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): **March 20, 2023**

MyMD Pharmaceuticals, Inc.
(Exact name of Registrant as specified in its charter)

New Jersey	**001-36268**	**22-2983783**
(State or other jurisdiction of incorporation)	(Commission File No.)	(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 March 20, 2023, MyMD Pharmaceuticals, Inc. (the "***Company***") issued a press release announcing that it will present data from a preclinical study of its MYMD-1® product candidate in a rheumatoid arthritis (RA) model at the 2023 Society of Toxicology Annual Meeting. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

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, 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 March 20, 2023 (furnished herewith pursuant to Item 7.01)
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: March 20, 2023

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

Exhibit 99.1

MyMD Pharmaceuticals® and Charles River Present Positive Data for Next Generation, Oral TNF-α Inhibitor MYMD-1® in Rheumatoid Arthritis

Preclinical results showed MYMD-1® significantly reduced histopathological changes and the severity of standard arthritis clinical trial measures compared to placebo; demonstrate future potential to disrupt the TNF-α inhibitor market

BALTIMORE, MD– March 20, 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, is presenting data from a preclinical study of investigational, oral TNF-α inhibitor MYMD-1® at the 2023 Society of Toxicology Annual Meeting (SOT) in Nashville, TN. Study results comparing MYMD-1 to placebo were very highly significant and showed MYMD-1 reduced histopathological changes and the severity of standard arthritis clinical trial measures.

The study was designed to investigate the anti-inflammatory effects of MYMD-1® in a rheumatoid arthritis (RA) model that mimics features of arthritis in humans and included commonly used clinical arthritis endpoints. Histopathology parameters were very highly significant vs placebo for composite score ($p<0.0001$), bone resorption ($p<0.0001$), periosteal/exostatic change ($p<0.001$), inflammation ($p<0.001$), pannus/synovial hyperplasia ($p<0.001$), and in life pawn volume ($p<0.001$). Disease severity (total composite score) was reduced by 47% with MYMD-1® at 450 mg/kg/day orally versus a 37% reduction for etanercept 10 mg/kg by subcutaneous injection (see attached graphs).

"These results demonstrate the potential of MYMD-1® to inhibit arthritis development as shown in this research model," said Sonia Edaye, Lead Investigator and Pharmacology/Discovery Scientist at Charles River Laboratories. "Unlike current TNF-α inhibitors, MYMD-1® can be given orally and is a promising investigational new drug for rheumatoid arthritis."

"These very highly significant results are exciting and pave the way for our plans to develop MYMD-1 as a potential treatment for rheumatoid arthritis," said Chris Chapman MD, President, Director, and Chief Medical Officer at MyMD Pharmaceuticals. "With its differentiated oral administration and selectivity, MYMD-1® has strong potential as a next-generation TNF-α inhibitor that may one day offer a new and meaningful therapeutic solution for the more than 1 million people affected by RA in the US[1], many of whom are not served by current options."

Poster #3046/P148 entitled "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," is scheduled for poster presentation today March 20, 2023, at 9:00 AM CT.

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.

Study Design

The research model was induced by an intravenous injection of a monoclonal antibodies cocktail that directed to collagen type II on Day 1 (sensitization), followed by an intraperitoneal injection of the endotoxin LPS on Day 6 (boost immunization). Three doses of MYMD-1® (50, 250 and 450 mg/kg/day) were tested, and the dose formulations were administered by oral gavage, twice daily, starting at the onset of the disease (Day 8 in this study). Etanercept (a biologic TNF-α inhibitor) and Dexamethasone (a glucocorticoid) were also administered respectively twice weekly by subcutaneous injection (10 mg/kg) and daily by oral gavage (3 mg/kg) as positive controls.

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) has determined that Supera-CBD will not be classified as a regulated chemical 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. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7085464/

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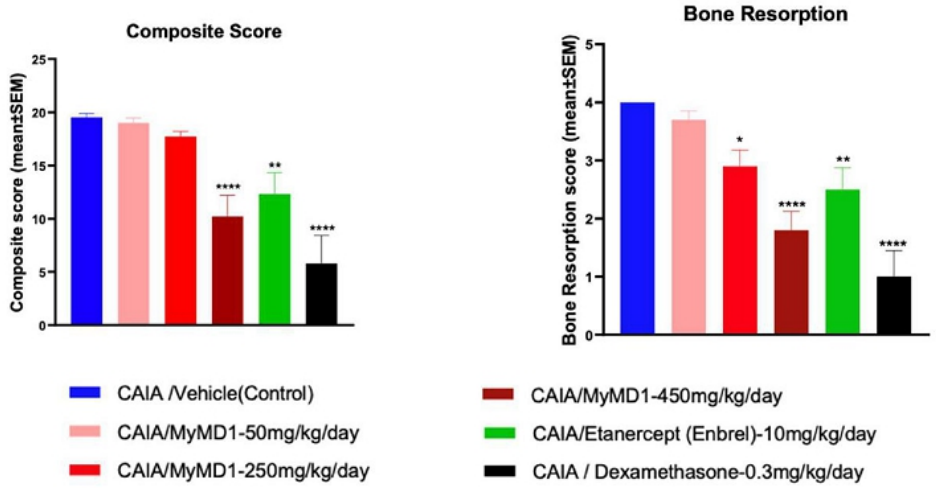
2023 Society of Toxicology/Poster #3046/P148

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



Statistical analyses 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.

Composite Score is the severity and sum of all histopathology parameters listed below from the results of the study.

Disease severity (total composite score) was reduced by 47% with MYMD-1® at 450 mg/kg/day orally versus a 37% reduction for etanercept 10 mg/kg by subcutaneous injection (see graph above).

Bone Resorption is found in areas in which osteoclasts are actively removing bone and bone loss occurs.

Periosteal and exostotic changes are found in areas in which a periosteal reaction occurs. The periosteum is active and is thickened by woven or mature bone formation.

Pannus and synovial hyperplasia occur when the synoviocytes are plump and/or increased in number. Pannus is a fibrovascular tissue, which corresponds to vascular granulation tissue.

MYMD-1® reduction in the severity of the combined histopathology disease results were better than etanercept by ten percentage points.

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

Sonia Edaye[1], Christopher Chapman[2], Gary W. Wolfe[3], Agathe Bedard[1], Rana Samadfam[1]
[1]CHARLES RIVER LABORATORIES, Senneville, Quebec, Canada; [2]MYMD Pharmaceuticals Inc®., Baltimore, Maryland USA; [3]GWTOX, Herndon, Virginia, USA

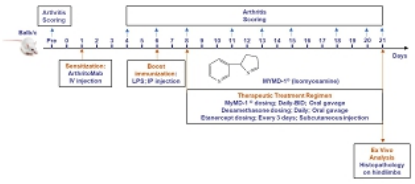
1 INTRODUCTION

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.

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.

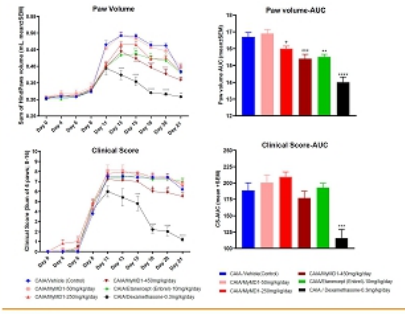
Statistical analysis were performed using Unpaired student t-test, One-Way or Two-way ANOVA in comparison to the CAIA/vehicle control. *:p<0.05; **: **p<0.01; ***:***p<0.001; ****:****p<0.0001.



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



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.

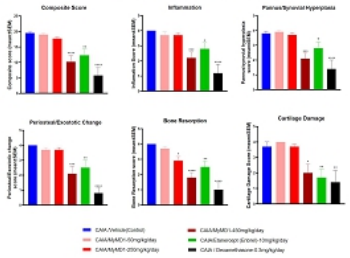
6 ACKNOWLEDGMENT

The authors would like to thank the operation team in In-Vivo Pharmacology and Pathology group for their dedicated work.

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



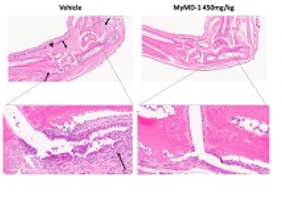


Figure 3: Representative Hematoxilin Eosin (H&E) staining of decalcified left hindpaw

Upon low and high magnification in the tibio-tarso-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.