

**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 26, 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 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
Common stock, no par value per share

Trading Symbol(s)
MYMD

Name of each exchange on which registered
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 26, 2022, MyMD Pharmaceuticals, Inc. (the “*Company*”) issued a press release announcing the completion of dosing for the first patient cohort in the Phase 2 clinical trial of its MYMD-1® product candidate as a treatment of chronic inflammation associated with sarcopenia/frailty in participants aged 65 years or older. 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 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

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press Release, dated July 26, 2022 (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 26, 2022

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

MyMD Pharmaceuticals[®] Advances Phase 2 Multi-Center Clinical Trial of MYMD-1[®] as a Therapy for Delaying Aging and Extending Healthy Lifespan

Sarcopenia trial shows no evidence of toxicity or safety issues and patients were enrolled in the next higher dose of MYMD-1

BALTIMORE, MD. – July 26, 2022 – 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, announced further advancement of its fully funded Phase 2 clinical trial of lead drug candidate MYMD-1[®] as a therapy for delaying aging and expanding healthy lifespan. To date, the trial has completed dosing for the first patient cohort and dosing has been initiated in the next higher dose cohort. The trial’s Safety Review Committee has confirmed no safety issues and no toxicity in the prior cohort and has voted unanimously to escalate to the next higher dose and begin enrolling the next cohort.

The Phase 2 multi-center double-blind, placebo controlled, randomized study (NCT05283486) investigates the efficacy, tolerability and pharmacokinetics of MYMD-1 in the treatment of chronic inflammation associated with sarcopenia/frailty in participants aged 65 years or older.

“As agreed upon with the FDA, the primary endpoint of our Phase 2 multi-center study is to demonstrate reduced levels of TNF-alpha (TNF- α), a key player in associated pathological aging, in the blood of patients,” said Chris Chapman, MD, President, Director and Chief Medical Officer of MyMD. “Having already demonstrated the drug’s mechanism of action and efficacy in Phase 1, achieving the same primary endpoint as our current trial, we are pleased with the progress in Phase 2 to date. We continue to advance the trial and expect efficacy data in the second half of 2022.”

In the Phase 1 dose-ranging study of MYMD-1 for delaying aging, subjects were treated with MYMD-1 or placebo and TNF- α levels were measured pre- and post-treatment. The data demonstrated a statistically significant decrease in TNF-alpha levels (p-value <0.05) found in MYMD-1 treated subjects, but no change in the participants given placebo. This data was consistent with outcomes from pre-clinical models pointing to the drug’s potential role in reducing both frailty and inflammatory cytokines.

Market Opportunity

MyMD has not identified any other FDA-approved drugs for treating aging disorders and extending healthy lifespan humans, a market expected to be at least \$600 billion by 2025¹ according to a major investment bank. TNF- α blockers are the most prescribed drugs by revenue, a global market of approximately \$40 billion per year.² Aging is closely linked to multi-morbidities, frailty, and death due to conditions such as neoplastic, cardiovascular, neurodegenerative, metabolic, or autoimmune diseases.³ Similarly, frailty, or a decline in physical function leading to greater risk of hospitalization, disability, and death, increases with age independent of underlying conditions or demographical characteristics.⁴

¹ <https://www.cnbc.com/2019/05/08/techs-next-big-disruption-could-be-delaying-death.html>

² October 9, 2019, Tumor Necrosis Factor (TNF) Inhibitor Drugs Market, Acumen Research and Consulting

³ St Sauver 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.

⁴ Kochanek KD, Murphy SL, Xu J, Arias E. Deaths: Final Data for 2017. *Natl Vital Stat Rep*. 2019;68:1-77.

About MYMD-1

MYMD-1, an 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. 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.

MYMD-1's ease of oral dosing is another differentiator compared to currently available TNF- α blockers, all of which require delivery by injection or infusion. No FDA-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. 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.

About MyMD Pharmaceuticals, Inc.

MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD), a clinical stage pharmaceutical company committed to developing novel therapies for autoimmune and inflammatory conditions, is focused on developing two novel therapeutic platforms that treat the causes of disease rather than only addressing the symptoms. MYMD-1 is a drug platform based on a clinical stage small molecule that regulates the immune system to control TNF- α , which drives chronic inflammation, and other pro-inflammatory cell signaling cytokines. MYMD-1 is being developed to delay aging, increase longevity, and treat autoimmune diseases. The Company's second drug platform, 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 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. 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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