

**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): **July 31, 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 July 31, 2023, MyMD Pharmaceuticals, Inc. (the "**Company**") issued a press release announcing results from its randomized Phase 2 study of oral TNF- α inhibitor, MYMD-1® in patients with chronic inflammation associated with sarcopenia, or age-related frailty. 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 July 31, 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: July 31, 2023

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

**MyMD Pharmaceuticals Reports Statistically Significant Positive Topline
Phase 2 Results for Next Generation Oral TNF- α Inhibitor MYMD-1[®] in Sarcopenia/Age-Related Frailty**

- MYMD-1 significantly reduced serum levels of chronic inflammatory markers and met all primary pharmacokinetic and secondary safety and tolerability endpoints across multiple doses over 28 days of treatment

- MYMD-1 demonstrated statistical significance across three biomarkers: TNF- α (P=0.008), sTNFR1 (P=0.02), and IL-6 (P=0.03)

- First Oral TNF- α inhibitor, if approved, would offer potential patient benefit in large markets

- Company to present the data to FDA and intends to advance the clinical program for MYMD-1; will hold conference call on August 2, 2023 at 4:30 PM Eastern Time

BALTIMORE, MD. – July 31, 2023 – MyMD Pharmaceuticals, Inc.[®] (Nasdaq: MYMD) (“MyMD” or the “Company”), a clinical stage pharmaceutical company committed to developing novel therapies for age-related diseases, autoimmune and inflammatory conditions, today announced statistically significant positive topline results from its randomized Phase 2 study of oral TNF- α inhibitor, MYMD-1[®] in patients with chronic inflammation associated with sarcopenia, or age-related frailty. The study met its primary endpoints of significantly reducing chronic inflammatory markers in participants treated with MYMD-1. MYMD-1 has the potential to be the first drug approved by the United States Food and Drug Administration (FDA) for sarcopenia, an age-related decline in physical function which leads to greater risk of hospitalization, disability, and death.

The study met both of its primary endpoints, significantly reducing serum levels of three biomarkers, TNF- α (P=0.008), sTNFR1 (P=0.02), and IL-6 (P=0.03) and maintaining appropriate plasma concentrations and parameters in pharmacokinetic evaluations. The study also achieved all secondary endpoints related to safety and tolerability. There were no treatment-related adverse events (AEs) or serious adverse events (SAEs) over the course of the study.

“We are very excited about these results indicating MYMD-1 demonstrated statistically significant reductions in all three inflammatory markers and met all additional pharmacokinetic and safety endpoints needed to advance our sarcopenia clinical program, with guidance from the FDA,” said Chris Chapman, M.D., President, Director, and Chief Medical Officer at MyMD. “These results support the unique advantages of MYMD-1 as the first oral, selective TNF- α inhibitor candidate and potential future treatment option for sarcopenia and other autoimmune conditions such as rheumatoid arthritis.”

The Phase 2 multi-center double-blind, placebo controlled, randomized study (NCT05283486) was designed to investigate the efficacy, tolerability and pharmacokinetics of MYMD-1 in participants aged 65 years or older with chronic inflammation associated with sarcopenia/frailty, a condition linked to elevated levels of proinflammatory cytokines. Patients in the study were dosed weekly with MYMD-1 or placebo over a 28-day period. The study consisted of 4 dosing cohorts versus placebo (600mg, 750mg, 900mg and 1050mg).

1

“We are encouraged by the reduction of inflammatory markers along with the favorable safety profile demonstrated in this study of an oral TNF- α inhibitor,” continued Dr. Chapman “Sarcopenia can significantly affect people as they age, and there are currently no approved treatments for the condition. A selective, oral treatment that reduces TNF- α and inflammation and does not require infusion or injection would be a welcome advance for this population.”

Full results from the study will be presented or published at a later date to be determined. The company plans to initiate discussions with the FDA regarding a Phase 3 study of MYMD-1 in sarcopenia.

Conference Call Information

MyMD management will host a conference call on Wednesday, August 2, 2023 at 4:30 PM ET. The webcast can be accessed under the ‘Events & Presentations’ section on the Investors page at www.MYMD.com. A replay of the webcast will be archived on the MyMD website for 30 days. Dial-in information for conference participants may be obtained by registering for the event here.

About MYMD-1

MYMD-1, a next generation, oral selective inhibitor of tumor necrosis factor-alpha (TNF- α), a driver of chronic inflammation, is being studied to slow the aging process, prevent sarcopenia and frailty, and extend healthy lifespan. Its ease of oral dosing is a significant differentiator compared to currently available TNF- α inhibitors, all of which require delivery by injection or infusion.

MYMD-1 has shown effectiveness in pre-clinical and clinical studies in regulating the immune system. Unlike other therapies, MYMD-1 has been shown in these studies to selectively block TNF- α when it becomes overactivated in autoimmune diseases and cytokine storms, but not block it from doing its normal job of being a first responder to any routine type of moderate infection. In addition, it has not been shown to cause serious side effects common with traditional immunosuppressive therapies that treat inflammation.

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. The company has completed Phase 2 studies of MYMD-1[®] 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.

2

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 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.

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