

Novel small molecule drugs to treat high cholesterol

Nyrada Inc (ASX:NYR) is a pre-clinical stage, drug discovery and development company, specialising in novel small molecule drugs to treat cardiovascular and neurological diseases. Nyrada has two main programs: a cholesterol-lowering drug and a drug to treat brain injury, specifically traumatic brain injury and stroke. The company was formed in 2017 by Noxopharm (ASX:NOX), which remains the largest shareholder, and listed on the ASX in January 2020 after raising \$8.5m at \$0.20/CHES Depository interests (CDIs) to give a market capitalisation of \$21.8m (excluding restricted CDIs). The company subsequently raised \$11.5m in June 2021 to fund Phase I trials for both programmes. The company has recently announced exploratory analysis results from its *in vivo* cholesterol efficacy study in a specialised transgenic mouse model (APOE*3-Leiden.CETP) to evaluate NYX-PCSK9i in combination with a statin. Over the study period, NYX-PCSK9i reduced total cholesterol by 65% when dosed in combination with the statin drug Lipitor^R and by 46% as a monotherapy, compared with the reduction achieved using Lipitor^R alone of 27%. Nyrada has selected NYX-PCSK9i as the preferred compound for safety pharmacology and toxicology studies to commence in CY2021, with a Phase I, first-in-human study expected to commence in mid-CY2022.

Business model

Nyrada is pursuing two main drug development programmes: a cholesterol-lowering drug, NYX-PCSK9i, and a drug to treat brain injury, NYR-BI01. The two FDA-approved PCSK9 inhibitors are potent monoclonal antibody drugs, that lower LDL (“bad”) cholesterol by targeting the protein PCSK9 to reduce the degradation of LDL receptors, which act to remove LDL cholesterol from the bloodstream. Nyrada is aiming to develop the first oral, small molecule PCSK9 inhibitor that can be taken in pill form. NYX-PCSK9i is intended to be used in conjunction with or without a statin drug, the standard cholesterol-lowering medication. The PCSK9 inhibitor drugs currently available are expensive and need to be injected bi-weekly or monthly. Nyrada’s NYR-BI01 is advancing in a collaboration study with the Walter Reed Army Institute (WRAIR) and University of NSW, Sydney, for its brain injury program, validating the potential of its drug candidates. The company has noted that NYR-BI01 is a more potent and improved version of its predecessor, NYX-1010. Nyrada’s business model is to focus on discovery and early-stage drug development i.e., Phase I/II clinical trials, and after safety and efficacy has been confirmed, seek to on-sell or out-licence its drug candidates to established pharma companies.

Advancing the pathway to Phase I clinical trials

Nyrada noted that in FY21 it had advanced its preclinical programs with R&D expenditure of \$2.2m versus \$1.4m in FY20. Nyrada is focused on completing the remaining studies ahead of commencing a first-in-human trial for its cholesterol-lowering Program in mid-2022. As part of these preparations, the company will be conducting safety pharmacology and toxicology studies in the interim. A pharmacokinetic study showed NYR-BI01 crossed the blood-brain-barrier at above therapeutic levels which means it can reach the area of the brain damaged by traumatic brain injury. Nyrada anticipates testing of NYR-BI01 in WRAIR’s TBI animal model later in 2021, with initial results expected before the end of the year.

Listed peers are early stage with novel technologies

An independent review of peers by acuity Technology Management which was published in the Chimeric Therapeutics’ November 2020 prospectus highlighted AdAlta, Chimeric, Nyrada, Prescient and Exopharm as the closest Australian-listed peers based on their early stage. Other peers include Argenica and Neuroscientific Pharmaceuticals.

Pharmaceuticals & Biotech

10th September 2021

Share details

ASX Code	NYR
Share price	\$0.275
Market Capitalisation	\$42.9M
CDIs listed on issue	122.9M
CDIs restricted (unlisted)	33.1M
Net cash at 30/06/2021	\$13.8M
Free float	48.96%

Share performance (12 months)



Upside Case

- Exploratory analysis results from *in vivo* cholesterol efficacy study promising
- Well-funded for Phase I trials
- Large potential markets for both programs

Downside Case

- Very early stage and pre-clinical
- Further equity raisings likely
- No guarantee of success in trials or licencing

Catalysts/upcoming events

Safety pharmacology & toxicology studies of NYX-PCSK9i commence in 2H CY21

Phase I clinical trials to commence in mid- 2022

Comparable companies (Aust/NZ)

Argenica (ASX:AGN), AdAlta (ASX:1AD), Cellmid (ASX:CDY) Chimeric Therapeutics (ASX:CHM) Neuroscientific Pharmaceuticals (ASX:NSB), Prescient (ASX:PTX), Exopharm (ASX:EX1)

Top 5 shareholders

Noxopharm Ltd	21.39%
Altnia Holding (I Dixon Family A/C)	6.36%
Sunset Capital Management	1.63%
Colin Housley & Freda Housley	1.19%
Kohen Enterprises	1.11%

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