



Leading a New Paradigm in  
Preventative Cardiovascular Care

Jefferies Virtual Healthcare Conference

June 2, 2021



**Vascepa**<sup>®</sup>  
*(icosapent ethyl)*

## Forward-looking statements

This presentation contains forward-looking statements, such as those relating to the commercial potential of VASCEPA® (VAZKEPA in Europe), clinical and regulatory efforts and timelines, potential regulatory and pricing approvals, patent litigation, generic product launch, intellectual property, cash flow, research and development, and other statements that are forward-looking in nature and 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 Forms 10-K and 10-Q filed with the SEC and cautionary statements outlined in recent press releases for more complete descriptions of risks in an investment in Amarin.

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# Problem: Cardiovascular Disease (CVD) Is an Enormous and Worsening Public Health Burden



## US CV disease burden



**1 stroke, heart attack or death from CVD**  
every 13 seconds in the US



**\$555bn**  
annual treatment cost  
expected to double in 20  
years



**38M**  
patients on statins

## EU CV disease burden



**~83.5M with CVD**  
in ESC member countries



**€210bn**  
annual spending on CV  
disease management



**44M**  
patients on statins

## ROW CV disease burden



**486M**  
living with CVD globally



**>\$1.0tn**  
estimated economic  
burden by 2030



**China alone**  
52M people have CVD and  
high TG with broad and  
growing statin use



**Leading cause of  
death globally**



**Increasing prevalence**



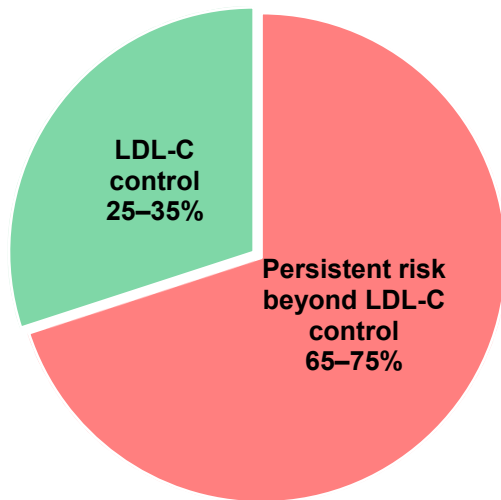
**High and increasing  
economic burden**

Sources: [http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm\\_491543.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491543.pdf); Centers for Disease Control and Prevention, <https://www.cdc.gov/nchs/fastats/leadingcauses-of-death> AHA: Cardiovascular Disease: A Costly Burden for America — Projections through 2035.htm, January, 20, 2017; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation. 2020; 141:e1–e458; European Society of Cardiology: Cardiovascular Disease Statistics 2017, European Heart Journal, Volume 39, Issue 7, 14 February 2018, Pages 508–579; European Heart Network Report, 2017; World Health Organization, <https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-cvds>; 2020 AHA Fact Sheet, <https://www.heart.org/-/media/files/about-us/statistics/2020-heart-disease--stroke-statistical-update-fact-sheet-ucm505489.pdf>; WEF-Harvard Global Economic Burden, [http://www3.weforum.org/docs/WEF\\_Harvard\\_HE\\_GlobalEconomicBurdenNonCommunicableDiseases\\_2011.pdf](http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf); Chinese Circulation Journal, July, 2019, Vol 34 Number 7 (Series Number 253); IMS China database 2014–2018Q3

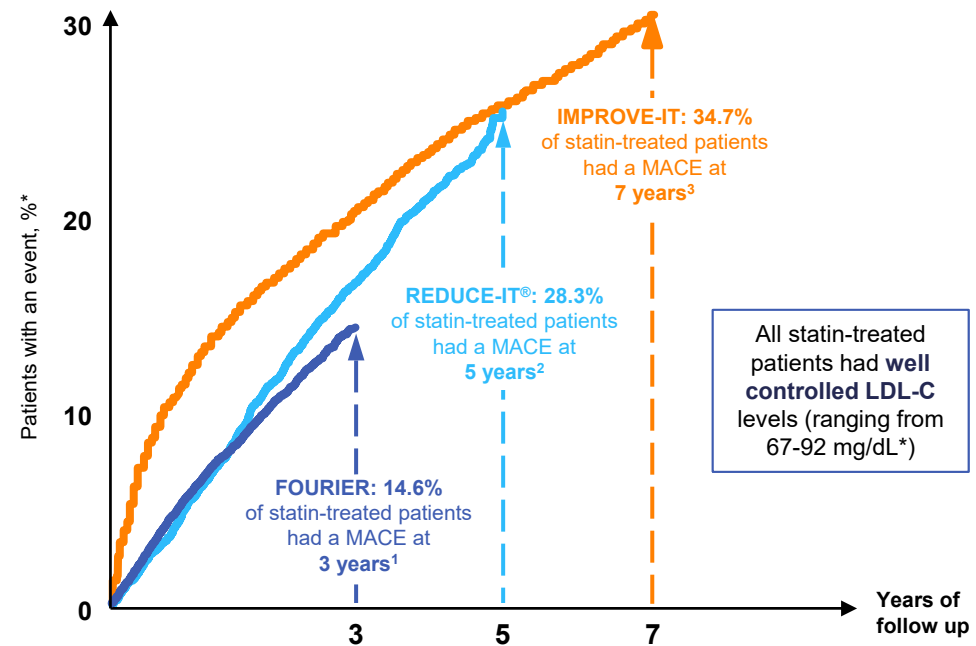
# Need: Many Patients Suffer Strokes, Heart Attacks or Die from CVD Despite Conventional Therapy



Controlled LDL-C doesn't eliminate CV risk; P-CVR often remains  
 25%-35% lowering major adverse CV events (MACE) shown in CV outcome studies of statin therapies



Placebo groups from multiple recent trials show high P-CVR despite statin-based standard-of-care  
 14.6% to 34.7% of patients treated for LDL-C but not for P-CVR experienced a major adverse cardiovascular event (MACE) in 3-7 Years



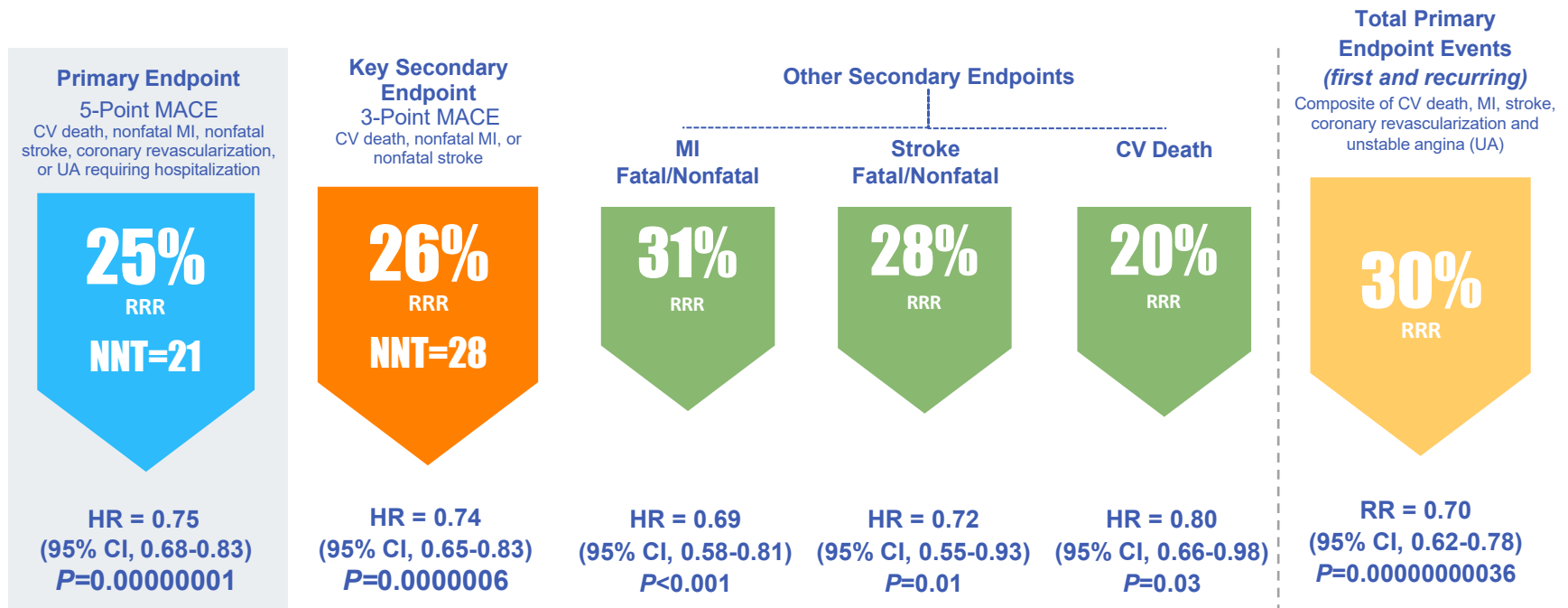
Cross-trial comparisons are subject to differences in populations, primary outcomes, and other trial design aspects

Note: FOURIER, REDUCE-IT<sup>®</sup> and IMPROVE-IT trials evaluated evolocumab, icosapent ethyl and ezetimibe / simvastatin, respectively

\* 67 mg/dL is equivalent to 0.8 mmol/L and 92 mg/dL is equivalent to 1.0 mmol/L

1. Sabatine MS, et al. *N Engl J Med.* 2017;376(18):1713-1722; 2. Bhatt DL, et al; for REDUCE-IT<sup>®</sup> Investigators. *N Engl J Med.* 2019;380(1):11-22; 3. Cannon CP, et al. *N Engl J Med.* 2015;372(25):2387-2397

# Solution: VASCEPA/VAZKEPA Demonstrated CV Risk Reduction Beyond Standard-of-Care (including Statins) in Landmark CVOT



- ✓ Significant reductions across the prespecified testing hierarchy <sup>1</sup>
- ✓ Generally consistent reductions across subgroups
- ✓ Analyses suggest lipid, lipoprotein, and inflammatory markers (including TG) likely have limited contribution to the overall CV benefit demonstrated with icosapent ethyl (IPE)
- ✓ Analysis suggests CV benefit derived from multifactorial effects of icosapent ethyl administered at high levels
- ✓ Well-tolerated safety profile with overall adverse event rates similar for both VASCEPA and placebo patients as per US FDA, Health Canada, and European Commission approved labels for VASCEPA/VAZKEPA and peer-reviewed publication

HR = hazard ratio; NNT = number needed to treat

1. Bhatt DL et al; for REDUCE-IT<sup>®</sup> Investigators. *N Engl J Med.* 2019;380(1):11-22

# Global Growth of VASCEPA/VAZKEPA Is Just Beginning No Other Product Has Similar Clinical Results or Approved Label



## United States

- 2020 total revenue of \$610 million driven by prescription growth of VASCEPA in US
  - Launched VASCEPA in early 2020 for cardiovascular risk reduction
  - Launch slowed by COVID-19; market awareness of VASCEPA remains low
- >10 million at-risk patients would could potentially benefit from VASCEPA in US representing multi-billion dollar opportunity for this chronically-used unique therapy
- Generic competition in US is atypical and currently limited
  - Opportunity, particularly post-COVID-19, to growth branded drug faster than generics
  - Managed care coverage for brand continues to improve

## Europe

- Regulatory approval of VAZKEPA for EU and Great Britain completed in March-April '21
- Preparing for country-by-country market access and launch starting with Germany in Q3'21
- Ready to launch a product with proven long-term outcomes data, strong pharmacoeconomic arguments and recommendations of key medical societies in EU
- 10-years regulatory exclusivity plus potential patent protection to 2039

## China and Rest of World (RoW)

- China regulatory approval of VASCEPA, via commercial partner, expected by end of 2021
- Canada and MENA also partnered; other RoW opportunities to be pursued after EU launch

# Broad Third-Party Support for VASCEPA (Icosapent Ethyl)



## 17 leading medical societies recognizing importance of Icosapent Ethyl:

- American Association of Clinical Endocrinologists
- American Diabetes Association
- American College of Endocrinology
- American Heart Association
- American Stroke Association
- Brazilian Society of Cardiology
- Canadian Cardiovascular Society
- Chinese Journal of Internal Medicine (a journal of the Chinese Medical Association (CMA))
- Chinese Society of Cardiology
- Colombian Society of Cardiology & Colombian Association of Endocrinology, Diabetes and Metabolism
- Egyptian Heart Journal
- Endocrine Society
- European Society of Cardiology
- European Atherosclerosis Society
- Japanese Circulation Society
- National Lipid Association
- Thrombosis Canada



## Analyses show VASCEPA to be cost effective

- Institute for Clinical and Economic Review (ICER) report shows VASCEPA as cost effective for CV risk reduction in US (Oct'19)
- Comprehensive analysis determined Icosapent Ethyl to be highly cost-effective in patients from the REDUCE-IT study, and may even demonstrate cost-savings in the majority of simulations (Nov'19)

## Cardiovascular outcomes study results published in leading medical journals

- *The New England Journal of Medicine*
- *Journal of American College of Cardiology*
- *European Heart Journal*
- *Circulation (AHA)*

Dozens of publications and scientific presentations describe multifactorial effects of icosapent ethyl not shown for any other molecule or product

VASCEPA has been prescribed over 10 million times

## Current President and CEO Retiring

- After 12-years with Amarin, John Thero is retiring effective August 1, 2021
- He will provide part-time support, as needed, thereafter

## New President and CEO will be Karim

- Currently SVP Commercial Head of Europe
  - Responsible for preparing for commercialization of VAZKEPA in Europe
- Global Commercial Leadership positions in 7 different countries, spanning 3 continents - Merck (22 years) in positions including:
  - Global Commercial Leader for \$4 billion lipid franchise
  - Chief Marketing Officer for Europe, Middle East and Africa
  - Operating Officer for Emerging Markets



## Increase US VASCEPA use and profits



- Increase education of healthcare professionals and patients
  - Continue to adapt during and after COVID-19 era
  - Leverage medical guidelines and data showing that **no other drug has the same effect** as VASCEPA
- Increase in-person meetings with healthcare professionals in a phased manner as patients resume routine physician visits as the impact of COVID-19 recedes
  - Leverage sales force expansion completed in Mar'20 to reach more doctors more frequently
- Sponsor numerous medical education programs and scientific presentations/publications;
  - >100 presented/published in recent years
- Leverage recent improvements in already broad managed care coverage
- Manage spending to reflect variability of COVID-19 and generic entry to support profit growth while allowing for quarterly variability

## Adjust to threat of generic competition in atypical market environment for generics

- VASCEPA is not a mature product – still largely unknown
- Generic supply is expected to remain limited and potentially variable due to manufacturing complexities, costs and lead times combined with limited investment by generic companies in supply capacity
- Historical analogue from EPADEL in Japan – ~60% branded share maintained despite generic competition for >10 years



### ~49M people in the European Union (EU) with CV disease<sup>1</sup>

- Includes 38 million diagnosed with ischemic heart disease (IHD), stroke or peripheral heart disease
- IHD and stroke are, respectively, the first and second most common single causes of death in the EU

### Recent VAZKEPA approvals open door to commercialization in EU and Great Britain (GB)<sup>2</sup>

- European Commission and MHRA authorization of IPE to be marketed and sold in EU and GB for icosapent ethyl to reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides ( $\geq 150$  mg/dL) and:
  - established cardiovascular disease, or
  - diabetes, and at least one other cardiovascular risk factor
- Approved label acknowledges IPE's multifactorial mechanisms of action
- Brand name VAZKEPA for Europe supports effective translation into multiple languages
  - Pronounced using a short "e" Vaz-kě-pah
- First and only drug approved for its approved cardiovascular risk reduction indication

1) <http://www.ehnheart.org/cvd-statistics.html>. 2) <https://ec.europa.eu/health/documents/community-register/html/h1524.htm>

## Market Access



- Expect to file reimbursement dossiers in 10 European countries soon
  - Dossiers include the largest countries of Europe
  - Market access timing can vary significantly by country; Germany allows early access with one-year declared pricing before price is negotiated for second year
  - Market access negotiations to leverage robust clinical efficacy of VAZKEPA and supportive pharmacoeconomic data (e.g., high costs associated with treating strokes, heart attacks and other major adverse cardiovascular events (MACE))

## Market Awareness

- Amarin team in Europe of ~50 professionals in January 2021, expanded in May 2021 to include 150 sales professionals for pre-launch market awareness initiatives in Germany, with further expansion of the EU team to ~300 expected by the end of 2021
  - Currently focus on disease and product awareness to cardiologists and select other health care professionals
  - Building strong team of people with significant experience in market access, marketing and sales, including new product launches
- ESC and EAS already include icosapent ethyl in their medical guidelines
- Launch in Germany expected before the end of Q3'21 after initial awareness campaign
  - Germany launch to be followed by launches elsewhere subject to successfully securing market access
  - Level of sales staffing to vary by country based on numerous factors, including market size, geography and effectiveness of digital outreach
  - Avoiding putting large number of people into countries before market access and reimbursement is secured

## Positive Phase 3 Clinical Trial Results Announced Late in 2020

- Study achieved primary endpoint with VASCEPA lowering TG levels by 19.9% ( $p < 0.001$ ) compared to placebo at the end of 12-week treatment period
- VASCEPA was well-tolerated with a safety profile similar to placebo and there were no treatment-related serious adverse events
- Mirrored MARINE study results, demonstrating consistency in treatment outcomes across Western and Asian patient populations



## Seeking to position VASCEPA as first-in-class therapy

- First approval in China creates potentially high hurdle for future competitive product(s), if any

## Commercial partner, Edding, preparing for product launch

- Successfully promotes multiple products in China
- Understands the importance of VASCEPA's high quality manufacturing through Amarin for both product effectiveness and market growth reasons

## Chinese Society of Cardiology already includes icosapent ethyl in their medical guidelines for primary prevention of CV diseases

## Regulatory, reimbursement and commercialization plans underway

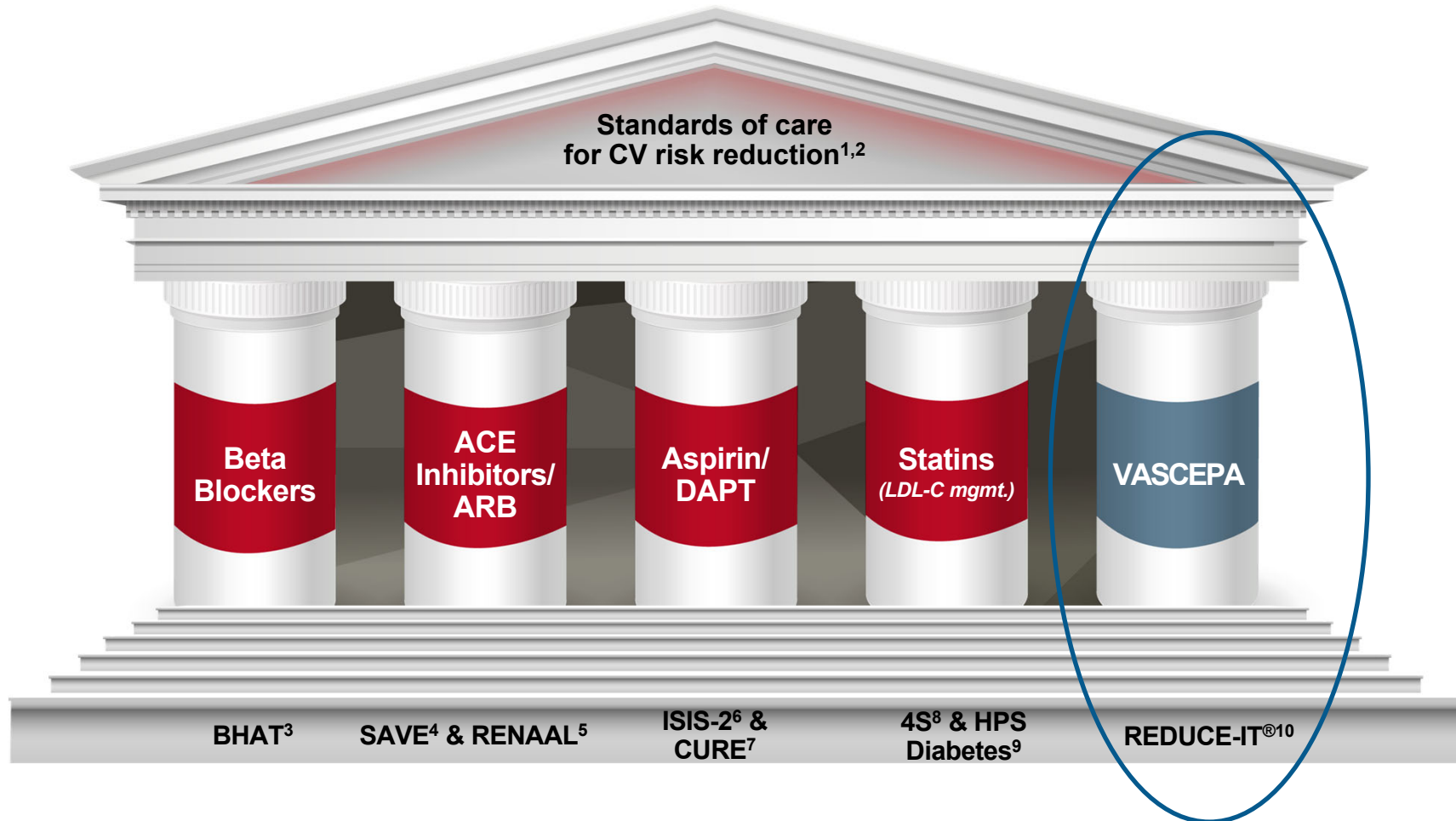
- NMPA accepted for review the New Drug Application for VASCEPA, approval decision for Mainland China anticipated near end of 2021; similar review underway in Hong Kong
- Similar to Europe, market access and launch initiatives to accelerate approaching and after regulatory approval

## Resources Exist to Support Launch in Europe (Millions) (Unaudited) Capitalization as of March 31, 2021



<b>Cash and Investments</b>	\$538.7	
<b>Debt</b>		
NOTES	None	
ROYALTY-BEARING INSTRUMENTS	None	Repayment completed in 2020
<b>Common Stock and Equivalent Shares<sup>1</sup></b>		
COMMON SHARES	395	
OPTIONS AND RESTRICTED STOCK	30	Aggregate of all outstanding regardless of price or vesting
TOTAL IF ALL EXERCISED	425	
<b>Tax Jurisdiction (primary)</b>	Ireland	Loss carryforwards of ~\$900

# VASCEPA Is Becoming the Next Pillar of CV Care



1. American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2019;139(10):e56-e66; 2. Jernberg T et al. *JAMA*. 2011;305(16):1677-1684; 3. Goldstein S. *Circulation*. 1983;67(6 pt 2):153-157; 4. SAVE Investigators. *N Engl J Med*. 1992;327(10):669-677; 5. RENAAL Study Investigators. *N Engl J Med*. 2001;345:861-869; 6. ISIS-2 (Second International Study of Infarct Survival) Collaborative Group. *Lancet*. 1988;2(8607):349-360; 7. Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators. *N Engl J Med*. 2001;345(7):494-502; 8. Scandinavian Simvastatin Survival Study Group. *Lancet*. 1994;344(8934):1383-1389; 9. Heart Protection Study Collaborative Group. *Lancet*. 2003;361(9374):2005-2016; 10. REDUCE-IT<sup>®</sup> Investigators. *N Engl J Med*. 2019;380(1):11-22.

## **Strong scientific foundation**

- Clinical success, including landmark REDUCE-IT® outcomes study, achieved with science as guide
- Well respected by key opinion leaders and medical societies around the world

## **Commercial experience in US can be leveraged globally**

- Strong pharmacoeconomic arguments led to broad managed care coverage in the US; similar arguments together with strong clinical data should support successful global market access

## **Cardiovascular disease is a global issue**

- Near-term priorities are to increase growth in the US, to successfully launch in Europe and to secure regulatory approval in China
- RoW opportunities to be pursued after market access is secured in Europe

## **Diversification**

- Beyond being successful with near-term priorities in the US, Europe and China, product diversification will be sought
- Increasingly evaluating product pipeline opportunities (e.g., ongoing COVID-19 studies)
- A strong commercial team in Europe, together with US team, is expected to provide Amarin with greater leverage/access to products needing science-based, primary care promotion



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