The light at the end of the tunnel for Awakn Life Sciences addiction treatment by Psychedelic therapeutics

written by InvestorNews | January 27, 2022 As an investor, I like to look for companies that have tremendous leverage to success. I often write about junior mining stocks and get pretty interested when they have plenty of drill results pending. If it is a pure exploration play, then news of any sort of economic drill holes can often make a stock pop (unless you are unfortunate enough to announce your information in a market like we've seen over the last week or so, in which case who knows what will happen). It's not often you can find this same kind of opportunity in a biotech company. Typically, there is a bloated share structure given it often takes many years, and a lot of money, to achieve any notable success. Certainly, it can happen, if you find a cure for cancer or perhaps create a vaccine that stops a pandemic, then it doesn't really matter what your share structure looks like, you can still get that magnificent rally that every shareholder dreams about. But today we are going to look at a company that isn't your typical biotech firm.

Awakn Life Sciences Corp. (NEO: AWKN | OTCQB: AWKNF) is in the unique position of having a relatively tight share structure (only 25 million shares outstanding), recently announced positive results from a Phase IIb Clinical Trial, recorded its first-ever quarterly revenue in Q3/21, and has ample cash in the treasury (C\$ 5.7 as of Oct 31/21) to fund operations for the foreseeable future. I view this as an outstanding starting point

for a biotech company that could provide an investor with pretty good upside to any future successes along the way. So, let's have a closer look at Awakn and what that upside could be.

Awakn Life Sciences is a biotechnology company, researching, developing, and delivering psychedelic therapeutics to better treat addiction. Awakn's team consists of world leading chemists, scientists, psychiatrists, and psychologists who are advancing the next generation of psychedelic drugs and therapies to be used together in treatments. Unlike other medical disciplines, psychiatry focuses on maintenance rather than cure, and on symptom suppression rather than addressing the root causes of these illnesses. The exception is psychedelics and psychedelic-assisted psychotherapy which have the potential to radically change addiction treatment and deliver significantly better patient outcomes.

But why the focus on addiction? It is because addiction is one of the biggest unmet medical needs globally with substance and behavioral addictions affecting a significant proportion of the global adult population. As a potential investor here are some key metrics: The global substance addiction treatment industry was valued at US\$16 billion in 2021 and is forecast to increase to US\$25 billion by 2027, while the overall global addiction rehabilitation and recovery industry was estimated to be valued at US\$140 billion per annum in 2021. The latter includes behavioral disorders like gambling, binge eating, and internet gaming (which my wife claims I suffer from).

Awakn is making excellent progress in tapping into the addiction market, particularly Alcohol Use Disorder (AUD). AUD is a pervasive and persistent public health issue, affecting at least 390 million people globally. Treatment rates are low and relapse rates, post-treatment, tend to be high. New and more effective treatments are urgently needed. To that end, on January 11th the Company announced ground-breaking positive data from their <u>Phase</u> <u>II A/B trial</u> using Ketamine-Assisted Therapy for the treatment of AUD. Primary and secondary endpoints were achieved, including 86% abstinence over 6 months post-treatment and no serious adverse events (results were published in the American Journal of Psychiatry). The positive Phase II trial outcome paves the way to progress this trial into Phase III, with the ultimate aim of securing regulatory approval for Ketamine-Assisted Therapy to treat AUD in the UK through the NHS and potentially in other regions.

On the revenue front, Awakn achieved its first earning of patient service revenue through the acquisition of Axon, a leading ketamine-assisted psychotherapy clinic in Norway, which the Company acquired on October 5, 2021. Additionally, their Bristol, UK clinic was opened in October 20, 2021 with patient intake beginning in November. Each clinic is anticipated to generate on average £3 million (US\$4 million) revenue per annum and Awakn targets 20 clinics by the end of 2024. A third clinic in London is expected to open in Q1/22 with leases currently under negotiation in Manchester and Dublin.

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Source: Awakn Life Sciences Corporate Presentation

Depending on the rollout of the clinics and the corresponding uptake of the associated services it's not unreasonable to see Awakn get close to generating enough revenue to self-fund its ongoing research and clinical trials. Awakn had a market cap of C\$51 million as of yesterday's close, which could be a paltry 2x annualized patient service revenue by mid-2022. All of a sudden that would make this Company very positively levered to any clinical success given the small number of shares outstanding and potentially little to no further dilution required to fund R&D.

Awakn Life Sciences' new psychedelic drug treatment for alcohol addiction moving to clinical trial

written by InvestorNews | January 27, 2022 As we all know alcohol addiction is one of the worst addictions in society costing billions per year. A 2010 study found that alcohol abuse in the USA costs the country <u>US\$249 billion a</u> <u>year</u>. A Washington Post report <u>stated</u> that "total cost manifests itself primarily in things like early mortality due to alcohol (\$75 billion of the total), lost productivity and absenteeism at work (\$82 billion), health-care costs (\$28 billion), crime (\$25 billion) and car crashes (\$13 billion)."

Awakn <u>states</u>: "Between 15-20% of adults suffer from substance addictions, and many others from behavioral addictions.....\$17 billion per year (and rising) is spent on private addiction treatment."

With this in mind, the company has recently had some very encouraging results proving the effectiveness of ketamineassisted psychotherapy on alcohol use disorder (AUD).

Some comments from patients in the study *included*:

- "It helped family wise, relationship wise, in every, every single avenue of my life, It's changed it."
- "I wouldn't be here now if it wasn't for it. I can definitely say that."

"I feel I have much less desire to drink now than I used to. And I think what it is, I actually, I think I enjoy it less now."

The Company is <u>Awakn Life Sciences Corp.</u> (NEO: AWKN | OTCQB: AWKNF) ("Awakn") and they believe their treatment can "revolutionise the treatment of alcohol use disorder."

Awakn is developing a revolutionary new approach for treating substance and behavioral addictions

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<u>Source</u>

The 'Ketamine in the Reduction of Alcoholic Relapse' (KARE) psychotherapy intervention study results

The actual study results will be published in the American Journal of Psychiatry later this year. However, judging from the patient's comments above and the insider's comments below the results appear to be outstanding.

Professor of Psychopharmacology at the UK's University of Exeter (UoE), Celia Morgan <u>commented</u>: "We are delighted that the findings are to be published in *the American Journal of Psychiatry*. This new approach looks set to revolutionize the treatment of alcohol use disorder. We are excited to partner with Awakn for the next steps in the journey of ketamine-assisted therapy into a licensed treatment for this group of patients with limited treatment options."

Awakn CEO, Anthony Tennyson, <u>commented</u>: "This is a very exciting moment for ketamine-assisted psychotherapy. For so many people who are suffering from alcohol addiction, for whom the current treatments just aren't working, a successful phase II a/b trial and a unified ambition to progress this forward to a pivotal trial, gives real hope to those seeking a better and healthier future."

Note: Professor Morgan headed up the KARE study. Awakn has acquired the rights to this research.

More about Awakn Life Sciences

Awakn is a biotechnology company with clinical operations that researches, develops, and delivers psychedelic and other medicines to treat all types of addiction, as well as some other mental health disorders. Some examples of the conditions treated by Awakn include anxiety, depression, PTSD, eating disorders, and various types of addiction (alcohol, drugs, gambling etc).

Awakn's team consists of world leading chemists, scientists, psychiatrists, and psychologists who are developing and advancing the next generation of psychedelic drugs, therapies, and enabling technologies to treat addiction. The team was <u>recently strengthened by adding Kate Butler</u> as CFO. Ms. Butler joins Awakn from Vectura Group plc, where she was the Group Financial Controller leading the team's strategic, finance and M&A activity. Prior to that, she was Head of Finance for EMEA Cell Therapy (Kite Europe) and EMEA Controller for Gilead Sciences Inc.

In terms of commercialization, Awakn is still in the early stages. Awakn did <u>announce</u> in November 2021 a MOU with UK National Health Service ("NHS") provider Devon Partnership NHS Trust, to increase access to psychedelic-assisted psychotherapy in the UK. The announcement <u>stated</u>:

"The partnership establishes a framework and strategic relationship to assess NHS organizational readiness for ketamine-assisted psychotherapy. It will investigate how to enhance the evidence base for ketamine-assisted psychotherapy as an alternative treatment for Alcohol Use Disorder and treatmentresistant depression within the NHS. The partnership will also assess how best to accelerate the on-label use of ketamineassisted psychotherapy to treat AUD at scale."

Awakn plans to deliver their evidence backed psychedelic therapies in clinics in the UK and Europe and through licensing partnerships, globally, starting already. As <u>announced</u> in October 2021, Awakn Clinics Bristol has received Care Quality Commission's (CQC) formal approval to begin treatments. The news <u>stated</u>: "The clinic will begin delivering ketamine-assisted psychotherapy treatments in October."

There is also now an <u>Awakn Clinics Oslo</u>, in Norway.

A summary of Awakn's business plan

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Source: <u>Awakn Life Sciences company presentation</u>

Closing remarks

Awakn is developing a revolutionary new approach for treating substance and behavioral addictions. Awakn's latest alcohol study results will also soon be followed with their gambling addiction study results (some details on the study <u>here</u>), also conducted by the University of Exeter.

Alcohol addiction is just one of many addictions that Awakn is working on to deliver effective and safe treatment. All of this means that Awakn is beginning to tap into a truly massive untapped sector where for years treatments either didn't exist or were often ineffective. Awakn is now commercializing their products with their new Awakn clinics in Bristol in the UK and Oslo in Norway, as well as plans for further expansion. Awakn Life Sciences trades on a market cap of just C\$71 million. One to watch as the stock has been on the rise in 2021 and the Company looks to be making some serious progress.

Further reading

 <u>"This Is Something That Changed My Life": A Qualitative</u> <u>Study of Patients' Experiences in a Clinical Trial of</u> <u>Ketamine Treatment for Alcohol Use Disorders</u>

FSD Pharma, Developing Treatments for Mental Health Disorders

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In a recent InvestorIntel interview, Tracy Weslosky spoke with Anthony Durkacz, Founder, Interim CEO and Executive Co-Chairman of <u>FSD Pharma Inc.</u> (NASDAQ: HUGE | CSE: HUGE) about FSD Pharma's recent <u>acquisition</u> of Lucid Psycheceuticals Inc., and how it adds potential for neurodegenerative disease treatments and mental health in a novel way.

In this InvestorIntel interview, which may also be viewed on YouTube (click here to subscribe to the InvestorIntel Channel), Anthony said that the Lucid acquisition adds two leading edge compounds to FSD Pharma's diversified drug development pipeline. He told InvestorIntel that the acquisition gives FSD Pharma an exclusive worldwide patent, from the University Health Network, to a family of compounds from which it could develop unique potential treatments for some of the most challenging neurodegenerative diseases, such as Multiple Sclerosis, in addition to a psychedelic drug candidate targeting mental health disorders.

To watch the full interview, <u>click here</u>.

About FSD Pharma Inc.

FSD Pharma is a life sciences holding company dedicated to building a portfolio of diversified therapeutic assets and innovative healthcare and biotech services. Currently, FSD is actively pursuing potential acquisition targets in the healthcare and biotech space to bring innovative treatments to market to treat various mental health disorders and neurodegenerative diseases.

To learn more about FSD Pharma Inc., click here

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If you have any questions surrounding the content of this interview, please email <u>info@investorintel.com</u>.

Awakn researching psychedelics for a better future

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Whether you are familiar with it or not there have been relatively rapid advancements in health care and research utilizing psychedelic-centered solutions to treat addiction and mental illness. In fact, in Canada, Horizons ETFs have a Psychedelic Stock Index ETF (TSX: PSYK) which should tell you that this isn't a new or underground market theme. In the U.S. there is Defiance ETFs' Next Gen Altered Experience ETF (AMEX: PSY) that focuses on the usage of psychedelics, medical cannabis, and ketamine for medicinal and health treatment purposes. In other words, this is an evolving industry that interested investors should already be paying attention to. If you haven't paid any attention thus far or weren't even aware of this, then today is your lucky day as we are going to have a look at one of these life science companies involved in the psychedelic industry. Awakn Life Sciences Corp. (NEO: AWKN) is a biotechnology company with clinical operations; researching, developing, and delivering psychedelic medicine to better treat addiction. Awakn's team consists of world leading chemists, scientists, psychiatrists, and psychologists who are developing and advancing the next generation of psychedelic drugs, therapies and enabling technologies to treat addiction. Unlike other medical disciplines, psychiatry focuses on maintenance rather than cure, and symptom suppression rather than addressing the root causes of these illnesses. The exception is psychedelics and psychedelic-assisted psychotherapy which has the potential to radically change addiction treatment and deliver significantly better patient outcomes.

Mental health and addictions are the 5th leading cause of illness globally. A WHO report on the percentage of people aged 15 years and older with harmful alcohol use or dependence globally in 2016, suggested that 15-20% of the global adult population, or between 840 million and 1.1 billion people, suffer from addiction such as alcohol, gambling or tobacco use. And 70% of that global treatment market is estimated to be from the U.S. and Europe. The global substance addiction treatment industry is currently valued at US\$17.5 billion per annum and is forecast to increase to US\$31.5 billion per annum by 2027. Without trying to make light of the situation, I wouldn't be surprised if a global pandemic doesn't help spur this increase on a little quicker.

It's obvious there is a problem, and conventional methods to remediate or cure this problem appear to be having limited success. Of those who are deemed to suffer from Alcohol Use Disorder (AUD), only 16% of those suffering seek treatment, with a 70% relapse rate within 12 months. Hence the need to build a better mouse trap, so to speak. The team at Awakn is focused on being the leader in psychedelic drug and therapy research to treat addiction. They ascribe to deliver psychedelic treatments for addiction and other mental health conditions in a <u>chain of Awakn owned clinics</u> in the UK and EU.

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Source: Awakn Life Sciences Corporate Presentation

Along with the clinics the Company recently announced it had undertaken a program of clinical research designed to demonstrate the effectiveness for ketamine-assisted psychotherapy against multiple addictions. Awakn's ketamine research program will focus initially on treating AUD and gambling addiction. The program will consist of a late-stage clinical trial focused on AUD, a mechanistic study focused on gambling addiction and intellectual property development activities. Awakn will be the only company in the world providing evidence-backed ketamine-assisted psychotherapy for AUD. They are also in a Phase IIB clinical trial to assess the efficacy of MDMA-Assisted Therapy for AUD, having recently announced the filing of patent applications in the U.S. for two next-generation novel MDMA-derived new chemical entities. This further strengthens Awakn's intellectual property portfolio and pipeline for the treatment of a broad range of addictions.

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Source: Awakn Life Sciences Corporate Presentation

If you haven't heard of Awakn before, it may be because they just <u>started trading on the Neo Exchange</u> on June 23rd as a result of a reverse takeover. Concurrent with this transaction they closed an \$8.3 million financing at \$2.50 which, combined with prior working capital, is anticipated to provide enough funding for the next 12 months. By then the Company should be generating at least some revenue from its clinics and hopefully, have a lot more news out about its development drug pipeline. With only 24.5 million shares outstanding (23% owned by management and insiders) and a \$44 million market cap, there could be a lot of leverage to good news. So it's time to get up to speed on psychedelics.