

Advancing the First Potential FDA-Approved Treatment for Cannabis Withdrawal

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Jason Goodson, Chief Business Officer of PleoPharma, discusses the company's pivotal Phase 3 programme for PP-01, the growing burden of cannabis use disorder, and why addressing withdrawal symptoms may be key to improving long-term recovery outcomes.



As cannabis use expands globally and regulatory frameworks continue to evolve, healthcare systems are increasingly confronting the growing burden of cannabis use disorder (CUD). Despite affecting more than 20 million people in the United States alone, there are currently no FDA-approved therapies specifically designed to treat cannabis withdrawal symptoms—one of the primary drivers of relapse and treatment failure. **At BIO International Convention 2026 in San Diego, BioSpectrum Asia spoke with Jason Goodson, Chief Business Officer of PleoPharma,** about the company's pivotal Phase 3 programme for PP-01, its FDA Fast Track designation, and the broader public health opportunity to bring evidence-based treatments to a rapidly growing patient population.

PleoPharma recently achieved the first-patient-in milestone for its pivotal Phase 3 trial of PP-01. What does this milestone represent for the company and for the broader treatment landscape in cannabis use disorder?

Our first randomized patient in our Ph 3 study represents an important milestone which brings us significantly closer to helping the 20.6 million people in the US (per US Gov) with Cannabis Use Disorder (CUD), and potentially the first safe and effective FDA approved treatment to mitigate Cannabis Withdrawal Symptoms (CWS) in patients suffering with CUD. Although there is no FDA approved or unapproved or effective treatment for Cannabis Addiction today, an estimated 1.4 million people received some type of treatment in 2024 (per US Gov) which highlights the magnitude of this problem and how important it is that PP-01 has reached this milestone.

Cannabis withdrawal remains an under-recognised clinical challenge. What unmet needs do you believe are still not being adequately addressed for patients undergoing withdrawal?

CWS is a major contributor to Cannabis addiction and has been shown to predict if a patient can achieve abstinence or reduction of cannabis use. Cannabis Withdrawal is not a short 3 to 5-day acute intense event as with opioids or alcohol but rather a protracted severe withdrawal that can last for over 30 days. This is one of the reasons the relapse rates are over 90%

when treating CUD. Many patients who try to take a break, reduce use, or quit experience anxiety, significant agitation, lack of or impaired sleep for weeks to months, depression, severe GI upset, and many uncomfortable physical symptoms. Individuals are often not aware that they are suffering from Cannabis Withdrawal. Focusing on and mitigating withdrawal makes recovery possible by giving the patient with CUD the chance for abstinence and/or harm reduction.

PP-01 has received FDA Fast Track designation. How does this recognition influence your development strategy and anticipated regulatory pathway?

Our Fast Track designation underscores the importance of finding a solution for CWS/CUD with the FDA acknowledgment that CUD/CWS is a significant serious condition and unmet medical need for which a safe and effective treatment is not currently available.

What insights from the recent CPDD presentations most strongly reinforce the need for new therapeutic options targeting cannabis withdrawal symptoms?

There has been a great deal of interest from investigators and healthcare providers who are seeking an effective treatment to help their patients. Many have expressed that there is currently a huge void that PP-01 may be able to fill for their patients who are seeking help with their cannabis dependence.

As cannabis use continues to evolve globally, how significant do you believe the commercial and public health opportunity is for effective evidence-based treatments in this space?

Given that the US alone has over 20 million people with CUD and the treated population has been growing on average by over 20% a year over the past 6 years, we believe the US is representative of need throughout the world.

Looking ahead, what are the key milestones investors, clinicians, and potential partners should watch for from PleoPharma over the next 12–18 months?

Our next big milestone is last patient/last visit for our current P3 study and starting work on a program to help adolescents who are struggling with cannabis dependence/SUD/addiction.