# Nyrada

## **Annual General Meeting Presentation**

James Bonnar Chief Executive Officer

19 November 2021 Sydney NSW

Authorised by Mr. John Moore, Non-Executive Chairman, on behalf of the Board.



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#### **Company Overview**



- Drug discoverer and early-stage developer
- Two lead drug development programs with significant therapeutic and commercial potential:
  - Cholesterol-Lowering Program
  - Brain Injury Program
- Lead drug development programs funded through Phase I
- Collaborations with world leading institutions, Walter Reed Army
  Institute of Research (WRAIR) and UNSW Sydney
- Cash position as at the end of Q1 FY2022 was \$12.4M
- Commercial business model focused on maximising the value of early-stage drug candidates
- Well connected industry and research experts comprise Nyrada's Board and Scientific Advisory Board (spanning US, Europe, Japan and Australia)



### **Vision & Strategy**



- To improve lives and offer hope through innovation
- We aim to deliver novel treatments for diseases where:
  - There is an unmet clinical need; or
  - Current treatments are suboptimal



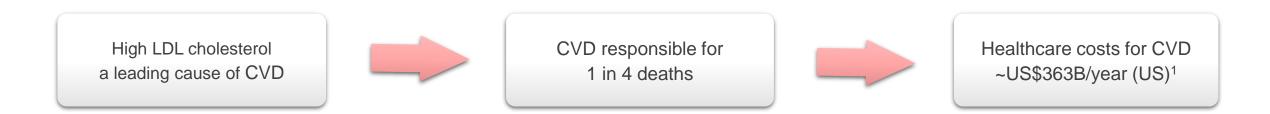
Our strategy is to advance highly optimised drug candidates towards a key value inflection point, such as an efficacy signal, and out-licence them early, where the risk reward equation is most favourable for Nyrada shareholders Nyrada

# Cholesterol-Lowering Program

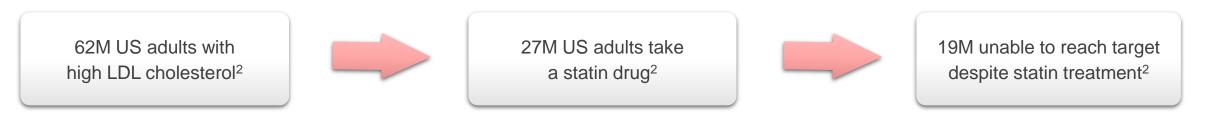
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#### High LDL Cholesterol and Cardiovascular Disease (CVD) Problem and key statistics





#### Statins are suboptimal for 70% of patients and often poorly tolerated



## Statins reduce risk of CVD but ~1 in 5 patients are statin intolerant, a key reason treatment is discontinued<sup>3</sup> Intolerance symptoms include muscle pain, liver dysfunction, renal insufficiency, diabetes and eye conditions<sup>4</sup>

- <sup>1</sup> Virani SS, Alonso A, Aparicio HJ, Benjamin EJ, Bittencourt MS, Callaway CW, et al. Heart disease and stroke statistics 2021 update: A report from the American Heart Association, 2021; average annual indirect and direct CVD related costs estimated for 2016-17.
- <sup>2</sup> Wong ND et al. Prevalence of the American College of Cardiology/American Heart Association statin eligibility groups, statin use, and low-density lipoprotein cholesterol control in US. J Clin Lipidology. 2016
- <sup>3</sup> Management of Statin Intolerance in 2018: Still More Questions Than Answers, Toth PP, Patti AM, Giglio RV, Nikolic D, Castellino G, Rizzo M, Banach M. Am J Cardiovasc Drugs. 2018 Jun;18(3):157-173
- <sup>4</sup> Cai T, Abel L, Langford O, Monaghan G, Aronson J K, Stevens R J et al. Associations between statins and adverse events in primary prevention of cardiovascular disease: systematic review with pairwise, network, and dose-response metaanalyses, BMJ 2021

#### **Current PCSK9 inhibitors**

- ✓ Effective as a single treatment or combined with a statin
- × Expensive (~US\$5,800/year) and require 2-4 weekly injections
- Amgen and Sanofi/Regeneron reduced the price of their injectable PCSK9 inhibitors, Repatha® (evolocumab) and Praluent® (alirocumab) by 60%, supporting increased sales and patient uptake<sup>1</sup>
- Repatha® sales grew 34% in FY2020 to US\$887M<sup>1</sup>
- Leqvio® (inclisiran, Novartis) recently approved in Europe<sup>2</sup>
  - Three then six-monthly injections on top of statin treatment



- Merck & Co announced results from two early clinical studies showing the first version of an oral PCSK9 inhibitor cholesterol-lowering medicine was well tolerated and highly effective at reducing high levels of LDL cholesterol<sup>3</sup>
  - Demonstrates industry interest in development of oral vs injectable PCSK9 inhibitors
- Improved access to injectable PCSK9 inhibitors through government health benefit schemes:
  - Repatha® and Praluent® now funded under PBS (Australia) but only for patients with familial hypercholesterolemia<sup>4</sup>
  - Leqvio® to be funded by NHS in UK for 300,000 patients with negotiated discount (undisclosed) to list price of US\$2,750 per dose<sup>5</sup>

1 Amgen press release dated 24 October 2018., Regeneron press release dated 11 February 2019, FY2020 Amgen Annual Report, page 64

<sup>2</sup> Novartis press release dated 11 December 2020

<sup>3</sup> Results from clinical studies by Merck & Co. presented at the American Heart Association's Scientific Sessions 2021, 15 November 2021

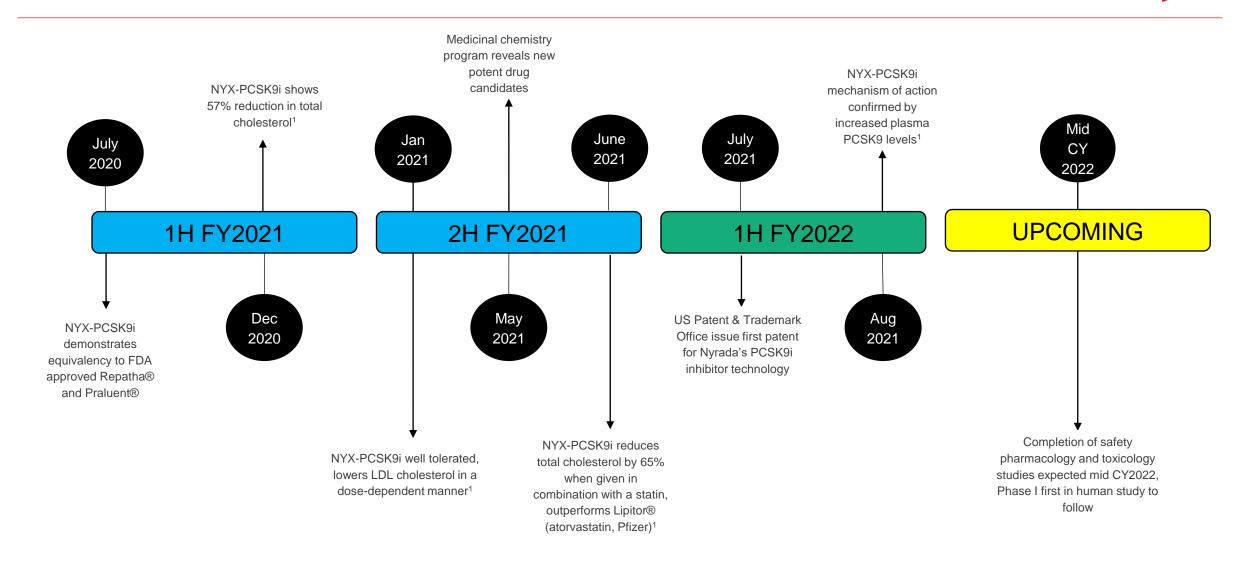
<sup>4</sup> Sanofi press release dated 1 August 2021; Australian Federal Department of Health press release dated 1 May 2020

<sup>5 &#</sup>x27;Novartis finalizes deal to make new heart drug widely available in England', Shoshana Dubnow, Biopharmadive, 1 September 2021



- We are developing an oral PCSK9 inhibitor drug (taken as a pill) for the treatment of high LDL (bad) cholesterol levels in patients at risk of cardiovascular disease
- Nyrada's drug would replace expensive and inconvenient injectable PCSK9 inhibitor drugs and could be taken on its own or in combination with a statin

#### Program Milestones – FY2021 & FY2022



<sup>1</sup> In vivo study conducted in specialised mouse model (APOE\*3-Leiden.CTP) genetically modified to mimic human-like characteristics concerning cholesterol metabolism and cardiovascular health.

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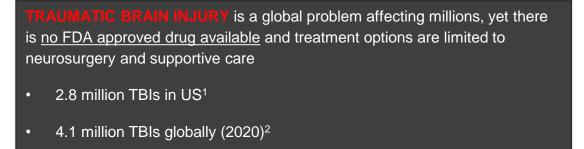
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# **Brain Injury Program**

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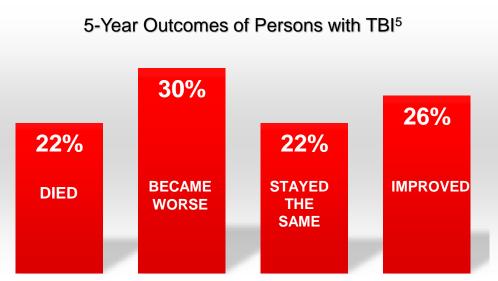
Nyrada is developing a neuroprotectant drug to reduce the impact of secondary brain injury in patients following a stroke or traumatic brain injury (TBI), which can occur following a motor vehicle accident, fall, or sporting injury.



5.3M Americans living with brain injury<sup>3</sup>

#### **STROKE**

- 800,000 strokes annually (US)<sup>4</sup>
- One drug class for stroke, suitable to less than 15% of patients



Data are US population estimates based on the TBIMS National Database. Data refer to people 16 years of age and older who received inpatient rehabilitation services for a primary diagnosis of TBI.

<sup>1</sup> Brain Injury Alliance (Connecticut): <u>http://www.biact.org/understanding-brain-injury/brain-injury-facts-statistics</u>

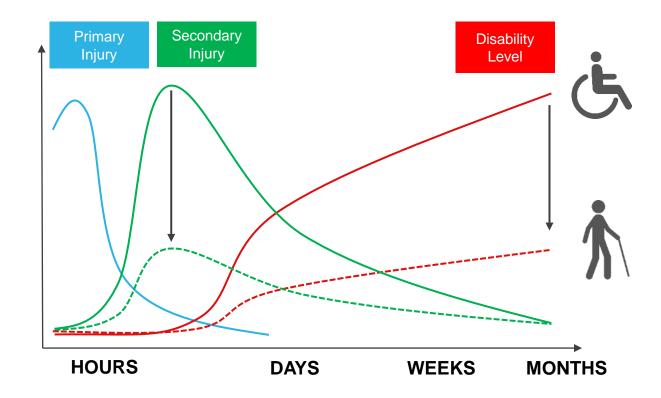
- <sup>2</sup> Total TBIs in US, Germany, France, Italy, Spain, UK and Japan, Traumatic Brain Injury, Market Insight, Epidemiology and Market Forecast, DelveInsight, published January 2021
- <sup>3</sup> US Brain Injury Alliance: <u>https://usbia.org/</u>
- <sup>4</sup> US Centers for Disease Control and Prevention: <u>https://www.cdc.gov/stroke/index.htm</u>

<sup>5</sup> 'Moderate to Severe Traumatic is a Lifelong Condition', CDC publication available at: <u>https://www.cdc.gov/traumaticbraininjury/pdf/moderate\_to\_severe\_tbi\_lifelong-a.pdf</u>

## **Reducing Secondary Brain Injury After TBI or Stroke**

First-ever drug to improve survivability and patient quality of life

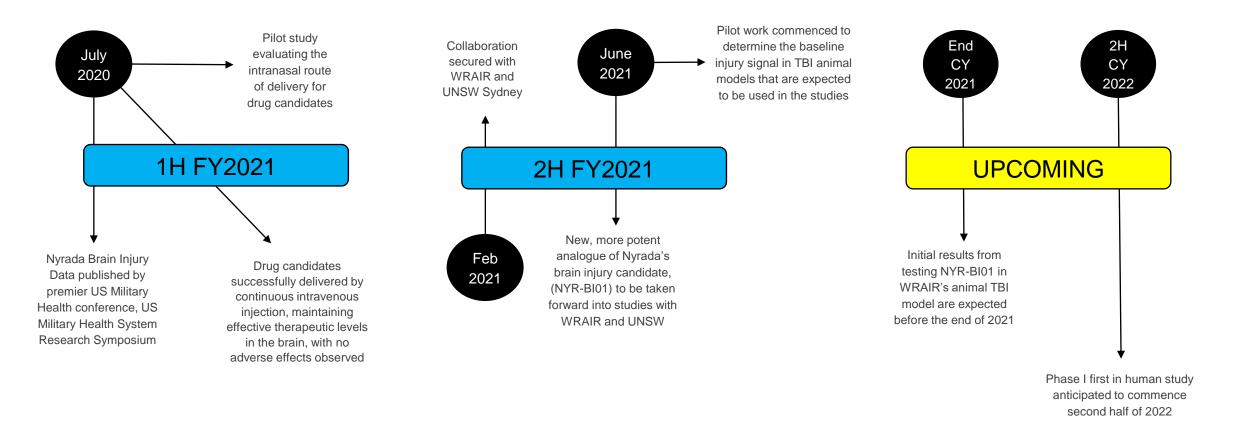
- Treatment for secondary brain injury following TBI or Stroke
- Administered intravenously (TBI and Stroke) or intranasally (Concussion)
  - Prevent cell death
  - Attenuate damaged brain volume
  - Improve survivability, limit disability, improve quality of life
- In the US, UK, Europe and Japan alone, the size of the TBI market in 2020 was US\$6.7 billion and estimated to grow at a CAGR of 5.54% between 2018–2030<sup>1</sup>
- Stroke market estimated to surpass US\$3.5B by 2027<sup>2</sup>



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<sup>&</sup>lt;sup>1</sup> Traumatic Brain Injury, Market Insight, Epidemiology and Market Forecast, DelveInsight, published January 2021 <sup>2</sup> Coherent Market Insights press release dated 10 May 2021

#### Program Milestones – FY2021 & FY2022



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# **Corporate Update**

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### **FY2021 Financial Performance**

#### Highlights

- Nyrada ended FY2021 with cash of \$13.8M
- Cash position as at the end of Q1 FY2022 was \$12.4M
- R&D Tax Incentive refund of \$2.3M relating to the accrued FY2021 refund of \$1.3M and received FY2020 refund of \$1.0M
- Anticipate R&D Tax Incentive refund of \$1.3M in Q4 CY2021, further boosting capital resources
- Capital raise of \$11.5M completed via a two-tranche Placement, with strong demand from new and existing shareholders
- Placement proceeds will be used to fund Phase I clinical trials for both programs, and enable further proof-of-concept studies

#### **Operating Results Summary**

	FY2021 (A\$)	FY2020 (A\$)
R&D Costs	2,175,050	1,399,999
Corporate and admin expenses	895,839	571,862
Share-based payment expense	1,111,622	2,204,324
Professional services expense	509,842	1,005,316
Employment benefits expense	929,931	1,342,993



### **Strong Intellectual Property Position**

- In July 2021, the US Patent & Trademark Office granted Nyrada's first patent for the Cholesterol-Lowering Program's PCSK9i inhibitor, with an expiry date of 16 March 2038
- The composition of matter patent protects Nyrada's intellectual property for its PCSK9 inhibitor technology in the US and marks an important achievement in our active IP strategy







#### **COVID Update**





- No significant impact on operations despite multiple government mandated COVID-19 lockdowns in Sydney and Melbourne
- Successfully transitioned to remote working model
- Team appreciate greater flexibility, leading to enhanced productivity and morale
- Remote working model reduces fixed costs and frees up capital to invest back into R&D activities
- Minimal disruption to CROs engaged overseas to undertake preclinical studies (China, India)
- Relaxation of COVID-19 restrictions including international travel will allow for greater focus on in-person investor engagement, and conference presentations (market and industry) in CY2022

#### **Scientific Advisory Board**





Professor Gary Housley Chair, M.Sc Ph.D

Chair in Physiology (UNSW) and founding Director of the Translational Neuroscience Facility.

Pioneered the science behind Nyrada's Brain Injury Program.



Professor David Burke MD, DSc, AC

Professor of Neurology at Royal Prince Alfred Hospital and Sydney Medical School (USYD).



Professor Gilles Lambert Ph.D

Professor in Cell Biology at University of La Réunion Medical School (France) and group leader, Inserm laboratory of Diabetes & Atherothrombosis of the University Hospital of La Réunion.



Professor Junichi Nabekura, Ph.D

Professor of Physiology and Neuroscience and Director General of the National Institute of Physiological Sciences, a leading research institution in Japan.



Dr. Jim Palmer Ph.D

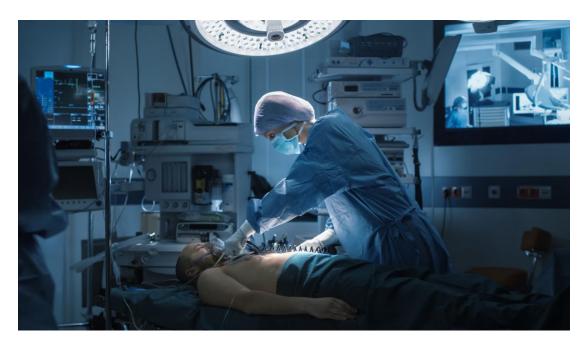
More than 30 years of experience in drug discovery programs targeting oncology, cardiovascular, inflammation, joint and bone disease, and infectious diseases.

### **Key Metrics & Timing of Phase I Studies**



Market capitalisation (as at 18 November 2021)	\$36.6M	
Share price (as at 18 November 2021)	\$0.235	
CDIs free float	122,902,847	
CDIs 24 months escrow	33,105,853	
Cash at bank 30 Sept 2021	A\$12.4M	
ASX listing	January 16, 2020	

Program Pathways to Phase I	1H CY2022	2H CY2022
<u>Cholesterol-Lowering Program</u> Expect to enter clinic following completion of preclinical studies in Mid CY2022		
Brain Injury Program Expect to enter clinic in 2H CY2022		



### **Reporting on Program Milestones**



Anticipated upcoming news flow

#### Cholesterol-Lowering Program



**Brain Injury Program** 



- Anticipated completion of safety pharmacology and toxicology studies expected mid-CY2022
   Mid-CY2022
- Phase I first in human studies to follow once preclinical studies are complete (to be run in Australia)

- Initial results from testing NYR-BI01 in WRAIR's animal TBI model
   Before end of CY2021
  - Phase I first in human studies anticipated to commence second half of 2022 (to be run in Australia)

• 2H CY2022



## **Questions?**

Brain Injury Solution Animation Cholesterol-Lowering Animation





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