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Which Biopharma Stocks Are Looking To Score Big In Cannabis Medicine?

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Lost in the fray of countless efforts to bring recreational marijuana to a storefront near you, the advent of cannabis medicine by biotech stocks and pharma companies hit several key milestones in 2018, with little fanfare.

The Food and Drug Administration took a historic leap in June when it [approved Epidiolex](#). Made by **GW Pharmaceuticals**([GWPH](#)), Epidiolex is the first medicine derived from the cannabis plant. The FDA's nod allows it to treat two seizure disorders.

Then in September, the Drug Enforcement Administration made a major policy shift. The [DEA listed Epidiolex under Schedule 5](#) of the Controlled Substances Act, thus declaring that it has a lower potential for abuse than recreational marijuana. Ultimately, [Epidiolex hit the market](#) in November.

These steps were the first to approve the controversial substance from a federal government that for decades was reluctant to accept the concept of legal marijuana. Experts believe the door will open further.

Companies ranging from small biotech stocks to giant pharma companies like **AbbVie** ([ABBV](#)) are exploring cannabis medicine and what products can be derived from it. Many companies are in the startup phase. But hundreds of studies are underway on possible uses for cannabis, including many dealing in pain management. And billions of dollars in potential revenue await the biotech stocks and pharma companies that can navigate the tightrope between growing demand and wary regulators.

"There's too much revenue to be made by states and the federal government (to not allow) cannabis-related drugs and products to become available," said Miracle Mile Advisors

portfolio manager Brian Sterz. Miracle Mile is an independent advisory firm in L.A. that works with high-net-worth clients.

Cannabis Uses Still Unidentified

Still, the medicinal cannabis market is in its infancy. Industry and academic experts have yet to identify all the potential uses for the plant — or the molecules that come from it. Some say the market could be in the billions of dollars just in treating pain.

The advent of cannabis medicine and legal marijuana sales are joined at the hip, Sterz says. As more states legalize marijuana — and reap the fruits of sales taxes — cannabis medicine will grab broader appeal.

"We're all taking steps to remove the stigma," he told Investor's Business Daily.

Other biopharma companies and academics are looking to break into this new realm. The U.S. National Library of Medicine's ClinicalTrials.org lists more than [350 studies in cannabis medicine](#). These are studies of cannabinoids, molecules that come from the cannabis plant.

Laboratory-Created Cannabis

But few have yet to dive into this market with GW Pharma. Other biotech stocks working in cannabis medicine are studying laboratory-created cannabinoids. They include **Cara Therapeutics** ([CARA](#)), **Corbus Pharmaceuticals** ([CRBP](#)), **Insys Therapeutics** ([INSY](#)) and **Zynerba Pharmaceuticals** ([ZYNE](#)).

AbbVie is the only Big Pharma stalwart in the mix, with a drug that treats certain types of nausea and anorexia. A top-rated stock in IBD's Medical-Ethical Drugs industry group, AbbVie has a best-possible [Composite Rating](#) of 99. This means AbbVie stock trades in the top 1% of all stocks in terms of key growth metrics. The remaining biopharma stocks active in cannabis medicine all rank in the bottom half of stocks.

Right now, GW Pharma is easily the biggest biotech stock working exclusively in cannabis medicine. The company believes the FDA's approval of Epidiolex in June was an inflection point for cannabis medicine — and others agree.

Cannabis medicine differs from medical marijuana. Medical marijuana is not subject to stringent clinical studies per the FDA. As a result, it can't be reimbursed through insurance.

"We've always believed that we were blazing a trail for the development of cannabinoid medicines in various therapeutic areas," Stephen Schultz, GW's vice president of investor relations, told IBD. "I think the work we're doing clearly points the way on how to do this."

GW Pharma has yet to offer details from the Epidiolex launch. Schultz said "there is significant demand and expectation for access to this product." Epidiolex costs about \$32,500 for the first year. That number varies based on the patient's age or weight and the dose of cannabis medicine.

Tough To Size Up The Market

So sizing the market is a challenge, Schultz says. The [National Organization for Rare Diseases](#) estimates two in 100,000 children born each year will have Lennox-Gastaut syndrome, one of two disorders that Epidiolex can treat. The population of Dravet syndrome patients — the other disorder — is even smaller.

"Beyond the regulatory approved medicines, it's almost impossible to try to size the market," he said.

Unlike its brethren, GW Pharma uses the cannabis plant in its drug development. The biotech stock also plans to soon seek FDA approval of another cannabis medicine called Sativex in spasticity tied to multiple sclerosis.

There are certain hurdles to using the cannabis plant or creating the molecules that come from it, says Zynerba Chief Executive Armando Anido. To do so, biotech stocks like Zynerba must have the proper DEA licenses. But that's not abnormal, he says. Many experimental drugs are subject to DEA scrutiny.

"If you want to go down the pathway of getting a drug approved by the Food and Drug Administration, and we currently have a Schedule 1 requirement on our CBD (cannabidiol), you have to work with the DEA in order to do that," he told IBD. "To me, that's something that's part of how we develop drugs."

Hard Time Accessing Cannabis

The DEA considers Schedule 1 drugs, like the CBD used by Zynerva, as having a higher potential for abuse and no proven medical benefit. Thus, biotech stocks can have a hard time accessing the plant itself for testing. Zynerva, for example, uses laboratory-created cannabinoids — molecules from cannabis.

There are benefits to doing so, Anido told IBD. When a biotech stock uses the cannabis plant, it must extract the oil and then purify it, adding time and complicating the process. By using molecules created in a lab, Zynerva ensures its CBD is 99.9% pure.

CBD is one of two well-known molecules found in cannabis. The other is tetrahydrocannabinol, or THC. THC is responsible for the euphoric high associated with marijuana. Patients using a CBD oil or gel — like Epidiolex from GW Pharma or Zynerva's experimental medicine — want assurance it's pure.

But that's not always the case, Anido says. In a September 2018 article, Forensic Science International wrote about a study of nine CBD e-liquids used in e-cigarettes. They were from a single maker of cannabinoids and other psychoactive compounds. The website for the products claimed they were 100% CBD extracts.

In the study, however, researchers found two of the nine e-liquids contained THC. Four of the nine contained another lesser-known cannabinoid. One contained dextromethorphan, used in cold medicines with the potential to cause hallucinations at high doses.

Understanding FDA On Cannabis

This isn't the case for FDA-approved products, Anido says. Zynerva is testing a 250-milligram to 500-milligram CBD gel for [Fragile X syndrome](#), a genetic condition that can lead to learning disabilities and cognitive impairment. That dose would be fairly expensive at a dispensary, he says.

"Today, in the medical marijuana space, it's all over the place," he said. "What you may get this week from a dispensary is probably different than what you're going to get a month from now when you come back in order to get some additional product."

In this vein, cannabis medicine remains like any other class of drugs regulated by the FDA. Biotech stocks and Big Pharma companies must develop stringent clinical studies, GW

Pharma's Schultz says. The goal is to ensure a patient gets exactly the same amount of medicine every time, he says.

"The medicine is fully characterized for safety through well-controlled studies, which is what physicians rely on as they utilize the medicine in their patient population," he told IBD.

"What we're doing is very different from the dispensary approach."

Biotech Stocks Aim For CBD, THC Drugs

Most cannabis medicine companies seem to be doing research today in CBD. Some examine the impact of cannabis medicine on cannabinoid receptors known as CB1 and CB2. The body uses these in processes like appetite, pain, mood and memory.

Corbus Pharma's lead cannabis medicine would bind to an [agonist of CB2](#). An agonist initiates a physiological response when combined with sensors in the body. The biotech stock's goal is to ameliorate chronic inflammation and fibrotic problems. It's also testing a CB1 drug that could have a use in several fibrotic conditions.

Fellow biotech stock Cara is working on a [cannabinoid receptor agonist](#) in preclinical development for neuropathic pain.

Insys has an approved cannabis medicine — created synthetically — to [treat anorexia in patients with AIDS](#) and to ease nausea caused by anti-cancer medicine chemotherapy. AbbVie's Marinol has the same purpose. Both contain THC.

The DEA treats cannabis medicines — those derived from a plant and those created in a lab — differently from the plant itself. Epidiolex is a Schedule 5 drug. Marinol is a Schedule 3 drug. Both have a lower potential for abuse than cannabis itself, the DEA says.

Will DEA Relax Its Stance On Cannabis?

Miracle Mile's Sterz expects the DEA to "relax" its stance on cannabis medicine over time.

"Primarily because most of this is not [new science](#)," he said. "There's putting it into a new format, but this is not a new space like maybe [CRISPR technology](#) or [CAR-T](#) or some of these other new technologies that are really coming into their own."

Julie Raque, vice president of marketing for [Cannabistry Labs](#), says the U.S. has reached "critical mass" in terms of Americans approving marijuana use across the board. Cannabistry Labs is a research and development firm for cannabis-infused products.

Raque offers several examples of the swing in public opinion for cannabis. Congress recently [passed the Farm Bill](#), legalizing industrial hemp, a boon for the CBD oil industry. [Canada legalized cannabis](#) for recreational and medicinal purposes. The approval of Epidiolex only helps that effort, she told IBD.

"The approval of this was eye-opening for everyone on the [pharmaceutical side](#) who saw that this was outside of the molecules and the type of engineering that goes on in their traditional research and development," she said. "This plant is so unique with a myriad of therapeutic abilities."

There's Big Money In Cannabis Medicine

Miracle Mile's Sterz expects Big Pharma to get into cannabis medicine in a big way. Many Big Pharma companies are experiencing generic rivalries for some of their mature medicines.

He expects Big Pharma companies to acquire biotech stocks with promising cannabis drugs to help diversify.

"Keep an eye on what's coming out of the mouths of major pharma," he said. "I think that will be your indication. Once one gets bought, they'll all get bought."

There's a lot of money in cannabis medicine, says [Katexco Pharmaceuticals](#) Chief Executive Jonathan Rothbard. Katexco, a private company, is the brainchild of Rothbard and Lawrence Steinman, both members of the [Steinman Lab at Stanford University](#).

Katexco is investigating cannabis medicine in inflammation. But Rothbard sees a big future for cannabis medicine in treating pain. He says it could reduce demand for highly addictive painkillers now on the market. The National Institute on Drug Abuse says more than 115 people die of [opioid overdoses daily in the U.S.](#)

Could Cannabis Medicine Replace Opioids?

Cannabis medicine could help change that paradigm, Rothbard says. [Globally, the opioid market](#) will reach nearly \$35 billion by 2025, according to Grand View Research.

"I think they're going to be a fantastic substitute for opioids in pain relief," Rothbard told IBD. "Ten years from now, no one will be using opioids other than those patients directly out of the operating room. Then, they will be switched to (activators) of CB1 or CB2."

Opioids are highly addictive. But that's not a problem with cannabis, he says.

"Patients (on opioids) reach a dose at which it starts affecting the heart," he said. "That will never happen with a cannabis-based drug, because the wiring of the signaling in the brain is fundamentally different."

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