# **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): October 4, 2023

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

New Jersey	001-36268	22-2983783
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File No.)	Identification No.)
(.	MyMD Pharmaceuticals, Inc. 855 N. Wolfe Street, Suite 601 Baltimore, MD 21205 Address of principal executive offices and zip c	ode)
Registra	nt's telephone number, including area code: (850	6) 848-8698
(Form	ner name or former address, if changed since las	t report.)
Check the appropriate box below if the Form 8-K filing is inter-	nded to simultaneously satisfy the filing obligati	on of the registrant under any of the following provisions:
□ Written communications pursuant to Rule 425 under the S	ecurities Act (17 CFR 230.425)	
□ Soliciting material pursuant to Rule 14a-12 under the Excl	nange Act (17 CFR 240.14a-12)	
□ Pre-commencement communications pursuant to Rule 14d	-2(b) under the Exchange Act (17 CFR 240.14d	I-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 § the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)		Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of
Emerging growth company □		
If an emerging growth company, indicate by check mark if the accounting standards provided pursuant to Section 13(a) of the		transition period for complying with any new or revised financial
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## Item 7.01 Regulation FD Disclosure.

On October 4, 2023, MyMD Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it will present certain information relating to the Company and its product pipeline, including an update to certain results of the Phase 2 study of its MYMD-1® product candidate at the BioFuture 2023 Meeting. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. 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
99.1 104	Press Release, dated October 4, 2023 (furnished herewith pursuant to Item 7.01).  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: October 4, 2023

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

President

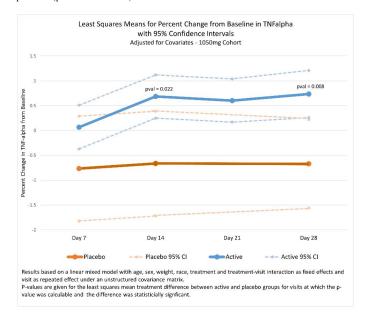
## MyMD Pharmaceuticals to Present Updated Statistically Significant Phase 2 Data for MYMD-1, Potential TNF-α Market Disrupter, at BioFuture 2023

- Company to share new positive, statistically significant results across Cohort 4 (1050mg) from Phase 2 study of MYMD-1 in sarcopenia, an age-related frailty disorder -

BALTIMORE, MD – October 4, 2023 – MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD) ("MyMD" or "the Company"), a clinical stage biopharmaceutical company committed to developing novel therapies for age-related diseases, autoimmune and inflammatory conditions, announced that it plans to share information on the Company and its product pipeline, including an update on recent positive phase 2 study results for MYMD-1 in sarcopenia, at the upcoming BioFuture 2023 Meeting.

Chris Chapman, MD, president, director, and chief medical officer at MyMD Pharmaceuticals, is scheduled to present at the conference on October 6<sup>th</sup>, 2023, at 9:30am EST. Jenna Brager, PhD, executive vice president of drug development at MyMD Pharmaceuticals, is scheduled to participate in a panel discussion, *Longevity: Stopping Age-Related Disease at the Cellular Level* on October 5<sup>th</sup>, 2023, at 11:45am EST.

MyMD recently announced positive topline Phase 2 study results in participants with sarcopenia/frailty which showed MYMD-1 demonstrated statistical significance in reducing serum levels of TNF- $\alpha$ , IL-6 and sTNFR1, biomarkers common to a number of chronic inflammatory diseases, and met all primary pharmacokinetic and secondary safety and tolerability endpoints across multiple doses over 28 days of treatment. New key findings from the Phase 2 study showed that cohort 4 (1050mg) showed a reduction in TNF- $\alpha$ , a key cytokine, across 28 days versus placebo (p=0.002 to 0.008).



"The scientific data clearly indicate statistical significance across 28 days at the high dose group and we are extremely excited about the completion of the phase 2 clinical trial," said Dr. Chris Chapman, MD, president, director, and chief medical officer at MyMD Pharmaceuticals.

Continued Dr. Chapman, "We are pleased to share information about our company and pipeline at BioFuture 2023, particularly related to our lead candidate and next generation TNF- $\alpha$  inhibitor, MYMD-1, which we believe is showing tremendous promise in inflammatory diseases. Its potential to ease the burden of these diseases, which affect millions of patients, caregivers and their healthcare professionals, is what compels us to continue this important research."

The Company will present the clinical safety report to the FDA with plans to seek future guidance for a Phase 3 clinical trial in sarcopenia. If approved, MYMD-1 has the potential to be the first drug approved by FDA for the condition, an age-related decline in muscle mass and physical function which leads to greater risk of hospitalization, disability, and death.

MyMD also recently <u>announced</u> that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug Application (IND) to evaluate the safety, efficacy, pharmacodynamics and pharmacokinetics of oral TNF- $\alpha$  inhibitor MYMD-1<sup>®</sup> in patients with active rheumatoid arthritis (RA). Phase 2 trials are planned in RA.

MYMD-1 is an oral, next-generation TNF- $\alpha$  inhibitor with the potential to transform the way TNF- $\alpha$  based diseases are treated due to its selectivity and ability to cross the blood brain barrier. Its ease of oral dosing is a significant differentiator compared to currently available TNF- $\alpha$  inhibitors, all of which require delivery by injection or infusion. MYMD-1 has also been shown to selectively block TNF- $\alpha$  action where it is overactivated without preventing it from doing its normal job of responding to routine infection. In addition, in early clinical studies it has not been associated with serious side effects known to occur 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- $\alpha$  inhibitor with the potential to transform the way that TNF- $\alpha$  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- $\alpha$  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, as well as early-stage trials for rheumatoid arthritis (RA), with the potential to expand into other applications. The U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug Application (IND) to evaluate the safety, efficacy, pharmacodynamics, and pharmacokinetics of oral TNF- $\alpha$  inhibitor MYMD-1® in patients with active rheumatoid arthritis (RA).

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 <a href="https://www.mymd.com">www.mymd.com</a>.

## **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 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

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