Anthony Tennyson of Awakn Life Sciences on commercializing its addiction treatment therapeutics

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In this InvestorIntel interview with host Tracy Weslosky, <u>Awakn</u> <u>Life Sciences Corp.</u>'s (NEO: AWKN | OTCQB: AWKNF) Co-Founder & CEO Anthony Tennyson talks about advances in the company's commercializing therapeutics to treat addiction, particularly Alcohol Use Disorder, which affects 400 million people globally.

In the interview, which can also be viewed in full on the InvestorIntel YouTube channel (click here), Anthony discusses adding Dennis Purcell, founder of major life sciences venture capital firm Aisling Capital LLC, as a Special Advisor to the CEO as part of Awakn's strategy to pursue an uplisting to the NASDAQ next year. Anthony also talks about Awakn being unique in that it has four R&D programs and two commercialization streams which include clinics currently operating in the U.K. and are currently producing revenue for the company with a 24% quarter over quarter revenue growth from Q4 last year to Q1 in 2022.

Anthony talks about how Awakn's therapeutics represents the third generation of addiction treatment, with therapeutics that disrupt the "brain circuits that house the behaviors that drive the addiction, and that approach enables us to develop therapeutics to treat both substance and also behavioral addictions." Awakn's lead program that combines ketamine and therapy together to treat Alcohol Use Disorder has "delivered three times better results than the current standard of care, and that really has the ability to transform the treatment of Alcohol Use Disorder on a global basis, and has the ability to provide hope for individuals, families and communities."

To access the full InvestorIntel interview, click here

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About Awakn Life Sciences Corp.

Awakn Life Sciences is a biotechnology company, researching, developing, and delivering revolutionary therapeutics to treat addiction. Awakn's team consists of renowned research experts and world leading chemists, scientists, psychiatrists, and psychologists. Addiction is one of the biggest unmet medical needs of our time, affecting over 20% of the global population and is an industry valued at over \$100bn per annum. Awakn is disrupting this underperforming industry by rapidly advancing the next generation of psychedelic drugs and therapies to be used in combination, through preclinical research and clinical stage trials.

To learn more about Awakn Life Sciences Corp., click here

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Addiction may have met its match in Awakn Life Sciences

therapeutics

written by InvestorNews | July 18, 2022 Addiction is one of the biggest unmet medical needs globally with substance and behavioral addictions affecting a significant proportion of the global adult population. 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 & 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, all of which I'm sure have increased rapidly over the past 2 years which saw much of the world locked in our rooms like a bunch of insolent school children.

The challenge with behavioral and substance addictions is that it tends to be a poorly treated, chronic disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. Treatment rates are typically low and relapse rates are typically high. For example, with Alcohol Use Disorder (AUD), which affects 5% of the global adult population, only 16% of those suffering with AUD seek treatment and there is a 70% relapse rate within the first 12 months for those that do seek treatment. Up to another 27% of the US adult population are affected by behavioral addictions. Which really puts the market valuations noted above into context. Imagine if treatment were more effective and easy to access what the overall market could be valued at.

The good news is, there is a company out there that is trying to make a difference, <u>Awakn Life Sciences Corp</u>. (NEO: AWKN | OTCQB: AWKNF). Awakn is a biotechnology company, researching, developing, and commercializing combined therapeutics to treat

addiction, with a focus on Alcohol Use Disorder. Awakn's team consists of renowned research experts, world leading chemists, scientists, psychiatrists, and psychologists. Awakn is working to disrupt this underperforming industry by advancing the next generation of drugs and therapies to be used in combination, through preclinical research and clinical stage trials.

What differentiates Awakn from peers who are simply researching drugs to cure whatever ails you is their new proprietary combined therapeutics that approach the treatment of addiction in a radically different way than before. Based on new research, Awakn's drugs will target the brain circuits that drive addiction through multiple receptors rather than single drug receptors. These circuits control the behavioral drivers of addiction. By focusing on circuit mechanisms rather than isolated receptors Awakn's approach has the potential to be effective in the treatment of both substance and behavioral addictions. This disruption allows the individual to escape from the repetitive addictive behaviors and thoughts, and in doing so engage with a psychotherapeutic process to enable lasting positive change. This is where Awakn's proprietary therapy comes in. Their therapies work in conjunction with their medicines, enabling the patients to regain control over their lives and helping them to learn new more adaptive ways to respond to addictive urges, cravings and the underlying processes that drive them.

Recent news flow from the Company is confirming that success with the May 19th announcement of the completion of the <u>world's</u> <u>first ketamine treatment study for behavioral addictions</u>. The study investigated ketamine as a new treatment approach for these behavioral addictions by opening a window in which the brain can make new connections to change behavior. The results from the study indicate the desired effects via potentially

novel mechanisms and these results merit a larger study and further exploration, which Awakn is now initiating. The study also supports Awakn's Intellectual Property (IP) strategy and existing filed patent applications, positioning Awakn as a leading company in the behavioral-addiction therapeutic research and development industry. This news was followed a week later with the filing of a Patent Cooperation Treaty (PCT) application for the treatment of behavioral addictions with ketamine and ketamine-assisted psychotherapy. The patent claims would give Awakn exclusive rights to use ketamine and ketamine-assisted therapy for the treatment of behavioral addictions. With no effective pharmacological treatments available globally at present for behavioral addictions, the study results, and the patent filing, position Awakn at the forefront of the industry at a time when rates of behavioral addictions are increasing at an alarming pace and sufferers have few treatment options which deliver poor outcomes.

Additionally, the Company has opened three fully-operational ketamine-assisted therapy clinics, two in the UK and one in Norway, which are now generating revenue for Awakn. Each clinic is anticipated to generate on average £3 million (US\$3.75 million) revenue per annum. The target is 15 - 20 clinics by the end of 2024, with an average of 6 treatment rooms per clinic. The next step is to then take the protocols established at these operational clinics and license them to partners outside of the environments where Awakn has a physical footprint, starting with the US and Canada in Q3 of this year.

At the end of their last quarter (Jan 31/22) the Company still had some work to do to generate enough revenue to cover its cash flow needs but that could be changing quickly. With a market cap of C\$32 million and a tight share structure with only 27 million shares outstanding, of which 61% are escrowed, future good news could have a material impact on the share price of Awakn.

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

written by InvestorNews | July 18, 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 <u>Phase IIb Clinical Trial</u>, recorded its first-ever <u>quarterly revenue in Q3/21</u>, 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.

Hemostemix steps into the new year with capital and its critical clinical study data in hand

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With a new management team spearheading <u>Hemostemix Inc.</u> (TSXV: HEM | OTC: HMTXF), the Company started 2021 with its <u>critical</u> <u>clinical study data</u> in hand. Raising over \$4 million in 2020 and then in December adding an additional \$4 million to the coffers (\$2.75 million at a 50% premium), Hemostemix completed a 1for-20 share consolidation as it charges into the New Year.

Receiving a copy of its entire clinical trial database relating to the clinical trial for Critical Limb Ischaemia (CLI) using its ACP-01 therapy (Angiogenic Cell Precursors) in <u>November 2020</u> was a key event for Hemostemix's management team and it garnered real interest from the market.

Hemostemix – Platform for Stem Cell Therapies

Based in Calgary and founded in 2006, Hemostemix is a clinicalstage biotechnology company specializing in blood-derived stem cell therapeutics with its lead product (ACP-01) in Stage 2 clinical trials for the treatment of CLI. CLI is a disease caused by the narrowing of arteries in the limbs, particularly the legs, hands, and feet, causing chronic pain and soreness. Untreated CLI can sometimes require the amputation of the specific limb.

Stem cell treatments have been used for over 30 years to treat people with cancer conditions such as leukemia and lymphoma.

There are two main types of stem cell transplants: allogeneic and autologous. In an allogeneic stem cell transplant procedure, the patient receives stem cells from a donor. In an autologous stem cell transplant procedure, the patient provides themselves the stem cells for the procedure from various sources, including bone marrow or blood.

Hemostemix's autologous stem cell therapy platform uses the patient's own blood to harvest the stem cells and the treatment helps to restore circulation in the damaged tissues.

Hemostemix has a strong intellectual property (IP) portfolio of <u>91 patents</u> and has treated more than 500 patients with clinical results showing an improvement in 83% of the patients receiving its ACP-01 stem cell therapy.

Advantages with Hemostemix's process include the use of blood, which is safer and less invasive than extracting bone marrow, and since you are using the patient's own blood, there is no immune rejection.

The clinical trials have shown that ACP-01 is safe and effective in the treatment of CLI. Now that Hemostemix has received the entire clinical trial database, it has entered into a contract with a new Clinical Research Organization (CRO) to complete the midpoint statistical analyses of the efficacy of ACP-01 and expects to publish the results this quarter.

Hemostemix - Not a 1-Trick Pony Company

ACP-01 has the potential to treat other conditions such as Angina, Ischemic & Dilated Cardiomyopathy, and Peripheral Artery Disease (PAD). Currently, Hemostemix is preparing for Phase 2 trials for the treatment of Angina and is seeking joint-venture partners to fund the other Phase 2 trials.

Hemostemix has also developed NCP-01 (Neural Cellular Precursor) from blood with the potential, through building new neuronal lineage cells in a patient, to treat Alzheimer's disease, Amyotrophic Lateral Sclerosis (ALS), Parkinson's disease, spinal cord injuries, and stroke-related issues. NCP-01 is currently in the R&D phase and is pre-clinical.

Market Size

According to the American Heart Association, Cardiovascular disease (CVD) accounted for approximately 1 of every 3 deaths in the United States in 2019.

Factors that increase the risk of CLI include diabetes, high cholesterol levels, high blood pressure, obesity, or smoking, all risk factors also associated with CVD.

Unfortunately, most of these factors are increasing at an alarming rate – a study by the Centers for Disease Control and Prevention (CDC) in the United States, showed the prevalence of diagnosed diabetes has more than doubled from 3.3% in 1995 to 7.40% in 2015, affecting 23.4 million Americans.

According to a market research report released in 2019, the value of just the global CLI treatment market is projected to reach US\$5.39 billion by 2025, up from US\$3.13 billion in 2018, at an annual growth rate of 8%.

Competitive Landscape and Market Cap Comparisons

Even with Hemostemix's recent market surge, its market cap is only C\$32.5 million. Similar-sized biotech companies focusing on CLI trade much higher.

Cynata Therapeutics Limited (ASX: CYP) is an Australian biotechnology company with a Phase 2 clinical-stage trial for its stem cell therapy for CLI using bone marrow and has a market cap of C\$93.6 million.

Pluristem Therapeutics Inc. (NASDAQ: PSTI) is a Phase 3 biotherapeutics company, based in Israel, that also has an allogeneic cell therapy for the treatment of CLI using the placenta and has a market cap of C\$231.9 million.

In November 2020, Bristol-Myers Squibb Company (NYSE: BMY) bought MyoKardia, Inc. for US\$13.1 billion. MyoKardia was a clinical-stage biopharmaceutical company that developed therapies for the treatment of cardiovascular diseases and its lead product was a Phase III clinical trial drug used in the treatment of hypertrophic cardiomyopathy (HCM).

As a company shifts from Phase 2 to Phase 3 clinical trials, the market cap often has a step-function shift higher, making it an ideal time to look at Hemostemix.

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SOURCE: