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Kinosis Therapeutics: A transformative approach to restoring social function

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Abstract: Kinosis, a University of Sydney spin out, is developing first-in-class therapeutics with the potential to revolutionise the treatment of substance use disorders, and social dysfunction in neurological and psychiatric disorders. The collaborative model employed by Kinosis has driven the expeditious commercialisation of its research through continued industry-academic collaborations.

Keywords: substance use disorders, social dysfunction, brain oxytocin system.

1. The success story

Kinosis is an Australian-based, biotech company pioneering a novel approach for treating disorders of the brain and mind, through the development of a range of therapeutic, small molecule compounds. Specifically, Kinosis have identified the lack of specific treatments targeting defective social pathways in the brain that characterise debilitating neurological and psychiatric disorders. The transformative research by the Kinosis team may hold the potential to restore normal social function by, *“vastly revamping the treatment of mental health conditions, and alleviating the suffering of patients who grapple with social dysfunction and substance use”* says CEO of Kinosis, Hugh Alsop. Ultimately, the successful University of Sydney spin-out aims to commercialise neuroscientific research through industry-academic collaboration, in efforts to improve the treatment of substance use disorders and social dysfunction.

2. How did we start?

A research collaboration at the University of Sydney, between the School of Chemistry and School of Psychology, identified compounds stimulating the oxytocin pathway within the brain. Associate Professor Michael Bowen, CSO of Kinosis, was deeply motivated by the dire need for life-saving treatments for disorders of the brain and mind, *“There is a profound dysregulation of social behaviour, and we hope that the drug we’ve developed will see a desperately needed,*

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major breakthrough in the way we treat these disorders”. The founders of Kinosis are deeply motivated to impart a positive impact on the way that mental healthcare is approached. Alsop explains that “in the field of addiction, we all see the damage done from substance use disorders, and many of us have been touched personally in our families with such issues. Addiction remains a global issue, and is in desperate need of new solutions to help patients overcome their challenges. The potential to play a role in helping these patients is a real motivator for the Kinosis team”.

3. Our technology

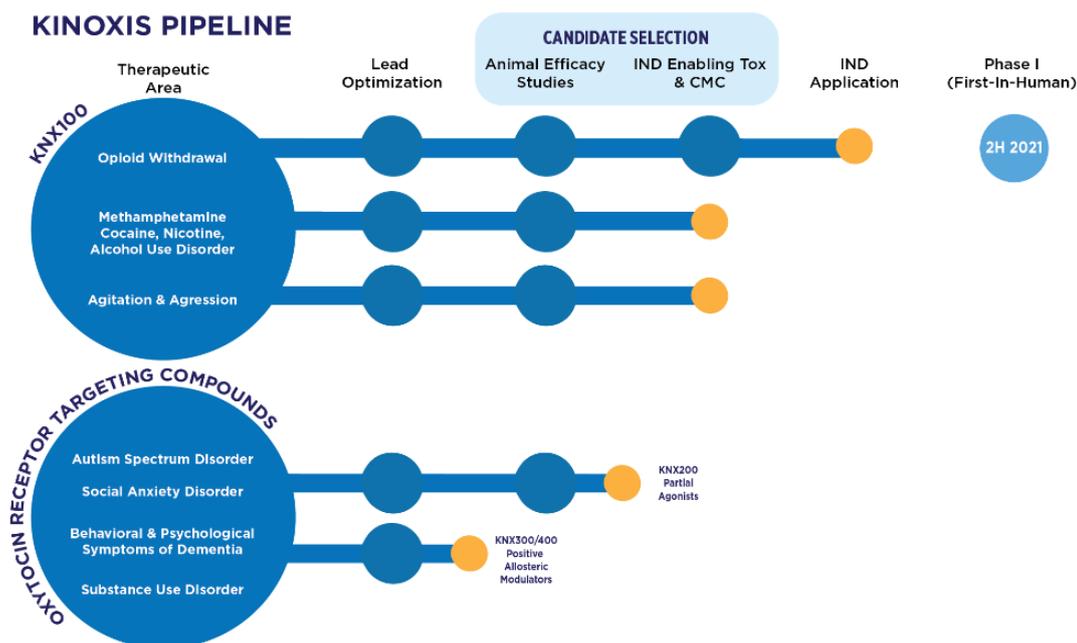


Figure 1. The Kinosis Pipeline. Kinosis Therapeutics currently have two main arms in development, KNX100 and Oxytocin receptor targeting compounds.

Kinosis is the only company progressing several promising first-in-class molecules targeting the oxytocin system to treat neurological and psychiatric conditions. The lead compound candidate, KNX100, has demonstrated potent anti-addictive and prosocial effects in various animal models and is on track to commence a Phase 1 clinical study in the second half of 2021. It also has shown potential for treating a variety of disease indications including behavioural symptoms of autism, treatment of agitation and aggression in Alzheimer’s, schizophrenia, and several other substance use disorders. Multiple other compounds are undergoing lead optimisation and selection, with their primary target being the brain oxytocin system, which is of considerable interest owing to its salient role in the regulation of social behaviour.

4. The journey so far

In 2015, the collaboration between Professors Michael Kassiou, Iain McGregor and Associate Professor Bowen were communicated to the University of Sydney’s commercialisation office.

From there, initial patent applications were filed, and the commercialisation office presented the research to Uniseed. They quickly identified the commercial potential of the developed compounds, which subsequently led the funding round that launched Kinoxis Therapeutics in 2018.

Since 2018, Kinoxis has successfully raised \$10.5 million of private capital through a Series A financing round and is also a recipient of a major grant from the US National Institutes of Health, National Institute on Drug Abuse (NIH/NIDA). Announced in September 2019, the grant was awarded under The Helping to End Addiction Long-term, or NIH HEAL Initiative, with up to \$US 4.6 million (\$AU 6.8 million) of funding to support the preclinical and clinical development of KNX100, for the treatment of symptoms associated with opioid withdrawal. Kinoxis is the only company outside North America to receive the grant. Alsop laments *“our goal is fairly simple, we are aiming to develop products eligible for approval by the US Food and Drug Administration. This is the final step in drug development before our products can be made available for patients in the US.”*

Kinoxis has actively established an industry-university collaboration model. Alsop believes that *“the partnership brings the conceptual treatment to life, allowing for its real world application which further enhances its development.”* The company funds eight postdoctoral researchers, one research officer and three research assistants across multiple institutes, including the University of Sydney and more recently Macquarie University and the Florey Institute of Neuroscience and Mental Health. These collaborations continue vital work exploring the behavioural effects of Kinoxis compounds on neurological conditions such as anxiety, aggression, autism, and frontotemporal dementia. This approach facilitates active collaborations between institutes, providing opportunities for brilliant Australian researchers to be exposed to commercialisation supporting the translation of academic research from the lab into clinics.

5. Look into the future

The future looks promising for Kinoxis, with its lead candidate, KNX100, due to start first-in-human clinical trials in the second half of 2021. Kinoxis' second series of compounds is advancing rapidly, with the aim of progressing into a preclinical toxicology program in the first half of 2022.

Despite Kinoxis' achievements, the past decade has seen the withdrawal of Big Pharma in the development of 'brain drugs' and neuroscience. Alsop is hopeful that there will be a *“renewed interest in Neuroscience by the world's largest pharmaceutical companies”* which may facilitate a *“huge opportunity for clinical success”* for Kinoxis. Alsop insists that the focus remains on *“progressing our compounds into human clinical trials and ultimately ascertaining approval in the US market. The annual average number of new drug approvals in the US is 37, so to achieve the status of FDA approval is a big goal, even more so for an Australian company. Most importantly, the potential to make a contribution to the mental health of millions of people is what drives the team on a daily basis”*.

Alsop insists that despite the “challenges of neuroscience, and the time, risk and cost of developing new therapeutics to treat such intractable conditions, Kinosis is a thriving brilliant team, supported by committed investors, and outstanding science, which garners confidence that Kinosis will grow to become a leading neuroscience team”. Alsop concludes that “with the current prosperity attained by Kinosis, our plan to improve the treatment of social dysfunction in humans is well on its way to fruition”.

Acknowledgments

Kinosis would like to acknowledge the continued involvement of the research team at the University of Sydney, who continue to provide a significant contribution to the success of the company. The company would also like to acknowledge its investors, in particular Uniseed and Devine, who continue to support the company and its team.

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The company



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Investment Rounds (collected in 15.08.21)

| A Series | 2018-2019 | AU\$ 10.25 million | Uniseed (20.4%) and the University of Sydney (15.9%)

| Grant | 2019 | NIH HEAL Initiative | AU \$ 6.8 million

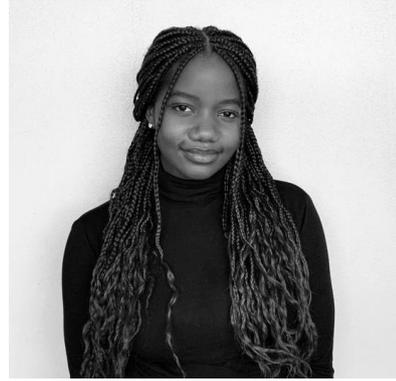
Main facts (collected in 15.08.21)

The company was founded in 2018 and is a spin out of the University of Sydney.

The company currently employs 5 core team members and funds the salary of 12 additional staff from Universities and Research Institutes.

The next milestone is to conduct a first-in-human phase I clinical trial for Kinosis' lead compound KNX100 for the treatment of opioid withdrawal symptoms.

Victoria Maseko is a Medical Student at the University of Wollongong (UOW), and a Research Clinician at Wollongong Hospital, where she provides district-wide research support services to all clinical services. Victoria completed a Bachelor of Pre-Medicine, Science and Health (Nutrition) also at UOW. Throughout her degree, Victoria has conducted, analysed and appraised research in the disciplines biochemistry, physiology and public health nutrition.



As a medical student, Victoria is committed to and passionate about improving the health outcomes of individuals, communities and populations. She continues to enhance her research and critical analysis skills, in order to best implement evidence-based medicine, as a doctor in training. At Wollongong Hospital Research Central, Victoria manages research projects undertaken by clinicians in the fields of medicine, surgery, and allied health. Victoria oversees the collection, organisation and analysis of clinical research data within the Illawarra Shoalhaven Health District.