

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **April 12, 2023**

MyMD Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

New Jersey
(State or other jurisdiction
of incorporation)

001-36268
(Commission
File No.)

22-2983783
(IRS Employer
Identification No.)

MyMD Pharmaceuticals, Inc.
855 N. Wolfe Street, Suite 601
Baltimore, MD 21205
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(856) 848-8698**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities Registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, no par value per share	MYMD	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On April 12, 2023, MyMD Pharmaceuticals, Inc. (the "**Company**") issued a press release describing developments in the Phase 2 clinical trial of its MYMD-1® product candidate for sarcopenia and frailty. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. Also furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K is a slide presentation that the Company intends, from time to time, to present and/or distribute to the investment community and utilize at various industry and other conferences. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1 and Exhibit 99.2.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing. Furthermore, the furnishing of information under Item 7.01 of this Current Report on Form 8-K is not intended to constitute a determination by the Company that the information contained herein, including the exhibits hereto, is material or that the dissemination of such information is required by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated April 12, 2023 (furnished herewith pursuant to Item 7.01)
99.2	Corporate Presentation, dated April 2023 (furnished herewith pursuant to Item 7.01)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MYMD PHARMACEUTICALS, INC.

Date: April 12, 2023

By: /s/ Chris Chapman
Chris Chapman, M.D.
President

MyMD Pharmaceuticals® Provides Dosing Update on Phase 2 Multi-Center Clinical Trial of MYMD-1® as a Therapy for Delaying Aging and Extending Healthy Lifespan

- Currently, there are no FDA-approved treatments for sarcopenia/frailty -

- MyMD is only 3 patients away from dosing its final patient in its first Phase 2 clinical trial of lead drug candidate MYMD-1® -

BALTIMORE, MD – April 12, 2023 — MyMD Pharmaceuticals, Inc.® (Nasdaq: MYMD) (“MyMD” or “the Company”), a clinical stage biopharmaceutical company developing groundbreaking therapies for the treatment of serious and debilitating autoimmune and inflammatory diseases, today announced a dosing update on its fully-funded Phase 2 clinical trial of lead drug candidate MYMD-1®, an orally available next-generation TNF-alpha inhibitor, as a therapy for chronic inflammation associated with sarcopenia and frailty (NCT05283486).

The Safety Review Committee has confirmed no safety or toxicity issues with the first 30 patients enrolled in this study and has voted unanimously to escalate to the final dose level. Thirty patients enrolled in Cohorts 1, 2, and 3 have completed dosing and end of study visits. To date, three subjects from Cohort 4 have completed end of study visits. There are no outstanding study visits and all 30 patients have officially completed all study parameters and been discharged from the study.

“We are proud of the notable progress that we have made thus far on our first Phase 2 study of MYMD-1,” said Chris Chapman MD, President, Director, and Chief Medical Officer at MyMD Pharmaceuticals. “As we move into the final cohort of this study, we remain hopeful in MYMD-1’s potential to transform future treatment of sarcopenia/frailty in the aging population.”

The Phase 2 multi-center double-blind, placebo controlled, randomized study (NCT05283486) is currently ongoing to investigate the efficacy, tolerability and pharmacokinetics of MYMD-1 in the treatment of chronic inflammation associated with sarcopenia/frailty inpatients aged 65 years or older. The study’s primary objective is to demonstrate reduction of chronic inflammatory markers in patients treated with MYMD-1® versus placebo. To qualify for the clinical trial, patients’ biomarkers during the screening period must be within the following criteria: IL-6 \geq 2.5pg/mL; and/or sTNFR-1 \geq 1500pg/mL. To date, MyMD has randomized and dosed 37 of 40 total patients across Cohorts 1 (n=10; 600mg), 2 (n=10; 750mg), 3 (n=10; 900mg) and 4 (n=7; 1050mg).

On average, it is estimated that 5 to 13% of elderly people between the ages of 60 and 70 are affected by sarcopenia. These numbers increase to 11 to 50% for those aged 80 or above.¹ Currently, there are no FDA approved treatments for chronic inflammation associated with sarcopenia/frailty for those aged 65 years or older.

“The aging disorders market is expected to be at least \$600 billion by 2025²,” continued Dr. Chapman. “TNF- α blockers are the most prescribed drugs by revenue, a global market of approximately \$40 billion per year.³ Studies have shown that a slowdown in aging that increases life expectancy by one year is worth \$38 trillion and by 10 years is worth \$367 trillion.⁴”

MYMD-1® is an oral next-generation TNF- α inhibitor with the potential to transform the way that TNF- α based diseases are treated due to its selectivity and ability to cross the blood brain barrier. MyMD is planning early-stage trials for rheumatoid arthritis and will provide guidance as the program develops.

About MyMD Pharmaceuticals

MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD), is a clinical stage biopharma company developing groundbreaking therapies for the treatment of serious and debilitating autoimmune and inflammatory diseases. MyMD’s lead clinical candidate, MYMD-1®, is an orally available next-generation TNF- α inhibitor with the potential to transform the way that TNF- α based diseases are treated. MYMD-1®, with its small molecule design, improved safety profile and ability to cross the blood brain barrier, has the promise to provide meaningful therapeutic solutions to patients not served by current TNF- α inhibitors and as a potential therapy for CNS-based inflammatory and autoimmune diseases. MYMD-1® has demonstrated the potential to slow the aging process and extend healthy lifespan. The company is evaluating MYMD-1® in Phase 2 studies for sarcopenia/frailty, a result of the aging process, as well as early-stage trials for rheumatoid arthritis (RA), with the potential to expand into other applications.

MyMD’s second therapeutic candidate is Supera-CBD, a novel, synthetic, non-toxic cannabidiol (CBD) analog that is 8000 times more potent a CB2 agonist (activator) than plant-based CBD. The U.S. Drug Enforcement Administration (DEA)’s scientific review concluded Supera-CBD will not be considered a controlled substance or listed chemical under the Controlled Substances Act (CSA) and its governing regulations or require scheduling during development. In addition to its potential role in managing addiction, anxiety, chronic pain and seizures, Supera-CBD has also been shown to have anti-inflammatory effects. For more information, visit www.mymd.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release may contain forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance, or achievements to be materially different from any expected future results, performance, or achievements. Forward-looking statements speak only as of the date they are made and none of MyMD nor its affiliates assume any duty to update forward-looking statements. Words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “may,” “plan,” “will,” “would” and other similar expressions are intended to identify these forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, without limitation: the timing of, and MyMD’s ability to, obtain and maintain regulatory approvals for clinical trials of MyMD’s pharmaceutical candidates; the timing and results of MyMD’s planned clinical trials for its pharmaceutical candidates; the amount of funds MyMD requires for its pharmaceutical candidates; increased levels of competition; changes in political, economic or regulatory conditions generally and in the markets in which MyMD operates; MyMD’s ability to retain and attract senior management and other key employees; MyMD’s ability to quickly and effectively respond to new technological developments; MyMD’s ability to protect its trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on MyMD’s proprietary rights; and the impact of the ongoing COVID-19 pandemic on MyMD’s results of operations, business plan and the global economy. A discussion of these and other factors with respect to MyMD is set forth in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, filed by MyMD on March 31, 2022, as may be supplemented or amended by the Company’s Quarterly Reports on Form 10-Q. Forward-looking statements speak only as of the date they are made and MyMD disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise.

References:

1. von Haehling S, Morley JE, Anker SD. An overview of sarcopenia: facts and numbers on prevalence and clinical impact. *J Cachexia Sarcopenia Muscle*. 2010 Dec;1(2):129-133. doi: 10.1007/s13539-010-0014-2. Epub 2010 Dec 17. PMID: 21475695; PMCID: PMC3060646.
2. <https://www.cnbc.com/2019/05/08/techs-next-big-disruption-could-be-delaying-death.html>

3. October 9, 2019, Tumor Necrosis Factor (TNF) Inhibitor Drugs Market, Acumen Research and Consulting

4. *Nature Aging* | VOL 1 | July 2021 | p. 616–623

Investor:

Robert Schatz
(646) 421-9523
rschatz@mymd.com

Media:

Andrea Cohen
Sam Brown, Inc.
(917) 209 7163
AndreaCohen@sambrown.com



New approaches to treat autoimmune diseases and combat aging

Chris Chapman, M.D.

President, Director and Chief Medical Officer

April 2023

© 2023 MyMD Pharmaceuticals. All Rights Reserved



NASDAQ: MYMD

Forward-Looking Statement

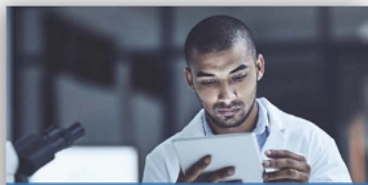


This presentation may contain forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any expected future results, performance, or achievements. Forward-looking statements speak only as of the date they are made and none of MyMD nor its affiliates assume any duty to update forward-looking statements. Words such as "anticipate," "believe," "could," "estimate," "expect," "may," "plan," "will," "would" and other similar expressions are intended to identify these forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, without limitation: the timing of, and MyMD's ability to, obtain and maintain regulatory approvals for clinical trials of MyMD's pharmaceutical candidates; the timing and results of MyMD's planned clinical trials for its pharmaceutical candidates; the amount of funds MyMD requires for its pharmaceutical candidates; increased levels of competition; changes in political, economic or regulatory conditions generally and in the markets in which MyMD operates; MyMD's ability to retain and attract senior management and other key employees; MyMD's ability to quickly and effectively respond to new technological developments; MyMD's ability to protect its trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on MyMD's proprietary rights; and the impact of the COVID-19 pandemic or similar public health emergencies on MyMD's results of operations, business plan and the global economy. A discussion of these and other factors with respect to MyMD is set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed by MyMD on March 31, 2023 as may be supplemented or amended by the company's quarterly reports on Form 10-Q. Forward-looking statements speak only as of the date they are made and MyMD disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Targeting large markets with groundbreaking, next-generation approaches



The MyMD Opportunity



NEXT-GENERATION APPROACH

Positive Data

MYMD-1[®] first oral, selective
TNF-alpha inhibitor

SUPERA-CBD[™] novel,
potent synthetic cannabidiol
(CBD) analog



PIPELINE WITH BROAD POTENTIAL

Two Candidates Targeting Large Markets

- Inflammatory/Autoimmune (RA)
- Sarcopenia/frailty (Aging)
- Neurologic (Epilepsy, chronic pain, anxiety)



POSITIONED FOR SUCCESS

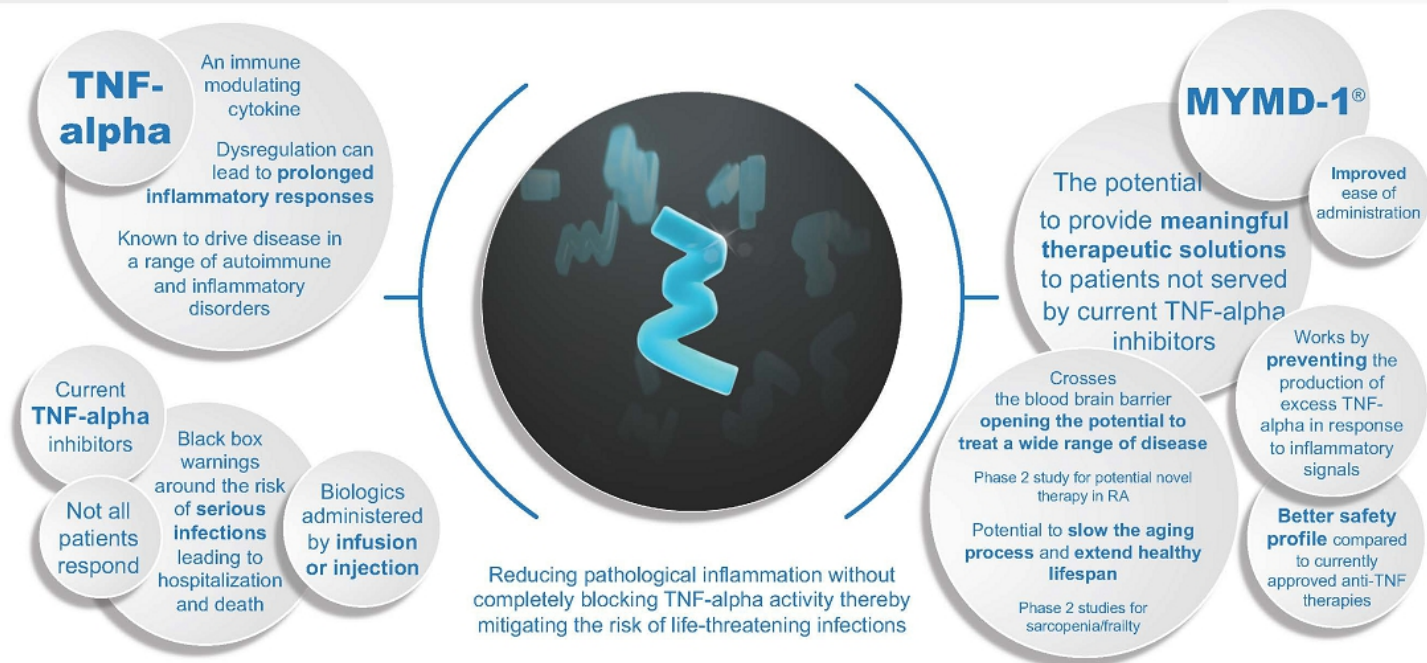
The Right Team to Execute

- High-value IP portfolio
- Experienced team
- Prominent advisors
- Reputable collaborations

DRUG CANDIDATE	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
MYMD-1® Immune Regulator	Sarcopenia (Aging)	[Progress bar: Preclinical to Phase 2]				
	Rheumatoid Arthritis	[Progress bar: Preclinical to Phase 1]				
	Hashimoto's Thyroiditis	[Progress bar: Preclinical to Phase 1]				
	Additional Programs	[Progress bar: Preclinical]				
Supera-CBD™ Synthetic CBD Analog	Epilepsy	[Progress bar: Preclinical]				
	Chronic Pain	[Progress bar: Preclinical]				
	Anxiety	[Progress bar: Preclinical]				

Crossing the Blood Brain Barrier

MYMD-1®: Next-Generation Oral, Selective TNF-Alpha Inhibitor



1 INTRODUCTION

Rheumatoid arthritis (RA) is the most prevalent chronic inflammatory disease and is characterized by inflammation of the synovium of the joints, resulting in joint destruction. It is associated with chronic pain, loss of function, and disability. The murine model of Collagen Antibody Induced Arthritis (CAIA) mimics many of the features of arthritis in humans and has been used successfully in addressing questions of disease pathogenesis and to screen candidate therapeutic agents. Tumor necrosis factor-alpha (TNF- α) is a proinflammatory cytokine that plays a pivotal role in regulating the inflammatory response in chronic autoimmune diseases such as RA. The discovery of the role of TNF- α in the pathogenesis of RA has led to anti-TNF biological therapies as a breakthrough in the treatment of RA. The objective of this study was to investigate anti-inflammatory effects of MYMD-1®, a small molecule selective inhibitor of tumor necrosis factor alpha (TNF- α) with easy access to the body including the brain, in the murine CAIA model.

Adapted from poster presentation at the 2023 SOT Annual Meeting: P148

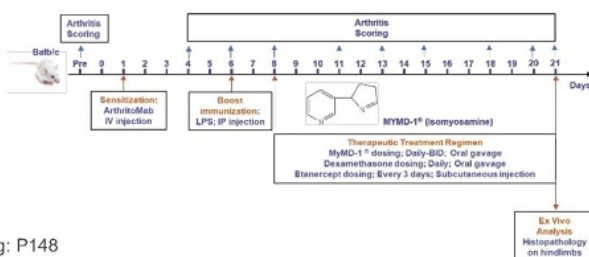
11

MyMD | Corporate Overview

April 2023

2 EXPERIMENTAL PROCEDURES

The CAIA model was induced in female Balb/c mice by an intravenous injection of a monoclonal antibodies cocktail that are directed to collagen type II on Day 1 (sensitization), followed by an intraperitoneal injection of the endotoxin LPS on Day 6 (boost immunization). Three oral doses of MYMD-1® (50, 250 and 450 mg/kg/day) given BID (two times a day) were tested starting at the onset of the disease (Day 8 in this study). In addition, Dexamethasone was given daily by oral gavage at 0.3mg/kg and Etanercept was administered subcutaneously twice weekly at 10 mg/kg, both as positive controls. The therapeutic effect of MYMD-1® on inflammation was assessed by measuring the clinical score and paw inflammation (volume). At termination, the histopathological features such as infiltration of polymorphonuclear and mononuclear cells, pannus formation, cartilage degradation and bone resorption of the affected joints were analyzed. Statistical analysis were performed using Unpaired student t-test, One-Way or Two-way ANOVA in comparison to the CAIA/vehicle control. *, +p<0.05; **, ++p<0.01; ***, +++p<0.001; ****, ++++p<0.0001.



Adapted from poster presentation at the 2023 SOT Annual Meeting: P148

12

MyMD | Corporate Overview

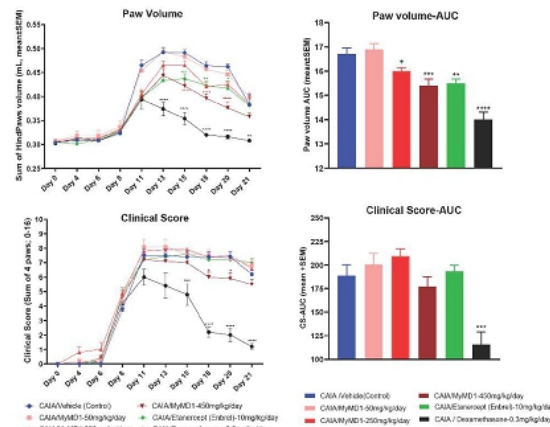
April 2023

A Naturally Occurring Novel Therapeutic and Oral Selective Inhibitor of TNF- α , MYMD-1® (Isomyosamine), Significantly Reduced the Inflammation and Disease Severity in Murine Model of Collagen Antibody Induced Arthritis

3 IN-LIFE RESULTS

Following arthritis induction, paw inflammation was observed starting from Day 8, peaked on Days 11 to 13 and then slowly decreased towards the end of the study (Days 20 to 21). Treatment with MYMD-1® 450 mg/kg/day significantly reduced the clinical score and the paw volume in BALB/c arthritic mice when compared to CAIA disease control (Figure 1). A similar observation was noted with MYMD-1® at 250 mg/kg/day but at lesser extent. There was no clinical signs and no effect on body weights associated with MYMD-1® treatment.

Figure 1: Clinical Score and Paw Volume Measurements



Adapted from poster presentation at the 2023 SOT Annual Meeting: P148

A Naturally Occurring Novel Therapeutic and Oral Selective Inhibitor of TNF- α , MYMD-1® (Isomyosamine), Significantly Reduced the Inflammation and Disease Severity in Murine Model of Collagen Antibody Induced Arthritis

4 HISTOPATHOLOGY RESULTS

Histopathological changes associated with arthritis (inflammation, erosion, synovial hyperplasia, bone degeneration and periosteal changes) were observed in CAIA/vehicle control animals. Disease severity (total composite score) was reduced by 47% with MYMD-1® at 450 mg/kg/day while the reduction was 37% with Etanercept at 10 mg/kg (Figure 2). MYMD-1® at 50mg/kg/day had no reductive effect on the disease state. Scanned images obtained from decalcified left hindlimbs stained with H&E show the thickening of the joint space by pannus and inflammation in the vehicle control when compared to MYMD-1® (450mg/kg) treatment (Figure 3).

Figure 2: Effect of MYMD-1® on histopathology changes

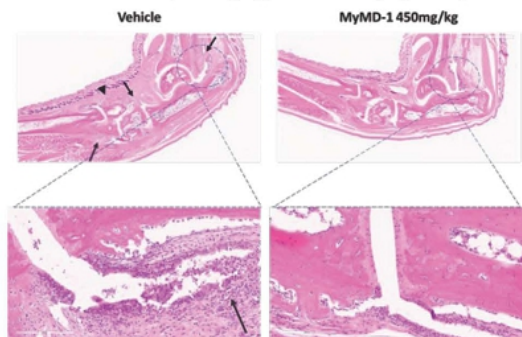
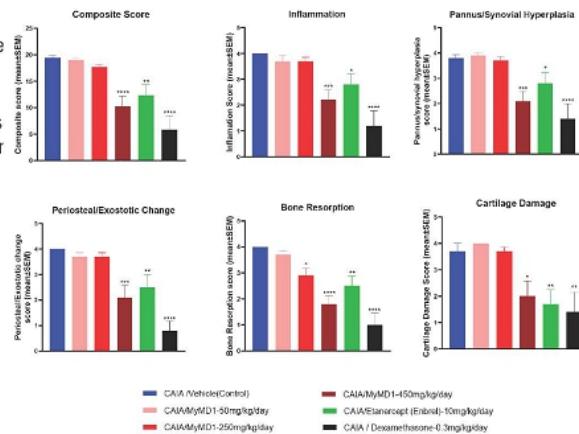


Figure 3: Representative Hematoxylin Eosin (H&E) staining of decalcified left hindpaw

Upon low and high magnification in the tibiotarso-metatarsal joint, joint space is thickened by pannus and inflammation (arrows) in vehicle control when compared to MYMD-1® treated animal. Periosteal reaction (bone exostosis) is also noted (arrowhead) in the vehicle control.

Adapted from poster presentation at the 2023 SOT Annual Meeting: P148

5 CONCLUSION

MYMD-1[®] administration at 450 mg/kg/day inhibited arthritis development in Collagen Antibody Induce Arthritis murine model, with in-life data consistent with histopathological findings. Moreover, no clinical signs or body weight loss was associated with MYMD-1[®] treatment at 450mg/kg/day. Unlike currently available TNF- α inhibitors, MYMD-1[®] can be given orally and is a promising drug for rheumatoid arthritis.

Adapted from poster presentation at the 2023 SOT Annual Meeting; P148

MYMD-1[®] Regulatory Pathway in RA



Double-Blind, Placebo-Controlled Study: Recruiting 3rd Quarter of 2023



12 weeks



Oral Capsule



Male and Female Adults



Rheumatoid Arthritis



United States

Phase 2 study investigating the efficacy, tolerability and pharmacokinetics of MyMD-1[®] in the treatment of participants with RA

Planned IND Submission
2Q2023

Planned IRB Protocol Approval
2Q2023

Planned Patient Recruitment
3Q2023

Planned Enrollment/Dosing to Begin
3Q2023

OBJECTIVES

Primary

- Demonstrate that MYMD-1[®] added to MTX, in participants with moderate-to-severe active RA, is effective for reduction of signs and symptoms of rheumatoid arthritis at 28 days.
- To evaluate the biological activity of MyMD-1[®] added to MTX, in participants with moderate-to-severe active RA.

ENDPOINTS

Primary Efficacy Endpoint

- Percentage of Participants Achieving American College of Rheumatology 20% (ACR20) Response at 28 days
- Percent change from baseline: TNF- α

Tackling Sarcopenia in Aging Populations



MYMD-1®: Next-Generation Oral TNF-alpha Inhibitor

Opportunity in Aging



Aging is closely linked to **frailty, multiple morbidities, and death**

due to conditions such as **neoplastic, cardiovascular, neurodegenerative, metabolic, or autoimmune diseases**

Cost of hospitalizations for individuals with sarcopenia in the U.S. was estimated at **\$40.4 Billion**

25% of +65 year olds are affected by sarcopenia

Global Population +65 is **~700 million**

Americans 65+ projected to grow from **52 M in 2018 to 95M** by 2060

16% to 23% of total population

Sarcopenia, or age-related frailty and decline in physical function, leads to **increased hospitalization, disability, and death**

References

1. Si, Sawyer JL, Boyd CM, Grossardt BR, Bobo WV, Finney Rutten LJ, Roger VL, et al. Risk of developing multimorbidity across all ages in an historical cohort study: differences by sex and ethnicity. *BMJ Open*. 2015;5:e006413. 2. Kochanek KD, Murphy SL, Xu J, Anas E. Deaths: Final Data for 2017. *Natl Vital Stat Rep*. 2019;68:1-77. 3. <https://www.prb.org/resources/fact-sheet-aging-in-the-united-states/> 4. United Nations World Population Aging 2019; 5. Economic Impact of Hospitalizations in US Adults with Sarcopenia

Published in *Journal of Drug Research*

- Shown to be safe and well tolerated.
- Pharmacokinetics of Oral Dose in Capsules in Healthy Subjects
- Decrease in TNF-α levels in MYMD-1® over placebo



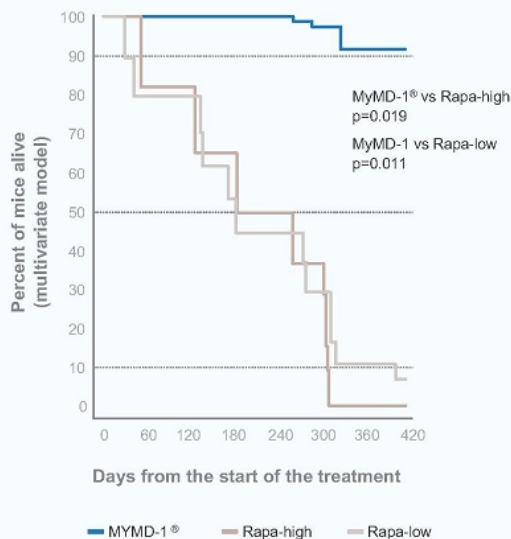
Conducted at Johns Hopkins School of Medicine and published in *Journal of Gerontology: Biological Sciences*

- 4x more effective than rapamycin in delaying aging
- Extended life of mice, even at advanced age
- Improved health span characteristics in terms of weight loss, muscle strength, and frailty progression

References
<https://www.thieme-connect.de/products/ejournals/abstract/10.1055/ia-1962-6834>
<https://doi.org/10.1093/gerona/glac142>

MYMD-1®: Significant Four-Fold Improvement with MYMD-1® vs Rapamycin

MYMD-1 vs Rapa-high and Rapa-low



- Preclinical data, conducted at Johns Hopkins School of Medicine with exciting implications
 - ✓ Delayed aging and extended the lifespan of mice, even at advanced age
 - ✓ Improved health span characteristics
 - ✓ Milder weight loss
 - ✓ Greater muscle strength maintenance
 - ✓ Amelioration of progression to frailty
- No concerns of increased beta amyloid accumulation in the brain in the study

Double-Blind, Placebo-Controlled Study: Recruiting Active/Ongoing



28 days



Oral Capsule



Male and Female
aged 65 years or older



Sarcopenia/Frailty



United States

Phase 2 study investigating the efficacy, tolerability and pharmacokinetics of MYMD-1[®] in the treatment of participants with with chronic inflammation associated with sarcopenia/frailty

IND Cleared FDA
October 2021

Screening
February 2022

Enrollment/Dosing
February 2022

Last Patient Enrolled
2nd Quarter 2023
(anticipated)

OBJECTIVES

Primary

- Demonstrate reduction of chronic inflammatory markers in participants treated with MYMD-1[®]
- Evaluate the PK of oral doses of MYMD-1[®] capsules

ENDPOINTS

Primary Efficacy Endpoint

- Effect on serum levels of sTNFR1, IL-6, and TNF α over 28 days of treatment
- Plasma concentrations and parameters of MYMD-1[®]
- Urine parameters of MYMD-1[®]



Jeremy D. Walston, MD
Lead PI
Scientific Advisor



Additional Preclinical Targets

MYMD-1[®]: Next-Generation TNF-Alpha Inhibitor



Published in The Journal of Immunology

MYMD-1®, a Novel Immuno-Regulator, Ameliorates Autoimmune Thyroiditis via Suppression of Th1 Responses and TNF- α Release



Published in Journal of Neuroimmunology

MYMD-1®, a novel alkaloid compound, ameliorates the course of experimental autoimmune encephalomyelitis (MS Model)

References

<https://www.jimmunol.org/content/202/5/1350>
[https://www.jni-journal.com/article/S0165-5728\(19\)30220-6/fulltext](https://www.jni-journal.com/article/S0165-5728(19)30220-6/fulltext)

Additional Programs Underway

Bascom Palmer Collaboration

- On July 12, 2022, we announced a new collaboration with Bascom Palmer Eye Institute of Miami, Florida to collaborate on a pre-clinical study using MYMD-1® as a potential treatment for traumatic optic neuropathy (TON). To date, our collaboration with Bascom Palmer has included pre-clinical and clinical investigations.

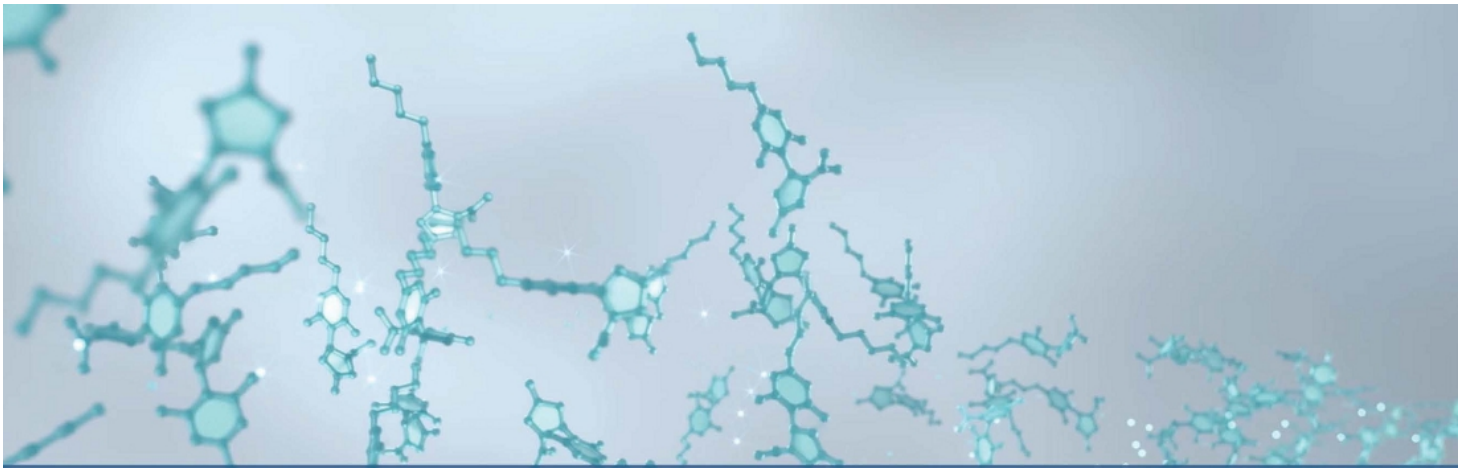
Pre-Clinical

- In July 2022 we entered into a Material Transfer Agreement with Bascom Palmer. Our collaboration was announced in a press release and in an article in *Ophthalmology Times*. Bascom Palmer confirmed in August 2022 that it had received a quantity of our MYMD-1® product candidate and MyMD provided a material safety datasheet and certification of analysis.
- In August 2022, Bascom Palmer researchers conducted a preliminary introductory study of TON in mice. Investigators ran a crush injury of the mice's optic nerves with and without MYMD-1®. The study drug was given once per day via oral gavage at a dosage of 30 mg/kg of body weight. The mice were treated for five days, untreated for two days, and then sacrificed, and their TNF- α levels were measured. Data from this study is pending. We intend to plan additional pre-clinical studies.

Clinical

- In addition to the pre-clinical study described above, we are collaborating with Bascom Palmer to plan future a clinical study. In August 2022, Bascom Palmer researchers executed a confidentiality and non-disclosure agreement, and Bascom Palmer produced a draft protocol synopsis entitled, Assessment of the Anti-Inflammatory Effects of MYMD-1® in Non-infectious Anterior Uveitis: A Randomized Controlled, Double Blind Clinical Study.

Neurology/Depression Program	
Pre-Clinical Completed	Immune-Mediated Depression
Pre-Clinical Completed	Multiple Sclerosis
Pre-Clinical Completed	MS Depression



Exploring Unmet Needs In Epilepsy, Chronic Pain And Anxiety



Supera-CBD™ : Next-Generation Synthetic Cannabinoid

DEA scientific review concluded Supera-CBD will not be considered a controlled substance or listed chemical

Epilepsy

Epilepsy in seniors is up to **240** per 100,000 per year

Adults with epilepsy ~**3M** in the U.S.

~**470,000** Children have active epilepsy in the U.S.

Chronic Pain

It is estimated that the **total value of lost productivity** due to chronic pain is **\$300B** annually

50.2 Million (20.5%) U.S. adults experience chronic pain based on analysis of NHIS data

Anxiety

Generalized anxiety disorder (GAD) affects **6.8M** adults

3.1% of the U.S. population

An estimated **31.1%** of U.S. adults experience an anxiety disorder at some time in their lives

43.2% only are receiving treatment

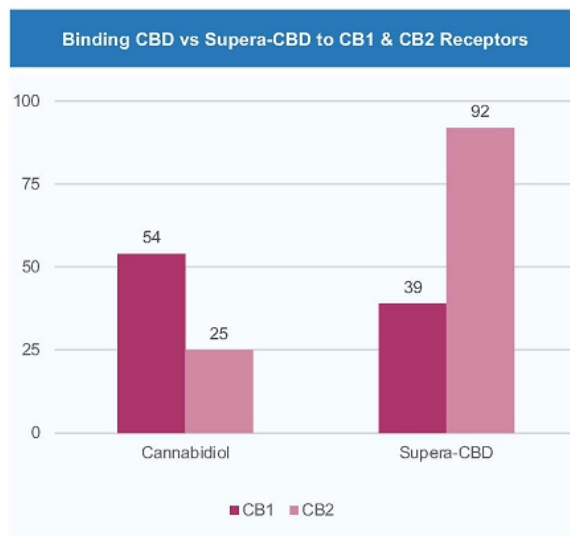
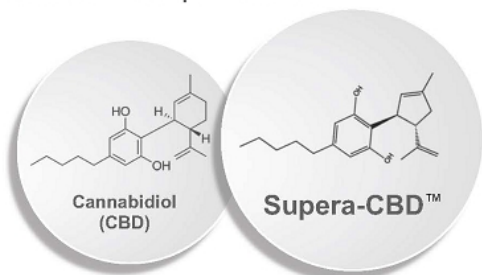
References
 CDC 2020, Neuropsychiatric Disease and Treatment, 2016, Harvard Medical School, 2007, National Comorbidity Survey (NCS), (2017, August 21). Retrieved from <https://www.hcp.med.harvard.edu/ncs/index.php>. Data Table 1: Lifetime prevalence DSM-IV/WMH-CIDI disorders by sex and cohort.

Positive Preclinical Data Supports Development

Studies have shown **Supera-CBD™** to be **dramatically more potent** compared to plant-derived CBD in its ability to **effectively target CB2 receptors**.

Agonists targeting CB2 receptors have the potential to treat acute, chronic and inflammatory pain, as well as neurological diseases.

Supera-CBD™ can be **synthesized** at a **fraction of the cost** of plant-derived CBD purification.



Supera-CBD™

- Potent agonist at the CB2 Receptor
- The EC50 for Supera-CBD™ is 3.7 nM
- The EC50 is >8000 times greater than CBD which is >30,000 nM
- EC50=concentration that gives half-maximal effect at receptor activation

Plant-Derived CBD

- Has no physiological agonist activity at the CB2 receptor
- EC50 is >30 uM

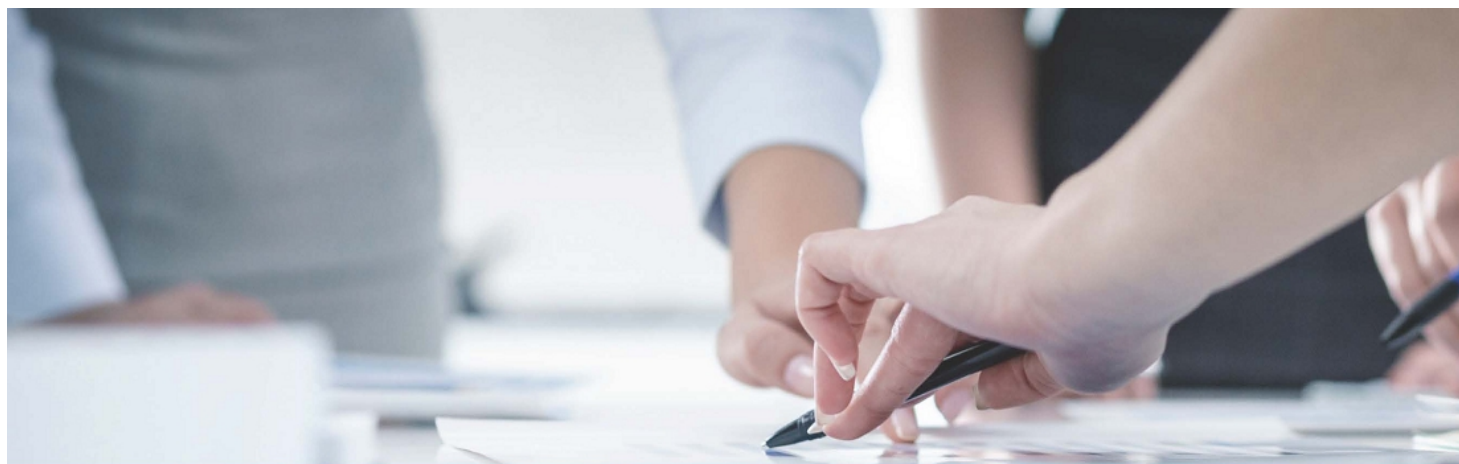
Since CB2 receptor is the primary anti-inflammatory mechanism of action of cannabinoids, this suggests that **Supera-CBD™ could have dramatic therapeutic applications for diseases involving immune activation, such as autoimmune diseases, dementias and epilepsy.**

Since CB2 receptor is the primary anti-inflammatory mechanism of action of cannabinoids, this suggests:

Supera-CBD™ could have dramatic therapeutic applications for diseases involving immune activation, such as autoimmune diseases, dementias and epilepsy.

Supera-CBD is >8,000 Times More Potent a CB2R Agonist than CBD

Compound	Assay Name	Assay Format	Assay Target	EC50	Unit	Hill	Curve Bottom	Curve Top	Max Response
Supera-CBD™	cAMP	Agonist	CNR2	0.00368	uM	1.0761	0	90.158	94.699
CBD	cAMP	Agonist	CNR2	>30	uM	98.94			



Positioned for Significant Value and Growth



Corporate Overview

World-Class Leadership Team With A Proven Track Record



Chris Chapman, MD

President, Director and Chief Medical Officer



Adam Kaplin, MD, PhD

Chief Scientific Officer



Paul Rivard, Esq.

Chief Legal Officer






Jenna Brager, PhD, RN, MS

VP of Drug Development



Excellent IP Portfolio

 Molecule	 Program	 Base Composition	 Extensions
MYMD-1[®]	Rheumatoid Arthritis	March 31, 2036	TBD
	Sarcopenia	March 31, 2036	
	Type 2 Diabetes	April 16, 2037	
	Uveitis	March 31, 2036	
SUPERA CBD[™]	Chronic Pain	February 11, 2039	TBD
	Epilepsy	February 11, 2039	
	Addiction	February 11, 2039	
	Epilepsy	February 11, 2039	

Funded Through Value-Generating Milestones

MYMD-1®

Sarcopenia (Aging)

Data readout 3Q2023 (anticipated)

Rheumatoid Arthritis

Planned IND Submission 2Q2023

Planned IRB Protocol Approval 2Q2023

Planned Patient Recruitment 3Q2023

Planned Enrollment/Dosing to Begin 3Q2023

Hashimoto's Thyroiditis

IND Cleared 2Q 2020

Phase I Completed 3Q 2021 (Ready to proceed to Phase 2)

SUPERA-CBD™

✓ POC Studies completed in Epilepsy, Chronic Pain, Anxiety

Genotoxicity Completed 3Q 2022

File IND TBD

**PHASE 2 STUDY FOR
SARCOPENIA**
Johns Hopkins University

Clinical Research of West
Florida
*Tampa
Clearwater*

The MyMD Opportunity



Promising Data



Two Candidates
Targeting Large Markets



The Right Team
to Execute

**Groundbreaking biotech research on
first-in-class drug therapies**

- Works by preventing the production of excess TNF-alpha in response to inflammatory signals
- Improved ease of administration
- Better safety profile compared to currently approved anti-TNF therapies
- Crosses the blood brain barrier opening the potential to treat a wide range of disease (autoimmune and inflammatory)
 - Phase 1 study for potential novel therapy in RA
- Potential to slow the aging process and extend healthy lifespan
 - Phase 2 studies for sarcopenia/frailty



Reducing pathological inflammation without completely blocking TNF-alpha activity thereby mitigating the risk of life-threatening infections

- TNF-alpha is an immune modulating cytokine
 - Dysregulation can lead to prolonged inflammatory responses
 - Known to drive disease in a range of autoimmune and inflammatory disorders
- Current TNF-alpha inhibitors
 - Black box warnings around the risk of serious infections leading to hospitalization and death
 - Biologics administered by infusion or injection
 - Not all patients respond



MYMD-1®: The potential to provide meaningful therapeutic solutions to patients not served by current TNF-alpha inhibitors

Committed Board



Joshua Silverman

Chairman of the Board of Directors



Bill J. White

Director



Craig Eagle

Director



Chris Chapman, M.D.

President, Director and Chief Medical Officer



Chris Schrieber

Director



Jude Uzonwanne

Director



Patient
Aging
Approach