Awakn Life Sciences' Phase III Trial Approved for Approximately CA$2.5 Million Funding from UK State Covering 66% of Costs

written by Raj Shah | July 20, 2022

Phase III Trial to Cost approximately CA$3.75 million with Awakn's contribution expected to be approximately CA$1.25 million, Marks First Psychedelic Phase III Trial Ever to Receive Government Funding

July 20, 2022 (Source) – Awakn Life Sciences Corp. (NEO: AWKN) (OTCQB: AWKNF) (FSE: 954) ('Awakn'), a revenue-generating biotechnology company researching, developing, and commercializing therapeutics to treat addiction with a near-term focus on Alcohol Use Disorder (AUD), announced today that the National Institute for Health and Care Research (NIHR), a UK government agency, has approved grant funding for 66% of the costs of Awakn's Phase III clinical trial exploring the use of ketamine-assisted therapy for the treatment of AUD. The trial is currently forecast to cost approximately CA$3.75 million in total, with Awakn funding approximately CA$1.25 million of that.

The funding will support Awakn's lead clinical development program, Project Kestrel, which aims to deliver clear Intellectual Property (IP) and marketing authorization/regulatory approval for ketamine-assisted therapy to treat AUD in the UK and the US.

The Phase III trial is expected be the largest ketamine-assisted

therapy clinical trial to date and the only Phase III psychedelic clinical trial to receive government funding. Awakn will partner with the University of Exeter (UoE) and the UK's National Health Service (NHS) to deliver the landmark trial. It is planned to be conducted across seven sites in the UK, with the treatment being administered within the NHS infrastructure. The trial is currently designed to include 280 patients and they will be followed up over the course of six to 12 months. The trial will also pilot bespoke ongoing peer support groups post-treatment.

The trial, which is targeted to be a pivotal trial, follows on from the ground-breaking results of Awakn's Phase II a/b trial announced in January 2022, which resulted in AUD participants experiencing on average 86% abstinence at six-months post treatment versus 2% pre-trial. The Phase III trial will focus on establishing further definitive evidence of the efficacy of ketamine-assisted therapy for the treatment of AUD and to move towards the novel treatment being licensed for this indication. Awakn, UoE and the NHS will be working with the UK Department of Health and Social Care and other key stakeholders throughout the trial to facilitate the swift uptake within the NHS post trial, should the results be positive.

The Phase III trial will be led by Professor Celia Morgan, Awakn's Head of Ketamine-Assisted Therapy and Professor of Psychopharmacology at the University of Exeter.

Professor Morgan commented: *"It is a true honour to lead the team that will deliver this research. The trial represents a huge leap forward in the treatment of AUD. I know this will be a great source of hope for the patients we work with, their families and friends. The financial commitment by the UK Government emphasises the promise of this treatment and the scientific rigour behind the trial. This, coupled with running*

the trial in the NHS settings and working closely with regulators throughout, means that the probability of quick adoption is very high, should the results of this trial fulfil their early promise."

Awakn selected AUD as its lead indication because it is a chronic disease constrained by a significant treatment gap, and a poor current standard of care. AUD affects 400 million[1] people globally; with only 8% of people with this disease seeking treatment[2], and typically a 75% relapse rate within 12 months among those who have[3]. Despite this significant treatment gap and poor efficacy, the US AUD treatment market is valued at CA$45 billion[4], while the NHS in the UK spends more than CA$5.5 billion a year[5] on AUD related illness.

Anthony Tennyson, Awakn's CEO commented: *"We are pleased with today's news for several reasons. A government showing such strong support for this new type of treatment is a global first. Secondly, working with the NHS to deliver the treatment in their existing infrastructure is a huge statement of intent, but most importantly, for so many millions of people around the world suffering from alcohol addiction, a new treatment hope has just got one big 'step' closer. I could not be prouder of the Awakn team and our partners for making this a reality."*

About Awakn Life Sciences Corp.

Awakn Life Sciences Corp. is a revenue-generating biotechnology company researching, developing, and commercializing therapeutics to treat substance and behavioral addictions. Awakn has a near-term focus on Alcohol Use Disorder (AUD), a condition affecting 400m people globally for which the current standard of care is inadequate. Our goal is to provide effective therapeutics to addiction sufferers in desperate need and our

strategy is focused on commercializing our R&D pipeline across multiple channels.

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About Project Kestrel

Project Kestrel is the lead clinical development program of Awakn Life Sciences. Project Kestrel is supported by Awakn's Phase II a/b 'KARE' clinical trial which examined ketamine-assisted therapy for the treatment of Alcohol Use Disorder (AUD). The trial resulted in patients experiencing on average 86% abstinence at 6 months post treatment versus 2% before the trial which means that study participants went from being sober on average 7 days a year to being sober on average 314 days a year. Awakn is planning to initiate a Phase III trial in the UK in 2022 and plans to seek regulatory approval in the UK and the US in due course.

Notice Regarding Forward-Looking Information

This news release contains certain forward-looking information and forward-looking statements, as defined in applicable securities laws (collectively referred to herein as "forward-looking statements"). Forward-looking statements reflect current expectations or beliefs regarding future events or the Company's future performance. All statements other than statements of historical fact are forward-looking statements. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "expects", "is expected", "budget", "scheduled", "estimates", "continues", "forecasts", "projects", "predicts", "intends", "anticipates", "targets" or "believes", or variations of, or the negatives of, such words and phrases or state that certain actions, events or results "may", "could", "would", "should", "might" or "will" be taken, occur or be

achieved, including statements relating the business of the Company. All forward-looking statements, including those herein are qualified by this cautionary statement.

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filings on SEDAR at www.sedar.com. The Company disclaims any intention or obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, other than as required by law.

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