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): **August 14, 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 August 14, 2023, MyMD Pharmaceuticals, Inc. (the "***Company***") issued a press release announcing the acceptance of its Investigational New Drug Application (IND) by the U.S. Food and Drug Administration. 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 August 14, 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: August 14, 2023

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

Exhibit 99.1

FDA Accepts MyMD Pharmaceuticals' Investigational New Drug Application (IND) for Phase 2 Study of oral TNF-α inhibitor MYMD-1® in Rheumatoid Arthritis (RA)

- Next-generation and first oral TNF-α inhibitor, which completed Phase 2 study for age-related condition sarcopenia, represents a potentially groundbreaking advance in the treatment of RA and disruption of a $41 billion industry

- Acceptance follows statistically significant Phase 2 data in sarcopenia showing MYMD-1 reduced TNF-α and other inflammatory markers common to RA, while demonstrating safety and tolerability

- MyMD now advancing 3 clinical programs for MyMD-1 in chronic inflammatory conditions including Sarcopenia, RA and Hashimoto's Thyroiditis

BALTIMORE, MD – August 14, 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 today 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-α inhibitor MYMD-1® in patients with active rheumatoid arthritis (RA). The application was based on preclinical data showing that MYMD-1 significantly reduced swelling and other clinical arthritis measures compared to widely used RA therapy, Enbrel® (etanercept).[1] The Company plans to initiate discussions with CRO vendor IQVIA on timing of a Phase 2 study in this indication.

MYMD-1 is an oral, next-generation TNF-α inhibitor with the potential to transform the way TNF-α 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-α inhibitors, all of which require delivery by injection or infusion. MYMD-1 has also been shown to selectively block TNF-α action where it is overactivated without preventing it from doing its normal job of responding to routine infection. MYMD-1 is doubly effective at inhibiting inflammation by blocking both TNF-a and IL-6 activity, whereas currently approved anti-TNF and anti-IL-6 treatments for RA can only target one or the other. 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.

"FDA acceptance of an IND in RA for our next-generation oral TNF-α inhibitor, MYMD-1, is our most significant milestone as it adds substantial momentum to our clinical program with sufficient funding and targets one of the largest potential market opportunities," said Chris Chapman, M.D., president, director, and chief medical officer of MyMD. "We are excited to initiate discussions with our CRO regarding a Phase 2 clinical trial in RA and believe the statistically significant biomarker data from the Phase 2 study in sarcopenia show MYMD-1 has the potential to disrupt the TNF-α inhibitor market and offer therapeutic benefit to patients with a range of chronic inflammatory conditions."

Recently, MyMD announced positive, statistically significant Phase 2 study results in participants with sarcopenia/frailty which showed MYMD-1 reduced TNF-α, IL-6 and sTNFR1, biomarkers which are common to a number of chronic inflammatory diseases, and met all safety and tolerability endpoints. The Company plans to initiate Phase 3 trials. If approved, MYMD-1 has the potential to be the first drug approved by FDA for the sarcopenia, an age-related decline in muscle mass and physical function which leads to greater risk of hospitalization, disability, and death.

"This is significant news and suggests MYMD-1 may hold promise to be the first oral TNF-α inhibitor and a potential future treatment for rheumatoid arthritis," said clinical researcher, rheumatologist and past President of the Florida Society of Rheumatology, Robert W. Levin, MD. "There remains a need for new oral therapies with novel mechanism of action for patients not served by current options and I look forward to leading upcoming Phase 2 studies of MYMD-1 to determine its full potential in RA. I look forward to reviewing the study outcomes."

About Rheumatoid Arthritis

Rheumatoid arthritis, an autoimmune disorder characterized by inflammation (painful swelling) and bone erosion, affects nearly 14 million people worldwide, including 1.5 million Americans.[2] Although typically associated with older adults, RA can occur at any age, and it is three times more likely to affect women than men.[3] TNF-α has played a central role in treatments for RA since 1998, all of which are administered via injection or infusion.

Furthermore, the burden to patients, care providers and society is striking, with an estimated annual cost of $39.2 billion.[4] The price tag includes healthcare costs, loss of employment, costs to employers, government and caregivers as well as costs associated with a deterioration of quality of life, among other societal costs.

About MYMD-1

MYMD-1, a next generation, oral selective inhibitor of tumor necrosis factor-alpha (TNF-α), a driver of chronic inflammation, and this drug is being studied to slow the aging process, prevent sarcopenia and frailty, extend healthy lifespan, as well as treat rheumatoid arthritis. 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 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. In addition, it has not been shown to cause serious side effects common 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-α inhibitor with the potential to transform the way that TNF-α 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-α 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, 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. 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 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 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-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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References:

[1]ENBREL ETANERCEPT is a registered trademark of Immunex Corporation

[2]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8352468/

[3]https://www.arthritis.org/diseases/rheumatoid-arthritis

[4]https://pubmed.ncbi.nlm.nih.gov/19908947/