MyMD Pharmaceuticals, Inc.

2022 Annual Report to Stockholders

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to

Commission file number: 001-36268

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

New Jersey	22-2983783
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
855 N. Wolfe Street, Suite 601 Baltimore, MD	**21205**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (856) 848-8698

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s)	Name of Each Exchange on Which Registered:
Shares of Common Stock, no par value	**MYMD**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definition of "large accelerated filer," "accelerated filer, "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2022, based on a closing price of $2.17 was $70,298,348.

As of March 29, 2023, the registrant had 39,470,009 shares of its Common Stock, no par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

This report is the Annual Report on Form 10-K for the year ended December 31, 2022 of MyMD Pharmaceuticals, Inc., which was formerly known as Akers Biosciences, Inc. prior to the consummation on April 16, 2021 of the merger described below.

On April 16, 2021, pursuant to the previously announced Agreement and Plan of Merger and Reorganization, dated November 11, 2020 (the "Original Merger Agreement"), as amended by Amendment No. 1 thereto, dated March 16, 2021 (the Original Merger Agreement, as amended by Amendment No. 1, the "Merger Agreement"), by and among MyMD Pharmaceuticals, Inc., a New Jersey corporation previously known as Akers Biosciences, Inc. (the "Company"), XYZ Merger Sub Inc., a Florida corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and MyMD Pharmaceuticals (Florida), Inc., a Florida corporation previously known as MyMD Pharmaceuticals, Inc. ("MyMD Florida"), Merger Sub was merged with and into MyMD Florida, with MyMD Florida continuing after the merger as the surviving entity and a wholly owned subsidiary of the Company (the "Merger"). At the effective time of the Merger, without any action on the part of any stockholder, each issued and outstanding share of pre-Merger MyMD Florida's Common Stock, par value $0.001 per share (the "MyMD Florida Common Stock"), including shares underlying pre-Merger MyMD Florida's outstanding equity awards, was converted into the right to receive (x) 0.7718 shares (the "Exchange Ratio") of the Company's Common Stock, no par value per share (the "Company Common Stock" or "Common Stock"), (y) an amount in cash, on a pro rata basis, equal to the aggregate cash proceeds received by the Company from the exercise of any options to purchase shares of MyMD Florida Common Stock outstanding at the effective time of the Merger assumed by the Company upon closing of the Merger prior to the second-year anniversary of the closing of the Merger (the "Option Exercise Period"), such payment (the "Additional Consideration"), and (z) potential milestone payments in shares of Company Common Stock up to the aggregate number of shares issued by the Company to pre-merger MyMD Florida stockholders at the closing of the Merger payable upon the achievement of certain market capitalization milestone events during the 36-month period immediately following the closing of the Merger. Upon completion of the Merger and the transactions contemplated in the Merger Agreement, (i) the former MyMD Florida equity holders owned approximately 77.05% of the outstanding equity of the Company on a fully diluted basis, assuming the exercise in full of the pre-funded warrants to purchase 986,486 shares of Company Common stock and including 4,188,315 shares of Company Common Stock underlying options to purchase shares of MyMD Florida Common Stock assumed by the company at closing and after adjustments based on the Company's net cash at closing; and (ii) former Akers Biosciences, Inc. stockholders owned approximately 22.95% of the outstanding equity of the Company.

As of 4:05 pm Eastern Time on April 16, 2021, immediately following the effective time of the Merger, the Company effected a 1-for-2 reverse stock split of the issued and outstanding Company Common Stock (the "Reverse Stock Split"). All share numbers and exercise prices included herein have been adjusted to give retroactive effect to the Reverse Stock Split.

The Merger is being treated as a reverse recapitalization effected by a share exchange for financial accounting and reporting purposes. MyMD Florida is being treated as the accounting acquirer, as its stockholders control the Company after the Merger, even though Akers Biosciences, Inc. was the legal acquirer.

See Note 1 of the Consolidated Financial Statements for additional information.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report and the documents we have filed with the Securities and Exchange Commission (which we refer to herein as the "SEC") that are incorporated by reference herein contain "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of forward-looking terms such as "anticipates," "assumes," "believes," "can," "could," "estimates," "expects," "forecasts," "future," "guides," "intends," "is confident that,", "may," "plans," "seeks," "projects," "targets," and "would" or the negative of such terms or other variations on such terms or comparable terminology. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements.

Examples of forward-looking statements in this Annual Report and our other SEC filings include, but are not limited to, our expectations regarding our business strategy, business prospects, operating results, operating expenses, working capital, liquidity and capital expenditure requirements. These statements are based on our management's expectations, beliefs and assumptions concerning future events affecting us, which in turn are based on currently available information and are subject to significant risks and uncertainties that could cause actual outcomes and results to differ materially. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, without limitation, the risks and uncertainties set forth under "Risk Factors" in Item 1A of this Annual Report on Form 10-K, which discussions are incorporated herein by reference.

These risks and uncertainties include, but are not limited to:

- fluctuation and volatility in market price of our Common Stock due to market and industry factors, as well as general economic, political and market conditions;
- the impact of dilution on our shareholders;
- our ability to realize the intended benefits of the Merger (as defined below) and the Contribution Transaction (as defined below);
- the impact of our ability to realize the anticipated tax impact of the Merger;
- delisting of our Common Stock from the Nasdaq Capital Market;
- our availability and ability to continue to obtain sufficient funding to conduct planned research and development efforts and realize potential profits;
- our ability to develop and commercialize our product candidates, including MYMD-1, Supera-CBD and other future product candidates;
- the impact of the complexity of the regulatory landscape on our ability to seek and obtain regulatory approval for our product candidates, both within and outside of the U.S.;
- the required investment of substantial time, resources and effort for successful clinical development and marketization of our product candidates;
- challenges we may face with maintaining regulatory approval, if achieved;
- the potential impact of changes in the legal and regulatory landscape, both within and outside of the U.S.;
- the impact of the COVID-19 pandemic on the administration, funding and policies of regulatory authorities, both within and outside of the U.S.;
- our dependence on third parties to conduct pre-clinical and clinical trials and manufacture its product candidates;
- the impact of the COVID-19 pandemic on our results of operations, business plan and the global economy;
- challenges we may face with respect to our product candidates achieving market acceptance by providers, patients, patient advocacy groups, third party payors and the general medical community;
- the impact of pricing, insurance coverage and reimbursement status of our product candidates;

- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain, maintain and protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on its proprietary rights;
- our ability to maintain adequate cyber security and information systems;
- our ability to achieve the expected benefits and costs of the transactions related to the acquisition of Supera Pharmaceuticals, Inc. ("Supera");
- our ability to effectively execute and deliver our plans related to commercialization, marketing and manufacturing capabilities and strategy;
- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain adequate financing in the future on reasonable terms, as and when needed;
- challenges we may face in identifying, acquiring and operating new business opportunities;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- the outcome of litigation or other proceedings to which are subject as described in the "Legal Proceedings" section of this Annual Report on Form 10-K, or to we may become subject to in the future;
- increased levels of competition;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate;
- changes in the market acceptance of our products and services;
- our compliance with all laws, rules, and regulations applicable to our business and drug product candidates;
- risks of mergers and acquisitions including the time and cost of implementing transactions and the potential failure to achieve expected gains, revenue growth or expense savings;
- other risks, including those described in the "Risk Factors" section of this Annual Report on Form 10-K.

We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all of those risks, nor can we assess the impact of all of those risks on our business or the extent to which any factor may cause actual results to differ materially from those contained in any forward-looking statement. The forward-looking statements in this Annual Report on Form 10-K and our other filings with the SEC are based on assumptions management believes are reasonable. However, due to the uncertainties associated with forward-looking statements, you should not place undue reliance on any forward-looking statements. Further, forward-looking statements speak only as of the date they are made, and unless required by law, we expressly disclaim any obligation or undertaking to publicly update any of them in light of new information, future events, or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Annual Report and the documents we have filed with the SEC.

PART I

Item 1. Business.

On April 16, 2021, pursuant to the previously announced Agreement and Plan of Merger and Reorganization, dated November 11, 2020 (the "Original Merger Agreement"), as amended by Amendment No. 1 thereto, dated March 16, 2021 (the Original Merger Agreement, as amended by Amendment No. 1, the "Merger Agreement"), by and among MyMD Pharmaceuticals, Inc., a New Jersey corporation previously known as Akers Biosciences, Inc. (the "Company"), XYZ Merger Sub Inc., a Florida corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and MyMD Pharmaceuticals (Florida), Inc., a Florida corporation previously known as MyMD Pharmaceuticals, Inc. ("MyMD Florida"), Merger Sub was merged with and into MyMD Florida, with MyMD Florida continuing after the merger as the surviving entity and a wholly owned subsidiary of the Company (the "Merger"). In this Annual Report on Form 10-K, unless the context otherwise requires, references to "we," "us," "our," "our company" and "MyMD" refer to MyMD Pharmaceuticals, Inc. and its subsidiaries. References to "Akers" refer to Akers Biosciences, Inc. prior to the Merger. For more information on the merger or the sale of assets, see "MyMD Background and Corporate History – Merger."

MyMD is a clinical stage pharmaceutical company committed to extending healthy lifespan. MyMD is focused on developing and commercializing two therapeutic platforms based on well-defined therapeutic targets, MYMD-1 and Supera-CBD:

- MYMD-1 is a clinical stage small molecule that regulates the immunometabolic system to treat autoimmune disease, including (but not limited to) multiple sclerosis, diabetes, rheumatoid arthritis, and inflammatory bowel disease. MYMD-1 is being developed to treat age-related illnesses such as frailty and sarcopenia. MYMD-1 works by regulating the release of numerous pro-inflammatory cytokines, such as TNF-α, interleukin 6 ("IL-6") and interleukin 17 ("IL-17")

- Supera-CBD is a synthetic analog of CBD being developed to treat various conditions, including, but not limited to, epilepsy, pain and anxiety/depression, through its effects on the CB2 receptor, opioid receptors and monoamine oxidase enzyme ("MAO") type B.

The rights to Supera-CBD™ were previously owned by Supera and were acquired by MyMD Florida immediately prior to the closing of the Merger.

MyMD Background and Corporate History

MyMD was organized under the laws of the State of Florida in November 2014 for the purpose of developing and commercializing certain technology and patent rights relating to MYMD-1 that were developed and/or held by the company's founder, Jonnie R. Williams, Sr. The company's sole initial stockholder was The Starwood Trust, a trust for which Mr. Williams is settlor/grantor. During the period from November 2014 through November 2016, MyMD was primarily focused on drug discovery and establishing its patent position through SRQ Patent Holdings, an entity affiliated with Mr. Williams. In November 2016, SRQ Patent Holdings assigned to MyMD all of the patent rights and other intellectual property relating to MYMD-1 pursuant to an agreement under which MyMD granted to SRQ Patent Holdings a royalty based on product sales and other revenue arising from the assigned intellectual property (as further described below).

During the period 2016 through October of 2020, MyMD's principal business activities consisted of the execution and completion of *in vitro* assays, *in vivo* pre-clinical animal studies, and genotoxicity and toxicology studies relating to MYMD-1 (as further described below). On June 25, 2019, MyMD commenced a Phase 1 trial in healthy volunteers for pharmacokinetics and tolerability studies, and in December of 2019 MyMD filed an IND for MYMD-1 for treatment of Hashimoto thyroiditis. The Phase 1 trial was completed on January 30, 2020, after which MyMD commenced preparation of a Phase 2 clinical trial for MYMD-1 focused on the treatment of depression and inflammation in COVID-19 positive patients. The company has also commenced a Phase 2 clinical trial for patients with sarcopenia, with dosing begin in the first quarter of 2022.

As of December 31, 2022, MyMD had 500,000,000 shares of authorized Common Stock, of which approximately 39,470,009 shares were outstanding and 14,202,928 shares were reserved for issuance of Common Stock upon the exercise of outstanding stock options, Common Stock warrants, restricted stock units and convertible preferred stock and warrants.

Merger

On April 16, 2021, pursuant to the Merger Agreement, by and among the Company, Merger Sub and MyMD Florida, Merger Sub was merged with and into MyMD Florida, with MyMD Florida continuing after the merger as the surviving entity and a wholly owned subsidiary of the Company. At the effective time of the Merger, without any action on the part of any stockholder, each issued and outstanding share of pre-Merger MyMD Florida's Common Stock, par value $0.001 per share (the "MyMD Florida Common Stock"), including shares underlying pre-Merger MyMD Florida's outstanding equity awards, was converted into the right to receive (x) 0.7718 shares (the "Exchange Ratio") of the Company's Common Stock, no par value per share (the "Company Common Stock" or "Common Stock"), (y) an amount in cash, on a pro rata basis, equal to the aggregate cash proceeds received by the Company from the exercise of any options to purchase shares of MyMD Florida Common Stock outstanding at the effective time of the Merger assumed by the Company upon closing of the Merger prior to the second-year anniversary of the closing of the Merger (the "Option Exercise Period"), such payment (the "Additional Consideration"), and (z) potential milestone payments in shares of Company Common Stock up to the aggregate number of shares issued by the Company to pre-merger MyMD Florida stockholders at the closing of the Merger payable upon the achievement of certain market capitalization milestone events during the 36-month period immediately following the closing of the Merger. Immediately following the effective time of the Merger, the Company effected a 1-for-2 reverse stock split of the issued and outstanding Company Common Stock (the "Reverse Stock Split"). Upon completion of the Merger and the transactions contemplated in the Merger Agreement, (i) the former MyMD Florida equity holders owned approximately 77.05% of the outstanding equity of the Company on a fully diluted basis, assuming the exercise in full of the pre-funded warrants to purchase 986,486 shares of Company Common stock and including 4,188,315 shares of Company Common Stock underlying options to purchase shares of MyMD Florida Common Stock assumed by the company at closing and after adjustments based on the Company's net cash at closing; and (ii) former Akers Biosciences, Inc. stockholders owned approximately 22.95% of the outstanding equity of the Company.

The Merger was treated as a reverse recapitalization effected by a share exchange for financial accounting and reporting purposes. MyMD Florida was being treated as the accounting acquirer, as its stockholders control the Company after the Merger, even though Akers Biosciences, Inc. was the legal acquirer. As a result, the assets and liabilities and the historical operations that are reflected in our consolidated financial statements are those of MyMD Florida as if MyMD Florida had always been the reporting company. All references to MyMD Florida shares of common stock, warrants and options have been presented on a post-merger, post-reverse split basis.

Supera Asset Purchase Agreement

On November 11, 2020, in connection with entering into the Merger Agreement, MyMD Florida entered into the Supera Asset Purchase Agreement pursuant to which MyMD Florida agreed to acquire from Supera substantially all of the assets (including all rights to Supera-CBD) and certain obligations of Supera in consideration of the issuance to Supera of an aggregate of 13,096,640 shares of MyMD Florida Common Stock. Supera is owned principally by The Starwood Trust and is controlled by Mr. Williams. Supera is a Florida corporation that was incorporated in September 2018 by Mr. Williams and The Starwood Trust in order to develop and commercialize Supera-CBD. In December 2018, Mr. Williams assigned his rights and intellectual property relating to Supera-CBD to Supera. As partial consideration for such assignment, Supera has granted to SRQ Patent Holdings II, LLC a royalty with respect to product sales and other consideration arising from the assigned intellectual property (as further described below).

Acquisition and Disposition of Cystron

The Company acquired 100% of the membership interests of Cystron pursuant to a Membership Interest Purchase Agreement, dated March 23, 2020 (as amended by Amendment No. 1 on May 14, 2020, the "MIPA") from certain selling parties (the "Cystron Sellers"). The acquisition of Cystron was accounted for as a purchase of an asset. Cystron is a party to a License and Development Agreement (as amended and restated on March 19, 2020, in connection with our entry into the MIPA, the "License Agreement") with Premas Biotech PVT Ltd. ("Premas") whereby Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other coronavirus infections. Cystron was incorporated on March 10, 2020. Since its formation and through the date of its acquisition by the Company, Cystron did not have any employees and its sole asset consisted of the exclusive license from Premas.

On March 18, 2021, the Company and the Cystron Sellers, which are also shareholders of Oravax, entered into a Termination and Release Agreement terminating the MIPA effective upon consummation of the Contribution Agreement. In addition, the Cystron Sellers agreed to waive any change of control payment triggered under the MIPA as a result of the Merger.

On April 16, 2021, pursuant to the Contribution and Assignment Agreement, dated March 18, 2021 (the "Contribution Agreement") by and among the Company, Cystron, Oravax Medical, Inc. ("Oravax") and, for the limited purpose set forth therein, Premas, the parties consummated the transactions contemplated therein. Pursuant to the Contribution Agreement, among other things, the Company caused Cystron to contribute substantially all of the assets associated with its business of developing and manufacturing Cystron's COVID-19 vaccine candidate to Oravax (the "Contribution Transaction").

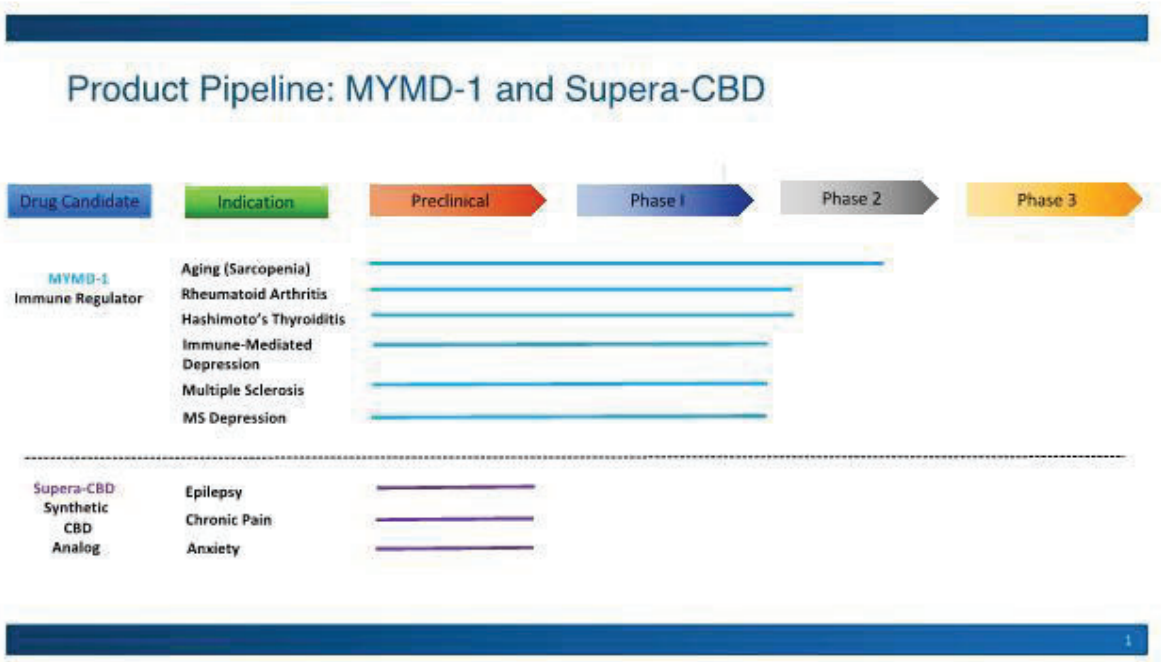
Oravax is pursuing the development of the COVID-19 vaccine candidate. MyMD has evaluated several options with respect to its interest in Oravax, including a potential distribution of Oravax shares to the MyMD shareholders. This would make Oravax a publicly held company. MyMD's interest in Oravax consists of 13% of Oravax's outstanding shares of capital stock and the rights to a 2.5% royalty on all future net sales. In addition, MyMD currently has the right to designate a member of the board of directors of Oravax, pursuant to which Mr. Joshua Silverman, our Chairman of the Board, has been designated to serve as a director of Oravax.

Status of MyMD Florida

On April 8, 2022, the MyMD Florida subsidiary was dissolved and merged into the New Jersey corporation MyMD Pharmaceuticals, Inc. pursuant to an Agreement and Plan of Merger dated April 8, 2022.

Drug Development

MyMD is developing two platform drugs targeting numerous disease indications. Below is MyMD's development pipeline:



Strategy

MyMD's strategy is to focus on extending healthy life span through the development and commercialization of novel drug platforms based on well-defined therapeutic targets. Below are MyMD's key clinical strategies:

- Complete Phase 2 clinical trial in sarcopenia (i.e., age-related muscle loss) in the second quarter of 2023;
- Advance MYMD-1 into Phase 2 clinical trials for treatment of diabetes, rheumatoid arthritis, and inflammatory bowel disease;
- Execute on IND-enabling studies of Supera-CBD to enable submission of an IND for a Phase 1 clinical trial in healthy volunteers followed by Phase 2 clinical trials in epilepsy, addiction and anxiety disorders;
- Identify and validate additional novel targets and utilize translational platforms to develop a pipeline of product candidates for aging and other autoimmune disease;
- Maintain broad commercial rights to MyMD's product candidates; and
- Continue to strengthen and expand MyMD's intellectual property portfolio.

MYMD-1

Overview

MYMD-1 is a clinical stage drug that targets the immune system by inhibiting the release of pro-inflammatory cytokines, such as TNF-α. Cytokines are a broad category of molecules involved in immune system coordination. Immunometabolic regulation is the system of regulating the immune system and its pro-inflammatory cytokines in order to prevent and treat autoimmune diseases and age-related illnesses. By affecting the initial triggers that drive autoimmunity, MYMD-1 targets the underlying cause of these diseases rather than just their symptoms. Based on MYMD-1's Phase 1 clinical trial, completed in January 2020, MyMD has commenced a Phase 2 clinical trial for sarcopenia (age-related muscle loss) and is planning multiple Phase 2 clinical trials in autoimmune disease, including (1) multiple sclerosis, diabetes, inflammatory bowel disease and rheumatoid arthritis; (2) inflammation related depression and anxiety; and (3) COVID-19 associated depression. MyMD has an active IND with the Endocrinology Division at the FDA for other autoimmune diseases. Studies have been completed on the mechanisms of action and efficacy of MYMD-1 in several pre-clinical models of autoimmune diseases (i.e., experimental autoimmune encephalomyelitis ("EAE") that models multiple sclerosis and autoimmune thyroiditis), and these studies have been published in peer reviewed journals. MyMD plans to pursue these indications.

MYMD-1*: An Immunometabolic Regulator*

Inflammation, activated through the release of TNF-α and other cytokines, is the body's normal physiological defense against infections and pathogens, and under normal circumstances such inflammation quickly resolves once the intruder is neutralized. However, elevated levels of pro-inflammatory cytokines, including TNF-α, can lead to prolonged, chronic inflammation, which is closely linked to autoimmune diseases (such as multiple sclerosis, diabetes, rheumatoid arthritis) and aging (i.e., inflamm-aging) as well as cardiovascular disease and cancers, all of which may result in reduced health span (the period of life spent in good health).

The goal of immunometabolic regulatory drugs such as MYMD-1 is to target immune cells that overproduce pro-inflammatory cytokines, such as TNF-α, without preventing normal immune cell function. TNF-α is a cytokine that is released by immune cells that plays a key role in acute and chronic inflammation, autoimmune diseases and aging. Examples of currently approved immunometabolic regulating drugs include Dimethyl Fumarate ("DMF") (approved for the treatment of multiple sclerosis) and Rapamycin (used in kidney transplants and being studied in aging).

MYMD-1 is a novel immunometabolic regulator that has demonstrated *in vitro* and *in vivo* ability to regulate the release of multiple cytokines from immune cells, including TNF-α. MYMD-1 is being developed to treat chronic inflammatory diseases, such as multiple sclerosis, diabetes, inflammatory bowel disease, rheumatoid arthritis, and aging.

MYMD-1 *Regulates Multiple Cytokines*

MyMD conducted an in vitro study to demonstrate that MYMD-1 regulates a broad range of cytokines, including TNF-α, interferon gamma (INFγ) and interleukins, including interleukin 2 ("IL-2") and IL-17A. By blocking these cytokines that have been shown to play key roles in the development and maintenance of autoimmune diseases, MYMD-1 treats the causes—and not just the symptoms—of this class of illnesses.

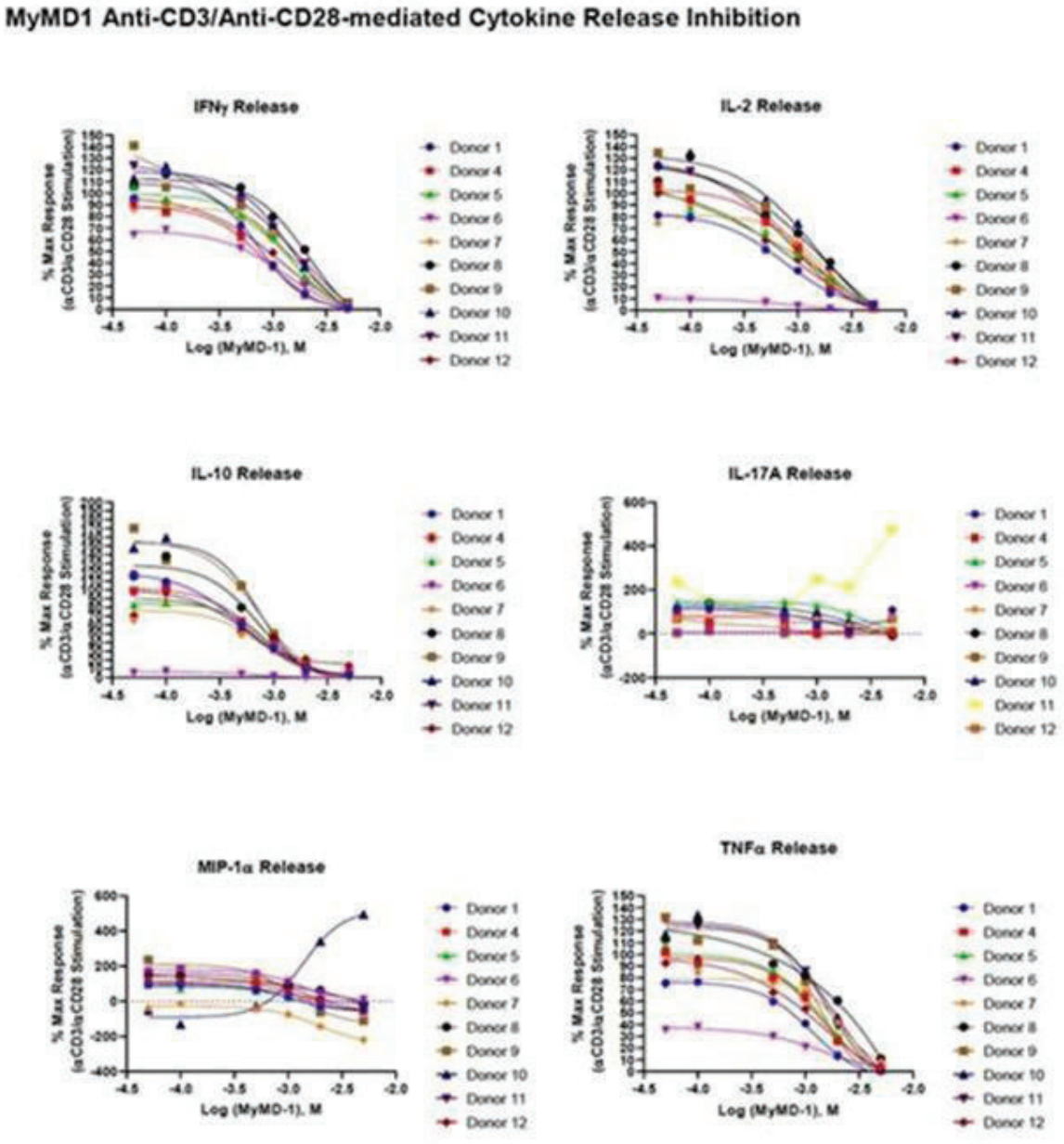
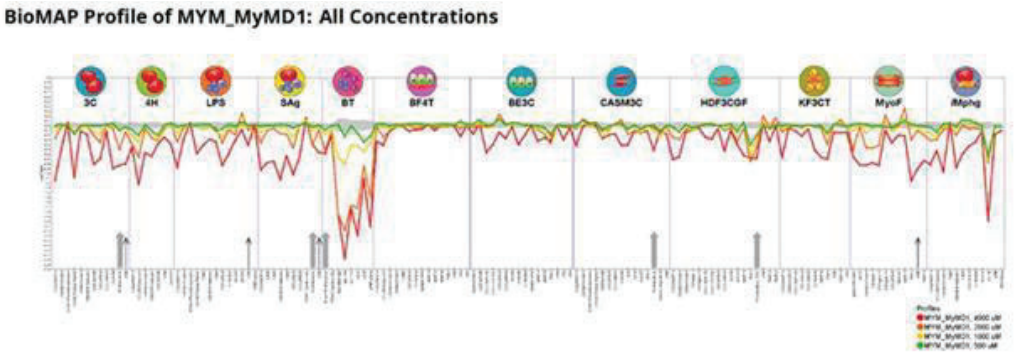


Figure 1. MYMD-1 *modulates the release of a broad spectrum of cytokines.*

An additional *in vitro* study demonstrates that MYMD-1 has broad cytokine inhibiting activity including inhibition of TNF-α, IL-16 and IL-17. The study also suggested MYMD-1 has limited toxicity, even at high doses, and none up to 2,000 micromoles.



In an *in vivo* study (NOD.H2 mouse model), MYMD-1 decreased serum levels of TNF-α and INFγ.

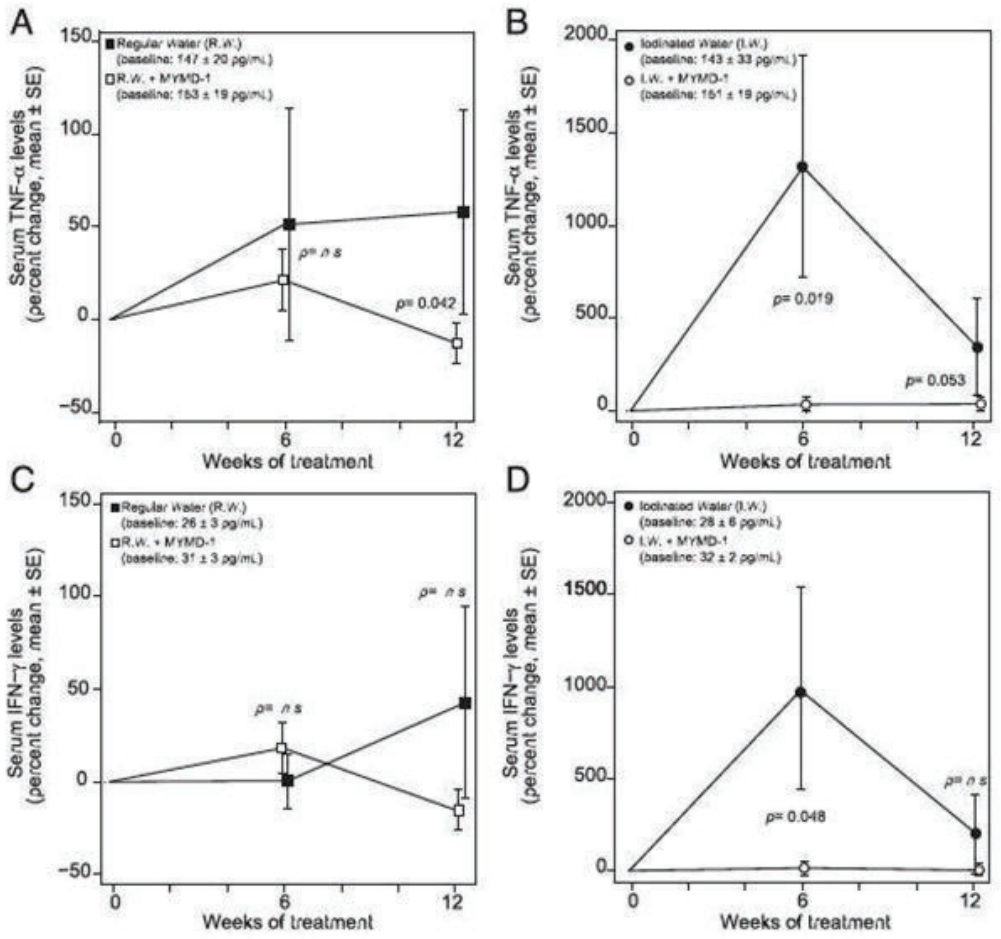


Figure 2. MYMD-1 decreases the serum levels TNF-α and IFN-g in NOD.H-2h4 mice. NOD.H-2h4 mice were treated with either regular water or iodinated water (500 mg/l of sodium iodide), and each group was treated or not treated with MYMD-1 (185 mg/l). Cytokines were measured at baseline and after 6 and 12 weeks of treatment using a multiplex magnetic bead array. (A and B) MYMD-1 significantly decreased serum TNF-α levels in the regular water group and tended to decrease it in the iodinated water group. (C and D) MYMD-1 showed a modest effect on serum IFN-g in the iodinated water group. Results are from three independent experiments. Statistical comparisons were made by longitudinal data analysis with generalized estimating equations.

MYMD-1 Targets Autoimmune Diseases

MYMD-1 is designed to regulate the immunometabolic system and intended for development as a potential treatment for certain autoimmune diseases, including (but not limited to) multiple sclerosis, diabetes, rheumatoid arthritis, and/or inflammatory bowel disease. MYMD-1 is also being developed to treat age-related illnesses such as frailty and sarcopenia. Autoimmune diseases are a broad category of diseases that result from an overactive immune response, where immunometabolic system dysregulation is believed to play an important role. A healthy immune system defends the body against disease and infection. If the immune system malfunctions, it can mistakenly attack healthy cells, tissues, and organs. In response to an often-unknown trigger, the immune system starts producing antibodies that attack the body's own cells instead of fighting infections.

TNF-α, produced primarily by specific white blood cells, belongs to a category of proteins called cytokines that act as chemical messengers throughout the body to regulate many aspects of the immune system. Other key cytokines include IL-6, IL-17A, interleukin 10 ("IL-10") and Interferon gamma ("INFγ"). Cytokines are essential to mounting an inflammatory response. However, chronic or excessive production of cytokines has been implicated in a number of acute and chronic inflammatory diseases.

A number of drugs target the immunometabolic system to treat autoimmune diseases, including DMF (approved for the treatment of multiple sclerosis) and Rapamycin (being studied in aging, rheumatoid arthritis, and other autoimmune diseases). Additional therapies for autoimmune diseases include anti-inflammatory drugs and immunosuppressive agents including drugs that non-selectively inhibit or block TNF-α (generally referred to as "TNF-α blocking drugs"). Currently available TNF-α blocking drugs must be injected or infused to work. In some instances, the efficacy of a given dosage of TNF-α blockers declines with repeated administration, and side effects can also be a concern. These non-selective TNF-α blockers can cause serious bacterial, fungal, and viral infections. MYMD-1 is a selective, oral TNF-α inhibitor that might provide a safer alternative to existing products on the market. The global market for TNF-α blockers was estimated at $41.6 billion in 2020 and is projected to reach $45.5 billion by 2027.

An *in vitro* study involving human blood cells analyzed the cytokine inhibitory effects of MYMD-1 together with leading approved TNF-α blockers (monoclonal antibodies).

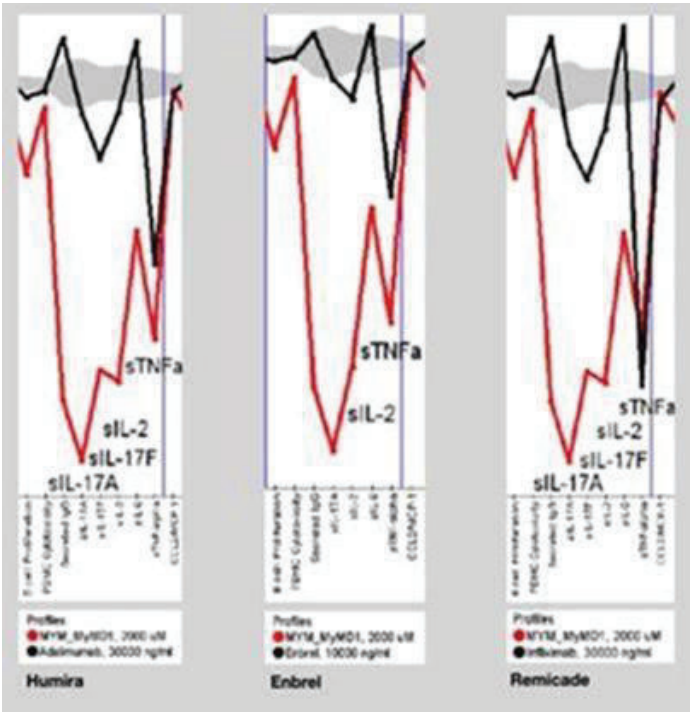


Figure 3. Comparison of inhibitory effect of MYMD-1 with other TNF-α blockers. MYMD-1 exhibits a dose-dependent reduction in release of several cytokine more effectively than Humira, Enbrel and Remicade.

We believe MYMD-1 is distinguishable from currently marketed TNF-α blockers because it selectively blocks TNF-α production related to adaptive immunity (involved in autoimmunity) but spares the role of this cytokine in innate immunity (which plays a primary protective role in fighting off invading organisms). Because of the crucial role that TNF-α plays in front line protection by the innate immune system (e.g., from bacterial, fungal, and viral infections), the indiscriminate blockade of TNF-α by TNF-α blocking agents can cause serious and even fatal infections, which is one of the primary limiting factors in the use of this class of drugs. Based on our belief regarding the selectivity of MYMD-1 in blocking TNF-α, therefore, we intend to explore the extent to which MYMD-1 may be a safer alternative to treat infectious, inflammatory, and autoimmune conditions, as well as its potential to ameliorate immune mediated depression in such illnesses.

Pre-Clinical Study of MYMD-1 in Multiple Sclerosis Study (EAE Mouse Model)

Multiple sclerosis is an autoimmune disease in which T cells lead an attack on oligodendrocytes and neurons. Multiple sclerosis is the leading neurological cause of disability in adults aged 30–50, and approximately one million people in the United States are affected with this debilitating disease. T cells are one of the major components of the adaptive immune system. Their roles include directly killing infected host cells, activating other immune cells, producing cytokines and regulating the immune response. When naïve, undifferentiated T cells become activated, they differentiate and acquire effector functions that can be delineated by the cytokines they secrete.

Preliminary *in vivo* studies of the therapeutic efficacy of MYMD-1 in the animal model for multiple sclerosis, known as EAE, indicate that MYMD-1 modulates autoreactive T cell activation in a dose-dependent manner, suppresses T cell activation and ameliorates the course of EAE. Further EAE mouse studies suggest that MYMD-1 suppresses the influx of CD4+ T cells into the brain.

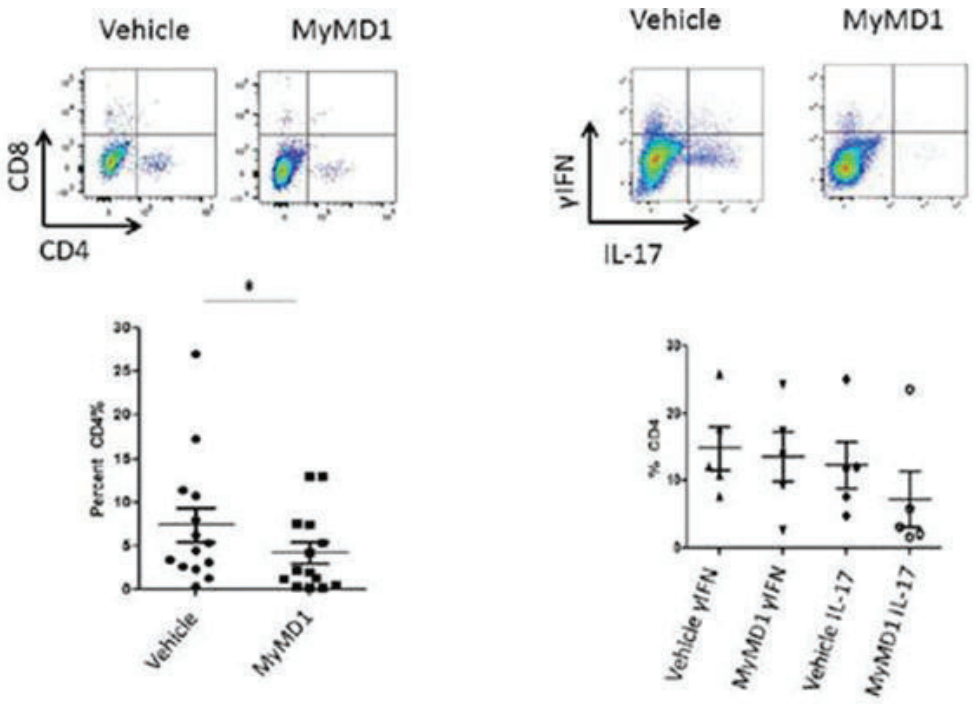


Figure 4. Effects of MYMD-1 on the influx of T cells into the CNS early in EAE. To assess the effects of MYMD-1 on the infiltration of T cells into the CNS, mice were immunized and treated with either vehicle control or 25 mg/mouse/day MYMD-1. Ten to 14 days later, mice were perfused and brains collected for analysis. Infiltration was determined by flow cytometry. Analysis of Th1 and Th17 subsets are shown; data compiled from 2 to 3 experiments, n > 3/group per experiment). Student's t-test was conducted for statistics.

MYMD-1 In Vivo Study of Autoimmune Thyroiditis (NODH.2 Mouse Model)

Thyroiditis or Hashimoto thyroiditis is an autoimmune disease characterized by lymphocytic infiltration of the thyroid gland. It has been shown that tobacco smoking has a protective effect against Hashimoto thyroiditis as tobacco smokers have a lower prevalence of thyroid autoantibodies than non-smokers.

MyMD conducted an *in vivo* study of autoimmune thyroiditis in a spontaneous thyroiditis (NODH.2) mouse model. We believe the results of this study show MYMD-1's ability to suppress TNF-α production by CD-4+ T cells in a dose dependent manner. Additionally, the study reported that MYMD-1 statistically decreases the incidence and severity ($p < 0.001$) of thyroiditis in this mouse model. Pre-clinical studies have demonstrated that MYMD-1 ameliorated autoimmune thyroiditis in the thyroiditis mouse model.

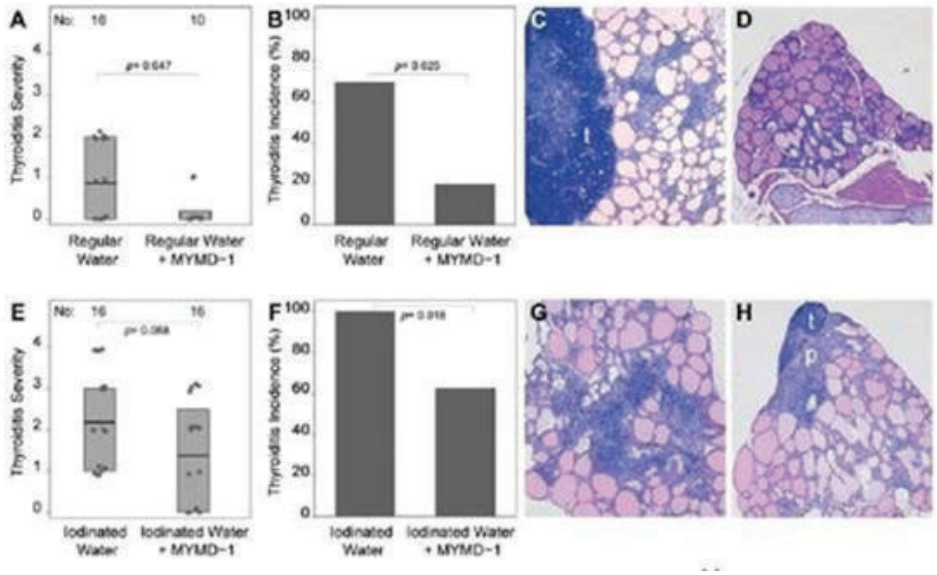


Figure 5. MYMD-1 decreases the incidence and severity of autoimmune thyroiditis in NOD.H-2h4 mice, as assessed by H&E histopathology. At 8 weeks old, 58 NOD.H-2h4 mice were divided into regular water and iodinated water groups. In the regular water group, 10 mice (7 M, 3 F) drank water that contained MYMD-1 (185 mg/l), and 16 mice (10 M, 6 F) drank water without it. In the iodinated water group, the water was supplemented with 500 mg/l of sodium iodide and contained (16 mice: 10 M, 6 F) or did not contain (16 mice: 10 M, 6 F) MYMD-1 (185 mg/l). After 12 weeks of treatment, thyroids were removed and divided in half. (A and B) Thyroiditis severity and incidence assessed by histopathology in the regular water group. (C) A representative thyroid from a mouse in the regular water group, showing a severity score of 2. (D) A representative thyroid from a mouse in the regular water group treated with MYMD-1, showing thyroid follicle preservation and an overall normal glandular size (severity score of 0). (E and F) Thyroiditis incidence and severity scores assessed by histopathology in the iodinated water group. (G) A representative thyroid from a mouse in the iodine group, showing marked lymphocytic infiltration, follicular enlargement, and architectural disruption (severity score of 4). (H) A representative thyroid from a mouse in the iodine plus MYMD-1 group (severity score of 2). Results represent the summary of 10 independent experiments, each analyzing 4 to 6 mice, for a total of 58 mice.

MYMD-1 Targets Inflamm-Aging and Related Disorders

Aging is associated with a loss of tight regulation of the immune system. This leads to increased inflammatory activity in the body, including increased circulating levels of TNF-α. Chronic inflammation is a hallmark of aging, referred to as inflamm-aging. Inflamm-aging and chronic inflammation are closely linked to a number of disorders such as obesity, insulin resistance/type 2 diabetes, cardiovascular diseases, and cancers. TNF-α is a multifunctional pro-inflammatory cytokine which may play a part in the pathogenesis of certain age-related disorders such as atherosclerosis. A multi-year pre-clinical, proof of concept *in vivo* study in aging and longevity confirmed our belief regarding MYMD-1's potential therapeutic effect on inflamm-aging and other age-related disorders, which we intend to explore further in clinical trials, pending our submission, and the corresponding acceptance, of the requisite regulatory and other relevant submissions.

Bascom Palmer Eye Institute Collaboration

On July 12, 2022, we announced a new collaboration with Bascom Palmer Eye Institute of Miami, Florida ("Bascom Palmer") to collaborate on a pre-clinical study using MYMD-1 as a potential treatment for traumatic optic neuropathy (TON). To date, our collaboration with Bascom Palmer has included pre-clinical and clinical investigations.

Pre-Clinical

In July 2022 we entered into a Material Transfer Agreement with Bascom Palmer. Our collaboration was announced in a press release and in an article in *Ophthalmology Times*. Bascom Palmer confirmed in August 2022 that it had received a quantity of our MYMD-1 product candidate and MYMD provided a material safety datasheet and certification of analysis. In August 2022, Bascom Palmer researchers conducted a preliminary introductory study of TON in mice. Investigators ran a crush injury of the mice's optic nerves with and without MYMD-1. The study drug was given once per day via oral gavage at a dosage of 30 mg/kg of body weight. The mice were treated for five days, untreated for two days, and then sacrificed, and their TNF-α levels were measured. Data from this study is pending. We intend to plan additional pre-clinical studies.

Clinical

In addition to the pre-clinical study described above, we are collaborating with Bascom Palmer to plan future a clinical study. In August 2022, Bascom Palmer researchers executed a confidentiality and non-disclosure agreement and Bascom Palmer produced a draft protocol synopsis entitled, Assessment of the Anti-Inflammatory Effects of MYMD-1 in Non-Infectious Anterior Uveitis: A Randomized Controlled, Double Blind Clinical Study.

MYMD-1 Commercialization Targets

MYMD-1 is being developed to address serious and debilitating autoimmune and inflammatory diseases, including sarcopenia, frailty resulting from aging process, and rheumatoid arthritis (RA). According to the U.S. Census Bureau, in 2020, there were approximately 54 million U.S. residents over 65 years of age, representing 16% of the U.S. population. This figure is expected to increase to nearly 22% by the year 2040.[1] The Arthritis Foundation estimates that approximately 1.5 million people in the U.S. have RA.[2]

Supera-CBD

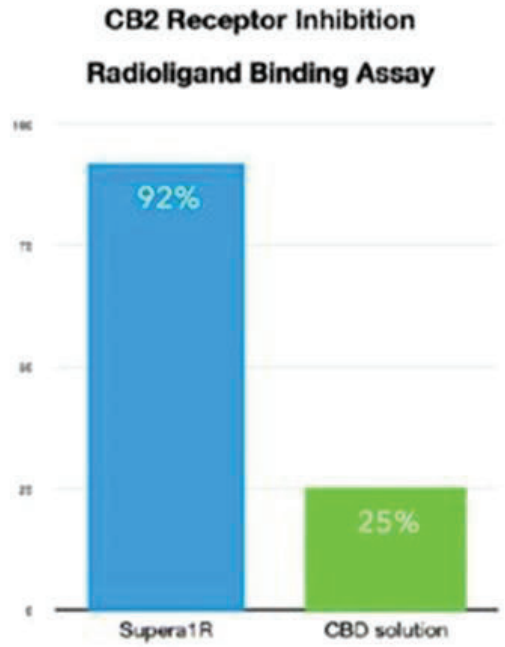
Supera-CBD is a synthetic small molecule that is an analog of naturally grown CBD derived from the Cannabis sativa plant. Supera-CBD is being developed to treat conditions with which CBD is often anecdotally associated but for which no natural or synthetic CBD-containing drugs have been approved by the FDA, such as pain, anxiety/depression and seizures from epilepsy. While naturally grown CBD is a constituent of Cannabis sativa, Supera-CBD is a synthetic analog of CBD, thus eliminating potential complications associated with the psychoactive effects of Tetrahydrocannabinol ("THC"), which is also a constituent of the Cannabis sativa plant. Studies have suggested that CBD may have broad therapeutic properties, including the treatment of neuropsychiatric disorders.

[1] U.S. Department of Health and Human Services. 2020 Profile of Older Americans. May 2021 Page 3.
[2] The Arthritis Foundation. Rheumatoid Arthritis: Causes, Symptoms, Treatments and More.

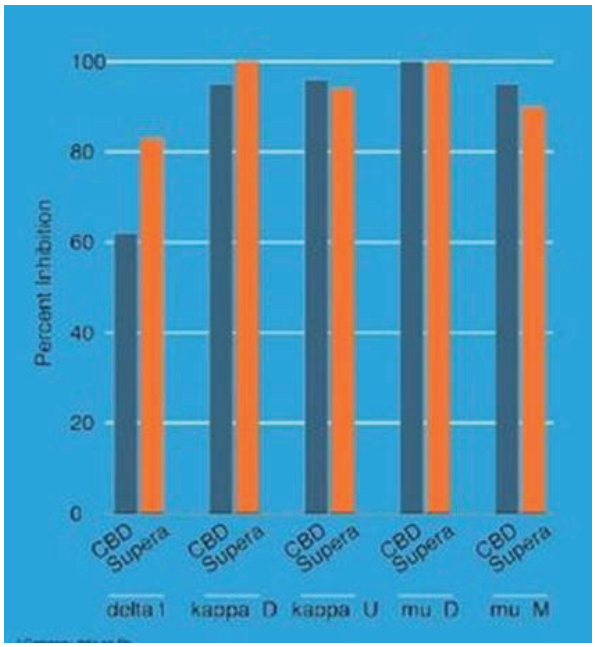
Overview

General Pharmacology and Therapeutic Profile

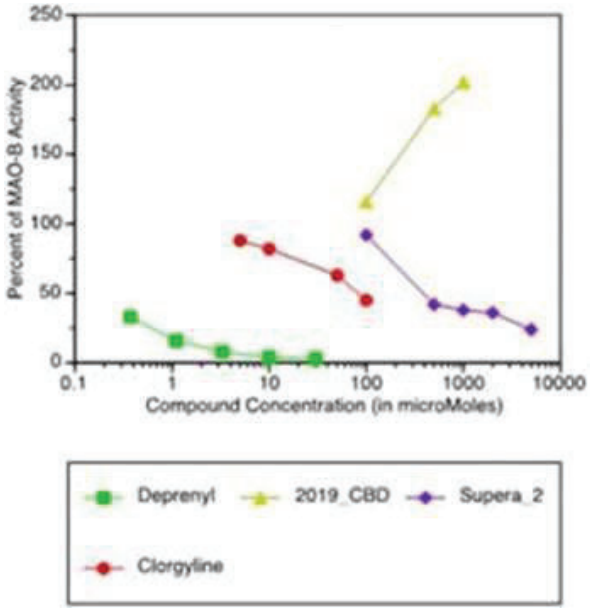
CBD inhibits a number of important receptors, including the CB2 receptor and opioid receptors, and can also inhibit MAO enzymes. In the immune system, one of the important functions of the CB2 receptor is in the regulation of cytokine release from immune cells. Antagonists targeting the CB2 receptor have been proposed for the treatment or management of a range of painful conditions as well as for treating several neurological diseases. The Company conducted an *in vitro* binding assay study to analyze the CB2 inhibition of Supera-CBD together with that of CBD derived from naturally grown plants.



Opioid receptors are widely expressed in the brain, spinal cord, peripheral nerves and digestive tract. MyMD conducted an *in vitro* binding analysis of Supera-CBD with the three types of opioid receptors. The profile suggests that Supera-CBD could possibly play a role in treating opioid addiction.



MAOs are enzymes involved in the catabolism, or digestion, of certain neurotransmitters. MyMD conducted an *in vitro* MAO inhibition study. In this study, Supera-CBD and commercial CBD were analyzed against positive and negative controls. In this study, Supera-CBD far exceeded CBD in dose-dependent inhibition of MAOs, particularly MAO-B. Drugs that inhibit MAOs have been commercially used for decades to treat depression, and more recent studies have suggested MAO-B inhibiting drugs might have a role to play in treating cognitive decline in aging.



Supera-CBD Early-Stage Plans for Development and Potential Commercialization Targets

Supera-CBD is in early-stage development for pain, anxiety, and sleep disorders. There are currently a number of over-the-counter CBD products marketed with unapproved therapeutic claims relating to these conditions, among other conditions. While there are a substantial number of such products on the market that have not been subject to regulatory enforcement action, the FDA has consistently reiterated, in guidance and warning letters against a number of the companies marketing such CBD products for such uses, that CBD products may not be lawfully marketed for therapeutic uses in the United States without first-obtaining FDA approval via the NDA process. CBD product sales in the US reportedly reached $5.3 billion in 2021, 15% growth over 2020 sales, and are projected to reach $16 billion by 2026.[3] MyMD believes that if Supera-CBD is approved by the FDA, it may have competitive advantages over currently marketed CBD products that have not been approved by FDA as drug products, as approved drugs must undergo rigorous premarket study and generate results sufficient to support a finding that they are safe and effective for their intended use(s) and remain subject to ongoing FDA postmarket regulation, which provides additional assurances relating to quality, consistency and safety.

Currently, there is one FDA-approved drug with plant-derived CBD as an active ingredient. FDA subsequently approved three other cannabinoid-containing drugs, two of which utilize synthetic cannabinoids analogous or similar to THC as the active ingredient and the other, a combination of synthetic CBD and THC. Epidiolex is being commercialized by GW Pharmaceuticals, plc ("GWPH") to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age and older. The reported revenues from Epidiolex in fiscal year 2019 were approximately $296 million. MYMD believes that, by utilizing synthetic, rather than naturally derived, CBD in Supera-CBD may mitigate a number of obstacles generally associated with growing and processing an active drug ingredient produced from naturally grown plant extracts.

On March 2, 2023, we announced that the U.S. Drug Enforcement Administration (DEA) has conducted a scientific review and determined that it would not Supera-CBD a controlled substance or listed chemical under the Controlled Substances Act (CSA) and its governing regulations. We believe that this decision will expedite future research involving Supera-CBD by relieving us or our research partners from having to comply with regulations relating to controlled substances.

[3] Benzinga: US Hemp CBD Market To Hit $5.3B In Sales In 2021.

Sales and Marketing

MyMD does not currently have sales and marketing infrastructure to support the launch of its products. MyMD intends to build such capabilities in North America prior to launch the commercial MYMD-1, if successfully developed and granted the requisite FDA approval. Outside of North America, MyMD may rely on licensing, co-sale and co-promotion agreements with strategic partners for commercialization of its products. If MyMD builds a commercial infrastructure to support marketing in North America, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, MyMD would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that MYMD-1 or Supera-CBD will be approved, which cannot be guaranteed.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and vigorous defense of intellectual property. Any product candidates that MyMD successfully develops and commercializes will have to compete with existing and future new therapies. While MyMD believes that its drug candidates, development experience and scientific knowledge may provide it with certain competitive advantages, MyMD faces potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions.

Existing therapies for autoimmune diseases include anti-inflammatory drugs and immunosuppressive agents, including drugs that seek to selectively inhibit or block TNF-α (generally referred to as "TNF-α blocking drugs"). TNF-α blocking drugs are large molecules that are generally injected or infused. In some instances, the period of efficacy of a given dosage of TNF-α blockers can decline with repeated administration and side effects can be a concern. Leading TNF-α blocking drugs include Etanercept (Enbrel), Infliximab (Remicade), and Adalimumab (Humira). The total TNF-α market collectively represented approximately $41 billion in global sales in 2022.[4] All of these existing TNF-α blocking drugs require injection, whereas MYMD-1 is being developed to be orally bioavailable. Our management believes patients and providers would view the fact that MYMD-1 can be administered orally as a significant advantage.

Unlike currently marketed TNF-α blockers, MYMD-1 is designed to selectively block TNF-α production related to adaptive immunity (involved in autoimmunity) but to spare the role of this cytokine in innate immunity (which plays the primary initial role in fighting off invading organisms). Because of the crucial role that TNF-α plays in front line protection by the innate immune system from bacterial, fungal, and viral infections, the indiscriminate blockade of TNF-α by TNF-α blocking agents can cause serious and even fatal infections, which is the primary limiting factor in the use of this class of drugs. MyMD thus believes that, if MYMD-1 is approved for marketing, the potential selectivity of MYMD-1 in blocking TNF-α might make it a preferrable alternative to some existing treatments for infectious, inflammatory, and autoimmune conditions, as well as simultaneously resulting in amelioration of immune mediated depression in such illnesses if it is also approved for such indication.

Intellectual Property

MyMD's policy is to develop and maintain MyMD's proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and applications related to MyMD's drug candidates and methods of treatment that are material to the development and implementation of MyMD's business. MyMD also relies on trademarks, know-how, confidentiality agreements and invention assignment agreements to develop and maintain MyMD's proprietary position.

MyMD's patent portfolio includes protection for MYMD's lead product candidates, MYMD-1 and Supera-CBD. Currently, there are multiple patent families relating to (i) age reversal and treatments of age-related disorders including sarcopenia; (ii) reduction of TNF-α levels and treatments of autoimmune disorders; (iii) addiction treatments; (iv) methods of increasing hair growth and (v) plant nutrition. As of the date of this document, MyMD has 16 issued U.S. patents, four pending U.S. patent applications, 50 issued foreign patents, and 15 foreign patent applications pending in such jurisdictions as Australia, Canada, China, European Union, Israel, Japan and South Korea, which, if issued, are expected to expire between 2036 and 2039.

[4] https://www.thebusinessresearchcompany.com/report/tnf-alpha-inhibitor-global-market-report

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which MyMD files, the patent term is 20 years from the date of filing of the first non-provisional application in which priority is claimed. In the U.S. patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the U.S., the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

MyMD's commercial success depends in part on its ability to obtain and maintain proprietary protection for MyMD's product candidates, as well as novel discoveries, core technologies, and know-how, as well as its ability to operate without infringing on the proprietary rights of others and to prevent others from infringing its proprietary rights.

Assignment and Royalty Agreements

MyMD is a party to two Amended and Restated Confirmatory Patent Assignment and Royalty Agreements, both dated November 11, 2020, with SRQ Patent Holdings and SRQ Patent Holdings II, under which MyMD (or its successor) will be obligated to pay to SRQ Patent Holdings or SRQ Patent Holdings II (or its designees) certain royalties on product sales or other revenue received on products that incorporate or are covered by the intellectual property that was assigned to MyMD. The royalty is equal to 8% of the net sales price on product sales and, without duplication, 8% of milestone revenue or sublicense compensation. SRQ Patent Holdings and SRQ Patent Holdings II are affiliates of Mr. Williams.

Government Regulation

Government authorities in the U.S. at the federal, state, and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drugs and biological products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety, and efficacy in connection with the target indication(s) for use must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

FDA Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation under the FD&C Act and the FDA's implementing regulations and other federal and state statutes and regulations governing, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety enforcement actions and/or administrative or judicial sanctions, including, but not limited to clinical holds, FDA refusal to approve NDA submissions and/or revocation or limitation of existing NDAs for approved products, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new drug product or certain changes to an approved product in the U.S. typically requires pre-clinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing on human subjects may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements are inherently uncertain, expensive, and it typically takes many years to generate sufficient data to apply for approval, even when such approval is not ultimately granted, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB and ethics committee for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial may be sufficient in rare instances, including (1) where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when in conjunction with other confirmatory evidence.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all pre-clinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $3.1 million for fiscal year 2022 (for applications containing clinical data), which increased from $2.9 million for fiscal year 2021. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved NDA is also subject to annual program fees, currently exceeding $369,413 for fiscal year 2022 for each prescription product. The FDA adjusts the user fees on an annual basis, and the fees typically increase annually.

The FDA reviews each submitted NDA before it determines whether to file it and may request additional information. The FDA must make a decision on whether to file an NDA within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is filed, the FDA begins an in-depth review of the NDA. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines may offer significant improvement in safety or effectiveness compared to marketed products or where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its goal dates for standard and priority NDAs, and the review process can be extended by FDA requests for additional information or clarification.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also typically inspects clinical trial sites to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter ("CRL"). A CRL generally outlines the deficiencies in the submission, which may be minor and more technical, or major and more substantive and, in the latter case may require substantial additional testing or data to be eligible for substantive review by FDA upon resubmission, such as additional clinical data, additional pivotal clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a CRL is issued, the applicant may resubmit the NDA addressing all of the deficiencies identified in the letter, withdraw the application, engage in formal dispute resolution or request an opportunity for a hearing. The FDA has committed to reviewing resubmissions in two to six months depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If the deficiencies identified in the CRL are addressed to FDA's satisfaction in a resubmission of the NDA (and FDA does not identify any other issues that need to be corrected prior to approval or that, otherwise, cause the agency to determine that approval is not appropriate at the given time), the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. In addition, under the Pediatric Research Equity Act of 2003 ("PREA"), as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

As a condition of NDA approval, the FDA may also require a REMS, to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of an NDA supplement or, in some case, a new NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, MyMD will be required to develop and implement additional clinical study policies and procedures designed to help protect study participants from the SARS-CoV-2 virus, which may include using telemedicine visits and remote monitoring of patients and clinical sites. MyMD will also need to ensure data from its clinical studies that may be disrupted as a result of the pandemic is collected pursuant to the study protocol and is consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB. Patients who may miss scheduled appointments, any interruption in study drug supply, or other consequence that may result in incomplete data being generated during a study as a result of the pandemic must be adequately documented and justified. For example, on March 18, 2020, the FDA issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of COVID-19; a list of all study participants affected by COVID-19-related study disruption by unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information to the U.S. public by publishing such information on clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation, and priority review designation. MyMD has not applied for expedited approval under any of these pathways to-date but intends to explore the extent to which any of its current or future product candidates may be eligible for one or more such pathways. There is no guarantee that FDA will grant any of MyMD's products candidates the expedited designation(s) for which it is submitted, if any, or that MyMD will secure any of the applicable benefits associated with any of any expedited designations that may be granted to its current or future product candidates, if applicable.

Fast-Track Designation

Fast track designation may be granted for a product that is intended to treat a serious or life-threatening disease or condition for which pre-clinical or clinical data demonstrate the potential to address unmet medical needs for the condition. The sponsor of an investigational drug product may request that the FDA designate the drug candidate for a specific indication as a fast-track drug concurrent with, or after, the submission of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast-track designation within 60 days of receipt of the sponsor's request. For fast-track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast-track product's NDA before the application is complete. This rolling review is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. At the time of NDA filing, the FDA will determine whether to grant priority review designation. Additionally, fast track designation may be withdrawn if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Priority Review Designation

The FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case- by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, MyMD will be required to develop and implement additional clinical study policies and procedures designed to help protect study participants from the SARS-CoV-2 virus, which may include using telemedicine visits and remote monitoring of patients and clinical sites. MyMD will also need to ensure data from its clinical studies that may be disrupted as a result of the pandemic is collected pursuant to the study protocol and is consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB. Patients who may miss scheduled appointments, any interruption in study drug supply, or other consequence that may result in incomplete data being generated during a study as a result of the pandemic must be adequately documented and justified. For example, on March 18, 2020, the FDA issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of COVID-19; a list of all study participants affected by COVID-19-related study disruption by unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

Post-marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA. Drug manufacturers' and/or sponsors' post-marketing FDA obligations, include, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities, and a number of other specific requirements for prescription-drug advertising. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote their approved drug products for off-label uses. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may also require the implementation of other risk management measures, including a REMS, or the conduct of post-marketing studies to assess a newly discovered safety issue.

FDA regulations require that drug products be manufactured in registered drug-manufacturing facilities and in accordance with cGMP regulations. MYMD currently relies on third parties to produce clinical quantities of its drug candidates under development in accordance with applicable GCPs and GLPs, and expects to continue to rely, on third parties to produce clinical and commercial quantities of MYMD's products that are approved for marketing in the United States, if any, in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in a wide range of enforcement actions against the manufacturer, including, but not limited to, recalls, warning letters, "dear doctor" letters, civil lawsuits, fines, and criminal prosecution. And the discovery of previously unknown safety or efficacy problems with a product after approval may result in restrictions on, revocation of, or the addition of conditions to the product's approval, among other potential adverse actions.

In addition to the requirements applicable to approved drug products, sponsors may also be subject to enforcement action in connection with any promotion of any investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote or market the product.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, including the CMS, other divisions of the HHS, the DOJ, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other Healthcare Laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which MyMD may obtain marketing approval. MyMD's current and future arrangements with third-party payors, healthcare providers and physicians may expose MyMD to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which MyMD markets, sells and distributes any drugs for which MYMD obtains marketing approval. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below. MYMD's business operations, including its research, marketing, and activities relating to the reporting of wholesale or estimated retail prices for MyMD's products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for MyMD's products, and the sale and marketing of MyMD's product and any future product candidates, are subject to scrutiny under these laws.

- The AKS, makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

- The federal civil and criminal false claims laws, including the FCA, which can be enforced through civil whistleblower or qui tam actions, which impose penalties against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims that include items or services resulting from a violation of the AKS are false or fraudulent claims for purposes of the FCA.

- The federal anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.

- HIPAA imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

- HIPAA, as amended by HITECH, and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The PPSA, enacted as part of the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners.

- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. These laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. In addition, certain state and local laws require the registration of pharmaceutical sales representatives.

State and foreign laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. Furthermore, most states in the United States have enacted laws regulating the confidentiality and security of medical information and increased public focus on privacy may result in amendments or changes to these laws in ways that may have an impact on MyMD's business activities related to the collection and use of health-related information.

The increased attention on privacy in the United States may also impact MyMD's business activities for the processing of personal information not otherwise governed by HIPAA. The EU General Data Protection Regulation ("GDPR") imposes significant privacy and cybersecurity requirements related to the handling of all types of personal information, with heightened requirements on sensitive personal information, such as health information. The GDPR imposes significant limitations on the use of this personal information and grants individuals in the EU certain rights associated with the collection and use of personal information. In the U.S., California recently enacted the CCPA, which creates new individual privacy rights for California consumers (generally defined as any resident of California, including employees and other business relations) and places increased privacy and security obligations on entities handling personal information of consumers or households. The CCPA also greatly extends the obligations of entities that process personal information to include information not traditionally viewed as personal information and regulated by laws, such as Internet Protocol (IP) addresses, unique identifiers for individuals, and information in online cookies and other online technologies. A majority of other states have already proposed laws similar to the CCPA, each differing in scope of the personal information covered and the rights of individuals. Furthermore, the CCPA has already been replaced with the passage of California's Proposition 24 (the California Privacy Rights Act, "CPRA"), which adds additional rights and obligations. While the CCPA and CPRA currently provide relatively broad exclusions for protected health information regulated by HIPAA and clinical trials and a limited exception for consumer and business to business information, some of the proposed laws in other states may not contain the same exceptions. Furthermore, there have been a number of competing proposals for federal laws, some of which propose to not preempt other state laws. The uncertainty surrounding proposed new and changes to existing privacy laws may lead to operational challenges for MYMD to comply with multiple, potentially conflicting, privacy and cybersecurity laws related to the collection and use of personal information in each jurisdiction.

Various state and federal laws and regulations also require entities to implement "reasonable" or "adequate" security measures to protect personal information, but generally do not provide any specific sets of security measures that would be considered compliant to avoid liability. Instead, different regulators have adopted inconsistent and evolving standards based on the regulator's view of what is appropriate given the nature and scope of the personal information and the processing performed, resulting in unclear obligations. This may result in potential liability if a regulator finds that MYMD's security practices do not meet or exceed the types of security measures that the regulator believes to be adequate or reasonable under the circumstances.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially considering the lack of applicable precedent and regulations. Federal and state enforcement bodies have continued to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that MyMD's business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If MyMD's operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to it, MyMD may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if MyMD becomes subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of MyMD's operations. If any of the physicians or other healthcare providers or entities with whom MyMD expects to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Current and Future Healthcare Reform Legislation

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) (the "ACA") and on March 30, 2010, he signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in our product candidates, to the extent approved for commercialization in the future, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children's Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, including any products hat we may commercialize or promote in the future. If reimbursement for the products we currently commercialize or promote, any product we may commercialize or promote, or approved therapeutic candidates is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for any product we may commercialize or promote in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, in particular, the ACA, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the ACA at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the ACA and judicial challenges have continued. We cannot predict the impact on our business of future legislative and legal challenges to the ACA or other aspects of the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

During his time in office, former President Trump supported the repeal of all or portions of the ACA. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the ACA to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the ACA, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the ACA's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the ACA and was intended to reduce the rate of growth in Medicare spending).

Additionally, in December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the ACA is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the ACA. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the ACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the ACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, in November 2021, President Biden announced the "Prescription Drug Pricing Plan" as part of the Build Back Better Act (H.R. 5376) passed by the House of Representatives on November 19, 2021, which aims to lower prescription drug pricing by, among other things, allowing Medicare to negotiate prices for certain high-cost prescription drugs covered under Medicare Part D and Part B after the drugs have been on the market for a certain number of years and imposing tax penalties on drug manufacturers that refuse to negotiate pricing with Medicare or increase drug prices "faster than inflation." If enacted, this bill could have a substantial impact on our business. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States or the effect of any future legislation or regulation. Furthermore, we cannot predict what actions the Biden administration will implement in connection with the Health Reform Law. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for our product candidates approved for commercialization in the United States, if any, or any other drug products we may commercialize in the future or that reduce medical procedure volumes could adversely affect our operations and/or future business plans.

Packaging and Distribution in the United States

If MyMD's product candidates that are approved for commercialization in the United States, if any, are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements may apply. In relevant part, products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against MyMD for violation of these laws, even if MyMD is successful in defending against it, could cause MyMD to incur significant legal expenses and divert MyMD's management's attention from the operation of its business. Prohibitions or restrictions on sales or withdrawal of future products marketed by MyMD could materially affect its business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact MyMD's business in the future by requiring, for example: (i) changes to MyMD's manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of MyMD's products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of MyMD's business.

Reimbursement

Sales of any of MyMD's product candidates that are approved for marketing in the United States or any other products MyMD may commercialize in the future, as applicable, will depend, in part, on the extent to which MyMD's products, if approved, will be covered by third-party payors, such as government health programs, commercial insurers and managed healthcare organizations, as well as the level of reimbursement such that those third-party payors provide for MyMD's products. Patients and providers are unlikely to use MyMD's products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of MyMD's products in which MyMD's products are used. In the U.S., no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of MyMD's products candidates, if approved, will be made on a payor-by-payor basis. As a result, the coverage determination process may be a time-consuming and costly process that will require MyMD to provide scientific and clinical support for the use of MyMD's products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new method by which rebates owed by pharmaceutical manufacturers are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of average manufacturer's price ("AMP"). The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which MyMD receives marketing approval. However, any negotiated prices for MyMD's products covered by a Part D prescription drug plan likely will be lower than the prices MyMD might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The 340B program imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. It is unclear how this decision could affect covered hospitals who might purchase MyMD's products in the future and affect the rates MyMD may charge such facilities for its approved products. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

As noted above, the marketability of any products for which MyMD receives regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the U.S. has increased and MyMD expects it will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which MyMD receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices MyMD may obtain for any of its product candidates for which MyMD may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced Member States, can further reduce prices. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, MyMD may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of MyMD's product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of MyMD's products. Historically, products launched in the EU do not follow price structures of the U.S. and, generally, prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

Employees

As of December 31, 2022, MyMD had nine full-time employees and no part-time employees. MyMD has not experienced any work stoppages. None of MyMD's employees are represented by a labor union or covered by collective bargaining agreements, and MyMD considers its relationship with its employees to be good.

Management Plans for 2023

In November 2022, the company published data from the Phase 1 dosing study for MYMD-1 as a treatment for aging. There was a statistically significant decrease in TNF-α levels (p-value <0.05) found in one MYMD-1 treated cohort, but no change in the levels in subjects given placebo.

We are focused on closing out our pivotal Phase 2 aging and sarcopenia study. Final efficacy data from the Phase 2 study is expected in the second quarter of 2023. We anticipate that we will review the safety and efficacy of this study and present the mandatory end of Phase 2 data to the FDA.

The company intends to submit an IND to the FDA in the second quarter 2023 for the indication of Rheumatoid Arthritis. This will be followed by a Phase 2 clinical trial with patients with Rheumatoid Arthritis.

In October 2020 we completed several in vitro studies from human primary cell-based BioMap systems at Eurofins contrasting MYMD-1 with Humira, Enbrel and Remicade.

MYMD-1 Product Candidate

We are currently completing enrollment in the fourth and final cohort of patients in the Phase 2 Aging and Sarcopenia Study ("A Double-Blind, Placebo-controlled, Randomized Study to Investigate the Efficacy, Tolerability and Pharmacokinetics of MYMD-1 in The Treatment of Participants Aged 65 Years or Older with Chronic Inflammation Associated with Sarcopenia/Frailty").

We completed a Phase 1 Dosing Study ("A Double-blind, Placebo-controlled, Randomized, Single Ascending and Multiple Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Oral Dose of MYMD-1 Capsules in Healthy Male and Female Adult Subjects").

- The Investigational New Drug (IND) application for Aging and Sarcopenia was accepted by FDA.

- The IND was submitted to support a Phase 2 study focused on Aging and Sarcopenia in adults 65 years and older. The FDA reviewed the IND with its corresponding protocol and allowed the company to proceed to a Phase 2 clinical trial on November 1, 2021.

- We obtained IRB approval on November 16, 2021 which permitted us to start enrollment and dosing qualified participants. To date, the trial has dosed 80% of its goal sample size of 40 subjects. The primary objects of the study are to a) Demonstrate reduction of chronic inflammatory markers in participants treated with MYMD-1® versus placebo and b) To evaluate the PK of oral doses of MYMD-1® capsules.

  This will be accomplished by analyzing the effect on serum levels of sTNFR1, IL-6, and TNF-α over 28 days of treatment as well as plasma concentrations and urine and parameters of MYMD-1®, respectively. To qualify for the clinical trial, subjects' biomarkers during the screening period must be within the following Criteria: IL-6 ≥ 2.5pg/mL; and/or sTNFR-1 ≥ 1500pg/mL

  To date, we have randomized and dosed 30/40 subjects across Cohorts 1 (n=10; 600mg), 2 (n=10; 750mg), 3 (n=10; 900mg) and 4 (n=pending; 1050mg).

IND for Autoimmune Diseases

Animal Studies

- 10-month Dog Study – completed on December 20, 2021: A 39-Week Toxicity and Toxicokinetic Study of MYMD-1 by Oral Gavage in Beagle Dogs.

- 6-month Rat Study – completed on December 17, 2021: A 26-Week Toxicity and Toxicokinetic Study of MYMD-1 by Oral Gavage in Rats.

- 5-Day Mouse Study – Completed May 2020 with results pending: A Preliminary Introductory Traumatic Optic Neuropathy (TON) in a Mouse study

- Studies produced guidance on dosing levels and overall safety in the human studies.

Publications

A scientific journal article on MYMD-1 was published in The Journals of Gerontology in August 2022. This manuscript supports our continued efforts to conduct a second Phase 2 Trial for Rheumatoid Arthritis in 2023 and additional autoimmune diseases that we may pursue. Additionally, "MyMD-1 Improves Health Span and Prolongs Life Span in Old Mice: A Noninferiority Study to Rapamycin" by Johns Hopkins Medical School. This journal article details a 12-month mouse trial studying aging and longevity with MYMD-1. We also completed several in vitro studies from human primary cell-based BioMap systems at Eurofins contrasting MYMD-1 versus Rapamycin further supporting our transition to Rheumatoid Arthritis.

In November 2022, MyMD published "A Double-blind, Placebo-controlled, Randomized, Single Ascending, and Multiple Dose Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Oral Dose Isomyosamine Capsules in Healthy Adult Subjects" Authors: Jenna Brager, Chris Chapman, Leonard Dunn, and Adam Kaplin in Drug Research. This became available in print in February 28, 2023. This journal article details the results from the Phase 1 clinical trial.

Later, an abstract was accepted for presentation at the British Society of Immunology, Liverpool, UK in December 2022. "Pharmacology and clinical profile of MYMD-1® (isomyosamine), an oral, selective, next-generation, TNF- α inhibitor that crosses the blood brain barrier" authored by Jenna Brager, Ronald Christopher, Adam Kaplin, and Chris Chapman.

Moving in to the 2023, an abstract was accepted for presentation at the Society of Toxicology to be presented in March 2023, entitled, "A Naturally Occurring Novel Therapeutic and Oral Selective Inhibitor of TNFa, MYMD-1 (Isomyosamine), Significantly Reduced the Inflammation and Disease Severity in Murine Model of Collagen Antibody-Induced Arthritis" authored by Chris Chapman and Sonia Edaye.

All publications and abstracts support the continued development of MYMD-1® across various indications.

IND for Hashimoto's Thyroiditis

- On February 18, 2022, we submitted an Annual Update to the FDA for the previously opened Hashimoto's Thyroiditis IND.

- In April 2021, the FDA gave clearance for a Phase 1 dosing study in normal healthy volunteers; Institutional Review Board (IRB) approval was obtained on April 4, 2021. The clinical trial was conducted by The Clinical Research of West Florida Phase 1 unit with a closeout visit taking place on November 22, 2021.

- Analyses of laboratory parameters, vital sign, ECG, and physical findings did not reveal any clinically relevant effect of MYMD-1. In one dose group, there was a decrease in TNF-α levels found in MYMD-1 treated subjects, but no change in the levels in subjects given placebo. In one dose group, there was a decrease in TNF-α levels found in MYMD-1 treated subjects, but no change in the levels in subjects given placebo.

- The data from the Phase 1 clinical trial was submitted to the FDA on September 14, 2021 as part of the Annual IND update for Hashimoto's Thyroiditis IND. The FDA responded by providing guidance on moving forward with Phase 2 clinical trials.

- This data was also included in a new commercial IND to the FDA on September 22, 2021.

The company completed CYP in vitro studies which concluded that clinical drug-drug interactions are not expected with MYMD-1. CYP induction is the most commonly studied form of induction in drug metabolism and is required by regulatory authorities.

We had MYMD-1 synthesized in August 2021 to [14C] MYMD-1 radiolabeled product for Mass Balance, Pharmacokinetic, and Metabolism. Analysis of the rat study results demonstrated that MYMD-1 was metabolized extensively throughout the tissues, crosses the blood brain barrier, was cleared in the urine and feces, and there were no nitrosated metabolite biological samples detected.

Lastly, a Metabolite Identification and Quantitation of MYMD-1 in Rat, Dog, and Human Plasma Samples: Metabolites in Safety Testing (MIST) was completed in October 2022. MYMD-1 was extensively metabolized, and was detected at low levels (<5%) in human plasma.

In November 2022, the company published data from the Phase 1 dosing study for MYMD-1 as a treatment for aging. There was a statistically significant decrease in TNF-α levels (p-value <0.05) found in one MYMD-1 treated subjects cohort, but no change in the levels in subjects given placebo.

We plan to manage our pivotal Phase 2 aging and sarcopenia study. Final efficacy data from the Phase 2 study is expected in the second quarter 2023. We anticipate that we will review the safety and efficacy of this study and present the mandatory end of Phase 2 data to the FDA.

The company intends to submit an IND to the FDA in the second quarter 2023 for the indication Rheumatoid Arthritis. MyMD Pharmaceuticals, Inc. completed several in vitro studies from human primary cell-based BioMap systems at Eurofins contrasting MYMD-1 to Humira, Enbrel and Remicade.

On July 27, 2021, Eurofins showed Commonality in a Comparative Study with FDA-Approved Anti-Inflammatory and Anti-Autoimmune Drugs Used for Arthritis, Colitis and Dermatitis. On October 26, 2021, our President and Chief Medical Officer, Chris Chapman, M.D., was named Honoree of the year by the Arthritis Foundation.

On August 5, 2021, our lead product candidate MYMD-1 was shown to suppress cytokines, which are the major cause of death in COVID-19 patients, in a human cell study. The company plans to consult with the FDA on this indication for post COVID-19 immune mediated depression in the second quarter 2024. During this time, MyMD Pharmaceuticals, Inc. also expects to seek additional FDA guidance on depression in MS patients under an Orphan Drug Designation (ODD).

We have an active IND to start a Phase 2 study for the indication Hashimoto's Thyroiditis, and plan to present the FDA with a protocol for this pilot Phase 2 study in the fourth quarter 2024.

We intend to begin long-term reproductive toxicity studies in the fourth quarter 2022. These will include study of Fertility and Early Embryonic Development to Implantation in Mice, and study for Effects on Embryo Fetal Development in Mice and Rabbits with a toxicokinetic evaluation. These studies will continue to support long-term dosing in humans.

In manufacturing, we will continue to provide GMP MYMD-1 capsules for Phase 2 clinical trials. We plan to continue analytical analysis to provide GMP product other that capsules for long-term human trials.

We have received domestic patent protection for MYMD-1, including its use in methods of extending lifespan and treating arthritis, autoimmune diseases, and inflammatory and age-related disorders including sarcopenia. We will continue to prosecute patents to protect intellectual property for MYMD-1 in the United States and abroad.

Supera-CBD Product Candidate

Data from Eurofins studies involving human primary cell-based BioMap system demonstrated that Supera-CBD delivers an extremely potent therapeutic benefit of 8,000 times that of plant-derived CBD at activating CB2 receptors, permitting its delivery at a very low non-toxic dose.

On August 10, 2021 the company was awarded U.S. Patent 11,085,047 B2, titled "Synthetic Cannabinoid Compounds for Treatment of Substance Addiction and Other Disorders," covering the Super-CBD product candidate and its pharmaceutical formulations. During 2021 and 2022 corresponding foreign patents were awarded in Australia, Canada, Europe, Israel, and South Korea, and patents are pending in China and Japan.

Johns Hopkins Medicine researchers presented Supera-CBD data at the 3rd annual Neuroimmunology Drug Development Summit on April 26, 2021.

The company presented data referencing Super-CBD at the 4th Annual International Cannabinoid Summit on September 9, 2021.

On March 2, 2023, we announced that the U.S. Drug Enforcement Administration (DEA) has conducted a scientific review and determined that it would not Supera-CBD a controlled substance or listed chemical under the Controlled Substances Act (CSA) and its governing regulations. We believe that this decision will expedite future research involving Supera-CBD by relieving us or our research partners from having to comply with regulations relating to controlled substances.

We plan to continue our preclinical program starting genotoxicity studies in Europe. Those studies include:

- Metabolic profiling and Ames test (initiation December 21, 2021; completion January 20, 2022) and
- Micronucleus test (initiation December 21, 2021; completion February 20, 2022).

A study of Behavioral Biology at Johns Hopkins University Supera-CBD vs. CBD Acute Pain and Inflammation begins has been funded for 2022 and 2023.

The National Institutes of Health is planning to work on a grant for Supera-CBD in Epilepsy for the third quarter 2023.

In manufacturing, we expect to continue providing GMP Supera-CBD materials for the preclinical toxicity programs. We plan to continue analytical analysis to provide GMP materials for long term toxicity and Human trials.

An example of continued efforts include the JHM Research is conducting a study with MYMD-1 and L/R-Supera-CBD for Depression and Anxiety.

- Forced Swim Test
- Tail suspension
- Elevated Plus Maze and Fear Conditioning
- Dose response study.

- Supera-CBD open field and Y maze study.

- MYMD-1 LPS induced depression.

Available information

Our website address is www.mymd.com. We do not intend our website address to be an active link or to otherwise incorporate by reference the contents of the website into this Annual Report on Form 10-K. The SEC maintains an Internet website (www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

An investment in our Common Stock involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks described below, together with other information in this Annual Report on Form 10-K and the other information and documents we file with the SEC. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly, or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding other statements in this Form 10-K. The following information should be read in conjunction with our consolidated financial statements and related notes thereto and with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our Common Stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our Common Stock.

Risks Related to the Company Following the Merger

- Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they experienced in connection with the Merger.

- The market price of our Common Stock may be subject to significant fluctuations and volatility, and the stockholders of the Company may be unable to resell their shares at a profit and may incur losses.

- We may issue additional equity securities in the future, which may result in dilution to existing investors.

- The concentration of the capital stock ownership with insiders of the Company following the Merger will likely limit the ability of our stockholders to influence corporate matters.

- The sale or availability for sale of a substantial number of shares of our Common Stock after expiration of the lock-up period could adversely affect the market price of such shares.

- We may not be able to adequately protect or enforce our intellectual property rights, which could harm our competitive position.

- An active trading market for our Common Stock may not be sustained.

- The intended benefits of the Contribution Transaction may not be realized.

- Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security or those of third-party providers.

Risks Related to our Product Development and Regulatory Approval

- If we are unable to develop, obtain regulatory approval for and commercialize MYMD-1, Supera-CBD, or other future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

- Success in pre-clinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, including our Phase 2 clinical trial for MYMD-1, which may delay or prevent obtaining regulatory approval.

- Even if we complete the necessary pre-clinical studies and clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate and the approval may be for a narrower indication than we seek.

- The COVID-19 pandemic, or similar public health crises, could have a material adverse impact the execution of our planned clinical trials.

- Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if it experiences unanticipated problems with our product candidates, when and if any of them are approved.

- Our development program for Supera-CBD, a synthetic analog of CBD, is uncertain and may not yield commercial results and is subject to significant regulatory risks.

Risks Related to Commercialization and Manufacturing

- The commercial success of our product candidates, including MYMD-1 and Supera-CBD, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors, and the general medical community.

- The pricing, insurance coverage, and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

- If third parties on which we depend to conduct our planned pre-clinical studies or clinical trials, do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with adverse effects on our business, financial condition, results of operations and prospects.

- We face significant competition in an environment of rapid pharmacological change and it is possible that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may harm our business, financial condition and our ability to successfully market or commercialize MYMD-1, Supera-CBD and our other product candidates.

- The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of MYMD-1, Supera-CBD or our other product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.

Risks Related to Government Regulation

- Enacted and future legislation may increase the difficulty and cost for us to commercialize and obtain marketing approval of our product candidates and may affect the prices we may set.

- The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, statutory, regulatory and policy changes and global health concerns.

- Our operations and relationships with future customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Risks Related to Our Intellectual Property

- Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their adequate protection.

- Our potential strategy of obtaining rights to key technologies through in-licenses may not be successful.

- Changes in patent law in the U.S. and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Risks Related to Our Series F Convertible Preferred Stock

- Our Series F Convertible Preferred Stock (the "Series F Preferred Stock") provides for the payment of dividends in cash or in shares of our Common Stock. If we pay such dividends in shares of Common Stock, it may result in dilution to existing investors.

- If we do not receive approval from our stockholders, we will be unable to pay dividends due to the holders of our Series F Preferred Stock in shares of Common Stock and we will be required to pay such dividends in cash, which may force us to divert cash from other uses.

- The certificate of designation for the Series F Preferred Stock and the warrants issued concurrently contain anti-dilution provisions that may result in the reduction of the conversion price of the Series F Preferred Stock or the exercise price of such warrants in the future. These features may result in an indeterminate number of shares of Common Stock being issued upon conversion of the Series F Preferred Stock or exercise of the warrants.

In addition, we face other business, financial, operational and legal risks and uncertainties set forth under "Risk Factors" in Item 1A of this Annual Report on Form 10-K.

Risks Related to the Company Following the Merger

Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they experienced in connection with the Merger.

If we are unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests in their respective pre-Merger companies without receiving any commensurate benefit, or only while receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the strategic and financial benefits anticipated at the time of the Merger. Furthermore, if we fail to realize the intended benefits of the Merger, the market price of our Common Stock could decline to the extent that the market price reflects those benefits.

The market price of our Common Stock after the Merger has been and may continue to be subject to significant fluctuations and volatility, and the stockholders of the Company may be unable to resell their shares at a profit and may incur losses.

Prior to April 2021, there was no public market for the combined Company's Common Stock. The market price of our Common Stock following the Merger has begun and could continue to be subject to significant fluctuation following the Merger. The pre-Merger business of the Company differs from its post-Merger business in important respects and, accordingly, the results of operations of the combined Company and the market price of the combined Company's Common Stock following the Merger may be affected by factors different from those affecting the results of operations of the Company prior to the Merger. Market prices for securities of life sciences and biopharmaceutical companies in particular have historically been volatile and have shown extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our Common Stock, regardless of the actual operating performance of the combined company. Some of the factors that may cause the market price of our Common Stock to fluctuate include:

- investors reacting negatively to the effect on our business and prospects from the Merger;

- the announcement of new products, new developments, services or technological innovations by us or our competitors;

- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by the us or our competitors;
- conditions or trends in the life sciences and biopharmaceutical industries;
- changes in the economic performance or market valuations of other life sciences and biopharmaceutical companies;
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition;
- sale of our Common Stock by stockholders, including executives and directors;
- volatility and limitations in trading volumes of our Common Stock;
- volatility in the market prices and trading volumes of the life sciences and biopharmaceutical stocks;
- our ability to finance our business;
- ability to secure resources and the necessary personnel to pursue our plans;
- failure to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of Common Stock by stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- analyst research reports, recommendations and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigation related to intellectual properties, proprietary rights, and contractual obligations;
- investigations by regulators into our operations or those of our competitors;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In the past, following periods of volatility in the overall market and the market prices of particular companies' securities, securities class action litigation has often been instituted against these companies. Litigation of this type, if instituted against us, could result in substantial costs and a diversion of management's attention and resources of the Company. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Moreover, the COVID-19 pandemic, inflation, war and other macroeconomic and geopolitical factors have resulted in significant financial market volatility and uncertainty in recent years. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our Common Stock.

We have a history of operating losses, and we may not achieve or sustain profitability. We anticipates that we will continue to incur losses for the foreseeable future. If we fails to obtain additional funding to conduct our planned research and development efforts, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.

We are a clinical-stage pharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited primarily to business planning, raising capital and conducting research and development activities for our product candidates. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates and we have funded our operations to date through proceeds from private placements of Common Stock and a line of credit from an affiliate of MyMD's founder.

We have incurred net losses in each year since our inception. We incurred net losses of $15,197,336 and $29,889,045 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $93,758,904. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in the company incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

MyMD's predecessor, MyMD Florida, was formed in late 2014. Our operations to date have been limited primarily to business planning, raising capital and conducting research and development activities for our product candidates. We have not yet demonstrated the ability to complete clinical trials of our product candidates, obtain marketing approvals, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability are speculative and no assurances can be given about our future performance.

After the Merger was consummated, the business operations, strategies and focus of the Company fundamentally changed, and these changes may not result in an improvement in the value of our Common Stock.

Following the Merger, our primary products are MyMD Florida's therapeutic platforms: MYMD-1, a clinical-stage immunometabolic regulator and Supera-CBD, a pre-clinical stage patented synthetic CBD analog. We expect to incur losses as we develop our product candidates, and our product candidates, may never get approved by the FDA or, even if approved for marketing, may not be profitable. The failure to successfully develop product candidates will significantly diminish the anticipated benefits of the Merger and have a material adverse effect on our business. There is no assurance that our business operations, strategies or focus will be successful, which could depress the value of our Common Stock.

The concentration of the capital stock ownership with insiders of the Company after the Merger will likely limit the ability of our stockholders to influence corporate matters.

Following the Supera Purchase and the Merger, the executive officers, directors, five percent or greater stockholders, and the respective affiliated entities of the Company, in the aggregate, beneficially owned more than 10% of the Company's outstanding Common Stock. As a result, these stockholders, acting together, had, and continue to have, control over matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other stockholders may view as beneficial.

Certain stockholders could attempt to influence changes within the Company, which could adversely affect our operations, financial condition and the value of our Common Stock.

Our stockholders may from time to time seek to acquire a controlling stake in the Company, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming and could disrupt our operations and divert the attention of our Board of Directors and senior management. These actions could adversely affect our operations, financial condition, and the value of our Common Stock.

The sale or availability for sale of a substantial number of shares of our Common Stock after expiration of the lock-up period could adversely affect the market price of such shares.

Sales of a substantial number of shares of our Common Stock in the public market after expiration of the lock-up period and other legal restrictions on resale, or the perception that these sales could occur, could adversely affect the market price of such shares and could materially impair our ability to raise capital through equity offerings in the future. Upon completion of the Merger and the transactions contemplated in the Merger Agreement, the Company issued 28,553,307 post reverse stock split shares of Company Common Stock to the former stakeholders of pre-Merger MyMD Florida at the Exchange Ratio. Shares that were issued to pre-Merger MyMD Florida stockholders as merger consideration could be resold in the public market immediately without restriction, unless such stockholder was subject to a lock-up or other restriction on resale. All of the previous executive officers, directors and principal stockholders of pre-Merger MyMD Florida, and all of our directors who continued to serve on the Board of Directors of the combined Company after the Merger, were subject to lock-up agreements pursuant to which such stockholders agreed, except in limited circumstances, not to transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber, any shares of Company capital stock for 180 days following the effective time of the Merger; such lock-up agreements have now expired, so the shares of our Common Stock (excluding securities underlying options and warrants) held by our directors, executive officers and principal stockholders may now be sold, subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. We are unable to predict what effect, if any, market sales of securities held by our significant stockholders, directors or officers or the availability of these securities for future sale will have on the market price of our Common Stock in the future.

We also assumed approximately 4,188,315 shares of Common Stock subject to outstanding options to purchase pre-Merger MyMD Florida Common Stock. We registered all of the shares of Common Stock issuable upon exercise of outstanding options to purchase MyMD Florida Common Stock, and therefore upon the exercise of any options or other equity incentives we may grant in the future, for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the lock-up agreements described above.

Anti-takeover provisions under New Jersey corporate law may make it difficult for our stockholders to replace or remove our Board of Directors and could deter or delay third parties from acquiring us, which may be beneficial to our stockholders.

We are subject to the anti-takeover provisions of New Jersey law, including Section 14A-10A of the New Jersey Shareholders Protection Act. These statutes prohibit an "interested stockholder" of the Company from effecting a business combination with us for a period of five years unless our Board of Directors approved the combination or transaction or series of related transactions that caused such person to become an interested stockholder prior to the stockholder becoming an interested stockholder or after the stockholder becomes an interested stockholder if the subsequent business combination is approved by (i) our Board of Directors (or a committee thereof consisting solely of persons independent from the interested stockholder), and (ii) the affirmative vote of a majority of the voting stock not beneficially owned by such interested stockholder. In addition, but not in limitation of the five-year restriction, we may not engage at any time in a business combination with any interested stockholder the Company unless the combination is approved by our Board of Directors (or a committee thereof consisting solely of persons independent from such interested stockholder) prior to the consummation of the business combination, and the combination receives the approval of a majority of the voting stock of the Company not beneficially owned by the interested stockholder if the transaction or series of related transactions which caused the interested stockholder to become an interested stockholder was approved by the Board of Directors prior to the stockholder becoming an interested stockholder. These provisions could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 14A-10A of the New Jersey Shareholders Protection Act, "interested stockholder" means, generally, any beneficial owner of 10% or more of the voting power of the outstanding voting stock of the corporation and any affiliate or associate of the corporation who within the prior five year period has at any time owned 10% or more of the voting power of the then outstanding stock of the corporation.

We expect that we will need to raise additional funding before we can expect to become profitable from any potential future sales of our product candidates. This additional financing may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We will require substantial future capital in order to complete planned and future pre-clinical and clinical development for MYMD-1 and Supera-CBD and potentially commercialize these product candidates. We expect increased spending levels in connection with our clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to commercial launch, product sales, medical affairs, regulatory, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations before any commercial revenue may occur.

Any additional capital raised through the sale of equity or equity-backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

Additional capital might not be available when we need it and our actual cash requirements might be greater than anticipated. If we require additional capital at a time when investment in its industry or in the marketplace in general is limited, we might not be able to raise funding on favorable terms, if at all. If we are not able to obtain financing when needed or on terms favorable to us, we may need to delay, reduce or eliminate certain research and development programs or other operations, sell some or all of our assets or merge with another entity.

We must attract and retain highly skilled employees to succeed.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan, harm our results of operations and increase our capabilities to successfully commercialize MYMD-1, Supera-CBD and our other product candidates. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

We operate in a highly competitive industry.

We face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions pursuing research and development of technologies, drugs or other therapies that would compete with our products or product candidates. The pharmaceutical market is highly competitive, subject to rapid technological change and significantly affected by existing rival drugs and medical procedures, new product introductions and the market activities of other participants. Our competitors may develop products more rapidly or more effectively than us. If our competitors are more successful in commercializing their products than us, their success could adversely affect our competitive position and harm our business prospects and may also lead to the diversion of funding away from us and toward other companies.

Our business may be materially adversely affected by the COVID-19 pandemic.

The global health crisis caused by the COVID-19 pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite vaccination efforts, remains uncertain and cannot be predicted with confidence. The ultimate impact of COVID-19, including its variants, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against future COVID-19 variants and the response by governmental bodies and regulators to any resurgences. Given the ongoing and dynamic nature of the circumstances, it is difficult to predict the impact of the COVID-19 pandemic on our business.

In response to public health directives and orders, we have implemented and continue to maintain work-from-home policies for many of our employees. The effects of the orders and related adjustments in our business have delayed and may continue to delay our timelines, including those with respect to patient enrollment in clinical trials.

Moreover, the COVID-19 pandemic has had and may continue to have indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations have been and may continue to be adversely affected to the extent that COVID-19 or any other epidemic harms the global economy generally.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations will involve the use of hazardous materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security or those of third-party providers.

In the ordinary course of our business, we and our third-party providers rely on electronic communications and information system to conduct our operations. We and our third-party providers have been, and may continue to be, targeted by parties using fraudulent e-mails and other communications in attempts to misappropriate bank accounting information, passwords, or other personal information or to introduce viruses or other malware to our information systems. Between August and October 2021, we experienced a cybersecurity incident. A third-party forensic technology company's investigation confirmed that we were a victim of wire fraud due to a compromised electronic mail account. As of the date of this filing, we have identified losses totaling $1,260,864 related to this incident, net of amounts recovered. Following the incident, we have taken measures to enhance our electronic mail security and have modified our internal procedures to ensure the authenticity of payment instructions and we continue to evaluate additional measures for improving cybersecurity. Despite these prophylactic measures, the risk of such cyber-attacks against us or our third-party providers and business partners remains a serious issue. Cybersecurity incidents are pervasive, and the risks of cybercrime are complex and continue to evolve. Although we are making significant efforts to maintain the security and integrity of our information systems and are exploring various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging.

In addition, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyberintrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyberintrusions, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business.

Risks Related to our Product Development and Regulatory Approval

With regard to our Supera-CBD product candidate, we must conduct pre-clinical testing and prepare and submit an IND to the FDA. With regard to both our MYMD-1 and Supera-CBD product candidates, we must conduct all phases of clinical studies (which may include post-market or "Phase 4" studies), which will likely take several years and substantial expenses to complete, before we can submit an application for marketing approval to the FDA. There is no guarantee that we will complete such clinical development in a timely manner or at all or that we will obtain regulatory approval for either product candidate.

Potential Risks

- FDA – IND review is conducted and feedback is delivered within 30 days of receipt of the initial application. At the time, changes to the study protocol may be requested in order to proceed with the proposed Phase 2 clinical trial.

- Institutional Review Board (IRB) – If the FDA requests changes to the protocol included in the initial application, an amendment must be submitted to the IRB for an additional review. This review may include changes to the protocol, informed consent form, surveys, and other assessments planned over the course of the clinical trial.

- COVID-19 – Clinical sites must follow specific COVID-19 guidelines. Clinical trial activity must adhere to those guidelines which may change over the course of the study. For example, the protocol may need to be revised to accommodate for in-home visits (if necessary) to maximize patient and research staff safety.

- Site Initiation Visit (SIV) – Site initiation visits are scheduled around principal investigator (PI) availability. Due to changing clinic schedules, SIVs may need to be rescheduled to accommodate various PI demands.

- Central Lab – Central labs are responsible for creating all the kits (supplies) required for patient visits. Kits are created to execute all aspects of screening through study completion. Kits are developed based on specifications from core labs and third-party vendors (as applicable). All shipping and storing requirements need to be clearly articulated and lab manuals provided to make the kits. The central lab is also responsible for building a database to store all the lab results.

- Electronic Database – The overall database used for the study must be built around the schedule of assessments planned for each patient over the course of the clinical trial. This includes every assessment and data element collected. The complexity of the Phase 2 trial also requires development and testing of drug randomization across treatment groups to ensure blinding is maintained. Thorough user-acceptability testing (UAT) is required and is time-intensive.

- CoreRx – To maintain adequate blinding across treatment groups, new labels were created and applied to the active drug and placebo bottles. Logistics and manufacturing need to work together to ensure capsules were not only filled appropriately, but also labelled correctly to ensure the electronic database and randomization schemes maintain alignment over the course of the study.

Clinical drug development is a lengthy, expensive, and inherently uncertain process, and we may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The FDA must approve any new drug products before they can be marketed in the United States, and such approval is contingent upon the collection of sufficient safety- and efficacy-data from preclinical and clinical studies. We must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates for their respective targeted indications. With regard to Supera-CBD, we are still in the pre-clinical stage, and we are in relatively early clinical stages with regard to certain indications for which MyMD-1 is being developed and in pre-clinical stages for others. Clinical trials are expensive, difficult to design and implement, and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials and, nonetheless, were denied marketing approval for such candidates due to insufficient safety or efficacy data and/or other clinical-study deficiencies. It is impossible to predict whether we will be able to prove that either or both of our product candidates are safe and effective for any of the indications for which they are, respectively, being developed and, accordingly, when they will be approved for commercialization in the United States for any given indication, if ever.

After completing the requisite preclinical testing, IND submission, internal review board ("IRB") review, and any other applicable early-development obligations, sponsors must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. We have completed such early-stage preclinical testing and IND-submission for some, but not all, indications for which MyMD-1 is being developed and are currently working towards completion of such pre-IND activities for Supera-CBD. Even if the results of our clinical trials are favorable, we expect our product candidates to remain in clinical development for several years before they may be considered for regulatory approval, and clinical development of either or both candidates for one or more targeted indications may take significantly longer to complete and may never be successful. Failures in connection with one or more clinical trials can occur at any stage of testing.

Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organization ("CRO") and clinical trial sites;
- delays in opening clinical trial sites or obtaining required IRB or independent ethics committee approval at each clinical trial site;
- actual or perceived lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues, such as drug interactions, including those which cause confounding changes to the levels of other concomitant medications;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects for the entire duration of applicable clinical studies (as study subjects may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- inadequacy of or changes in its manufacturing process or product candidate formulation;
- delays in obtaining regulatory authorization s, such as INDs and any others that must be obtained, maintained, and/or satisfied to commence a clinical trial, including "clinical holds" or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- changes in applicable regulatory policies and regulation, including changes to requirements imposed on the extent, nature or timing of studies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- failure of its CROs, or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- Our failure, or the failure of any individuals, entities, or organizations involved in one or more aspects of our clinical development activities, to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;

- regulatory concerns and additional difficulties associated with cannabinoid products, generally;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow its clinical protocols; or
- difficulty in maintaining contact with patients during or after treatment, which may result in incomplete data.

If any of the clinical trials of any of our current or future therapeutic candidates do not produce favorable results or are found to have been conducted in violation of the FDA's or other regulatory body's standards governing such studies, our ability to request and obtain regulatory approval for the therapeutic candidate may be adversely impacted, which could have a material adverse effect on our reputation, business, financial condition or results of operations.

If we are unable to develop, obtain regulatory approval for and commercialize MYMD-1, Supera-CBD or other future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We have invested a substantial amount of effort and financial resources in MYMD-1 and Supera-CBD. We plan to initiate Phase 2 clinical trials for treatment of diabetes, rheumatoid arthritis, aging and multiple sclerosis with MYMD-1 and IND-enabling pre-clinical studies of Supera-CBD to enable submission of an Investigational New Drug ("IND") application for a Phase 1 in healthy volunteers followed by clinical trials in epilepsy, addiction and anxiety disorders. In order to conduct human clinical trials, we are required obtain approval from Institutional Review Boards ("IRBs") or Ethics committees. IRBs are independent committee organizations that operate in compliance with U.S. federal regulations (including, but not limited to 21 C.F.R. Parts 50 and 56, and 45 C.F.R. Part 46) in order to help protect the rights of research subjects under the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). IRBs provide expertise in examining research for its ethical implications, including research involving vulnerable populations, such as pediatrics, critically ill, and cognitively impaired participants. There is no guarantee that an IRB will approve our current product candidates for human clinical trials. Without IRB approval, the Company would not be able to perform clinical research on humans and our products would not be able to move through the regulatory approval process.

Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of MYMD-1, Supera-CBD and our other product candidates, which may never occur. We currently generate no revenue from sales of any product and we may never be able to develop or commercialize a marketable product.

Each of our programs and product candidates will require further clinical and/or pre-clinical development, regulatory approval in multiple jurisdictions, obtaining pre-clinical, clinical and commercial manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. MYMD-1 and Supera-CBD and our other product candidates must be authorized for marketing by the FDA and certain other foreign regulatory agencies before we may commercialize any of our product candidates.

The success of our product candidates depends on multiple factors, including:

- successful completion of pre-clinical studies, including those compliant with Good Laboratory Practices ("GLP") or GLP toxicology studies, biodistribution studies and minimum effective dose studies in animals, and successful enrollment and completion of clinical trials compliant with current Good Clinical Practices ("GCPs");
- effective INDs and Clinical Trial Authorizations ("CTAs") that allow commencement of our planned clinical trials or future clinical trials for our product candidates in relevant territories;
- approval from IRBs or Ethics committees to conduct human clinical trials;
- establishing and maintaining relationships with contract research organizations ("CROs"), and clinical sites for the clinical development of our product candidates;
- successful clearance of products arriving from foreign countries, needed to perform clinical trials, through U.S. customs;
- maintenance of arrangements with third-party contract manufacturing organizations ("CMOs") for key materials used in our manufacturing processes and to establish backup sources for clinical and large-scale commercial supply;

- positive results from our clinical programs that are supportive of safety and efficacy and provide an acceptable risk-benefit profile for our product candidates in the intended patient populations;

- receipt of regulatory approvals from applicable regulatory authorities, including those necessary for pricing and reimbursement of our product candidates;

- establishment and maintenance of patent and trade secret protection and regulatory exclusivity for our product candidates;

- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;

- acceptance of our product candidates, if and when approved, by patients, patient advocacy groups, third-party payors and the general medical community;

- our effective competition against other therapies available in the market;

- establishment and maintenance of adequate reimbursement from third-party payors for our product candidates;

- our ability to acquire or in-license additional product candidates;

- prosecution, maintenance, enforcement and defense of intellectual property rights and claims;

- maintenance of a continued acceptable safety profile of our product candidates following approval, including meeting any post-marketing commitments or requirements imposed by or agreed to with applicable regulatory authorities; or

- political factors surrounding the approval process, such as government shutdowns, political instability or global pandemics such as the outbreak of the novel strain of coronavirus, COVID-19.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We may not have the resources to conduct clinical protocols sufficient to yield data suitable for publication in peer-reviewed journals and our inability to do so in the future could have an adverse effect on marketing our products effectively.

In order for our products targeted for use by hospital laboratory professionals and healthcare providers to be widely adopted, we would have to conduct clinical protocols that are designed to yield data suitable for publication in peer-reviewed journals. These studies are often time-consuming, labor-intensive and expensive to execute. We have not previously had the resources to effectively implement such clinical programs within our clinical development activities and may not be able to do so in the future. In addition, if a protocol is initiated, the results of such protocol may ultimately not support the anticipated positioning and benefit proposition for the product. Either of these scenarios could hinder our ability to market our products, and revenue may decline.

Success in pre-clinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, including our Phase 2 clinical trial for MYMD-1, which may delay or prevent obtaining regulatory approval.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in pre-clinical studies and early clinical trials may not be predictive of results in later-stage clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome in later-stage or larger clinical trials, even if successful. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective for their intended uses before we can seek regulatory approvals for their commercial sale. The conduct of Phase 2 and Phase 3 trials, and the submission of a New Drug Application ("NDA") is a complicated process. We have not previously conducted any clinical trials, and have limited experience in preparing, submitting and supporting regulatory filings. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials and other requirements in a way that leads to NDA submission and approval of any product candidate we are developing.

Many companies in the pharmaceutical industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and there is a high failure rate for product candidates proceeding through clinical trials. In addition, different methodologies, assumptions and applications we utilize to assess particular safety or efficacy parameters may yield different statistical results. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval. If our study data do not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, including MYMD-1 and Supera-CBD, to the satisfaction of the FDA or foreign regulatory authorities, then the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld or withdrawn.

Even if we complete the necessary pre-clinical studies and clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate and the approval may be for a narrower indication than we seek.

Prior to commercialization in the United States, MYMD-1, Supera-CBD and our other product candidates must be approved by the FDA pursuant to an NDA for their respective target indication(s). The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market MYMD-1, Supera-CBD or any of our other product candidates from regulatory authorities in any jurisdiction. We have limited experience in submitting and supporting the applications necessary to gain marketing approvals, and, in the event regulatory authorities indicate that we may submit such applications, we may be unable to do so as quickly and efficiently as desired. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept or file any application or may decide that our data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

Approval of MYMD-1, Supera-CBD or our other product candidates may be delayed or refused for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for any of their proposed indications;
- the populations studied in clinical trials may not be sufficiently broad or representative to assure efficacy and safety in the populations for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;
- the facilities of third-party manufacturers with which we contract or procure certain service or raw materials, may not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if our product candidates meet their pre-specified safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner and may not consider such the clinical trial results sufficient to grant, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings, contraindications or Risk Evaluation and Mitigation Strategies ("REMS"). These regulatory authorities may also grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations and prospects.

Public health crises, such as the COVID-19 pandemic, could have a material adverse impact the execution of our planned clinical trials.

Our Phase 2 clinical trial for MYMD-1 currently in progress has been and may continue to be affected by the pandemic. Protocols put into place for COVID-19 have delayed and may continue to delay patient enrollment in our current and planned clinical trials. Any such delays to our planned Phase 2 and Phase 3 clinical trials for MYMD-1 could impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional capital earlier than we had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans.

Further, infections and deaths related to COVID-19 have disrupted certain healthcare and healthcare regulatory systems globally. Lingering effects from such disruptions and/or any similar issues in the future could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. There is substantial uncertainty in connection with the extent to which the pandemic may impact or disrupt development plans and/or operations, generally, in the future. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials and our product candidates, components, parts, and consumables, and to perform quality testing. If either we or any third-party in the supply chain for materials used in the production of its product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our clinical trials.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if it experiences unanticipated problems with our product candidates, when and if any of them are approved.

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including current Good Manufacturing Practices ("cGMPs"), quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA also closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed in a manner consistent with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. For example, under applicable FDA marketing regulations, prescription drug promotions must be consistent with and not contrary to approved labeling, present a "fair balance" between the product's risks and benefits, be truthful and not false or misleading, and be sufficiently substantiated with appropriate documentary evidence, among numerous other requirements. If we promote our products that are approved for marketing in the United States, if any, in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Violations of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") relating to the promotion of prescription drugs may lead to investigation or prosecution by the DOJ or other applicable agencies and could give rise to ancillary violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions. Additionally, our marketing activities relating to any products we may commercialize in the United States in the future may also be subject to enforcement by the FTC and/or state attorneys general, and we may face consumer class-action liability if our marketing practices are actually or allegedly misleading or deceptive.

In addition to the requirements applicable to approved drug products, we may also be subject to enforcement action in connection with any promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the therapeutic candidate. Sponsors must strike the often difficult balance of communicating sufficient information about its product candidates to inform investors and engaging in valid scientific exchanges with the medical community without crossing the often-difficult-to-ascertain line into "promotion," which is not defined by regulation but is generally interpreted broadly by FDA. Accordingly, if FDA finds any of our communications regarding MyMD-1 or Supera-CBD to be promotional, we may be subject to a wide range of enforcement actions, and our candidates' prospects for regulatory approval may be adversely affected.

The occurrence of any event or penalty described above could give rise to material reputational harm to our business and our current, and any future, product candidates we may develop and may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we have obtained, and we may not achieve or sustain profitability.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the U.S.

To market and sell MYMD-1, Supera-CBD or our other product candidates in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time and data required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals or non-compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Our development program for Supera-CBD, a synthetic analog of CBD, is in its infancy and subject to substantial uncertainty and may not yield commercial results and is subject to significant regulatory risks.

We are only in the pre-clinical stage of development for Supera-CBD, which is essentially the earliest stage of a candidate's development process and must be followed by regulatory submissions (such as, an IND application and FDA's acceptance thereof), IRB approval, as well as the complex, onerous clinical-trial process (which must be conducted in accordance with FDA's IND regulations), and ultimately, NDA submission, the approval of which is not guaranteed. There can be no assurance that our development program for Supera-CBD, a synthetic analog of CBD, will be successful, or that any research and development and product testing efforts will result in commercially saleable products, or that the market will accept or respond positively to products based on Supera-CBD.

Federal Regulation of CBD. The market for cannabinoids is heavily regulated. Synthetic cannabinoids may be viewed as qualifying as controlled substances under the federal Controlled Substances Act of 1970 (CSA) and may be subject to a high degree of regulation including, among other things, certain registration, licensing, manufacturing, security, record keeping, reporting, import, export, inspection by DEA clinical and non-clinical studies, insurance and other requirements administered by the U.S. Drug Enforcement Administration (DEA) and/or the FDA.

State Regulation of CBD. Individual states and countries have also established controlled substance laws and regulations, which may differ from U.S. federal law. States have also developed CBD-specific laws and regulations that govern a wide range of CBD-related activities, from cultivation to processing to marketing. There is substantial variation among states' CBD laws, and we will have to devote substantial time, expenses, and resources toward compliance, and such laws are also subject to ongoing evolution and, thus, must be actively monitored. We or our business partners may be required to obtain separate state or country registrations, permits or licenses in order to be able to develop produce, sell, store and transport cannabinoids.

Compliance is Complex and Costly. Complying with laws and regulations relating to cannabinoids is evolving, complex and expensive, and may divert management's attention and resources from other aspects of our business. Failure to maintain compliance with such laws and regulations may result in regulatory action that could have a material adverse effect on our business, results of operations and financial condition. The DEA, FDA or state agencies may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Clinical trials. Because synthetic CBD products may be regulated as controlled substances in the U.S., to conduct clinical trials in the U.S., each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense products based on Supera-CBD and to obtain product from our manufacturer. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites.

Negative public perception of cannabis-related businesses, misconceptions about the nature of our business or Supera-MD, and regulatory uncertainties relating to the legality of cannabinoids could each have a material adverse effect on our business, financial condition, and results of operations.

We believe the cannabinoid industry is highly dependent upon consumer perception regarding the safety, efficacy, quality, and legality of cannabinoids, whether naturally derived or synthetic. Consumer perception of cannabinoid products can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention, and other publicity regarding the consumption of CBD products. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention, or other research findings or publicity will be favorable to the CBD market or Supera-CBD, in particular. Our dependence upon consumer perceptions with regard to Supera-CBD, particularly once it is approved for commercialization, if ever, means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention, or other publicity relating to cannabinoid products, generally, or any particular cannabinoid products or derivatives, in particular, regardless of merit or accuracy, could have a material adverse effect on our business, the development of, or ultimate commercial demand for (if applicable), Supera-CBD. Such adverse publicity or other negative media attention could arise even if the adverse effects reportedly associated with such products resulted from consumers' failure to consume such products appropriately or as directed. Any adverse publicity or other similar occurrences affecting consumer perception may have a material adverse impact on our reputation, perception of Supera-CBD, and our ability to obtain the necessary regulatory approvals for Supera-CBD and its prospective commercial viability.

Risks Related to Commercialization and Manufacturing

The commercial success of our product candidates, including MYMD-1 and Supera-CBD, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community.

Even with the requisite approvals from the FDA and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of providers, patients and third-party payors of our product candidates, as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of MYMD-1, Supera-CBD and our other product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy, durability and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA or the European Commission;
- the willingness of providers to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the quality of our relationships with patient advocacy groups;
- publicity concerning our product candidates or competing products and treatments; and
- sufficient third-party payor coverage and adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in pre-clinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

If we are unable to establish or sustain coverage and adequate reimbursement for our product candidates from third-party payors, the adoption of those product candidates and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

We expect that coverage and reimbursement by third-party payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of MYMD-1, Supera-CBD and our other product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older, disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. One payor's determination to provide coverage for a drug product, however, does not assure that other payors will also provide coverage for the drug product. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In addition to government and private payors, professional organizations such as the American Medical Association ("AMA"), can influence decisions about coverage and reimbursement for new products by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our product candidates may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the U.S. and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of certain third-party payors, such as health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. Recently there have been instances in which third-party payors have refused to reimburse treatments for patients for whom the treatment is indicated in the FDA-approved product labeling. Even if we are successful in obtaining FDA approvals to commercialize our product candidates, we cannot guarantee that we will be able to secure reimbursement for all patients for whom treatment with our product candidates is indicated.

If third parties on which we depend to conduct our planned pre-clinical studies or clinical trials, do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with adverse effects on our business, financial condition, results of operations and prospects.

We rely on third party CROs, CMOs, consultants and others to design, conduct, supervise and monitor key activities relating to, discovery, manufacturing, pre-clinical studies and clinical trials of our product candidates, and we intend to do the same for future activities relating to existing and future programs. Because we rely on third parties and do not have the ability to conduct all required testing, discovery, manufacturing, preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of discovery, manufacturing, pre-clinical studies and clinical trials than we would if we conducted them on our own. These investigators, CROs, CMOs and consultants are not our employees, and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties we contract with might not be diligent or timely in conducting our discovery, manufacturing, pre-clinical studies or clinical trials, resulting in discovery, manufacturing, pre-clinical studies or clinical trials being delayed or unsuccessful, in whole or in part.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of pre-clinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we are responsible for ensuring that each of our pre-clinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, as well as in accordance with GLP, GCPs and other applicable laws, regulations and standards. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. The FDA and other regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fails to comply with applicable GCPs, the clinical data generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving its marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials have complied with GCPs. In addition, our clinical trials must be conducted with product produced in accordance with cGMPs. Our failure to comply with these regulations may require us to repeat clinical trials, which could delay or prevent the receipt of regulatory approvals. Any such event could have an adverse effect on our business, financial condition, results of operations and prospects.

We face significant competition in an environment of rapid pharmacological change and it is possible that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may harm our business, financial condition and our ability to successfully market or commercialize MYMD-1, Supera-CBD and our other product candidates.

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, competition and a strong emphasis on intellectual property. We are aware of several companies focused on developing immunometabolic treatments in various indications as well as several companies addressing other treatments for anti-aging, anxiety and depression. We may also face competition from large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization.

Several companies are focused on developing treatments for immunometabolic dysregulation in treatment of autoimmune disorders.

Many of our potential competitors, alone or with their strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. Additionally, new or advanced technologies developed by our competitors may render our current or future product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of MYMD-1, Supera-CBD or our other product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.

We intend to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance and finished product of any product candidate for which we are responsible for pre-clinical or clinical development. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and its processes are required to be qualified by the FDA prior to regulatory approval. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the U.S. may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The process of manufacturing drugs is complex, highly regulated and subject to multiple risks. Manufacturing drugs is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny NDA approval until the deficiencies are corrected or we replace the manufacturer in our NDA with a manufacturer that is in compliance. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

We could be adversely affected if healthcare reform measures substantially change the market for medical care or healthcare coverage in the U.S.

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) (the "ACA") and on March 30, 2010, he signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in our current commercial products, products we may commercialize or promote in the future, and our therapeutic candidates, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children's Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, including our current commercial products, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for the products we currently commercialize or promote, any product we may commercialize or promote, or approved therapeutic candidates is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including our current commercial products, our development or commercialization partners or any product we may commercialize or promote, or those therapeutic candidates currently being developed by us), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for our current commercial products, any product we may commercialize or promote, or any therapeutic candidate, or for which we receive marketing approval in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, in particular, the ACA, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the ACA at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the ACA and judicial challenges have continued. We cannot predict the impact on our business of future legislative and legal challenges to the ACA or other aspects of the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

During his time in office, former President Trump supported the repeal of all or portions of the ACA. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the ACA to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the ACA, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the ACA's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the ACA and was intended to reduce the rate of growth in Medicare spending).

Additionally, in December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the ACA is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the ACA. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the ACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the ACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, in August 2022, the Inflation Reduction Act ("IRA") was signed into law, which will, among other things, allow U.S. Department of Health and Human Services ("HHS") to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services ("CMS") reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S. or the effect of any future legislation or regulation. Furthermore, we cannot predict what actions the Biden administration will implement in connection with the Health Reform Law. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the U.S. in the future, as applicable.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions which may materially affect our business operations.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, with one or more applicable requirements the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions and civil penalties;
- recall, detention or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension or total shutdown of production;
- refusing MyMD's requests for a 510(k) clearance of new products;
- withdrawing a 510(k) clearance already granted; and
- criminal prosecution.

Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, statutory, regulatory and policy changes and global health concerns.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the pharmaceutical industry.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and, subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our operations and relationships with future customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with providers, third-party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain marketing approval.

Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute ("AKS") prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it in order to have committed a violation;

- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payment Sunshine Act of 2010 ("PPSA") requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report payments and other transfers of value provided during the previous year to physicians, as defined by such law, certain other healthcare providers starting in 2022 (for payments made in 2021), and teaching hospitals, as well as certain ownership and investment interests held by such physicians and their immediate family, which includes annual data collection and reporting obligations;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and

- some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Our internal computer systems, or those of its third-party vendors, collaborators, or other contractors may be subject to various federal and state confidentiality and privacy laws in the United States and abroad and could sustain system failures, security breaches, or other disruptions, any of which could have a material adverse effect on our business.

Numerous international, national, federal, provincial and state laws, including state privacy laws (such as the California Consumer Privacy Act), state security breach notification and information security laws, and federal and state consumer protection laws govern the collection, use, and disclosure of personal information. In addition, most healthcare providers who may, in the future, prescribe and dispense our products in the United States and research institutions in the United States with whom we may collaborate in the future are "covered entities" subject to privacy and security requirements under HIPAA. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. We could be subject to a wide range of penalties and sanctions under HIPAA, including criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a covered entity in a manner that is not authorized or permitted by HIPAA. Failure to comply with applicable HIPAA requirements or other current and future privacy laws and regulations could result in governmental enforcement actions (including the imposition of significant penalties), criminal and civil liability, and/or adverse publicity that negatively affects our business.

Moreover, we rely on our internal and third-party provided information technology systems and applications to support our operations and to maintain and process company information including personal information, confidential business information and proprietary information. If these information technology systems are subject to cybersecurity attacks, or are otherwise compromised, due to cyberattacks, human error or malfeasance, system errors or otherwise, it may adversely impact our business, disrupt our operations, or lead to the loss, theft, destruction, corruption, or compromise of our information or that of our collaborators, study subjects, or other third-party contractors, as applicable. Such information technology or security events could also lead to legal liability, regulatory investigations or enforcement actions, loss of business, negative media coverage, and reputational damage. While we seek to protect our information technology systems from these types of incidents, the healthcare sector continues to see a high frequency of cyberattacks and increasingly sophisticated threat actors, and our systems and the information maintained within those systems remain potentially vulnerable to data security incidents.

Any of the above-described cyber or other security-related incidents may trigger notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under foreign, federal, provincial and state laws that protect the privacy and security of personal information. Our proprietary and confidential information may also be accessed. Any one of these events could cause our business to be materially harmed and our results of operations may be adversely impacted. Finally, as cyber threats continue to evolve, and privacy and cybersecurity laws and regulations continue to develop, we may need to invest additional resources to implement new compliance measures, strengthen our information security posture, or respond to cyber threats and incidents.

Risks Related to Our Intellectual Property

Our success largely depends on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their adequate protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark, trade secret and other intellectual property protection of our proprietary technologies and product candidates, which include MYMD-1, Supera-CBD and the other product candidates we have in development, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending our patents and other intellectual property rights against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development activities before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we may license from or license to third parties and may be reliant on our licensors or licensees to do so. Our pending and future patent applications may not result in issued patents. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with adequate protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates will be protectable or remain protected by valid and enforceable patents. In addition, our existing patents and any future patents we obtain may not provide an adequate scope of protection or otherwise may not be enforceable to prevent others from using our technology or from developing competing products and technologies.

We may not be able to adequately protect or enforce our intellectual property rights, which could harm our competitive position.

Our success and future revenue growth will depend, in part, on our ability to protect our intellectual property. We will primarily rely on patent, copyright, trademark and trade secret laws, as well as nondisclosure agreements and other methods, to protect our proprietary technologies or processes. It is possible that competitors or other unauthorized third parties may obtain, copy, use or disclose proprietary technologies and processes, despite efforts by us to protect our proprietary technologies and processes. While we hold rights in several patents, there can be no assurances that any additional patents will be issued, or additional rights will be granted, to us. Even if new patents are issued, the claims allowed may not be sufficiently broad to adequately protect our technology and processes. Our competitors may also be able to develop similar technology independently or design around the patents to which we have rights.

Currently, MyMD has 16 issued U.S. patents, 50 foreign patents, four pending U.S. patent applications, and 15 foreign patent applications pending in such jurisdictions as Australia, Canada, China, European Union, Israel, Japan and South Korea, which if issued are expected to expire between 2036 and 2041. Although we expect to obtain additional patents and in-licenses in the future, there is no guarantee that we will be able to successfully obtain such patents or in-licenses in a timely manner or at all. Further, any of our rights to existing patents, and any future patents issued to us, may be challenged, invalidated or circumvented. As such, any rights granted under these patents may not provide us with meaningful protection. Even if foreign patents are granted, effective enforcement in foreign countries may not be available. If our patents or rights to patents do not adequately protect our technology or processes, competitors may be able to offer products similar to our products.

Our potential strategy of obtaining rights to key technologies through in-licenses may not be successful.

The future growth of our business may depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates and technologies. We cannot assure that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship with a given partner may be owned solely by either us or our third-party research partner, or jointly between us and the third party. If we determine that exclusive rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our drug candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party in order to use the improvements and continue developing, manufacturing or marketing our drug candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our drug candidates or allow our competitors or others the opportunity to access technology that is important to our business. We also may need the cooperation of any co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us.

In addition, the in-licensing and acquisition of these technologies is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business and prospects could be materially and adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information (or as otherwise permitted by applicable law), are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, such as through a data breach, or if any of that information was independently developed by a competitor, our competitive position could be harmed. Additionally, certain trade secret and proprietary information may be required to be disclosed in submissions to regulatory authorities. If such authorities do not maintain the confidential basis of such information or disclose it as part of the basis of regulatory approval, our competitive position could be adversely affected.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any claims against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. To date, none of our employees have been subject to such claims.

Third-party claims of intellectual property infringement may prevent, delay or otherwise interfere with our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the United States Patent and Trademark Office ("USPTO") or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;

- a court prohibiting us from developing, manufacturing, marketing, selling or importing our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights or proprietary technology to us, which it is not required to do in the U.S. and certain other countries, on commercially reasonable terms or at all;

- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates;

- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and

- there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that we are employing their proprietary technology without authorization, including by enforcing its patents against us by filing a patent infringement lawsuit against us. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof.

We may not have identified all patents, published applications or published literature that affect our business by blocking our ability to commercialize our products, by preventing the patentability of one or more aspects of our products to us or our licensors, or by covering the same or similar technologies that may affect our ability to market our products. For example, we (or the licensor of a product to us) may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

Therefore, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, or materials used in or formed during the manufacturing process, or any final product itself, the holders of those patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until those patents were to expire or those patents are finally determined to be invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of that patent may be able to block our ability to develop and commercialize a product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, a license may not be available on commercially reasonable terms, or at all, particularly if such patent is owned or controlled by one of our primary competitors. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee time and resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any license of this nature would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates and we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could significantly harm our business.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful and could result in a finding that such patents are unenforceable or invalid.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid, is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Conversely, we may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings), or we may choose to challenge a third party's patent in patent opposition proceedings in the Canadian Intellectual Property Office ("CIPO") the European Patent Office ("EPO") or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, CIPO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our Common Stock. Any of the foregoing could have a material adverse effect on our business financial condition, results of operations and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We currently have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. For example, patents covering therapeutic methods of treating humans are not available in many foreign countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we do not have or have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal and political systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could be impossible or impractical due to sanctions or trade disputes between countries, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable laws and rules, there are situations in which noncompliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Were a noncompliance event to occur, our competitors might be able to enter the market, which would have a material adverse effect on our business financial condition, results of operations and prospects.

Changes in patent law in the U.S. and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Past or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, in March 2013, under the Leahy-Smith America Invents Act ("America Invents Act"), the U.S. moved from a "first to invent" to a "first-inventor-to-file" patent system. Under our "first-inventor-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes continue to evolve as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-inventor-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. Moreover, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Recent cases by the U.S. Supreme Court have held that certain methods of treatment or diagnosis are not patent-eligible. U.S. law regarding patent-eligibility continues to evolve. While we do not believe that any of our patents will be found invalid based on these changes to US patent law, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after our or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. U.S. and ex-U.S. law concerning patent term extensions and foreign equivalents continue to evolve. Even if we were to seek a patent term extension, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy applicable requirements. Moreover, the applicable time period of extension or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration sooner than expected, and our business, financial condition, results of operations and prospects could be materially harmed.

Risks Related to Our Series F Preferred Stock

Holders of our Series F Preferred Stock are entitled to certain payments under the Certificate of Designation that may be paid in cash or in shares of Common Stock depending on the circumstances. If we make these payments in cash, it may require the expenditure of a substantial portion of our cash resources. If we make these payments in Common Stock, it may result in substantial dilution to the holders of our Common Stock.

Under the Certificate of Designations (the "Certificate of Designation") of our Series F Convertible Preferred Stock ("Series F Preferred Stock"), we are required to redeem the shares of Series F Preferred Stock in 12 equal monthly installments, commencing on July 1, 2023. Holders of our Series F Preferred Stock are also entitled to receive dividends, payable in arrears monthly, and dividends payable on installment dates shall be paid as part of the applicable installment amount. Installment amounts are payable, at the company's election, in shares of Common Stock or, subject to certain limitations, in cash. Installment amounts paid in cash must be paid in the amount of 105% of the applicable payment amount due. For an installment amounts paid in shares of Common Stock, the number of shares of Common Stock shall be calculated by dividing the applicable payment amount due by the "installment conversion price." The installment conversion price shall be equal to the lower of (i) the Conversion Price (as defined in the Certificate of Designation) in effect as of the applicable payment date and (ii) the greater of (A) 80% of the average of the three lowest closing prices of our Common Stock during the thirty trading day period immediately prior to the date the payment is due or (B) the lower of (x) $0.4014 and (y) 20% of the "Minimum Price" (as defined in Rule 5635 of the Rules of the Nasdaq Stock Market) on the date of the Stockholder Approval (as defined below) (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Stock Market.

Our ability to make payments due to the holders of our Series F Preferred Stock using shares of Common Stock is subject to certain limitations set forth in the Certificate of Designation, including a limit on the number of shares that may be issued until the time, if any, that our stockholders have approved the issuance of more than 19.9% of our outstanding shares of Common Stock in accordance with the rules of the Nasdaq Stock Market (the "Stockholder Approval"). If we are unable to make installment payments in shares of Common Stock, we may be forced to make such payments in cash. If we do not have sufficient cash resources to make these payments, we may need to raise additional equity or debt capital, and we cannot provide any assurance that we will be successful in doing so. If are unable to raise sufficient capital to meet our payment obligations, we may need to delay, reduce or eliminate certain research and development programs or other operations, sell some or all of our assets or merge with another entity.

Our ability to make payments due to the holders of our Series F Preferred Stock using cash is also limited by the amount of cash we have on hand at the time such payments are due as well as certain provisions of the New Jersey Business Corporations Act. Further, we intend to make the installment payments due to holders of Series F Preferred Stock in the form of Common Stock to the extent allowed under the Certificate of Designation and applicable law in order to preserve our cash resources. The issuance of shares of Common Stock to the holders of our Series F Preferred Stock with increase the number of shares of Common Stock outstanding and could result in substantial dilution to the existing holders of our Common Stock.

The Certificate of Designation for the Series F Preferred Stock and the warrants issued concurrently therewith contain anti-dilution provisions that may result in the reduction of the conversion price of the Series F Preferred Stock or the exercise price of such warrants in the future. These features may increase the number of shares of Common Stock being issuable upon conversion of the Series F Preferred Stock or upon the exercise of the warrants.

The Certificate of Designation and the warrants issued concurrently with the Series F Preferred Stock (the "February 2023 Warrants") contain anti-dilution provisions, which provisions require the lowering of the applicable conversion price or exercise, as then in effect, to the purchase price of equity or equity-linked securities issued in subsequent offerings. If in the future, while any of our Series F Preferred Stock or February 2023 Warrants are outstanding, we issue securities for a consideration per share of Common Stock (the "New Issuance Price") that is less than the Conversion Price of our Series F Preferred Stock or the exercise price of the February 2023 Warrants, as then in effect, we will be required, subject to certain limitations and adjustments as provided in the Certificate of Designation or the February 2023 Warrants, to reduce the Conversion Price or the exercise price to be equal to the New Issuance Price, which will result in a greater number of shares of Common Stock being issuable upon conversion or exercise, as applicable, which in turn will increase the dilutive effect of such conversion or exercise on existing holders of our Common Stock. It is possible that we will not have a sufficient number of shares available to satisfy the conversion of the Series F Preferred Stock or the exercise of the February 2023 Warrants if we enter into a future transaction that reduces the applicable Conversion Price or exercise price. If we do not have a sufficient number of available shares for any Series F Preferred Stock conversions or February 2023 Warrant exercises, we may need to seek shareholder approval to increase the number of authorized shares of our Common Stock, which may not be possible and will be time consuming and expensive. The potential for such additional issuances may depress the price of our Common Stock regardless of our business performance and may make it difficult for us to raise additional equity capital while any of our Series F Preferred Stock or February 2023 Warrants are outstanding.

Under the February 2023 Securities Purchase Agreement we are subject to certain restrictive covenants that may make it difficult to procure additional financing.

The Securities Purchase Agreement pursuant to which we issued the Series F Preferred Stock ("February 2023 SPA") contains the following restrictive covenants: (i) until all of the February 2023 Warrants are exercised, we agreed not to enter into any variable rate transactions; (ii) for approximately ten months after the execution of the February 2023 SPA, we agreed not to issue or sell any equity security or convertible security, subject to certain exceptions; and (iii) we agreed to offer to the investors party to the February 2023 SPA, until the later of no Series F Preferred Shares being outstanding and the maturity date of the Series F Preferred Shares, the opportunity to participate in any subsequent securities offerings by us. If we require additional funding while these restrictive covenants remain in effect, we may be unable to effect a financing transaction while remaining in compliance with the terms of the February 2023 SPA, or we may be forced to seek a waiver from the investors party to the February 2023 SPA.

If we do not receive approval from our stockholders, we will be unable to pay amounts due to the holders of our Series F Preferred Stock in shares of Common Stock and we will be required to pay such amounts in cash, which may force us to divert cash from other uses.

Under the February 2023 SPA, we are required to hold a meeting of our stockholders to seek approval under Nasdaq Listing Rule 5635(d) for the sale, issuance or potential issuance by us of our Common Stock (or securities convertible into or exercisable for our Common Stock) in excess of 7,894,001 shares, which is 20% of the shares of Common Stock outstanding immediately prior to the execution of the February 2023 SPA. Certain stockholders, who beneficially held approximately 44% of our outstanding Common Stock as of the date of the February 2023 SPA, are party to a voting agreement pursuant to which, among other things, each such stockholder agreed, solely in their capacity as a stockholder, to vote all of their shares of Common Stock in favor of the approval, and if an insufficient number of our remaining stockholders vote in favor of the proposal we will be unable to issue shares of Common Stock in order to pay amounts due under the Certificate of Designation to holders of our Series F Preferred Stock in shares of Common Stock. If we are unable to pay such amounts when due in shares of Common Stock, we will have to satisfy our payment obligations by means of cash payments. If we do not have sufficient cash resources to make these payments, we may need to delay, reduce or eliminate certain research and development programs or other operations, sell some or all of our assets or merge with another entity.

General Risk Factors

Offers or availability for sale of a substantial number of shares of our Common Stock may cause the price of our Common Stock to decline.

Sales of a significant number of shares of our Common Stock in the public market could harm the market prices of our Common Stock and make it more difficult for us to raise funds through future offerings of Common Stock or other securities. Our stockholders and the holders of our options and warrants may sell substantial amounts of our Common Stock in the public market. In addition, we may be required to issue shares of Common Stock to the holders of our Series F Preferred Stock upon conversion of shares of our Series F Preferred Stock and the payment of the dividends thereunder in Common Stock as a result of the full ratchet anti-dilution price protection in the Certificate of Designation if the effective Common Stock purchase price in a subsequent offering is less than the then current Series F Preferred Stock conversion price, which in turn will increase the number of shares of Common Stock available for sale. See "Risk Factors—Risks Related to Our Series F Preferred Stock—The Certificate of Designation for the Series F Preferred Stock and the warrants issued concurrently contain anti-dilution provisions that may result in the reduction of the conversion price of the Series F Preferred Stock or the exercise price of such warrants in the future. These features may increase the number of shares of Common Stock being issuable upon conversion of the Series F Preferred Stock or upon the exercise of the warrants."

In addition, the fact that our stockholders can sell substantial amounts of our Common Stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all.

An active trading market for our Common Stock may not be sustained.

The listing of our Common Stock on The Nasdaq Capital Market ("Nasdaq") does not assure that a meaningful, consistent and liquid trading market exists. An active trading market for shares of our Common Stock may not be sustained. If an active market for our Common Stock is not sustained, it may be difficult for investors to sell their shares either without depressing the market price for the shares or at all.

The intended benefits of the Contribution Transaction may not be realized.

The Contribution Transaction poses risks for our ongoing operations, including, among others:

- following consummation of the Contribution Transaction, if Oravax is not successful in developing the COVID-19 Vaccine Candidate, we may not realize any value out of its ownership of Oravax shares;
- costs and expenses associated with any undisclosed or potential liabilities.

As a result of the foregoing, we may be unable to realize the full strategic and financial benefits originally anticipated from the Contribution Transaction, and we cannot assure you that the Contribution Transaction will be accretive in the near term or at all. Furthermore, if we fail to realize the intended benefits of the Contribution Transaction, the market price of our Common Stock could decline to the extent that the market price reflects those benefits.

We are subject to various internal control reporting requirements under the Sarbanes-Oxley Act. We can provide no assurance that we will at all times in the future be able to report that our internal controls over financial reporting are effective.

As a public company, we are required to comply with Section 404 ("Section 404") of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"). In any given year, we cannot be certain as to the time of completion of our internal control evaluation, testing and remediation actions or of their impact on our operations. Upon completion of this process, we may identify control deficiencies of varying degrees of severity under applicable SEC and Public Company Accounting Oversight Board (U.S.) rules and regulations. Our management, including our principal executive officer and principal financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, as a public company, we are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual consolidated financial statements will not be prevented or detected on a timely basis. If we fail to comply with the requirements of Section 404 or if we report a material weakness, we might be subject to regulatory sanction and investors may lose confidence in our consolidated financial statements, which may be inaccurate if we fail to remedy such material weakness.

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act and the Dodd-Frank Act, as well as rules implemented by the SEC and Nasdaq, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our Common Stock. The delisting could adversely affect the market liquidity of our Common Stock and the market price of our Common Stock could decrease.

Our Common Stock is listed on The Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital and a minimum price per share. We cannot assure you that we will continue to meet the continued listing requirements in the future.

If Nasdaq delists our Common Stock from trading on its exchange, due to failure to meet its continued listing requirements, and we are not able to list our Common Stock on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our Common Stock;
- reduced liquidity for our Common Stock;
- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our Common Stock;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We may issue additional equity securities in the future, which may result in dilution to existing investors.

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. The combined Company may, from time to time, sell additional equity securities in one or more transactions at prices and in a manner it determines. If we sell additional equity securities, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences. In addition, the number of shares available for future grant under our equity compensation plans may be increased in the future. In addition, the exercise or conversion of outstanding options or warrants to purchase shares of capital stock may result in dilution to our stockholders upon any such exercise or conversion.

All of our outstanding shares of Common Stock are, and any Milestone Shares of our Common Stock that may be issued in the future, will be, freely tradable without restrictions or further registration under the Securities Act of 1933, as amended (the "Securities Act"), except for shares subject to lock-up agreements, and any shares held by affiliates, as defined in Rule 144 under the Securities Act. Rule 144 defines an affiliate as a person who directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the Company and would include persons such as our directors and executive officers and large shareholders. In turn, resales, or the perception by the market that a substantial number of resales could occur, could have the effect of depressing the market price of our Common Stock.

In addition, we may be required to issue an indeterminate number of shares of Common Stock to the holders of our Series F Preferred Stock and the February 2023 Warrants upon the conversion or exercise of either, as applicable. See "Risk Factors—Risks Related to Our Series F Preferred Stock— Holders of our Series F Preferred Stock are entitled to certain payments under the Certificate of Designation that may be paid in cash or in shares of Common Stock depending on the circumstances. If we make these payments in cash, it may require the expenditure of a substantial portion of our cash resources. If we make these payments in Common Stock, it may result in substantial dilution to the holders of our Common Stock." and "Risk Factors—Risks Related to Our Series F Preferred Stock—The Certificate of Designation for the Series F Preferred Stock and the warrants issued concurrently contain anti-dilution provisions that may result in the reduction of the conversion price of the Series F Preferred Stock or the exercise price of such warrants in the future. These features may increase the number of shares of Common Stock issuable upon conversion of the Series F Preferred Stock or upon the exercise of the warrants."

We do not anticipate paying cash dividends on our Common Stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our Common Stock and do not expect to do so in the foreseeable future. So long as any shares of Series F Preferred Stock are outstanding, as they are at this time, we are not able to declare or pay any cash dividend or distribution on any of our capital stock (other than as required by the Certificate of Designation) without the prior written consent of the Required Holders (as defined in the Certificate of Designation). The declaration of dividends is further subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant our board of directors. You should not rely on an investment in us if you require dividend income from your investment in us. The success of your investment will likely depend entirely upon any future appreciation of the market price of our Common Stock, which is uncertain and unpredictable. There is no guarantee that our Common Stock will appreciate in value.

If securities analysts do not publish research or reports about our business, or if they publish negative evaluations, the price of our Common Stock could decline.

The trading market for our Common Stock relies in part on the availability of research and reports that third-party industry or financial analysts publish about us. There are many large, publicly traded companies active in the life sciences and biopharmaceutical industries, which may mean it will be less likely that we receive widespread analyst coverage. Furthermore, if one or more of the analysts who do cover the Company (if any) downgrades our stock, our stock price would likely decline. If one or more of these analysts cease coverage of the Company, we could lose visibility in the market, which in turn could cause our stock price to decline. Additionally, if securities analysts publish negative evaluations of competitors in the life sciences and biopharmaceutical industries, the comparative effect could cause our stock price to decline.

We have been subject to a number of securities litigations, and we may be subject to similar or other litigation in the future.

We have been subject to a number of litigations as described elsewhere in these "Risk Factors" and in Note 9 to our consolidated financial statements. In connection with certain of these litigations, we have entered into settlements of claims for significant monetary damages. We may also be subject to judgements or enter into additional settlements of claims for significant monetary damages for the securities litigations that we have yet to enter into settlement agreements. Defending against the current litigations is or can be time-consuming, expensive and cause diversion of our management's attention.

Companies that have experienced volatility in the market price of their stock have frequently been the objects of securities class action litigation. We may be the target of this type of litigation in the future. Class action and derivative lawsuits could result in substantial costs to us and cause a diversion of our management's attention and resources, which could materially harm our financial condition and results of operations.

With respect to any litigation, our insurance may not reimburse us, or may not be sufficient to reimburse us, for the expenses or losses we may suffer in contesting and concluding such lawsuit. Substantial litigation costs, including the substantial self-insured retention that we are required to satisfy before any insurance applies to a claim, unreimbursed legal fees or an adverse result in any litigation may adversely impact our business, operating results or financial condition. We believe that our directors' and officers' liability insurance will cover our potential liability with respect to any securities class-action lawsuit; however, the insurer has reserved its rights to contest the applicability of the insurance to such claims and the limits of the insurance may be insufficient to cover any eventual liability.

We are subject to various internal control reporting requirements under the Sarbanes-Oxley Act. We can provide no assurance that we will at all times in the future be able to report that our internal controls over financial reporting are effective.

As a public company, we are required to comply with Section 404. In any given year, we cannot be certain as to the time of completion of our internal control evaluation, testing and remediation actions or of their impact on our operations. Upon completion of this process, we may identify control deficiencies of varying degrees of severity under applicable SEC and Public Company Accounting Oversight Board (United States) rules and regulations. Our management, including our principal executive officer and principal financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in us have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, as a public company, we are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual consolidated financial statements will not be prevented or detected on a timely basis. If we fail to comply with the requirements of Section 404 or if we report a material weakness, we might be subject to regulatory sanction and investors may lose confidence in our consolidated financial statements, which may be inaccurate if we fail to remedy such material weakness.

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act and the Dodd-Frank Act, as well as rules implemented by the SEC and Nasdaq, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

The company leases as its corporate headquarters an office facility located at 855 North Wolfe Street, Suite 601, Baltimore, Maryland 20215. The lease as amended has a twelve-month term beginning on December 1, 2022, which term shall automatically renew thereafter until termination by either party upon 60 days' notice. The monthly rent is approximately $4,532 and will increase 3% on each anniversary of the December 1, 2022 effective date.

We believe our current facilities are sufficient and adequate for our current needs.

Item 3. Legal Proceedings.

From time to time we are a party to litigation and subject to claims incident to the ordinary course of business. Future litigation may be necessary to defend ourselves and our customers by determining the scope, enforceability, and validity of third-party proprietary rights or to establish our proprietary rights. For a discussion of material legal proceedings affecting us as of December 31, 2022, please read Note 9 to the consolidated financial statements under "Litigation and Settlements," which information is incorporated herein by reference.

Item 4. Mine Safety Disclosures.

Not Applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock began trading on the Nasdaq Capital Market under the symbol "AKER" on January 23, 2014. On April 19, 2021, the symbol for our Common Stock changed to "MYMD."

Holders

As of March 29, 2023, there were approximately 737 holders of record of our Common Stock.

Dividends

Except as described herein, we have never paid any cash or other dividends to our stockholders and we do not plan to declare or pay any cash or other dividends in the foreseeable future. On or around September 9, 2020, our Board declared a dividend of one preferred share purchase right for each share of our Common Stock outstanding held by stockholders of record on September 21, 2020. We currently intend to retain earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board and will depend on such factors as earning levels, contractual restrictions, capital requirements, our overall financial condition and any other factors deemed relevant by the Board.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2022.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The information set forth below should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements based on our current expectations, assumptions, estimates and projections. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those indicated in these forward-looking statements as a result of certain factors, including those discussed in Item 1 of this Annual Report on Form 10-K, entitled "Business," under "Forward-Looking Statements" and Item 1A of this Annual Report on Form 10-K, entitled "Risk Factors." References in this discussion and analysis to "us," "we," "our," or "the Company" refer collectively to MyMD Pharmaceuticals, Inc.

Our financial statements are prepared in accordance with GAAP. These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP and does not require management's judgment in its application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result. The following discussion should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

This annual report on Form 10-K and other reports filed by the Company from time to time with the Securities and Exchange Commission (the "SEC" and such reports, collectively, the "Filings") contain or may contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used in the Filings, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company's business, industry, and the Company's operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Important factors that could cause actual results to differ materially from the results and events anticipated or implied by such forward-looking statements include, but are not limited to:

- fluctuation and volatility in market price of our Common Stock due to market and industry factors, as well as general economic, political and market conditions;
- the impact of dilution on our shareholders;
- our ability to realize the intended benefits of the Merger (as defined below) and the Contribution Transaction (as defined below);
- the impact of our ability to realize the anticipated tax impact of the Merger;
- the outcome of litigation or other proceedings we may become subject to in the future;
- delisting of our Common Stock from the Nasdaq;
- our availability and ability to continue to obtain sufficient funding to conduct planned research and development efforts and realize potential profits;
- our ability to develop and commercialize our product candidates, including MYMD-1, Supera-CBD and other future product candidates;
- the impact of the complexity of the regulatory landscape on our ability to seek and obtain regulatory approval for our product candidates, both within and outside of the U.S.;
- the required investment of substantial time, resources and effort for successful clinical development and marketization of our product candidates;
- challenges we may face with maintaining regulatory approval, if achieved;
- the potential impact of changes in the legal and regulatory landscape, both within and outside of the U.S.;
- the impact of the ongoing COVID-19 pandemic on the administration, funding and policies of regulatory authorities, both within and outside of the U.S.;
- our dependence on third parties to conduct pre-clinical and clinical trials and manufacture its product candidates;
- the impact of the ongoing COVID-19 pandemic on our results of operations, business plan and the global economy;
- challenges we may face with respect to our product candidates achieving market acceptance by providers, patients, patient advocacy groups, third party payors and the general medical community;

- the impact of pricing, insurance coverage and reimbursement status of our product candidates;
- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain, maintain and protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on its proprietary rights;
- our ability to maintain adequate cyber security and information systems;
- our ability to achieve the expected benefits and costs of the transactions related to the acquisition of Supera Pharmaceuticals, Inc. ("Supera");
- our ability to effectively execute and deliver our plans related to commercialization, marketing and manufacturing capabilities and strategy;
- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain adequate financing in the future on reasonable terms, as and when we need it;
- challenges we may face in identifying, acquiring and operating new business opportunities;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate; and
- our compliance with all laws, rules, and regulations applicable to our business.

Overview

Following the closing of the Merger and the Contribution Transaction described below that occurred on April 16, 2021, we have been focused on developing and commercializing two therapeutic platforms based on well-defined therapeutic targets, MYMD-1 and Supera-CBD:

- MYMD-1 is a clinical stage small molecule that regulates the immunometabolic system to treat autoimmune disease, including (but not limited to) multiple sclerosis, diabetes, rheumatoid arthritis, and inflammatory bowel disease. MYMD-1 is being developed to treat age-related illnesses such as frailty and sarcopenia. MYMD-1 works by regulating the release of numerous pro-inflammatory cytokines, such as TNF-α, interleukin 6 ("IL-6") and interleukin 17 ("IL-17"). MYMD-1 currently is being evaluated in patients with sarcopenia (age-related muscle loss). The company has significant intellectual property coverage to protect these autoimmune indications, as well as therapy as an anti-aging product;
- Supera-CBD is a synthetic analog of cannabidiol ("CBD") being developed to treat various conditions, including, but not limited to, epilepsy, pain, and anxiety/depression, through its effects on the CB2 receptor, and a monoamine oxidase enzyme ("MAO") type B. Supera-CBD has shown tremendous promise in treating neuroinflammatory and neurodegenerative diseases, and will be a major focus as the Company moves forward.

The rights to Supera-CBD were previously owned by Supera and were acquired by MyMD Florida (as defined below) immediately prior to the closing of the Merger.

Closing of the Merger and Reverse Stock Split

On April 16, 2021, pursuant to the previously announced Agreement and Plan of Merger and Reorganization, dated November 11, 2020 (the "Original Merger Agreement"), as amended by Amendment No. 1 thereto, dated March 16, 2021 (the Original Merger Agreement, as amended by Amendment No. 1, the "Merger Agreement"), by and among MyMD, a New Jersey corporation previously known as Akers Biosciences, Inc., XYZ Merger Sub, Inc. ("Merger Sub"), and MyMD Pharmaceuticals (Florida), Inc., a Florida corporation previously known as MyMD Pharmaceuticals, Inc. ("MyMD Florida"), Merger Sub was merged with and into MyMD Florida, with MyMD Florida continuing after the merger as the surviving entity and a wholly owned subsidiary of the Company (the "Merger"). At the effective time of the Merger, without any action on the part of any stockholder, each issued and outstanding share of pre-Merger MyMD Florida's Common Stock, par value $0.001 per share (the "MyMD Florida Common Stock"), including shares underlying pre-Merger MyMD Florida's outstanding equity awards, was converted into the right to receive (x) 0.7718 shares (the "Exchange Ratio") of the Company's Common Stock, no par value per share (the "Company Common Stock" or "Common Stock"), (y) an amount in cash, on a pro rata basis, equal to the aggregate cash proceeds received by the Company from the exercise of any options to purchase shares of MyMD Florida Common Stock outstanding at the effective time of the Merger assumed by the Company upon closing of the Merger prior to the second-year anniversary of the closing of the Merger (the "Option Exercise Period"), such payment (the "Additional Consideration"), and (z) potential milestone payment in shares of Company Common Stock up to the aggregate number of shares issued by the Company to pre-Merger MyMD Florida stockholders at the closing of the Merger (the "Milestone Payments") payable upon the achievement of certain market capitalization milestone events (the "Milestone Events") during the 36-month period immediately following the closing of the Merger (the "Milestone Period"). The Milestone Events and corresponding Milestone Payments are set forth in the table below.

Milestone Event	Milestone Payment
Market capitalization of the combined company for at least ten (10) trading days during any 20 consecutive trading day period during the Milestone Period is equal to or greater than $500,000,000 (the "First Milestone Event").	$20,000,000
For every $250,000,000 incremental increase in market capitalization of the combined company after the First Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period, up to a $1,000,000,000 market capitalization of the combined company.	$10,000,000 per each incremental increase (it being understood, however, that, if such incremental increase results in market capitalization equal to $1,000,000,000, such $10,000,000 payment in respect of such incremental increase shall be payable without duplication of any amount payable in respect of a Second Milestone Event, as defined below).
Market capitalization of the combined company for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period is equal to or greater than $1,000,000,000 (the "Second Milestone Event")	$25,000,000
For every $1,000,000,000 incremental increase in market capitalization of the combined company after the Second Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period.	$25,000,000 per each incremental increase

For purposes of the table above, "market capitalization" means, with respect to any trading day, the product of (i) the total outstanding shares of the combined company Common Stock and (ii) the volume weighted average trading price for the combined company Common Stock for such trading day.

Immediately following the effective time of the Merger, the Company effected a 1-for-2 reverse stock split of the issued and outstanding Company Common Stock (the "Reverse Stock Split"). Upon completion of the Merger and the transactions contemplated in the Merger Agreement, (i) the former MyMD Florida equity holders owned approximately 77.05% of the outstanding equity of the Company on a fully diluted basis, assuming the exercise in full of the pre-funded warrants to purchase 986,486 shares of Company Common stock and including 4,188,315 shares of Company Common Stock underlying options to purchase shares of MyMD Florida Common Stock assumed by the company at closing and after adjustments based on the Company's net cash at closing; and (ii) former Akers Biosciences, Inc. stockholders own approximately 22.95% of the outstanding equity of the Company.

Effective as of 4:05 pm Eastern Time on April 16, 2021, we filed an amendment to its Amended and Restated Certificate of Incorporation to effect the Reverse Stock Split. As a result of the Reverse Stock Split, immediately following the effective time of the Merger, every two shares of our Common Stock held by a stockholder immediately prior to the Reverse Stock Split were combined and reclassified into one share of our Common Stock. No fractional shares were issued in connection with the Reverse Stock Split. Each stockholder who did not have a number of shares evenly divisible pursuant to the Reverse Stock Split ratio and who would otherwise be entitled to receive a fractional share of our Common Stock was entitled to receive an additional share of our Common Stock.

In connection with the closing of the Merger, we changed our name to MyMD Pharmaceuticals, Inc. and our trading symbol on The Nasdaq Capital Market to MYMD. For additional information concerning the Merger, please see Note 3 to the Company's Consolidated Financial Statements.

Closing of Contribution and Assignment Agreement

We acquired 100% of the membership interests of Cystron Biotech, LLC ("Cystron") pursuant to a Membership Interest Purchase Agreement, dated March 23, 2020 (as amended by Amendment No. 1 on May 14, 2020, the "MIPA") from certain selling parties (the "Cystron Sellers"). Cystron is a party to a License and Development Agreement (as amended and restated on March 19, 2020, in connection with our entry into the MIPA, the "License Agreement") with Premas Biotech PVT Ltd. ("Premas") whereby Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' genetically engineered yeast (S. cerevisiae)-based vaccine platform, D-Crypt™, for the development of a vaccine against COVID-19 and other coronavirus infections. We had partnered with Premas on this initiative as we sought to advance this COVID-19 vaccine candidate through the regulatory process, both with the U.S. Food and Drug Administration ("FDA") and the office of the drug controller in India. Premas was primarily responsible for the development of the COVID-19 vaccine candidate through proof of concept and was entitled to receive milestone payments upon achievement of certain development milestones through proof of concept.

As of May 14, 2020, Premas had successfully completed its vaccine prototype and obtained transmission electron microscopic (TEM) images of the recombinant virus like particle (VLP) assembled in yeast. In July 2020, animal studies for the COVID-19 vaccine candidate were initiated in India. In addition, we announced that Premas had successfully completed the manufacturing process for the VLP vaccine candidate. On August 27, 2020, we announced with Premas positive proof of concept results from the animal studies conducted during a four-week test of the COVID-19 vaccine candidate in mice. On March 18, 2021, the Company and the Cystron Sellers, which are also shareholders of Oravax Medical, Inc. ("Oravax"), entered into a Termination and Release Agreement terminating the MIPA effective upon consummation of the Contribution Agreement (as defined below). In addition, the Cystron Sellers agreed to waive any change of control payment triggered under the MIPA as a result of the Merger.

On April 16, 2021, pursuant to the Contribution and Assignment Agreement, dated March 18, 2021 (the "Contribution Agreement") by and among the Company, Cystron, Oravax and, for the limited purpose set forth therein, Premas, the parties consummated the transactions contemplated therein. Pursuant to the Contribution Agreement, effective upon the closing of the Merger, the Company agreed (i) to contribute an amount in cash equal to $1,500,000 to Oravax and (ii) cause Cystron to contribute substantially all of the assets associated with its business or developing and manufacturing Cystron's COVID-19 vaccine candidate to Oravax (the "Contribution Transaction"). In consideration for the Company's commitment to consummate the Contribution Transaction, Oravax issued to the Company 390,000 shares of its capital stock (equivalent to 13% of Oravax's outstanding capital stock on a fully diluted basis) and assumed all of the obligations or liabilities in respect of the assets of Cystron (excluding certain amounts due to Premas), including the obligations under the license agreement with Premas. In addition, Oravax agreed to pay future royalties to the Company equal to 2.5% of all net sales of products (or combination products) manufactured, tested, distributed and/or marketed by Oravax or its subsidiaries. For additional information concerning the Contribution Transaction, please see Note 3 to the Company's Consolidated Financial Statements.

Following the Contribution Transaction, Oravax is pursuing the development of the COVID-19 vaccine candidate. MyMD is currently evaluating several options with respect to its interest in Oravax, including a potential distribution of Oravax shares to the MyMD shareholders. This would make Oravax a publicly held company. MyMD's interest in Oravax consists of 13% of Oravax's outstanding shares of capital stock and the rights to a 2.5% royalty on all future net sales. In addition, MyMD currently has the right to designate a member of the board of directors of Oravax, pursuant to which Mr. Joshua Silverman, our Chairman of the Board, has been designated to serve as a director of Oravax.

Financial Operations Overview

We will not generate revenue from product sales unless and until we successfully complete clinical development, obtain regulatory approval for, and successfully commercialize our MYMD-1 and Supera-CBD product candidates. The lengthy process of securing marketing approvals for new drugs requires the expenditure of substantial resources. Any significant delay or failure to obtain regulatory approvals would materially adversely affect our product candidate's development efforts and our business overall. In addition, if we obtain regulatory approval for MYMD-1 and/or Supera-CBD, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

We anticipate that our expenses will increase significantly as we:

- advance the development of our MYMD-1 and Supera-CBD;
- initiate and continue research and preclinical and clinical development of potential new product candidates;
- maintain, expand and protect our intellectual property as it pertains to MYMD-1 and Supera-CBD;
- expand our infrastructure and facilities to accommodate our growing employee base and ongoing development activities;
- establish agreements with contract research organizations, or CROs, and third-party contract manufacturing organizations, or CMOs, in connection with our Supera-CBD preclinical studies, MYMD-1 ongoing and planned clinical trials, Supera-CBD clinical trials and the development of our manufacturing capabilities for MYMD-1 and Supera-CBD;
- develop the large-scale manufacturing processes and capabilities for the commercialization of our MYMD-1 and Supera-CBD drug products;
- seek marketing approvals for our MYMD-1 and Supera-CBD product candidates that successfully complete clinical trials and
- establish a sales, marketing and distribution infrastructure to commercialize MYMD-1 and Supera-CBD should we obtain marketing approval

As a result of these anticipated expenditures, we will need substantial additional funding to support our continuing operations and pursue our growth strategy.

Components of our Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our research and development efforts with MYMD-1 and Supera-CBD are successful, we may generate revenue from product sales or through license agreements with third parties.

Operating Expenses

Our operating expenses are broken into several components, including research and development and general and administrative costs.

We expect operating expenses to increase as we progress through the various clinical trials in the development of MYMD-1 and Supera-CBD.

Research and Development

Our research and development expenses primarily consist of costs associated with the development of MYMD-1 and Supera-CBD. These costs include, but are not limited to:

- Salaries, wages and benefits of the research and development staff;
- Contractual agreements with third parties including contract research organizations, preclinical activities and clinical trials;
- Outside consultants including fees and expenses;
- Laboratory supplies and equipment;

- Regulatory compliance; and

- Patent application and maintenance costs to protect our intellectual property.

Six of our nine employees are principally involved in research and development activities for either MYMD-1 or Supera-CBD. Their salaries, wages and benefits are captured as a component of research and development but not allocated to specific projects.

We utilize third party contractors and consultants with expertise in specific research or development activities to perform work under the supervision of our researchers. We believe this allows us to control costs and to progress through the development cycle and to utilize our staff more efficiently.

It is difficult to project with absolute accuracy the duration or final cost of the development of MYMD-1 and Super-CBD or if revenue will be generated from the commercialization of these components. The process of achieving regulatory approval is very costly and time consuming. A few of the many factors that contribute to costs of duration include:

- Size and scope of pre-clinical trials;

- The phases of clinical development and the stage of our product candidates in the cycle;

- Per subject trial costs;

- The number of sites required for the trials and the availability of appropriate sites to perform the trials;

- The time that is required to enroll the appropriate number of trial participants; and

- The time required to achieve the approval of regulatory agencies.

General and Administrative

General and administrative expenses primarily consist of salaries, wages and benefits for our employees in the executive, legal and accounting functions and third-party costs for legal, accounting, insurance, investor relations, stock market and board expenses.

We expect general and administrative expenses to decline over the near-term. We incurred significant non-recurring legal and accounting fees in 2021 associated with the Merger with Akers Biosciences and we do not anticipate the addition of new general and administrative staff.

Although treated as components of general and administrative expenses, we have chosen to disclose the following significant items separately:

Interest Expense and Accretion of Debt Discount (related party)

Interest expense and accretion of debt discount are the financing costs associated with the line-of-credit established between MYMD and The Starwood Trust (the "Line of Credit"), which was terminated upon the closing of the Merger with Akers Biosciences and paid in full along with the accumulated interest due.

Stock Based Compensation

Stock based compensation includes the fair market value, as determined by Black-Scholes, of stock options issued to key staff and consultants.

Stock Option Modification Expenses

Stock option modification expenses includes the re-valuation of the outstanding stock options that was performed in relation to the Merger with Akers Biosciences.

Other Income (Expense), net

Other income (expense), net consists of interest and dividends earned on our cash, cash equivalents, and investments, gains on the sale marketable securities, losses on equity investments, gains on the forgiveness of debt and an uninsured casualty loss.

Results of Operations

Summary of Statements of Operations for the Fiscal Years Ended December 31, 2022 and 2021

We are focused on developing and commercializing two therapeutic platforms based on well-defined therapeutic targets, MYMD-1 and Supera-CBD. The following table summarized the results of operations for the years ended December 31, 2022 and 2021.

Description	For the Year Ended December 31, 2022	2021	Percent Change
Operating Expenses			
Research and Development	$ 9,067,422	6,745,104	34.4
General and Administrative	5,520,150	6,420,092	(14.0)
Interest Expense & Accretion of Debt Discount	-	608,460	(100.0)
Stock Based Compensation	695,191	-	100.0
Stock Option Modifications	-	15,036,051	(100.0)
Total Operating Expenses	15,282,763	28,809,707	(47.0)
Loss from Operations	(15,282,763)	(28,809,707)	(47.0)
Other Income (Expense), net	85,427	(1,079,338)	(107.9)
Net Loss	$ (15,197,336)	$ (29,889,045)	(49.2)

Revenue

We had no revenue from operations during the years ended December 31, 2022 and 2021.

Research and Development Expenses

The table below summarizes our research and development expenses for the years ended December 31, 2022 and 2021 as well as the percentage of change year-over-year:

Description	For the Year Ended December 31, 2022	2021	Percent Change
Salaries and Wages	$ 1,087,574	$ 808,554	34.5
Development Programs	3,728,568	4,815,617	(22.6)
Professional Services	119,809	34,790	244.4
Regulatory Expenses	4,121,848	1,057,702	289.7
Other Research and Development Expenses	9,623	28,441	(66.2)
Total Research and Development Expenses	$ 9,067,422	$ 6,745,104	34.4

Salaries and wages increased $279,020 during the year ended December 31, 2022. The increase is attributed to the full year costs of a staff member added in May 2021 and bonuses paid to three employees.

Development program costs include those associated with pre-clinical development, clinical trials and other material and development programs. Costs decreased $1,087,049 during the year ended December 31, 2022 as a result of the completion of pre-clinical toxicology studies, the completion of Phase 1 clinical trials and the acquisition of base compounds for current and future trails.

Professional services costs increased $85,019 during the year ended December 31, 2022. These costs are primarily related to legal and patent related fees associated with the protection of our intellectual property.

Regulatory expenses increased $3,064,146 during the year ended December 31, 2022. Regulatory expenses include clinical research organizations (CRO) and regulatory consulting fees associated with Phase 2 clinical study designs, protocol preparations and the maintenance of the investigator brochures.

Other research and development expenses declined $18,818 during the year ended December 31, 2022. These expenses include laboratory supplies, training and travel for department personnel while working with third-party trial sites.

Administrative Expenses

The table below summarizes our administrative expenses for the years ended December 31, 2022 and 2021 as well as the percentage of change year-over-year:

Description	For the Years Ended December 31, 2022	2021	Percent Change
Personnel Costs	$ 1,169,180	$ 1,396,375	(16.3)
Professional Service Costs	1,609,513	1,725,200	(6.7)
Stock Market & Investor Relations Costs	961,540	895,741	7.3
Other Administrative Costs	1,779,917	2,402,776	(25.9)
Total Administrative Expense	$ 5,520,150	$ 6,420,092	(14.0)

Personnel costs decreased $227,195 during the year ended December 31, 2022. During the year ended December 31, 2021, bonuses were included in general and administrative expenses, regardless of the employee's primary responsibilities. During the year ended December 31, 2022, these bonuses were allocated to the appropriate department based upon the employee's responsibilities.

Professional services costs decreased $115,687 during the year ended December 31, 2022. These costs included legal and accounting and specialized consulting services related to the Merger as well as other legal and accounting services regularly incurred in the course of business. The decrease is primarily related to non-recurring legal and accounting expenses recorded during the year ended December 31, 2021 that were related to the Merger.

Stock market and investor relations costs increased $65,799 during the year ended December 31, 2022. These costs include the annual Nasdaq listing fees, activities related to keeping the shareholder base informed through press releases, presentations and other communication efforts and the costs of annual shareholder meetings.

Other administrative expenses decreased $622,859 during the year ended December 31, 2022. These costs include Board expenses, business insurance, corporate travel and the settlement of shareholder litigation related to the Merger. We incurred significant decreases in costs associated with the terminated aircraft lease, corporate travel and legal settlements which was offset by increases director's fees and business insurance costs.

Interest Expense and Accretion of Debt Discount

The Line of Credit included a requirement to issue one share of stock for each dollar borrowed. The fair market value, as determined using Black-Scholes, was amortized over the remaining life of the Line of Credit. The Line of Credit also carried an annualized 5% interest rate.

The Line of Credit was terminated on April 16, 2021 in connection with the Merger and was paid in full on April 28, 2021.

Stock-Based Compensation

During the year ended December 31, 2022, stock-based compensation totaled $695,191. These expenses include stock options issued to staff and service providers, restricted stock units and Common Stock warrants issued for services. During the year ended December 31, 2021, we did not incur any stock-based compensation expenses.

Stock Option Modification Expenses

During the year ended December 31, 2022, we did not incur any stock option modification expenses. During the year ended December 31, 2021, we recorded $15,036,051 in stock option modification expenses related to the 4,188,315 pre-Merger MyMD Florida options that were assumed by MyMD upon the consummation of the Merger.

Other Income and Expense

The table below summarizes our other income and expenses for the years ended December 31, 2022 and 2021 as well as the percentage of change year-over-year:

Description	For the Years Ended December 31, 2022	2021	Percent Change
Interest and Dividend Income	$ (83,991)	$ (8,907)	843.0
Gain on Debt Forgiveness	-	(180,257)	(100.0)
(Gain)/Loss on FMV of Equity Investments	(2,958)	42,793	(106.9)
(Gain)/Loss on Investments	5,964	(39,597)	(115.1)
Uninsured Casualty (Gain)/Loss	(4,442)	1,265,306	(100.4)
Total Other (Income)/Expense	$ (85,427)	$ 1,079,338	(107.9)

Other income, net of expenses, totaled $85,427 for the year ended December 31, 2022, and other expenses, net of income, totaled $1,079,338 for the year ended December 31, 2021.

During the year ended December 31, 2022 interest and dividend income, the changes in fair value of our investments and realized gains from the sale of investments are primarily the result of rising interest rates.

The gain on debt forgiveness totaling $180,257 resulted from (i) $109,657 from the negotiated settlement of the amounts due under the related party Line of Credit, aircraft lease and personal loans and (ii) $70,600 from the forgiveness of the Payroll Protection Program loans received in 2020.

For the year ended December 31, 2021, we identified an uninsured casualty loss of $1,265,306 related to wire fraud due to a compromised electronic mail account. This incident began in late August 2021 and was discovered on October 26, 2021. The Company's internal review of disbursements made during the period of the incident did not identify any additional losses.

A third-party forensic technology company's investigation confirmed that we were a victim of wire fraud due to a compromised electronic mail account. Following the incident, we have taken measures to enhance our electronic mail security and have modified our internal procedures to ensure the authenticity of payment instructions. Despite these prophylactic measures, the risk of such cyber-attacks against us or our third-party providers and business partners remain a serious issue. Cybersecurity incidents are pervasive, and the risks of cybercrime are complex and continue to evolve. Although we are making significant efforts to maintain the security and integrity of our information systems and are exploring various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging.

During the year ended December 31, 2022, we recovered $4,442 from the receiving financial institution.

Income Taxes

As of December 31, 2022, and 2021, we had U.S. federal net operating loss carry forwards of approximately $107.1 million and $101.9 million, respectively. Approximately $57.7 million of the U.S. federal net operating loss generated in tax years beginning before January 1, 2018 expire beginning with the year ending December 31, 2023 through 2037. The remaining U.S. federal net operating loss of approximately $49.4 million does not expire, however it is limited to 80% of each subsequent year's net income. As of December 31, 2022, and 2021, we had U.S. state net operating loss carry forwards of approximately $41.0 million and $38.2 million, respectively, some of which expire beginning with the year ending December 31, 2023 through 2042.

Under Section 382 of the Code, use of our net operating loss carryforwards is limited if we experience a cumulative change in ownership of greater than 50% in a moving three-year period. We experienced an ownership change as a result of the Merger and therefore our ability to utilize our net operating loss carryforwards and certain credit carryforwards are limited. The limitation is determined by the fair market value of our common stock outstanding immediately prior to the ownership change, multiplied by the applicable federal rate. It is expected that the Merger caused our net operating loss carryforwards to be limited. However, the limitation had no impact on our financial statements since we recorded a full valuation allowance for our deferred tax assets as of December 31, 2022 and 2021. (See Note 8 to the Consolidated Financial Statements)

Liquidity and Capital Resources

As of December 31, 2022, the Company's cash and cash equivalents on hand was $749,090 and marketable securities were $4,086,902. The Company has incurred net losses of $15,197,336 and $29,889,045 for the years ended December 31, 2022 and 2021, respectfully. As of December 31, 2022, the Company had working capital of $2,632,796 and a stockholders' equity of $14,695,056 including an accumulated deficit of $93,758,904. During the year ended December 31, 2022, cash flows used in operating activities were $12,270,068, consisting primarily of a net loss from operations of $15,197,336 offset by an increase in trade and other payables of $1,686,595, a decrease in prepaid expenses of $540,560 and non-cash stock compensation expenses of $695,191. Since inception, the Company has met its liquidity requirements principally through the sale of its Common Stock in public and private placements. See also "Recent Developments" below.

Management has evaluated the Company's current cash requirements for operations in conjunction with management's strategic plan and believes that the Company's current financial resources as of the date of the issuance of these consolidated financial statements, are sufficient to fund its current operating budget and contractual obligations as of December 31, 2022 as they fall due within the next twelve-month period , alleviating any substantial doubt raised by the Company's historical operating results and satisfying its estimated liquidity needs for twelve months from the issuance of these consolidated financial statements.

Operating Activities

Our net cash used by operating activities totaled $12,270,068 during the year ended December 31, 2022. Net cash used consisted principally of the net loss from operations of $15,197,336 partially offset by an increase in trade and other payables of $1,686,595, a decrease in prepaid expenses of $540,560 and non-cash stock compensation expenses of $695,191.

Our net cash used by operating activities totaled $19,516,475 during the year ended December 31, 2021. Net cash used consisted principally of the net losses from operations of $29,889,045 and a decrease in trade and other payables of $4,268,961 partially offset by non-cash option modification expenses of $15,036,051.

Investing Activities

Our net cash provided by investing activities totaled $6,913,163 for the year ended December 31, 2022 as compared to cash provided by investing activities totaling $19,850,625 during the year ended December 31, 2021. During the year ended December 31, 2022 we purchased securities totaling $4,836,837 and sold securities totaling $11,750,000. During the year ended December 31, 2021 we purchased securities totaling $13,403, sold securities totaling $18,483,176 and received $1,380,852 from the merger.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2022 was $5,550,028 which consisted of the net proceeds from the sale of Common Stock. Net cash provided by financing activities during the year ended December 31, 2021 was $73,533 which consisted of the payoff of our Line of Credit totaling $3,062,444 offset by proceeds of $120,000 from the Line of Credit and $1,826,137 from a Secured Promissory Note made to us by pre-Merger MyMD Florida which was paid off at the time of the Merger and net proceeds of $1,189,840 from the exercise of warrants for Common Stock.

August 2022 Offering

On August 15, 2022, we entered into a securities purchase agreement (the "August 2022 SPA") with certain accredited and institutional investors pursuant to which we agreed to issue 1,411,764 shares of Common Stock (the "August 2022 Shares") in a registered direct offering and unregistered warrants to purchase up to an aggregate of 1,411,764 shares of Common Stock in a concurrent private placement (the "August 2022 Warrants"). The August 2022 Warrants have an exercise price of $5.25 per share, became exercisable six months following the date of issuance and have a term of exercise equal to five years from the initial exercise date. We received net proceeds from the sale of the August 2022 Shares and the August 2022 Warrants, after deducting fees and other estimated offering expenses payable by the Company, of approximately $5.5 million. As of March 29, 2023, none of the August 2022 Warrants have been exercised and 1,411,764 of the August 2022 Warrants remain outstanding.

Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("US GAAP") requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Future events and their effects cannot be determined with absolute certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results inevitably will differ from those estimates, and such differences may be material to the financial statements. The most significant accounting estimates inherent in the preparation of our financial statements include estimates associated with revenue recognition, impairment analysis of intangibles and stock-based compensation.

Our financial position, results of operations and cash flows are impacted by the accounting policies we have adopted. In order to get a full understanding of our financial statements, one must have a clear understanding of the accounting policies employed. A summary of our critical accounting policies is presented within the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may materially differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most significant to the judgments and estimates used in the preparation of our consolidated financial statements.

Income Taxes

The Company utilizes an asset and liability approach for financial accounting and reporting for income taxes. The provision for income taxes is based upon income or loss after adjustment for those permanent items that are not considered in the determination of taxable income. Deferred income taxes represent the tax effects of differences between the financial reporting and tax basis of the Company's assets and liabilities at the enacted tax rates in effect for the years in which the differences are expected to reverse.

The Company evaluates the recoverability of deferred tax assets and establishes a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized. Management makes judgments as to the interpretation of the tax laws that might be challenged upon an audit and cause changes to previous estimates of tax liability. In management's opinion, adequate provisions for income taxes have been made. If actual taxable income by tax jurisdiction varies from estimates, additional allowances or reversals of reserves may be necessary.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. For the years ended December 31, 2022 and 2021, no liability for unrecognized tax benefits was required to be reported.

There was no income tax benefit recorded for the losses for the years ended December 31, 2022 and 2021 since management determined that the realization of the net deferred tax assets is not more likely than not to be realized and has recorded a full valuation allowance on the net deferred tax assets.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the years ended December 31, 2022 and 2021. The Company does not expect its uncertain tax position to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

Tax years from 2019 through 2022 remain subject to examination by federal and state jurisdictions.

Share-based compensation

We account for share-based payments by recognizing compensation expense based upon the estimated fair value of the share-based payments on the date of grant. We determine the estimated fair value of the share-based payments granted using the fair market value of the stock in the case of restricted stock awards or Black-Scholes option pricing model in the case of stock options and recognize compensation costs ratably over the requisite service period which approximates the vesting period using the graded method. To calculate the fair value of the options, certain assumptions are made regarding components of the model, including the fair value of the underlying Common Stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to the valuation. We calculate our volatility assumptions using the actual changes in the market value of our stock. Forfeitures are recognized as they occur. Our historical option exercises do not provide a reasonable basis to estimate an expected term due to the lack of sufficient data. Therefore, we estimate the expected term by using the simplified method. The simplified method calculates the expected term as the average of the vesting term plus the contractual life of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The assumptions used in determining the fair value of share-based awards represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our share-based compensation expense could be materially different in the future.

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

Recent Developments

February 2023 Offering

On February 21, 2023, we entered into a Securities Purchase Agreement (the "February 2023 SPA") with certain accredited investors, pursuant to which we agreed to sell in a registered direct offering (the "February 2023 Offering") (i) an aggregate of 15,000 shares (the "Series F Preferred Shares") of our newly-designated Series F Convertible Preferred Stock, with a stated value of $1,000 per Preferred Share and without par value (the "Series F Preferred Stock"), convertible into shares of Common Stock (the "Series F Conversion Shares") pursuant to the terms of the Certificate of Designations of the Series F Preferred Stock (the "Certificate of Designation"), and (ii) 6,651,885 warrants (the "February 2023 Warrants") to acquire up to an aggregate of 6,651,885 shares of Common Stock, subject to adjustment (the "February 2023 Warrant Shares"). The Conversion Price (as defined below) is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Conversion Price (subject to certain exceptions).

At closing, we received net proceeds from the February 2023 Offering of approximately $14.1 million, after deducting various fees and expenses. We intend to use the net proceeds from this offering for general corporate purposes.

Series F Preferred Shares

The terms of the Series F Preferred Shares are as set forth in the form of Certificate of Designation. The Series F Preferred Shares will be convertible into the Conversion Shares at the election of the holder at any time at an initial conversion price of $2.255 (the "Conversion Price"). The Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Conversion Price (subject to certain exceptions). The Company will be required to redeem the Series F Preferred Shares in 12 equal monthly installments, commencing on July 1, 2023. The amortization payments due upon such redemption are payable, at the company's election, in cash, or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Conversion Price then in effect and (ii) the greater of (A) 80% of the average of the three lowest closing prices of the Company's Common Stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) the Floor Price (as defined below). For purposes of the Certificate of Designation, the "Floor Price" means the lower of (x) $0.4014 and (y) 20% of the "Minimum Price" (as defined in Rule 5635 of the Rules of the Nasdaq Stock Market) on the date of the Nasdaq Stockholder Approval (as defined below) (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Stock Market. The Company may require holders to convert their Series F Preferred Shares into Conversion Shares if the closing price of the Common Stock exceeds $6.765 per share (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock exceeds $3,000,000 per day during the same period and certain equity conditions described in the Certificate of Designation are satisfied.

The holders of the Series F Preferred Shares will be entitled to dividends of 10% per annum, compounded monthly, which will be payable in cash or shares of Common Stock at the Company's option, in accordance with the terms of the Certificate of Designation. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Certificate of Designation), the Series F Preferred Shares will accrue dividends at the rate of 15% per annum. In connection with a Triggering Event, each holder of Series F Preferred Shares will be able to require the Company to redeem in cash any or all of the holder's Series F Preferred Shares at a premium set forth in the Certificate of Designation. Upon conversion or redemption, the holders of the Series F Preferred Shares are also entitled to receive a dividend make-whole payment. The holders of Series F Preferred Shares have no voting rights on account of the Series F Preferred Shares, other than with respect to certain matters affecting the rights of the Series F Preferred Shares.

The Company will be subject to certain affirmative and negative covenants regarding the incurrence of indebtedness, acquisition and investment transactions, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends (other than dividends pursuant to the Certificate of Designation), distributions or redemptions, and the transfer of assets, among other matters. There is no established public trading market for the Series F Preferred Shares and the Company does not intend to list the Series F Preferred Shares on any national securities exchange or nationally recognized trading system.

February 2023 Warrants

The February 2023 Warrants are exercisable immediately upon issuance at an exercise price of $2.255 per share (the "Exercise Price") and expire five years from the date of issuance. The Exercise Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Exercise Price (subject to certain exceptions). There is no established public trading market for the February 2023 Warrants and the Company does not intend to list the February 2023 Warrants on any national securities exchange or nationally recognized trading system

Nasdaq Stockholder Approval

Our ability to issue Series F Conversion Shares and February 2023 Warrant Shares using shares of Common Stock is subject to certain limitations set forth in the Certificate of Designation, including a limit on the number of shares that may be issued until the time, if any, that our stockholders have approved the issuance of more than 19.9% of our outstanding shares of Common Stock in accordance with the Nasdaq Listing Rules (the "Nasdaq Stockholder Approval"). In the February 2023 SPA we agreed to seek the Nasdaq Stockholder Approval at a meeting of stockholders. Certain stockholders, who beneficially held approximately 44% of our outstanding Common Stock as of the date of the February 2023 SPA, are party to a voting agreement pursuant to which, among other things, each such stockholder agreed, solely in their capacity as a stockholder, to vote all of their shares of Common Stock in favor of the approval of the Nasdaq Stockholder Approval and against any actions that could adversely affect our ability to perform our obligations under the February 2023 SPA. The voting agreement also places certain restrictions on the transfer of the shares of Common Stock held by the signatories thereto.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 is included at the end of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act") Rule 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we filed or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officers as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and board of directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management evaluated the effectiveness of our internal control over financial reporting based on the 2013 framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation management concluded that our internal control over financial reporting was effective as of December 31, 2022.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, which permits us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our last fiscal quarter ended December 31, 2022 that have materially affected, or are reasonably likely to affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Directors and Executive Officers

The following table sets forth the names, ages and positions of all of our directors and executive officers and the positions they hold as of the date hereof. Our directors serve until their successors are elected and shall qualify. Executive officers are elected by our board of directors (the "Board") and serve at the discretion of the directors.

Name	Age	Position with the Company
Chris Chapman, M.D.	70	Director, President and Chief Medical Officer
Adam Kaplin, M.D., Ph.D.	56	Chief Scientific Officer
Paul Rivard, Esq.	52	Chief Legal Officer
Ian Rhodes	50	Interim Chief Financial Officer
Craig Eagle, M.D.	56	Director
Christopher Schreiber	58	Director
Joshua Silverman	52	Director, Chairman of the Board
Jude Uzonwanne	48	Director
Bill J. White	62	Director

Set forth below is a brief description of the background and business experience of each of our executive officers and directors.

Chris Chapman, M.D., has been our director since April 16, 2021 and currently serves as our President and Chief Medical Officer. Dr. Chapman previously served as President and Chief Medical Officer of MyMD Pharmaceuticals (Florida), Inc., a Florida corporation previously known as MyMD Pharmaceuticals, Inc. ("MyMD Florida") effective as of November 1, 2020. Prior to joining MYMD Florida and since 1999, Dr. Chapman has also served as the Chief Executive Officer of Chapman Pharmaceutical Consulting, Inc., a consulting organization that provides support to pharmaceutical and biotech companies in North America, Europe, Japan, India and Africa on issues such as product safety, pharmacovigilance, medical devices, clinical trials and regulatory issues. In addition, from 2003-2004, Dr. Chapman served as the Associate Director of Drug Safety, Pharmacovigilance, and Clinical Operations for Organon Pharmaceuticals, where he was responsible for the supervision of four fellow M.D.s and 10 drug safety specialists. Prior to his time at Organon, Dr. Chapman served as Director, Medical Affairs, Drug Safety and Medical Writing Departments at Quintiles (currently known as IQVIA), from 1995-2003, where he grew the division from no employees to forty employees, including eight board certified physicians, four RNs, two pharmacists, eight medical writers and supporting staff. Dr. Chapman has also served on the board of directors of Rock Creek Pharmaceuticals, Inc. (f/k/a Star Scientific, Inc.) from 2007-2016, including as a member of the Audit Committee from 2007-2014, chairperson of the Compensation Committee from 2007-2014, and chairperson of the Executive Search Committee from 2007 to 2014. Dr. Chapman is an experienced executive and global medical expert and has extensive experience in providing monitoring and oversight for ongoing clinical trials including both adult and pediatric subjects. Dr. Chapman is also the founder of the Chapman Pharmaceutical Health Foundation, an IRS Section 501(c)(3) nonprofit organization established to solicit public funds and to support healthcare needs such as AIDS, diabetes, hypertension, lupus, sickle cell anemia, malaria and tuberculosis, which was organized in 2006. Dr. Chapman is a graduate of the Harvard Kennedy School of Cambridge, Massachusetts for financial management in 2020. Dr. Chapman received his M.D. degree from Georgetown University in Washington, D.C. in 1987, and completed his internship in Internal Medicine, a residency in Anesthesiology and a fellowship in Cardiovascular and Obstetric Anesthesiology at Georgetown. Dr. Chapman's qualifications to sit on the Board include his extensive experience and leadership roles within the pharmaceutical industry.

Adam Kaplin, M.D., Ph.D., has been our Chief Scientific Officer since April 16, 2021. He previously served as Chief Scientific Officer of MYMD Florida effective as of December 18, 2020. Since June 20, 2022, Dr. Kaplin has served as the President and Chief Scientific Officer of Mira Pharmaceuticals, which is developing novel synthetic cannabinoid analogs for a range of neuropsychiatric conditions. He has been an adjunct faculty member at Johns Hopkins since December 18, 2020, and he served as the Chief Psychiatric Consultant to the Johns Hopkins Multiple Sclerosis and Transverse Myelitis Centers from July 1, 2004 to December 18, 2020. Dr. Kaplin completed his undergraduate training at Yale University and his M.D. and Ph.D. training at the Johns Hopkins School of Medicine. His research training experience includes having trained in the labs of two Nobel Laureates and completed his Ph.D. and postdoctoral training in the Lab of Solomon Snyder, M.D., who was the 2005 recipient of the National Medal of Science (the highest science honor in the United States). Dr. Kaplin investigated the biological basis of the effects of the immune system on mood regulation and cognition, and he provided neuropsychiatric care to patients afflicted with such comorbidities. His research is focused on understanding the biological basis of depression and dementia and discovering new ways to diagnose prognosticate and treat these diseases.

Paul Rivard, Esq. has been our Chief Legal Officer since March 22, 2023, and prior to that time he served as Executive Vice President of Operations and General Counsel since April 16, 2021. He previously served as Executive Vice President of Operations and General Counsel of MYMD Florida effective as of September 21, 2020. Prior to joining MYMD Florida, Mr. Rivard was a principal shareholder of Banner Witcoff, a national law firm specializing in intellectual property law, from 2003–2020, and in that capacity also served as Chair of the firm's Prosecution Policies and Procedures Committee, developing and refining internal procedures, workflow, and docketing practices to improve efficiencies and mitigate risk. Before becoming a principal shareholder, Mr. Rivard was an associate at Banner Witcoff from 1998–2002. In addition, prior to his time at Banner Witcoff, Mr. Rivard served as a patent examiner for the United States Patent and Trademark Office from 1992–1998. Mr. Rivard brings more than 20 years of experience as intellectual property counsel for clients ranging from startups to Fortune 100 companies in the life sciences, chemical and consumer product industries, including primary outside intellectual property counsel for MYMD Florida from 2014–2020. Since May 2022, Mr. Rivard has also served as Executive Vice President and General Counsel of MIRA Pharmaceuticals, Inc., a privately held company developing a synthetic cannabinoid analog for treating chronic pain and anxiety, and from November 2021 until May 2022 served as President of that company. Mr. Rivard received his Juris Doctor from Catholic University of America's Columbus School of Law, graduating cum laude in 1998, and his B.S. in Chemical Engineering from Clarkson University in 1992.

Ian Rhodes has been our Interim Chief Financial Officer since February 1, 2021. Mr. Rhodes joined Brio Financial Group ("Brio") in January 2021. From March 2020 to December 2020, Mr. Rhodes served as the Interim CFO of Roadway Moving and Storage. From November 2018 to July 2019, he served as Interim CFO of Greyston Bakery and Foundation. From December 2016 to September 2018, Mr. Rhodes served as President, CEO and Director of GlyEco, Inc., and served as CFO of GlyEco, Inc. from February 2016 to December 2016. From May 2014 to January 2016, he served as CFO of Calmare Therapeutics. Mr. Rhodes began his career at PricewaterhouseCoopers, where he worked for 15 years. Mr. Rhodes holds a Bachelor of Science degree in Business Administration with a concentration in Accounting from Seton Hall University and is a licensed CPA in New York

Craig Eagle, M.D. has been our director since April 16, 2021. Dr. Eagle is currently the Chief Medical Officer of Guardant Health, Inc. since 2021. Previously, Dr. Eagle was Vice President of Oncology for Genentech, where he oversaw the medical programs across Genentech's oncology portfolio. Prior to his current role, Dr. Eagle worked in several positions at Pfizer from 2009 to 2019, including as the oncology business lead in the United Kingdom and Canada, the global lead for Oncology Strategic Alliances and Partnerships based in New York, and as the head of the Oncology Therapeutic Area Global Medical and Outcomes Group, including the U.S. oncology medical business. Through his multiple roles at Pfizer, Dr. Eagle delivered significant business growth and was involved in multiple strategic acquisitions and divestitures. In addition, while at Pfizer, Dr. Eagle oversaw extensive oncology clinical trial programs, multiple regulatory and payer approvals across Pfizer's oncology portfolio, health outcomes assessments and scientific collaborations with key global research organizations like the National Cancer Institute (NCI), and the European Organization for Research and Treatment of Cancer (EORTC), and led worldwide development of several compounds including celecoxib, aromasin, irinotecan, dalteparin and ozagomicin. Dr. Eagle currently serves as a member of the board of directors and chair of the Science and Policy Committee of Pierian Biosciences, a privately held life sciences company. Dr. Eagle attended Medical School at the University of New South Wales, Sydney, Australia and received his general internist training at Royal North Shore Hospital in Sydney. He completed his hemato-oncology and laboratory hematology training at Royal Prince Alfred Hospital in Sydney and was granted Fellowship in the Royal Australasian College of Physicians (FRACP) and the Royal College of Pathologists Australasia (FRCPA). After his training, Dr. Eagle performed basic research at the Royal Prince of Wales hospital to develop a new monoclonal antibody to inhibit platelets before moving into the pharmaceutical industry. Dr. Eagle's qualifications to sit on the Board include his long and successful career in the international pharmaceutical industry, his senior executive experience in areas such as business growth, strategic alliances and mergers and acquisition transactions, his experience as a member of both public and private company boards in the healthcare and life science industries, and his wealth of oncology experience, including leading and participating in scientific research, regulatory, pricing & re-imbursement negotiations for compounds in therapeutic areas.

Christopher C. Schreiber has been our director since August 8, 2017 and he previously at various times as our Chief Executive Officer, President, and Executive Chairman of the Board. Mr. Schreiber combines over 30 years of experience in the securities industry. As the Managing Director of Capital Markets at Taglich Brothers, Inc., Mr. Schreiber builds upon his extensive background in capital markets, deal structures, and syndications. Prior to his time at Taglich Brothers, Inc., he was a member of the board of directors of Paulson Investment Company, a 40-year-old full-service investment banking firm. In addition, Mr. Schreiber serves as a director and partner of Long Island Express North, an elite lacrosse training organization for teams and individuals. Mr. Schreiber is a graduate of Johns Hopkins University, where he received a bachelor's degree in political science. Mr. Schreiber's qualifications to sit on the Board include his financial expertise and his experience with the Company.

Joshua Silverman has been our director since September 6, 2018 and currently serves as Chairman of the Board. Prior to the completion of the Merger, Mr. Silverman was also the lead independent director. Mr. Silverman currently serves as the managing member of Parkfield Funding LLC. Mr. Silverman was the co-founder, and a principal and managing partner of Iroquois Capital Management, LLC ("Iroquois"), an investment advisory firm. Since its inception in 2003 until July 2016, Mr. Silverman served as co-chief investment officer of Iroquois. While at Iroquois, he designed and executed complex transactions, structuring and negotiating investments in both public and private companies and has often been called upon by the companies solve inefficiencies as they relate to corporate structure, cash flow, and management. From 2000 to 2003, Mr. Silverman served as co-chief investment officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as assistant press secretary to the president of the United States. Mr. Silverman currently serves as a director of Ayro Inc. and Petros Pharmaceutical, Inc., both of which are public companies. He previously served as a director of National Holdings Corporation from July 2014 through August 2016 and as a director of Marker Therapeutics, Inc. from August 2016 until October 2018. Mr. Silverman received his B.A. from Lehigh University in 1992. Mr. Silverman's qualifications to sit on the Board include his experience as an investment banker, management consultant and as a director of numerous public companies.

Jude Uzonwanne has been our director since April 16, 2021. Mr. Uzonwanne has been the Chief Executive Officer for Mira Pharmaceuticals Inc. since June 2022. Mira is a US based biopharmaceutical company focused on developing an oral FDA approved marijuana analog. Prior to Mira, he was the Chief Business Officer at a genetics-based healthcare company, 54gene from March 2021 to June 2022. Prior to 54gene, he was a Principal with ZS Associates, Inc., a consulting and professional services firm, a position he held from January 2021 to March 2021. Prior to joining ZS Associates, Mr. Uzonwanne was a Principal at IQVIA, Inc. from 2018 to 2020, where he served as the head of the firm's US Financial Investors Consulting practice and as management consulting lead for IQVIA's service to a top-6 global pharmaceutical company and select emerging biopharmaceutical companies. Prior to joining IQVIA, Mr. Uzonwanne served as Vice President (Associate Partner) at EY-Parthenon LLP from 2016 to 2018, where he managed teams advising corporate and private equity investors on a range of commercial due diligence targets in healthcare strategies and advised clients on growth accelerating strategies and investments. Prior to this role, Mr. Uzonwanne has worked for several other companies including Bain & Company, Dalberg Global Development Advisers, the Bill and Melinda Gates Foundation, and Monitor Group. Mr. Uzonwanne is a graduate of Swarthmore College (double Honors B.A in Economics and Political Science). Mr. Uzonwanne's qualifications to sit on the Board include his experience as a corporate strategy and transaction services adviser in the healthcare markets globally..

Bill J. White has been our director since August 8, 2017. Mr. White has more than 30 years of experience in financial management, operations and business development. Most recently he has served as the chief financial officer for ProPhase Labs Inc. (Nasdaq: PRPH), and the chief financial officer, chief operating officer, treasurer and secretary of Intellicheck, Inc., (Nasdaq: IDN). Prior to working at Intellicheck, Inc., he served 11 years as the chief financial officer, chief operating officer, secretary and treasurer of FocusMicro, Inc. ("FM"). As co-founder of FM, Mr. White played an integral role in growing the business from the company's inception to leading its international expansion into Dubai, UAE. Mr. White has broad domestic and international experience including managing rapid and significant growth, import/export, implementing tough cost management initiatives, exploiting new growth opportunities, merger and acquisitions, strategic planning, resource allocation, tax compliance and organization development. Prior to co-founding FM, he served 15 years in various financial leadership positions in the government sector. Mr. White started his career in Public Accounting. Mr. White holds a Bachelor of Arts in Business Administration from Washington State University and is a Certified Fraud Examiner. Mr. White was selected to serve on the Board of Directors in part because of his significant financial and accounting experience with public companies.

Family Relationships

There are no family relationships between any of our officers or directors.

Corporate Governance Reforms

On May 28, 2020, the United States District Court for the District of New Jersey approved that certain Amended Stipulation and Agreement of Settlement, dated October 1, 2019 (the "Settlement") among the settling parties in connection with a consolidated shareholder derivative action, Case No.: 2:18-cv-15992. Pursuant to the Settlement, effective as of July 21, 2020, we made various modifications to our corporate governance and business ethics practices as further discussed below.

Code of Ethics

We have adopted a Code of Business Ethics and Conduct, which applies to our Board, our executive officers and our employees, outlines the broad principles of ethical business conduct we adopted, covering subject areas such as, compliance with applicable laws and regulations, handling of books and records, public disclosure reporting, insider trading, conflicts of interest, competition and fair dealing, and other violations. Our Code of Business Ethics and Conduct is available on our website at www.mymd.com in the "Corporate Governance" section found under the "Investors" tab. Pursuant to the Settlement, we will conduct a review of our Code of Business Ethics and Conduct on an annual basis and to monitor compliance. We intend to disclose any amendments to, or waivers from, our Code of Business Ethics and Conduct at the same website address provided above.

In addition, pursuant to the Settlement, we adopted a Whistleblower Policy to encourage employees, officers and directors to bring forward ethical and legal violations. We have disclosed a copy of the Whistleblower Policy and intend to disclose any amendments to the Whistleblower Policy at the same website address provided above.

Pursuant to the Settlement, we formed a Risk and Disclosure Committee, which is served by the members of the Audit Committee, which reviews our ethics and risk program and internal controls over compliance and identifies and recommends to the Board any changes that it deemed necessary. The Risk and Disclosure Committee also monitors compliance with our Code of Business Ethics and Conduct, reviews and evaluates our public disclosures and disclosure controls and procedures and handle any whistleblower complaints.

Board Composition and Committees

Our Amended and Restated Certificate of Incorporation, as amended (the "Charter"), and our Amended and Restated Bylaws ("Bylaws") provide that our Board will consist of a number of directors to be determined from time to time solely by resolution of the Board, which is currently set at seven directors. Vacancies or newly created directorships resulting from an increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

We have no formal policy regarding Board diversity. Our Board believes that each director should have a basic understanding of the principal operational and financial objectives and plans and strategies of the Company, our results of operations and financial condition and relative standing in relation to our competitors. We take into consideration the overall composition and diversity of the Board and areas of expertise that director nominees may be able to offer, including business experience, knowledge, abilities and customer relationships. Generally, we will strive to assemble a Board that brings to us a variety of perspectives and skills derived from business and professional experience as we may deem are in our and our stockholders' best interests. In doing so, we will also consider candidates with appropriate non-business backgrounds.

Director Independence

We are currently listed on the Nasdaq Capital Market and therefore rely on the definition of independence set forth in the Nasdaq Listing Rules ("Nasdaq Rules"). Under the Nasdaq Rules, a director will only qualify as an "independent director" if, in the opinion of our Board, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Based upon information requested from and provided by each director concerning his background, employment, share ownership, and affiliations with other board members, shareholders, business, contractor and family relationships, as well as the amount of the compensation we pay to each director, we have determined that Mr. Silverman, Mr. White, Dr. Eagle, and Mr. Uzonwanne have no material relationships with us that would interfere with the exercise of independent judgment and are "independent directors" as that term is defined in the Nasdaq Listing Rules.

Pursuant to the Settlement, we also adopted amendments to our Bylaws to require that at least 50% of the Board will qualify as "independent directors" under the Nasdaq Rules and that the Chairman of the Board will be an independent director. Currently, more than 50% of the Board qualify as "independent directors" under the Nasdaq Rules. We are currently in compliance with these requirements.

Board Committees

The Board delegates various responsibilities and authority to different Board committees. Committees regularly report on their activities and actions to the full Board. Currently, the Board has established an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee and a Risk and Disclosure Committee. Committee assignments are re-evaluated annually. Each of these committees operates under a charter that has been approved by our Board. The current charter of each of these committees is available on our website at www.mymd.com in the "Corporate Governance" section under "Investors." Pursuant to the Settlement, we adopted several amendments to the committee charters. We disclosed these amendments and intend to disclose any future amendments to the charters of these committees at the same website address provided above.

The following table sets forth the membership of each of the Board committees listed above.

Name	Audit Committee	Compensation Committee	Nomination Corporate Governance Committee	Risk and Disclosure Committee
Chris Chapman, M.D.				
Craig Eagle, M.D.		Member		
Christopher C. Schreiber				
Joshua Silverman	Member	Chair	Member	Member
Jude Uzonwanne	Member	Member	Chair	Member
Bill J. White	Chair		Member	Chair

Audit Committee

Our Audit Committee is responsible for, among other matters:

- monitoring the integrity of our financial reporting process, including critical accounting policies and estimates, and systems of internal controls regarding finance, accounting, legal and regulatory compliance;
- monitoring the independence and performance of our independent auditors and our accounting personnel;
- providing an avenue of communication among the independent auditors, management, our accounting personnel, and the Board;
- appointing and providing oversight for the independent auditors engaged to perform the audit of the financial statements;
- discussing the scope of the independent auditors' examination;
- reviewing the financial statements and the independent auditors' report;
- reviewing areas of potential significant financial risk and exposure to us, to the extent that there are any, and assess the steps management has taken to monitor such risks;
- monitoring compliance with legal and regulatory requirements;
- soliciting recommendations from the independent auditors regarding internal controls and other matters;
- making recommendations to the Board;
- resolving any disagreements between management and the auditors regarding financial reporting;
- preparing the report required by Item 407(d) of Regulation S-K, as required by the rules of the SEC;
- reviewing issues regarding accounting principles and financial statement presentation (including any significant changes in our selection or application of accounting principles); and
- reviewing the effectiveness of any special accounting steps adopted in light of identified significant and/or material control deficiencies.

Our Audit Committee is composed of Bill J. White (Chair), Joshua Silverman, and Jude Uzonwanne. Our Board has determined that each of the current members of the Audit Committee is independent in accordance with Nasdaq Rules and Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our Board has also reviewed the education, experience and other qualifications of each member of the Audit Committee. Based upon that review, our Board has determined that Mr. White qualifies as an "audit committee financial expert," as defined by the rules of the SEC.

Compensation Committee

Our Compensation Committee is responsible for, among other matters:

- reviewing and approving on an annual basis goals and objectives relevant to our Chief Executive Officer's compensation, evaluating our Chief Executive Officer's performance in light of those goals and objectives, and determining the compensation of our Chief Executive Officer based on this evaluation or recommending such goals, objectives and compensation of our Chief Executive Officer's to the Board for its approval;

- reviewing and approving on an annual basis the compensation of our executive officers other than our Chief Executive Officer;

- reviewing on an annual basis, the fees and equity compensation paid to the Company's non-employee directors for service on the Board and Board committees and recommending any changes to the Board as necessary;

- selecting, retaining and terminating any compensation consultant to be used by the Compensation Committee or us to assist in the evaluation of the compensation of non-employee directors, the Chief Executive Officer or the other executive officers and approving such compensation consultant's fees and other retention terms, and overseeing the work of such compensation consultant;

- reviewing, approving and, when appropriate, making recommendations to the Board for approval, incentive-compensation programs and equity-based plans and the adoption of or material changes in material employee benefit, bonus, severance and other compensation plans;

- reviewing and approving and, when appropriate, recommending to the Board for approval, any employment agreements and change in control agreements for each of our executive officers and any other officers recommended by the Chief Executive Officer or the Board, which includes the ability to adopt, amend and terminate such agreements, arrangements or plans;

- determining and approving the options and other equity-based compensation to be granted to executive officers, including the Chief Executive Officer, and shall recommend to the Board for approval options and other equity-based compensation to be granted to non-employee directors, and

- in conjunction with the Chief Executive Officer, determining the issuance of options and other equity-based compensation under the Company's incentive compensation and other stock-based plans to all other officers and employees.

Our Compensation Committee is composed of Joshua Silverman (Chair), Craig Eagle, M.D., and Jude Uzonwanne. Our Board has determined that each of the current members of the Compensation Committee is independent in accordance with Nasdaq Rules. The Compensation Committee may delegate the determination with respect to persons other than officers to the Chief Executive Officer but will approve the aggregate amount granted to all employees and all new hire grants.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee is responsible for, among other matters:

- overseeing the administration of our Code of Business Ethics and Conduct and related policies;

- leading the search for and recommending individuals qualified to become members of the Board, and selecting director nominees to be presented for election by the shareholders at each annual meeting;

- ensuring, in cooperation with the Compensation Committee, that no agreements or arrangements are made with directors or relatives of directors for providing professional or consulting services to us or our affiliate or individual officer or one of their affiliated, without appropriate review and evaluation for conflicts of interest;

- ensuring that Board members do not serve on more than six other for-profit public company boards that have a class of securities registered under the Exchange Act in addition to the Board;

- reviewing the Board's committee structure and to recommend to the Board for its approval;
- reviewing recommendations received from shareholders for persons to be considered for nomination to the Board;
- monitoring compliance with our corporate governance guidelines;
- developing and implementing an annual self-evaluation of the Board, both individually and as a Board, and of its committees;
- reviewing and recommending changes to procedures whereby shareholders may communicate with the Board;
- assessing the independence of directors annually and report to the Board;
- recommending to the Board for its approval, the leadership structure of the Board, including whether the Board should have an executive or non-executive Chairman, whether the roles of Chairman and Chief Executive Officer should combine, and whether a Lead Director of the Board should be appointed; provided that such structure shall be subject to the bylaws of the Company then in effect.

Our Nominating and Corporate Governance Committee is composed of Jude Uzonwanne (Chair), Bill J. White, and Joshua Silverman. Each of the current appointed Nominating and Corporate Governance Committee members is "independent" within the meaning of the Nasdaq Stock Market Rules.

Risk and Disclosure Committee

Our Risk and Disclosure Committee is responsible for, among other matters:

- reviewing the effectiveness of our Code of Ethics annually, including our ethics and risk program, and recommending to the Board any changes to our policies and internal controls as necessary;
- monitoring compliance with our Code of Ethics, and specifically reviewing and evaluating our public disclosures and annually reviewing and evaluating our disclosure controls and procedures;
- reviewing and approving any waivers of provisions of the Code of Ethics;
- addressing any whistleblower complaints and ensuring that all whistleblower complaints are appropriately reviewed by the Risk and Disclosure Committee and that any appropriate remedial action if necessary is taken based on the results of its review; and
- ensuring that non-retaliation policies are instituted and strictly complied with in order to protect any Company employee who reports a whistleblower complaint.

Our Risk and Disclosure Committee is composed of Bill J. White (Chair), Joshua Silverman and Jude Uzonwanne. Our Board has determined that each of the current members of the Risk and Disclosure Committee is independent in accordance with Nasdaq Rules.

Involvement in Certain Legal Proceedings

There have been no material legal proceedings that would require disclosure under the federal securities laws that are material to an evaluation of the ability or integrity of our directors or executive officers, or in which any director, officer, nominee or principal stockholder, or any affiliate thereof, is a party adverse to us or has a material interest adverse to us.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our directors and officers, and persons who own more than ten percent of our Common Stock, to file with the SEC initial reports of ownership and reports of changes in ownership of our Common Stock.

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2022, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

Item 11. Executive Compensation.

The following is a discussion of the material components of the executive compensation arrangements of our named executive officers, comprised of (i) our principal executive officer, (ii) the two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of the 2022 fiscal year and whose salary, as determined by Regulation S-K, Item 402, exceeded $100,000 and (iii) up to two most highly compensated former executive officers who were no longer serving as an executive officer at the end of the 2022 fiscal year (the individuals falling within categories (i), (ii) and (iii) are collectively referred to as the "named executive officers").

Our named executive officers for 2022 were as follows:

- Chris Chapman, M.D., President and Chief Medical Officer
- Adam Kaplin, M.D., Ph.D., Chief Scientific Officer
- Paul Rivard, Esq., Chief Legal Officer and Former Executive Vice President of Operations and General Counsel

Effective as of 4:05 pm Eastern Time on April 16, 2021, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a Reverse Stock Split of the issued and outstanding shares of our Common Stock, at a ratio of 1 for 2. The stock awards listed below have been adjusted to give effect to the Reverse Stock Split.

Summary Compensation Table

Name and Principal Position	Notes	Year	Salary	Bonus	Stock Awards[1]	Option Awards[2]	All Other Compensation[3]	Total
Christopher Chapman, M.D.[4]. President, Chief Medical Officer		2022	$161,827	$100,000	-	-	-	$ 261,827
		2021	165,000	121,540	4,854,000[7]	-	-	5,140,540
Adam Kaplin, M.D., PhD[5]		2022	245,153	100,000	-	-	8,580	353,733
Chief Scientific Officer		2021	250,000	126,724	4,854,000[7]	-	-	5,230,724
Paul Rivard, Esq.[6]		2022	161,827	20,000	-	-	6,412	188,239
Chief Legal Officer		2021	165,000	60,000	1,618,000[8]	-	-	1,843,000

(1) In accordance with SEC rules, this column reflects the aggregate fair value of stock awards granted during the fiscal year ended December 31, 2021, computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification ("FASB ASC") Topic 718 for share-based compensation transactions.

(2) In accordance with SEC rules, this column reflects the aggregate fair value of option awards granted during the fiscal year ended December 31, 2020, computed as of their respective grant dates in accordance with FASB ASC Topic 718 for share-based compensation transactions.

(3) This column reflects the matching contribution paid to participants of the MyMD Pharmaceuticals 401(k) PS Plan (the "401(k) Plan").

(4) Dr. Chapman was appointed President and Chief Medical Officer of MyMD effective April 16, 2021. Prior to the Merger, Dr. Chapman served as the President and Chief Medical Officer of MyMD Florida effective November 1, 2020.

(5) Dr. Kaplin was appointed Chief Scientific Officer of MyMD effective April 16, 2021. Prior to the Merger, Dr. Kaplin served as Chief Scientific Officer of MyMD Florida effective December 18, 2020.

(6) On April 16, 2021, Mr. Rivard entered into an employment agreement, under which he would receive an annual salary of $165,000. On March 22, 2023, Mr. Rivard was appointed as Chief Legal Officer and his annual salary was increased to $275,000, retroactively to January 1, 2023. Prior to the Merger, Mr. Rivard served as Executive Vice President of Operations and General Counsel of MyMD Florida effective September 21, 2020.

(7) On October 14, 2021, the Company granted 600,000 restricted stock units ("RSUs") to each of Dr. Chapman and Dr. Kaplin..

(8) On October 14, 2021, the Company granted 200,000 RSUs to Mr. Rivard.

Narrative Disclosure to Summary Compensation Table

We have entered into employment agreements with each of our Named Executive Officers.

Employment of Chris Chapman, M.D.

Pre-Merger Employment Agreement

Effective November 1, 2020, MyMD Florida and Dr. Chapman entered into an employment agreement, which was subsequently amended by that certain First Amendment to Employment Agreement, dated December 18, 2020, that certain Second Amendment to Employment Agreement dated January 8, 2021, and that certain Third Amendment to Employment Agreement dated February 11, 2021 (such agreement, as amended, the "Chapman Employment Agreement"), pursuant to which Dr. Chapman was appointed President and Chief Medical Officer of MyMD Florida. Under the Chapman Employment Agreement, Dr. Chapman is entitled to an annual base salary of $165,000, payable monthly. Dr. Chapman is also eligible to receive bonus compensation in the form of lump-sum cash payments made within 30 days following the completion of certain specified "Bonus Events" (as defined in the Chapman Employment Agreement). The aggregate amount of bonus compensation payable to Dr. Chapman upon achievement of all specified Bonus Events is $800,000. In addition, Dr. Chapman is eligible to receive additional bonus compensation in connection with his annual performance, determined in the sole discretion of MyMD Florida's board of directors. Pursuant to and on the effective date of the Chapman Employment Agreement, Dr. Chapman was also granted options to purchase 250,000 shares of MyMD Florida Common Stock, at an exercise price of $1.00 per share. (After giving effect to the Exchange Ratio and the Reverse Stock Split, such MyMD Florida options became options to purchase 96,475 shares of the Company's Common Stock at an exercise price of $2.59.) Such options all vested immediately upon grant. The options had an original term of lasting until the earlier of (i) ten years from the date of grant or (ii) the second-year anniversary of the effective date of a "Reorganization Event" as defined in the MyMD Pharmaceuticals, Inc. Amended and Restated 2016 Equity Incentive Plan (as amended, the "MyMD Florida Incentive Plan") (the practical effect of which makes the term of such options expire on the second-year anniversary of the effective date of the merger, which occurred on April 16, 2021). MyMD Florida also agreed to provide and cover the cost of health insurance and disability policies for Dr. Chapman during the term of employment under the Chapman Employment Agreement.

Dr. Chapman's employment with MyMD Florida pursuant to the Chapman Employment Agreement commenced as of the effective date of the Chapman Employment Agreement and was to continue for a period of two years, unless earlier terminated by either party, with such termination effective upon the provision of written notice to the other party. In the event of termination of Dr. Chapman's employment with MyMD Florida for cause, MyMD Florida was to pay to Dr. Chapman his monthly base salary for a period of three months following the date that notice of termination of employment is provided, which would be the full extent of MyMD Florida's obligations with respect to severance payments to Dr. Chapman under the Chapman Employment Agreement.

The Chapman Employment Agreement also contains certain standard confidentiality, work for hire and assignment of inventions provisions.

On August 2, 2020, Dr. Chapman received a discretionary grant of options to purchase 200,000 shares of MyMD Florida Common Stock, at an exercise price of $1.00 per share. All such options vested immediately upon grant. The options had an original term of ten years from the date of grant, subject to certain events described in the applicable award agreement, including Dr. Chapman's, death, disability, retirement or an "Event of Cause" (as defined in the applicable award agreement). In connection with the Merger Agreement, certain terms of such options were amended. After giving effect to the Exchange Ratio and the Reverse Stock Split, such MyMD Florida options became options to purchase 77,180 shares of the Company's Common Stock at an exercise price of $2.59.

Post-Merger Employment Agreement

Immediately following the effective time of the Merger, the Board appointed Dr. Chapman to the offices of President and Chief Medical Officer on the terms of the Chapman Employment Agreement.

On November 24, 2021, the Company and Dr. Chapman entered into a Fourth Amendment to Employment Agreement. This agreement provided that certain performance criteria applicable to Dr. Chapman's bonus compensation under the Chapman Employment Agreement would be waived and deemed to have been achieved, and that Dr. Chapman would be entitled to a bonus payment of $100,000 as a result. On August 30, 2022, the Company and Dr. Chapman entered into a Fifth Amendment to amend one of the performance criteria under the Chapman Employment Agreement, upon the achievement of which by the Company Dr. Chapman would be entitled to an additional bonus payment of $100,000. On February 1, 2023, the Company and Dr. Chapman entered into a Sixth Amendment providing for Dr. Chapman's annual base salary to be set at $310,000, effective retroactively to January 1, 2023.

Employment of Adam Kaplin, M.D., Ph.D.

Pre-Merger Employment Agreement

Effective December 18, 2020, MyMD Florida and Dr. Kaplin entered into an employment agreement, which was subsequently amended by that certain First Amendment to Employment Agreement, dated February 11, 2021 (such agreement, as amended, the "Kaplin Employment Agreement"), pursuant to which Dr. Kaplin was appointed Chief Scientific Officer of MyMD Florida. Under the Kaplin Employment Agreement, Dr. Kaplin is entitled to an annual base salary of $250,000, payable monthly. Dr. Kaplin is also eligible to receive bonus compensation in the form of lump-sum cash payments made within 30 days following the completion of certain specified "Bonus Events" (as defined in the Kaplin Employment Agreement). The aggregate amount of bonus compensation payable to Dr. Kaplin upon achievement of all specified Bonus Events is $800,000. In addition, Dr. Kaplin is eligible to receive additional bonus compensation in connection with his annual performance, determined in the sole discretion of MyMD Florida's board of directors. On the effective date of the Kaplin Employment Agreement, Dr. Kaplin received a signing bonus in the form of a lump-sum cash payment in the amount of $100,000 and was also granted options to purchase 400,000 shares of MyMD Florida Common Stock, at an exercise price of $1.00 per share. (After giving effect to the Exchange Ratio and the Reverse Stock Split, such MyMD Florida options became options to purchase 154,360 shares of the Company's Common Stock at an exercise price of $2.59.) Such options all vested immediately upon grant. The options had an original term of lasting until the earlier of (i) ten years from the date of grant or (ii) the second-year anniversary of the effective date of a "Reorganization Event" as defined in the MyMD Florida Incentive Plan (the practical effect of which makes the term of such options expire on the second-year anniversary of the effective date of the merger, which occurred on April 16, 2021). MyMD Florida also agreed to provide and cover the cost of health insurance and disability policies for Dr. Kaplin during the term of employment under the Kaplin Employment Agreement.

Dr. Kaplin's employment with MyMD Florida pursuant to the Kaplin Employment Agreement commenced on December 18, 2020 and was to continue for a term of two years unless earlier terminated by either party, with such termination effective upon the provision of written notice to the other party. In the event of termination of Dr. Kaplin's employment with MyMD Florida for cause, MyMD Florida was to pay to Dr. Kaplin his monthly base salary for a period of three months following the date that notice of termination of employment is provided, which would be the full extent of MyMD Florida's obligations with respect to severance payments to Dr. Kaplin under the Kaplin Employment Agreement.

The Kaplin Employment Agreement also contained certain standard confidentiality, work for hire and assignment of inventions provisions.

Post-Merger Employment Agreement

Immediately following the effective time of the Merger, the Board appointed Dr. Kaplin to the office of Chief Scientific Officer on the terms of the Kaplin Employment Agreement.

On November 24, 2021, the Company and Dr. Kaplin entered into a Second Amendment to Employment Agreement. This agreement provided that certain performance criteria applicable to Dr. Kaplin's bonus compensation under the Kaplin Employment Agreement would be waived and deemed to have been achieved, and that Dr. Kaplin would be entitled to a bonus payment of $100,000 as a result. On August 30, 2022, the Company and Dr. Kaplin entered into a Third Amendment to amend one of the performance criteria under the Kaplin Employment Agreement, upon the achievement of which by the Company Dr. Kaplin would be entitled to an additional bonus payment of $100,000.

Employment of Paul Rivard, Esq.

Pre-Merger Employment Agreement

Effective September 21, 2020, MyMD Florida and Mr. Rivard entered into an employment agreement (such agreement, as amended, the "Rivard Employment Agreement"), pursuant to which Mr. Rivard was appointed Executive Vice President of Operations and General Counsel of MyMD Florida. Under the Rivard Employment Agreement, Mr. Rivard is entitled to an annual base salary of $165,000, payable monthly. Mr. Rivard is also eligible to receive bonus compensation in the form of lump-sum cash payments made within 30 days following the completion of certain specified "Bonus Events" (as defined in the Rivard Employment Agreement). The aggregate amount of bonus compensation payable to Mr. Rivard upon achievement of all specified Bonus Events is $160,000. In addition, Mr. Rivard is eligible to receive additional bonus compensation in connection with his annual performance, determined in the sole discretion of MyMD Florida's board of directors. On the effective date of the Rivard Employment Agreement, Mr. Rivard was granted options to purchase 200,000 shares of MyMD Florida Common Stock, at an exercise price of $1.00 per share. (After giving effect to the Exchange Ratio and the Reverse Stock Split, such MyMD Florida options became options to purchase 77,180 shares of the Company's Common Stock at an exercise price of $2.59.) Such options all vested immediately upon grant. The options had an original term of lasting until the earlier of (i) ten years from the date of grant or (ii) the second-year anniversary of the effective date of a "Reorganization Event" as defined in the MyMD Florida Incentive Plan (the practical effect of which makes the term of such options expire on the second-year anniversary of the effective date of the merger, which occurred on April 16, 2021). MyMD Florida also agreed to provide and cover the cost of health insurance and disability policies for Mr. Rivard during the term of employment under the Rivard Employment Agreement.

Mr. Rivard's employment with MyMD Florida pursuant to the Rivard Employment Agreement commenced on September 21, 2020 and was to continue until terminated by either party, with such termination effective upon the provision of written notice to the other party. In the event of termination of Mr. Rivard employment with MyMD Florida, MyMD Florida was to pay to Mr. Rivard his monthly base salary for a period of three months following the date that notice of termination of employment is provided.

The Rivard Employment Agreement also contained certain standard confidentiality, work for hire and assignment of inventions provisions.

Post-Merger Employment Agreement

Immediately following the effective time of the Merger, the Board appointed Mr. Rivard to the office of Executive Vice President of Operations and General Counsel on the terms of the Rivard Employment Agreement.

On March 22, 2023, Mr. Rivard was appointed Chief Legal Officer and his annual salary was increased to $275,000, retroactively to January 1, 2023.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning the outstanding equity awards that have been previously awarded to each of our Named Executive Officers and which remain outstanding as of December 31, 2022:

Named Executive Officer	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Option exercise price	Option expiration date[1]	Number of shares or units of stock that have not vested	Market value of shares or units of stock that have not vested
Christopher Chapman, M.D.....	38,590[3]	-	$ 2.59	4/16/2023	-	$ -
President, Chief Medical Officer	77,180[4]	-	2.59	4/16/2023	-	-
	77,180[5]	-	2.59	4/16/2023	-	-
	96,475[6]	-	2.59	4/16/2023	-	-
	-	-	-	n/a	600,000[2]	4,854,000
Adam Kaplin, M.D., PhD	154,360[7]	-	2.59	4/16/2023	-	-
Chief Scientific Officer	-	-	-	n/a	600,000[2]	4,854,000
Paul Rivard, Esq	77,180[8]	-	2.59	4/16/2023	-	-
Chief Legal Officer	-	-	-	n/a	200,000[2]	1,618,000

(1) All such options vested immediately upon grant. The options had an original term of lasting until the earlier of (i) ten years from the date of grant or (ii) the second-year anniversary of the effective date of a "Reorganization Event" as defined in the MyMD Florida Incentive Plan (the practical effect of which makes the term of such options expire on the second-year anniversary of the effective date of the merger, which occurred on April 16, 2021).

(2) Granted on October 14, 2021. These RSUs vest at various times based upon the market capitalization of the company.

(3) Granted on December 3, 2018.

(4) Granted on December 31, 2019.

(5) Granted on August 3, 2020.

(6) Granted on October 26, 2020.

(7) Granted on December 18, 2020.

(8) Granted on August 21, 2020.

Director Compensation

The following table presents the total compensation for each person who served as a member of our Board during 2022. All compensation paid to Dr. Chapman during 2022 is reported under the Summary Compensation Table. Other than as set forth in the table and described more fully below, we did not pay any compensation, reimburse any expense of, make any equity awards or non-equity awards to, or pay any other compensation to any of the other members of our Board in such period.

Name	Fees earned or paid in cash	Stock Awards[1]	All Other Compensation[2]	Total
Josh Silverman[3]	$ 216,000	$ -	-	$ 216,000
Bill J. White[4]	96,000	-	-	96,000
Craig Eagle, M.D[5]	96,000	-	-	96,000
Jude Uzonwanne[6]	96,000	-	-	96,000
Christopher Schreiber[7]	-	-	306,000	306,000

(1) In accordance with SEC rules, this column reflects the aggregate fair value of stock awards granted during the fiscal year ended December 31, 2022, computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for share-based compensation transactions.
(2) This column includes salaries and matching contributions paid to participants of the 401(k) Plan for non-executive employee members of the Board.
(3) As of December 31, 2022, Mr. Silverman had 673,776 outstanding RSUs.
(4) As of December 31, 2022, Mr. White had 223,776 outstanding RSUs.
(5) As of December 31, 2022, Dr. Eagle had 150,000 outstanding RSUs.
(6) As of December 31, 2022, Mr. Uzonwanne had 150,000 outstanding RSUs.
(7) On January 24, 2020, Mr. Schreiber entered into an employment agreement with the Company, under which he would receive an annual salary of $300,000. Since then he has served the Company in various positions, and his employment agreement with the Company remains in effect. As of December 31, 2022, Mr. Schreiber had 238,238 outstanding RSUs.

Narrative Disclosure to Director Compensation Table

As approved by the Compensation Committee of the Board on March 29, 2019, beginning in April 2019, each serving director who is not also holding a position as an executive officer is paid $8,000 per month. On or around May 2020, the Compensation Committee of the Board approved payments to Mr. Silverman of $18,000 per month, beginning in May 2020. All director fees were paid on a monthly basis. There was no other compensation for directors during the year ended December 31, 2022.

On October 14, 2021, the Compensation Committee of the Board authorized the issuance of 2,795,000 restricted stock units with a fair market value of $8.09 per RSU to the directors and key employees of the Company. These RSUs will vest in thirds when certain market capitalization milestones are met and maintained for twenty consecutive trading sessions. Upon achievement of a vesting milestone, the expenses related to the vested RSUs will be recorded at the fair market value of the Company's Common Stock on the date of vesting.

Equity Compensation Plans

2021 Equity Incentive Plan

Pursuant to the Merger Agreement, at the effective time of the Merger, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"), which was approved by the Company's stockholders on April 15, 2021. The 2021 Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, and other awards which may be granted singly, in combination or in tandem, and which may be paid in cash or shares of Common Stock. At the effective time of the Merger, the number of shares of Common Stock that were reserved for issuance pursuant to awards under the 2021 Plan was 7,228,184 shares. As of December 31, 2022, 4,078,977 shares remain available for issuance under the 2021 Plan.

Purpose. The purpose of the 2021 Plan is to enable the Company to remain competitive and innovative in its ability to attract and retain the services of key employees, key contractors, and non-employee directors of the Company or any of its subsidiaries. The 2021 Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, and other awards, which may be granted singly, in combination, or in tandem, and which may be paid in cash or shares of the Company's Common Stock. The 2021 Plan is expected to provide flexibility to the Company's compensation methods in order to adapt the compensation of key employees, key contractors, and non-employee directors to a changing business environment, after giving due consideration to competitive conditions and the impact of applicable tax laws.

Effective Date and Expiration. The 2021 Plan was approved by the Company's Board of Directors on March 18, 2021 (the "Plan Effective Date") and approved by the Company's stockholders on April 15, 2021. The 2021 Plan will terminate on the tenth anniversary of the Plan Effective Date, unless sooner terminated by the Company's Board of Directors. No awards may be made under the 2021 Plan after its termination date, but awards made prior to the termination date may extend beyond that date in accordance with their terms.

Share Authorization. At the effective time of the Merger, the number of shares of Common Stock that were reserved for issuance pursuant to awards under the 2021 Plan was 7,228,184 shares, 100% of which may be delivered as incentive stock options. Shares to be issued may be made available from authorized but unissued shares of the Company's Common Stock, shares held by the Company in its treasury, or shares purchased by the Company on the open market or otherwise. During the term of the 2021 Plan, the Company will at all times reserve and keep enough shares available to satisfy the requirements of the 2021 Plan. If an award under the 2021 Plan is cancelled, forfeited, or expires, in whole or in part, the shares subject to such forfeited, expired, or cancelled award may again be awarded under the 2021 Plan. Awards that may be satisfied either by the issuance of Common Stock or by cash or other consideration shall be counted against the maximum number of shares that may be issued under the 2021 Plan only during the period that the award is outstanding or to the extent the award is ultimately satisfied by the issuance of shares. An award will not reduce the number of shares that may be issued pursuant to the 2021 Plan if the settlement of the award will not require the issuance of shares, as, for example, a stock appreciation right that can be satisfied only by the payment of cash. Shares of Common Stock that are otherwise deliverable pursuant to an award under the 2021 Plan that are withheld in payment of the option price of an option or for payment of applicable employment taxes and/or withholding obligations resulting from the award shall be treated as delivered to the award recipient and shall be counted against the maximum number of shares of our Common Stock that may be issued under the 2021 Plan. Only shares forfeited back to the Company or cancelled on account of termination, expiration, or lapse of an award shall again be available for grant of incentive stock options under the 2021 Plan but shall not increase the maximum number of shares described above as the maximum number of shares of the Company's Common Stock that may be delivered pursuant to incentive stock options.

Administration. The 2021 Plan is administered by the compensation committee of the Board or such other committee of the board as is designated by it to administer the 2021 Plan (the "2021 Plan Administration Committee"). If necessary to satisfy the requirements of Rule 16b-3 promulgated under the Exchange Act, membership on the 2021 Plan Administration Committee shall be limited to those members of the Board who are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act. At any time there is no 2021 Plan Administration Committee to administer the 2021 Plan, any reference to the 2021 Plan Administration Committee is a reference to the Board.

The 2021 Plan Administration Committee will determine the persons to whom awards are to be made; determine the type, size, and terms of awards; interpret the 2021 Plan; establish and revise rules and regulations relating to the 2021 Plan as well as any sub-plans for awards to be made to eligible award recipients who are not resident in the United States; establish performance goals for awards and certify the extent of their achievement; and make any other determinations that it believes are necessary for the administration of the 2021 Plan. The 2021 Plan Administration Committee may delegate certain of its duties to one or more of the Company's officers as provided in the 2021 Plan. Notwithstanding the foregoing, to the extent necessary to satisfy the requirements of Rule 16b-3 promulgated under the Exchange Act, any function relating to an award recipient subject to the reporting requirements of Section 16 of the Exchange Act shall be performed solely by the 2021 Plan Administration Committee.

Upon the adoption of the 2021 Plan, awards granted under the 2018 Plan (as defined below) remained in full force and effect under the terms and conditions of the 2018 Plan and in accordance with each award's respective terms.

Eligibility. Employees (including any employee who is also a director or an officer), contractors, and non-employee directors of the Company or any of its subsidiaries, whose judgment, initiative, and efforts contributed to or may be expected to contribute to the Company's successful performance, are eligible to participate in the 2021 Plan. As of the December 31, 2022, the Company had 9 employees, 0 contractors, and 4 non-employee directors who would be eligible for awards under the 2021 Plan.

Stock Options. The 2021 Plan Administration Committee may grant either incentive stock options ("ISOs") qualifying under Section 422 of the Code, or nonqualified stock options, provided that only employees of the Company and its subsidiaries (excluding subsidiaries that are not corporations) are eligible to receive ISOs. Stock options may not be granted with an option price less than 100% of the fair market value of a share of Common Stock on the date the stock option is granted. If an ISO is granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of the Company's stock (or of any parent or subsidiary), the option price shall be at least 110% of the fair market value of a share of Common Stock on the date of grant. The 2021 Plan Administration Committee will determine the terms of each stock option at the time of grant, including, without limitation, the methods by or forms in which shares will be delivered to participants or registered in their names. The maximum term of each option, the times at which each option will be exercisable, and provisions requiring forfeiture of unexercised options at or following termination of employment or service generally are fixed by the 2021 Plan Administration Committee, except that the 2021 Plan Administration Committee may not grant stock options with a term exceeding 10 years or, in the case of an ISO granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of our stock (or of any parent or subsidiary), a term exceeding five years.

Recipients of stock options may pay the option price (i) in cash, check, bank draft, or money order payable to the order of the Company; (ii) by delivering to the Company shares of the Company's Common Stock (including restricted stock) already owned by the participant having a fair market value equal to the aggregate option price and that the participant has not acquired from the Company within six months prior to the exercise date; (iii) by delivering to the Company or its designated agent an executed irrevocable option exercise form, together with irrevocable instructions from the participant to a broker or dealer, reasonably acceptable to the Company, to sell certain of the shares purchased upon the exercise of the option or to pledge such shares to the broker as collateral for a loan from the broker and to deliver to the Company the amount of sale or loan proceeds necessary to pay the purchase price; (iv) by requesting that Company withhold the number of shares otherwise deliverable upon exercise of the stock option by the number of shares having an aggregate fair market value equal to the aggregate option price at the time of exercise (*i.e.,* a cashless net exercise); and (v) by any other form of valid consideration that is acceptable to the 2021 Plan Administration Committee in its sole discretion. No dividends or dividend equivalent rights may be paid or granted with respect to any stock options granted under the 2021 Plan.

Stock Appreciation Rights. The 2021 Plan Administration Committee is authorized to grant stock appreciation rights ("SARs") as a stand-alone award, or freestanding SARs, or in conjunction with options granted under the 2021 Plan, or tandem SARs. SARs entitle a participant to receive an amount equal to the excess of the fair market value of a share of Common Stock on the date of exercise over the fair market value of a share of our Common Stock on the date of grant. The exercise price of a SAR cannot be less than 100% of the fair market value of a share of the Company's Common Stock on the date of grant. The 2021 Plan Administration Committee will determine the terms of each SAR at the time of the grant, including, without limitation, the methods by or forms in which shares will be delivered to participants or registered in their names. The maximum term of each SAR, the times at which each SAR will be exercisable, and provisions requiring forfeiture of unexercised SARs at or following termination of employment or service generally are fixed by the 2021 Plan Administration Committee, except that no freestanding SAR may have a term exceeding 10 years and no tandem SAR may have a term exceeding the term of the option granted in conjunction with the tandem SAR. Distributions to the recipient may be made in Common Stock, cash, or a combination of both as determined by the 2021 Plan Administration Committee. No dividends or dividend equivalent rights may be paid or granted with respect to any SARs granted under the 2021 Plan.

Restricted Stock and Restricted Stock Units. The 2021 Plan Administration Committee is authorized to grant restricted stock and restricted stock units. Restricted stock consists of shares of our Common Stock that may not be sold, assigned, transferred, pledged, hypothecated, encumbered, or otherwise disposed of, and that may be forfeited in the event of certain terminations of employment or service, prior to the end of a restricted period as specified by the 2021 Plan Administration Committee. Restricted stock units are the right to receive shares of Common Stock at a future date in accordance with the terms of such grant upon the attainment of certain conditions specified by the 2021 Plan Administration Committee, which include a substantial risk of forfeiture and restrictions on their sale or other transfer by the participant. The 2021 Plan Administration Committee determines the eligible participants to whom, and the time or times at which, grants of restricted stock or restricted stock units will be made; the number of shares or units to be granted; the price to be paid, if any; the time or times within which the shares covered by such grants will be subject to forfeiture; the time or times at which the restrictions will terminate; and all other terms and conditions of the grants. Restrictions or conditions could include, but are not limited to, the attainment of performance goals (as described below), continuous service with the Company, the passage of time, or other restrictions and conditions. Except as otherwise provided in the 2021 Plan or the applicable award agreement, a participant shall have, with respect to shares of restricted stock, all of the rights of a shareholder of the Company holding the class of Common Stock that is the subject of the restricted stock, including, if applicable, the right to vote the Common Stock and the right to receive any dividends thereon, provided that (i) any dividends with respect to such a restricted stock award may be withheld by the Company for the participant's account until such award is vested, subject to such terms as determined by the 2021 Plan Administration Committee, and (ii) any dividends so withheld by the Company and attributable to any particular restricted stock award shall be distributed to such participant in cash or, at the discretion of the 2021 Plan Administration Committee, in shares of the Company's Common Stock having a fair market value equal to the amount of such dividends, if applicable, upon vesting of the award. If, however, such restricted stock award is forfeited, the participant's rights as to such dividends will also be forfeited.

Performance Awards. The 2021 Plan Administration Committee may grant performance awards payable at the end of a specified performance period in cash, shares of Common Stock, units, or other rights based upon, payable in, or otherwise related to the Company's Common Stock. Payment will be contingent upon achieving pre-established performance goals (as discussed below) by the end of the applicable performance period. The 2021 Plan Administration Committee will determine the length of the performance period, the maximum payment value of an award, and the minimum performance goals required before payment will be made, so long as such provisions are not inconsistent with the terms of the 2021 Plan and, to the extent an award is subject to Section 409A of the Code, are in compliance with the applicable requirements of Section 409A of the Code and any applicable regulations or guidance. In certain circumstances, the 2021 Plan Administration Committee may, in its discretion, determine that the amount payable with respect to certain performance awards will be reduced from the maximum amount of any potential awards. If the 2021 Plan Administration Committee determines, in its sole discretion, that the established performance measures or objectives are no longer suitable because of a change in the Company's business, operations, corporate structure, or for other reasons that the 2021 Plan Administration Committee deems satisfactory, the 2021 Plan Administration Committee may modify the performance measures or objectives and/or the performance period.

Performance Goals. Awards of restricted stock, restricted stock units, performance awards, and other awards under the 2021 Plan may be made subject to the attainment of performance goals relating to one or more business criteria which shall consist of one or more or any combination of the following criteria ("Performance Criteria"): cash (cash flow, cash generation or other cash measures); cost; revenues; sales; ratio of debt to debt plus equity; net borrowing, credit quality or debt ratings; profit before tax; economic profit; earnings before interest and taxes; earnings before interest, taxes, depreciation and amortization; gross margin; earnings per share (whether on a pre-tax, after-tax, operational or other basis); operating earnings; capital expenditures; improvements in capital structure; expenses (expense management, expense ratio, expense efficiency ratios, expense levels or other expense measures); economic value added; ratio of operating earnings to capital spending or any other operating ratios; free cash flow; profit (net profit, gross profit, operating profit, economic profit, profit margin or other corporate profit measures); net income (before or after taxes, operating income or other income measures); net sales; net asset value per share; business expansion or consolidation (the accomplishment of mergers, acquisitions, dispositions, public offerings or similar extraordinary business transactions); sales growth; price of the Company's Common Stock; return measures (including, without limitation, return on assets, capital, equity, investments or sales, and cash flow return on assets, capital, equity, or sales); market share; inventory levels, inventory management, inventory turn or shrinkage; stock price or performance; internal rate of return or increase in net present value; working capital targets relating to inventory and/or accounts receivable; service or product delivery or quality; customer satisfaction; employee retention; safety standards; productivity measures; cost reduction measures; strategic plan development and implementation; or total return to shareholders. Any Performance Criteria may be used to measure our performance as a whole or of any of our business units and may be measured relative to a peer group or index. Any Performance Criteria may include or exclude (i) events that are of an unusual nature or indicate infrequency of occurrence, (ii) gains or losses on the disposition of a business; (iii) changes in tax or accounting regulations or laws; (iv) the effect of a merger or acquisition, as identified in the Company's quarterly and annual earnings releases; or (v) other similar occurrences. In all other respects, Performance Criteria shall be calculated in accordance with the Company's financial statements, under generally accepted accounting principles, or under a methodology established by the 2021 Plan Administration Committee prior to the issuance of an award, which is consistently applied and identified in the Company's audited financial statements, including in footnotes, or the Compensation Discussion and Analysis sections of the Company's annual report and definitive proxy statement, as applicable.

Other Awards. The 2021 Plan Administration Committee may grant other forms of awards, based upon, payable in, or that otherwise relate to, in whole or in part, shares of the Company's Common Stock, if the 2021 Plan Administration Committee determines that such other form of award is consistent with the purpose and restrictions of the 2021 Plan. The terms and conditions of such other form of award shall be specified in the grant. Such other awards may be granted for no cash consideration, for such minimum consideration as may be required by applicable law, or for such other consideration as may be specified in the grant.

Vesting, Forfeiture and Recoupment, Assignment. The 2021 Plan Administration Committee, in its sole discretion, may determine that an award will be immediately vested, in whole or in part, or that all or any portion may not be vested until a date, or dates, subsequent to its date of grant, or until the occurrence of one or more specified events, subject in any case to the terms of the 2021 Plan. If the 2021 Plan Administration Committee imposes conditions upon vesting, then, subsequent to the date of grant, the 2021 Plan Administration Committee may, in its sole discretion, accelerate the date on which all or any portion of the award may be vested.

The 2021 Plan Administration Committee may impose on any award at the time of grant or thereafter, such additional terms and conditions as the 2021 Plan Administration Committee determines, including terms requiring forfeiture of awards in the event of a participant's termination of employment or service. The 2021 Plan Administration Committee will specify the circumstances on which performance awards may be forfeited in the event of a termination of service by a participant prior to the end of a performance period or settlement of awards. Except as otherwise determined by the 2021 Plan Administration Committee, restricted stock will be forfeited upon a participant's termination of employment or service during the applicable restriction period. In addition, the Company may recoup all or any portion of any shares or cash paid to a participant in connection with any award in the event of a restatement of the Company's financial statements as set forth in the Company's clawback policy, if any, as such policy may be approved or modified by the Board from time to time.

Awards granted under the 2021 Plan generally are not assignable or transferable except by will or by the laws of descent and distribution, except that the 2021 Plan Administration Committee may, in its discretion and pursuant to the terms of an award agreement, permit transfers of nonqualified stock options or SARs to (i) the spouse (or former spouse), children, or grandchildren of the participant ("Immediate Family Members"); (ii) a trust or trusts for the exclusive benefit of such Immediate Family Members; (iii) a partnership in which the only partners are (a) such Immediate Family Members and/or (b) entities which are controlled by the participant and/or his or her Immediate Family Members; (iv) an entity exempt from federal income tax pursuant to Section 501(c)(3) of the Code or any successor provision; or (v) a split interest trust or pooled income fund described in Section 2522(c)(2) of the Code or any successor provision, provided that (x) there shall be no consideration for any such transfer, (y) the applicable award agreement pursuant to which such nonqualified stock options or SARs are granted must be approved by the 2021 Plan Administration Committee and must expressly provide for such transferability, and (z) subsequent transfers of transferred nonqualified stock options or SARs shall be prohibited except those by will or the laws of descent and distribution.

Adjustments Upon Changes in Capitalization. In the event that any dividend or other distribution (whether in the form of cash, shares of the Company's Common Stock, other securities or other property), recapitalization, stock split, reverse stock split, rights offering, reorganization, merger, consolidation, split-up, spin-off, split-off, combination, subdivision, repurchase, or exchange of shares of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase shares of Common Stock or other securities of the Company, or other similar corporate transaction or event affects the fair value of an award, then the 2021 Plan Administration Committee shall adjust any or all of the following so that the fair value of the award immediately after the transaction or event is equal to the fair value of the award immediately prior to the transaction or event: (i) the number of shares and type of Common Stock (or the securities or property) which thereafter may be made the subject of awards; (ii) the number of shares and type of Common Stock (or other securities or property) subject to outstanding awards; (iii) the number of shares and type of Common Stock (or other securities or property) specified as the annual per-participant limit under the 2021 Plan; (iv) the option price of each outstanding stock option; (v) the amount, if any, the Company pays for forfeited shares in accordance with the terms of the 2021 Plan; and (vi) the number of or exercise price of shares then subject to outstanding SARs previously granted and unexercised under the 2021 Plan, to the end that the same proportion of the Company's issued and outstanding shares of Common Stock in each instance shall remain subject to exercise at the same aggregate exercise price; provided, however, that the number of shares of Common Stock (or other securities or property) subject to any award shall always be a whole number. Notwithstanding the foregoing, no such adjustment shall be made or authorized to the extent that such adjustment would cause the 2021 Plan or any stock option to violate Section 422 of the Code or Section 409A of the Code. All such adjustments must be made in accordance with the rules of any securities exchange, stock market, or stock quotation system to which the Company is subject.

Amendment or Discontinuance of the 2021 Plan. The Board may, at any time and from time to time, without the consent of participants, alter, amend, revise, suspend, or discontinue the 2021 Plan in whole or in part; provided, however, that (i) no amendment that requires shareholder approval in order for the 2021 Plan and any awards under the 2021 Plan to continue to comply with Sections 421 and 422 of the Code (including any successors to such sections or other applicable law) or any applicable requirements of any securities exchange or inter-dealer quotation system on which our stock is listed or traded, shall be effective unless such amendment is approved by the requisite vote of our shareholders entitled to vote on the amendment; and (ii) unless required by law, no action by the Board regarding amendment or discontinuance of the 2021 Plan may adversely affect any rights of any participants or obligations of the Company to any participants with respect to any outstanding awards under the 2021 Plan without the consent of the affected participant.

No Repricing of Stock Options or SARs. The 2021 Plan Administration Committee may not, without the approval of our shareholders, "reprice" any stock options or SARs. For purposes of the 2021 Plan, "reprice" means any of the following or any other action that has the same effect: (i) amending a stock option or SAR to reduce its option price or exercise price, respectively; (ii) canceling a stock option or SAR at a time when its option price or exercise price, respectively, exceeds the fair market value of a share of our Common Stock in exchange for cash or a stock option, SAR, award of restricted stock, or other equity award with an option price or exercise price that is less than the option price or exercise price of the original stock option or SAR; or (iii) taking any other action that is treated as a repricing under generally accepted accounting principles.

MyMD Florida Pre-Merger Plan

In 2016, pre-Merger MyMD Florida adopted the MyMD Pharmaceuticals, Inc. Amended and Restated 2016 Equity Incentive Plan (the "2016 Plan"). The MyMD Florida Incentive Plan provided for the issuance of up to 50,000,000 shares of pre-Merger MyMD Florida Common Stock. As of December 31, 2022, options to purchase 4,188,315 shares of Company Common Stock have been issued pursuant to the plan and 0 shares of Company Common Stock remain available for issuance.

Pursuant to the Merger Agreement, effective as of the effective time of the Merger, the Company assumed pre-Merger MyMD Florida's Second Amendment to Amended and Restated 2016 Stock Incentive Plan (collectively with the 2016 Plan, the "MyMD Florida Incentive Plan"), assuming all of pre-Merger MyMD Florida's rights and obligations with respect to the options issued thereunder (except that the term of the option will be amended to expire on the second-year anniversary of the effective time of closing). The assumed pre-Merger MyMD Florida's options became a number of shares of Company Common Stock equal to the product of (a) the number of shares of MyMD Florida Common Stock subject to such option, multiplied by (b) the Exchange Ratio and rounding the resulting number down to the nearest whole share of Company Common Stock, at an exercise price per share of Company Common Stock equal to the quotient of (i) the exercise price per share of MyMD Florida Common Stock subject to such option immediately prior to the effective time of the merger divided by (ii) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent, and then subsequently adjusted for the reverse stock split of the MyMD Florida Common Stock. Upon the closing of the Merger, the Company assumed all of pre-Merger MyMD Florida's rights and obligations under pre-Merger MyMD Florida stock options that were outstanding immediately prior to the effective time of the Merger, and no additional awards can be issued under the MyMD Florida Incentive Plan.

The MyMD Florida Incentive Plan authorized the grant of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, and other stock-based awards, or a combination of the foregoing. MyMD Florida granted only incentive stock options and non-qualified stock options under the plan.

Authorized Shares. A total of 50,000,000 shares of MyMD Florida Common Stock were authorized for the grant of awards under the MyMD Florida Incentive Plan.

Plan Administration. The MyMD Florida Incentive Plan was administered by the MyMD Florida board of directors. The MyMD Florida board had the authority to grant awards under the plan and to adopt, amend, and repeal such administrative rules, guidelines, and practices relating to the plan as it deemed advisable. The MyMD Florida board had the authority to determine the persons to whom and the dates on which awards will be granted, the number of shares of Common Stock to be subject to each award, the time or times during the term of each award within which all or a portion of such award may be exercised, the exercise price, the type of consideration to be paid, and the other terms and provisions of each award, which need not be identical. The MyMD Florida board had the power to construe and interpret the MyMD Florida Incentive Plan and awards granted under it. All decisions, determinations and interpretations by the MyMD Florida board regarding the plan were to be final, binding and conclusive on all participants or other persons claiming rights under the plan or any award.

Options. Options granted under the MyMD Florida Incentive Plan could (i) either be "incentive stock options" within the meaning of Section 422 of the Code, or "nonqualified stock options," and (ii) become vested upon such conditions as were determined by the MyMD Florida board. Such vesting could be based on continued service to MyMD Florida over a certain period, the occurrence of certain performance milestones, or other criteria as determined by the MyMD Florida board. Options granted under the MyMD Florida Incentive Plan could be subject to different vesting terms. Options could not have an exercise price per share of less than 100% of the fair market value of a share of MyMD Florida Common Stock on the date of grant or a term longer than 10 years. To the extent provided by the terms of an option, a participant could satisfy any federal, state or local tax withholding obligation relating to the exercise of such option by a cash payment upon exercise, by authorizing MyMD Florida to withhold a portion of the stock otherwise issuable to the participant upon exercise, or by such other method as may be set forth in the option agreement or authorized by the MyMD Florida board. The treatment of options under the MyMD Florida Incentive Plan upon a participant's termination of employment with or service to MyMD Florida was set forth in the applicable award agreement, which typically provided that the options would terminate 24 months after a termination of employment or service. In connection with the Merger Agreement, on November 10, 2020, MyMD Florida amended each of the option grant award agreements noted above to, among other things, revise the term of exercisability of such option to expire on the earlier of (i) the 10th anniversary of the date of grant or (ii) the second anniversary of the effective date of a "Reorganization Event" as defined in the MyMD Florida Incentive Plan. Accordingly, the term of each such option was amended to expire on the second anniversary of the effective date of the Merger. Incentive stock options are not transferable except by will or by the laws of descent and distribution. Non-qualified stock options are transferable to certain permitted transferees (as provided in the MyMD Florida Incentive Plan) to the extent included in the option award agreement.

Restricted Stock and Restricted Stock Unit Awards. Subject to certain limitations, the MyMD Florida board was authorized to grant awards of restricted stock and restricted stock units, which are rights to receive shares of MyMD Florida Common Stock or cash, as determined by the MyMD Florida board and as set forth in the applicable award agreement, upon the settlement of the restricted stock units at the end of a specified time. The MyMD Florida board could impose any restrictions or conditions upon the vesting of restricted stock or restricted stock unit awards, or that would provide for a delay in the settlement of a restricted stock unit award after it vests, that the committee deemed appropriate and in accordance with the requirements of Section 409A of the Code. Dividend equivalents could be credited in respect of shares covered by a restricted stock or a restricted stock unit award, as determined by the MyMD Florida board. At the discretion of the MyMD Florida board, such dividend equivalents could be converted into additional shares covered by restricted stock or restricted stock units, as applicable. If a restricted stock or restricted stock unit award recipient's employment or service relationship with MyMD Florida terminated, any unvested portion of the restricted stock or restricted stock unit award would be forfeited, unless the participant's award agreement provided otherwise. Restricted stock and restricted stock unit awards are generally not transferable except (i) by will or by the laws of descent and distribution or (ii) to certain permitted transferees, to the extent provided in the award agreement.

Other Stock-Based Awards. The MyMD Florida Incentive Plan authorized the grant of other awards that are valued in whole or in part by reference to, or are otherwise based on, shares of MyMD Florida Common Stock or other property, including awards entitling recipients to receive shares of MyMD Florida Common Stock to be delivered in the future.

Certain Adjustments; Reorganization Events. In connection with any stock split, reverse stock split, stock dividend, dividend in property other than cash, recapitalization, share combination, share reclassification, spin-off, or other similar change in capitalization or event, the MyMD Florida board would equitably adjust the type(s), class(es) and number of shares of stock subject to the MyMD Florida Incentive Plan, and any outstanding awards would also be appropriately adjusted as to the type(s), class(es), number of shares and exercise price per share of Common Stock subject to such awards.

In the event of a "Reorganization Event" (as defined in the MyMD Florida Incentive Plan) such as certain mergers or consolidations, the MyMD Florida board could take any one or more of the following actions as to all or any (or any portion of) outstanding awards on such terms as the board determines: (i) provide that awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a participant, provide that all of the participant's unexercised awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding awards shall become exercisable, realizable, or deliverable, or restrictions applicable to an award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of MyMD Florida Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (A) the number of shares of MyMD Florida Common Stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the acquisition price in the Reorganization Event over (II) the exercise price of such award and any applicable tax withholdings, in exchange for the termination of such award, (v) provide that, in connection with a liquidation or dissolution of MyMD Florida, awards shall convey into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of above actions, the MyMD Florida board would not be obligated by the MyMD Florida Incentive Plan to treat all awards of the same type identically.

Amendment, Termination. The MyMD Florida board could amend, alter, suspend, discontinue, or terminate the MyMD Florida Incentive Plan, provided that no such amendment would adversely affect the rights of any participant without the participant's consent. The MyMD Florida Incentive Plan will terminate in 2026, unless earlier terminated earlier by the Company.

Company Pre-Merger Plans

On January 23, 2014, we adopted the 2013 Stock Incentive Plan (the "2013 Plan"). The 2013 Plan was amended by the Board on January 9, 2015 and September 30, 2016, and such amendments were ratified by stockholders on December 7, 2018. The 2013 Plan provides for the issuance of up to 2,162 shares of the Company's Common Stock, and as of December 31, 2022 756 shares of Common Stock remain available for grants under the 2013 Plan.

On December 21, 2016, the shareholders approved, and the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of up to 50,000,000 shares of the Company's common stock. As of December 31, 2022, grants of options to purchase 4,188,315 shares of Common Stock have been issued pursuant to the 2016 Plan, and 0 shares of Common Stock remain available for issuance.

On August 7, 2017, the stockholders approved, and the Company adopted the 2017 Stock Incentive Plan ("2017 Plan"). The 2017 Plan provides for the issuance of up to 3,516 shares of the Company's Common Stock. The purpose of the 2017 Plan is to provide additional incentive to those of our officers, employees, consultants and non-employee directors and our parents, subsidiaries and affiliates whose contributions are essential to the growth and success of our business. As of December 31, 2022, grants of restricted stock and options to purchase totaling 2,538 shares of Common Stock have been issued pursuant to the 2017 Plan and as of December 31, 2022, 978 shares of Common Stock remain available for grants under the 2017 Plan. The 2017 Plan provides for the issuance of shares of the Company's Common Stock through the grant of non-qualified options, incentive options, restricted stock and unrestricted stock to directors, officers, consultants, attorneys, advisors and employees.

On December 7, 2018, the stockholders approved, and we adopted the 2018 Stock Incentive Plan (the "2018 Plan") and on August 27, 2020, the stockholders approved, and we adopted an amendment to the plan to increase the number of shares of Common Stock available for issuance pursuant to awards under the 2018 Plan by an additional 521,000 shares. The 2018 Plan, as amended, provides for the issuance of up to 560,063 shares of the Company's Common Stock. The purpose of the 2018 Plan is to provide additional incentive to those of our officers, employees, consultants and non-employee directors and to promote the success of our business. As of December 31, 2022, grants of RSUs to purchase 263,026 shares of Common Stock had been issued pursuant to the 2018 Plan, and 297,037 shares of Common Stock remained available for issuance. The 2018 Plan provides for the issuance of shares of the Company's Common Stock through the grant of options, restricted stock, stock appreciation rights, other stock-based awards, performance compensation awards to directors, officers, consultants, advisors and employees. In addition, the 2018 Plan provides the Compensation Committee of the Board with discretion to accelerate the vesting and exercisability of outstanding awards upon the occurrence of a change of control (as defined in the 2018 Plan).

On March 29, 2019, the Compensation Committee of the Board approved the grant of 2,601 RSUs to Mr. Schreiber. Each RSU had a grant date fair value of $46.56 which was amortized on a straight-line basis over the vesting period into administrative expenses within our Consolidated Statement of Comprehensive Loss. Such RSUs were granted under the 2018 Plan, and vested on January 1, 2020.

On September 11, 2020, the Compensation Committee of our Board approved the grant of 131,750 RSUs to Mr. Schreiber. Each RSU had a grant date fair value of $4.48 which was amortized on a straight-line basis over the vesting period into administrative expenses within our Consolidated Statement of Comprehensive Loss. Such RSUs were granted under the 2018 Plan, with 50% to vest on the first anniversary of the date of grant, and the remaining 50% to vest on the second anniversary of the date of grant, provided that the RSUs would vest immediately upon the occurrence of (i) a change in control, provided that Mr. Schreiber is employed or providing services to us and our affiliates on the closing date of such change in control, (ii) Mr. Schreiber's termination of employment or services to us and our affiliates by reason of death or disability, or (iii) Mr. Schreiber's termination of employment or services by us without cause. At our election, the vested RSUs may be settled for cash. The RSUs accelerated and vested in full upon the closing of the Merger on April 16, 2021.

Equity Compensation Plan Information

The following table provides information regarding the number of securities to be issued under the 2021 Plan, the 2013 Plan, the 2016 Plan, the 2017 Plan and the 2018 Plan (collectively, the "Equity Compensation Plans") as of December 31, 2022:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options (b)	Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[(1)]	7,604,492	$ 2.64	4,377,748
Equity compensation plans not approved by security holders ...	-	-	-
Total.....	7,604,492	$ 2.64	4,377,748

(1) Represents shares available for issuance under the Equity Compensation Plans.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.

The following table sets forth information regarding the beneficial ownership of our voting securities as of March 29, 2023 by (i) each person known to us to beneficially own five percent (5%) or more of any class of our voting securities; (ii) each of our named executive officers and directors; and (iii) all of our named directors and executive officers as a group. The percentages of voting securities beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. Except as indicated in the footnotes to this table, to our knowledge and subject to community property laws where applicable, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned and each person's address is c/o MyMD Pharmaceuticals, Inc., 855 N. Wolfe Street, Suite 601, Baltimore, MD 21205. Percentage of Common Stock ownership is based on 39,470,009 shares of Common Stock issued and outstanding as of March 29, 2023. Percentage of Series D Convertible Preferred Stock (the "Series D Preferred Stock") ownership is based on 72,992 shares of Series D Preferred Stock issued and outstanding as of March 29, 2023.

The number of shares of Common Stock beneficially owned by the principal stockholders and the percentage of shares outstanding, as set forth below, take into account certain limitations on the exercise of warrants to purchase Common Stock.

Beneficial ownership is determined in accordance with the rules of the SEC. For the purpose of calculating the number of shares beneficially owned by a stockholder and the percentage ownership of that stockholder, shares of Common Stock subject to options or warrants that are currently exercisable or exercisable within sixty (60) days of March 29, 2023 by that stockholder are deemed outstanding.

Name	Number of Shares of Common Stock Beneficially Owned[(1)]	Percentage of Class	Number of Shares of Series D Preferred Stock Beneficially Owned[(2)]	Percentage of Class	Total Voting Power
5% Beneficial Owner					
Richard Abbe / Iroquois Capital Investment Group LLC[(3)]	2,667,622	6.47%	-	*	6.46%
Caroline Williams / Starwood Trust[(4)]	5,020,182	12.32%	-	*	12.31%
Samuel Duffey[(5)]	2,241,812	5.65%	-	*	5.65%
Premas Biotech PVT Ltd.[(6)]	103,782	*	72,992	100%	*
Named Executive Officers and Directors					
Joshua Silverman[(7)]	88,776	*	-	*	*
Bill J White[(8)]	73,776	*	-	*	*
Craig Eagle, M.D.[(9)]	482,375	1.21%	-	*	1.21%
Jude Uzonwanne[(10)]	115,770	*	-	*	*
Christopher C Schreiber[(11)]	88,238	*	-	*	*
Christopher Chapman, M.D.[(12)]	289,425	*	-	*	*
Adam Kaplin, M.D., PhD[(13)]	154,360	*	-	*	*
Paul Rivard[(14)]	179,360	*	-	*	*
All current executive officers and Directors as a group (9 persons)	1,472,080	3.60%	-	*	3.60%

* Less than 1%.

(1) Shares of Common Stock beneficially owned and the respective percentages of beneficial ownership of Common Stock assume the exercise of all options and other securities convertible into Common Stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 29, 2023, except as otherwise noted. Shares issuable pursuant to the exercise of stock options and other securities convertible into Common Stock exercisable within 60 days are deemed outstanding and held by the holder of such options or other securities for computing the percentage of outstanding Common Stock beneficially owned by such person but are not deemed outstanding for computing the percentage of outstanding Common Stock beneficially owned by any other person. Percentage of Common Stock ownership is based on 39,470,009 shares of Common Stock issued and outstanding as of March 29, 2023.

(2) Shares of Series D Preferred Stock beneficially owned and convertible into Common Stock and the respective percentages of beneficial ownership of Series D Preferred Stock assume the exercise of all options and other securities convertible into Common Stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 29, 2023, except as otherwise noted. Shares issuable pursuant to the exercise of stock options and other securities convertible into Common Stock exercisable within 60 days are deemed outstanding and held by the holder of such options or other securities for computing the percentage of outstanding Common Stock beneficially owned by such person but are not deemed outstanding for computing the percentage of outstanding Common Stock beneficially owned by any other person. Percentage of Series D Preferred Stock ownership is based on 72,992 shares of Series D Preferred Stock issued and outstanding as of March 29, 2023.

(3) This information is based on a Schedule 13G/A (the "Schedule 13G") filed with the SEC on February 14, 2023 by Iroquois Capital Management, LLC ("Iroquois Capital") and on information available to the Company. The principal business office is 125 Park Avenue, 25th Floor, New York, NY 10017. Iroquois Capital is the investment advisor for Iroquois Master Fund, Ltd. ("IMF"). As directors of IMF, Kimberly Page and Richard Abbe make voting and investment decisions on behalf of IMF. As a result of the foregoing, Ms. Page and Mr. Abbe may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange) of the securities held by Iroquois Capital and IMF.

According to the Schedule 13G, IMF owns 31,384 shares of Common Stock and warrants to purchase 1,126,105 shares of Common Stock (all of which are subject to a 9.99% beneficial ownership blocker). In connection with the February 2023 Offering, we issued to IMF warrants to purchase up to 2,217,295 shares of Common Stock, which warrants are subject to a 4.99% beneficial ownership blocker.

Mr. Abbe also has voting control and investment discretion over securities held by Iroquois Capital Investment Group LLC ("ICIG"). As such, Mr. Abbe may be deemed to be the beneficial owner (as determined under Section 13(d) of the Exchange Act) of the securities held by ICIG. ICIG owns 700,414 shares of Common Stock and warrants to purchase 645,039 shares of Common Stock (that are subject to a 9.99% beneficial ownership blocker). In connection with the February 2023 Offering, we issued to ICIG additional warrants to purchase up to 1,219,512 shares of Common Stock, which warrants are subject to a 4.99% beneficial ownership blocker. In addition, by virtue of his position as a custodian or trustee of certain Accounts (The Samantha Abbe Irrevocable Trust, The Talia Abbe Irrevocable Trust and The Bennett Abbe Irrevocable Trust), Mr. Abbe may be deemed to be the beneficial owner of the 115,770 shares of Common Stock held in aggregate by such Accounts. In addition, by virtue of his position as trustee of the Abbe Berman Foundation, Mr. Abbe may be deemed to be the beneficial owner of the 49,110 shares of Common Stock held by the Abbe Berman Foundation.

(4) This information is based on a Schedule 13D filed with the SEC on April 16, 2021 by Caroline Williams, Individually and as Trustee of the Starwood Trust ("Trust"). The Schedule 13D reports shared voting power for 3,747,210 shares of Common Stock and shared dispositive power for 3,747,210 shares of Common Stock. The Common Stock is held directly by the Trust. As trustee of the Trust, Ms. Williams makes voting and investment decisions on behalf of the Trust. As a result of the foregoing, Ms. Williams may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by The Starwood Trust. The principal business address of The Starwood Trust is 324 South Hyde Park Avenue, Suite 350, Tampa, Florida 33606. The Trust owns 2,471,479 shares of Common Stock and options to purchase 1,275,731 shares of Common Stock.

Ms. Williams individually owns 1,272,972 shares of Common Stock as such is deemed to have beneficial ownership.

(5) This information is based on a Schedule 13D filed with the SEC on September 8, 2022 by Samuel Duffey, individually and as trustee of the Rachel Jean Williams 2021 Irrevocable Trust ("RJW Trust"). The Schedule 13D reports that Mr. Duffey holds sole voting and dispositive power over 968,841 shares of Common Stock, which includes (i) 775,891 shares of Common Stock and (ii) 192,950 shares of Common Stock that may be acquired by Mr. Duffey pursuant to options. Mr. Duffey holds shared voting and dispositive power with respect to 1,272,971 shares of Common Stock that are held by the Trust as its sole trustee.

(6) On March 23, 2020, Premas Biotech PVT., Ltd received 103,782 shares of Common Stock and 72,992 shares of Series D Preferred Stock as partial compensation for their rights to Cystron.

Prabuddha Kundu has sole voting and dispositive power over the securities held for this account.

(7) Represents (i) 15,000 shares of Common Stock held by Mr. Silverman and (ii) 73,776 restricted stock unit ("RSU") awards to Mr. Silverman that are vested or scheduled to vest within 60 days of March 29, 2023.

(8) Represents 73,776 RSU awards to Mr. White that are vested or scheduled to vest within 60 days of March 29, 2023.

(9) Represents 482,375 shares of Common Stock issuable upon the exercise of options held by Dr. Eagle which vested immediately upon grant and expire April 16, 2023.

(10) Represents 115,770 shares of Common Stock issuable upon the exercise of options held by Mr. Uzonwanne exercisable within 60 days of March 29, 2023.

(11) Represents 88,238 RSU awards to Mr. Schreiber that are vested or scheduled to vest within 60 days of March 29, 2023.

(12) Represents 289,425 shares of Common Stock issuable upon the exercise of options held by Dr. Chapman which vested immediately upon grant and expire on April 23, 2023.

(13) Represents 154,360 shares of Common Stock issuable upon the exercise of options held by Dr. Kaplin which vested immediately upon grant and expire April 16, 2023.

(14) Represents (i) 25,000 shares of Common Stock held by Mr. Rivard, (ii) 77,180 shares of Common Stock issuable upon the exercise of options held by Mr. Rivard which fully vested upon grant and expire on April 16, 2023 and (iii) 77,180 shares of Common Stock issuable upon the exercise of options held by The Paul & Jennifer Rivard Revocable Living Trust (the "Rivard Trust") which fully vested upon grant and expire on April 16, 2023. Mr. Rivard makes voting and investment decisions on behalf of the Rivard Trust. As a result of the foregoing, Mr. Rivard may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of securities held by the Rivard Trust.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Transactions with related persons are governed by our Code of Business Ethics and Conduct, which applies to all of our employees, as well as each of our directors and certain persons performing services for us. This code covers a wide range of potential activities, including, among others, conflicts of interest, self-dealing and related party transactions. Waiver of the policies set forth in this code will only be permitted when circumstances warrant. Such waivers for directors and executive officers, or that provide a benefit to a director or executive officer, may be made only by the Board, as a whole, or the Audit Committee and must be promptly disclosed as required by applicable law or regulation. Absent such a review and approval process in conformity with the applicable guidelines relating to the particular transaction under consideration, such arrangements are not permitted. All related party transactions for which disclosure is required to be provided herein were approved in accordance with our Code of Business Ethics and Conduct and Whistleblower Policy.

Other than compensation agreements, and other arrangements which are described below and under "Item 11. Executive Compensation" herein, since January 1, 2021, there has not been, and there is not currently proposed, any transaction or series of similar transactions to which we were or will be a party in which the amount involved exceeded or will exceed the lesser of $120,000 or the average of our total assets at year-end for the last two completed fiscal years and in which any director, executive officer, holder of 5% or more of any class of our capital stock, or any member of their immediate family had or will have a direct or indirect material interest.

On August 17, 2022, pursuant to a securities purchase agreement with certain institutional and accredited investors, dated August 15, 2022, the Company issued and sold, in a registered direct offering (the "August RD"), an aggregate of 1,411,764 shares of its Common Stock at an offering price of $4.25 per share and, in a concurrent private placement (together with the August RD, the "August Offerings"), 1,411,764 unregistered investor warrants to purchase up to 1,411,764 shares of its Common Stock at an exercise price of $5.25, for gross and net proceeds of $5,999,997 and $5,550,028, respectively. In connection with the August Offering, we issued to Iroquois Capital Investment Group LLC ("ICIG") 235,294 shares of Common Stock and warrants to purchase an additional 235,294 shares of Common Stock. ICIG is the beneficial owner of more than five percent of our Common Stock. In connection with the August Offering, we also issued to Iroquois Master Fund Ltd., an affiliate of ICIG ("IMF"), 352,941 shares of Common Stock and warrants to purchase an additional 352,941 shares of Common Stock.

In addition, in connection with the February 2023 Offering we issued to ICIG 2,750 shares of our Series F Preferred Stock and warrants to purchase up to 1,219,512 shares of Common Stock. In connection with the February 2023 Offering we also issued to IMF 5,000 shares of Series F Preferred Stock and warrants to purchase up to 2,217,295 shares of Common Stock.

Related Party Transactions of MyMD Florida

On November 11, 2020, in connection with the merger (the "Merger") by and between XYZ Merger Sub Inc., a Florida corporation and wholly owned subsidiary of the Company, and MyMD Pharmaceuticals (Florida), Inc., a Florida corporation formerly known as MyMD Pharmaceuticals, Inc. ("MyMD Florida"), MyMD Florida entered into the Supera Asset Purchase Agreement, pursuant to which MyMD Florida agreed to acquire from Supera substantially all of the assets (including all rights to Supera-1R) and certain obligations of Supera in consideration of the issuance to Supera of an aggregate of 33,937,909 shares of MyMD Florida Common Stock. (After giving effect to the Exchange Ratio and the Reverse Stock Split, such shares of MyMD Florida Common Stock are equivalent to 13,096,639 shares of Company Common Stock.) Supera is owned principally by The Starwood Trust, a trust for which MyMD Florida's founder Jonnie R. Williams, Sr. was the settlor/grantor; Mr. Williams did not have voting or investment power of the MyMD Florida shares held by the trust. Supera is a Florida corporation that was incorporated in September 2018 by Mr. Williams and The Starwood Trust to develop and commercialize Supera-1R, and in December 2018, Mr. Williams assigned his rights and intellectual property relating to Supera-1R to Supera. As partial consideration for such assignment, Supera has granted to SRQ Patent Holdings II, a royalty with respect to product sales and other consideration arising from the assigned intellectual property.

On November 11, 2020, Supera entered into an Amended and Restated Confirmatory Patent Assignment and Royalty Agreement, with SRQ Patent Holdings II under which Supera (or its successor) is obligated to pay to SRQ Patent Holdings II (or its designees) certain royalties on product sales or other revenue received on products that incorporate or are covered by the intellectual property that was assigned to Supera by Mr. Williams. The royalty is equal to 8% of the net sales price on products sales and, without duplication, 8% of milestone revenue or sublicense compensation. This agreement was assumed by MyMD Florida in connection with the Supera Purchase and remained in place following the Merger. SRQ Patent Holdings II is an affiliate of Mr. Williams.

On November 11, 2020 MyMD Florida entered into an Amended and Restated Confirmatory Patent Assignment and Royalty Agreement with SRQ Patent Holdings under which MyMD Florida (or its successor) would be obligated to pay to SRQ Patent Holdings (or other designees) certain royalties on product sales or other revenue received on products that incorporate or are covered by the intellectual property that was assigned to MyMD Florida by SRQ Patent Holdings. The royalty is equal to 8% of the net sales price on product sales and, without duplication, 8% of milestone revenue or sublicense compensation. This agreement remained in place following the Merger. SRQ Patent Holdings is an affiliate of Mr. Williams.

On November 11, 2020, MyMD Florida, The Starwood Trust and Mr. Williams agreed to cancel options to purchase an aggregate of 31,300,000 of MyMD Florida Common Stock and terminate the underlying stock option award agreements. After giving effect to the Exchange Ratio and the Reverse Stock Split, such options to purchase MyMD Florida Common Stock are equivalent to options to purchase 12,078,670 shares of Company Common Stock.

Upon the completion of the Merger, all amounts due and owing with respect to the Line of Credit established between MyMD Florida and The Starwood Trust were paid off in full.

Item 14. Principal Accountant Fees and Services.

	2022	2021
Audit Fees	$ 85,204	$ 121,500
Audit-Related Fees	56,720	179,187
Tax Fees	26,212	26,000
All Other Fees	1,000	-
TOTAL	$ 169,136	$ 326,687

Audit Fees. This category includes the audit of our annual consolidated financial statements, reviews of our financial statements included in our Form 10-Qs and services that are normally provided by our independent registered public accounting firm in connection with its engagements for those years.

Audit-Related Fees. This category consists of assurance and related services by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and are not reported above under "Audit Fees." The services for the fees disclosed under this category include consents regarding equity issuances.

Tax Fees. This category typically consists of professional services rendered by our independent registered public accounting firm for tax compliance and tax advice.

All Other Fees. This category includes aggregate fees billed in each of the last two fiscal years for products and services provided by the Morison Cogen LLP, other than the services reported in the categories above.

Pre-Approval Policies and Procedures

Under the Audit Committee's pre-approval policies and procedures, the Audit Committee is required to pre-approve all fees paid to, and all services performed by, our independent registered public accounting firm. At the beginning of each year, the Audit Committee pre-approves the proposed services, including the nature, type and scope of services contemplated and the related fees to be rendered by our independent registered public accounting firm during the year. In addition, Audit Committee pre-approval is also required for those engagements that may arise during the course of the year that are outside the scope of the initial services and fees pre-approved by the Audit Committee.

All of the services rendered by Morison Cogen LLP in 2022 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

(2) Financial Statements Schedule

None. Financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

(3) Exhibits

See "Index to Exhibits" for a description of our exhibits.

Item 16. Form 10-K Summary.

Not applicable

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
2.1**	Agreement and Plan of Merger and Reorganization, dated November 11, 2020, by and among Akers Biosciences, Inc., XYZ Merger Sub Inc., and MYMD Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated March 16, 2021, by and among Akers Biosciences, Inc., XYZ Merger Sub Inc., and MyMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.2 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021)
3.1	Amended and Restated Certificate of Incorporation, effective April 16, 2021 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation, effective April 16, 2021 (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
3.3	Amended and Restated Bylaws of MyMD Pharmaceuticals, Inc., effective April 16, 2021 (incorporated herein by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
3.4	Form of Certificate of Designations of Series F Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2023).
4.1+	Description of Securities
4.2	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018).
4.3	Form of Series C Convertible Preferred Stock Warrant Certificate (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).

Exhibit Number	Exhibit Description
4.4	Form of Pre-Funded Warrant Certificate (incorporated herein by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
4.5	Form of Placement Agent Warrant Certificate (incorporated herein by reference to Exhibit 4.12 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022).
4.6	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020).
4.7	Form of Placement Agent Warrant (incorporated herein by references to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020).
4.8	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020).
4.9	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 18, 2020).
4.10	Rights Agreement dated as of September 9, 2020 between Akers Biosciences, Inc. and VStock Transfer, LLC as Rights Agent (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2020).
4.11	Amendment No. 1 to Rights Agreement, dated as of March 18, 2021, by and between Akers Biosciences, Inc. and VStock Transfer, LLC, as Rights Agent (incorporated herein by reference to Exhibit 4.19 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021).
4.12	Form of Pre-Funded Warrant. of Akers Biosciences, Inc. (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
4.13	Form of Investor Warrant. of Akers Biosciences, Inc. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
4.14	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 15, 2022).
4.15	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2023).
10.1#	2013 Incentive Stock and Award Plan (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.2#	Form of Nonqualified Stock Option Agreement (Non-Employee) (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.3#	Form of Nonqualified Stock Option Agreement (Employee) (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.4#	Form of Restricted Stock Agreement (incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.5#	Form of Incentive Stock Option (incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).

Exhibit Number	Exhibit Description
10.6#	Amended and Restated 2013 Incentive Stock and Award Plan of the Company (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2015).
10.7#	First Amendment to the Amended and Restated 2013 Incentive Stock and Award Plan of the Company (incorporated by referenced to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 12, 2016).
10.8	Form of Placement Agency Agreement, dated March 30, 2017, by and between the Company and Joseph Gunnar and Co., LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.9	Form of Securities Purchase Agreement, dated March 30, 2017, by and between the Company and various purchasers. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.10	Form Registration Rights Agreement, dated March 30, 2017, by and between the Company and various purchasers (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.11#	2017 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2017).
10.12#	Form of Resignation Agreement of John J. Gormally (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 11, 2018).
10.13	Form of Securities Purchase Agreement, dated October 31, 2018, by and among the Company and the investors signatory thereto (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018).
10.14#	2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2018).
10.15	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
10.16#	Offer of Employment to Christopher C. Schreiber, dated January 31, 2020 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 31, 2020).
10.17	Membership Interest Purchase Agreement, dated as of March 23, 2020, by and among the members of Cystron Biotech, LLC and the Company (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.18	Support Agreement, dated as of March 23, 2020, by and among the Company and certain of its stockholders (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.19	Registration Rights Agreement, dated as of March 23, 2020, by and among certain members of Cystron Biotech, LLC and the Company (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.20	Amended and Restated License and Development Agreement by and among Premas Biotech PVT Ltd and Cystron Biotech, LLC (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.21	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020).

Exhibit Number	Exhibit Description
10.22	Amendment No.1 to the Membership Interest Purchase Agreement, dated May 14, 2020 (incorporated herein by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2020).
10.23	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020).
10.24#	CFO Consulting Agreement, dated as of July 21, 2020, between the Company and Brio Financial Group (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 22, 2020).
10.25	Settlement Agreement and General, Release, dated as of August 3, 2020, by and among the Company and ChubeWorkx Guernsey Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 07, 2020).
10.26	Leak-Out and Support Agreement, dated as of August 3, 2020, by and among the Company and ChubeWorkx Guernsey Limited (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 07, 2020).
10.27	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020).
10.28#	First Amendment to the Akers Biosciences, Inc., 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 28, 2020).
10.29	Secured Promissory Note, dated November 11, 2020, by and between the Company and MYMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
10.30	Form of Securities Purchase Agreement, dated November 11, 2020, by and between the Company and purchasers named therein (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
10.31	Contribution and Assignment Agreement, dated March 16, 2021, by and among Akers Biosciences, Inc., Cystron Biotech LLC, and Oravax Medical Inc. (incorporated herein by reference to Exhibit 10.48 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021).
10.32	Termination and Release Agreement, dated March 16, 2021, by and among Akers Biosciences, Inc., Cystron Biotech LLC, Premas Biotech Pvt. Ltd., and the other parties signatory thereto (incorporated herein by reference to Exhibit 10.49 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021).
10.33#	MyMD Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
10.34#	Form of Nonqualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
10.35#	Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
10.36#	Form of Restricted Stock Award Agreement (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).

Exhibit Number	Exhibit Description
10.37	Asset Purchase Agreement, dated November 11, 2020, by and between MyMD Pharmaceuticals, Inc. and Supera Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.38#	MyMD Pharmaceuticals (Florida) Inc. Second Amendment to Amended and Restated 2016 Stock Incentive Plan, dated July 1, 2019 (incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.39	Amended and Restated Confirmatory Patent Assignment and Royalty Agreement dated November 11, 2020, by and between SRQ Patent Holdings II, LLC and Supera Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.40	Amended and Restated Confirmatory Patent Assignment and Royalty Agreement dated November 11, 2020, by and between SRQ Patent Holdings, LLC and MyMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.41#	Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals (Florida), Inc., effective December 18, 2020 (incorporated herein by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.42#	Amendment No. 1 to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals (Florida), Inc, dated February 11, 2021 (incorporated herein by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.43#	Employment Agreement between Chris Chapman and MyMD Pharmaceuticals (Florida), Inc., effective November 1, 2020 (incorporated herein by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.44#	Amendment No. 1 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals (Florida), Inc., dated December 18, 2020 (incorporated herein by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.45#	Amendment No. 2 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals (Florida), Inc., dated January 8, 2021 (incorporated herein by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.46#	Amendment No. 3 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals (Florida), Inc., dated February 11, 2021 (incorporated herein by reference to Exhibit 10.16 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.47#	Employment Agreement between Paul Rivard and MyMD Pharmaceuticals (Florida), Inc., dated September 21, 2020 (incorporated herein by reference to Exhibit 10.17 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.48#	Amendment No. 1 to Employment Agreement between Paul Rivard and MyMD Pharmaceuticals (Florida), Inc., dated November 24, 2020 (incorporated herein by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.49#	Amendment No. 2 to Employment Agreement between Paul Rivard and MyMD Pharmaceuticals (Florida), Inc., dated December 18, 2020 (incorporated herein by reference to Exhibit 10.19 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.50#+	Amendment No. 4 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals, Inc., dated November 24, 2021 (incorporated herein by reference to Exhibit 10.66 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022).
10.51#+	Amendment No. 2 to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals, Inc., dated November 24, 2021 (incorporated herein by reference to Exhibit 10.67 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022).

Exhibit Number	Exhibit Description
10.52	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 15, 2022).
10.53#	Fifth Amendment to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals, Inc., dated August 30, 2022 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 2022).
10.54#	Third Amendment to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals, Inc., dated August 30, 2022 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 2022).
10.55#	Sixth Amendment to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals, Inc., dated January 1, 2023 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 3, 2023).
10.56	Form of Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2023).
10.57#	Third Amendment to Employment Agreement between Paul Rivard, Esq. and MyMD Pharmaceuticals, Inc., dated March 22, 2023. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 23, 2023).
21.1+	List of Subsidiaries of MyMD Pharmaceuticals, Inc.
23.1+	Consent of Morison Cogen LLP, Independent Registered Public Accounting Firm.
31.1+	Certification of the Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2+	Certification of the Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1+	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Interactive Data Files of Financial Statements and Notes.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Filed herewith

Management contract or compensatory plan or arrangement.

** The schedules and exhibits to the Agreement and Plan of Merger and Reorganization have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MYMD PHARMACEUTICALS, INC.

Date: March 31, 2023

By: */s/ Christopher C. Chapman*
Name: Christopher C. Chapman, M.D.
Title: President and Chief Medical Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Christopher C. Chapman Christopher C. Chapman, M.D.	President, Chief Medical Officer and Director (Principal Executive Officer)	March 31, 2023
/s/ Ian Rhodes Ian Rhodes	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2023
/s/ Joshua Silverman Joshua Silverman	Chairman of the Board	March 31, 2023
/s/ Bill J. White Bill J. White	Director	March 31, 2023
/s/ Christopher C. Schreiber Christopher C. Schreiber	Director	March 31, 2023
/s/ Jude Uzonwanne Jude Uzonwanne	Director	March 31, 2023
/s/ Craig Eagle Craig Eagle, M.D.	Director	March 31, 2023

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
MyMD Pharmaceuticals, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of MyMD Pharmaceuticals, Inc. and Subsidiaries (the Company) as of December 31, 2022 and 2021 and the related consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2022 and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021 and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Going Concern Assessment

As discussed in Note 3 to the consolidated financial statements, historically, the Company has incurred net losses. Since its inception, the Company has met its liquidity requirements principally through the sale of its common stock in public and private placements. The Company believes that its current financial resources as of the date of issuance of the consolidated financial statements are sufficient to fund its current operating budget and contractual obligations as of December 31, 2022 as they fall due in the next twelve-month period, and as such have concluded that there are no material uncertainties related to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern. In making such a determination, management prepared a short-term cash flow projection. Management used significant assumptions in preparing the short-term cash flow projection, which included operating costs and financing obligations.

The principal considerations for our determination that performing procedures relating to the going concern assessment is a critical audit matter are the significant judgments in management's plans to fund its operating budget and contractual obligations. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate management's conclusion that it is probable the Company's plans will be effectively implemented within twelve months after the date the consolidated financial statements are issued and will provide the necessary cash flows to fund the Company's operating budget and contractual obligations.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- Evaluation of the reasonableness of key assumptions and estimates used by the management in the short-term cash flow projection in the light of its existing operating requirements and plans.
- Evaluation of the reasonableness of management's plans on the cash flow requirements of the operations.
- Testing the completeness, accuracy, and relevance of underlying data in the short-term cash flow projection.
- Evaluation of the adequacy of the Company's disclosure of these circumstances in the consolidated financial statements.

Assessment of Impairment for Investment in Oravax, Inc.

As discussed in Note 2 to the consolidated financial statements, the Company has elected to measure its investment in Oravax Medical, Inc. as an equity security without a readily determinable fair value. Under this election, an equity security without a readily available fair value is reflected at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. At each reporting period, the Company is required to make a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. If deemed impaired, the Company is required to estimate the fair value of the investment and recognize an impairment loss equal to the difference between the fair value of the investment and its carry amount. As of December 31, 2022, the Company performed a qualitative assessment to evaluate whether the investment is impaired and determined that the investment was not impaired and thus no adjustment to fair market value was required as of December 31, 2022. In making such a determination, management prepared a detailed qualitative analysis considering various impairment indicators. Management used significant judgment in their qualitative assessment.

The principal considerations for our determination that performing procedures relating to the impairment assessment of investments in equity securities without readily determinable fair value is a critical audit matter is the significant judgment by management in making the qualitative assessment of whether investments in equity securities were impaired. This in turn led to significant auditor judgment and effort in performing procedures to evaluate the reasonableness of significant judgments management applied in determining whether events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- Analyzing management's detailed qualitative analysis considering various impairment indicators that may indicate that the carrying amount of the investment might not be recoverable for reasonableness.
- Reviewing management's assessment of events or changes in circumstances for reasonableness.
- Evaluating management's significant accounting policies related to the election to measure its investment in Oravax Medical, Inc. as an equity security without a readily determinable fair value.

/s/ Morison Cogen LLP

We have served as the Company's auditor since 2010.

Blue Bell, Pennsylvania
March 31, 2023

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2022 and 2021

	As of	
	December 31, 2022	**December 31, 2021**
ASSETS		
Current Assets		
Cash and Cash Equivalents	$ 749,090	$ 555,967
Marketable Securities	4,086,902	11,003,071
Prepaid Expenses	565,787	1,106,347
Total Current Assets	5,401,779	12,665,385
Non-Current Assets		
Operating Lease Right-of-Use Assets	139,662	149,009
Goodwill	10,498,539	10,498,539
Investment in Oravax, Inc.	1,500,000	1,500,000
Total Non-Current Assets	12,138,201	12,147,548
Total Assets	$ 17,539,980	$ 24,812,933
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$ 2,673,221	$ 986,626
Due to MyMD Florida Shareholders	29,982	-
Operating Lease Liability	65,780	53,240
Total Current Liabilities	2,768,983	1,039,866
Non-Current Liabilities		
Due to MyMD Florida Shareholders, net of current portion	-	29,982
Operating Lease Liability, net of current portion	75,941	95,911
Total Non-Current Liabilities	75,941	125,893
Total Liabilities	$ 2,844,924	$ 1,165,759
Commitments and Contingencies		
SHAREHOLDERS' EQUITY		
Preferred Stock, no par value, 50,000,000 total preferred shares authorized		
Series D Convertible Preferred Stock, 211,353 shares designated, no par value and a stated value of $0.01 per share, 72,992 shares issued and outstanding as of December 31, 2022 and December 31, 2021	144,524	144,524
Common stock, no par value, 500,000,000 shares authorized 39,470,009 and 37,673,110 issued and outstanding as of December 31, 2022 and December 31, 2021	108,309,436	102,064,218
Accumulated Deficit	(93,758,904)	(78,561,568)
Total Shareholders' Equity	14,695,056	23,647,174
Total Liabilities and Shareholders' Equity	$ 17,539,980	$ 24,812,933

The accompanying notes are an integral part of these consolidated financial statements

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Comprehensive Loss

	For the Years Ended December 31,	
	2022	**2021**
Product Revenue	$ -	$ -
Product Cost of Sales	-	-
Gross Income	-	-
Administrative Expenses	5,520,150	6,420,092
Research and Development Expenses	9,067,422	6,745,104
Accretion of Debt Discount	-	608,460
Stock Based Compensation	695,191	-
Stock Option Modification Expenses	-	15,036,051
Loss from Operations	(15,282,763)	(28,809,707)
Other (Income) Expenses		
Interest and Dividend Income	(83,991)	(8,907)
(Gain)/Loss on Sales of Marketable Securities	5,964	(39,597)
Unrealized (Gain)/Loss on Marketable Securities	(2,958)	42,793
Gain on Debt Forgiveness	-	(180,257)
Uninsured Casualty Losses	(4,442)	1,265,306
Total Other (Income) Expenses	(85,427)	1,079,338
Loss Before Income Tax	(15,197,336)	(29,889,045)
Income Tax Benefit	-	-
Net Loss	$ (15,197,336)	$ (29,889,045)
Basic and Dilutive net loss per common share	$ (0.39)	$ (0.85)
Weighted average basic and diluted common shares outstanding	38,825,763	35,017,244

The accompanying notes are an integral part to these consolidated financial statements.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statement of Changes in Stockholders' Equity /(Deficit)
For the Years Ended December 31, 2022 and 2021

	Series D Convertible Preferred Stock		Common Stock			
	Shares	Series D	Shares	Common Stock	Accumulated Deficit	Total Equity
Balance at December 31, 2021	72,992	$ 144,524	37,673,110	$ 102,064,218	$ (78,561,568)	$ 23,647,174
Net loss	-	-	-	-	(15,197,336)	(15,197,336)
Net proceeds from private placement of 1,411,764 common shares, net of offering costs of $449,500	-	-	1,411,764	5,550,028	-	5,550,028
Exercise of prepaid equity forward contracts for Common Stock	-	-	385,135	-	-	-
Stock-based compensation – stock options	-	-	-	444,342	-	444,342
Stock-based compensation – restricted stock units	-	-	-	165,997	-	165,997
Stock-based compensation – warrants	-	-	-	84,851	-	84851
Balance at December 31, 2022	72,992	$ 144,524	39,470,009	$ 108,309,436	$ (93,758,904)	$ 14,695,056

	Series D Convertible Preferred Stock		Common Stock					
	Shares	Series D	Shares	Common Stock No Par	Common Stock Par $0.0001	Additional Paid-In Capital	Accumulated Deficit	Total Equity
Balance at December 31, 2020	-	$ -	28,553,307		$ 4,004	43,411,487	$ (48,672,523)	$ (5,257,032)
Net loss	-	-	-	-	-	-	(29,889,045)	(29,889,045)
Reverse merger with Akers Biosciences Inc effective April 16, 2021	72,992	144,524	8,335,627	42,332,834	-	-	-	42,477,358
Issuance of post-merger MyMD Pharmaceutical Inc common shares at an exchange ratio of 0.7718 per pre-merger MyMD common share	-	-	-	43,415,491	(4,004)	(43,411,487)	-	-
Modification of the terms of 4,188,315 pre-merger MyMD stock options per the terms of the merger agreement	-	-	-	15,036,051	-	-	-	15,036,051
Exercise of per-merger MyMD stock options	-	-	11,576	-	-	-	-	-
Exercise of prepaid equity forward contracts for Common Stock	-	-	466,716	-	-	-	-	-
Stock based compensation for services	-	-	16,826	90,002	-	-	-	90,002
Exercise of warrants for Common Stock	-	-	289,058	1,189,840	-	-	-	1,189,840
Balance at December 31, 2021	72,992	$ 144,524	37,673,110	$ 102,064,218	$ -	$ -	$ (78,561,568)	$ 23,647,174

The accompanying notes are an integral part of these consolidated financial statements

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss from ongoing operations	$ (15,197,336)	$ (29,889,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued interest/dividends	-	(3,024)
Accretion of debt discount	-	608,460
(Gain)/loss on sale of marketable securities	5,964	(39,597)
Unrealized (gain)/loss on marketable securities	(2,958)	42,793
Gain on forgiveness of debt	-	(180,258)
Stock based compensation:		
Option modification expense	-	15,036,051
Options issued to key employees	338,922	-
Options issued to non-employees	105,420	90,002
Warrants issued for services	84,851	-
Restricted stock units to non-employees	165,997	-
Change in assets and liabilities		
Prepaid expenses	540,560	(912,815)
Trade and other payables	1,686,595	(4,268,961)
Operating leases	1,917	(81)
Net cash used by operating activities	(12,270,068)	(19,516,475)
Cash flows from investing activities:		
Purchases of marketable securities	(4,836,837)	(13,403)
Proceeds from sale of marketable securities	11,750,000	18,483,176
Net cash received in business combination	-	1,380,852
Net cash provided by investing activities	6,913,163	19,850,625
Cash flows from financing activities		
Repayment of the line of credit – related party	-	(3,062,444
Net proceeds from borrowings	-	120,000
Net proceeds from note payable	-	1,826,137
Net proceeds from issuance of Common Stock	5,550,028	-
Net proceeds from the exercise of warrants for Common Stock	-	1,189,840
Net cash provided by financing activities	5,550,028	73,533
Net increase in cash and cash equivalents	193,123	407,683
Cash and cash equivalents at beginning of year	555,967	148,284
Cash and cash equivalents at end of year	$ 749,090	$ 555,967
Supplemental cash flow information		
Cash paid for:		
Interest	$ 13,322	$ 271,800
Income Taxes	$ -	$ -
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Operating lease right-of-use asset obtained in exchange for lease obligation	$ 53,196	$ 141,387
Investment in Oravax Medical, Inc.	$ -	$ 1,500,000

The accompanying notes are an integral part to these consolidated financial statements.

Note 1 – Organization and Description of Business

MyMD Pharmaceuticals, Inc., previously known as Akers Biosciences, Inc., is a New Jersey corporation ("MyMD"). These consolidated financial statements include four wholly owned subsidiaries as of December 31, 2022, MyMD Pharmaceuticals (Florida), Inc. ("MyMD Florida"), XYZ Merger Sub, Inc. ("Merger Sub"), Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation, (together, the "Company"). All material intercompany transactions have been eliminated in consolidation.

MyMD Florida was formed in 2014 and is a Florida-based clinical development stage biopharmaceutical company that is developing its product candidate, MYMD-1, as an immuno regulator to treat autoimmune diseases, ageing-related diseases. Substantive operations began in 2016 and the Company's Investigative New Drug application was filed with the U.S. Food and Drug Administration in December 2018. MyMD Florida completed its first-in-human Phase 1 clinical trial in December 2019. A second Phase 1 dosing study was completed in December 2021. MYMD-1 is being developed to treat age-related illnesses such as frailty and sarcopenia. MYMD-1 works by regulating the release of numerous pro-inflammatory cytokines, such as TNF-α, interleukin 6 ("IL-6") and interleukin 17 ("IL-17"). MYMD-1 currently is being evaluated in a multicenter Phase 2 clinical trial in patients with sarcopenia and frailty (age-related muscle loss). MyMD Florida's intellectual property portfolio consists of 16 U.S. granted patents, 15 granted foreign patents and 19 pending applications (3 US, 16 foreign).

Supera Pharmaceuticals, Inc. ("Supera") was formed in September 2018 and is a Florida based development company that is developing its product candidate "Supera-CBD" as an FDA-approved synthetic analog of naturally grown cannabidiols. Substantially all of Supera's research and development activities in 2020 and 2021 were related to intellectual property development and securing patents, along with product manufacturing and planning initial pre-clinical development activities. During the year ended December 31, 2021, these activities included preclinical work on Supera-CBD confirming it effectiveness in treating anxiety. The preclinical data was presented at the 4th Annual International Cannabinoid Summit describing the superior potency of Supera-CBD. Supera-CBD preclinical genotoxicity studies were completed in February 2022.

On April 16, 2021, pursuant to the previously announced Agreement and Plan of Merger and Reorganization, dated November 11, 2020 (the "Original Merger Agreement"), as amended by Amendment No. 1 thereto, dated March 16, 2021 the Original Merger Agreement, as amended by Amendment No. 1 (the "Merger Agreement"), by and among MyMD, Merger Sub and MyMD Florida, Merger Sub was merged with and into MyMD Florida, with MyMD Florida continuing after the merger as the surviving entity and a wholly owned subsidiary of MyMD (the "Merger"). At the effective time of the Merger, without any action on the part of any stockholder, each issued and outstanding share of pre-Merger MyMD Florida's Common Stock, par value $0.001 per share (the "MyMD Florida Common Stock"), including shares underlying pre-Merger MyMD Florida's outstanding equity awards, was converted into the right to receive (x) 0.7718 shares (the "Exchange Ratio") of MyMD's Common Stock, no par value per share (the "Company Common Stock" or "Common Stock"), (y) an amount in cash, on a pro rata basis, equal to the aggregate cash proceeds received by the Company from the exercise of any options to purchase shares of MyMD Florida Common Stock outstanding at the effective time of the Merger assumed by the Company upon closing of the Merger prior to the second-year anniversary of the closing of the Merger (the "Option Exercise Period"), such payment (the "Additional Consideration"), and (z) potential milestone payment in shares of Company Common Stock up to the aggregate number of shares issued by the Company to pre-Merger MyMD Florida stockholders at the closing of the Merger (the "Milestone Payments") payable upon the achievement of certain market capitalization milestone events during the 36-month period immediately following the closing of the Merger (the "Milestone Period"). Immediately following the effective time of the Merger, the Company effected a 1-for-2 reverse stock split of the issued and outstanding Company Common Stock (the "Reverse Stock Split").

On April 16, 2021, MyMD Florida entered into an Asset Purchase Agreement with Supera, a related company through common control, in which Supera was acquired by MyMD Florida through the issuance of 33,937,909 shares of pre-Merger MyMD Florida Common Stock. The Supera entity was dissolved pursuant to this transaction.

In connection with the closing of the Merger, the Company changed its name to MyMD Pharmaceuticals, Inc. and the Company Common Stock, listed previously trading through the close of business on April 16, 2021 under the trading symbol "AKER", commenced trading on The Nasdaq Capital Market, on a post-Reverse Stock Split adjusted basis, under the trading symbol "MYMD" on April 19, 2021.

On April 8, 2022 , the MyMD Florida subsidiary was dissolved and merged into the New Jersey corporation MyMD Pharmaceuticals, Inc. pursuant to an Agreement and Plan of Merger dated April 8, 2022.

Note 2 – Significant Accounting Policies

(a) Basis of Presentation

The Consolidated Financial Statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

The Company effected a 1-for-2 reverse stock split immediately following the effective time of the Merger. No fractional shares were issued in connection with the Reverse Stock Split. Each stockholder who did not have a number of shares evenly divisible pursuant to the Reverse Stock Split ratio and who would otherwise be entitled to receive a fractional share of Company Common Stock was entitled to receive an additional share of Company Common Stock. The number of shares on equity related disclosures included in this Annual Report on Form 10-K, including the consolidated financial statements and accompanying notes, were retroactively adjusted to reflect the effects of the Reverse Stock Split and the Exchange Ratio.

(b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. Information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements is included in the following notes for recording research and development expenses, impairment of intangible assets and the valuation of share-based payments.

(c) Functional and Presentation Currency

These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information has been rounded to the nearest dollar. Foreign Currency Transaction Gains or Losses, resulting from cash balances denominated in Foreign Currencies, are recorded in the Consolidated Statements of Operations and Comprehensive Loss.

(d) Comprehensive Loss

The Company follows Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC") 220 in reporting comprehensive loss. Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income. Since the Company has no items of other comprehensive income (loss), comprehensive loss is equal to net loss.

(e) Cash and Cash Equivalents

The Company considers all highly liquid investments, which include short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal date or use, to be cash equivalents.

(f) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities.

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

Level 1 Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company can access.

Level 2 Inputs to the valuation methodology include:

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;

- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3 Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Valuation techniques maximize the use of relevant observable inputs and minimize the use of unobservable inputs.

(f) Fair Value of Financial Instruments, continued

The following is a description of the valuation methodologies used for assets measured at fair value as of December 31, 2022 and December 31, 2021.

Marketable Securities: Valued using quoted prices in active markets for identical assets.

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Quoted Prices for Similar Assets or Liabilities in Active Markets (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities at December 31, 2022	$ 4,086,902	$ -	$ -
Marketable securities at December 31, 2021	$ 11,003,071	$ -	$ -

Marketable securities are classified as available for sale and are valued at fair market value. Maturities of the securities are less than one year.

As of December 31, 2022 and 2021, the Company held certain mutual funds, which, under FASB ASC 321-10, were considered equity investments. As such, the change in fair value in the year ended December 31, 2022 and 2021 was a gain of $2,958 and a loss of $42,793, respectively.

Gains and losses resulting from the sales of marketable securities were losses of $5,964 and gains of $39,597 for the years ended December 31, 2022 and 2021, respectively.

Proceeds from the sales of marketable securities were $11,750,000 and $18,483,176 in the years ended December 31, 2022 and 2021, respectively. Purchases of marketable securities were $4,836,837 and $13,403 during the years ended December 31, 2022 and 2021, respectively.

(g) Prepaid Expenses

Prepaid expenses represent expenses paid prior to the date that the related services are rendered or used are comprised principally of prepaid insurance and research and development expenses.

(h) Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash on deposit with financial institutions and accounts receivable. At times, the Company's cash in banks is in excess of the FDIC insurance limit. The Company has not experienced any loss as a result of these cash deposits. These cash balances are maintained with three banks as of December 31, 2022.

(i) Risk Management of Cash and Investments

It is the Company's policy to minimize the Company's capital resources to investment risks, prioritizing the preservation of capital over investment returns. Investments are maintained in securities, primarily publicly traded, short-term money market funds based on highly rated federal, state and corporate bonds, that minimize the risk to the Company's capital resources and provide ready access to funds.

The Company's investment portfolios are regularly monitored for risk and are held with one brokerage firm.

(j) Investments

Investments recorded using the cost method will be assessed for any decrease in value that has occurred that is other than temporary and the other than temporary decrease in value shall be recognized. As and when circumstances and facts change, the Company will evaluate the Company's ability to significantly influence operational and financial policy to establish a basis for converting the investment accounted for using the cost method to the equity method of valuation in accordance with FASB ASC 323.

In accordance with FASB ASC 323, the Company recognizes investments in joint ventures based upon the Company's ability to significantly influence the operational or financial policies of the joint venture. An objective judgment of the level of influence is made at the time of the investment based upon several factors including, but not limited to the following:

a) Representation on the Board of Directors
b) Participation in policy-making processes
c) Material intra-entity transactions
d) Interchange of management personnel
e) Technological dependencies
f) Extent of ownership and the ability to influence decision making based upon the makeup of other owners when the shareholder group is small.

The Company follows the equity method for valuating investments in joint ventures when the existence of significant influence over operational and financial policy has been established, as determined by management; otherwise, the Company will valuate these investments using the cost method.

In accordance with FASB ASC 321-10-35-2, the Company has elected to measure its investment in Oravax Medical, Inc. ("Oravax") (Note 3) as an equity security without a readily determinable fair value. Under this election, an equity security without a readily available fair value is reflected at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. At each reporting period, the Company is required to make a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. If deemed impaired, the Company is required to estimate the fair value of the investment and recognize an impairment loss equal to the difference between the fair value of the investment and its carry amount. As of December 31, 2022, the Company performed a qualitative assessment to evaluate whether the investment is impaired and determined that the investment was not impaired and thus no adjustment to fair market value was required as of December 31, 2022.

(k) Property, Plant and Equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized within "other (income)/expense" in the Consolidated Statements of Comprehensive Loss.

Depreciation is recognized over the estimated useful lives of the property, plant and equipment. Leased assets are depreciated over the shorter of the lease term or their useful lives.

The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Plant and equipment	5-12
Furniture and fixtures	5-10
Computer equipment & software	3-5
Leasehold Improvements	Shorter of the remaining lease or estimated useful life

Depreciation methods, useful lives and residual values are reviewed at each reporting date.

(l) Intangible Assets

The Company's long-lived intangible assets, other than goodwill, are assessed for impairment when events or circumstances indicate there may be an impairment. These assets were initially recorded at their estimated fair value at the time of acquisition and assets not acquired in acquisitions were recorded at historical cost. However, if their estimated fair value is less than the carrying amount, other intangible assets with indefinite lives are reduced to their estimated fair value through an impairment charge in the Consolidated Statements of Comprehensive Loss.

Patents and Trade Secrets

Propriety protection for the Company's products, technology and process is important to its competitive position. As of December 31, 2022, the Company has 16 issued U.S. patents, 50 foreign patents, four pending U.S. patent applications and 15 foreign patent applications pending in such jurisdictions as Australia, Canada, China, European Union, Israel, Japan and South Korea, which if issued are expected to expire between 2036 and 2041. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

The Company records expenses related to the application for and maintenance of patents as a component of research and development expenses on the Consolidated Statement of Comprehensive Loss.

Patent Costs

Patents may be purchased from third parties. The costs of acquiring the patent are capitalized as patent costs if it represents a future economic benefit to the Company. Once a patent is acquired it is amortized over its remaining useful life and assessed for impairment when necessary.

Other Intangible Assets

Other intangible assets that are acquired by the Company, which have definite useful lives, are measured at cost less accumulated amortization and accumulated impairment losses.

Amortization

Amortization is recognized on a straight-line basis over the estimated useful lives of intangible assets, other than goodwill, from the date that they are available for use. The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Patents and trademarks	12-17

(m) Goodwill

Goodwill is evaluated annually for impairment or whenever we identify certain triggering events or circumstances that would more likely than not reduce the fair value below its carrying amount. Events or circumstances that might indicate an interim evaluation is warranted include, among other things, unexpected adverse business conditions, economic factors (for example, the loss of key personnel), supply costs, unanticipated competitive activities, and acts by governments and courts.

(n) Recoverability of Long-Lived Assets

In accordance with FASB ASC 360-10-35 "Impairment or Disposal of Long-lived Assets", long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable or that the useful lives of those assets are no longer appropriate. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment.

The Company determines the existence of such impairment by measuring the expected future cash flows (undiscounted and without interest charges) and comparing such amount to the carrying amount of the assets. An impairment loss, if one exists, is then measured as the amount by which the carrying amount of the asset exceeds the discounted estimated future cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value of such assets less costs to sell. Asset impairment charges are recorded to reduce the carrying amount of the long-lived asset that will be sold or disposed of to their estimated fair values. Charges for the asset impairment reduce the carrying amount of the long-lived assets to their estimated salvage value in connection with the decision to dispose of such assets.

(o) Right-of-Use Assets

The Company leased a facility in Tampa, Florida ("Hyde Park") under an operating lease ("Hyde Park Lease") with annual rentals of $22,048 to $23,320 plus certain operating expenses. The Hyde Park facility housed the MyMD Florida operations. The Hyde Park Lease took effect on July 1, 2019 for a term of 36 months to expire on June 30, 2022. The Company cancelled the Hyde Park lease in March 2022 without penalty.

The Company leased an aircraft under an operating lease ("Supera Aviation Lease") with annual rentals of $600,000 plus certain operating expenses. The Supera Aviation Lease took effect on October 26, 2018 for a term of 36 months to expire on September 26, 2021. The Company cancelled the Supera Aviation Lease in April 2021 without penalty.

The Company leased a facility in Baltimore, Maryland ("2020 Wolfe St") under an operating lease ("2020 Baltimore Lease") with annual rentals of $24,000 to $25,462 plus certain operating expenses. The 2020 Baltimore Lease took effect on November 9, 2020 for a term of 12 months with automatic renewals unless a sixty-day notice was provided. The initial term expired on November 30, 2021. On November 17, 2021, the 2020 Baltimore Lease was cancelled without penalty.

The Company leases a facility in Baltimore, Maryland ("2021 Wolfe St") under an operating lease ("2021 Baltimore Lease") with annual rentals of $52,800 to $56,016 plus certain operating expenses. The 2021 Baltimore Lease took effect on November 17, 2021 for a term of 12 months with automatic renewals unless a sixty-day notice is provided. The initial term expires on November 30, 2022. The lease renewed effective December 1, 2022 for a term of 12 months with automatic renewals unless a sixty-day notice is provided.

The Company leases a facility in Tampa, Florida ("Platt St") under an operating lease ("Platt Street Lease") with annual rentals of $22,030 to $23,259 plus certain operating expenses. The Platt Street Lease took effect on April 1, 2022 for a term of 36 months. The initial term expires on March 31, 2025.

On January 1, 2019 ("Effective Date"), the Company adopted FASB ASC, Topic 842, Leases ("ASC 842"), which increases transparency and comparability by recognizing a lessee's rights and obligations resulting from leases by recording them on the balance sheet as lease assets and lease liabilities. The new guidance requires the recognition of the right-of-use ("ROU") assets and related operating and finance lease liabilities on the balance sheet. The Company adopted the new guidance using the modified retrospective approach on January 1, 2019.

The Company elected the package of practical expedients permitted within the standard, which allows an entity to forgo reassessing (i) whether a contract contains a lease, (ii) classification of leases, and (iii) whether capitalized costs associated with a lease meet the definition of initial direct costs. Also, the Company elected the expedient allowing an entity to use hindsight to determine the lease term and impairment of ROU assets and the expedient to allow the Company to not have to separate lease and non-lease components. The Company has also elected the short-term lease accounting policy under which the Company would not recognize a lease liability or ROU asset for any lease that at the commencement date has a lease term of twelve months or less and does not include a purchase option that the Company is more than reasonably certain to exercise.

For contracts entered into on or after the Effective Date, at the inception of a contract, the Company will assess whether the contract is, or contains, a lease. The Company's assessment is based on: (i) whether the contract involves the use of a distinct identified asset, (ii) whether the Company obtained the right to substantially all the economic benefit from the use of the asset throughout the period, and (iii) whether the Company has the right to direct the use of the asset. Leases entered into prior to January 1, 2020, which were accounted for under ASC 840, were not reassessed for classification.

For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments. The Company generally uses its incremental borrowing rate as the discount rate for leases, unless an interest rate is implicitly stated in the lease. The present value of the lease payments is calculated using the incremental borrowing rate for operating leases, which was determined using a portfolio approach based on the rate of interest that the Company would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term. The lease term for all the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend the lease that the Company is reasonably certain to exercise, or an option to extend the lease controlled by the lessor. All ROU assets are reviewed for impairment.

Lease expense for operating leases consists of the lease payments plus any initial direct costs and is recognized on a straight-line basis over the lease term.

The Company's operating leases are comprised of the 2021 Baltimore Lease and the Platt Street Lease on the Consolidated Balance Sheet. The information related to these leases are presented below:

	As of December 31, 2022			As of December 31, 2021		
Balance Sheet Location	Platt Street Lease	2021 Baltimore Lease	Total	Hyde Park Lease	2021 Baltimore Lease	Total
Operating Lease						
Lease Right of Use	$45,353	$ 94,309	$139,662	$12,156	$ 136,853	$149,009
Lease Payable, current	18,741	47,039	65,780	12,164	41,076	53,240
Lease Payable - net of current	27,070	48,871	75,941	-	95,911	95,911

The following provides details of the Company's lease expense:

	Year Ended December 31, 2022				Year Ended December 31, 2021				
Lease Expenses	Hyde Park Lease	Platt Street Lease	2021 Baltimore Lease	Total	Supera Aviation Lease	Hyde Park Lease	2020 Baltimore Lease	2021 Baltimore Lease	Total
Operating Leases									
Lease Costs	$6,251	$16,981	$ 54,400	$77,632	$150,000	$25,026	$ 22,667	$ 4,533	$202,226

Other information related to leases is presented below:

	As of December 31, 2022			
Other Information	Hyde Park Lease	Platt Street Lease	2021 Baltimore Lease	Total
Operating Leases				
Operating cash used	$ 4,622	$ 19,628	$ 51,602	$ 75,852
Average remaining lease term	-	27	23	25
Average discount rate	10.0%	10.0%	10.0%	10.0%

As of December 31, 2022, the annual minimum lease payments of the Company's operating lease liabilities were as follows:

	As of December 31, 2022		
	Platt Street Lease	2021 Baltimore Lease	Total
For Years Ending December 31,			
2023	$ 22,485	$ 54,520	$ 77,005
2024	23,103	51,348	74,451
2025	5,814	-	5,814
Total future minimum lease payments, undiscounted	$ 51,402	$ 105,868	$ 157,270
Less: Imputed interest	5,591	9,958	15,549
Present value of future minimum lease payments	$ 45,811	$ 95,910	$ 141,721

(p) Revenue Recognition

The Company will recognize revenue under ASC 606, Revenue from Contracts with Customers. The core principle of the revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods and services transferred to the customer. The following five steps are applied to achieve that core principle:

1) Identify the contract with the customer
2) Identify the performance obligations in the contract
3) Determine the transaction price
4) Allocate the transaction price to the performance obligations in the contract
5) Recognize revenue when the company satisfies a performance obligation

(q) Income Taxes

The Company utilizes an asset and liability approach for financial accounting and reporting for income taxes. The provision for income taxes is based upon income or loss after adjustment for those permanent items that are not considered in the determination of taxable income. Deferred income taxes represent the tax effects of differences between the financial reporting and tax basis of the Company's assets and liabilities at the enacted tax rates in effect for the years in which the differences are expected to reverse.

The Company evaluates the recoverability of deferred tax assets and establishes a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized. Management makes judgments as to the interpretation of the tax laws that might be challenged upon an audit and cause changes to previous estimates of tax liability. In management's opinion, adequate provisions for income taxes have been made. If actual taxable income by tax jurisdiction varies from estimates, additional allowances or reversals of reserves may be necessary.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. For the years ended December 31, 2022 and 2021, no liability for unrecognized tax benefits was required to be reported.

There was no income tax benefit recorded for the losses for the years ended December 31, 2022 and 2021 since management determined that the realization of the net deferred tax assets is not more likely than not to be realized and has recorded a full valuation allowance on the net deferred tax assets.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the years ended December 31, 2022 and 2021. The Company does not expect its uncertain tax position to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

Tax years from 2019 through 2022 remain subject to examination by federal and state jurisdictions.

(r) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common share is based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share is computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period. Potential common shares that would have the effect of increasing diluted earnings per share are considered anti-dilutive.

Diluted net loss per share is computed using the weighted average number of shares of Common Stock and dilutive potential Common Stock outstanding during the period.

As the Company reported a net loss for the years ended December 31, 2022 and 2021, Common Stock equivalents were anti-dilutive.

As of December 31, 2022 and 2021, the following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	For the Years Ended December 31,	
	2022	2021
Stock Options	4,376,737	4,176,739
Unvested Restricted Stock Units	2,795,000	2,795,000
Warrants to purchase Common Stock	6,514,827	5,074,489
Pre-funded Warrants to purchase Common Stock	135,135	520,270
Series C Preferred Convertible Warrants	27,500	27,500
Series D Preferred Convertible Stock	36,496	36,496
Total potentially dilutive shares	13,885,695	12,630,494

(s) Stock-based Payments

The Company accounts for stock-based compensation under the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, "Compensation - Stock Compensation", which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting (the "2018 Update"). The amendments in the 2018 Update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Prior to the 2018 Update, Topic 718 applied only to share-based transactions to employees. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied.

The Company has elected to account for forfeiture of stock-based awards as they occur.

(t) Research and Development Costs

In accordance with FASB ASC 730, research and development costs are expensed as incurred and consist of fees paid to third parties that conduct certain research and development activities on the Company's behalf.

(u) Recently Issued Accounting Pronouncements

Recently Issued Accounting Pronouncements Adopted

In July 2017, FASB issued ASU 2017-11, Earnings per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): The new guidance amends ASC 815 to exclude consideration of a down-round feature in the evaluation of whether an instrument is indexed to an entity's own stock under ASC 815-40-15-7C. That is, a down-round provision would not preclude an entity from concluding that an instrument or feature that includes a down-round feature is indexed to the entity's own stock. This guidance applies to both freestanding financial instruments and embedded conversion options (e.g., in convertible instruments with beneficial conversion features (BCFs) or cash conversion features (CCFs)). The ASU is effective for annual reporting periods beginning after December 15, 2019. The Company adopted this guidance as of January 1, 2020. The adoption of this standard did not have a material impact on their consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. ASU 2020-06 simplifies the guidance in U.S. GAAP on the issuer's accounting for convertible debt instruments. The new guidance removes from U.S. GAAP the separation models for (1) convertible debt with a CCF and (2) convertible instruments with a BCF. As a result, after adopting the ASU's guidance, entities will not separately present in equity an embedded conversion feature in such debt. Instead, they will account for a convertible debt instrument wholly as debt, and for convertible preferred stock wholly as preferred stock. This ASU is effective for fiscal years beginning after December 15, 2021 and early adoption is allowed. The Company early adopted this guidance as of January 1, 2021. The adoption of this standard did not have a material impact on their consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt - Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40), Issuer's Accounting for Certain Modifications or Exchanges or Freestanding Equity - Classified Written Call Options.* The amendments in this Update clarify an issuer's accounting for modifications or exchanges of freestanding equity - classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted for all entities, including adoption in an interim period. If an entity elects to early adopt the amendments in this Update in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes the interim period. The adoption of this ASU had no material impact on the Company's consolidated financial statements and related disclosure.

Recently Issued Accounting Pronouncements Not Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments ("ASU-2016-13"). ASU 2016-13 affects loans, debt securities, trade receivables, and any other financial assets that have the contractual right to receive cash. The ASU requires an entity to recognize expected credit losses rather than incurred losses for financial assets. ASU 2016-13 is effective for the fiscal year beginning after December 15, 2022, including interim periods within that fiscal year. The Company expects that there would be no material impact on the Company's consolidated financial statements upon the adoption of this ASU.

Note 3 – Recent Developments, Liquidity and Management's Plans

Acquisition and Disposition of Cystron

The Company acquired 100% of the membership interests of Cystron pursuant to a Membership Interest Purchase Agreement, dated March 23, 2020 (as amended by Amendment No. 1 on May 14, 2020, the "MIPA") from certain selling parties (the "Cystron Sellers"). The acquisition of Cystron was accounted for as a purchase of an asset. Cystron is a party to a License and Development Agreement (as amended and restated on March 19, 2020, in connection with our entry into the MIPA, the "License Agreement") with Premas Biotech PVT Ltd. ("Premas") whereby Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other coronavirus infections. Cystron was incorporated on March 10, 2020. Since its formation and through the date of its acquisition by the Company, Cystron did not have any employees and its sole asset consisted of the exclusive license from Premas.

On March 18, 2021, the Company and the Cystron Sellers, which are also shareholders of Oravax, entered into a Termination and Release Agreement terminating the MIPA effective upon consummation of the Contribution Agreement. In addition, the Cystron Sellers agreed to waive any change of control payment triggered under the MIPA as a result of the Merger.

On April 16, 2021, pursuant to the Contribution and Assignment Agreement, dated March 18, 2021 (the "Contribution Agreement") by and among the Company, Cystron, Oravax and, for the limited purpose set forth therein, Premas, the parties consummated the transactions contemplated therein. Pursuant to the Contribution Agreement, among other things, the Company caused Cystron to contribute substantially all of the assets associated with its business of developing and manufacturing Cystron's COVID-19 vaccine candidate to Oravax (the "Contribution Transaction").

As of December 31, 2021, all amounts due to Premas under the Contribution Agreement have been paid. (*Note: Pursuant to the Contribution Agreement, a total of $1,500,000 was owed to Premas, of which $1,200,000 was paid by pre-merger Akers Biosciences, Inc.*)

Agreement and Plan of Merger and Reorganization

On November 11, 2020, MyMD, Merger Sub, and MyMD Florida entered into the Merger Agreement (Note 1).

Upon completion of the Merger and the transactions contemplated in the Merger Agreement, the Company issued 28,553,307 post reverse stock split shares of Company Common Stock to the former stakeholders of pre-Merger MyMD Florida at the Exchange Ratio. Upon completion of the Merger and the transactions contemplated in the Merger Agreement, the former stakeholders of pre-Merger MyMD Florida held approximately 77.05% of the Company's Common Stock outstanding on a fully diluted basis, assuming the exercise in full of the pre-funded warrants to purchase 986,486 shares of Company Common Stock and including 4,188,315 shares of Company Common Stock underlying options to purchase shares of pre-Merger MyMD Florida Common Stock assumed by the company at closing and after adjustments based on the Company's net cash at closing. Holders of pre-Merger Company Common Stock held approximately 22.95% of the outstanding equity of the Company. Also upon completion of the Merger and the transactions contemplated by the Merger Agreement, the Company assumed 4,188,315 MyMD Florida stock options subject to certain terms contained in the Merger Agreement (including, but not limited to, the amendment of such stock option to extend the term of such stock option for a period expiring on April 16, 2023, the second-year anniversary of the Merger.

In accordance with ASC 805, the Company accounted for the transaction as a reverse merger with Akers Biosciences, Inc. ("Akers") as the legal acquirer and pre-Merger MyMD Florida as the accounting acquirer. As a result of the transaction, the Company recognized Goodwill totaling $10,498,539 based upon Akers' pre-merger market capitalization of $42,477,346 less net tangible assets of $31,978,807.

Akers' valuation was based upon 8,335,627 common shares outstanding and 263,026 vested restricted stock units ("RSU') with a fair market value of $4.94 per share, the closing price of Akers common shares on the NASDAQ Stock Exchange on April 16, 2021.

	Valuation Analysis
Total Consideration	$ 42,477,346
Cash and Cash Equivalents	1,380,852
Marketable Securities	29,480,524
Other Receivables	3,026,137
Prepaid Expenses	192,314
Investment in Oravax, Inc.	1,500,000
Trade and Other Payables	(3,601,020)
Net Tangible Assets Acquired	$ 31,978,807
Excess of Purchase Price Over Net Assets Acquired to be Allocated to Goodwill	$ 10,498,539

The holders of approximately 49.68% of outstanding shares of Company Common Stock are subject to lockup agreements pursuant to which such stockholders have agreed, except in limited circumstances, not to transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber, any shares of Company capital stock for 180 days following the effective time of the Merger. For the subsequent 180 days after the initial 180-day lock-up period, any disposal of Company Common Stock must be only in accordance with the volume limitations set forth in paragraph (2) of Rule 144 promulgated under the Securities Act of 1933, as amended (the "Act").

Pursuant to the terms and conditions of the Merger Agreement, not later than 30 days after the Option Exercise Period, the Company will pay stockholders of MyMD Florida the Additional Consideration from the exercise of any MyMD Florida options assumed by the Company prior to the second-year anniversary of the Merger; provided, however, the amount of such payment will not exceed the maximum amount of cash consideration that may be received by stockholders of MyMD Florida without affecting the intended tax consequences of the Merger. As of the date of this report, there have been no exercises of the MyMD Florida options assumed by the Company.

Under the terms of the Merger Agreement, the Company has agreed to pay contingent consideration in combined Company Common Stock to MYMD Florida stockholders if the combined company meets certain market capitalization milestones, referred to as Milestone Events, during the period commencing on the business day following the closing date of the merger and ending on the 36-month anniversary of such date, referred to as the Milestone Period. The Milestone Events and corresponding Milestone Payments are set forth in the table below.

Milestone Event	Milestone Payment
Market capitalization of the combined company for at least ten (10) trading days during any 20 consecutive trading day period during the Milestone Period is equal to or greater than $500,000,000 (the "First Milestone Event").	$20,000,000
For every $250,000,000 incremental increase in market capitalization of the combined company after the First Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period, up to a $1,000,000,000 market capitalization of the combined company.	$10,000,000 per each incremental increase (it being understood, however, that, if such incremental increase results in market capitalization equal to $1,000,000,000, such $10,000,000 payment in respect of such incremental increase shall be payable without duplication of any amount payable in respect of a Second Milestone Event, as defined below).
Market capitalization of the combined company for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period is equal to or greater than $1,000,000,000 (the "Second Milestone Event")	$25,000,000
For every $1,000,000,000 incremental increase in market capitalization of the combined company after the Second Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period.	$25,000,000 per each incremental increase

For purposes of the table above, "market capitalization" means, with respect to any trading day, the product of (i) the total outstanding shares of the combined Company Common Stock and (ii) the volume weighted average trading price for the combined Company Common Stock for such trading day.

As of December 31, 2022, none of the contingencies noted above have been met.

Liquidity

As of December 31, 2022, the Company's cash on hand was $749,090 and marketable securities were $4,086,902. The Company has incurred a net loss from operations of $15,197,336 for the year ended December 31, 2022. As of December 31, 2022, the Company had working capital of $2,632,796 and stockholders' equity of $14,695,056 including an accumulated deficit of $93,758,904. During the year ended December 31, 2022, cash flows used in operating activities were $12,270,068, consisting primarily of a net loss of $15,197,336 offset by non-cash share-based compensation of $695,191 and an increase in trade and other payables of $1,686,595 and a decrease in prepaid expenses of $540,560. Since its inception, the Company has met its liquidity requirements principally through the sale of its Common Stock in public and private placements.

The Company evaluated the current cash requirements for operations in conjunction with management's strategic plan and believes that the Company's current financial resources as of the date of the issuance of these consolidated financial statements are sufficient to fund its current operating budget and contractual obligations as of December 31, 2022 as they fall due within the next twelve-month period, alleviating any substantial doubt raised by the Company's historical operating results and satisfying its estimated liquidity needs for twelve months from the issuance of these consolidated financial statements.

Note 4 – Trade and Other Payables

Trade and other payables consist of the following:

	December 31, 2022	December 31, 2021
Accounts Payable – Trade	$ 2,356,555	$ 867,518
Accrued Expenses	316,666	119,108
	$ 2,673,221	$ 986,626

Note 5 – Notes Payable

Secured Promissory Note

On November 11, 2020, concurrently with the execution of the Merger Agreement, the Company agreed to provide a bridge loan up to an aggregate principal amount of $3,000,000 to pre-Merger MyMD Florida pursuant to the Bridge Loan Note. Advances under the Bridge Loan Note ("Bridge Loan Advances") were made in the amounts and at the times as needed to fund MyMD Florida's operating expenses. Bridge Loan Advances accrue interest at 5% per annum, which may be increased to 8% per annum upon occurrence of any event of default, from the date of such default. The principal and the accrued interest thereon are to be repaid on the earliest of (a) April 15, 2022; (b); if the Merger was consummated, then upon demand of the Company following the consummation of the Merger; or (c) the date on which the obligations under the Bridge Loan Note are accelerated upon event of default as set forth in the Bridge Loan Note. The payment and performance of all obligations under the Bridge Loan Note are secured by a first priority security interest in all of MyMD Florida's right, title and interest in and to its assets as collateral. The outstanding principal amount and the accrued interest of the Bridge Loan Note were convertible into shares of MyMD Florida Common Stock in accordance with the terms of the Merger Agreement.

As of December 31, 2022 and December 31, 2021 MyMD had advanced MyMD Florida $3,000,000 under the Bridge Loan Note plus accrued interest totaling $26,137. The balance of $3,026,137 as of December 31, 2022 and December 31, 2021, respectively, were eliminated on consolidation.

Note 6 – Stock-based Payments

Equity incentive Plans

2013 Stock Incentive Plan

On January 23, 2014, the Company adopted the 2013 Stock Incentive Plan ("2013 Plan"). The 2013 Plan was amended by the Board on January 9, 2015 and September 30, 2016, and such amendments were ratified by shareholders on December 7, 2018. The 2013 Plan provides for the issuance of up to 2,162 shares of the Company's Common Stock. As of December 31, 2022, grants of restricted stock and options to purchase 1,406 shares of Common Stock have been issued pursuant to the 2013 Plan, and 755 shares of Common Stock remain available for issuance.

2016 Stock Incentive Plan

On December 21, 2016, the shareholders approved, and the Company adopted the 2016 Stock Incentive Plan ("2016 Plan"). The 2016 Plan provides for the issuance of up to 50,000,000 shares of the Company's Common Stock. As of December 31, 2022, grants of options to purchase 4,188,315 shares of Common Stock have been issued pursuant to the 2016 Plan, and 0 shares of Common Stock remain available for issuance.

2017 Stock Incentive Plan

On August 7, 2017, the shareholders approved, and the Company adopted the 2017 Stock Incentive Plan ("2017 Plan"). The 2017 Plan provides for the issuance of up to 3,516 shares of the Company's Common Stock. As of December 31, 2022, grants of restricted stock and options to purchase 2,538 shares of Common Stock have been issued pursuant to the 2017 Plan, and 978 shares of Common Stock remain available for issuance.

2018 Stock Incentive Plan

On December 7, 2018, the shareholders approved, and the Company adopted the 2018 Stock Incentive Plan ("2018 Plan"). On August 27, 2020, the 2019 Plan was modified to increase the total authorized shares. The 2018 Plan, as amended, provides for the issuance of up to 560,063 shares of the Company's Common Stock. As of December 31, 2022, grants of RSUs and restricted stock to purchase 263,026 shares of Common Stock have been issued pursuant to the 2018 Plan, and 297,037 shares of Common Stock remain available for issuance.

2021 Stock Incentive Plan

On April 15, 2021, the shareholders approved, and the Company adopted the 2021 Stock Incentive Plan ("2021 Plan"). The 2021 Plan provides for the issuance of up to 7,228,184 shares of the Company's Common Stock. As of December 31, 2022, grants of RSUs and stock options to purchase 3,149,207 shares of Common Stock have been issued pursuant to the 2021 Plan, and 4,078,977 shares of Common Stock remain available for issuance.

Stock Options

The following table summarizes the activities for MyMD stock options for the year ended December 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2021	4,176,737	$ 2.59	$ 2.59	1.29	$14,493,284
Granted	300,000	3.41	3.41	5.80	$ -
Exercised	-	-	-	-	-
Forfeited	-	-	-	-	-
Canceled/Expired	-	-	-	-	-
Balance at December 31, 2022	4,476,737	2.64	2.64	0.64	$ -
Exercisable as of December 31, 2022	4,376,737	2.61	2.61	0.52	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.15 for the Company's common shares on December 31, 2022 and the closing stock price of $6.06 for the Company's common shares on December 31, 2021.

On January 28, 2022, the Company's Compensation Committee approved the issuance of 200,000 stock options under the 2021 Stock Incentive Plan. These shares had a grant date fair value of $3.59 per share or a cumulative fair market value of $717,660 as calculated using Black-Scholes (exercise price $3.96 per share, stock price $3.96 per share, volatility of 124.43%, discount rate of 1.74% and seven-year term). The grant was segmented into four vesting tranches triggered by performance achievements and expire on January 28, 2029. The Company is amortizing the expenses over the vesting cycles of the individual tranches.

On June 21, 2022, the Company granted 100,000 stock options under the 2021 Stock Incentive Plan to a third-party consultant in consideration of services rendered. These shares had a grant date fair value of $2.30 per share or a cumulative fair market value of $199,360 as calculated using Black-Scholes (exercise price $2.30 per share, stock price $2.30 per share, volatility of 130.51%, discount rate of 3.24% and five-year term). The grant vested immediately and expire on June 21, 2027. The Company is amortizing the expense over twelve months, the term of the consulting agreement.

During the years ended December 31, 2022 and 2021, the Company incurred stock option expenses totaling $444,342 and $0, respectively. The unamortized stock option expenses as of December 31, 2022 and 2021 totaled $113,847 and $0, respectively.

Assumption of MyMD Florida Stock Options

In 2016, pre-Merger MyMD Florida adopted the MyMD Pharmaceuticals, Inc. Amended and Restated 2016 Equity Incentive Plan (the "2016 Plan"). The 2016 Plan provided for the issuance of up to 50,000,000 shares of pre-Merger MyMD Florida Common Stock. As of December 31, 2022, options to purchase 4,188,315 shares of Company Common Stock have been issued pursuant to the plan and 0 shares of Company Common Stock remain available for issuance.

Pursuant to the Merger Agreement, effective as of the effective time of the Merger, the Company assumed pre-Merger MyMD Florida's Second Amendment to Amended and Restated 2016 Stock Incentive Plan (the "2016 Plan"), assuming all of pre-Merger MyMD Florida's rights and obligations with respect to the options issued thereunder. As of the effective date of the Merger, no additional awards could be issued under the 2016 Plan.

In addition, under the terms of the Merger Agreement, the Company assumed all of pre-Merger MyMD Florida's rights and obligations under pre-Merger MyMD Florida's stock options that were outstanding immediately prior to the effective time of the Merger, and each such stock option, whether or not vested, was converted into a stock option representing the right to purchase shares of Company Common Stock, on terms substantially the same as those in effect immediately prior to the effective time, except that the number of shares of Company Common Stock issuable and the exercise price per share of such stock options was adjusted by the Exchange Ratio. Additionally, the number of shares and exercise price per share of Company Common Stock under the assumed pre-Merger MyMD Florida stock options was further adjusted by the Reverse Stock Split.

The Company assumed 4,188,315 MyMD Florida stock options subject to certain terms contained in the Merger Agreement (including, but not limited to, the amendment of such stock option to change the term of such stock option for a period expiring on April 16, 2023, the second-year anniversary of the Merger). The Company recorded expenses of $15,036,051 for the assumption of the options and the modification of the terms which is included on the Consolidated Statement of Comprehensive Loss for the year December 31, 2021. The Company utilized Black-Scholes using an exercise price of $2.59, an issue date fair value of $4.94, a volatility index of 122.31% and a discount rate of 0.16% to determine the fair value of the modification. The pre-Merger MyMD options were valued at $0 on April 16, 2021, as there was no reliable method of determining the fair value given the material events that had occurred since the last arms-length trade of common shares.

Restricted Stock Units

On September 11, 2020, the Compensation Committee of the Board of Directors approved grants totaling 394,680 Restricted Stock Units to the Company's four directors. Each RSU had a grant date fair value of $4.48 which shall be amortized on a straight-line basis over the vesting period into administrative expenses within the Consolidated Statement of Comprehensive Loss. Such RSUs were granted under the 2018 Plan, as amended. Fifty percent (50%) of each RSU will vest on the first anniversary date of the Grant and the remaining fifty percent (50%) will vest on the second anniversary date; provided that the RSUs shall vest immediately upon the occurrence of (i) a change in control, provided that the director is employed by or providing services to the Company and its affiliates on the closing date of such change of control, or (ii) the director's termination of employment of service by the Company was without cause.

On April 16, 2021, concurrently with the closing of the Merger, pursuant to the terms of the RSU Agreements between the Company and four board of directors, the 394,680 RSUs granted on September 11, 2020 under the 2018 Plan, as amended, accelerated and vested in full.

Per the terms of the RSU agreements, the Company, at the Company's sole discretion, may settle the RSUs in cash, or part cash and part Common Stock. As there is no intention to settle the RSUs in cash, the Company accounted for these RSUs as equity.

Pre-merger Akers Biosciences, Inc. recorded expenses totaling $979,758 for the acceleration of the vesting of 394,680 RSUs, the holders immediately surrendered 139,457 RSUs with a fair market value of $688,913 for the withholding of federal and state income taxes, as directed by the holders, which was recorded as Payroll Taxes Payable on the date of the Merger. The withholding obligations were paid by the Company on June 30, 2021. As of March 29, 2023, the vested RSUs have not been converted to common shares of the Company.

On October 14, 2021, the Compensation Committee of the Board of Directors approved grants totaling 2,795,000 Restricted Stock Units to the Company's six directors and seven key employees. Each RSU had a grant date fair value of $8.09 which will be amortized upon vesting into administrative expenses within the Consolidated Statement of Comprehensive Loss. Such RSUs were granted under the 2021 Plan. Vesting of each RSU is:

- One-third (33%) of each RSU will vest when the Company's market capitalization is equal to or greater than $500,000,000 for at least ten trading days during any twenty (20) consecutive trading day period ending on or after December 15, 2021 and the fair market value of the Common Stock equals or exceeds $5.00 during such trading day period.

- One-third (33%) of each RSU will vest when the Company's market capitalization is equal to or greater than $750,000,000 for at least ten trading days during any twenty (20) consecutive trading day period ending on or after December 15, 2021 and the fair market value of the Common Stock equals or exceeds $5.00 during such trading day period.

- The remaining awarded units will vest when the Company's market capitalization is equal to or greater than $1,000,000,000 for at least ten trading days during any twenty (20) consecutive trading day period ending on or after December 15, 2021 and the fair market value of the Common Stock equals or exceeds $5.00 during such trading day period.

- In the event that (i) a change in control occurs or (ii) the participant incurs a termination of service by the Company without cause or due to the participant's death or total and permanent disability, then all unvested units shall become vested units immediately upon the occurrence of such event.

As of December 31, 2022, none of the vesting milestones have been met.

On January 28, 2022, the Compensation Committee of the Board of Directors approved a grant of 4,040 RSUs to a sub-contractor with a grant date fair value of $15,998 and vested immediately. Such RSUs were granted under the 2021 Plan. The Company recorded expenses of $15,998 which is included Stock Based Compensation on the Consolidated Statement of Comprehensive Loss during the year ended December 31, 2022.

On July 7, 2022, the Compensation Committee of the Board of Directors approved a grant of 50,167 RSUs to a sub-contractor with a grant date fair value of $150,000 and vested immediately. Such RSUs were granted under the 2021 Plan. The Company recorded expenses of $138,587 which is included Stock Based Compensation on the Consolidated Statement of Comprehensive Loss during the year ended December 31, 2022.

The following is the status of outstanding unvested restricted stock units outstanding as of December 31, 2022 and the changes for the year ended December 31, 2022:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at December 31, 2021	2,795,000	$ 8.09
Granted	54,207	3.06
Exercised	-	-
Vested	(54,207)	3.06
Forfeited	-	-
Canceled/Expired	-	-
Balance at December 31, 2022	$ 2,795,000	$ 8.09

As of December 31, 2022 and 2021, the unamortized value of the RSUs was $22,611,550.

Note 7 – Equity

Preferred Stock

The holders of preferred shares or preferred warrants are entitled to vote per share, as limited by the certificate of designation for each class of preferred shares or warrants, at meetings of the Company. As of December 31, 2022, 50,000,000 shares of Preferred Stock were authorized and four classes of Preferred Stock or Warrants are designated.

Series D Convertible Preferred Stock

On March 24, 2020, the Company designated 211,353 Series D Convertible Preferred Shares, no par value with a stated value of $0.01 per share and filed the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Series D Certificate of Designation") with the Secretary of State of the State of New Jersey. Pursuant to the Series D Certificate of Designation, in the event of the Company's liquidation or winding up of its affairs, the holders of its Series D Convertible Preferred Stock (the "Preferred Stock") will be entitled to receive the same amount that a holder of the Company's Common Stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations set forth in the Series D Certificate of Designation) to Common Stock which amounts shall be paid pari passu with all holders of the Company's Common Stock. Each share of Preferred Stock has a stated value equal to $0.01 (the "Stated Value"), subject to increase as set forth in Section 7 of the Series D Certificate of Designation.

A holder of Preferred Stock is entitled at any time to convert any whole or partial number of shares of Preferred Stock into shares of the Company's Common Stock determined by dividing the Stated Value of the Preferred Stock being converted by the conversion price of $0.01 per share.

A holder of Preferred Stock will be prohibited from converting Preferred Stock into shares of the Company's Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of the Company's Common Stock then issued and outstanding (with such ownership restriction referred to as the "Beneficial Ownership Limitation"). However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to the Company.

Subject to the Beneficial Ownership Limitation, on any matter presented to the Company's stockholders for their action or consideration at any meeting of the Company's stockholders (or by written consent of stockholders in lieu of a meeting), each holder of Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of the Company's Common Stock into which the shares of Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of the Company's certificate of incorporation, the holders of Preferred Stock will vote together with the holders of the Company's Common Stock and any other class or series of stock entitled to vote thereon as a single class.

A holder of Preferred Stock shall be entitled to receive dividends as and when paid to the holders of the Company's Common Stock on an as-converted basis.

As of December 31, 2022, the Company had 72,992 shares of Series D Convertible Preferred Stock outstanding which represent 36,496 underlying shares of the Company Common Stock.

Common Stock

Pursuant to the Merger Agreement, on April 16, 2021, the Company filed an amended and restated certificate of incorporation (the "A&R Charter") with the Secretary of State of the State of New Jersey, which was approved by the Company's stockholders on April 15, 2021. Among other things, the A&R Charter (i) changed the Company's name to MyMD Pharmaceuticals, Inc., (ii) increased the number of shares of Company Common Stock available from 100,000,000 shares to a total of 500,000,000 shares of the Company's Common Stock, (iii) changed the structure of the board of directors from a classified board of three classes to a non-classified board of a single class, and (iv) simplified and consolidated various provisions.

The holders of common shares are entitled to one vote per share at meetings of the Company.

On February 11, 2021, 466,216 shares of Common Stock issued pursuant to that certain Securities Purchase Agreement, dated November 11, 2020, by and between the Company and certain institutional and accredited investors were cancelled and 466,216 prefunded warrants (as defined therein) were issued at the request of a shareholder.

On May 18, 2021, 466,216 prefunded warrants were exercised in exchange for 466,716 shares of Common Stock.

On August 5, 2021, the Company issued 16,826 shares of Common Stock with a fair market value of $90,002 for services.

On December 9, 2021, holders of 11,576 Common Stock options were exercised for 11,576 shares of Common Stock at an exercise price of $2.59 per common share. The net proceeds of $29,982 is recorded as a current liability on the Consolidated Balance Sheet as of December 31, 2022. The accumulated proceeds from the exercise of these stock options will be distributed to the former shareholders of MyMD Florida per the terms of the Merger Agreement.

On February 16, 2022, 385,135 prefunded warrants were exercised in exchange for 385,135 shares of Common Stock.

On August 17, 2022, pursuant to a securities purchase agreement with certain institutional and accredited investors, dated August 15, 2022, the Company issued and sold in a registered direct offering (the "August Offering") an aggregate of 1,411,764 shares of its Common Stock at an offering price of $4.25 per share and 1,411,764 unregistered investor warrants to purchase up to 1,411,764 shares of its Common Stock at an exercise price of $5.25, for gross and net proceeds of $5,999,997 and $5,550,028, respectively.

Common Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2022:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2021	5,074,489	$ 5.25	4.34	$ 9,554,827
Granted	1,450,029	5.27	4.88	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	(9,691)	222.55	-	-
Balance at December 31, 2022	6,514,827	$ 4.93	3.63	$ -
Exercisable as of December 31, 2022	6,514,827	$ 4.93	3.63	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.15 for the Company's common shares on December 31, 2022 and the closing stock price of $6.06 for the Company's common shares on December 31, 2021. All warrants were vested on date of grant.

On July 7, 2022, the Company issued warrants to purchase up to 38,265 shares of its Common Stock at an exercise price of $5.98 to a vendor for services. The cumulative fair market value of $93,233 as calculated using Black-Scholes (exercise price $5.98 per share, stock price $2.99 per share, volatility of 131.06%, discount rate of 3.07% and a five- year term). The warrants will be exercisable at any time and from time to time, in whole or in part, following the date of issuance and for a term of five years from the effective date. The fair-market value of the warrants was amortized over the life of the service contract. During the year ended December 31, 2022, the Company recognized $84,851 in expense which is included in Stock-Based Compensation on the Consolidated Statement of Comprehensive Loss.

On August 17, 2022, in connection with the August Offering, the Company issued unregistered investor warrants to purchase up to 1,411,764 shares of its Common Stock at an exercise price of $5.25 (the "August Investor Warrants") in a private placement. The August Investor Warrants will be exercisable at any time and from time to time, in whole or in part, beginning six-months following the date of issuance and for a term of five years from the initial exercise date.

Pre-funded Common Stock Warrants

The table below summarizes the pre-funded warrant activity for the year ended December 31, 2022:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2021	520,270	$ 0.002	-	$ 3,151,796
Granted	-	-	-	-
Exercised	(385,135)	0.002	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2022	135,135	$ 0.002	-	$ 155,135
Exercisable as of December 30, 2022	135,135	$ 0.002	-	$ 155,135

All pre-funded warrants were vested on date of grant and are exercisable at any time. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying award and the closing stock price of $1.15 for the Company's common shares on December 31, 2022 and the closing stock price of $6.06 for Common Stock on December 31, 2021.

Series C Convertible Preferred Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2022:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2021	27,500	$ 8.00	2.94	$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2022	27,500	$ 8.00	1.94	$ -
Exercisable as of December 31, 2022	27,500	$ 8.00	1.94	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.15 for the Company's common shares on December 31, 2022 and the closing stock price of $6.06 for the Company's common shares on December 31, 2021. All Series C Convertible Preferred Stock Warrants were vested on date of grant.

Note 8 – Income Taxes

The Company's income tax (benefit)/provision is as follows for the years ended December 31, 2022 and 2021:

	2022	2021
Current	$ -	$ -
Deferred	(5,914,000)	(6,219,000)
Change in Valuation Allowance	5,914,000	6,219,000
Income Tax Benefit	$ -	$ -

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2022 and 2021 are as follows:

	2022	2021
Statutory U.S. Federal Income Tax Rate	(21.0)%	(21.0)%
New Jersey State income taxes, net of U.S. Federal tax effect	(14.5)%	(9.0)%
Adjustment to deferred tax assets	(4.1)%	9.3%
Other	0.7%	(0.1)%
Change in Valuation Allowance	38.9%	20.8%
Net	0.0%	0.0%

As of December 31, 2022, and 2021, the Company had U.S. federal net operating loss carry forwards of approximately $107.1 million and $101.9 million, respectively. Approximately $57.7 million of the U.S. federal net operating loss generated in tax years beginning before January 1, 2018 expire beginning with the year ending December 31, 2023 through 2037. The remaining U.S. federal net operating loss of approximately $49.4 million does not expire, however it is limited to 80% of each subsequent year's net income. As of December 31, 2022, and 2021, the Company had U.S. state net operating loss carry forwards of approximately $41.0 million and $38.2 million, respectively, some of which expire beginning with the year ending December 31, 2023 through 2042. U.S. federal net operating losses of approximately $3.8 million expired during 2022. The timing and manner in which the Company can utilize operating loss carryforwards in any year may be limited by provisions of the Internal Revenue Code regarding changes in ownership of corporations. Such limitation may have an impact on the ultimate realization of its carryforwards and future tax deductions.

Under Section 382 of the Code, use of the Company's net operating loss carryforwards is limited if the Company experiences a cumulative change in ownership of greater than 50% in a moving three-year period. The Company experienced an ownership change as a result of the Merger and therefore the Company's ability to utilize its net operating loss and certain credit carryforwards are limited. The limitation is determined by the fair market value of the Company's common stock outstanding immediately prior to the ownership change, multiplied by the applicable federal rate. It is expected that the Merger caused the Company's net operating loss carryforwards to be limited. However, the limitation had no impact on the Company's financial statements since the Company recorded a full valuation allowance for the deferred tax assets as of December 31, 2022 and 2021.

The principal components of the deferred tax assets and related valuation allowances as of December 31, 2022 and 2021 are as follows:

	2022	2021
Reserves and other	$ 745,000	$ 179,000
Net operating loss carry-forwards	26,176,000	23,526,000
Capitalized research and development	2,177,000	-
Research and development tax credit	610,000	610,000
Share-based compensation	4,542,000	4,021,000
Valuation Allowance	(34,250,000)	(28,336,000)
Net deferred tax asset	$ -	$ -

The valuation allowance for deferred tax assets increased by approximately $5.9 million and $6.2 million, for the years ended December 31, 2022 and 2021, respectively, due mainly to increases in the Company's deferred tax asset related to its net operating loss carryforward. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets may be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating losses and temporary differences become deductible. Management considers projected future taxable income and tax planning strategies in making this assessment.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the years ended December 31, 2022 and 2021. The Company does not expect its uncertain tax position to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

The Company files U.S. federal income tax returns and state income tax returns. Since the Company had losses in the past, all prior years that generated net operating loss carryforwards are open and subject to audit examination in relation to the net operating loss generated from those years.

Note 9 – Commitments and Contingencies

Scientific Advisory Board

On February 1, 2021, the Company formed the Scientific Advisory Board to (i) provide strategic advice and make recommendations to management regarding current and planned research and development programs, (ii) advise management regarding the scientific merit of technology or products involved in licensing and acquisition opportunities and (iii) provide strategic advice to management regarding emerging science and technology issues and trends. During the years ended December 31, 2022 and 2021, the Company incurred costs of $148,000 and $174,000, respectively. These expenses are included in Research and Development Expenses on the Consolidated Statement of Comprehensive Loss. The Scientific Advisory Board was disbanded effective September 30, 2022.

COVID-19

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures, including in the United States and India. On March 12, 2020, the WHO declared COVID-19 to be a global pandemic. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 have had and may continue to have an adverse effect on the global markets and global economy. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will not be put in place again due to a resurgence in COVID-19 cases.

The ultimate impact of the global COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on the Company's business, vaccine development efforts, healthcare systems or the global economy as a whole. However, the effects have had and will likely continue to have a material impact on the Company's operations, liquidity and capital resources, and the Company will continue to monitor the COVID-19 situation closely.

Severe and/or long-term disruptions in the Company's operations may negatively impact the Company's business, operating results and financial condition in other ways as well. Specifically, the Company anticipates that the stress of COVID-19 on healthcare systems generally around the globe may negatively impact regulatory authorities and the third parties that the Company may engage in connection with the development and testing of its product candidates.

The anticipated economic consequences of the COVID-19 pandemic have adversely impacted financial markets, resulting in high share price volatility, reduced market liquidity, and substantial declines in the market prices of the shares of most publicly traded companies, including MyMD. Volatile or declining markets for equities could adversely affect the Company's ability to raise capital when needed through the sale of shares of Common Stock or other equity securities. Should these market conditions persist when the Company needs to raise capital, and if the Company is able to sell shares of its Common Stock under then prevailing market conditions, it might have to accept lower prices for its shares and issue a larger number of shares than might have been the case under better market conditions, resulting in significant dilution of the interests of the Company's shareholders.

Litigation and Settlements

Raymond Akers Actions

On April 14, 2021, Raymond F. Akers, Jr., Ph.D. filed a lawsuit against MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.) in the Superior Court of New Jersey, Law Division, Gloucester County (the "First Raymond Akers Action"). Mr. Akers asserts one common law whistleblower retaliation claim against the Company.

On September 23, 2021, the Court granted MyMD Pharmaceutical, Inc.'s ("MyMD's") Motion to Dismiss Plaintiff's Amended Complaint and dismissed Plaintiff's Amended Complaint. The Court indicated that Mr. Akers is "free to file another complaint, however, tort-based 'Pierce' allegations, and/or CEPA claims are barred by the statute of limitations."

On March 1, 2022, Mr. Akers filed a second action against MyMD in the Superior Court of New Jersey, Law Division, Gloucester County (the "Second Raymond Akers Action") again asserting one common law whistleblower retaliation claim against the Company. The Company believes that the Second Raymond Akers Action is without merit and, moreover, was filed against the Court's specific admonition that Plaintiff does not attempt to circumvent the statute of limitations.

On May 27, 2022, the Court granted-in-part and denied-in-part MyMD's Motion to Dismiss Plaintiff's Complaint. The Court reaffirmed the ruling in the First Raymond Akers Action that any tort-based Pierce claims are time-barred. However, the Court denied the Motion as it pertained to Plaintiff's contract-based Pierce claim and "Repayment of Monies Owed" claim. On July 29, 2022, MyMD filed its Answer, which included affirmative defenses. As of December 31, 2022, the Second Raymond Akers Action is in the discovery phase.

All legal fees incurred were expensed as and when incurred.

Note 10 – Related Parties

Taglich Brothers, Inc.

On November 23, 2020, the Company retained Taglich Brothers, Inc. ("Taglich Brothers") on a non-exclusive basis as a consultant to render consulting services, assist with review, and analysis of, financial planning and budgeting matters of the Company for a term of 12 months. Pursuant to the Consulting Agreement with Taglich Brothers, the Company agreed to pay Taglich Brothers $10,000 per month. During the year ended December 31, 2021, the Company paid $80,000 for consulting services to Taglich Brothers, Inc. which is included in administrative expenses on the Consolidated Statement of Comprehensive Loss. This agreement was cancelled on August 31, 2021.

Mr. Schreiber, a Director, is the Managing Director of Capital Markets at Taglich Brothers. Mr. Schroeder, a former Director was the Vice President of Investment Banking at Taglich Brothers until his death on September 1, 2021.

SRQ Patent Holdings and SRQ Patent Holdings II

MyMD is a party to two Amended and Restated Confirmatory Patent Assignment and Royalty Agreements, both dated November 11, 2020, with SRQ Patent Holdings and SRQ Patent Holdings II, under which MyMD (or its successor) will be obligated to pay to SRQ Patent Holdings or SRQ Patent Holdings II (or its designees) certain royalties on product sales or other revenue received on products that incorporate or are covered by the intellectual property that was assigned to MyMD. The royalty is equal to 8% of the net sales price on product sales and, without duplication, 8% of milestone revenue or sublicense compensation. SRQ Patent Holdings and SRQ Patent Holdings II are affiliates of Mr. Jonnie Williams, Sr. No revenue has been received subject to these agreements as of December 31, 2022 and 2021.

Mr. Jonnie Williams, Sr.

The Company recorded an obligation to Mr. Williams, a shareholder, for various expenses incurred on behalf of the Company between 2016 and 2019. The balance due of $14,577 was paid on April 28, 2021.

Supera Aviation I, LLC

In October 2018, the Company entered a three-year leasing agreement with Supera Aviation I, LLC, a company owned by a shareholder, for a Gulfstream IV-SP aircraft with an annual leasing fee of $600,000. The Company incurred expenses totaling $150,000 for the year ended December 31, 2021.

On April 28, 2021, the Company reached a negotiated settlement with Supera Aviation I, LLC to retire the $627,042 debt due under the leasing agreement for $517,384.

Lines of credit payable

In November 2018, Supera entered into a revolving credit facility which allows for borrowings of up to $1,000,000 with a shareholder. The facility had an initial term of 38 months, which was extended to December 31, 2022 at which time all outstanding borrowings and accrued interest, if any, are due in full. Borrowings accrue interest at a rate of 5% per annum.

In May 2019, the pre-Merger MyMD entered into a revolving credit facility which allows for borrowings of up to $5,000,000 with a shareholder. The facility had an initial term of 18 months, which was extended to July 31, 2021 and further extended to December 31, 2022, at which time all outstanding borrowings and accrued interest, if any, are due in full. Borrowings accrue interest at a rate of 5% per annum. Pursuant to the terms of the agreement, the Company must issue a number of Common Stock options to the lender based on the total borrowings under the facility, with each dollar borrowed requiring the issuance of one Common Stock option. Upon issuance, each Common Stock option will immediately vest at an exercise price of $2.59. The Company recorded accretion of the debt discount totaling $0 and $608,460, respectively, during the years ended December 31, 2022 and 2021.

On April 28, 2021, in accordance with the Merger, the Company paid $3,208,426, inclusive of interest and net of the debt discount, to retire the amounts due to the shareholder under the two lines of credit as of April 28, 2021.

Note 11 – Employee Benefit Plan

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code covering substantially all qualified employees of the Company (the "401(k) Plan"). Under the 401(k) Plan, the Company matches 100% up to a 3% contribution, and 50% over a 3% contribution, up to a maximum of 5%.

The Company made matching contributions to the 401(k) Plan during the years ended December 31, 2022 and 2021 of $41,443 and $16,514, respectively.

Note 12—Paycheck Protection Program Loan

On April 16, 2020, the Company received loan proceeds in the amount of approximately $70,600 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels.

The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the eight-week period. The unforgiven portion of the PPP loan is payable over two years at an annual interest rate of 1%, with a deferral of payments through the date that the Small Business Administration remits the borrower's loan forgiveness amount to the lender. The Company was notified on June 1, 2021 that the loan totaling $70,600 was forgiven which was recorded as a gain on debt forgiveness on the Consolidated Statement of Comprehensive Loss.

Note 13—Patent Assignment and Royalty Agreement

In November 2016, the Company entered into an agreement with the holders of certain intellectual property relating to the Company's current product candidate. Under the terms of the agreement, the counterparty assigned its rights and interest in certain patents to the Company in exchange for future royalty payments based on a fixed percentage of future revenues, as defined. The agreement is effective until the later of (1) the date of expiration of the assigned patents or (2) the date of expiration of the last strategic partnership or licensing agreement including the assigned patents. No revenue has been received subject to these agreements as of December 31, 2022 and 2021.

Note 14 – Subsequent Events

On February 23, 2023, pursuant to a securities purchase agreement with certain institutional and accredited investors, dated February 21, 2023, the Company issued and sold in a registered direct offering i) an aggregate of 15,000 shares of the Company's newly-designated Series F Convertible Preferred Stock with a stated value of $1,000 per share, convertible into shares of Common Stock pursuant to the terms of the securities purchase agreement, and (ii) warrants to acquire up to an aggregate of 6,651,885 shares of Common Stock, subject to adjustment, for gross and net proceeds of $15,000,000 and $14,041,500, respectively.

Exhibit 4.1

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXHANGE ACT OF 1934

This description of the capital stock of MyMD Pharmaceuticals, Inc., a New Jersey corporation ("we," "our" and the "Company") is intended as a summary and is qualified in its entirety by reference to our amended and restated certificate of incorporation, as amended (the "Amended and Restated Certificate of Incorporation") and the amended and restated by-laws, as amended (the "By-laws") as currently in effect, copies of which are filed as exhibits to our Annual Report on Form 10-K and are incorporated herein by reference.

Authorized Capital Stock

Our authorized capital stock consists of 550,000,000 shares, of which 500,000,00 are shares of Common Stock, without par value (the "Common Stock"), and 50,000,000 are shares of preferred stock, without par value, 1,990,000 of which have been designated as Series C Convertible Preferred Stock (the "Series C Preferred Stock"), 211,353 of which have been designated as Series D Convertible Preferred Stock (the "Series D Preferred Stock"), 100,000 of which have been designated as Series E Junior Participating Preferred Stock and 15,000 of which have been designated as Series F Convertible Preferred Stock (the "Series F Preferred Stock"). As of March 29, 2023, there were 39,470,009 shares of Common Stock issued and outstanding and no shares of Series C Convertible Preferred Stock or Series E Junior Participating Preferred Stock issued and outstanding. As of March 29, 2023, there were 72,992 shares of Series D Preferred Stock issued and outstanding, warrants to purchase Series C Preferred Stock convertible into 27,500 shares of Common Stock outstanding and 15,000 shares of Series F Preferred Stock issued and outstanding.

Common Stock

Voting Rights

Each stockholder has one vote for each share of Common Stock held on all matters submitted to a vote of stockholders. A stockholder may vote in person or by proxy. Elections of directors are determined by a plurality of the votes cast and all other matters are decided by a majority of the votes cast by those stockholders entitled to vote and present in person or by proxy.

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of Common Stock will be able to elect all of our directors. Our Amended and Restated Certificate of Incorporation and By-laws provide that stockholder actions may be affected at a duly called meeting of stockholders or pursuant to written consent of the majority of stockholders. A special meeting of stockholders may be called by the president, chief executive officer or the board of directors pursuant to a resolution approved by the majority of the board of directors.

Dividend Rights

The holders of outstanding shares of Common Stock are entitled to receive dividends out of funds legally available at the times and in the amounts that our board of directors may determine, provided that required dividends, if any, on preferred stock have been paid or provided for. However, to date we have not paid or declared cash distributions or dividends on our Common Stock and do not currently intend to pay cash dividends on our Common Stock in the foreseeable future. We intend to retain all earnings, if and when generated, to finance our operations. The declaration of cash dividends in the future will be determined by the board of directors based upon our earnings, financial condition, capital requirements and other relevant factors.

No Preemptive or Similar Rights

Holders of our Common Stock do not have preemptive rights, and Common Stock is not convertible or redeemable.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders and remaining after payment to holders of preferred stock of the amounts, if any, to which they are entitled, are distributable ratably among the holders of our Common Stock subject to any senior class of securities.

The Nasdaq Capital Market Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "MYMD".

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Securities Transfer Corporation, 13577 Feather Sound Drive, Suite 500, Clearwater, Florida 33762.

Options, Warrants and RSUs

As of March 29, 2023, we had 4,176,739 shares of Common Stock issuable upon exercise of outstanding options, 5,072,432 shares of Common Stock issuable upon the exercise of warrants, and 135,135 shares of Common Stock issuable upon the exercise of pre-funded warrants, 27,500 shares of Common Stock issuable upon the exercise of warrants to purchase Series C Preferred Stock and an aggregate of 263,026 shares of Common Stock issuable upon settlement of vested restricted stock units ("RSUs") and upon vesting and settlement of outstanding unvested RSUs. There are 2,795,000 outstanding RSUs and no other outstanding warrants or options at this time.

Preferred Stock

We may issue any class of preferred stock in any series. Our board of directors has the authority, subject to limitations prescribed under New Jersey law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the Common Stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the Company and may adversely affect the market price of Common Stock and the voting and other rights of the holders of Common Stock.

Series C Convertible Preferred Stock

As of March 29, 2023, the Company has 27,500 warrants to purchase an aggregate of 27,500 shares of Series C Preferred Stock outstanding, with an exercise price of $8.00 per share of Series C Preferred Stock (the "Series C Warrants"). The Series C Warrants were issued on December 9, 2019 and expire on January 6, 2025.

Rank

The Series C Preferred Stock ranks (1) on parity with Common Stock on an "as converted" basis, (2) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series C Preferred Stock, (3) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series C Preferred Stock, and (4) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series C Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

Conversion Rights

Each share of the Series C Preferred Stock is convertible into one (1) share of Common Stock, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of Common Stock if, as a result of such conversion, the holder would own more than 4.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of the shares of Common Stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of the shares of Common Stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividend Rights

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends are payable on shares of Series C Preferred Stock.

Voting Rights

Except as provided in the Certificate of Designation of Series C Convertible Preferred Stock (the "Series C Certificate of Designation") or as otherwise required by law, the holders of Series C Preferred Stock will have no voting rights. However, we may not, without the consent of holders of a majority of the outstanding shares of Series C Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock, or enter into any agreement with respect to the foregoing.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series C Preferred Stock are entitled to receive, *pari passu* with the holders of Common Stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into Common Stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the beneficial ownership limitation, as described above.

Exchange Listing

Akers does not plan on making an application to list the shares of Series C Preferred Stock on the Nasdaq, any national securities exchange or other nationally recognized trading system. Our Common Stock issuable upon conversion of the Series C Preferred Stock is listed on the Nasdaq under the symbol "MYMD".

Failure to Deliver Conversion Shares

If we fail to timely deliver shares of Common Stock upon conversion of the Series C Preferred Stock (the "Series C Conversion Shares") within the time period specified in the Series C Certificate of Designation (within two trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), then we are obligated to pay to the holder, as liquidated damages, an amount equal to $50 per trading day (increasing to $100 per trading day after the third trading day and $200 per trading day after the tenth trading day) for each $5,000 of Series C Conversion Shares for which the Series C Preferred Stock being converted are not timely delivered. If we make such liquidated damages payments, we are not also obligated to make Series C Buy-In (as defined below) payments with respect to the same Series C Conversion Shares.

Compensation for Series C Buy-In on Failure to Timely Deliver Shares

If we fail to timely deliver the Series C Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the holder of the Series C Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Series C Buy-In"), then we are obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Series C Conversion Shares that we were required to deliver times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Series C Preferred Stock and equivalent number of Series C Conversion Shares for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of Common Stock that would have been issued had we timely complied with our conversion and delivery obligations.

Subsequent Rights Offerings; Pro Rata Distributions

If we grant, issue or sell any Common Stock equivalents pro rata to the record holders of any class of shares of Common Stock (the "Series C Purchase Rights"), then a holder of Series C Preferred Stock will be entitled to acquire, upon the terms applicable to such Series C Purchase Rights, the aggregate Series C Purchase Rights which the holder could have acquired if the holder had held the number of shares of Common Stock acquirable upon conversion of the Series C Preferred Stock (without regard to any limitations on conversion). If we declare or make any dividend or other distribution of our assets (or rights to acquire our assets) to holders of Common Stock, then a holder of Series C Preferred Stock is entitled to participate in such distribution to the same extent as if the holder had held the number of shares of Common Stock acquirable upon complete conversion of the Series C Preferred Stock (without regard to any limitations on conversion).

Fundamental Transaction

If, at any time while the Series C Preferred Stock is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each a "Series C Preferred Stock Fundamental Transaction"), then upon any subsequent conversion of Series C Preferred Stock, the holder will receive, for each Series C Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Series C Preferred Stock Fundamental Transaction (without regard to the beneficial ownership limitation), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Series C Preferred Stock Alternate Consideration") receivable as a result of such Series C Preferred Stock Fundamental Transaction by a holder of the number of shares of Common Stock for which the Series C Preferred Stock is convertible immediately prior to such Series C Preferred Stock Fundamental Transaction (without regard to the beneficial ownership limitation). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Series C Preferred Stock Alternate Consideration based on the amount of Series C Preferred Stock Alternate Consideration issuable in respect of one share of Common Stock in such Series C Preferred Stock Fundamental Transaction. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Series C Preferred Stock Fundamental Transaction, then the holder will be given the same choice as to the Series C Preferred Stock Alternate Consideration it receives upon automatic conversion of the Series C Preferred Stock following such Series C Preferred Stock Fundamental Transaction.

Series D Convertible Preferred Stock

Rank

The Series D Preferred Stock ranks (1) on parity with Common Stock on an "as converted" basis, (2) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series D Preferred Stock, (3) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series D Preferred Stock, and (4) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series D Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

Conversion Rights

A holder of Series D Preferred Stock is entitled at any time to convert any whole or partial number of shares of Series D Preferred Stock into shares of our Common Stock, determined by dividing the stated value equal to $0.01 by the conversion price of $0.01 per share. A holder of Series D Preferred Stock is prohibited from converting Series D Preferred Stock into shares of Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our Common Stock then issued and outstanding (with such ownership restriction referred to as the "Series D Beneficial Ownership Limitation") immediately after giving effect to the issuance of the shares of Common Stock issuable upon conversion of the Series D Preferred Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. The conversion rate of the Series D Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividend Rights

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series D Preferred Stock are entitled to receive dividends on shares of Series D Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends are payable on shares of Series D Preferred Stock.

Voting Rights

Subject to the Series D Beneficial Ownership Limitation, on any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of a meeting), each holder, in its capacity as such, shall be entitled to cast the number of votes equal to the number of whole shares of our Common Stock into which the Series D Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Series D Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of the Certificate of Designation of Series D Convertible Preferred Stock (the "Series D Certificate of Designation"), the holders of Series D Preferred Stock, in their capacity as such, shall vote together with the holders of our Common Stock and any other class or series of stock entitled to vote thereon as a single class.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series D Preferred Stock are entitled to receive, *pari passu* with the holders of Common Stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series D Preferred Stock been converted into Common Stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Series D Beneficial Ownership Limitation, as described above.

Exchange Listing

Series D Preferred Stock is not listed on the Nasdaq, any national securities exchange or other nationally recognized trading system. Our Common Stock issuable upon conversion of the Series D Preferred Stock is listed on the Nasdaq under the symbol "MYMD".

Failure to Deliver Conversion Shares

If we fail to timely deliver shares of Common Stock upon conversion of the Series D Preferred Stock (the "Series D Conversion Shares") within the time period specified in the Series D Certificate of Designation (within two trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), then we are obligated to pay to the holder, as liquidated damages, an amount equal to $25 per trading day (increasing to $50 per trading day on the third trading day and $100 per trading day on the sixth trading day) for each $5,000 of stated value of Series D Preferred Stock being converted which are not timely delivered. If we make such liquidated damages payments, we are not also obligated to make Series D Buy-In (as defined below) payments with respect to the same Series D Conversion Shares.

Compensation for Series D Buy-In on Failure to Timely Deliver Shares

If we fail to timely deliver the Series D Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the holder of the Series D Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Series D Buy-In"), then we are obligated to (A) pay in cash to such holder (in addition to any other remedies available to or elected by such holder) the amount, if any, by which (x) such holder's total purchase price (including any brokerage commissions) for the shares of Common Stock so purchased exceeds (y) the product of (1) the aggregate number of Series D Conversion Shares that such holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of such holder, either reissue (if surrendered) the shares of Series D Preferred Stock equal to the number of shares of Series D Preferred Stock submitted for conversion (in which case, such conversion shall be deemed rescinded) or deliver to such holder the number of Series D Conversion Shares that would have been issued if we had timely complied with its delivery requirements.

Series E Junior Participating Preferred Stock

In September 2020, our board of directors declared a dividend of one preferred share purchase right (a "Right") for each of our issued and outstanding shares of Common Stock, payable to the stockholders of record on September 21, 2020. Each such Right entitles the registered holder, subject to the terms of a Rights Agreement, dated as of September 9, 2020, between the Company and VStock Transfer, LLC (the "Rights Agreement"), to purchase from the Company one one-thousandth of a share of the Company's Series E Junior Participating Preferred Stock, no par value with a stated value of $0.001 (the "Series E Preferred Stock"), at $15.00, subject to certain adjustments. Pursuant to the Agreement and Plan of Merger, dated November 11, 2020, by and among the Company, XYZ Merger Sub Inc., a wholly owned subsidiary of the Company, and MyMD Pharmaceuticals, Inc. ("MYMD"), we agreed to take any and all necessary action to terminate such shareholder rights plan prior to closing of the merger.

The Rights will not be exercisable until the earlier to occur of (i) the tenth business day following a public announcement or filing that a person has, or affiliates or associates of such person have, become an "Acquiring Person," which is defined as a person, or affiliates or associates of such person, who, at any time after the date of the Rights Agreement, has acquired, or obtained the right to acquire, Beneficial Ownership of 10% or more of our outstanding shares of Common Stock, subject to certain exceptions, or (ii) the tenth business day (or such later date as may be determined by action of our board of directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person becoming an Acquiring Person (the earlier of such dates being called the "Distribution Date"). Beneficial Ownership, as defined in the Rights Agreement, includes certain interests in securities created by derivatives contracts, which are beneficially owned, directly or indirectly, by a counterparty (or any of such counterparty's affiliates or associates) under any derivatives contract to which such person or any of such person's affiliates or associates is a receiving party (as such terms are defined in Rights Agreement), subject to certain limitations.

Until the Distribution Date, (i) the Rights will be evidenced by the Common Stock certificates (or, for uncertificated shares of Common Stock, by the book-entry account that evidences record ownership of such shares) and will be transferred with, and only with, such Common Stock, and (ii) new Common Stock certificates issued after September 21, 2020 will contain a legend incorporating the Rights Agreement by reference (for book entry Common Stock, this legend will be contained in the notations in book entry accounts). Until the earlier of the Distribution Date and the Expiration Date (defined below), the transfer of any shares of Common Stock outstanding on September 21, 2020 will also constitute the transfer of the Rights associated with such shares of Common Stock. As soon as practicable after the Distribution Date, VStock Transfer, LLC (the "Rights Agent") will send by first-class, insured, postage prepaid mail, to each record holder of the Common Stock as of the close of business on the Distribution Date separate rights certificates evidencing the Rights ("Right Certificates"), and such Right Certificates alone will evidence the Rights. We may choose book entry in lieu of physical certificates, in which case, references to "Rights Certificates" shall be deemed to mean the uncertificated book entry representing the Rights.

The Rights, which are not exercisable until the Distribution Date, expire upon the earliest to occur of (i) the close of business on September 8, 2021; (ii) the time at which the Rights are redeemed or exchanged pursuant to the Rights Agreement; and (iii) the time at which the Rights are terminated upon the closing of any merger or other acquisition transaction involving the Company pursuant to a merger or other acquisition agreement that has been approved by our board of directors prior to any person becoming an Acquiring Person (the earliest of (i), (ii), and (iii) is referred to as the "Expiration Date").

Each share of Series E Preferred Stock will be entitled to a preferential per share dividend rate equal to the greater of (i) $0.001 and (ii) the sum of (1) 1,000 times the aggregate per share amount of all cash dividends, plus (2) 1,000 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions other than certain dividends or subdivisions of the outstanding shares of Common Stock. Each shares of Series E Preferred Stock will entitle the holder thereof to a number of votes equal to 1,000 on all matters submitted to a vote of our stockholders. In the event of any merger, consolidation or other transaction in which shares of Common Stock are exchanged, each share of Series E Preferred Stock will be entitled to receive 1,000 times the amount received per one share of Common Stock. Pursuant to the Rights Agreement, the preferential rates noted above may be adjusted in the event that we (i) pay dividends in Common Stock, (ii) subdivide the outstanding Common Stock or (iii) combine outstanding Common Stock into a smaller number of shares.

The purchase price payable, and the number of shares of Series E Preferred Stock or other securities or property issuable, upon exercise of the Rights are subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend, or a subdivision, combination or reclassification of the Series E Preferred Stock, (ii) if the holders of the Series E Preferred Stock are granted certain rights, options or warrants to subscribe for the applicable Series E Preferred Stock or securities convertible into the applicable Series E Preferred Stock at less than the current market price of the applicable Series E Preferred Stock, or (iii) upon the distribution to holders of Series E Preferred Stock of evidences of indebtedness, cash (excluding regular quarterly cash dividends), assets (other than dividends payable in Series E Preferred Stock) or subscription rights or warrants (other than those referred to in (ii) immediately above). The number of outstanding Rights and the number of one one-thousandths of a shares of Series E Preferred Stock issuable upon exercise of each Right are also subject to adjustment in the event of a stock split, reverse stock split, stock dividends and other similar transactions.

With some exceptions, no adjustment in the purchase price relating to a Right will be required until cumulative adjustments amount to at least one percent (1%) of the purchase price relating to the Right. No fractional shares of Series E Preferred Stock are required to be issued (other than fractions which are integral multiples of one one-thousandth of a share of Series E Preferred Stock) and, in lieu of the issuance of fractional shares, we may make an adjustment in cash based on the market price of the Series E Preferred Stock on the trading date immediately prior to the date of exercise.

In the event that a person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right will thereafter have the right to receive, upon exercise, Common Stock (or, in certain circumstances, other securities, cash or other assets of the Company) having a value equal to two (2) times the exercise price of the Right. Notwithstanding any of the foregoing, following the occurrence of a person becoming an Acquiring Person, all Rights that are, or (under certain circumstances specified in the Rights Agreement) were, beneficially owned by any Acquiring Person (or by certain related parties) will be null and void and any holder of such Rights (including any purported transferee or subsequent holder) will be unable to exercise or transfer any such Rights. However, Rights are not exercisable following the occurrence of a person becoming an Acquiring Person until the Distribution Date.

In the event that, after a person or a group of affiliated or associated persons has become an Acquiring Person, the Company is acquired in a merger or other business combination transaction, or 50% or more of the Company's assets or earning power are sold, proper provision will be made so that each holder of a Right will thereafter have the right to receive, upon the exercise of a Right that number of shares of Common Stock of the person with whom the Company has engaged in the foregoing transaction (or its parent) that at the time of such transaction have a market value of two (2) times the exercise price of the Right.

At any time before any person or group of affiliated or associated persons becomes an Acquiring Person, our board of directors may redeem the Rights in whole, but not in part, at a price of $0.001 per Right (subject to certain adjustments) (the "Redemption Price"). The redemption of the Rights may be made effective at such time, on such basis and with such conditions as our board of directors in its sole discretion may establish. Immediately upon the action of the board of directors electing to redeem or exchange the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price.

Our board of directors may, at its option, at any time after the first occurrence of a Flip-in Event (as defined in the Rights Agreement), exchange all or part of the then outstanding and exercisable Rights for shares of Common Stock at an exchange ratio of one share of Common Stock per Right, appropriately adjusted to reflect any stock split, stock dividend or similar transaction occurring after the effective date. However, the board of directors shall not effect such an exchange at any time after any person, together with all affiliates and associates of such person, becomes a beneficial owner of 50% or more of the outstanding shares of Common Stock. Immediately upon the action of our board of directors to exchange the Rights, the Rights will terminate and the only right of the holders of Rights will be to receive the number of shares of Common Stock equal to the number of Rights held by such holder multiplied by the exchange ratio.

Until a Right is exercised or exchanged, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

Our board of directors may amend or supplement the Rights Agreement without the approval of any holders of Rights at any time so long as the Rights are redeemable. At any time the Rights are no longer redeemable, no such supplement or amendment may (i) adversely affect the interests of the holders of Rights (other than an Acquiring Person or an affiliate or associate of an Acquiring Person), (ii) cause the Rights Agreement to become amendable other than in accordance with Section 27 of the Rights Agreement, or (iii) cause the Rights again to become redeemable.

Series F Convertible Preferred Stock

The following are the principal terms of the Series F Preferred Stock:

Dividends

The holders of the Series F Preferred Stock will be entitled to dividends of 10.0% per annum, compounded monthly, which will be payable in cash or shares of Common Stock at the Company's option, in accordance with the terms of the certificate of designation of the Series F Preferred Stock (the "Series F Certificate of Designation"). Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F Certificate of Designation), shares of Series F Preferred Stock will accrue dividends at the rate of 15.0% per annum. Upon conversion or redemption, the holders of shares of Series F Preferred Stock are also entitled to receive a dividend make-whole payment.

Voting Rights

The Series F Preferred Stock has no voting rights, except as required by law (including without limitation, the New Jersey Business Corporation Act (the "BCA")) and as expressly provided in the Series F Certificate of Designation. To the extent that under the BCA the vote of the holders of shares of Series F Preferred Stock, voting separately as a class or series, as applicable, is required to authorize a given action of the Company, the affirmative vote or consent of a majority of the outstanding shares of Series F Preferred Stock, voting together in the aggregate and not in separate series unless required under the BCA, represented at a duly held meeting at which a quorum is presented or by written consent of such majority (except as otherwise may be required under the BCA) shall constitute the approval of such action by both the class or the series, as applicable. To the extent that under the BCA holders of shares of Series F Preferred Stock are entitled to vote on a matter with holders of shares of Common Stock, voting together as one class, each share of Series F Preferred Stock shall entitle the holder thereof to cast that number of votes per share as is equal to the number of shares of Common Stock into which it is then convertible (subject to certain beneficial ownership limitations) using the record date for determining the stockholders of the Company eligible to vote on such matters as the date as of which the Conversion Price is calculated.

Liquidation

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the each holder shares of the Series F Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount per share of Series F Preferred Stock equal to the greater of (A) 125% of the stated value of such share of Series F Preferred Stock (plus any applicable make-whole amount, unpaid late charge or other applicable amount) on the date of such payment and (B) the amount per share such holder would receive if such holder converted such share of Series F Preferred Stock into Common Stock immediately prior to the date of such payment. All shares of capital stock of the Company shall be junior in rank to all shares of Series F Preferred Stock with respect to the preferences as to payments upon the liquidation.

Conversion

The Series F Preferred Stock is convertible into shares of Common Stock (the "Conversion Shares"). The initial conversion price, subject to adjustment as set forth in the Series F Certificate of Designation, is $2.255 (the "Conversion Price"). The Conversion Price can be adjusted as set forth in the Series F Certificate of Designation for stock dividends and stock splits or the occurrence of a fundamental transaction (generally including any reorganization, recapitalization or reclassification of the Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the outstanding Common Stock). The Conversion Price is also subject to "full ratchet" price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Conversion Price (subject to certain exceptions). If any shares of Series F Preferred Stock are converted or reacquired by us, such shares shall resume the status of authorized but unissued shares of Series F Preferred Stock of the Company and shall no longer be designated as Series F Preferred Stock.

The Company will be required to redeem the shares of Series F Preferred Stock in 12 equal monthly installments, commencing on July 1, 2023. The amortization payments due upon such redemption are payable, at the company's election, in cash, or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Conversion Price then in effect and (ii) the greater of (A) a 80% of the average of the three lowest closing prices of the Company's Common Stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) the Floor Price (as defined below). For purposes of the Series F Certificate of Designation, the "Floor Price" means the lower of (x) $0.4014 and (y) 20% of the "Minimum Price" (as defined in Rule 5635 of the Rules of the Nasdaq Stock Market) on the date of the Stockholder Approval (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Stock Market; provided that if the amount set forth in clause B is the lowest effective price, the Company will be required to pay the amortization payment in cash.

Exchange Cap

The Series F Preferred Stock will not be convertible into shares of Common Stock in excess of 19.99% of the shares of Common Stock outstanding as of the date immediately prior to the date of the prospectus supplement under which the shares of Series F Preferred Stock were registered (the "Issuable Maximum") except in the event that the Company (A) obtains the stockholder approval for issuances of shares of Common Stock in excess of the Issuable Maximum or ("Stockholder Approval") (B) obtains a written opinion from outside counsel to the Company that such approval is not required. Until such approval or such written opinion is obtained, no holder of Series F Preferred Stock shall be issued in the aggregate more shares of Common Stock than such holder's pro rata share of the Issuable Maximum. In the event that after July 1, 2023, the Company has not obtained the Stockholder Approval or is not otherwise permitted to issue shares in excess of the Issuable Maximum, then a holder of Series F Preferred Stock may elect to have his or her shares of Series F Preferred Stock redeemed for cash.

Optional Conversion

The Series F Preferred Stock can be converted at the option of the holder at any time and from time to time after the original issuance date. Holders shall effect conversions by providing us with the form of conversion notice (the "Notice of Conversion") specifying the number of shares of Series F Preferred Stock to be converted, the number of shares of Series F Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable holder delivers by email such Notice of Conversion to us.

Mandatory Conversion

If on any day after the issuance of the shares of Series F Preferred Stock the closing price of the Common Stock has exceeded 300% of the Conversion Price per share (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock has exceeded $3,000,000 per trading day during the same period and certain equity conditions described in the Series F Certificate of Designation are satisfied (the "Mandatory Conversion Date"), we shall deliver written notice of the Mandatory Conversion (as defined below) to all holders on the Mandatory Conversion Date and, on such Mandatory Conversion Date, we shall convert all of each holder's shares of Series F Preferred Stock into Conversion Shares at the then effective Conversion Price (the "Mandatory Conversion"). If any of the Equity Conditions shall cease to be satisfied at any time on or after the Mandatory Conversion Date through and including the actual delivery of all of the Conversion Shares to the holders, the Mandatory Conversion shall be deemed withdrawn and void ab initio.

Beneficial Ownership Limitation

The Series F Preferred Stock cannot be converted to Common Stock if the holder and its affiliates would beneficially own more than 4.99% or 9.99% at the election of the holder of the outstanding Common Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Anti-Takeover Provisions

The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of the Company.

These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

In addition, we are subject to Section 14A-10A of the New Jersey Shareholders Protection Act, a type of anti-takeover statute designed to protect stockholders against coercive, unfair or inadequate tender offers and other abusive tactics and to encourage any person contemplating a business combination with the Company to negotiate with our board of directors for the fair and equitable treatment of all stockholders. Subject to certain qualifications and exceptions, the statute prohibits an "interested stockholder" of a combined company from effecting a business combination with the combined company for a period of five years unless its board of directors approved the combination or transaction or series of related transactions that caused such person to become an interested stockholder prior to the stockholder becoming an interested stockholder or after the stockholder becomes an interested stockholder if the subsequent business combination is approved by (i) the combined company's board of directors (or a committee thereof consisting solely of persons independent from the interested stockholder), and (ii) the affirmative vote of a majority of the voting stock not beneficially owned by such interested stockholder. In addition, but not in limitation of the five-year restriction, the combined company may not engage at any time in a business combination with any interested stockholder of the combined company unless the combination is approved by its board of directors (or a committee thereof consisting solely of persons independent from such interested stockholder) prior to the consummation of the business combination, and the combination receives the approval of a majority of the voting stock of the combined company not beneficially owned by the interested stockholder if the transaction or series of related transactions which caused the interested stockholder to become an interested stockholder was approved by the board of directors prior to the stockholder becoming an interested stockholder.

An "interested shareholder" is defined to include any beneficial owner of 10% or more of the voting power of the outstanding voting stock of the corporation and any affiliate or associate of the corporation who within the prior five-year period has at any time owned 10% or more of the voting power of the then outstanding stock of the corporation.

The term "business combination" is defined to include a broad range of transactions including, among other things:

- the merger or consolidation of the corporation, or any of its subsidiaries, with the interested shareholder or any other corporation that is, or after the merger or consolidation, would be an affiliate or associate of the interested shareholder,

- the sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions) to an interested shareholder or any affiliate or associate of the interested shareholder of (i) 10% or more of the aggregate market value of corporation's assets, (ii) 10% or more of the aggregate market value of all the corporation's outstanding stock, or (iii) representing 10% or more of the earning power or income of the corporation, determined on a consolidated basis; or

- the issuance or transfer by the corporation, or any of its subsidiaries, (in one transaction or a series of transactions) to an interested shareholder or any affiliate or associate of the interested shareholder of 5% or more of the aggregate market value of the stock of the corporation, or any of its subsidiaries, except pursuant to an exercise of warrants or rights to purchase stock offered, or a dividend or distribution paid or made, pro rata to all stockholders of the corporation.

The effect of the statute is to protect non-tendering, post-acquisition minority stockholders from mergers in which they will be "squeezed out" after the merger, by prohibiting transactions in which an acquirer could favor itself at the expense of minority stockholders. The statute generally applies to corporations that are organized under New Jersey law.

Exhibit 21.1

Subsidiaries of the Registrant[1]

Name of Company	Jurisdiction of Organization
Akers Acquisition Sub, Inc.	New Jersey
Bout Time Marketing Corporation	New Jersey
XYZ Merger Sub Inc.	Florida

[1] This information is as of March 29, 2023.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-234447 and 333-235359), Form S-3 (File No. 333-217390, 333-234449, 333-238631, 333-248095 and 333-254698) and Form S-8 (File No. 333-266019) of MyMD Pharmaceuticals, Inc. of our report dated March 31, 2023 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ MORISON COGEN LLP

Blue Bell, Pennsylvania
March 31, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Christopher C. Chapman, President and Chief Medical Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of MyMD Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023

By: */s/ Christopher C. Chapman, M.D.*
Christopher C. Chapman, M.D.
President and Chief Medical Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Ian Rhodes, Interim Chief Financial Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of MyMD Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023

By: */s/ Ian Rhodes*
Ian Rhodes
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of MyMD Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Christopher C. Chapman, M.D., as the President of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2023

By: */s/ Christopher C. Chapman, M.D.*
Christopher C. Chapman, M.D., President and Chief Medical Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of MyMD Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Ian Rhodes, as the Interim Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2023

By: */s/ Ian Rhodes*
Ian Rhodes, Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.

CORPORATE INFORMATION

DIRECTORS AND EXECUTIVE OFFICERS

Joshua Silverman
Independent Director and Chairman of the Board of Directors

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

Christopher C. Schreiber
Director

Craig Eagle, M.D.
Independent Director

Bill J. White
Independent Director

Jude Uzonwanne
Independent Director

Adam Kaplin, M.D., Ph.D.
Chief Scientific Officer

Paul Rivard, Esq.
Chief Legal Officer

Ian Rhodes
Chief Financial Officer

CORPORATE HEADQUARTERS

855 N. Wolfe Street, Suite 601
Baltimore, MD 21205

STOCK LISTING

Nasdaq Capital Market: MYMD

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Morison Cogen LLP
484 Norristown Rd #100
Blue Bell, Pennsylvania 19422

TRANSFER AGENT AND REGISTRAR

Securities Transfer Corporation
2901 N Dallas Parkway, Suite 380
Plano, Texas 75093
Telephone: (469) 633-0101

ANNUAL GENERAL MEETING OF STOCKHOLDERS

The 2023 Annual General Meeting of Stockholders will be held in a virtual format at 10:00 a.m. Eastern Time on July 31, 2023, at www.virtualshareholdermeeting.com/MYMD2023. Stockholders of record on June 21, 2023, are entitled to notice of and to vote at the Annual General Meeting.

COMPANY WEBSITE

www.mymd.com