# 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): February 8, 2022

## 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 623 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 Ru	ale 14d-2(b) under the Exchange Act (17 C	FR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Ru	ule 13e-4(c) under the Exchange Act (17 C	FR 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
Emerging growth company   If an emerging growth company, indicate by check mark if t accounting standards provided pursuant to Section 13(a) of the		ended transition period for complying with any new or revised financial
Item 7.01 Regulation FD Disclosure.		
On February 8, 2022, MyMD Pharmaceuticals, Inc. (the " <i>Company</i> ") issued a press release announcing Phase 1 clinical trial data demonstrating MYMD-1's reduction of tumor necrosis factor-alpha (TNF-α). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. 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 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

## 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: February 8, 2022

By: /s/ Chris Chapman

Chris Chapman, M.D. President

#### MyMD Pharmaceuticals Announces Positive Clinical Data in Advance of Upcoming Phase 2 Trial of MYMD-1 for Extending Healthy Lifespan

- Phase 1 dose-ranging study results meet primary endpoints
- Drug demonstrates statistically significant efficacy in reducing levels of the root cause of aging, TNF-a, in the blood
- Data from fully funded Phase 2 trial anticipated in first half of 2022

BALTIMORE, MD. – February 8,  $2022 - \underline{\text{MyMD Pharmaceuticals, Inc.}}$  (Nasdaq: MYMD) ("MyMD" or "the Company"), a clinical stage pharmaceutical company committed to extending healthy lifespan, today announced Phase 1 clinical trial data demonstrating MYMD-1's reduction of tumor necrosis factor-alpha (TNF- $\alpha$ ), the molecules that are the root cause of aging, in the blood of healthy human subjects.

In the Phase 1 study, subjects were treated with MYMD-1 or placebo and TNF- $\alpha$  levels were measured pre and post treatment. There was a statistically significant decrease in TNF-alpha levels (p-value <0.05) found in MYMD-1 treated subjects, but no change in the levels in subjects given placebo. While consistent with all of the preclinical studies of MYMD-1, this is the first demonstration in humans of the ability of MYMD-1 to decrease TNF- $\alpha$  levels.

Chris Chapman, M.D., President, Director and Chief Medical Officer of MyMD, stated, "We believe that our drug's statistically significant reduction of TNF- $\alpha$  in the blood of healthy subjects is a great achievement in medicine because the TNF- $\alpha$  levels in this population were not elevated to begin with. Having demonstrated the drug's mechanism of action and efficacy in Phase 1, we are pleased that the FDA has approved TNF- $\alpha$  reduction as the primary endpoint for our Phase 2 trial. MYMD-1's oral delivery, selectivity, and low toxicity as compared with other TNF- $\alpha$  blockers, none of which are FDA-approved for aging, offers a distinctive drug profile that we believe is vastly superior to any TNF- $\alpha$  blocker on the market today."

MYMD-1's Phase 1 aging data is consistent with outcomes from pre-clinical models pointing to the drug's potential role in reducing both frailty and inflammatory cytokines. Details of the Phase 1 clinical trial design are available at clinicaltrials.gov.

MyMD has stated that there are no FDA-approved drugs for treating aging disorders and extending healthy lifespan in humans, a market expected to be at least \$600 billion by 2025<sup>1</sup> according to a major investment bank. The U.S. Patent and Trademark Office (USPTO) issued U.S. Patent 11,179,382 B2, titled "Methods of Reversing Normal Aging Process and Extending Lifespan." The allowed claims protect the use of MYMD-1 in a method designed to extend the lifespan of an individual.

TNF- $\alpha$  blockers are the most prescribed drugs by revenue, a global market of approximately \$40 billion per year<sup>2</sup> and, according to <u>Nature Aging</u> journal,<sup>3</sup> a slowdown in aging that would increase life expectancy by one year is worth \$38 trillion and by 10 years is worth \$367 trillion.

#### About MYMD-1

Originally developed for autoimmune diseases, MYMD-1's primary purpose is to slow the aging process, preventsarcopenia and frailty, and extend healthy lifespan. Because it can cross the blood-brain barrier and gain access to the central nervous system (CNS), MYMD-1 is also positioned to be a possible treatment for brain-related disorders. Its mechanism of action and efficacy in diseases including multiple sclerosis (MS) and thyroiditis have been studied through collaborations with several academic institutions. MYMD-1 is also showing promise in pre-clinical studies as a potential treatment for post- COVID-19 complications and as an anti-fibrotic and anti-proliferation therapeutic.

MYMD-1 has shown effectiveness in pre-clinical studies in regulating the immune system by performing as a selective inhibitor of tumor necrosis factor-alpha (TNF- $\alpha$ ), a driver of chronic inflammation. Unlike other therapies, MYMD-1 has been shown in these pre-clinical studies to selectively block TNF- $\alpha$  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. MYMD-1's ease of oral dosing is another differentiator compared to currently available TNF- $\alpha$  blockers, all of which require delivery by injection or infusion. No approved TNF inhibitor has ever been dosed orally. In addition, the drug is not immunosuppressive and has not been shown to cause the serious side effects common with traditional therapies that treat inflammation.

#### About MyMD Pharmaceuticals, Inc.

MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD), a clinical stage pharmaceutical company committed to extending healthy lifespan, is focused on developing two novel therapeutic platforms that treat the causes of disease rather than only addressing the symptoms.  $\underline{MYMD-1}$  is a drug platform based on a clinical stage small molecule that regulates the immune system to control TNF- $\alpha$ , which drives chronic inflammation, and other pro-inflammatory cell signaling cytokines.  $\underline{MYMD-1}$  is being developed to delay aging, increase longevity, and treat autoimmune diseases and COVID-19- associated depression. The Company's second drug platform,  $\underline{Supera-CBD}$ , is being developed to treat chronic pain, addiction and epilepsy. Supera-CBD is a novel synthetic derivative of cannabidiol (CBD) and is being developed to address and improve upon the rapidly growing CBD market, which includes both FDA approved drugs and CBD products not currently regulated as drugs. For more information, visit  $\underline{www.mymd.com}$ .

#### **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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, filed by MyMD on November 12, 2021 (as amended on November 15, 2021). Forward-looking statements speak only as of the date they are made and MyMD d

 $<sup>^{1}\</sup> https://www.cnbc.com/2019/05/08/techs-next-big-disruption-could-be-delaying-death.html$ 

 $<sup>^2</sup>$  October 9, 2019, Tumor Necrosis Factor (TNF) Inhibitor Drugs Market, Acumen Research and Consulting

<sup>&</sup>lt;sup>3</sup> Nature Aging | VOL 1 | July 2021 | p. 616–623

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