



Investor Summary

Opportunity

A unique, low-risk, extraordinary high return opportunity in the U.S. cannabis industry today.

MMJ Bio Pharma (MMJ) is seeking a strategic partner/investor to bring to market a highly anticipated, safe, and effective marijuana-based pharmaceutical, offering investors a unique, low risk business model in the U.S. cannabis industry. (See Note below for important information.)

Unlike companies dealing in “medical marijuana” it’s in flower state, MMJ is a bio-pharmaceutical company with a pioneering cannabis formulation (a prescribed pharmaceutical) of CBD+THC via purified botanical extract. The ultimate goal is to produce a targeted, personalized dose of a non-addictive, FDA-approved motor cortex and pain management drug as an alternative to the opiates. MMJ has developed a patent-pending product for symptomatic treatment of Huntington’s Disease, Multiple Sclerosis (MS), and several other pain related conditions. The Company initiated an FDA application process for the MS indication in 2018 that will be followed by an application process for Huntington’s Disease in early 2019. There are two additional pain related targets that are planned for IND application by EOY 2019.

The long history of cannabinoids use and research, its proven safety and efficacy, combined with the MMJ-pursued “accelerated” approval path leveraging the following FDA conventions; Orphan Status, Fast Track, Priority Review and potentially Breakthrough Therapy, support expedited development. Critical end-of-phase two milestones are expected to be reached for HD in late 2021, and for MS in early 2022. These milestones will set the path for additional accelerated development or out-licensing.

MMJ offers investors a “big pharma” return at a fraction of costs and risks typical of such ventures, and by far exceeding the returns of cannabis industry:

- Complete legal certainty, by FDA and DEA, unlike any other recreational cannabis business in the U.S. and Canada;
- Known safety and efficacy of cannabis for the proposed indications;
- Strong barriers of entry for competition from the grow, manufacturing through development;
- World-class, highly experienced team and key partnerships;
- Extraordinary high profitability and investor returns (more than 100% IRR);

Both indications present significant unmet need for an agent able to manage these
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MMJ BioPharma LLC
Website: <https://mmjih.com>

Industry: Pharmaceutical
Sub-Industry: Bio-Pharma

Stage: Clinical Development

Past Capitalization:
Contributed capital: over \$2M

Required Funding:
1st Round: \$15M Equity/Debt

Equity Exit Strategy:
EOP2 Exit via licensing;
HD—2021;
MS—2022

Estimated Annual Market:
Global Medical Marijuana (MM) Market:
\$11B in 2015 @ CAGR 17.1%, growing to \$55B by 2025;

U.S. MM Market:
\$4.8B in 2017 @ CAGR 22.0%, growing to over \$22B by 2025

Use of Proceeds
Operations & R&D: 78%
S&M and G&M: 22%

MMJ BioPharma LLC
Website: <https://mmjih.com>



spasticity and chorea symptoms. Available agents, such as baclofen, tizanidine, and benzodiazepines lack efficacy in some patients and have significant side effects, e.g., benzodiazepine causes a severe addiction, and tetrabenazine and neuroleptics are known to cause detrimental side effects such as depression.

Strategy

The Company intends to develop an efficient, accelerated process for commercializing personalized, cannabis-based CBD+THC medications for both chronic and short-term therapeutic relief, addressing smaller but significant patient groups that are currently underserved by the big pharma. There are four keys distinguishing our strategy:

1. We are exploring strain by strain nuances for a ‘personalized medicine’ approach. There are multiple sub-strains within both the sativa and indica primary strains that function slightly different as CBD to THC ratios; this approach separates MMJ from the one-size-fits-all associated with recreational or dispensary products.
2. We have integrated the entire supply chain in our foundation business arrangements to create a seamless vertical process from the grow stage, through R&D, to commercialization.
3. While focusing on potential orphan populations (We anticipate uncovering an subset of MS patients that will qualify) we are developing a long-term chronic dosing dossier and Health Economics outcomes that will also facilitate off-label use (expected to be at a minimum, 2X the targeted population)
4. We are engaged in developing a RNA diagnostic confirmation of the disease along with HEOR strategy that will summarize the pricing and data requirement of insurers prior to EOP2 activities so we will know exactly where we stand on reimbursement

Product

MMJ has developed a pharmaceutical—cannabinoid (CB) compound in a soft-gelatin capsule dose-form for the treatment of symptoms associated with multiple neurological diseases: Huntington’s Disease chorea (involuntary movements), and spasticity (muscle stiffness) associated with progressive MS. The product is developed as a high quality botanical extract of CBD plus THC along with the ‘tail’ from a chromatography standpoint. We are the first Biopharmaceutical company to engage the FDA on this dual-active component product profile and have received excellent feedback to date on this first-in-class approach.



Competitive Advantage

- Lowest risk cannabis business model
- FDA-approved cannabis-based pharmaceuticals
- Unique pharma-grade manufacturing capability -MMJ’s stakeholder is Schedule I-licensed pharmaceutical manufacturer
- FDA Orphan designation
- Patent-pending formulations and FDA’s 7 years exclusivity
- First-class expert team in big pharma, science, medicine, law and technology

Intellectual Property

Patents: 2 nonprovisional utility patent applications (US)

Targeting 3 additional patient applications by EOY 2019

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Competition

MMJ currently has few direct competitors among the CB pharma in the U.S. for the aforesaid indications and approaches. However, GW Pharmaceuticals (NASDAQ:GWPH) offers a synthetic CB product (Sativax) for MS spasticity that is not approved for U.S. but sold in 28 other countries. There are several other companies (United Pharm., Valeant Pharm. Int., (NASDAQ:VRX), etc.), offering CB pharmaceuticals for other indications that are also not approved for U.S.

There are several companies that offer synthetic CB products for neuro-pain and spasticity but they cause severe side effects due to the synthesis limitations, not present in natural CB products (Indevus (NASDAQ:IDEV), Zynerba Pharmaceuticals, etc.). Producers of non-CB products used for treatment of the aforesaid diseases may also pose competitive challenges by lowering prices, which appeals to the payers. Besides the business strategies that deter competition, MMJ develops a patent portfolio (2 U.S. nonprovisional utility patents are currently filed), and upon the FDA approval, MMJ will receive 7 years U.S. exclusivity for each medical indication.

Management

MMJ has assembled a team of world-known neurologists, genomic experts, bio-informaticians, experts in drug formulation, chemists, clinicians, researchers, and big pharma veterans.

- **Timothy C. Moynahan, Executive Chairman of the Board of Directors**

Mr. Moynahan is an accomplished attorney who serves as the Chairman of the Executive Board of the Global Virus Network—a global authority for the control of viral diseases. Mr. Moynahan also serves on the Advisory Board and Executive Committee of Institute of Human Virology (IHV)—a center of the University of Maryland Biotechnology Institute, affiliated with the University of Maryland School of Medicine, dedicated to the research and prevention of chronic viral diseases and virally linked cancers. Director, Robert Gallo, M.D., is the co-discoverer of the AIDS virus.

- **Duane Boise, President & CEO**

A series entrepreneur, former CEO of Falkirk Hospital (NY), co-founder of the St. Vincent DePaul Homeless Shelter, the first AIDS Hospice in the United States, founder of the EMED—a comprehensive emergency medical evacuation system throughout the Caribbean, and Central & South America, Mr. Boise brings over 25 years’ experience in the medical services industry. He has a strong international business background and a proven ability to establish relationships and organize operations throughout the world under the most demanding conditions.

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CEO

Duane Boise

President & CEO of MMJ
Duane Boise is a series entrepreneur with a history of success in his 25 years of medical services industry experience

Chairman of the Board

Mr. Timothy C. Moynahan

Mr. Moynahan serves as the Chairman of the Executive Board of the Global Virus Network, and serves on the Advisory Board and Executive Committee of the Institute of Human Virology (IHV)

Strategic Partnerships

- Patheon (Thermo Fisher Scientific)
- University of South Florida (USF) – College of Medicine Neurology
- ADMERA Health Genomics
- University of the West Indies
- UBMD Neurology/Jacobs Neurological Institute
- PAREXEL (NASDAQ: PRXL)
- Baker Hostetler (BH)



- **Brian McIlroy, Ph.D**

Former Exec. Dir., Buffalo Institute for Genomics and Data Analytics at UB, former GE executive.

- **Lee Rosebush, MBA, Pharm.D., J.D.**

Partner at BH, FDA “orphan drug” expert, Law360’s top life sciences attorneys under 40.

- **Elio Mariani, Ph.D**

Formulation, 40 years’ experience in big pharma leadership with more than 100 developed products.

- **Bianca Weinstock-Guttman, M.D.**

Director of the Jacobs Multiple Sclerosis Center at UBMD, and Exec. Director of NYSMSC.

- **Lance Shea**

BH Co-Chair Pharmacy Division with over 25 years of experience in law and science.

- **Frank Palumbo, M.D., J.D.**

BH FDA Policy Advisor, Exec. Director Center on Drugs and Public Policy MD School of Pharmacy.

- **Igor Kavalchuk, M.D, Ph.D**

Prof. at University of Lethbridge, med. doctor, expert in next gen. genome sequencing and analysis.

- **Juan Sanchez Ramos M.D., Ph.D**

Professor College of Medicine, Neurology, University of South Florida. Director Huntington Disease COE

- **Marlene Haffner**

Past Director of the FDA Office of Orphan Drugs and founder of Haffner Associates

- **Robert Soto, MBA**

Senior Director – Early Phase Development at PAREXEL

- **Karen Ivester, MSc.**

Senior executive in Global Clinical Operations for biopharma and CRO companies including Covance, Quintiles, PAREXEL and PPD

- **Kevin Brett**

VP Business Development MMJ, former Business Development executive at PAREXEL

Note

The FDA is presently issuing numerous “cease and desist” orders against companies producing products containing marijuana that claim to be effective against symptoms of various illnesses. In addition, the Attorney General of the United States has effectively withdrawn the effects of the “Cole Memorandum” which permitted U.S. Attorneys around the country to choose not to enforce federal marijuana laws. It is now in the discretion of U.S. Attorneys for each district to enforce the present severe restrictions on the growing and sale of marijuana or any products containing marijuana.

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MMJ International Holdings

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More information on the management and FDA study teams:

<http://mmjih.com/mji-management>