA have shown broad favorable effects on atherosclerotic processes<sup>1</sup>

- Endothelial function
- Plaque formation/progression
- Oxidative stress
- Platelet aggregation
- Foam cell formation
- Thrombus formation
- Inflammation/cytokines
- Plaque rupture

#### Supporting data examples:

- Inflammation: CANTOS study established inflammation as independent marker of CV risk; EPA lowered hsCRP in ANCHOR and MARINE
- Plaque: CHERRY study showed EPA added to high dose statin doubled incidence of plaque regression vs. high dose statin therapy alone
  - U.S. plaque study, EVAPORATE, is ongoing<sup>4</sup>

#### Protective effect of EPA shown post PCI

 Nosaka et al. showed early EPA + statin post PCI resulted in 11% reduction in CV events vs. statin alone; CV death reduced 3.4%<sup>2</sup>

#### Hybrid Example of Broad Favorable Effects of EPA from JELIS (large Japanese outcomes study)

Overall population without high TG levels:

- 19% reduction in CV events (p =0.011); little change in TG levels
- Subgroup TG >150 mg/dL and HDL-C <40 mg/dL:</p>
- 53% reduction in CV events (p=0.043)

<sup>1</sup>Borow KM et al. Atherosclerosis. 2015;242(1). <sup>2</sup>Absolute risk reduction at 1 year (9.2% vs 20.2%); absolute reduction in CV related deaths was 3.4%. Nosaka K et al. Int'l Journal Cardiology. 228 (2017); 173-179.

<sup>3</sup>Nordestgaard, BG. AHA. Triglyceride-Rich Lipoproteins and Atherosclerotic Cardiovascular Disease: New Insights From Epidemiology, Genetics, and Biology. 2016. <sup>4</sup>Budoff M, Effect of Vascepa (icosapent ethyl) on progression of coronary atherosclerosis in patients with elevated triglycerides (200–499 mg/dL) on statin therapy: Rationale and design of the EVAPORATE study. Clin Cardiol. 2018;1−7. https://doi.org/10.1002/clc.22856

## REDUCE-IT and JELIS Study Design Differences



### "Enriched" patient population in REDUCE-IT

- REDUCE-IT: all patients have elevated TGs and other CV risk factors despite statin therapy
  - Mean and median baseline TGs >200 mg/dL and ~1/2 of patients expected to also have low HDL-C
  - Fewer CV events likely classified as unstable angina in REDUCE-IT due to higher risk patient population. Also, advances in medicine better separate patients with unstable angina, a more subjective endpoint, from patients with myocardial infarction, a hard MACE endpoint
- JELIS: many patients had normal TG levels and a 19% risk reduction was achieved
  - Published subgroup with 53% risk reduction population had TG ≥150 mg/dL and low HDL-C

#### Higher treatment dose in REDUCE-IT

- REDUCE-IT 4 grams/day of ethyl-EPA (Vascepa); JELIS 1.8 grams/day of ethyl-EPA
- In 12-week Phase 3 ANCHOR study, 4 grams/day of Vascepa increased EPA in the plasma to approximately the same level as achieved with 1.8 grams/day of ethyl-EPA in JELIS
  - Difference likely due to high fish diet in Japan
  - EPA levels in REDUCE-IT control likely lower than JELIS due to dietary differences outside Japan
- Statin therapy targeted to US guidelines in REDUCE-IT, lower statin dose given in JELIS

### REDUCE-IT is a global study

- REDUCE-IT: enrollment in 11 countries including strong participation in the United States; randomized double-blinded study
- JELIS: Japan only, mostly women; open label, randomized with blinded endpoint analysis

## **REDUCE-IT: Recap of Positioning**





No previous CV outcomes trial was designed specifically to prospectively enroll patients who, despite statin therapy, have both persistent elevated TGs and other CV risk factors



REDUCE-IT is the first CV outcomes trial to test pure EPA VASCEPA 4 g/day in a high-risk statin-treated population<sup>1,2</sup>



Elevated TG levels correlate with CV risk<sup>3,4</sup>



EPA pleiotropic effects beyond improving lipid levels<sup>5</sup>

<sup>1.</sup> ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT01492361?term=Amarin+and+REDUCE-IT&rank=1. Updated March 4, 2016. Accessed April 4, 2016; 2. Amarin Pharma, Inc. http://www.amarincorp.com/products.html. Updated March 7, 2016. Accessed April 4, 2016. 3. Sarwar N et al. *Circulation*. 2007;115(4):450-458; 4. Miller M et al. *J Am Coll Cardiol*. 2008;51(7):724-730; 5. Borow KM et al. *Atherosclerosis*. 2015;242(1):357-366

## Capitalization Summary (Millions)

As of June 30, 2018 (unaudited)



	As of 6/30/2018	
Cash	\$102.3 <sup>1</sup>	
Debt Obligations <sup>2</sup>		
EXCHANGEABLE SENIOR NOTES <sup>3</sup>	\$30.0	First put date Jan. 2022
ROYALTY-BEARING INSTRUMENT	\$99.4	10% of revenues until fully paid; no maturity date; no compounding of interest
Common Stock and Equivalent Shares		
COMMON/PREFERRED SHARES <sup>4</sup>	329.2	Preferred shares mirror common but non-voting
OPTIONS AND RESTRICTED STOCK	37.5	
TOTAL IF ALL EXERCISED	366.7	
Tax Jurisdiction (primary)	Ireland	Loss carryforwards of ~\$700 million

<sup>&</sup>lt;sup>1</sup> Net quarterly cash burn in 2018 of \$26.8 million and \$14.6 million in Q2 and Q1, respectively, excluding net proceeds from equity offering completed in Q1 2018. Net cash flow was positive in the first half of 2018 excluding cash flow from financing activities and from R&D and REDUCE-IT related commercial preparation activities

<sup>&</sup>lt;sup>2</sup> Represents face value of debt balance remaining to be paid in cash; a lower carrying value is reported for accounting purposes in accordance with U.S. GAAP

<sup>&</sup>lt;sup>3</sup>\$30 million of 3.5% exchangeable senior notes due 2047; exchange price \$3.89/sh., adjusted under certain circumstances

<sup>&</sup>lt;sup>4</sup> Includes 32.8 million common share equivalents issuable upon conversion of preferred shares

# Consolidated Balance Sheet (unaudited)



	June	30, 2018	December 31, 2017		
		(in thou	ısands)		
ASSETS					
Current Assets:					
Cash and cash equivalents	\$	102,257	\$	73,637	
Restricted cash		600		600	
Accounts receivable, net		50,309		45,318	
Inventory, net		40,093		30,260	
Prepaid and other current assets		2,878		3,455	
Total current assets		196,137		153,270	
Property, plant and equipment, net		17		28	
Other long-term assets		174		174	
Intangible asset, net		7,803		8,126	
TOTAL ASSETS	\$	204,131	\$	161,598	
LIABILITIES AND STOCKHOLDERS' DEFICIT					
Current Liabilities:					
Accounts payable	\$	34,471	\$	25,155	
Accrued expenses and other current liabilities		73,753		58,902	
Current portion of exchangeable senior notes, net of discount		481		481	
Current portion of long-term debt from royalty-bearing instrument		27,876		22,348	
Deferred revenue, current		1,056		1,644	
Total current liabilities		137,637		108,530	
				·	
Long-Term Liabilities:					
Exchangeable senior notes, net of discount		29,103		28,992	
Long-term debt from royalty-bearing instrument		59,564		70,834	
Deferred revenue, long-term		17,750		17,192	
Other long-term liabilities		6,764		1,150	
Total liabilities		250,818		226,698	
				<u> </u>	
Stockholders' Deficit:					
Preferred stock		24,364		24,364	
Common stock		225,507		208,768	
Additional paid-in capital		1,040,743		977,866	
Treasury stock		(6,909)		(4,229)	
Accumulated deficit		(1,330,392)		(1,271,869)	
Total stockholders' deficit		(46,687)		(65,100)	
		(2,22.)		(-2,200)	
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$	204,131	\$	161,598	

## Consolidated Statements of Operations (unaudited)



	Three months ended June 30, (in thousands, except per share amounts)				Six months ended June 30, (in thousands, except per share amounts)			
	2018		2017		2018		2017	
Product revenue, net	\$	52,537	\$	44,948	\$	96,313	\$	79,292
Licensing revenue		106		293		248		586
Total revenue, net		52,643		45,241		96,561		79,878
Less: Cost of goods sold		12,846		11,401		23,494		19,599
Gross margin		39,797		33,840		73,067		60,279
Operating expenses:								
Selling, general and administrative (1)		53,944		31,545		97,350		65,716
Research and development (1)		18,159		13,694		29,921		24,517
Total operating expenses		72,103		45,239		127,271		90,233
Operating loss		(32,306)		(11,399)		(54,204)		(29,954)
Interest expense, net		(1,773)		(2,315)		(4,025)		(4,696)
Other (expense) income, net		(131)		80		(76)		75
Loss from operations before taxes		(34,210)		(13,634)		(58,305)		(34,575)
(Provision for) benefit from income taxes		<u> </u>		<u> </u>				
Net loss	\$	(34,210)	\$	(13,634)	\$	(58,305)	\$	(34,575)
Loss per share:								
Basic	\$	(0.12)	\$	(0.05)	\$	(0.20)	\$	(0.13)
Diluted	\$	(0.12)	\$	(0.05)	\$	(0.20)	\$	(0.13)
Weighted average shares:								
Basic		293,662		270,725		289,458		270,445
Diluted		293,662		270,725		289,458		270,445

<sup>(1)</sup> Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$50,878 and \$28,478 for the three months ended June 30, 2018 and 2017, respectively, and research and development expenses were \$17,607 and \$13,136, respectively, for the same periods. Excluding non-cash stock-based compensation as well as co-promotion fees paid to the company's U.S. co-promotion partner, selling, general and administrative expenses were \$40,594 and \$23,909 for the three months ended June 30, 2018 and 2017, respectively.