

# Awakn Life Sciences Signs Drug Development Agreement with Catalent for Zydys(R) Technology (An Orally Disintegrating Tablet) to Conduct Feasibility Studies to Improve Differentiation of Its MDMA Program

Toronto, Ontario--(Newsfile Corp. - September 12, 2022) - 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), today announces it has signed a drug development agreement with Catalent, the global leader in enabling biopharma, cell, gene, and consumer health partners to optimize development, launch, and supply of better patient treatments across multiple modalities.

The agreement will focus on investigating a market-ready proprietary formulation and optimized delivery route for MDMA using Catalent's proprietary Zydys<sup>®</sup> orally disintegrating tablet (ODT) technology. Zydys is a unique, freeze-dried, oral solid dosage form that disperses almost instantly in the mouth, without the need for water and has a dispersion speed of as little as three seconds. Zydys is the world's fastest and best-in-class orally disintegrating tablet and has the potential to deliver a faster onset of activity. Awakn plans to use Zydys technology in its late stage MDMA-assisted therapy clinical trials.

The agreement will allow Awakn to conduct feasibility studies using Zydys technology for addiction, including substance and behavioural addictions, as well as other mental health disorders, including anxiety, depression, post-traumatic stress disorder (PTSD), and eating disorders.

The outcome of Awakn's Phase IIa clinical trial, which examined MDMA-assisted therapy as a treatment for AUD, was very positive. The trial [results](#), which were published in *The Journal of Psychopharmacology* in February 2021, demonstrated the potential for MDMA-assisted therapy to be used as an effective treatment for AUD.

It is estimated that over 400 million people globally suffer with AUD and only 16% of those suffering seek out treatment. Unfortunately, even for those that do pursue treatment, relapse rates remain consistently high with 75% resuming dangerous levels of alcohol consumption within 12 months of treatment. A new more effective treatment for AUD is desperately needed, particularly given the increase of alcohol dependence following the COVID-19 global pandemic.

**Anthony Tennyson, Awakn CEO commented** *"We are very excited to be working with Catalent, who are a world leader in the drug delivery field. This agreement further strengthens the IP moat for our MDMA program. Having the right partner to help facilitate our upcoming Phase IIb clinical trial is key, but it also provides a defined pathway towards regulatory approval, which is the goal of the program. With such a large cohort of people globally suffering with AUD and a current standard of care that lacks long-term efficacy, a new more effective treatment has never been more needed."*

"Catalent has a proven track record of working with partners to develop, launch and supply new therapies that are differentiated from traditional and generic dose forms, and that are difficult to emulate," **commented Tom Hawkeswood, President, Division Head of Pharma Product Delivery, Catalent.** "Because it dissolves almost instantly in the mouth, Zydys technology provides multiple potential benefits including initial acceptance, adherence, convenience, and advantages for products where a rapid onset of action is possible."

**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.

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## **About Catalent**

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs.

Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply around 80 billion doses of nearly 8,000 products annually. Catalent's expert workforce of approximately 19,000 includes more than 3,000 scientists and technicians.

Headquartered in Somerset, New Jersey, the company generated nearly \$5 billion in revenue in its 2022 fiscal year. For more information, visit [www.catalent.com](http://www.catalent.com).

## **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.

Investors are cautioned that any such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking information. For more information on the Company, investors are encouraged to review the Company's public filings on SEDAR at [www.sedar.com](http://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.

This news release does not constitute an offer to sell, or a solicitation of an offer to buy, any securities in the United States. The Company's and Awakn's securities have not been and will not be registered under the United States Securities Act of 1933, as amended (the "**U.S. Securities Act**") or any state securities laws and may not be offered or sold within the United States or to U.S. Persons unless registered under the U.S. Securities Act and applicable state securities laws or an exemption from such registration is available.

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