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 3, 2021**

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 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	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 3, 2021, MyMD Pharmaceuticals, Inc. (the "Company") issued a shareholder letter, attached hereto as Exhibit 99.1, discussing the Company's prior and future operations. 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	Shareholder Letter, Winter 2021 (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 3, 2021

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

Exhibit 99.1


MyMD
Shareholder letter from
Chris Chapman, M.D.
President, Director and
Chief Medical Officer
MyMD Pharmaceuticals, Inc.
Nasdaq: MYMD

MyMD Pharmaceuticals Letter to Shareholders

Winter 2021

Dear fellow shareholders,

I'm delighted to report that 2021 has already been a year of historic growth and transformation for MyMD – and we believe that the best is yet to come.

Our merger with Akers Biosciences, closed in April, was a momentous event that enabled our uplisting to Nasdaq and strengthened our company financially with an $18 million capital raise. On behalf of our team and board of directors, we warmly welcome all of the Akers Biosciences shareholders who have joined us. Through the merger, we gained an ownership stake in Oravax Medical, a company seeking to bring an oral COVID-19 vaccine to the market. We now own 13 percent of Oravax's outstanding shares of capital stock and a 2.5 percent royalty on all future net sales. Oravax continues to be majority owned by Oramed Pharmaceuticals Inc. (Nasdaq: ORMP). We are evaluating options for our investment in Oravax, including a near-term distribution of our holdings to shareholders.

The near future is equally exciting as we prepare to launch the Phase 2 trial of our lead drug candidate MYMD-1 as a therapy for delaying aging and prolonging healthy lifespan. We have received Investigational New Drug (IND) clearance from the FDA to move forward with the trial, and efficacy data is expected by the end of the first quarter of 2022. To our knowledge, ours is the only IND application for a Phase 2 trial of a patented drug related to delaying aging.

Our recent research has demonstrated the multifunctionality of our second drug candidate, synthetic Supera-CBD, and its superior potency by a factor of 8,000 times over CBD (cannabidiol) at activating CB2 receptors involved in tempering the immune system. We believe this is an extraordinary achievement in the field of pharmaceutical cannabinoids. We also believe that both of our drug platforms have strong potential to become best-in-class treatments for some of the most notorious diseases and disorders that continue to challenge medical science.

MYMD-1

Every day we are working to create value and advance our prospects for bringing our MYMD-1 product to market.

Originally developed for autoimmune diseases, our primary focus for MYMD-1 today is to slow the aging process, prevent sarcopenia (loss of muscle tissue in aging) 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) (*The Journal of Neuroimmunology*) and thyroiditis (*The Journal of Immunology*) has been studied through our collaborations with major 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 regulating the immune system in pre-clinical studies by performing as an orally delivered, selective inhibitor of tumor necrosis factor-alpha (TNF-α), a driver of chronic inflammation involved in autoimmune diseases. In these studies, unlike other therapies, MYMD-1 has shown the potential 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 initial infection by bacteria, viruses, and fungi. MYMD-1's ease of oral dosing is another attractive 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. Also, the drug is selectively immunosuppressive and has not been shown to cause serious side effects common with traditional therapies that treat inflammation.

In addition to having anti-TNF-α effects, the mechanisms of action of MYMD-1 have been shown to include anti-Interleukin-6 and anti-Interleukin-17 activity, for which there are individually available FDA-approved drugs to treat autoimmune diseases. Thus, MYMD-1 seeks to deliver three approved mechanisms in one therapeutic. MYMD-1 also has shown in pre-clinical studies the potential to deliver the same outcomes as the market-leading drugs for JAK inhibition in blocking the genes that trigger inflammation and autoimmunity. Janus Kinases (JAKs) are enzymes found in cells in the immune system that are critical for the cell signaling process. JAK inhibitors block the inflammatory signaling pathways, inhibiting the genes that trigger autoimmune processes.

Based on its distinct action in targeting the root causes of chronic inflammation, we are confident that MYMD-1 could become a high-value next-generation immune regulator for autoimmune and age-related diseases.

In addition to aging, MYMD-1's potential ability to stop one of the leading causes of death in COVID-19 is another key development in our research to date. A study of the effects of MYMD-1 on human immune cells found it to be effective in suppressing cytokine storms, a major cause of severity and death in COVID-19 patients. Perhaps more importantly, given the 47 million people infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) in the U.S., MYMD-1 has the potential ability to address post-COVID syndromes such as depression and brain fog, which are the result of lingering inflammation.

Supera-CBD

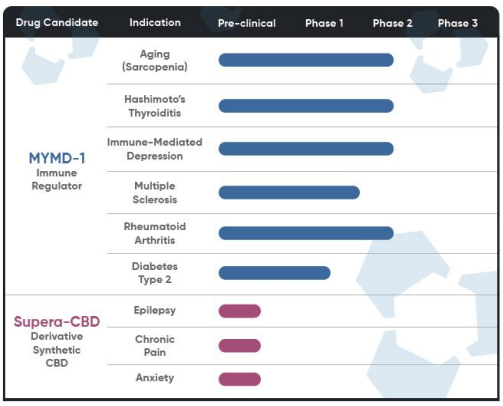
With our second drug candidate, Supera-CBD, we are seeking to address a widespread unmet need for pharmaceutical cannabinoids. Building on CBD's enormous pre-existing market acceptance, the removal of CBD from the list of controlled substances by the U.S. Drug Enforcement Administration (DEA), and the FDA's declared receptiveness to moving forward in this space, we believe that Supera-CBD is well positioned to become a leading prescription drug alternative to purified CBD.

Supera-CBD is a patented CBD derivative shown to be four times more effective than plant-derived CBD in binding to CB2 receptors, which play a key role in pain, inflammation, and neurodegeneration. More recent data indicates the potential of this candidate to deliver an extremely potent therapeutic benefit – 8,000 times more potent than CBD at activating the CB2 receptor – permitting its delivery at a very low non-toxic dose.

Supera-CBD is being developed to address anxiety, chronic pain, addiction, and seizures, and is on a path toward human clinical trials as a therapy for generalized anxiety, post-traumatic stress disorder (PTSD), epilepsy, and chronic pain.

Pipeline

Our product pipeline is diversified yet balanced with key indications for MYMD-1 as an immune regulator and Supera-CBD as a synthetic CBD derivative.



FDA Guidance received by the FDA's Center for Drug Evaluation and Research | CDER, Office of Cardiology, Hematology, Endocrinology and Nephrology - Division of General Endocrinology:

- IND for Phase 2 study of MYMD-1 for the treatment of sarcopenia, frailty, and aging. Recruiting for this study is underway.
- IND for Phase 2 pilot study of MYMD-1 for Hashimoto's thyroiditis.

Recent Achievements

In just over eight months as a publicly traded company, MyMD has delivered on a host of consequential initiatives.

We anticipate a major accomplishment in our immunotherapy research. In a Phase 1 dose-ranging study in human volunteers, the proof of concept for the mechanism of action of our oral anti-TNF-α drug MYMD-1 was verified. Given MYMD-1's distinctive drug profile of oral delivery, selectivity, and low toxicity as compared with other TNF-α blockers, none of which are FDA-approved for aging, we believe we have developed a drug that will be vastly superior to any TNF-α blocker on the market today.

Our earlier achievements include the following:

- Completed a dose ranging study of MYMD-1 to determine a safe therapeutic dose in normal volunteers, and began exploring biomarkers for selective inhibition of TNF-α.
- Demonstrated the ability of MYMD-1 to delay aging and prolong life in an in vivo study conducted at one of the nation's most prestigious research institutions, and supported the submission of a scientific manuscript detailing those findings to a major medical journal.
- Completed a regulatory dossier and IND application to the FDA for our Phase 2 clinical trial of MYMD-1 for aging, frailty, and sarcopenia. Our IND application was recently cleared by the FDA.
- Received clearance by the FDA for a Phase 2 pilot study of MYMD-1 for Hashimoto's thyroiditis.
- Submitted to the FDA a four-month interim analysis of a long-term animal study of MYMD-1 to support our long-term aging and lifespan program. We also completed in vitro studies of Cytochrome P450 (CYP) induction and drug transporters interaction in MYMD-1 for this program. CYP induction is the most commonly studied form of induction in drug metabolism and is

required by regulatory authorities. Drug transporters, which are membrane proteins involved in the uptake or efflux of drugs by various tissues, play a significant role in drug disposition. MyMD-1's performance in those assays was excellent.

- Completed a significant in vivo radiolabeled mass balance study to confirm that MYMD-1 is metabolized extensively in the tissues, crosses the blood brain barrier, and is cleared from the body in the urine and feces.

- Presented data referencing Supera-CBD's superior potency over CBD by factor of 8,000 times at the 4th Annual International Cannabinoid Derived Summit in September.

- Demonstrated preclinically that Supera-CBD is highly effective in treating anxiety, as presented by researchers of Johns Hopkins at a conference this year. Johns Hopkins is currently investigating the drug's effectiveness in various types of pain, including acute and neuropathic.

- Diversified and strengthened our growing intellectual property portfolio, which now contains 14 granted patents for MYMD-1 and two for Supera-CBD. We have an additional 31 patent applications pending worldwide.

    - We received a new patent for MYMD-1 covering fibrosis and asthma treatments. We also received a new patent for methods of extending lifespan.

    - We received a new patent for the treatment of inflammation and age-related disorders.

    - We received a Notice of Allowance for MYMD-1 in the treatment of sarcopenia.

    - The patents covering Supera-CBD protect its use as a treatment for neuroinflammatory and neurodegenerative diseases including substance addiction.

- Announced that our investment company Oravax Medical formed a joint venture with Genomma Lab to develop and commercialize its oral COVID-19 Vaccine in Mexico and drive business development in Latin America. Oravax has received clearance from the South African Health Products Regulatory Authority to begin patient enrollment in a first-in-human clinical trial for its vaccine, and preparations to begin the trial are underway. Oravax is also preparing to commence clinical trials in Israel. Oravax's COVID-19 vaccine is being developed for use both as a standalone vaccine and as a booster for people who have been previously vaccinated for COVID-19.

- In June, MYMD was added to the Russell Microcap® Index, raising our visibility on Wall Street and increasing market liquidity for our shares.

Events and Broadcasts

- We have accelerated our investor engagement efforts by presenting at the H.C. Wainwright 23rd Annual Global Investment Conference on September 13th, the Philadelphia Securities Association's virtual webinar on September 28th, Benzinga's Rising Stars: Catalytic Small Cap Growth Conference on October 7th and the Dawson James Securities 6th Annual Small Cap Growth Conference on October 21st. We were a featured guest on Benzinga's streaming news and talk show programs. The All Access Show on September 17th and Power Hour on September 27th. Benzinga also created and released a corporate video of MyMD on October 17th.

- We are participating in two December investor conferences: a one-on-one meeting conference, Benchmark Company Discovery, on December 2, and the Benzinga Small Cap Conference being held December 8-9.

- Soon after, we will participate in the Biotech Showcase conference being held in person January 10-12 and virtually January 17-19.

- Benzinga published two MyMD business articles, "The Anti-Aging Market Landscape" (October 18, 2021) and "Super CBD To The Rescue" (November 11, 2021).

- MyMD supported the Arthritis Foundation's Commitment to a Cure Gala on October 28th where I was recognized as the Medical Honoree. I am deeply honored by this recognition, and MyMD is proud to be associated with this highly regarded organization, consistently ranked as one of the very top charities in the U.S. In 2022, MyMD will be a featured speaker and participant in an ongoing program of discussions of arthritis with key opinion leaders.

- We are producing an educational segment for VIEWPOINT, a short-form documentary series hosted by Dennis Quaid. Our 5-6-minute corporate profile will be broadcast by PBS with primetime distribution to public television stations in all 50 states in over 84 million homes via MSNBC, CNBC, CNN, Fox Business Network, The Learning Channel, and the Discovery Channel. The segment will be filmed at Johns Hopkins University Medical School.

Market Opportunity

MYMD-1, unlike blockbuster biologics such as Humira, Enbrel and Remicade, is administered orally, a huge advantage for patients and providers. MYMD-1 potentially addresses massive markets, giving it an opportunity to transform major health sectors across the medical landscape.

Anti-TNF Medications
This market alone is $40 billion annually.

Aging and Related Diseases
According to Nature Aging, a slowdown in aging that would increase life expectancy by one year is worth $38 trillion, and by 10 years is worth $367 trillion. Treating aging disorders and extending healthy lifespan is a market expected to be at least $600 billion by 2025 according to a major investment bank.

Autoimmune Diseases
23 million Americans suffer from autoimmune diseases, a global drug market estimated at $100 billion. TNF-α blockers include Humira, which is the single largest grossing drug globally, with an annual revenue of $20 billion dollars. Studies estimate that the number of people suffering from rheumatoid arthritis may rise to over 78 million by 2040. Thyroid conditions affect approximately 12% of the U.S. population during their lifetimes.

Post- COVID-19 Depression
One in ten people over the age of 12 in the U.S. take an antidepressant, making antidepressants an annual $15 billion industry. Recent research shows that more than half of those sickened by COVID-19 report symptoms of moderate to severe major depression. There are currently no pharmacologic trials underway to address this public health crisis.

Supera-CBD is being developed to address pain, anxiety, and seizures. It also has the potential to address the significant unmet need for medications to treat addictions, including cocaine, that have no approved treatments. The size of the cannabidiol market surpassed $7 billion in 2020 and is estimated to grow at a compounded growth rate of 35 percent between 2021 and 2027.

Pain
More than 20 percent of Americans are affected by chronic pain at any given time.

Anxiety
Anxiety disorders are the most common mental illness in the U.S., affecting 40 million adults in the U.S. age 18 and older, or 18 percent of the population every year.

Seizures
Up to 10 percent of people will have a seizure at some time in their life, while 1 in 26 people will develop epilepsy.

Cocaine
Cocaine is the second most popular illicit recreational drug in the U.S. behind cannabis. There are no approved treatments indicated for cocaine addiction.

Looking Ahead

To summarize our outlook for the several quarters, we currently anticipate the following:

- During the current quarter we will begin recruiting patients and plan to initiate dosing in a Phase 2, double-blind, placebo-controlled study of MYMD-1's function in delaying aging, using inflammation, sarcopenia, and frailty as surrogate measures. The primary goal of this human trial is to achieve a reduction in the levels of TNF-α in the blood. Interim efficacy data is anticipated by the end of the first quarter of 2022.
- We plan to request guidance from the FDA for our planned Phase 2 clinical trial to investigate the effectiveness of MYMD-1 for post- COVID-19 depression and cytokine elevation. In preclinical studies, MYMD-1 had potent antidepressant effects on post- COVID-19 depression, which was presented by researchers from Johns Hopkins at a national conference earlier this year.

- We intend to begin writing protocols for a Phase 2 pilot study of MYMD-1 for Hashimoto's thyroiditis, the most common cause of hypothyroidism in the U.S.

- We intend to begin writing protocols for a Phase 2 pilot study of MYMD-1 for rheumatoid arthritis after our presentation at the Arthritis Foundation.

Our financial position is strong with $15 million on hand at the end of the third quarter. Even with increasing costs as we enter Phase II clinicals trials, we believe that we have the resources to fund a significant runway for drug research and development through early 2024.

I want thank all of our shareholders for your enthusiasm and confidence in our ability to create value as we advance our mission. I am privileged to work with an outstanding leadership team, highly credentialled and pedigreed, that share my passion, drive, and belief that MyMD can and will radically transform the medical landscape for the better in the years ahead. With our enormous progress in pharmaceutical development to date, MyMD has an exceptionally bright future.

Best regards,

Chris Chapman, M.D.
President, Director and Chief Medical Officer

MyMD Pharmaceuticals' management team meets in Washington DC: Jonnie Williams Jr., VP of Corporate Development; Adam Kaplin, M.D., Ph.D., Chief Scientific Officer, Adjunct Faculty at Johns Hopkins University School of Medicine; Chris Chapman, M.D., President, Director, and Chief Medical Officer; Jenna Brager, Ph.D., RN, MS, Director of Regulatory Affairs

www.mymd.com

Cautionary Statement Regarding Forward-Looking Statements

This document 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 disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise.

MyMD