

**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): **November 14, 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 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 November 14, 2022, MyMD Pharmaceuticals, Inc. (the "**Company**") issued a press release announcing the publication of results from a Phase 1 study of its MYMD-1 product candidate in a peer-reviewed journal. 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

Exhibit Number **Description**

99.1	Press Release, dated November 14, 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: November 14, 2022

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

MyMD Pharmaceuticals Announces Publication of Phase 1 Data for oral TNF-alpha Inhibitor MYMD-1® in Peer-Reviewed Journal *Data Research*

MYMD-1 demonstrated favorable safety and tolerability profile across multiple doses, with no clinically relevant adverse events, supporting advancement of the compound for Sarcopenia and Rheumatoid Arthritis

BALTIMORE, MD. – November 14, 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, today announced the publication of results from a Phase 1 study of oral TNF-alpha inhibitor, MYMD-1[®] (Isomyosamine), in peer-reviewed journal, *Data Research*. The randomized, double-blind, placebo-controlled, study, intended to evaluate the safety, tolerability, and pharmacokinetic profile of MYMD-1 in healthy adults, found that single daily doses for 3 days and multiple daily doses for 6 days were safe and well tolerated in healthy subjects. The study used single daily doses of 150 mg, 300 mg, and 450 mg, respectively, and multiple daily doses of 600 mg. There were no new or unexpected safety findings and no clinically relevant or severe adverse events reported.

MYMD-1 is an oral next-generation TNF- α inhibitor with the potential to transform the way that TNF- α based autoimmune diseases are treated. 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 also been shown to selectively block TNF- α where it is overactivated without preventing it from doing its normal job of responding to routine infection. In addition, it has not been shown to cause serious side effects common with traditional immunosuppressive therapies that treat inflammation.

“As the first TNF- α inhibitor to be dosed orally, publication of these data confirm our belief that MYMD-1 may one day offer a new treatment option for patients not served by currently available therapies,” said Chris Chapman MD, President, Director, and Chief Medical Officer at MyMD Pharmaceuticals. “We look forward to upcoming Phase 2 results in sarcopenia and to advancing our MYMD-1 programs in other autoimmune disorders including rheumatoid arthritis and Hashimoto’s thyroiditis.”

MYMD-1 is currently being evaluated in Phase 2 studies for sarcopenia/frailty, a result of the aging process, with data expected in 4Q 2022. MYMD-1 has the potential to be the first drug approved by FDA for the condition. The company also expects to initiate a clinical program in rheumatoid arthritis (RA), which affects more than 1.3 million Americans.¹ Along with the growing aging population, autoimmune diseases like RA are becoming more prevalent. The National Institutes of Health estimates that autoimmune diseases overall may affect as many as 24 million Americans.²

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.

¹ <https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Rheumatoid-Arthritis>

² <https://www.niehs.nih.gov/health/topics/conditions/autoimmune/index.cfm>

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

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. 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. 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.

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