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): **December 6, 2023**

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

New Jersey	**001-36268**	**22-2983783**
(State or other jurisdiction of incorporation)	(Commission File No.)	(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 December 6, 2023, MyMD Pharmaceuticals, Inc. (the "***Company***") issued a press release regarding its plans for a Phase 2 clinical trial of oral MYMD-1® as a treatment for rheumatoid arthritis. 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	Press Release, dated December 6, 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: December 6, 2023

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

Exhibit 99.1

MyMD Pharmaceuticals Plans FDA-Cleared Phase 2 Clinical Trial of MYMD-1 in Rheumatoid Arthritis

Company targets first quarter 2024 for trial initiation

Potential to be first orally-administered TNF-α inhibitor treatment for RA

BALTIMORE—December 6, 2023 (BUSINESS WIRE)— 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 today that its Investigational New Drug (IND) application for a Phase 2 clinical trial of oral MYMD-1® as a treatment for rheumatoid arthritis (RA) was recently cleared by the U.S. Food and Drug Administration (FDA), and plans are underway for trial launch in the first quarter of 2024.

"With the FDA's recent clearance of our IND in RA, we are moving forward with plans to initiate a Phase 2 trial within the next several months. Results from preclinical studies have demonstrated MYMD-1's potential to treat RA, and we believe this drug could one day be a disruptor in the massive market for similar treatments," said Chris Chapman, M.D., president, director, and chief medical officer of MyMD.

Differentiated by its ease of oral dosing and selectivity, MYMD-1 is a TNF-α inhibitor with a small molecule design that enables the drug to cross the blood brain barrier for entry into the central nervous system. In a preclinical trial, MYMD-1 was shown to significantly reduce swelling and other clinical arthritis measures compared to widely used RA therapy Enbrel® (etanercept).[1] Disease severity (total composite score) was reduced by 47% with MYMD-1 (450 mg/kg/day orally) versus a 37% reduction with etanercept (10 mg/kg by subcutaneous injection).

Under this IND, the Phase 2 clinical trial of MYMD-1 will be a randomized placebo-controlled study that is expected to enroll approximately 60 patients with active rheumatoid arthritis. Patients will receive oral MYMD-1 dosing of 1050 mg.

Market Opportunity

Rheumatoid arthritis is a chronic, systemic inflammatory disorder that causes chronic inflammation of the joints and affects approximately 1.5 million Americans. RA's cost to society, including healthcare costs; loss of employment; costs to employers, government, and caregivers; and costs associated with a deterioration of quality of life, is estimated to be over $40 billion annually.[2]

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[1] ENBREL ETANERCEPT is a registered trademark of Immunex Corporation
[2] https://reporter.nih.gov/project-details/10080141

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 has shown effectiveness in preclinical and clinical studies in regulating the immune system by performing as a selective inhibitor of tumor necrosis factor-alpha (TNF-α), a driver of chronic inflammation. 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 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. 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, 2022, filed by MyMD on March 31, 2023. 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.

Investor Contact:

Robert Schatz
(646) 421-9523
rschatz@mymd.com
www.mymd.com

Media Contact:

media@mymd.com