Awakn Life Sciences Signs Agreement with a Leading Drug Development Company to Deepen IP Moat for Its Lead Program

written by Raj Shah | August 25, 2022

Agreement Provides 12-Month Exclusive Period to Agree in-Licensing Deal for Proprietary Formulation of Ketamine

August 25, 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 it has signed a twelve month option agreement with a leading drug development, manufacturing, and delivery systems company to inlicense a proprietary formulation and route of administration for ketamine. The formulation and route of administration will be optimized for commercialization and has the potential to deepen the intellectual property (IP) moat for Awakn's lead clinical development program Project Kestrel, which targets AUD.

AUD is a chronic disease with a poor current standard of care. AUD affects 400 million¹ people globally with an approximate 25% abstinence rate within 12 months of treatment². Despite this poor efficacy, the AUD treatment market in Awakn's two core territories of the U.S. & U.K. is significant. The U.S. AUD treatment market is valued at CA\$45 billion³, while the U.K.

state spends more than CA\$5.5 billion a year⁴ on AUD related illness.

Awakn's Phase II b clinical trial, which was part of Project Kestrel, delivered 86% abstinence at 6 months post treatment compared to the standard 25% abstinence rate. Awakn is now progressing this program into Phase III in the U.K. Awakn also signed a Memorandum of Understanding with the U.K. public healthcare system, the NHS, in December 2021 to establish a partnership to assess NHS organizational readiness for ketamine-assisted therapy and to collaborate on how to accelerate the onlabel use of ketamine-assisted therapy to treat AUD within the NHS' existing infrastructure.

The proprietary formulation of ketamine and optimized route of administration in scope for this agreement has the potential to provide the best possible patient experience and outcomes in addition to deepening Awakn's IP moat. Awakn is planning for the new formulation to be evaluated in its Phase III clinical trial.

Anthony Tennyson, Awakn's CEO commented, "We are very happy to sign this agreement which is a key milestone in our strategy to bring our proprietary ketamine-assisted therapy for the treatment of AUD to market and to be able to help such a large cohort of people who are in such desperate need of an effective treatment and unfortunately do not currently have one."

About Awakn Life Sciences Corp.

Awakn Life Sciences Corp. is a revenue-generating biotechnology company researching, developing, and commercialising 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.

www.AwaknLifeSciences.com | Twitter | LinkedIn | Facebook | www. AwaknClinics.com

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.

Although the Company believes that the expectations expressed in such statements are based on reasonable assumptions, such statements are not guarantees of future performance and actual results or developments may differ materially from those in the statements. There are certain factors that could cause actual results to differ materially from those in the forward-looking information. These include, but are not limited to: COVID-19; fluctuations in general macroeconomic conditions; the business plans and strategies of the Company; the ability of the Company to comply with all applicable governmental regulations in a highly regulated business; the inherent risks in investing in target companies or projects which have limited or no operating history and are engaged in activities currently considered illegal in some jurisdictions; changes in laws; limited operating history; reliance on management; requirements for additional financing; competition; fluctuations in securities markets; inconsistent public opinion and perception regarding the medical-use of psychedelic drugs; expectations regarding the size of the addiction market; and regulatory or political change. Readers are cautioned that the foregoing list of factors is not exhaustive of the factors that may affect forward-looking statements. Accordingly, readers should not place undue reliance on forward-looking statements. The forward-looking statements in this news release speak only as of the date of this news release or as of the date or dates specified in such statements.

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^{1:} Global Burden of Alcohol Use Disorders and Alcohol Liver Disease. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6966598

^{2: &}quot;Treatment rates for alcohol use disorders: a systematic review and meta-analysis" by Tesfa Mekonen

^{3: &}lt;a href="https://www.researchnester.com/reports/alcohol-use-disorder-treatment">www.researchnester.com/reports/alcohol-use-disorder-treatment

<u>-market/3804</u>

4: www.england.nhs.uk/2019/01/nhs-long-term-plan-will-help-problem-drinkers-and-smokers