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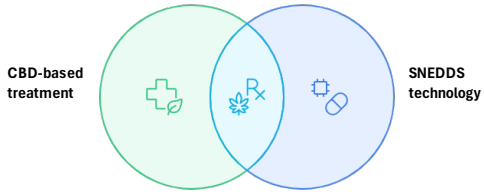
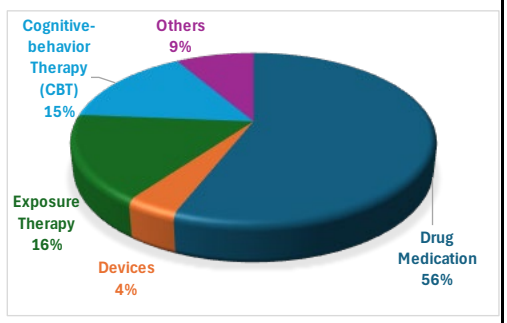
ENHANCED SOCIAL ANXIETY TREATMENT



PRESCRIPTION CANNABIDIOL (CBD)

GLOBAL SOCIAL ANXIETY TREATMENT REVENUE MARKET SHARE BY TREATMENT TYPE



COMPANY DESCRIPTION

EmpowerPharm Inc. (“EmpowerPharm” or "the Company") is a Canadian pharmaceutical company dedicated to developing pharmaceutical grade **cannabidiol (CBD)†** therapies in solid oral dose formats. Its primary focus is on advancing treatments for mental health disorders, particularly **social anxiety disorder (SAD).** The Company applies its proprietary formulations based on **Self-Nanoemulsifying Drug Delivery System (SNEDDS)** technology to improve the bioavailability of CBD to enhance its therapeutic effectiveness for a more impactful treatment. With promising Phase 2 trial outcomes, the Company is progressing to Phase 3 trials, targeting prescription drug approvals in Canada, the U.S., and select international markets, while preparing for a potential market launch. Phase 2 trials identified an effective CBD dose of 300 mg, prompting the development of new high-bioavailability 150 mg capsules for twice-daily use in Phase 3. EmpowerPharm’s expanding intellectual property (IP) portfolio secures market exclusivity and a competitive edge, supporting its focus on developing new products and indications, including proprietary tablet and soft gel capsule dosage forms. The Company operates state-of-the-art, fully licensed facilities that support both research and development (R&D) as well as the eventual commercial pharmaceutical production.

KEY POINTS

- Social anxiety affects over 15 million adults in the U.S. and more than 300 million worldwide, with the global market for treatments projected to expand from approximately $12 billion in 2022 to $16 billion by 2030.
- Current SAD treatments largely include **Selective Serotonin Reuptake Inhibitors (SSRIs)**, which carry side effects and represent upwards of 80% of social anxiety prescriptions, and **benzodiazepines**, which can be addictive.
- Approximately 60% of individuals with social anxiety self-medicate with cannabis, though it lacks FDA or Health Canada approval. Developing a federally approved, reimbursable prescription product within this category presents a unique market opportunity, with inelastic demand supporting a strong price point.
- EmpowerPharm’s co-founders Aubrey Dan and Peter Billiaert bring extensive experience from Novopharm and Teva, strengthening the Company’s capabilities in scaling, regulatory approval, and commercialization.
- EmpowerPharm has raised over CD$95 million, investing heavily in R&D, clinical trials, and manufacturing, and aims to secure an additional $100 million to fund Phase 3 SAD trials, as well as to expand its pipeline and scale up soft gel capsule production.
- The Company's growth plan includes potential exit opportunities like M&A, attracting institutional investors, or pursuing an IPO.
- With its cutting-edge technology, regulatory compliance, and solid financial foundation, EmpowerPharm believes that it is in a solid position for sustained growth and success within the pharmaceutical industry.

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Executive Overview

Note: All amounts are in U.S. dollars unless otherwise specified.

EmpowerPharm Inc. is pioneering prescription cannabidiol (CBD) therapies in solid oral dose formats, with a primary focus on treating mental health disorders, particularly social anxiety disorder (SAD). As a non-intoxicating compound derived from the Cannabis sativa plant, CBD is recognized for its therapeutic benefits without the intoxicating effects. EmpowerPharm's CBD product is designed to deliver a standardized, high-quality dose with enhanced bioavailability, providing a safer alternative to current SAD treatments, including Selective Serotonin Reuptake Inhibitors (SSRIs) and benzodiazepines, which carry significant side effects and risk of addiction, respectively. Through collaborations with psychiatric experts, the Company has identified a critical need for effective, non-addictive options for social anxiety. EmpowerPharm leverages its proprietary CBD drug formulations based on Self-Nanoemulsifying Drug Delivery System (SNEDDS) technology to boost CBD's bioavailability and to improve therapeutic impact and efficacy. Following promising results in a Phase 2 proof of concept clinical trial, the Company is advancing toward Phase 3 trials, aiming for prescription drug approvals in Canada, the U.S., and select international markets, quickly followed by commercial market launches.

Led by seasoned industry veterans, Aubrey Dan and Peter Billiaert, EmpowerPharm has raised over CD$95 million to date, with substantial investments directed toward R&D, clinical trials, and manufacturing. The Company now seeks an additional $100 million commitment based on milestone achievements to support its continued clinical program with Phase 3 trials, expand its therapeutic pipeline, and scale up the production of its soft gel capsules. EmpowerPharm's state-of-the art manufacturing facilities are GMP-compliant and fully licensed, holding a **Drug Establishment License (DEL)**, Cannabis Drug License (CDL), and Standard Processing License (SPL). These facilities are equipped for both research and development as well as commercial production. This positions the Company for strategic growth opportunities, including potential mergers and acquisitions (M&A), institutional investment (IM), or an initial public offering (IPO).

Cannabidiol

Cannabidiol, or CBD has garnered significant attention for its potential therapeutic benefits, such as relieving pain, reducing anxiety, aiding sleep disorders, and treating certain types of seizures. Unlike **tetrahydrocannabinol (THC)**, the well-known psychoactive component of cannabis, CBD does not produce a "high." CBD interacts with the body's endocannabinoid system in a non-intoxicating manner. It helps regulate essential physiological functions, including mood, pain perception, and immune response. Available in various forms, CBD can be found in recreational oils, tinctures, capsules, edibles, and topical creams, and is sold both over-the-counter (OTC) as well as in prescription medication, including the U.S market FDA-approved Epidiolex®, a CBD Oral Solution, with therapeutic indication for children's epilepsy. Epidiolex® was initially marketed by GW Pharmaceuticals, which was acquired by Jazz Pharmaceuticals.

Self-Nanoemulsifying Drug Delivery System (SNEDDS)

EmpowerPharm's cutting-edge, proprietary cannabinoid drug formulations are based on the Self-Nanoemulsifying Drug Delivery System (SNEDDS) technological platform. The primary goal of these proprietary drug formulations was to improve the bioavailability of CBD. Being water-insoluble, CBD is difficult to absorb when taken orally. It is also unstable and often loses potency due to light and air exposure. The Company's proprietary SNEDDS formulations improve drug absorption by forming nano-droplets in the stomach, allowing for higher drug delivery. EmpowerPharm's SNEDDS-based capsules and tablets support high CBD doses with a shelf life of 24 months and an easily scalable manufacturing process. EmpowerPharm's unique expertise with SNEDDS technology also opens the doors for the development of other low water solubility, hard to formulate drug products to reduce the required active ingredient, provide superior absorption and stability, and boost therapeutic effectiveness. Novel, patented drug formulations can extend commercial exclusivity of selected marketed products.

Market Opportunity for Approved CBD Therapies in Social Anxiety

Social anxiety disorder (SAD) affects 15 million U.S. adults or 7.1% of the U.S. population and 300 million worldwide, with symptoms often beginning around age 13. According to an Anxiety and Depression Association of America (ADAA) survey, 36% of people with SAD report experiencing symptoms for 10 or more years before seeking help. Despite the large market for treatment, valued at approximately $12 billion in 2022 and projected to reach $16 billion by 2030, innovation in SAD treatments has been limited over the past two decades.

SSRIs make up approximately 80% of prescriptions for treating SAD. However, up to 60% of individuals with SAD turn to self-medication with cannabis despite its lack of FDA or Health Canada approval for this use. A federally approved, clinically validated treatment eligible for third-party reimbursement offers a unique market opportunity, as demand for effective SAD solutions remains strong, supporting a substantial price point for an approved product. EmpowerPharm's SNEDDS platform, built on proprietary drug formulations and a scalable process for commercial manufacturing, has the potential to support expansion into new therapeutic areas, unlocking significant growth opportunities.

Phase 2 Proof of Concept Study

EmpowerPharm conducted a Phase 2 proof-of-concept clinical trial to assess the safety and efficacy of CBD for the treatment of SAD. This study has provided key information and parameters for the protocol design of pivotal Phase 3 trials. Although the Company aims to market CBD in capsule form, this study used a CBD Oral Solution. Intermediate formulations are often used for proof-of-concept trials. To save time, EmpowerPharm ran the study and capsule development in parallel, shaving two to three years off the development timeline. The trial included 239 U.S. patients across 19 clinics, divided into groups receiving 300 mg or 600 mg of CBD or a placebo daily in a randomized, double-blind setup. Results identified 300 mg as an effective daily dosage for patients with moderate to severe SAD.

Primary and Secondary Efficacy Measures

The primary efficacy measure used was the **Liebowitz Social Anxiety Scale (LSAS)**, an FDA-approved 24-question assessment that rates anxiety and avoidance levels across common social situations (shown in Figure 5, page 22), with improvements reflected in lower scores. The **Clinical Global Impression of Improvement (CGI-I)** served as a secondary measure, evaluating overall improvement from baseline through clinician assessments recorded weekly or biweekly (Figure 6, page 23).

Positive Phase 2 Results

On June 6, 2024, EmpowerPharm announced positive Phase 2 results for its CBD product in treating SAD. Testing doses of 300 mg and 600 mg, the study demonstrated effectiveness for a subset of patients, with a strong safety profile and high tolerability. These findings support the selection of the 300 mg daily dosing for a patient population with moderate to severe SAD for protocol design of a pivotal Phase 3 trial. Additionally, EmpowerPharm's proprietary CBD formulations meet International Council for Harmonization (ICH) guidelines, ensuring that key attributes meet pharmaceutical regulatory standards for quality.

Next Steps Prior to Phase 3 Trial

Preliminary planning is underway for Phase 3 activities during 2024 through 2025, including a medical consultation meeting, multiple discussions with the U.S. FDA, and a bridging study to link the Phase 2 CBD Oral Solution with the Phase 3 CBD capsule formulation. An exploratory Phase 1 comparative bioavailability study has already been completed with positive results. The Phase 3 program, scheduled for 2026 through 2027/8, includes two large studies involving approximately 400 patients, each with moderate to severe SAD. Participants are to receive either a 300 mg/day CBD capsule or a placebo, with a final bridging pharmacokinetic study running in parallel to Phase 3 trials. The estimated cost of the Phase 3 clinical program is CD$65 million, with an anticipated marketing approval targeted for 2029.

Epidiolex®: Key CBD Drug and EmpowerPharm's Advantage

Epidiolex®, approved by the FDA in 2018, was the first drug derived from purified CBD to treat seizures associated with rare epilepsy conditions in children, including **Dravet syndrome**, **Lennox-Gastaut syndrome**, and **tuberous sclerosis complex**. While it is a CBD Oral Solution, EmpowerPharm's product will be available in capsule form, offering greater patient convenience. The "blockbuster drug" concept—referring to drugs with annual sales over $1 billion—remains a key driver of profitability in the pharmaceutical industry. Epidiolex® achieved $845.5 million in sales in 2023, a 15% increase over the previous year, and reached $198.7 million in the first quarter of 2024, with year-end projections nearing $1 billion, underscoring the substantial market opportunity for pharmaceutical-grade CBD treatments. As the prescription CBD market is still emerging, companies like EmpowerPharm are strategically positioned to capitalize on its growth potential.

Intellectual Property (IP)

EmpowerPharm exclusively holds intellectual property (IP) rights for its tablet formulation technology under patent #PCT/CA2023/050819, filed June 14, 2023, and published December 21, 2023, with anticipated U.S. and Canadian approvals by 2028 and 2029, granting exclusivity until 2043. For the capsule formulation, a **Freedom to Operate (FTO)** search confirms its novelty in the U.S. and Canada. A provisional patent application is nearing filing, with U.S. and Canadian approvals expected by 2029 and 2030, respectively, securing exclusivity through 2045. Greater details on the Company's IP portfolio are provided in page 10.

Funding Requirements for Phase 3 Clinical Trials and Pre-Clinical Preparations

To support the Company's development efforts for Phase 3 clinical trials and pre-clinical preparations, a financial commitment of $100 million in equity is needed, with an initial portion to be paid upfront and the remaining funds disbursed upon achieving milestones over the next two to three years. This investment is intended to cover third-party **Clinical Research Organization (CRO)** costs, R&D for other indications using EmpowerPharm's SNEDDS technology, manufacturing scale-up, and working capital to ensure continued operations.

Funding Breakdown and Strategic Investments

Through August 2024, EmpowerPharm has raised over CD$95 million, initially through friends and family funding and later through convertible debt from Aubrey Dan, the primary funder (biography on page 7). Funds were largely allocated to R&D (CD$39.5 million), with additional spending on capital expenditures (CAPEX) for manufacturing facilities (CD$26 million) and general administrative (G&A) expenses (CD$27.3 million). Aubrey Dan holds 66% of the 58.6 million outstanding shares, granting him effective control of the Company through a voting trust and non-interest-bearing debentures totaling CD$79.0 million.

Exit Strategy

EmpowerPharm's exit strategy involves advancing through clinical, regulatory, and commercialization phases to attract big pharma interest for mergers and acquisitions (M&A) or possibly pursuing an initial public offering (IPO). By positioning its CBD capsule as a first-mover treatment for SAD with enhanced bioavailability, the Company aims to emulate high-value biopharma exits like Jazz Pharmaceuticals' $7.2 billion acquisition of GW Pharma. The Company believes that its early market entry and limited competition enhance its appeal as a strong investment opportunity.

CORPORATE INFORMATION (HEADQUARTERS, EMPLOYEES, AND HISTORY)

Founded in 2018, EmpowerPharm has a vision to transform CBD into a standardized pharmaceutical product. Both co-founders Aubrey Dan and Peter Billiaert (biographies on page 7), who have decades of industry expertise, including leadership roles at major pharmaceutical companies, recognize the untapped potential of CBD and seek to address the lack of consistency in the market by creating a reliable, clinically tested pill form. In 2017, with the legalization of CBD and THC in Canada, the opportunity to standardize and "pharmaceuticalize" CBD became clear, even as the legal landscape in the U.S. remained more complex.

The Company operates a cutting-edge, $30 million manufacturing and research & development (R&D) facility in Burlington, Ontario (shown in Figure 20, pages 33-34), equipped with GMP compliant production and R&D equipment essential for pharmaceutical commercialization. This pharmaceutical plant is Canada's first dedicated pharmaceutical company with a Drug Establishment License (DEL) specifically for cannabinoid-based prescription drugs. EmpowerPharm has headquarters in Burlington, ON, Canada and employs 24 individuals.

Company Leadership

EmpowerPharm's leadership team brings extensive experience across the pharmaceutical, healthcare, and regulatory sectors, positioning the Company for success in navigating the complex prescription drug landscape. Co-founders Aubrey Dan and Peter Billiaert, along with their highly skilled team, have decades of industry expertise, including leadership roles at major pharmaceutical companies, such as Novopharm Limited and Teva Pharmaceutical Industries Ltd. Their deep knowledge enhances the Company's ability to scale operations, secure regulatory approvals, and commercialize innovative products. The Company maintains a culture of strong corporate governance practices, including regular reporting, board oversight with independent directors, and separate Corporate Governance & Compensation, and Audit Committees. Biographies of key individuals are provided in the accompanying section.

Executive Team

Aubrey Dan, Chairman, Co-CEO, & Co-Founder

A former pharmaceutical executive at Novopharm and President of Wampole Canada Inc. with over 15 years of industry experience, Aubrey is a Canadian businessman, philanthropist, as well as a Tony-Award® winning producer (MEMPHIS). He is also the principal of the Dancap Family Investment Office (www.dancap.ca). He received an honorary Doctorate of Laws Degree (honoris causa) from Assumption University in 2008 and from Western University in 2019. He also received a Professional Achievement Award in 2015 from Western University. He is a Governor at Tel Aviv University. Aubrey received the Order of Canada in 2019.

Peter Billiaert, President, Co-CEO, & Co-Founder

A pharmaceutical industry veteran and senior manager with Novopharm and Teva with over 40 years' experience, Peter has extensive experience in R&D program management, decommissioning and construction of manufacturing facilities and laboratories, integration of companies, technology transfer, ERP selection, and implementation. He was the Vice President responsible for the integration of Novopharm with Teva Pharmaceuticals. Peter then became Vice President of Business Process Improvement, responsible for the standardization of all business processes across North America for Teva Pharmaceuticals. Peter holds a Master's degree from Western Carolina University, University of North Carolina and recently obtained the Chartered Director (C.Dir.) designation from The Directors College at the DeGroote School of Business, McMaster University, in 2022. He further received the designation Administrateur de sociétés certifié (ASC) from the University of Laval, in 2022.

Tamas Szederkenyi, Chief Scientific & Quality Officer

An experienced executive with progressive positions at Gedeon Richter Pharmaceuticals, Pharmaglobe Laboratories, Novopharm LTD, and Teva Pharmaceuticals Canada with over 35 years of progressive experience in the pharmaceutical industry, Tamas has demonstrated expertise in all aspects of pharmaceutical research and development and quality operations. Over his career, Tamas has developed strong theoretical knowledge and hands on expertise in the areas of analytical research, pharmaceutical development, regulatory affairs (including chemistry manufacturing and controls), biopharmaceutics (PK/BA/BE), clinical development, IP strategy, and GMP Quality Systems and Operations. Tamas has also served as an expert witness for Health Canada. Tamas holds an M. Sc, degree in Biochemical Engineering from the Technical University of Budapest, Hungary and an M.Eng. degree in Applied Chemistry from the University of Toronto, Canada.

Keith Pang, Vice President, Finance

Keith is a finance professional with over 20 years of public company experience across a wide range of industries, including pharmaceuticals and manufacturing. In his previous role as Corporate Controller of Cynapsus Therapeutics, he was responsible for building the finance function of a clinical-stage pharmaceutical development company. He was instrumental in completing an uplisting on the TSX, a private equity placement, an IPO on NASDAQ, as well as

the ultimate successful sale of the company. Other management level roles included Controller of Sublimity Therapeutics, Assistant Corporate Controller of SMTC and Audit Manager with PwC. Keith has considerable knowledge of financial reporting, controls, and regulatory compliance in both the U.S. and Canada. A designated Chartered Professional Accountant, Keith earned his MAcc degree from the University of Waterloo.

Anat Fields, Vice President Clinical and Scientific Affairs

Dr. Fields has 20 years of experience within the pharmaceutical industry, where she headed the global clinical program at Apotex, overseeing scientific affairs, clinical and bioanalytical operations, as well as data management and clinical project management. Dr. Fields was also responsible for the development of clinical/regulatory strategies of the product pipeline. In an earlier role, Dr. Fields was responsible for providing scientific and regulatory guidance on all aspects of study design, statistical analysis, and reporting of bioequivalence and clinical equivalence studies of various dosage forms.

Chirag Shah, Vice President Pharmaceutical Development

Chirag has over 21 years of extensive experience in pharmaceutical product development and manufacturing operations of Generic Drug Development (ANDAs, 505(b)(2), PIV, FTF), Novel Drug Delivery System, and drug discovery/NCEs. Chirag holds Master of Pharmacy degree from Gujarat University, India. Most recently, Chirag was Director, Formulation R&D with Apotex Inc., Canada. Prior to joining Apotex, he held leadership roles with Alembic Research Center, Zydus Lifesciences Ltd., Jubilant Organosys Ltd., and Dr. Reddy's Laboratories in India in formulation development R&D for 10 years. Chirag has a deep scientific understanding of pharmacokinetics and in-vitro dissolution testing complementary to bioequivalence studies to meet complex legal challenges and regulatory expectations for robust drug product development. Chirag has rich experience and expertise in technology transfer from lab scale to commercial (including scale up and validation) and global product transfers from one site to another for complex dosage forms.

Ildiko Riss, Vice President, Quality & Regulatory Affairs

Ildiko is an accomplished pharmaceutical executive with 30+ years of progressive experience and a strong portfolio of achievements. She has successfully led teams in different areas of pharmaceutical operations, including but not limited to pharmaceutical quality systems, scientific and technical affairs, analytical R&D, and quality control. She has proven expertise in development and commercialization of both prescription and non-prescription pharmaceutical dosage forms and in understanding related regulatory requirements. She has supported over 70 regulatory submissions (chemistry and manufacturing controls) to different regulatory bodies in her past, resulting in drug approval and commercialization. She has maintained site compliance, led regulatory audits and recently successfully guided her team to achieve EU GMP compliance for medicinal cannabis manufacturing, packaging and testing. Her previously held roles include pharmaceutical quality, regulatory, compliance, general management at ARA – Avanti Rx Analytics Inc., Contract Pharmaceuticals Limited, Dalton Pharma Services, Taro Pharmaceuticals Inc., and Novopharm Ltd.

Board of Directors

Aubrey Dan, Chairman, Co-CEO, & Co-Founder

Biography on page 7.

Jack Kay, Vice-Chairman

A former President & CEO of Apotex with 55 years' experience in the pharmaceutical industry, including generic and branded, Jack spent 10 years in the pharmaceutical industry as a detail sales representative for a branded pharmaceutical company before moving over to Director of Government sales for ICN Canada in Montreal. He then joined Apotex as Vice President, Sales and Marketing progressing to various roles, including Chief Executive Officer, Chief Operating Officer, President, and Vice Chairman.

Bob Andersen, Lead Director

Bob is a Professor of Business, Economics, and Public Policy, as well as a Professor of Strategy at the Ivey Business School, Western University. He holds cross-appointments in the Departments of Sociology, Political Science, and Statistics and Actuarial Science. His management experience includes roles as Associate Dean at Ivey and Dean of the Faculty of Social Science at Western. Previously, he served as a Distinguished Professor of Social Science at the University of Toronto and as a Senior Research Fellow at the University of Oxford. His research and teaching focus on inequality, diversity, and inclusion, with recent studies examining the mental health of university students and the effects of free public healthcare on health outcomes. He has also consulted for organizations such as the United Nations, the European Commission, and the Canadian Government.

Nancy Baines, Corporate Governance & Compensation Committee Chair

Nancy is a senior executive with over 20 years of experience in the over-the-counter (OTC) pharmaceutical industry, specializing in contract manufacturing for many of the world's top-20 research-based pharmaceutical companies. She has served as Director of New Business Development at Boehringer Ingelheim (Canada) Ltd., eventually advancing to Vice President of the Consumer Health Division, where she oversaw a vitamin and supplement manufacturing facility in Vancouver, B.C. and later as VP of North American Business Management for Patheon Inc. She managed customer relationships across Canada, the U.S., and Puerto Rico, focusing on product life cycle optimization, minimizing competitive risks, identifying line extensions, and making strategic decisions in manufacturing.

Lennie Ryer, CPA, CA, Audit Committee Chair

Lennie has held numerous Chief Financial Officer (CFO) and board positions in both public and private companies, guiding several organizations through transitions from private to public in Canadian and U.S. capital markets. With over 25 years in the life sciences sector, he has raised more than $750 million through equity transactions and secured credit facilities exceeding $225 million. His previous roles include CFO and Vice President of Finance at ConjuChem Biotechnologies Inc. and Paladin Labs Inc. Earlier, he was the Managing Partner of BDO's Montreal office, specializing in mergers, acquisitions, and taxation over 18 years in public accounting.

Complementary Medicine Research and Addiction Foundation

The Complementary Medicine Research and Addiction Foundation (CMRAF) (https://cmraf.org/) is a Canadian public charity foundation co-founded in 2022 by Aubrey Dan and Peter Billiaert. Jointly they have created a Canadian charitable foundation to fund and support those suffering from mental and physical health issues that have led to drug addiction. The foundation is set up to support academic institutions' research and discover alternatives to prescribing various medications such as opioids and benzodiazepines, and funds charitable organizations in Canada that provide direct help to those suffering from drug addiction.

Intellectual Property

EmpowerPharm is developing novel, highly bioavailable oral cannabinoid, including CBD formulations using the Self-Nanoemulsifying Drug Delivery System (SNEDDS) technological platform in various dosage forms for the regulated prescription and medicinal cannabis markets. To ensure commercial success, the Company is focused on protecting its products and brand through a comprehensive range of intellectual property (IP) protections, including patents, trademarks, copyrights, and trade secrets, both registered and unregistered, globally. By leveraging pharmaceutical innovation, the Company creates IP that secures a lasting competitive edge in the CBD market. Patent applications for these formulations began in Q2 2022, safeguarding EmpowerPharm's IP in Canada, the U.S., Europe, and other selected regions.

The Company is committed to prioritizing the development of new products and indications with two proprietary formulations developed to date: tablet and capsule dosage forms.

- *Tablet dosage form.* EmpowerPharm holds exclusive intellectual property rights for this formulation under patent #PCT/CA2023/050819, filed on June 14, 2023, and published on December 21, 2023. The International Search Report (ISR) and Written Opinion (WO) were favorable, confirming the novelty of the claims. The 30-month deadline for entering the national phase is December 14, 2024, by which time U.S. and Canadian national applications will be submitted. EU national application will be submitted prior to January 14, 2025, complying with the 31 month deadline for the European market. Based on the Company's estimates, patent approval is expected in 2028 for the U.S. market and 2029 for the Canadian market, providing patent exclusivity until 2043 in both regions.

- *Capsule dosage form.* Regarding the capsule formulation, a Freedom to Operate (FTO) search has been conducted to determine whether this innovative formulation can be commercialized without infringing on existing patents or IP rights held by others. The Company plans to submit a provisional patent application within the next 6 to 8 weeks. Based on this estimated timeline, patent approval is anticipated in 2029 for the U.S. and 2030 for Canada, securing patent exclusivity through 2045 in both markets.

EmpowerPharm currently has a PCT application for its CBD tablet formulation, covering 10, 25, and 50 mg tablet strengths. Additionally, the Company has also developed a 75 mg tablet, and according to legal counsel, the 75 mg dosage would also be covered under the existing application. Although this is currently a PCT tablet patent application, the Company expects to have the regional applications filed in the U.S. and Canada before the deadline of December 14, 2024, and in the EU by January 14, 2025, complying with the 31 month deadline for this jurisdiction. For its further clinical program, EmpowerPharm will be using a 150 mg dosage capsule containing proprietary CBD SNEDDS based solution. A summary of the Company's current patent status is provided in Figure 1.

Figure 1
INTELLECTUAL PROPERTY – PATENT STATUS

- **Tablet Formulation**
  - > EmpowerPharm exclusively owns the intellectual property rights for this technology under patent #PCT/CA2023/050819, filed on June 14, 2023, published on December 21, 2023.
  - > The 30 month national phase entry date is December 14, 2024, which is the date by when national applications for US and Canada will be filed.
  - > The 31 month EU entry date is January 14, 2025, which is the date by when national application for the EU will be filed.
  - > Estimated patent approvals: 2028 US, 2029 CAN, and TBD Global
  - > Patent exclusivity period: up to 2043 in both US and Canada

- **Capsule Formulation**
  - > Freedom to Operate (FTO) search is completed for US and Canada markets to establish the novelty of the drug formulation composition. Provisional patent application drafting for CBD capsule formulation with high drug loading is in late stage progressing towards filing in the near term.
  - > Estimated patent approvals: 2029 US, 2030 CAN and TBD Global
  - > Patent exclusivity period: up to 2045 in both US and Canada

Source: EmpowerPharm Inc.

Milestones

Recently Completed Milestones

EmpowerPharm has achieved several key milestones, as outlined below, demonstrating significant progress in advancing the Company's CBD-based treatments for Social Anxiety Disorder (SAD). These accomplishments reflect the Company's strong momentum in developing and positioning its innovative CBD therapies for market introduction.

- ***Phase 2 Success: CBD for Social Anxiety.*** EmpowerPharm recently concluded a Phase 2 clinical trial evaluating their CBD-based treatment for SAD. The trial, involving 239 participants across 19 clinical centers, demonstrated promising efficacy, safety, and tolerability of CBD 300 mg strength daily dosing for treating patients with moderate and severe SAD, laying the groundwork for the upcoming Phase 3 clinical trial program.
    - This is a significant achievement as it is the first large-scale clinical trial of its kind to show robust evidence supporting the use of CBD for this condition. The results of the study are laying the framework for the design of the upcoming Phase 3 trials.
- ***SNEDDS: Improved CBD Bioavailability & Stability.*** The Company has developed advanced proprietary formulations using its Self-Nanoemulsifying Drug Delivery System (SNEDDS), which enhances CBD bioavailability. These formulations are compliant with the quality standard required by regulatory agencies for a drug approval, such as FDA and Health Canada, and with the guidelines of ICH.
- ***Patent Application Secured: CBD Tablet Composition.*** EmpowerPharm exclusively owns the intellectual property rights under a key patent application for the **"Pharmaceutical Composition for Oral Administration of Cannabinoids,"** reinforcing its intellectual property (IP) position in CBD-based pharmaceuticals.
- **Current Capital Raised.** To date, EmpowerPharm has raised over CD$95 million, primarily through convertible debt from lead investor Aubrey Dan. Funds were allocated to R&D (CD$39.5M), manufacturing facilities (CAPEX: CD$26M), and general administrative expenses (G&A: CD$27.3M). Aubrey holds 66% of shares, securing his control of the Company through a voting trust and non-interest-bearing debentures totaling CD$78.0 million.

Potential Milestones

Key potential milestones for EmpowerPharm, which highlight the Company's strategic focus on business growth, regulatory achievements, and market opportunities, are expected to include:

- ***Advancing Phase 3 Clinical Trials.*** Progressing with its CBD-based drug for SAD, moving from successful Phase 2 trials to Phase 3, a crucial step toward commercialization.
- ***Regulatory Approvals.*** Obtaining FDA and Health Canada approvals for its CBD-based products, which is vital for establishing the product as a prescription drug and gaining third-party insurance coverage.
- ***Commercialization and Market Launch.*** Preparing for the potential market launch of its CBD formulation following Phase 3 trials, which could significantly impact the treatment of social anxiety and perhaps related conditions like depression and sleep disorders.
- ***Securing Market Exclusivity.*** Strengthening its IP portfolio, securing patents to maintain market exclusivity for its CBD products, expected to provide a significant competitive edge.

- ***Revenue Growth and Market Expansion.*** The Company projects a significant demand for its CBD product, foreseeing extensive market potential. Beyond addressing social anxiety, the product holds promise for treating additional conditions, such as depression and sleep disorders, potentially unlocking substantial new market opportunities.

- ***Exit Strategy.*** Achieving an exit strategy which includes potential M&A or IPO as it progresses through regulatory and commercialization stages, positioning the Company as a prime acquisition target, similar to Jazz Pharmaceuticals' $7.2 billion acquisition of GW Pharma.

- ***Phase 3 Clinical Trial Funding*****.** To support Phase 3 clinical trials and pre-clinical preparations, EmpowerPharm requires $100 million in equity funding, with an upfront portion and the remainder tied to milestones over the next 2 to 3 years. This capital will fund contract research organization (CRO) costs, R&D for additional SNEDDS indications, manufacturing scale-up, and working capital needs.

Core Story

Founded in 2018, EmpowerPharm set out with a clear mission to pharmaceuticalize cannabinoids, starting with cannabidiol (CBD) due to its therapeutic potential and history of medicinal use across cultures. Unlike many Canadian companies that turned to recreational cannabis following legalization, EmpowerPharm has remained focused on rigorous, evidence-based CBD research. As a non-intoxicating compound, CBD has shown significant therapeutic benefits, having received regulatory approval for epilepsy treatment in the U.S., Europe, and Australia. CBD's potential **anxiolytic** effects—its ability to help reduce anxiety—are thought to arise from its interaction with the **serotonergic system** and various neural receptors, a connection supported by extensive preclinical and clinical research. Among the various anxiety disorders, EmpowerPharm selected Social Anxiety Disorder (SAD) as the primary indication due to its low comorbidity rates and high expected patient recruitment potential. Recently, the Company has also entered discussions with undisclosed parties regarding a solid oral CBD formulation aimed at treating adult epilepsy, seeking to extend its reach within neurological care.

CBD's therapeutic potential is limited by bioavailability challenges, including water insolubility, rapid liver metabolism, and sensitivity to light and air, which reduce its potency. To address these, EmpowerPharm developed proprietary formulations based on Self-Nanoemulsifying Drug Delivery System (SNEDDS) technology, which combines CBD with oil, surfactants, and co-solvents to form nano-sized droplets upon contact with gastric fluids to significantly enhance permeability and absorption. Patentable, scalable drug formulations based on SNEDDS technology allow for higher drug doses and can be applied to other drugs with similar characteristics, making it a versatile and commercially viable solution for pharmaceutical development.

With the unique challenges posed by CBD's properties and the high doses needed to create an effective therapeutic oral dosage form in capsules or tablets, the Company's development strategy for addressing SAD integrates a dual focus on both clinical and pharmaceutical advancements. Clinically, EmpowerPharm designed a Phase 2 proof-of-concept trial targeting SAD, with dosing parameters of 300 mg and 600 mg of CBD daily, based on literature reviews and medical consultations. A CBD oral solution was used in this trial to streamline timelines while developing a solid oral formulation in parallel. On the pharmaceutical front, the goal was to create a patentable, patient-friendly, solid oral dosage form capable of delivering plasma levels equivalent to up to 600 mg of CBD, providing a high barrier to market entry and securing intellectual property (IP) protection for business interests. In June 2024, the Company announced the results of its Phase 2 clinical trial evaluating dose, efficacy, safety, and tolerability of its CBD product for SAD. Findings indicated efficacy in a subset of patients with moderate to severe SAD. This study (further described on page 20-26) provided valuable insights for continued clinical research and the development of a Phase 3 program.

EmpowerPharm's Beginnings: Achieving a Dual R&D Initiative

EmpowerPharm has advanced its dual research and development (R&D) mandate, reaching pivotal milestones in both clinical and pharmaceutical domains. The Company has established an effective daily dose of 300 mg of CBD in an Oral Solution, then progressed to a novel capsule formulation containing up to 150 mg of CBD per capsule with enhanced bioavailability. This twice-daily capsule format not only meets the rigorous standards required for Phase 3 clinical trials but also simplifies administration, boosting patient adherence and convenience. This achievement aligns EmpowerPharm's progress with its ultimate goal of launching a reliable CBD product for patients.

EmpowerPharm's research and development expertise, led by its accomplished R&D and Quality Leadership team (see biographies on page 7), encompasses proprietary and innovative drug delivery technologies, including the Self-Nanoemulsifying Drug Delivery System (SNEDDS). The team's advanced formulation capabilities and expertise also extend to pharmaceutical processes such as wet and dry granulation, hot melt processing, direct blending, Wurster fluid bed coating, and amorphous solid dispersion (ASD), positioning EmpowerPharm at the forefront of pharmaceutical innovation. These pharmaceutical advancements are paralleled by the Company's clinical research capabilities, which cover all phases of clinical trials (Phases 1 through 3) and additional studies necessary for regulatory submission and product approval. The Company's commitment to bringing therapeutic solutions to market is underscored by their comprehensive approach.

EmpowerPharm's Strategic Regulatory Process

The **505(b)(2) regulatory pathway** is particularly advantageous for EmpowerPharm as it pursues FDA approval for its CBD-based treatment for social anxiety.

Accelerated Approval Process

The 505(b)(2) pathway allows EmpowerPharm to leverage existing data on CBD's safety and efficacy, which is especially useful given the body of research already available for cannabinoids. By building on prior studies, EmpowerPharm can potentially reduce the scope and cost of additional clinical trials, speeding up the approval timeline. This means the Company can bring its product to market faster, creating earlier revenue opportunities and maximizing market impact.

Reduced Development Costs

Traditional drug development is costly, but 505(b)(2) enables EmpowerPharm to rely on published studies and other existing data, which decreases the need for new, extensive clinical trials. For an emerging company, this cost savings can be redirected toward other strategic initiatives, such as marketing, expanding manufacturing capabilities, or pursuing further R&D on additional indications.

Ability to Differentiate with New Formulation

EmpowerPharm's proprietary CBD drug formulation for social anxiety positions the Company to use 505(b)(2) effectively. With a modified formulation specifically designed to enhance efficacy for social anxiety, EmpowerPharm can capitalize on market exclusivity while differentiating itself from other CBD products.

Market Exclusivity Advantage

EmpowerPharm's product could benefit from 3 to 7 years of market exclusivity, depending on the specifics of the submission. This exclusivity protects the product from direct competition, allowing EmpowerPharm to establish a strong market presence and gain a return on investment without the immediate threat of generics or other CBD-based competitors.

Lower Regulatory Risk

For CBD-based treatments, the FDA's primary focus is on safety and efficacy. By utilizing 505(b)(2), EmpowerPharm can draw on the growing acceptance and safety data of CBD, which has been well-documented in other products. This pathway provides a lower regulatory hurdle by building on the safety profile of CBD, giving EmpowerPharm a more secure path to approval.

Enhanced Credibility and Market Positioning

Achieving FDA approval via the 505(b)(2) pathway provides a competitive advantage in the CBD space, where many products lack regulatory approval. For EmpowerPharm, this means establishing credibility as a science-backed, FDA-approved option for social anxiety, distinguishing it from unregulated CBD supplements. This could be particularly appealing to healthcare providers and patients looking for a safe, effective, and regulated CBD treatment.

Strategic Investor Takeaway

For EmpowerPharm, the 505(b)(2) pathway is a highly strategic choice. It reduces development time and cost, and enhances product differentiation. For investors, this pathway represents a lower-risk, cost-effective regulatory strategy that accelerates EmpowerPharm's time-to-market while positioning the Company as a leader in the growing CBD and mental health markets.

Cannabidiol (CBD) and Its Medical Use

Cannabis contains over 500 compounds, with THC and CBD being the most prominent cannabinoids. Unlike THC, CBD does not produce a high but holds significant medicinal promise, which has driven its popularity in recent years. CBD, first isolated from hemp oil in 1940, is unique in its structural similarity to THC but does not directly activate the brain's CB1 receptors, instead acting as a low-affinity inverse agonist, potentially counteracting some of THC's psychoactive effects.

As research grows—reflected in over 2,600 studies indexed in PubMed (https://pubmed.ncbi.nlm.nih.gov/)—CBD's therapeutic applications have broadened, with studies exploring its 65+ molecular targets across various diseases. Known especially for treating severe refractory epilepsy, CBD has been approved in the U.S., Europe, and Australia as it significantly reduces seizures in Lennox-Gastaut and Dravet syndromes when combined with antiepileptic drugs.

Interest in CBD's anxiolytic properties is growing, as studies indicate it reduces anxiety at low doses via interactions with serotonergic systems, particularly **5-HT1A receptors**, and brain regions like the bed nucleus of the **stria terminalis**. Beyond anxiety, CBD has shown potential in relieving chronic pain, enhancing sleep quality, reducing symptoms of **Post-Traumatic Stress Disorder (PTSD),** and serving as an anti-inflammatory and neuroprotective agent, making it a promising candidate for various conditions. Its role in possibly mitigating opioid addiction adds to its versatility in therapeutic settings.

CBD and the Endocannabinoid System (ECS)

CBD (cannabidiol) is a natural compound found in cannabis that interacts with the body's endocannabinoid system (ECS). The ECS is a network of receptors (mainly CB1 and CB2) and endogenous cannabinoids that help regulate various functions, including mood, pain, immune response, and homeostasis. While THC binds primarily to CB1 receptors and produces psychoactive effects, CBD influences the ECS in a more indirect manner, modulating its effects without causing intoxication. This unique interaction contributes to CBD's therapeutic potential for managing pain, anxiety, and inflammation.

The Broad Medical Benefits of CBD

The medical applications for CBD are expanding, making it one of the most versatile therapeutic substances. Despite its widespread potential, the only FDA-approved CBD is Epidiolex® to treats severe treatment-resistant children's epilepsy, including Dravet syndrome, Lennox-Gastaut syndrome, and Tuberous Sclerosis Complex (TSC). CBD is currently under investigation for various effects, including antiemetic, antipsychotic, anti-inflammatory, detoxifying, tumor-inhibiting, anxiolytic, and antidepressant properties, with EmpowerPharm's focus being the anxiolytic market to provide alternative options for anxiety management.

Anxiety Disorders and Existing Treatments

Anxiety disorders, which include **generalized anxiety disorder (GAD)**, social anxiety disorder (SAD), panic disorder, and phobias, affect approximately 300 million people worldwide, with women and younger adults showing particularly high prevalence rates. Anxiety significantly impacts daily functioning, often leading to chronic stress, sleep disturbances, and physical health issues. Traditional treatments for anxiety typically involve a combination of medications, psychotherapy, and lifestyle interventions, described below:

- ***Medications.*** First-line treatments Selective Serotonin Reuptake Inhibitors or SSRIs, such as Fluoxetine (Prozac); Sertraline (Zoloft); Citalopram (Celexa); Escitalopram (Lexapro); and Paroxetine (Paxil); and Serotonin-Norepinephrine Reuptake Inhibitors, or SNRIs, such as Venlafaxine (Effexor); Duloxetine (Cymbalta); Desvenlafaxine (Pristiq); and Levomilnacipran (Fetzima), have response rates of 58-68% but often cause side effects, including gastrointestinal issues and increased suicide risk in youth. Benzodiazepines, such as Alprazolam (Xanax); Lorazepam (Ativan); Diazepam (Valium); Clonazepam (Klonopin); Temazepam (Restoril); and Midazolam (Versed), are sometimes prescribed for short-term, fast-acting relief, with some prescribed in a medical setting, though they come with a higher risk of dependence and are generally not advised for long-term use.

- ***Psychotherapy***. **Cognitive-behavioral therapy (CBT)** is widely recognized as one of the most effective forms of talk therapy for anxiety disorders. CBT works by helping individuals identify and reshape negative thinking patterns, often through exposure therapy and coping skill development. **Acceptance and Commitment Therapy (ACT)** and other mindfulness-based therapies are also effective, especially for patients with chronic anxiety and stress.

- ***Emerging Treatments***

    - ***CBD and Natural Therapies.*** CBD is a non-psychoactive option showing promise for anxiety relief by potentially interacting with serotonin and GABA receptors, offering an alternative to benzodiazepines.

    - ***Digital and Telehealth Therapies.*** Virtual CBT, counseling apps, and mindfulness tools provide accessible mental health support, especially in underserved areas.

    - ***Psychedelic and Novel Therapies.*** Controlled studies on ketamine and psilocybin show potential for managing treatment-resistant anxiety.

    - ***Lifestyle Adjustments.*** Exercise, sleep, balanced nutrition, and practices like yoga and meditation support mental health and can naturally reduce anxiety.

The significant impact of anxiety on personal and professional life has driven global R&D efforts within this area, with increasing investments in anxiety-targeted therapeutics and mental health technologies rapidly expanding the market. With research advancing, particularly in areas like CBD, anxiety treatments are diversifying, offering individuals more personalized and innovative ways to manage symptoms effectively. Importantly, EmpowerPharm differentiates itself from providers, specifically unregulated cannabis products and wellness-oriented CBD supplements, by focusing on a federally approved, clinically tested, and insurance-reimbursable treatment. This approach delivers a higher standard of efficacy and regulatory reliability.

CBD THERAPIES FOR SOCIAL ANXIETY: EXPANDING PHARMACEUTICAL-GRADE OPPORTUNITIES

The CBD market for anxiety treatment is rapidly growing, driven by increasing interest in natural alternatives to traditional anti-anxiety medications. With anxiety affecting hundreds of millions of individuals worldwide, CBD's non-psychoactive profile has appealed to those seeking relief without the side effects associated with traditional pharmaceuticals. Research indicates that CBD may reduce anxiety by interacting with serotonin and GABA receptors, and as such, demand for CBD products is expanding as more people explore these options. The global CBD market is projected to grow, supported by ongoing studies and new CBD-based product developments targeting anxiety symptoms, such as is being developed by EmpowerPharm.

CBD as a Next-Generation Anxiety Treatment

Development of CBD-based drugs has been limited by CBD's poor bioavailability due to its low absorption in the gastrointestinal tract and extensive first-pass liver metabolism. Early studies show that oral bioavailability is only approximately 6%, though it increases fourfold when taken with food. As a result, high doses are often needed for therapeutic effects. Current CBD products are derived from cannabis sativa through a complex, costly extraction process, making them hard to standardize and prone to contamination from botanical compounds. Prices are also affected by harvest yield and supply.

Market Potential for Approved CBD Therapies in SAD

SAD affects 7.1% of the U.S. population or approximately 15 million adults, with symptoms often emerging around age 13. Many individuals with SAD delay seeking help, with 36% waiting over 10 years before pursuing treatment. The global market for social anxiety treatment was valued at approximately $12 billion in 2022 and is expected to grow to $16 billion by 2030, with a compound annual growth rate (CAGR) of 3.9%. The drug medication segment, accounting for 56% of the market, was valued at $6.6 billion in 2022 and is projected to reach $9 billion by 2030, growing at a CAGR of 3.89%. Despite the large market, there has been limited innovation in SAD treatments over the past 20 years.

Market research and consumer focus groups conducted with psychiatrists across North America reveal that approximately 80% of prescriptions for social anxiety are SSRIs. However, up to 60% of individuals with social anxiety are self-medicating with cannabis. While many are turning to cannabis, it lacks federal approval from agencies like the U.S. FDA or Health Canada. By developing a product that undergoes a rigorous clinical approval process and becomes eligible for third-party reimbursement—whether through state or provincial drug formularies or private insurance—there is a unique opportunity since the price point can be substantial due to the product's inelastic demand in the market.

CBD's Effects on Brain Activity and Potential Treatment for SAD

Neuroimaging studies in humans have shown that CBD reduces activity in brain regions, such as the amygdala, anterior cingulate, hippocampus, and hypothalamus, which are involved in cognitive and emotional processing during exposure to fear and stress. CBD further affects functional connectivity between various brain regions, suggesting it influences both cognitive and emotional responses. In patients with SAD, single oral doses of CBD (300-600 mg) significantly reduced anxiety symptoms and improved cognitive performance. CBD also demonstrated anxiolytic effects in a large case series, with a favorable safety profile and only mild to moderate adverse events when used as monotherapy, suggesting CBD as a promising treatment for anxiety disorders.

Clinical Evidence of CBD's Anxiolytic Effects in SAD

Beyond preclinical data supporting CBD's anxiolytic properties, several small and short-term clinical trials suggest that CBD may be an effective treatment for anxiety, particularly for social anxiety disorder (SAD). Many of these studies examined the effects of a single dose of CBD on anxiety symptoms in situations where anxiety was induced in either healthy participants or patients. One common method to induce anxiety is the simulated public speaking test. In this test, participants prepare a speech and deliver it in front of a video camera or an audience while being recorded. Anxiety levels are measured both before and during the speech. Since fear of public speaking is the most common fear in patients with SAD, this model is frequently used to assess treatments for the disorder.

In several studies with healthy volunteers, a single dose of 300 or 600 mg of CBD significantly reduced anxiety symptoms compared to a placebo. Similar results were observed in treatment-naïve patients with SAD, where a 600 mg dose of CBD significantly reduced anxiety, cognitive impairment, and discomfort during the speech, as well as decreased their overall alertness during the performance. While the majority of studies suggest that CBD holds promise as a treatment for SAD, larger and longer controlled trials are needed to confirm its efficacy. However, existing evidence offers a positive outlook for CBD as a potential treatment option.

Clinical Safety Profile

CBD, a key component of the cannabis plant, is widely used for its medicinal benefits without causing intoxication. An oral solution of purified CBD, known as Epidiolex®/Epidyolex®, has been approved by the FDA, EMA, and TGA for specific conditions, including children's epilepsy. In clinical trials, CBD doses ranged from 5 to 6000 mg in single doses and 20 to 3000 mg/day in multiple doses, and it was generally well tolerated. Common adverse events (AEs) included somnolence, headache, nausea, and abdominal discomfort. Mild to moderate AEs were more frequent, while serious adverse events (SAEs) were rare, typically related to the concurrent use of antiepileptic drugs.

In children's epilepsy patients treated with Epidiolex®, common adverse reactions included somnolence, diarrhea, and elevated liver enzymes. Serious but rare events in epilepsy patients included status epilepticus, pneumonia, and hepatotoxicity. In anxiety and psychiatric disorder patients, the side effects were similar to those seen in healthy individuals. Importantly, CBD use is not linked to abuse or withdrawal symptoms.

A 2020 study involving 400 patients prescribed CBD oil (100 mg/mL) for various conditions reported that CBD was well tolerated. Additionally, a systematic review and meta-analysis of 12 randomized, placebo-controlled trials involving 803 patients concluded that CBD is generally well tolerated with relatively few serious adverse effects. The authors noted that AEs and withdrawals were more common in studies involving high doses of CBD, particularly in pediatric patients with rare forms of epilepsy using antiepileptic medications. This was further supported by a review of SAEs, which found that most studies reported only mild to moderate AEs, with SAEs being rare and usually linked to antiepileptic drug use. However, recent studies on healthy adults taking a daily dose of 1500 mg of CBD indicated potential liver enzyme elevation, suggesting a risk of drug-induced liver injury.

Safety Assessments in Studies with Healthy Volunteers

In randomized clinical trials with healthy volunteers, common AEs of both plant-based and synthetic CBD included somnolence, headache, nausea, diarrhea, and abdominal discomfort. CBD was generally well tolerated, with most AEs being mild or moderate, and no serious adverse events reported. Safety monitoring in single-dose studies showed no significant changes in blood tests, vital signs, or ECGs, except for one case of elevated liver enzymes (AST) in a participant receiving 1500 mg of CBD. Longer studies, such as those supporting Epidiolex® registration, indicated no major safety concerns after short-term administration of 750-1500 mg/day of CBD. However, prolonged use at 1500 mg/day led to elevated liver enzymes (ALT) in some participants, causing study withdrawals due to potential liver injury. One study reported ALT elevations in 31% of participants after 4 weeks, while another saw two withdrawals due to liver enzyme increases. As described on pages 19-20, in EmpowerPharm's Phase 1 studies, single CBD doses of 50-300 mg were administered to 24 healthy volunteers, with AEs being mild or moderate and resolving quickly, with no liver enzyme elevations observed, aligning with previously reported CBD safety data.

The Importance of Prescription Status and Insurance Coverage for CBD Products

A critical element of federal approval is establishing the product as a prescription drug, ideally with third-party insurance coverage due to its direct link to SAD—a large and important market. For example, Epidiolex® costs approximately $1,200 for a 100 ml bottle but is covered by insurance, validating and authorizing its use, whereas an identical alternative might be available for just $90. This type of prescription coverage is the gold standard. Prescription drugs hold this importance because, in the medical market, out-of-pocket patients often prioritize cost, potentially opting for lower-priced options that may not meet the same quality standards.

When a product comes from a pharmaceutical company, it gains trust among healthcare professionals, especially psychiatrists, who act as primary gatekeepers. Once approved by psychiatrists, family doctors and insurance providers often follow, creating a cascade of acceptance. Securing prescription status is key, as it is the highest barrier to entry and provides patients with confidence. Instead of visiting a dispensary, patients can rely on their doctor and pharmacy, fostering trust and comfort in their treatment.

Nonclinical Studies

CBD has shown anxiolytic effects in various animal anxiety models, such as the elevated plus maze and social interaction tests, where it reduced anxiety-like behaviors. These effects are believed to occur through multiple molecular pathways, including activation of the serotonergic receptor 5-HT1A, which is significant in anxiety disorders, and interaction with the TRPV1 receptor in brain areas linked to anxiety. CBD also modulates the endocannabinoid system by negatively affecting CB1 and CB2 receptors and inhibiting anandamide breakdown. Pharmacokinetic studies indicate CBD has low oral bioavailability, a high volume of distribution, and undergoes extensive liver metabolism with most excretion occurring in feces.

EmpowerPharm's Clinical Development Strategy

EmpowerPharm has established a detailed clinical-regulatory program to support the approval of its solid oral CBD formulation for Social Anxiety Disorder (SAD). While current studies indicate CBD's potential benefits, their small sample sizes and limited controls have prevented definitive conclusions. To address this, EmpowerPharm conducted a Phase 2 clinical trial to identify safe and effective CBD doses for SAD. Since finalizing the solid dose formulation is time-intensive, the trial used an already-developed oral solution to prevent delays. Following Phase 2, a Comparative Bioavailability study will compare CBD blood levels from the solution and the solid dose to ensure equivalence. Once the optimal dose is established, EmpowerPharm will complete the final solid dose formulation and proceed with a Phase 3 trial to confirm efficacy and safety, aiming to secure FDA and Health Canada approval upon success. EmpowerPharm's clinical development strategy is summarized in Figure 2, followed by details of its clinical development efforts.

Figure 2
EMPOWERPHARM'S CLINICAL DEVELOPMENT STRATEGY

- Phase 2 trial using the oral solution.
- Concurrent development of the solid dose formulation.
- Comparative Bioavailability study between the oral solution and solid dose.
- Phase 3 trial with the final solid dose formulation.

Source: EmpowerPharm Inc.

Phase 1 Clinical Comparative Bioavailability Trial

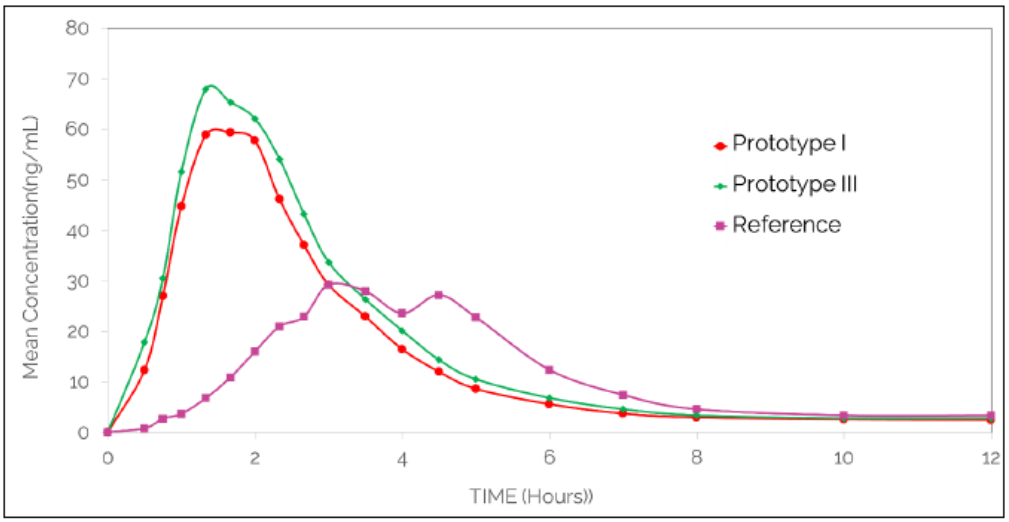
EmpowerPharm conducted a Phase 1 comparative bioavailability study for 3 CBD 150 mg capsule prototypes versus CBD Oral Solution used in the Phase 2 clinical trial. Data and figures of the two most promising prototypes are presented in Figures 3 and 4 (page 20) and discussed thereafter.

Figure 3
IN-VIVO TESTING DATA IN HUMAN VOLUNTEERS OF CBD CAPSULES 150 MG

Parameter	EPI's CBD Capsule 150 mg Prototype I (N=11)		EPI's CBD Capsule 150 mg Prototype III (N=11)		Cannabidiol Oral Solution Equivalent to Epidiolex® (Reference) (N=11)	
	Mean	%CV	Mean	%CV	Mean	%CV
C_{max} (ng/mL)	69.128	44.3	83.221	60.1	39.363	47.9
T_{max} (hours)	1.68	1.00-2.02	2.00	1.00-2.35	3.50	2.33-5.00
AUC_{0-T} (ng·h/mL)	176.842	43.8	203.850	46.9	133.015	32.8
T/R (AUC) Ratio	1.33		1.53			

Source: EmpowerPharm Inc.

Figure 4
MEAN PLOT OF CBD PLASMA CONCENTRATION OVER TIME PROFILE FOR EPI'S CBD CAPSULES 150 MG



Source: EmpowerPharm Inc.

It can be concluded that both capsule prototypes have significantly higher bioavailability (both Cmax and AUC) compared to reference CBD oral solution equivalent to Epidiolex®. The Tmax was shorter for both capsule prototypes compared to reference product, suggesting rapid onset of action achieved. EmpowerPharm's CBD Capsules 150 mg formulations containing CBD SNEDDS formulation have the potential for improved therapeutic applications. In addition to the presented capsule formulation, with minimal development work, EmpowerPharm's CBD SNEDDS formulation could be converted into an oral solution dosage form with anticipated bioavailability about 2.5 - 3.0 folds exceeding that of Epidiolex®, the only FDA approved pure CBD based pharmaceutical prescription drug product.

Phase 2 Proof of Concept Study

EmpowerPharm conducted a Phase 2 proof-of-concept study aimed at determining the safety and efficacy of CBD in patients with SAD. As with any Phase 2 trial, the findings help to refine parameters for the pivotal Phase 3 study protocol design, which involves larger, confirmatory studies focused on efficacy and safety, ultimately required for drug approval. Although the Company plans to market a capsule form of CBD, this study was conducted using a CBD oral solution. Proof-of-concept studies are not required to use the final formulation and are often conducted with an intermediate formulation.

Recognizing the lengthy nature of the process, EmpowerPharm opted to accelerate progress by running both clinical and pharmaceutical developments in parallel. With the results and the capsule now in hand, they successfully saved two to three years. Noteworthy is that they opted for CBD solution since most small scale clinical work was done on a similar product that had already been approved by the FDA. This CBD oral solution was relatively easy to replicate, and potentially helped with the FDA IND approval to conduct the study. The study involved 239 patients across 19 clinics in the U.S., divided into three equal-sized groups. Each group received either 300 mg of CBD per day, 600 mg of CBD per day, or a placebo, with all three products appearing identical. Neither the clinicians, the patients, nor anyone involved in the study could distinguish who received which treatment, ensuring the study remained properly blinded and randomized, crucial factors for the validity of such trials.

EmpowerPharm is focused on the dosage and patient population that has demonstrated favorable efficacy, specifically 300 mg of CBD per day in individuals with moderate to severe social anxiety. The Company plans to conduct its Phase 3 studies using the 300 mg daily dosing in patients with moderate to severe SAD. Accurately assessing social anxiety and tracking changes in the condition is challenging as there is no direct measure for anxiety. Instead, the evaluation relies on the use of questionnaires, as described below.

Primary Efficacy Measure: Utilizing the Liebowitz Social Anxiety Scale (LSAS) for FDA-Approved Anxiety Assessment

For the indication of social anxiety, a validated questionnaire already exists and has been confirmed that it is acceptable by the FDA. The same scale has been used for other approved drugs targeting the same condition. It is called the Liebowitz Social Anxiety Scale (LSAS), shown in Figure 5 (page 22), and consists of 24 questions representing daily situations that individuals with social anxiety find challenging. For each situation, the clinician asks the patient if they encountered—or would have encountered—the situation in the past week and how much anxiety they felt. They also assessed the extent to which the patient would avoid the situation. Both anxiety and avoidance are rated on a scale from 0 to 3, where 0 represents the lowest symptom level and 3 the highest. The total score, with a maximum of 144, serves as the key measure. As symptoms improve, a decrease in the score is expected.

Secondary Efficacy Measure: Clinical Global Impression of Improvement (CGI-I) in Social Anxiety Trials

One of the key secondary efficacy measures was the Clinical Global Impression of Improvement (CGII), a single, more qualitative questionnaire as shown in Figure 6 (page 23). In this assessment, the clinician is asked to evaluate how much the patient's SAD has changed compared to their condition at baseline. There are seven possible responses, with "very much improved" and "much improved" indicating the patient is a responder. These scales are administered before the patient begins the study or takes the first dose, and then during each clinic visit, which occurs weekly or biweekly, depending on the study schedule. The clinician completes the questionnaire, and the change from baseline is recorded each time to track the progression of the condition, whether the patient is receiving CBD or a placebo.

Figure 5
PRIMARY EFFICACY MEASURE: LIEBOWITZ SOCIAL ANXIETY SCALE (LSAS)

Liebowitz Social Anxiety Scale (LSAS)	**Fear or Anxiety** 0 = None 1 = Mild 2 = Moderate 3 = Severe		**Avoidance** 0 = Never (0%) 1 = Occasionally (1-33%) 2 = Often (34-66%) 3 = Usually (67-100%)	
Items	**Anxiety (S)**	**Anxiety (P)**	**Avoid (S)**	**Avoid (P)**
1. Telephoning in public. (P)				
2. Participating in small groups. (P)				
3. Eating in public places. (P)				
4. Drinking with others in public places. (P)				
5. Talking to people in authority. (S)				
6. Acting, performing or giving a talk in front of an audience. (P)				
7. Going to a party. (S)				
8. Working while being observed. (P)				
9. Writing while being observed. (P)				
10. Calling someone you don't know very well. (S)				
11. Talking with people you don't know very well. (S)				
12. Meeting strangers. (S)				
13. Urinating in a public bathroom. (P)				
14. Entering a room when others are already seated. (P)				
15. Being the center of attention. (S)				
16. Speaking up at a meeting. (P)				
17. Taking a test. (P)				
18. Expressing a disagreement or disapproval to people you don't know very well. (S)				
19. Looking at people you don't know very well in the eyes. (S)				
20. Giving a report to a group. (P)				
21. Trying to pick up someone. (P)				
22. Returning goods to a store. (S)				
23. Giving a party. (S)				
24. Resisting a high pressure sales person. (S)				
Total Performance (P) Subscore				
Total Social (S) Subscore				
Total Anxiety & Avoidance Subscore				
Total LSAS Score				

Source: EmpowerPharm Inc.

Figure 6
CLINICAL GLOBAL IMPRESSION OF IMPROVEMENT (CGI-I)

Compared to his/her condition at baseline, how much has the patient's Social Anxiety Disorder changed?
1 - Very much improved
2 - Much improved
3 - Minimally improved
4 - No change
5 - Minimally worse
6 - Much worse
7 – Very much worse
Responders = Answers 1 and 2

Source: EmpowerPharm Inc.

Positive Phase 2 Results

On June 6, 2024, EmpowerPharm announced promising results from its Phase 2 clinical trial evaluating its CBD drug for treating SAD. Conducted in collaboration with Syneos Health—a leading Clinical Research Organization (CRO) that provides end-to-end clinical development and commercialization services—the trial involved 239 patients across 19 clinical centers in the U.S., with 178 completing the study. This randomized, double-blind, placebo-controlled study assessed the efficacy, safety, and tolerability of CBD administered in daily doses of 300 mg and 600 mg to patients with moderate to very severe SAD. Results showed that the drug was effective for a subset of patients and demonstrated both a favorable safety profile and excellent tolerability. The trial is notable as one of the first robustly designed studies to evaluate CBD for chronic SAD using the Liebowitz Social Anxiety Scale (LSAS) to measure treatment efficacy.

The Phase 2 trial's findings have provided insight into the effective dosing for CBD in SAD treatment and are expected to support the design of the Company's upcoming Phase 3 clinical program. Following the report of Phase 2 clinical trials, EmpowerPharm intends to move into Phase 3 clinical trials which will precede the FDA approvals process, with potential availability to patients by 2029.

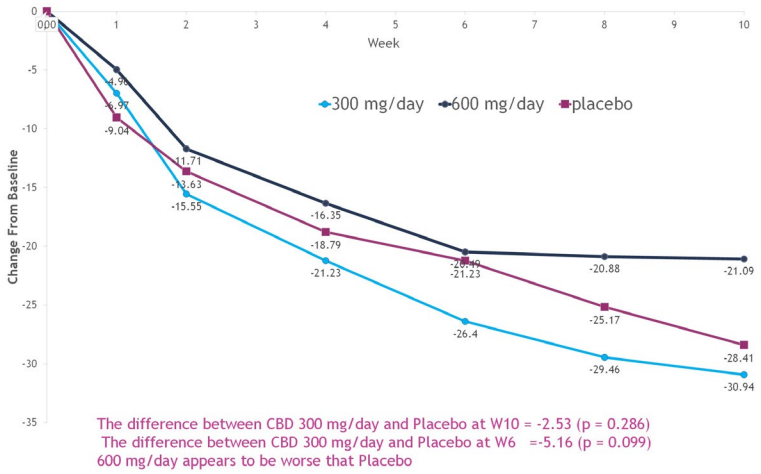
Favorable Tolerability and Safety Profile

A reduction in the LSAS Total Score reflects an improvement in SAD symptoms. Meeting the Primary Endpoint means that the difference in mean score changes from the study's start between daily doses of 300 mg or 600 mg of CBD and placebo is statistically significant, according to clinical standards. It is also important to recognize that the placebo effect can strongly influence treatment efficacy results in clinical trials.

A mean change of less than 5 points in the LSAS score between the CBD product and placebo at the 10-week mark is considered ineffective. Conversely, a change of more than 5 points indicates efficacy, with higher mean change scores reflecting greater drug-related effectiveness.

Figure 7 (page 24) shows the study results for the entire study population. The change from baseline in LSAS Total Scores between the CBD treatment and placebo was minimal and not statistically significant, with a difference of about 2.5 points for the strength indicated in blue. For the other strength, shown in black, no efficacy was observed, as the LSAS reduction for the placebo group, marked in red, was greater than that of the CBD product.

Figure 7
LSAS TOTAL SCORE – ALL SUBJECTS

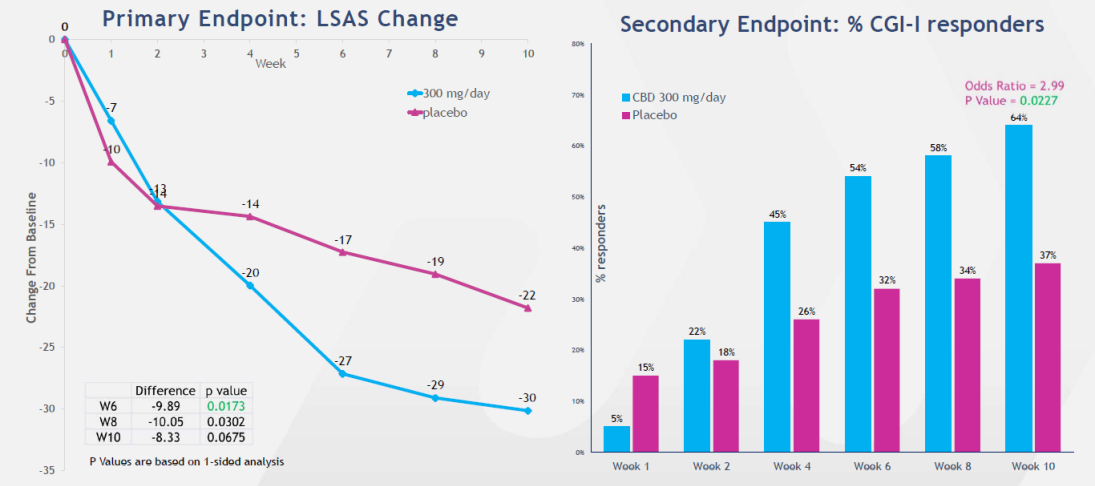


Source: EmpowerPharm Inc.

Figure 8 shows the results for CBD in patients with moderate to severe SAD, the target group for the Company's Phase 3 studies. On the left, it illustrates the change from baseline on the 24-item Liebowitz Social Anxiety Scale (LSAS). The baseline is set at zero, and the change from baseline is plotted over the 10-week study period, with time represented on the x-axis. As shown in Figure 8, the data indicates that the group receiving 300 mg of CBD daily experienced a significantly greater reduction in symptoms compared to the placebo group, with an eight-point difference between them. Based on consultations with psychiatrists, the Company understands that a five-point difference is generally considered clinically meaningful, making the observed eight-point change a highly significant clinical improvement. Beginning from week two, the data consistently shows a larger reduction in symptoms for the group receiving CBD compared to the placebo.

Similarly, the right pane of Figure 8 highlights the secondary endpoint, which measures the percentage of responders based on the single CGII question. From week two onward, the group taking 300 mg of CBD (blue) consistently shows a higher percentage of responders compared to the placebo group (pink). Statistically, a patient in the CBD group is three times more likely to be a responder than one in the placebo group. Overall, the results strongly suggest a clinically meaningful effect for CBD.

Figure 8
CBD IN PATIENTS WITH MODERATE TO SEVERE SOCIAL ANXIETY (THE TARGET POPULATION FOR PHASE-3 STUDIES)

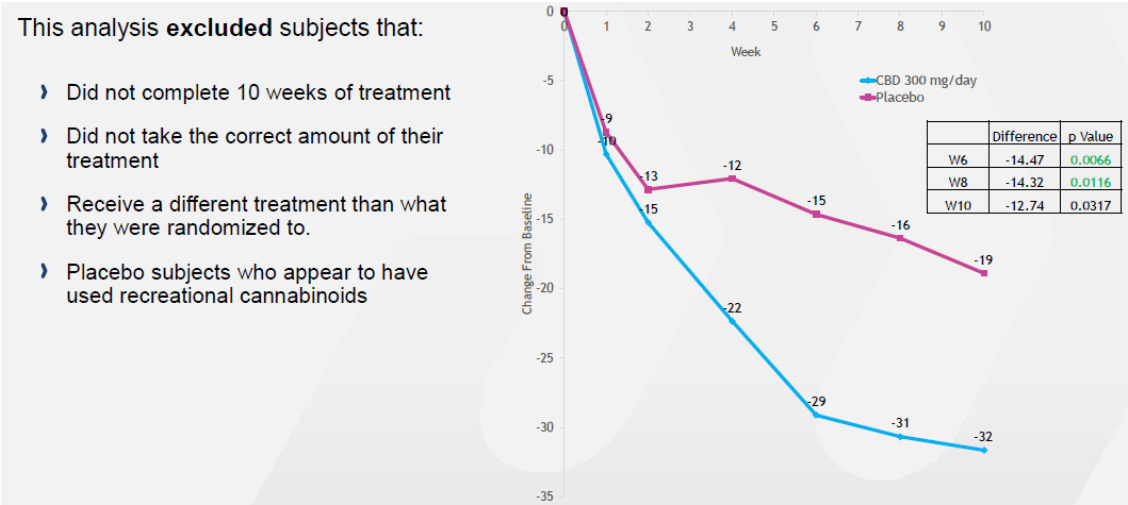


Source: EmpowerPharm Inc.

Refining Data for Clearer Insights: Analyzing Ideal Subjects in the CBD Study

The next phase was more exploratory, where the Company aimed to analyze the cleanest possible data set, focusing solely on 'ideal subjects.' These are participants who followed the study protocol perfectly, completing the full 10-week treatment and taking the correct dosage of the drug twice daily. By eliminating any variables or inconsistencies, EmpowerPharm worked with a cleaner data set, free from "noise," which allowed for a clearer view of CBD's potential effectiveness and a stronger response signal. In this case, the difference between the CBD group and the placebo group is 13 points by the end of week 10. As illustrated in Figure 9, there is a significant trend indicating a clinically meaningful effect of CBD.

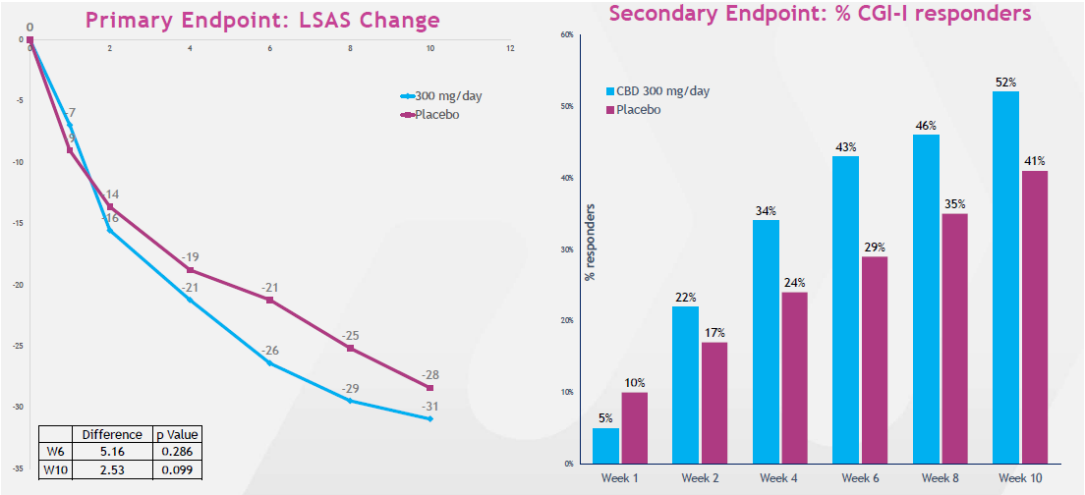
Figure 9
MODIFIED PER PROTOCOL ANALYSIS IN PATIENTS WITH MODERATE TO SEVERE SOCIAL ANXIETY



Source: EmpowerPharm Inc.

Figure 10 presents the two scales across all study participants. While the effects are smaller, a clear trend remains in both cases, demonstrating the impact of CBD.

Figure 10
ALL PATIENTS



Source: EmpowerPharm Inc.

Safety Profile: Monitoring Adverse Events

A key objective of the Phase 2 study was to assess safety, with the Company closely monitoring adverse events. The percentage of subjects experiencing at least one treatment-emergent adverse event, meaning events occurring after taking the drug, was comparable between the CBD and placebo groups (Figure 11), indicating that CBD has a strong safety profile for patients with SAD. Clinical findings of a daily dose of 300 mg of CBD consistently shows a strong trend toward clinically meaningful improvement in social anxiety symptoms for individuals with moderate to severe SAD with a favorable safety profile. While generally minor, side effects may include gastrointestinal issues (such as stomach aches), instances of dizziness, and occasional elevated liver enzyme levels.

Figure 11
SAFETY: ADVERSE EVENTS

	CBD 300 mg/day	Placebo
Overall	44%	42%
Mild	28%	27%
Moderate	15%	13%
Severe	1%	2%

Source: EmpowerPharm Inc.

Next Steps: Phase 3 Study

Between now and the end of 2025, the Company plans to hold a medical consultation meeting with key opinion leaders (KOLs) in anxiety and social anxiety, including several leading psychiatrists, as well as its statistical and regulatory consultants. The aim is to thoroughly review the Phase 2 results and design the Phase 3 study. EmpowerPharm also intends to engage in multiple discussions with the FDA, focusing on both the Phase 2 study and the Phase 3 plans, to finalize the clinical program.

Additionally, a bridging study is needed to link the CBD oral solution used in Phase 2 with the CBD capsule to be used in Phase 3. This small Phase 1 type study, which will involve only healthy subjects and focus on plasma concentrations (without assessing efficacy), is important for transitioning between formulations. Fortunately, the Company has already conducted an exploratory study comparing these two forms with positive results. The estimated cost of this Phase is up to CD$5 million.

The Company plans to begin Phase 3 studies in 2026, aiming to complete them by late 2027 or early 2028. EmpowerPharm is preparing for two Phase 3 trials involving patients with moderate to severe SAD, with each study expected to include approximately 400 participants and at a total estimated cost of CD$65 million. Patients are expected to receive either a 300 mg CBD capsule or a placebo, both designed to look identical. A final bridging/pharmacokinetics study to support leveraging of safety data for the Epidiolex® submission will also be conducted as a requirement for the discussed **505(b)2 pathway** regulatory filings and expected to be run in parallel with the Phase 3 trials. Given these timelines and plans, the Company anticipates obtaining marketing approval by 2029. A summary of these high level preliminary assumptions is provided in Figure 12 (page 27).

Figure 12
SUMMARY OF HIGH LEVEL PRELIMINARY ASSUMPTIONS

- Pre-Phase 3 Activities: 2024 through 2025
  - > Medical Consultation meeting
  - > Multiple discussions with the FDA
  - > Bridging study, linking CBD Oral Solution (Phase 2) and CBD Capsule (to be used in Phase 3)
    - > An exploratory study was already completed showing good results
  - > Estimated Cost: up to $5M CAD

- Phase 3 Program: 2026 through 2027/8
  - > Two Phase 3 studies in patients with moderate to severe social anxiety disorder
    - > # of patients: ~400/study
    - > Treatments: CBD Capsule 300 mg/day vs Placebo Capsule
  - > Final Bridging Study to be run in parallel with the Phase 3 clinical studies
  - > Total estimated cost: $65M CAD

Source: EmpowerPharm Inc.

Regulatory and Development Strategy

EmpowerPharm plans to seek marketing authorization for its CBD oral solid dose product for treating SAD. Since CBD is already approved by the FDA (Epidiolex®) and Health Canada (Sativex®), the Company intends to pursue a **New Drug Application** via the 505(b)2 pathway with the FDA and a **New Drug Submission** with Health Canada. This approach would leverage existing safety data from Epidiolex® and Sativex®, eliminating the need for new animal studies or abuse potential assessments. EmpowerPharm discussed its clinical and regulatory strategy with the FDA in a pre-IND meeting in January 2022 and with Health Canada in a pre-CTA meeting before beginning the Phase 3 clinical trial.

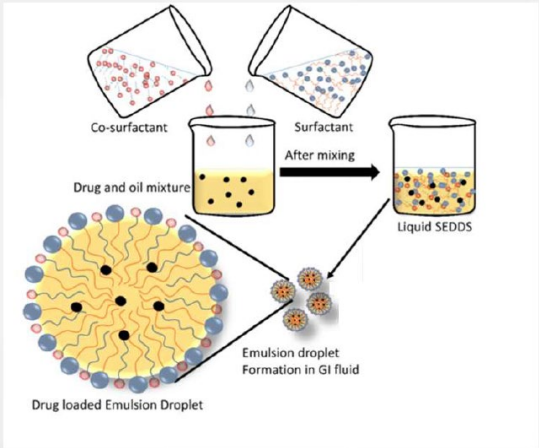
The Company has established an effective dose of 300 mg of CBD per day using the CBD Oral Solution during its Phase 2 clinical study. R&D has since developed capsules that deliver up to 150 mg of CBD per capsule, featuring a novel formulation that offers enhanced bioavailability compared to the oral solution. The developed capsules are designed to deliver the effective dose with a twice-daily administration and are suitable for both Phase 3 clinical trials and subsequent commercialization. Based on these milestones, both the clinical and pharmaceutical R&D objectives, as described on pages 11-12, have been successfully achieved. EmpowerPharm's diverse areas of expertise and extensive years of experience provide for comprehensive coverage of the entire pharmaceutical life cycle, from development and clinical scale-up to commercialization, with the combined skills of its employees enabling the Company to manage each phase effectively.

SNEDDS Technology

Prior to examining the Company's SNEDDS formulation and technology, it is important to understand the characteristics and bioavailability challenges of CBD as a molecule. CBD is insoluble in water, meaning it is lipophilic and dissolves well in fats or oils. This property affects how CBD is absorbed and distributed in the body. When taken orally, much of CBD is broken down in the liver before reaching systemic circulation, resulting in extremely low oral bioavailability. CBD is also extremely sensitive to light and air, leading to potential degradation and a reduction in potency when exposed to these elements. These physicochemical challenges, along with the formulation type and administration route, play a significant role in CBD's absorption and overall bioavailability. To address these challenges, the Company developed novel formulations based on Self-Nanoemulsifying Drug Delivery System (SNEDDS), which provides an innovative solution to CBD's bioavailability issues. This approach enables the Company to deliver consistent and effective therapeutic effects of CBD, as described below.

Understanding SNEDDS Technology and Its Key Components

Figure 13
SNEDDS TECHNOLOGY AND ITS KEY COMPONENTS



Source: EmpowerPharm Inc.

EmpowerPharm's SNEDDS Technology, as illustrated in Figure 13, is a pharmaceutical technology that enhances the solubility, absorption, and bioavailability of poorly water-soluble drugs. This system, composed of a mixture of drug, oil, surfactants, and co-solvents, forms nano-sized droplets when in contact with gastric fluid, improving drug delivery.

EmpowerPharm has developed solid dose formulations using SNEDDS technology that improve CBD solubilization and allow for higher drug loading (up to 75 mg per tablet and 500 mg per capsule), with a scalable manufacturing process and stability data supporting a shelf life of 24 months or more. This technology can potentially be extended to other drugs with similar properties, addressing approximately 60% of new molecules in development, which also struggle with poor solubility and low bioavailability. EmpowerPharm has filed patent applications for tablet formulations (described on page 10), securing intellectual property rights, with patents filed in June 2023 and national phase entries planned for December 2024. Provisional patent application for the CBD capsule formulation is in the final stage of filing.

SNEDDS-based formulations offer several advantages (Figure 14, page 29), including enhanced bioavailability by improving drug solubility and absorption, with some formulations bypassing first-pass metabolism. It also provides improved stability, as nano emulsions are thermodynamically stable, with small droplet sizes minimizing coalescence and creaming. Additionally, SNEDDS reduces variability in drug absorption among patients and offers versatility, making it suitable for various drug compounds, particularly those with poor water solubility. The manufacturing process is relatively simple, with components selected based on their compatibility and stability.

Figure 14
ADVANTAGES OF SNEDDS

- ***Enhanced Bioavailability*** : The nano emulsion formation improves drug solubility, leading to increased absorption and bioavailability. Some SNEDDS formulations are also absorbed by the lymphatic system leading to improved bioavailability of drug with extensive first-pass metabolism.
- ***Improved Stability*** : Nano emulsions are thermodynamically stable, and the small droplet size minimizes coalescence and creaming, ensuring a stable formulation.
- ***Reduced Variability*** : SNEDDS can reduce the impact of individual patient variability in drug absorption.
- ***Versatility*** : SNEDDS can be used for a variety of drug compounds, especially those with poor water solubility.
- ***Ease of Manufacturing*** : The formulation process is relatively simple, and the components are typically chosen based on their compatibility and stability.

Source: EmpowerPharm Inc.

Why SNEDDS formulations Can Be Unique, Patentable, and Viable

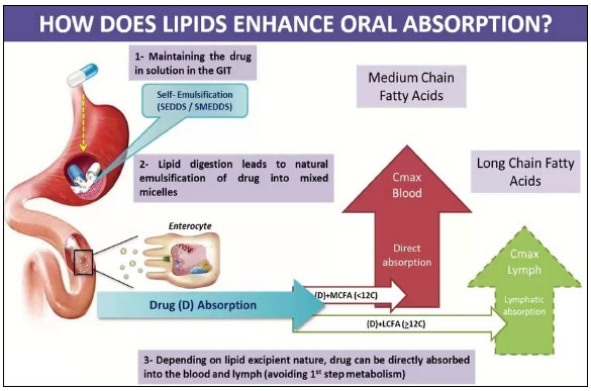
The Company's formulation utilizes techniques of reducing liver degradation and increasing CBD's bioavailability compared to conventional formulations. SNEDDS technology also has the potential to accommodate higher drug doses or enhance drug loading. Furthermore, it can be applied to improve the bioavailability of other poorly soluble or bioavailable drug candidates. According to research, approximately 60% of new drug candidates face challenges with solubility or bioavailability, making this technology highly versatile. Additionally, the Company's manufacturing process is robust and easily scalable, ensuring smooth commercialization.

Expanding the Application of SNEDDS Technology Beyond CBD

EmpowerPharm's formulations are designed to significantly enhance the bioavailability of CBD, enabling more effective absorption into the bloodstream. Beyond CBD, this advanced formulation technology has broader potential applications, as it may also improve the bioavailability of several FDA-approved drugs. EmpowerPharm's technology could further play a transformative role in increasing the effectiveness of these medications by ensuring they are more readily absorbed in the body. Each of these processes is illustrated in Figures 15, 16, and 17 (page 30).

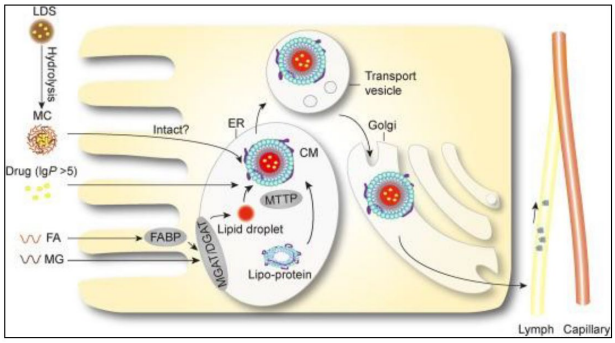
In addition to these existing drugs, EmpowerPharm's formulation technology holds promise for emerging therapeutic trends. Specifically, it may be applied to enhance the oral bioavailability of bio-polymers, and biopharmaceuticals, which traditionally face challenges in absorption due to their size and structure. By improving bioavailability for these types of molecules, EmpowerPharm's technology could open up new avenues for oral peptide therapies, making treatments more accessible and potentially improving patient adherence and outcomes.

Figure 15
MECHANISM OF LIPIDS ENHANCEMENT IN ORAL ABSORPTION



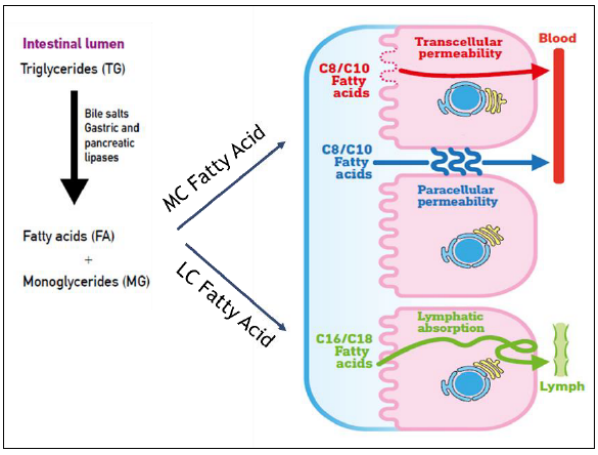
Source: EmpowerPharm Inc.

Figure 16
DRUG ABSORPTION IN ENTEROCYTES



Source: EmpowerPharm Inc.

Figure 17
DRUG ABSORPTION PATHWAY



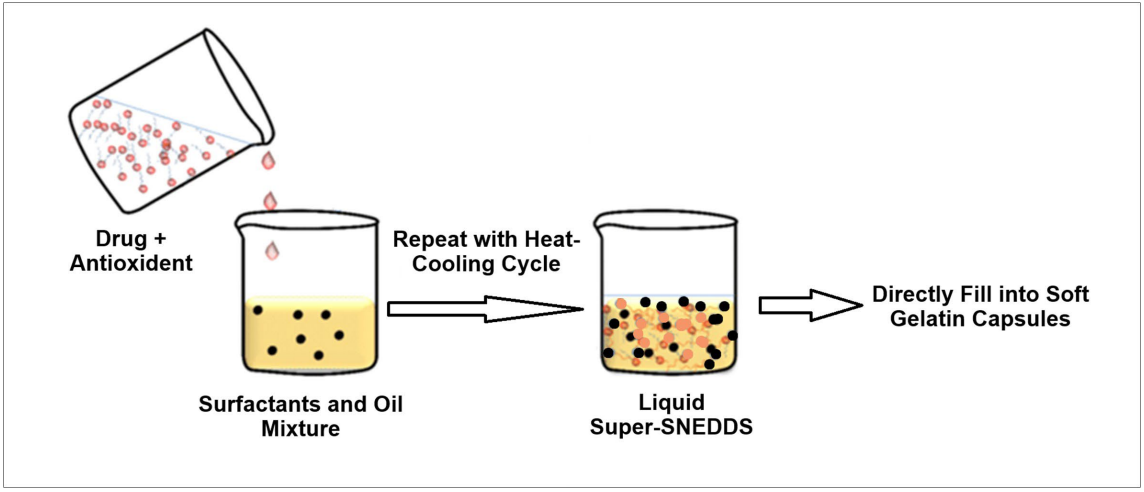
Source: EmpowerPharm Inc.

CBD IN ADULT EPILEPSY

EmpowerPharm recently engaged in discussions with leading pharmaceutical entities regarding a solid oral CBD formulation for treating adult epilepsy. The proposed R&D objectives involve evaluating strategic formulation technologies, assessing feasibility, and defining development timelines and associated costs to advance a suitable product to the clinical supply stage, ready for a Phase 1 study. The target is to achieve a solid oral dose capable of delivering up to 2.5 grams of CBD per day, comparable in potency to Epidiolex®. This initiative remains in the preliminary stages, focusing on foundational research to ensure feasibility and set the stage for subsequent clinical development.

Epidiolex® is dosed at 20 mg/kg/day, which translates to a range of 1.2 grams per day for a 60 kg adult to 2.0 grams per day for a 100 kg adult. Given that the EPI formulation has an estimated 1.3 times higher bioavailability than Epidiolex®, a corresponding dose adjustment results in a need for approximately 0.9 grams of CBD per day for a 60 kg individual and 1.5 grams for a 100 kg individual. To meet these requirements, a dosing regimen of 250-500 mg CBD per capsule, taken 1 or 2 capsules twice a day, would accommodate the full dosing range and allow for early dose titration before reaching a stable dosing stage. Super SNEDDS (Figure 18), an advanced version of the traditional SNEDDS technique, is designed to achieve higher drug loading per unit dose compared to conventional SNEDDS formulations.

Figure 18
METHOD OF PREPARATION FOR SUPER SNEDDS



Source: EmpowerPharm Inc.

The market opportunity for a solid oral CBD product targeting adult epilepsy is compelling, with significant interest from industry leaders. Some companies have recognized the potential of such a treatment, but they were not prepared to fund the clinical development needed to bring it to market. The market for epilepsy treatments is currently estimated at $5 billion, with ample room for growth, especially for products offering a solid oral dosage form with CBD's favorable side effect profile. EmpowerPharm's R&D team possesses the specialized expertise to develop high-strength CBD solid dose formulations suited to the needs of adult epilepsy patients, positioning the Company to potentially capture a valuable segment of this expanding market.

Contract Research Organization (CRO) Contracts

Initial Service Agreement: Syneos Health Project # 7029151

EmpowerPharm's service agreements with Syneos Health outlines the scope of clinical trial services and consulting provided for the development of a CBD-based treatment for Social Anxiety Disorder (SAD). In the Initial Service Agreement (dated October 2021), Syneos Health was engaged for preliminary activities, including project setup, with a budget of $10.6 million. No patient enrollment or site visits were included until a Comprehensive Agreement was executed, and the term ended in December 2021. The Clinical Services Agreement expanded the full clinical services provided, covering study management, data collection, and regulatory compliance, with payments tied to milestone completions. Additionally, the Consulting Services Agreement (March 2023) involved Syneos Health offering clinical research-related consulting on trial design, regulatory needs, and data management, on a fee-for-service basis. Together, these agreements established the framework for Syneos Health to manage EmpowerPharm's clinical trials, providing research services, data management, and regulatory support under specified budgets and timelines.

Key Licenses

In January 2021, EmpowerPharm was granted its cannabis drug license, allowing it to research and manufacture cannabis-containing products under pharmaceutical regulations. In addition, the Company holds a standard processing license, which permits the manufacture of cannabis for recreational and medical use in Canada. Importantly, EmpowerPharm is focused on the medical side, and has no interest in the recreational market. Figure 19 summarizes EmpowerPharm's key licenses, which allow the Company to legally produce, process, and distribute cannabis products under Canadian regulations. For the manufacturing of pharmaceutical products for the commercial market under GMP compliance, EmpowerPharm holds a Drug Establishment License (DEL).

Figure 19
EMPOWERPHARM'S LICENCES TO OPERATE

License Type	License Number	Date of Latest Issued Version	Date of Expiry	Purpose
Drug Establishment License	3-002624-A	7-Jul-22	N/A	For manufacturing pharmaceutical dosage forms for clinical and commercial purposes
Cannabis Drug License	LIC-ZXSUYC1 PCD-2023	12-Dec-23	12-Dec-28	For research and development as well as for manufacture of cannabis based drugs for clinical and commercial purposes
Cannabis Standard Processing License	LIC-AY32TXONGR-2023	26-Sep-23	18-Dec-25	For research and development as well as for manufacture of cannabis based products not supported by clinical research and therapeutic claim

Source: EmpowerPharm Inc.

Formulation and Process Development Strategy

Initially the formulation development of a CBD solid oral dose drug was a collaborative effort by the R&D teams of EmpowerPharm and SW Formula Inc. This innovative formulation aims to enhance bioavailability compared to the CBD oral solution, with the goal of meeting targets for CBD strength, purity, stability, and patentability. Three prototypes did undergo Comparative Bioavailability testing against the oral solution used in the Phase 2 study to establish dose bridging and demonstrate enhanced bioavailability. This ensures that the CBD plasma levels in the Phase 3 study match those that showed efficacy in Phase 2 for SAD. Pharmaceutical process development, including prototype manufacturing, scale-up, and GMP clinical batches, takes place at EmpowerPharm's GMP-licensed Burlington, Ontario, facility. This state-of-the-art site (described below) is equipped with advanced R&D and manufacturing capabilities and enables the efficient production of innovative, patentable formulations for both clinical trials and commercial production.

Manufacturing Facility

EmpowerPharm secured a facility, completely stripped it down, and rebuilt it into a cutting-edge manufacturing plant. This state-of-the-art facility now has the capacity to produce over a billion tablets and capsules annually, ensuring the scalability and efficiency needed to meet growing demand for the Company's pharmaceutical products. This facility is designed for commercial manufacturing and meets both FDA and Health Canada regulations. In 2021, EmpowerPharm obtained its Health Canada Drug Establishment License and plans to have the product ready for pre-approval inspection when the time is appropriate. Figure 20 (continued on page 34) provides pictures of key areas of the Company's manufacturing facility.

Figure 20
MANUFACTURING FACILITY

IPC Lab

Chillers on Roof

Tablet Press

Granulation Suite

Source: EmpowerPharm Inc.

Figure 20 (continued)
MANUFACTURING FACILITY

AHU1 and Compressor Area

Boiler Room

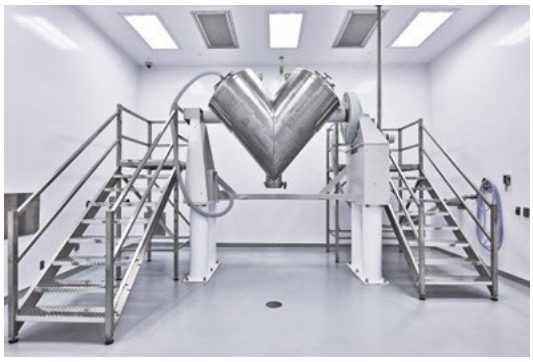
Coating Pan

Dust Collectors

Purified Water System

Sampling Room

V Blender



Weighing and Dispensing

Source: EmpowerPharm Inc.

Extensive Formulation Expertise and Clinical Trial Capabilities

In addition to the self-nano-emulsifying drug delivery system, the R&D team possesses expertise in several other formulation techniques and technologies tailored to optimize the delivery of specific molecules. These include granulation (wet or dry), hot melt processing, direct blending, and Wurster fluid bed coating, among others. On the clinical side, EmpowerPharm has the capability to manage all clinical phases (1, 2, and 3)—from the relatively straightforward Phase 1 trials, involving a small group of healthy subjects, to the rigorous Phase 3 trials, where patients with the targeted disease are recruited for comprehensive studies.

Potential for High-Market Success

The scalability of EmpowerPharm's proprietary SNEDDS platform enhances the Company's potential to expand into additional therapeutic areas, potentially creating new revenue streams and long-term growth opportunities. Developing a new drug in North America is typically a costly and time-consuming process, with average expenses ranging from $1.3 billion to $2.6 billion. This includes preclinical testing, clinical trials, and regulatory approvals, often taking 10 to 15 years. These high costs result from the complexities of R&D, trial failures, and stringent safety and efficacy standards. After successfully completing Phase 3 trials, commercialization expenses typically range from $50 million to $200 million, covering:

(1) ***Regulatory Approval***. Submitting the New Drug Application (NDA) to agencies, such as the FDA and Health Canada, including associated fees and managing regulatory inquiries.

(2) ***Manufacturing Scaling***. Preparing for large-scale production and distribution of the drug.

(3) ***Marketing and Distribution***. Building market presence, securing distribution networks, and promoting the drug to healthcare professionals.

The concept of a "blockbuster drug," with annual sales exceeding $1 billion, is a cornerstone of profitability in the pharmaceutical industry. Epidiolex®, the first FDA-approved CBD-based drug for rare children's epilepsy, demonstrates this potential, with sales reaching $736 million in 2022 and projected to reach nearly $1 billion in projected growth. This highlights the significant market opportunity for pharmaceutical-grade CBD treatments.

Funding Breakdown and Strategic Investments

As of the end of August 2024, EmpowerPharm has raised over CD$95 million. In 2019 and 2020, the Company completed two rounds of friends and family funding, raising CD$17.7 million in equity. Since then, all funding has come from Aubrey Dan (biography on page 7) through Convertible Debt. The majority of the funds have been allocated to research and development (R&D), with a cumulative R&D spend of CD$39.5 million, which includes salaries for the R&D team and pharmaceutical development as well as clinical trials. Capital expenditures (CAPEX) for EmpowerPharm's advanced manufacturing and lab facilities totaled CD$26 million, most of which was incurred earlier in the Company's life cycle. Additionally, CD$27.3 million has been spent on general administrative (G&A) expenses, covering operations, marketing, commercial business development, and other routine expenses.

EmpowerPharm's capital structure includes 150 shareholders with 58,570,500 outstanding shares. Of these, 66% (38,700,000 shares) are held by Aubrey Dan or companies controlled or related to him, giving him effective control through a voting trust and a multiple-voting share structure. Additionally, 4,600,228 options have been granted to employees, directors, and consultants for incentive purposes under the Long-Term Incentive Plan. The Company's primary source of funding comes from secured convertible debentures issued by Aubrey Dan Holdings Inc., with a current balance of CD$79.0 million. These debentures are non-interest-bearing, further strengthening Aubrey Dan's financial influence over the Company. In the event of an IPO, a strategic investment, or an M&A partnership, the debentures would convert into equity shares and the voting trust structure would be dissolved.

Investment Details and Use of Funds

EmpowerPharm is seeking a $100 million equity investment to advance its Phase 3 clinical trials for social anxiety disorder (SAD), pre-clinical preparations, and other key development efforts as it moves toward commercialization. A summary of the Compnay's use of funds is provided in Figure 21. This funding will mark the completion of critical milestones on its path to market, with flexible deal structures available for potential investors, including funding tranches aligned with EmpowerPharm's financial needs. Monthly costs are expected to range from CD$1 million to CD$3 million, depending on the level of clinical trial activity. EmpowerPharm is confident that achieving these milestones will not only bring it closer to commercialization but also reduce risk for investors, thereby increasing valuation for existing stakeholders. Additional resources will focus on expanding the Company's development pipeline, including continued research on its formulation for other indications, and the application of its SNEDDS technology to new drug candidates. Manufacturing scale-up is also a priority, as EmpowerPharm plans to adapt its tablet production line to produce the soft gel capsule dosage form for commercialization, alongside general working capital needs.

Figure 21
USE OF FUNDS

USD $100M required to fund the following over the next 2-3 years

1. SAD CLINICAL PROGRAM - ~$60M
   - Two large Phase-3 pivotal trials in parallel
   - Regulatory and submission activities for pathway in the US and Canada
   - Supporting studies as required
2. R&D AND BUSINESS DEVELOPMENT ON OTHER INDICATIONS/MOLECULES ~ $10M
   - Leverage SNEDDS technology
3. MANUFACTURING SCALE UP ~$20M
   - Including capital expenditures for Softgel dosage form
4. GENERAL WORKING CAPITAL

Source: EmpowerPharm Inc.

Exit Strategy

EmpowerPharm's exit strategy focuses on advancing through regulatory and commercialization phases to attract big pharma interest for mergers and acquisitions (M&A) or pursue an initial public offering (IPO). High-value biopharma exits, such as Jazz Pharmaceuticals' $7.2 billion acquisition of GW Pharma in 2021, highlight the potential for significant returns. EmpowerPharm aims for a similar outcome, positioning its patient-friendly CBD capsule with enhanced bioavailability as a first-mover treatment for social anxiety disorder (SAD), a condition affecting a large population. The Company's early market entry and lack of direct competition strengthen its appeal as a high-value investment.

Investment Highlights

- ***Innovative CBD Treatment for Social Anxiety Disorder (SAD).*** EmpowerPharm is at the forefront of developing a prescription-grade CBD therapy for SAD. Utilizing its proprietary SNEDDS technology, the Company enhances CBD's bioavailability and effectiveness, offering a clinically validated, safer alternative in a market dominated by SSRIs and benzodiazepines, fulfilling the need for non-addictive treatments.

- ***First Prescription CBD Pill for Social Anxiety.*** EmpowerPharm's flagship product, developed with patent-pending SNEDDS technology, is a THC-free, non-intoxicating CBD pill specifically for SAD. Positioned to be the first CBD prescription approved for this use, the formulation provides a safer treatment option with potential support from insurance and government programs.

- ***Promising Phase 2 Results.*** Strong Phase 2 clinical outcomes demonstrate the effectiveness of EmpowerPharm's CBD product for SAD, positioning the Company for a successful Phase 3 trial and, ultimately, commercialization.

- ***Federal Approval and Insurance Accessibility.*** With federal approval, the product can be established as a prescription drug, ideally covered by third-party insurance, which would significantly increase accessibility, sales, and market stability within this large market.

- ***Advanced, Patentable Drug Formulations.*** EmpowerPharm's unique drug formulations based on SNEDDS technology increases CBD bioavailability and efficacy, providing therapeutic advantages and creating competitive barriers. These proprietary formulations also strengthen the Company's intellectual property (IP) portfolio and offers potential applications for other low-bioavailability drugs.

- ***Meeting Unmet Needs in a Growing Market.*** SAD affects millions globally, with the treatment market projected to reach $16 billion by 2030. EmpowerPharm's pharmaceutical-grade CBD capsule addresses a significant gap, providing a non-addictive alternative to current anxiety treatments, positioning the Company for competitive advantage in a rapidly growing field.

- ***Strong Intellectual Property Portfolio.*** The Company's expanding IP portfolio secures market exclusivity, enhancing revenue potential from product sales.

- ***Scalable Manufacturing and Regulatory Positioning.*** EmpowerPharm's GMP-certified facility in Ontario, the first in Canada licensed for cannabinoid-based products, supports R&D, clinical development, and commercial production. This scalable infrastructure positions EmpowerPharm for regulatory approvals in the U.S., Canada, and other key markets, establishing a solid presence in the pharmaceutical-grade CBD sector.

- ***High Pharmaceutical Profitability Potential.*** The Company's patent-pending formulations and the high entry barriers in the pharmaceutical industry allow it to leverage strong profitability dynamics to meet growing demand for pharmaceutical-grade CBD solutions.

- ***Experienced R&D Team.*** EmpowerPharm's R&D team brings decades of pharmaceutical expertise, with a proven track record in developing and commercializing solid oral dosage forms.

- ***Epidiolex Success as a Model.*** GW Pharma's Epidiolex®—the first FDA-approved CBD drug for rare epilepsy—demonstrated the commercial viability of CBD, generating $845.5 million in 2023. EmpowerPharm differentiates itself by offering a convenient capsule form for SAD, compared to CBD oils.

- ***Funding and Strategic Direction.*** EmpowerPharm seeks $100 million in equity for Phase 3 trials, R&D, and scaling efforts, with funds to be disbursed over 2 to 3 years based on milestones. To date, CD$95 million has been raised, primarily from lead investor Aubrey Dan (66% ownership). The exit strategy includes potential M&A or IPO, positioning its pioneering CBD treatment for SAD as a high-value acquisition target.

Competition

Selective serotonin reuptake inhibitors (SSRIs) have been a cornerstone in treating anxiety and depression in adults, working by enhancing serotonin levels—a neurotransmitter vital for mood regulation—by preventing its reabsorption into the brain. By keeping serotonin more available, SSRIs help alleviate symptoms of anxiety and depression, making them a widely prescribed option for mental health treatment. Common SSRIs include: Fluoxetine (Prozac); Sertraline (Zoloft); Citalopram (Celexa); Escitalopram (Lexapro); and Paroxetine (Paxil).

Though effective, SSRIs can bring side effects like nausea, insomnia, sexual dysfunction, and weight gain. They are often a first-line treatment due to their overall tolerability, yet these side effects prompt many patients to seek alternative therapies with fewer adverse impacts. This search for options creates an opportunity for emerging therapies like cannabidiol (CBD)-based treatments, which offer a non-intoxicating, promising alternative with a strong therapeutic profile and fewer known side effects, particularly suited to adult anxiety.

EmpowerPharm sets itself apart from companies offering unregulated cannabis products and wellness-focused CBD supplements. By developing a federally approved, clinically validated, and insurance-reimbursable product, EmpowerPharm provides a superior level of efficacy and regulatory assurance, positioning it as a preferred choice for healthcare providers and patients seeking safe, effective treatment options.

Cannabidiol (CBD)-Based Treatments

The market for cannabis as a treatment for anxiety has been growing significantly in recent years, influenced mainly by a changing legal landscape, increased public awareness, and emerging research. Clinical research on the effect of CBD and cannabis as therapeutic agents for anxiety and other mental health conditions was tightly restricted because cannabis (and CBD) were classified as illegal substances by the DEA. However, in 2015 the DEA eased some of the regulatory constraints for those conducting FDA-approved clinical trials on CBD, and in 2018, the U.S. Farm Bill removed hemp from the federal Controlled Substances Act, effectively legalizing hemp-derived CBD (Source: WebMD's *CBD for Depression and Anxiety*, May 2023). This resulted in an increase on CBD-related research, with more than 20 studies either active or in the planning stage to test the effect of CBD on anxiety, as seen on Figure 22 (page 42).

However, the legal restrictions still play a role in the competitive landscape of CBD products for anxiety and metal health conditions. Most of the products currently available are over-the-counter (OTC) recreational products, which lack standardized dosing and labeling, leading to challenges for consumers seeking reliable products for anxiety treatment. Since these products are not regulated by the FDA, the quality, dosage, safety, and effectiveness of these CBD offerings can vary widely between products and manufacturers. For example, one test conducted on CBD OTC products to see if their labels accurately convey their content found a mismatch between claimed and actual CBD levels in 22 out of 25 of tested products (Source: AAMC's *CBD: Does it work? Is it safe? Is it legal?* July 2023).

The FDA has approved only one CBD product, Epidiolex® (Jazz Pharmaceuticals), a prescription drug product to treat seizures associated with Lennox Gastaut syndrome (LGS), Dravet syndrome (DS) in children, or tuberous sclerosis complex (TSC), with regulatory bodies calling for more rigorous clinical trials to better understand the safety, efficacy, and appropriate use of cannabis for anxiety. As clinical research on CBD for mental health disorders advances under eased legal restrictions, newly regulated products with proven safety and efficacy are anticipated to drive substantial market growth. EmpowerPharm believes that the Company is well-positioned to capitalize on this opportunity through its ongoing clinical research efforts.

As EmpowerPharm continues to develop and seeks to commercialize its products, the Company may encounter competition from existing CBD-based OTC products, including Medterra, Charlotte's Web, CBDistillery, and Lazarus, among others; research organizations; and other pharmaceutical and biotechnologies companies conducting clinical trials on the use of CBD on anxiety and other mental health conditions that the Company is targeting. A selection of the potential competition that EmpowerPharm may face is profiled in the accompanying section. It is not intended

to be an exhaustive collection of the Company's competitors; however, it is believed to be a sample of the type of competition that EmpowerPharm may face as it strives to commercialize its product candidates and technologies.

ANANDA Scientific, Inc.

ANANDA Scientific is a research-focused biopharmaceutical company developing life changing medicines to transform neuropsychiatric health. The company's investigational products are formulated using Liquid Structure™ Technology (licensed from Lyotropic Delivery Systems [LDS] Ltd), a patented innovative delivery technology that has been shown to enhance the effectiveness, bioavailability, absorption, and shelf-life stability of CBD formulations. The company's pipeline includes Nantheia™ ATL5 and Nantheia™ A1002N5S, investigational drugs that combine cannabidiol with Liquid Structure™ technology. These products are currently undergoing evaluation in multiple clinical trials, focused on indications with large unmet medical needs: Nantheia™ A1002N5S is being studied in three FDA-approved clinical trials, addressing PTSD, social anxiety disorder, and radiculopathic pain. Nantheia™ ATL5 is undergoing assessment in three FDA-approved clinical trials, addressing PTSD, social anxiety disorder, and opioid use disorder. These studies are being undertaken at prestigious institutions, including Geffen School of Medicine at UCLA, the Ichan School of Medicine at Mt. Sinai, the Grossman School of Medicine at NYU, and the University of Nebraska Medical Center. The company is headquartered in Greenwood Village, Colorado.

CNBX Pharmaceuticals (CNBX-OTCPK)

CNBX is a clinical-stage company focused on discovering, developing, and commercializing innovative cannabinoid-based products and technologies for cancer treatment, with a primary focus on gastrointestinal, skin, breast, and prostate cancers. The company also targets mental health conditions, Alzheimer's disease, and autoimmune disorders. CNBX's lead product candidate is RCC-33, an oral capsule containing a formulation of cannabinoids for the treatment of colorectal cancer. The company is also developing various drug candidates, including PLP-33 for the treatment of colorectal pre-cancerous polyps; BRST-33 to treat breast cancer; MLN-33 for the treatment of Melanoma; and PRST-33 to treat prostate cancer. In addition, CNBX is involved in the development of cannabinoid-based products for neuropsychiatry applications, with two product candidates (NP-01 and NP-02) in early discovery stage for mental health disorders. The company was formerly known as Cannabics Pharmaceuticals Inc. and changed its name to CNBX Pharmaceuticals Inc. in March 2022. CNBX was incorporated in 2004 and is based in Bethesda, Maryland.

Charlotte's Web Holdings (CWBHF-OTCQX, CWEB-TSX)

Charlotte's Web is involved in the farming, manufacture, marketing, and sale of hemp-derived CBD wellness products under a family of brands which includes Charlotte's Web™, CBD Medic™, CBD Clinic™, and Harmony Hemp. Charlotte's Web products are distributed through more than 22,000 retail locations. In 2020, the company formed its CW Labs Division to expand its science-based research and development efforts (including studies on safety and effectiveness), while advancing clinical trials. Part of this effort was a collaboration with the University of Colorado-Boulder to assess the effectiveness of the company's full spectrum hemp formulations with CBN (cannabinol) and CBD (cannabidiol) on anxiety and sleep quality. The randomized, controlled, clinical trial results indicated that the majority of patients taking Charlotte's Web's formula experienced clinically meaningful improvements in their quality of life, sleep quality, and feelings of daily stress or discomfort. CW Labs also entered into a long-term scientific collaboration with McLean Hospital, a Harvard Medical School affiliate, led by Dr. Staci A. Gruber, Associate Professor of Psychiatry at Harvard Medical School and Director of the Marijuana Investigations for Neuroscientific Discovery (MIND) program. On March 2024, Dr. Gruber released results of a clinical trial indicating that CBD was shown to be more effective at easing anxiety compared to THC, results that were published in the journal *Cannabis and Cannabinoid Research* (Vol.9 (4): 1015–1027). Dr. Gruber is also conducting a clinical trial of a hemp-derived cannabidiol product for anxiety (NCT04286594). The company was formerly known as Stanley Brothers Holdings Inc. and changed its name to Charlotte's Web Holdings, Inc. in July 2018. The company was founded in 2013 and is headquartered in Louisville, Colorado.

GW Pharmaceuticals (acquired by Jazz Pharmaceuticals—JAZZ-NASDAQ)

GW Pharmaceuticals—acquired by Jazz Pharmaceuticals for $7.2 billion in 2021—was a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. GW's product portfolio included its epileptic seizure treatment medicine, Epidiolex®, the first and only drug derived directly from the cannabis plant to gain FDA approval, as well as Sativex, an oromucosal spray for the treatment of spasticity due to multiple sclerosis (MS). The combined post-acquisition pipeline includes products and clinical-stage development programs addressing significant unmet patient needs across neuroscience and oncology, including sleep disorders, movement disorders, psychiatry, hematology, and solid tumors. In terms of its cannabinoid offerings, for the full year of 2023, Epidiolex® achieved net sales of $845.5 million, reflecting a 15% increase over the previous year. The product is also approved in Europe (under the tradename Epidyolex). Jazz is conducting ongoing research of Epidiolex® in additional indications, including exploring its potential benefits for anxiety disorders. Jazz is headquartered in Dublin, Ireland, serving patients in nearly 75 countries.

Lexaria Bioscience Corp. (LEXX-NASDAQ)

Lexaria is a biotechnology company focused on developing and out-licensing its patented drug delivery technology, DehydraTECH. This technology enhances the absorption and effectiveness of lipophilic molecules or active pharmaceutical ingredients by combining them with specific long-chain fatty acids and carrier compounds to improve bloodstream entry. The company's DehydraTECH is used with a range of active molecules encompassing fat-soluble vitamins, pain medications, hormones, PDE5 inhibitors, antivirals, oral nicotine and its analogs, and cannabinoids. Its cannabinoid-centric efforts, DehydraTECH-CBD, is currently being evaluated in multiple therapeutic indications, including hypertension, diabetes, dementia, and epilepsy/seizures. The company believes that its DehydraTECH technology is also suitable for other product formats in addition to pharmaceuticals, including nutraceuticals, over the counter (OTC), and consumer packaged goods. Lexaria was incorporated in 2004 and is headquartered in Kelowna, Canada.

Receptor Life Sciences

Receptor is a pharmaceutical company that applies FDA-approved drug-delivery technologies to develop innovative therapies to address central nervous system disorders that have few safe and effective treatments. The company uses these technologies to produce inhaled and oral cannabinoid products that are a validated solution for the three main challenges of cannabinoid medicine: low absorption, poor bioavailability, and inconsistent dosing. The company's pipeline includes RLS103, a cannabidiol inhaled dry powder currently being evaluated for acute anxiety in social anxiety disorder (Phase 1b/2a) and epileptic seizures (IND), and RLS102, a cannabidiol SNAC Oral Technology for irritability in autism spectrum disorder (Phase 1). Receptor Life Sciences is headquartered in Seattle, Washington.

Tilray Brands, Inc. (TLRY-NASDAQ)

Tilray engages in the research, cultivation, processing, and distribution of medical cannabis products in Canada, the U.S., Europe, Australia, New Zealand, and Latin America. In addition to its medical and adult use cannabis operations, Tilray offers a diverse portfolio of innovative brands and products across craft beer, spirits, beverages, and hemp foods. Tilray is the global leader in the advancement of cannabinoid-based medicine, with a keen focus on providing research-backed medical cannabis products to physicians, pharmacies, and patients around the world. The medical cannabis efforts centered around the operations of Tilray Medical and Aphia, which merged in 2021 to create one of the world's largest global cannabis companies, Tilray Medical partners with leading hospitals and universities to advance the clinical applications of cannabinoids. Tilray is working with McMaster University on assessing the effects of CBD oil capsules provided by the company for the treatment of anxiety disorders. Other research partnerships include clinical trials with the University of British Columbia and the NYU school of medicine (PTSD), Toronto's Hospital for Sick Children (pediatric epilepsy), and Australia's Murdoch Children's Research Center (Severe behavioral problems in children with intellectual disabilities), among others. The company was formerly known as Tilray, Inc. and changed its name to Tilray Brands, Inc. in January 2022. Tilray is headquartered in Leamington, Canada.

Zynerba Pharmaceuticals (acquired by Harmony Biosciences Holdings, Inc.—HRMY-NASDAQ)

Harmony a commercial-stage pharmaceutical company, focuses on developing and commercializing innovative therapies for patients with rare and other neurological diseases. In October 2023, Harmony acquired Zynerba Pharmaceuticals, a company focused on transdermal cannabinoid therapies. Zynerba's lead candidate was Zygel™ (ZYN002), the first and only pharmaceutically-manufactured (non-plant-derived) CBD, formulated as a patent-protected permeation-enhanced gel for transdermal delivery. Harmony is continuing the development of ZYN002 as part of its neurobehavioral program, with the candidate currently being evaluated for Fragile X syndrome (FXS) and 22q11.2 deletion syndrome (22q), both in Phase 3 trials. Harmony Biosciences was incorporated in 2017 and is headquartered in Plymouth Meeting, Pennsylvania.

Figure 22
CLINICAL EFFECTIVENESS OF CBD IN ANXIETY FOLLOWING ORAL ADMINISTRATION

Population	Design	Dose	Duration	n	Effects	Ref
Healthy volunteers, induced anxiety	Placebo-controlled RCT	100, 300, 900 mg	1 dose	12/group	CBD (300 mg) significantly reduced anxiety measures in a test of public speaking in a real situation. CBD doses of 100 and 900 mg CBD were ineffective.	48
Healthy volunteers, induced anxiety	Placebo-controlled RCT	150, 300, 600	1 dose	12-15/group	CBD (300 mg) significantly reduced anxiety during simulated public speech. 150 and 600 mg were ineffective.	49
Healthy volunteers, induced anxiety	Placebo controlled RCT	300 mg	1 dose	10/group	CBD reduced anxiety measures in a simulated public speaking test	50
SAD	Placebo-controlled RCT	600 mg	1 dose	12/group	CBD reduced anxiety, cognitive impairment and discomfort in speech performance, and significantly decreased alert in anticipatory speech	51
Patient with high risk of psychosis	RCT	600 mg daily	1 week	16/group	CBD-treated patients had lower level of anxiety and public speaking stress than the placebo group.	52
SAD	Placebo-controlled RCT	400 mg	1 dose	10/group	The anxiolytic properties of CBD correlated with changes in brain	53
					regions that are important in processing fear and emotion	
Healthy volunteers	Placebo controlled RCT	400 mg	1 dose	10/group	CBD reduced measures of anxiety, and these effects correlated with changes in the limbic and paralimbic brain areas.	54
Healthy volunteers subjected to negative emotional stimuli	RCT	600 mg	1 dose	15/group	CBD decreased function in limbic and paralimbic regions related to autonomic arousal and subjective anxiety	55
Healthy volunteers	Pseudo-randomized, clinical trial	600 mg	1 dose	15/group	CBD decreased amygdala response to fear processing and attenuated the psychotic effects of THC.	56
SAD	Placebo-controlled RCT	300 mg daily	4 weeks	17 or 20 /group	CBD for a 4-week period reduced the level of symptoms in teenagers with SAD, as measured by Fear of Negative Evaluation questionnaire and by the Liebowitz Social Anxiety Scale.	57
Patients with anxiety or sleep disorder	Large case series	25-175 mg	Variable (at least 1 month)	72	79% of study population reported decreased anxiety levels after one month of treatment	36
Healthy volunteers selected for Highly paranoid personalities	RCT	600 mg	1 dose	16/group	No behavioral or physiological anxiolytic effect of CBD in anxiety-provoking virtual reality simulation	24
Healthy volunteers subjected to negative emotional stimuli	RCT	300, 600, 900 mg	1 dose	8-10/group	CBD did not dampen responses to negative emotional stimuli and did not affect feelings of social rejection. CBD (900 mg) marginally reduced attentional bias toward happy and sad facial expressions, and slightly increased the late-session heart rate.	58

Source: EmpowerPharm Inc.

Historical Financial Results

Figures 23, 24, and 25 (pages 43-45) provide a summary of EmpowerPharm's most recent key financial statements for the quarter ended September 30, 2024.

Figure 23
STATEMENT OF LOSS AND COMPREHENSIVE LOSS

UNAUDITED	Three months ended September 30,		Nine months ended September 30,	
$	2024	2023	2024	2023
Revenue	**43,380**	**-**	**43,380**	**-**
Expenses				
Research and development	685,326	5,537,797	5,834,660	10,999,200
General and administrative	1,151,676	2,096,668	4,358,851	6,132,100
Depreciation on property and -equipment	714,669	569,259	2,003,991	1,728,252
Depreciation on right-of-use assets	36,797	36,797	110,391	110,391
Interest expense on lease liabilities	24,469	26,634	75,069	81,314
Loss on disposal of property and equipment	-	-	-	12,323
Foreign exchange loss (gain)	(9,274)	49,530	43,662	45,900
Total expenses	**2,603,663**	**8,316,685**	**12,426,624**	**19,109,480**
Other income				
Interest income	7,643	16,494	35,273	45,075
Net loss and comprehensive loss for the period	**(2,552,640)**	**(8,300,191)**	**(12,347,971)**	**(19,064,405)**

Source: EmpowerPharm Inc.

Figure 24
STATEMENT OF FINANCIAL POSITION

UNAUDITED As at	September 30, 2024	December 31, 2023
	$	$
ASSETS		
Current		
Cash	615,077	1,099,802
Harmonized sales tax recoverable and other receivables	61,351	154,603
Prepaid expenses and sundry	228,374	1,111,012
Total current assets	904,802	2,365,417
Property and equipment	15,433,948	17,312,635
Right-of-use assets	988,835	1,099,226
Deposits	28,757	28,757
Total assets	**17,356,342**	**20,806,035**
LIABILITIES		
Current		
Accounts payable and accrued liabilities	1,292,144	4,002,358
Current portion of lease liabilities	133,640	124,015
Convertible debentures	78,000,000	67,000,000
Total current liabilities	79,425,784	71,126,373
Lease liabilities	1,146,690	1,248,263
Total liabilities	**80,572,474**	**72,374,636**
SHAREHOLDERS' DEFICIENCY		
Capital stock	22,881,001	22,881,001
Contributed surplus	5,859,494	5,159,054
Deficit	(91,956,627)	(79,608,656)
Total shareholders' deficiency	**(63,216,132)**	**(51,568,601)**
Total liabilities and shareholders' deficiency	**17,356,342**	**20,806,035**

Source: EmpowerPharm Inc.

Figure 25
STATEMENT OF CASH FLOWS

UNAUDITED $	Nine months ended September 30, 2024	 2023
Operating activities		
Net loss and comprehensive loss for the period	(12,347,971)	(19,064,405)
Adjustments for items not affecting cash:		
Depreciation on property and equipment	2,003,991	1,728,252
Depreciation on right-of-use assets	110,391	110,391
Interest expense on lease liabilities	75,069	81,314
Share-based compensation	700,440	1,232,832
Loss on disposal of property and equipment	-	12,323
Changes in working capital items:		
Harmonized sales tax recoverable and other receivables	93,252	37,168
Prepaid expenses and sundry	882,638	(65,711)
Accounts payable and accrued liabilities	(2,710,214)	1,341,096
Cash used in operating activities	**(11,192,404)**	**(14,586,740)**
Investing activities		
Purchase of property and equipment	(125,304)	(860,012)
Proceeds on disposal of property and equipment	-	6,400
Cash used in investing activities	**(125,304)**	**(853,612)**
Financing activities		
Repayment of lease liabilities	(167,017)	(161,044)
Proceeds from issuance of convertible debentures	11,000,000	16,000,000
Cash provided by financing activities	**10,832,983**	**15,838,956**
Net (decrease) increase in cash during the period	**(484,725)**	**398,604**
Cash, beginning of period	**1,099,802**	**806,037**
Cash, end of period	**615,077**	**1,204,641**

Source: EmpowerPharm Inc.

Recent Events

November 8, 2024— EmpowerPharm Inc. announced that the Company is expanding its research initiative to focus on leveraging Super SNEDDS technology to enhance the delivery of antiepileptic medications, specifically designed for adult patients.

June 6, 2024—Announced positive results from their Phase 2 clinical trial of a cannabidiol (CBD) drug for Social Anxiety Disorder (SAD). The trial, managed by Syneos Health, involved 239 patients from 19 U.S. centers, with 178 completing the study. It was a randomized, double-blind, placebo-controlled trial evaluating the safety, efficacy, and tolerability of 300 mg and 600 mg CBD doses for moderate to severe SAD. The results will guide the design of a Phase 3 trial, focusing on the most effective dose using the Liebowitz Social Anxiety Scale (LSAS) as a measure of efficacy.

March 11, 2024—Announced the completion of its Phase 2 clinical trial evaluating pharmaceutical-grade CBD for SAD. The trial utilized EmpowerPharm's patented Self-Nanoemulsifying Drug Delivery System (SNEDDS) to enhance bioavailability and stability. Following the report's release, EmpowerPharm plans to move into Phase 3 trials, with anticipated market availability by 2028.

December 21, 2023—Announced that the Pharmaceutical Composition for Oral Administration of Cannabinoids patent was published.

December 20, 2023—Disclosed that the last participant concluded the treatment and active involvement in the Company-sponsored Phase 2 clinical investigation. EmpowerPharm is the sponsor of EPI-CBD-001 (NCT05600114), a multicenter, randomized, double-blind, parallel-group, placebo-controlled study focused on assessing the effectiveness, safety, and tolerability of cannabidiol in individuals with SAD. This pivotal Phase 2 study involved the enrollment of 239 patients from 19 clinical centers across the U.S.

November 28, 2023—EmpowerPharm and Stella's Place hosted a virtual Mental Health Forum focused on anxiety in Canada, covering existing and emerging treatments and trends. The panel featured clinical experts including Dr. Jitender Sareen from the University of Manitoba, Dr. Peggy Richter from Sunnybrook Health Sciences Centre, Dr. Mary Bartram from Stepped Care Solutions, and Nzinga Walker, Executive Director of Stella's Place. The discussion was moderated by Dr. Murray Stein, Senior Medical Consultant at EmpowerPharm and Vice Chair for Clinical Research in Psychiatry at UCSD.

September 5, 2023—EmpowerPharm was featured on the *Advancements with Ted Danson* series, broadcast across North America. The award-winning show highlights innovative technologies and discoveries aimed at creating a better future. EmpowerPharm was selected for its dedication to supporting patients with mental health conditions through innovation and advocacy.

October 27, 2022—Announced the dosing of the first patient in their Company-sponsored Phase 2 clinical trial (EPI-CBD-001; NCT05600114). This randomized, double-blind, placebo-controlled study will evaluate the efficacy, safety, and tolerability of cannabidiol in patients with SAD. The trial aims to enroll 225 patients across 22 clinical centers in the U.S.

October 4, 2022—Announced the enrollment of the first patient in their Company-sponsored Phase 2 clinical trial (EPI-CBD-001; NCT05600114).

June 21, 2022—Announced the appointment of Chirag Shah as Vice President of Pharmaceutical Development. With extensive experience in pharmaceutical product development, manufacturing operations, and novel drug delivery systems, Chirag will lead the Company's development initiatives. He holds a Master of Pharmacy degree and has expertise in scaling up and validating drug formulations, as well as managing global product transfers for complex dosage forms.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Crystal Research Associates, LLC ("CRA") with the assistance of EmpowerPharm Inc. ("EmpowerPharm" or "the Company") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions, and the actual events or results may differ from those discussed due to the risks described in EmpowerPharm's statements on forms filed from time to time.

The content of this report with respect to EmpowerPharm has been compiled primarily from information available to the public released by the Company through news releases and other public documents. EmpowerPharm is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by EmpowerPharm or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA has been compensated by the Company in cash of fifty thousand U.S. dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about EmpowerPharm's business, as described below. Investors should not interpret the order in which considerations are presented in this document or other filings as an indication of their relative importance. In addition, the risks and uncertainties covered in the accompanying sections are not the only risks that the Company faces. Additional risks and uncertainties not presently known to EmpowerPharm or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, EmpowerPharm's business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved of investing in the Company, please contact EmpowerPharm by calling (416) 291-2580.

RISK FACTORS

Investing in EmpowerPharm involves significant risks due to its early-stage nature, industry, and market dynamics. Below is a breakdown of some of the key risks associated with investing in the Company, each with potentially serious implications for investors.

Clinical Development and Regulatory Risks

As a clinical-stage pharmaceutical company, EmpowerPharm's future success hinges on the successful development, regulatory approval, and commercialization of its cannabidiol (CBD)-based therapies. Given the inherent unpredictability of clinical trials and the stringent regulatory environment, several risks exist:

Clinical Trial Uncertainty

EmpowerPharm's current CBD formulation for Social Anxiety Disorder (SAD) is advancing toward Phase 3 clinical trials following the positive results of Phase 2. However, clinical trials are inherently risky, with a high failure rate even in late-stage trials. The trial may fail to demonstrate the desired efficacy, safety, or tolerability in a broader population, or unforeseen adverse events may arise, which could halt further development. Additionally, challenges such as patient recruitment delays, unexpected trial costs, or regulatory interventions (e.g., trial holds) may prolong the trial timeline, inflate costs, or lead to failure.

Regulatory Approval Risks

Even if clinical trials are successful, gaining regulatory approval from authorities such as the FDA or Health Canada has its challenges. The FDA's approval process can involve delays, additional data requests, or outright rejections due to safety concerns, unclear efficacy, or manufacturing deficiencies. For CBD products, the regulatory landscape is evolving, and unexpected changes in cannabis or cannabinoid-based drug regulations could alter the approval process or restrict market access.

Compliance and Post-Approval Surveillance

Following approval, EmpowerPharm must comply with extensive post-market regulations, including adverse event reporting, product quality control, and ongoing manufacturing inspections. Any failure in post-approval compliance could lead to costly product recalls, additional regulatory scrutiny, or the withdrawal of market authorization, resulting in significant financial losses.

Market Competition and Commercialization Risks

The pharmaceutical market, particularly in the field of anxiety disorders, is highly competitive. EmpowerPharm faces several challenges related to market adoption, pricing pressures, and product differentiation:

Intense Competition

EmpowerPharm will compete not only with established treatments like SSRIs and benzodiazepines but also with other emerging CBD-based and non-CBD therapies. Competitors with deeper resources, established distribution networks, and existing market share may outperform EmpowerPharm in both marketing and sales execution. Over-the-counter (OTC) CBD products, which are already widely available, may further erode market potential, particularly if patients and prescribers are slow to adopt prescription-grade CBD formulations.

Commercialization and Market Adoption

Even if approved, market adoption is not guaranteed. Physicians and patients may remain hesitant to switch to CBD-based therapies without extensive long-term data supporting efficacy and safety. Convincing prescribers to adopt a new treatment, particularly when generic and OTC options exist, will require a robust commercial strategy, including educating healthcare providers and building strong relationships with key opinion leaders (KOLs) in the psychiatry and neurology fields.

Pricing and Reimbursement Challenges

EmpowerPharm's success will largely depend on its ability to secure favorable reimbursement terms from public and private payers. Securing inclusion in government drug formularies and obtaining coverage from private insurers are critical. Any failure to gain adequate reimbursement could make the product too costly for widespread use, limiting market penetration. Additionally, as healthcare payers continuously seek to control costs, there is a risk of price caps, reimbursement restrictions, or cost-sharing mechanisms that could reduce profitability.

Intellectual Property and Patent Risks

Intellectual property (IP) is a critical asset for EmpowerPharm, especially as it navigates the competitive pharmaceutical landscape. While the Company has developed a proprietary Self-Nanoemulsifying Drug Delivery System (SNEDDS) and has pending patents for its formulations, it still faces IP-related risks, including those described below.

Patent Protection and Enforcement

EmpowerPharm's long-term success depends on securing robust patents that can withstand challenges. Patent disputes are common in the pharmaceutical industry, and the Company could face litigation from competitors challenging the validity of its patents. Additionally, if EmpowerPharm fails to obtain adequate patent protection in key jurisdictions, it could be vulnerable to generic competition, especially as patents begin to expire.

Generic Competition

Should EmpowerPharm's patents be invalidated or expire, the entry of generic competitors could dramatically reduce the Company's market share and pricing power. Patent litigation can be lengthy and costly, draining resources that could otherwise be invested in R&D or commercialization efforts.

Funding and Financial Risks

As a clinical-stage company, EmpowerPharm is not yet generating revenue from product sales, relying heavily on external funding for ongoing operations, clinical trials, and commercialization preparations. Several financial risks are associated with this reliance, including those described below.

Capital Needs and Dilution

Developing a pharmaceutical product through late-stage clinical trials, regulatory approval, and commercialization is a capital-intensive process. If EmpowerPharm is unable to raise sufficient capital on favorable terms, it may need to delay or scale back its development programs, potentially resulting in missed market opportunities. If the Company raises additional funds through equity offerings, existing shareholders could face significant dilution. Debt financing could also impose financial strain, with repayment obligations limiting financial flexibility.

Cash Flow Constraints

Clinical trial delays, regulatory setbacks, or unforeseen operating expenses could place significant pressure on EmpowerPharm's cash flow. Without sufficient cash reserves, the Company may be forced to curtail R&D efforts or delay product launches, affecting future growth prospects.

Operational and Manufacturing Risks

EmpowerPharm is in the process of scaling its operations to meet anticipated demand for its CBD therapies. This includes expanding its manufacturing capacity and ensuring compliance with **Good Manufacturing Practice (GMP)** standards. Key risks associated with scaling and manufacturing include those described below.

Manufacturing Scale-Up

EmpowerPharm is building a state-of-the-art manufacturing facility to produce its CBD products. Scaling manufacturing from clinical to commercial levels is a complex process that requires significant capital investment, time, and expertise. Any issues with technology transfer, production quality, or scaling capacity could delay product availability and increase costs.

Supply Chain Vulnerabilities

The pharmaceutical manufacturing process relies on complex, global supply chains for raw materials, active pharmaceutical ingredients (APIs), and equipment. Any disruptions in the supply chain—due to political instability, global events (e.g., pandemics), or supplier failures—could delay production and impact the Company's ability to meet market demand.

Compliance with Regulatory Standards

Manufacturing pharmaceutical products requires strict adherence to GMP standards and regular inspections by regulatory bodies. Any failure to meet these standards could result in production shutdowns, regulatory fines, or product recalls. The cost of maintaining regulatory compliance could increase operational expenses, affecting profitability.

Management and Execution Risks

EmpowerPharm's leadership and management team will be key to executing its strategy and navigating the complexities of clinical development and commercialization. However, several risks could arise from management-related issues, including those described below.

Leadership Turnover

Key members of EmpowerPharm's executive team, including those with expertise in pharmaceutical development and commercialization, are critical to the Company's success. Any unexpected leadership turnover could disrupt operations, delay strategic initiatives, and diminish investor confidence.

Execution Risks

The Company's ability to execute its business plan—including completing Phase 3 trials, securing regulatory approvals, and commercializing products—depends on the management team's ability to make timely and effective decisions. Delays, poor strategic choices, or failure to execute on key objectives could hinder growth prospects.

Macroeconomic and External Risks

EmpowerPharm is subject to macroeconomic and external risks that can affect the broader pharmaceutical industry, including those described below.

Regulatory and Political Environment

Regulatory frameworks surrounding cannabis-based products are subject to change. Any shifts in federal or state policies related to CBD, medical cannabis, or drug approvals could impact EmpowerPharm's ability to gain market access.

Market Volatility

The broader financial markets and investor sentiment in the biotechnology and pharmaceutical sectors can be volatile. Factors such as interest rate hikes, changes in investor risk appetite, or economic downturns can affect the Company's ability to raise capital and influence stock performance.

While EmpowerPharm presents promising opportunities in the CBD pharmaceutical space, these potential risks must be carefully considered. The Company's ability to overcome clinical, regulatory, financial, and operational challenges will ultimately determine its success. Investors should weigh these risks against the potential for significant returns, especially in a rapidly evolving regulatory and competitive landscape.

Glossary

5-HT1A Receptors—A subtype of serotonin receptor, which is part of the 5-HT (serotonin) receptor family. Found primarily in the brain, it plays a key role in regulating mood, anxiety, and various neurological functions.

505(b)(2) Pathway—A regulatory pathway used by the FDA for drug approval that allows for the approval of modified versions of existing drugs. This pathway can shorten development timelines by allowing companies to use existing data to support safety and efficacy, rather than requiring entirely new studies.

Acceptance and Commitment Therapy (ACT)—A form of psychotherapy that encourages patients to accept their thoughts and feelings rather than fighting them. ACT uses mindfulness and commitment strategies to help individuals align with their core values, even in the presence of challenging emotions or thoughts, and is commonly used for anxiety, depression, and chronic pain.

Anxiolytic—A type of medication or intervention designed to reduce symptoms of anxiety. Anxiolytics can include pharmaceutical drugs like benzodiazepines, SSRIs, and herbal remedies, as well as therapeutic practices such as mindfulness and CBT.

Benzodiazepines—A class of psychoactive drugs used primarily to treat anxiety, insomnia, and seizures. They work by enhancing the neurotransmitter GABA, which has calming effects on the brain. Common benzodiazepines include diazepam (Valium), lorazepam (Ativan), and alprazolam (Xanax), though they are often prescribed short-term due to risks of dependency.

Cannabidiol (CBD)—A non-psychoactive compound found in cannabis plants, widely researched for its potential therapeutic benefits. CBD is believed to have anti-inflammatory, anti-anxiety, and neuroprotective effects, making it popular in the treatment of pain, anxiety, and certain seizure disorders.

Clinical Global Impression of Improvement (CGII)—A standardized assessment tool used in clinical trials to evaluate the overall improvement of a patient's condition from a baseline. CGII scores are used to measure efficacy in treatments for mental health and neurological conditions.

Clinical Research Organization (CRO)—A company that provides outsourced clinical research services, such as trial management and data collection, for pharmaceutical, biotechnology, and medical device companies. CROs help expedite clinical trial processes, allowing companies to bring products to market faster.

Cognitive-Behavioral Therapy (CBT)—A form of psychotherapy that focuses on identifying and changing negative thought patterns and behaviors that contribute to mental health issues. CBT is commonly used to treat anxiety, depression, and other mood disorders, and has a strong evidence base supporting its efficacy.

current Good Manufacturing Practices (cGMP)—Regulatory guidelines established by the FDA to ensure that products are consistently produced to quality standards. cGMPs cover every aspect of production, from raw materials to employee training, and are enforced through regular inspections to ensure consumer safety.

Dravet Syndrome—A rare, severe form of epilepsy that begins in infancy, characterized by prolonged and frequent seizures, developmental delays, and heightened risk of sudden death. Dravet syndrome is difficult to treat with traditional anti-epileptic drugs and often requires specialized care.

Drug Establishment License (DEL)—A license issued by Health Canada that is required for companies involved in manufacturing, packaging, labeling, and importing drugs. A DEL ensures that facilities adhere to Canadian GMP standards to produce safe and high-quality products.

Freedom to Operate—An analysis that assesses whether a product or process can be marketed without infringing on existing patents or intellectual property rights. Freedom to Operate studies are essential for companies aiming to launch new products without legal risks.

Generalized Anxiety Disorder (GAD)—A chronic mental health condition characterized by persistent and excessive worry about various aspects of life. Symptoms often include restlessness, muscle tension, difficulty concentrating, and fatigue. GAD is commonly treated with therapy, medication, or a combination of both.

Good Manufacturing Practice (GMP)-Certified—Certification that indicates a facility follows GMP standards, ensuring the consistent production of safe and effective products. GMP certification is required for companies in many industries, including pharmaceuticals and food, to ensure quality.

International Council for Harmonization (ICH) Standards—Guidelines established to ensure safety, quality, and efficacy in pharmaceutical development across different countries. ICH standards are intended to harmonize technical requirements and promote consistency in drug development and regulation globally.

Lennox-Gastaut Syndrome—A rare and severe form of epilepsy that usually begins in childhood, marked by multiple types of seizures and intellectual disability. It is often difficult to treat with conventional medications, and alternative therapies are frequently explored for management.

Liebowitz Social Anxiety Scale (LSAS)—A scale used to measure the severity of social anxiety disorder symptoms. LSAS assesses both fear and avoidance in social situations and is often used to evaluate treatment progress in clinical settings.

New Drug Application (NDA)—A formal application submitted to the FDA to gain approval to market a new drug in the United States. The NDA includes data on the drug's safety, efficacy, and manufacturing, as well as proposed labeling and packaging information.

New Drug Submission (NDS)—A formal application submitted to Health Canada for the approval to market a new drug in Canada. The NDS contains detailed information on a drug's safety, efficacy, and quality.

Patent Cooperation Treaty (PCT)—An international treaty that allows inventors to file a single patent application that is recognized in multiple countries. PCT applications streamline the process for seeking patent protection internationally.

Pharmaceutical Composition for Oral Administration of Cannabinoids—A formulation designed specifically to deliver cannabinoids orally, ensuring controlled release and consistent absorption for therapeutic use.

Post-Traumatic Stress Disorder (PTSD)—A mental health condition triggered by experiencing or witnessing a traumatic event. People with PTSD may experience intense, disturbing thoughts and feelings related to their trauma that persist long after the event has ended.

Selective Serotonin Reuptake Inhibitors (SSRIs)—A class of antidepressants that increase serotonin levels in the brain by blocking its reabsorption. SSRIs are commonly prescribed for anxiety and depression due to their efficacy and relatively favorable side-effect profile.

Self-Nanoemulsifying Drug Delivery System (SNEDDS)—A drug delivery technology that enhances the absorption of poorly water-soluble drugs by forming a nanoemulsion in the gastrointestinal tract. SNEDDS is often used to improve the bioavailability of compounds like cannabinoids.

Serotonergic System—The network of neurons that utilize serotonin as a neurotransmitter, playing a crucial role in regulating mood, anxiety, and various other physiological functions. Medications that affect the serotonergic system are commonly used in the treatment of depression and anxiety.

Social Anxiety Disorder (SAD)—A mental health disorder characterized by an intense fear of social interactions and concern about being judged or humiliated. SAD can lead to significant avoidance behaviors, impacting daily life and relationships.

Stria terminalis—A bundle of nerve fibers that forms part of the limbic system, connecting the amygdala (a key area for processing emotions, especially fear and anxiety) to other parts of the brain, including the hypothalamus.

Tetrahydrocannabinol (THC)—The primary psychoactive compound in cannabis, responsible for the "high" effect. THC also has therapeutic uses for conditions such as chronic pain, nausea, and muscle spasms.

Tuberous Sclerosis Complex—A genetic disorder that leads to the growth of benign tumors in various organs, including the brain, kidneys, and heart. It often causes seizures, developmental delays, and skin abnormalities and requires a comprehensive approach to management.

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