

Innovations in stroke therapy

US biotech to develop Australian science

Australian biotech Noxopharm Ltd will spin off a US company to develop three Australian drug developments of key current interest to the pharmaceutical industry that are relevant to the treatment of symptoms of stroke and diabetes.

The three drug assets are all pre-clinical, with an estimated 12-18 months before they become ready to enter clinical studies.

The new company, Nyrada Inc, will take advantage of the US capital markets' appreciation of cutting-edge biotechnology.

Nyrada will start with three pre-clinical drug assets – NYX-104, NYX-205 and NYX-330 – a pipeline reflecting the Federal Government's National Innovation and Science Program that encourages interaction between Australian industries and research institutions.

NYX-104 and NYX-205 have been designed to address neurodegenerative conditions and are possible because of a breakthrough drug delivery technology that Noxopharm has developed.

The technology, known as LIPROSE, shows promise in getting drugs past the body's blood-brain and blood-nerve barriers, which until now have proven effective obstacles to developing treatments for diseases affecting the brain, spinal cord and nerves.

LIPROSE technology has proven crucial in allowing Noxopharm to look at using its experimental anti-cancer drug, NOX66, to treat brain cancer. Nyrada was established to extend using the LIPROSE technology to treat conditions of the brain beyond cancer.

NYX-104 is the result of a collaboration between Noxopharm and a team of eminent neuroscientists at UNSW Sydney who, in their own ground-breaking research, identified a protein in the human brain that plays a key role in blocking the brain's ability to recover from stroke and trauma such as concussion.

A feature of brain cells is that, when injured for any reason, they dump their neurotransmitter chemicals, resulting in a chemical overload that over-stimulates neighbouring healthy brain cells to the point of killing them (known as excitotoxicity).

This radiation of cell death out from the original injury can continue over days to weeks after a stroke and can result in a final death count of brain cells up to 10 times greater than that from the original injury.

The protein identified by the UNSW scientists is key to this process. NYX-104 is a first-in-class, potent inhibitor of this protein, with the LIPROSE technology providing the means for NYX-104 to access the brain to block the excitotoxicity process.

Excitotoxicity is a major community problem that is without an effective treatment.

It contributes to long rehabilitation times from stroke, permanent paralysis and even death. NYX-104 is intended to prevent those outcomes by being administered in the early days after a stroke.

Excitotoxicity also is responsible for repeat concussion, such as can occur in the boxing ring or on the football field, leading to severe shrinkage of the brain and early-onset dementia; to repeated concussive noise leading to hearing loss, such as can affect soldiers; and to



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progressive brain injury with epilepsy.

NYX-205 is a related drug which happens to have strong anti-inflammatory properties. Again combined with the LIPROSE technology, it is designed to cross both the blood-brain barrier and the blood-nerve barrier.

Nyrada intends to bring NYX-205 into the clinic in the first instance to treat a disease of peripheral nerves known as peripheral neuropathy, a painful condition believed to afflict 20 million patients in the US in association with diabetes and viral diseases.

Graham Kelly, managing director of Noxopharm and interim chief executive officer and president of Nyrada, said the Noxopharm board was excited to bring two drugs to market to treat major neurodegenerative diseases affecting millions of people and costing the community many billions of dollars in lost productivity, not to mention suffering.

"As far as we know, these two drug candidates are first-in-class, offering in our view a realistic prospect of finally being able to do in due course something worthwhile for many millions of long-suffering patients and their families around the world."

Noxopharm is excited at the opportunity to bring two drugs to market to treat major neurodegenerative diseases affecting millions of people and costing the community many billions of dollars.

The proposal to spin out Nyrada and to transfer NYX-104 and NYX-205 into it is being put to shareholders at an Extraordinary General Meeting on November 6.

If approved, then a second proposal, also to be voted on, is the acquisition (for equity) by Nyrada of another Australian biotech company which will give Nyrada a third drug asset to be known as NYX-330.

NYX-330 is one of the new generation of anti-cholesterol drugs known as PCSK9-inhibitors, intended to replace the popular statin drugs, which are now nearing the end of their patent life.

Kelly said: "NYX-330 is a remarkable piece of Australian science by some very clever computational chemists who appear to have stolen a march on major pharmaceutical companies who some years ago tried and failed to develop a small molecule drug against PCSK9. NYX-330 proves that it is possible."

Nyrada will start with a pipeline of three first-in-class drugs, each targeting significant market opportunities, and each with lodged patent applications.

Noxopharm will own 67 per cent of Nyrada, and one of its non-executive directors, Dr Ian Dixon, will own 33 per cent.

After the EGM, Nyrada plans to seek to raise seed capital of \$US5 million by private equity placement to 708(8)(c) investors. Nyrada will have its own facilities, management and board and be resident in the state of New York.

Nyrada is designed to unlock value for NOX shareholders in potentially highly valuable IP in a non-dilutive way.

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