

**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, 2021

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 (State or other jurisdiction of incorporation or organization)	22-2983783 (I.R.S. Employer Identification Number)
855 N. Wolfe Street, Suite 601 Baltimore, MD (Address of principal executive offices)	21205 (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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

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, 2021, based on a closing price of \$6.30 was \$21,254,305.

As of March 31, 2022, the registrant had 38,058,245 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, 2021 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”), (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 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 Unaudited Condensed Consolidated Financial Statements for additional information.

TABLE OF CONTENTS

	<u>PAGE</u>
<u>PART I</u>	
Item 1. Business	5
Item 1A. Risk Factors	26
Item 1B. Unresolved Staff Comments	58
Item 2. Properties	58
Item 3. Legal Proceedings	58
Item 4. Mine Safety Disclosures	58
<u>PART II</u>	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	59
Item 6. Reserved	59
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	59
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	67
Item 8. Financial Statements and Supplementary Data	67
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	68
Item 9A. Controls and Procedures	68
Item 9B. Other Information	68
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	68
<u>PART III</u>	
Item 10. Directors, Executive Officers and Corporate Governance	69
Item 11. Executive Compensation	76
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	89
Item 13. Certain Relationships and Related Transactions, and Director Independence	91
Item 14. Principal Accounting Fees and Services	92
<u>PART IV</u>	
Item 15. Exhibits and Financial Statement Schedules	93
Item 16. Form 10-K Summary	93

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;
- 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 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-CBDTM 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, 2021, MyMD had 500,000,000 shares of authorized common stock, of which approximately 37,673,110 shares were outstanding and 12,630,494 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”), (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.

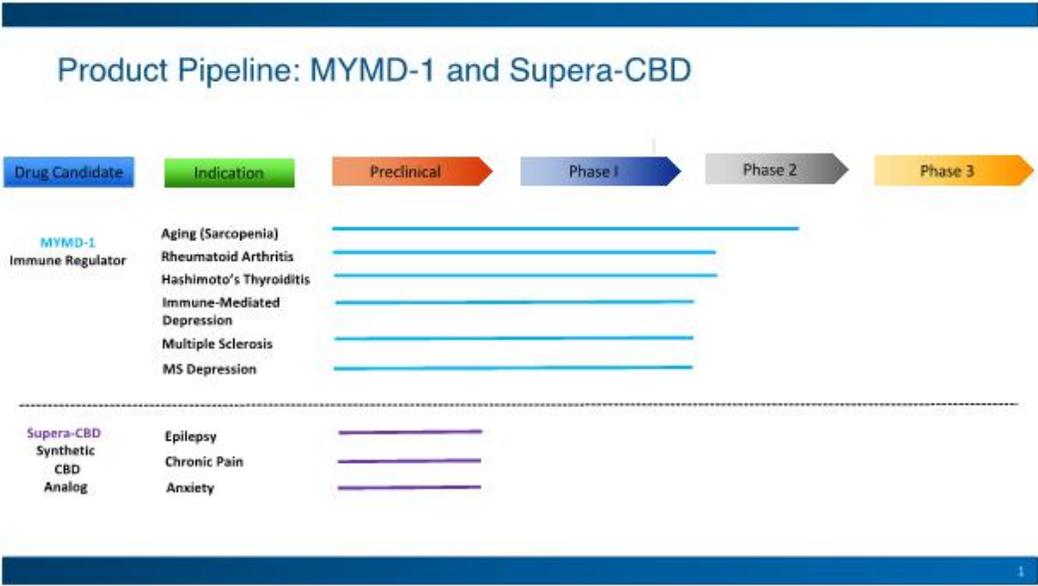
On March 18, 2021, the Company and the Cystron Sellers, which are also shareholders of Oravax, entered into a Termination and Release Agreement terminating the MIPA effective upon consummation of the Contribution Agreement. In addition, the Cystron Sellers agreed to waive any change of control payment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

Following the Contribution Transaction, Oravax is expected to pursue 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.

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 and third quarters of 2022;
- 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 (INF γ) 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.

MyMD1 Anti-CD3/Anti-CD28-mediated Cytokine Release Inhibition

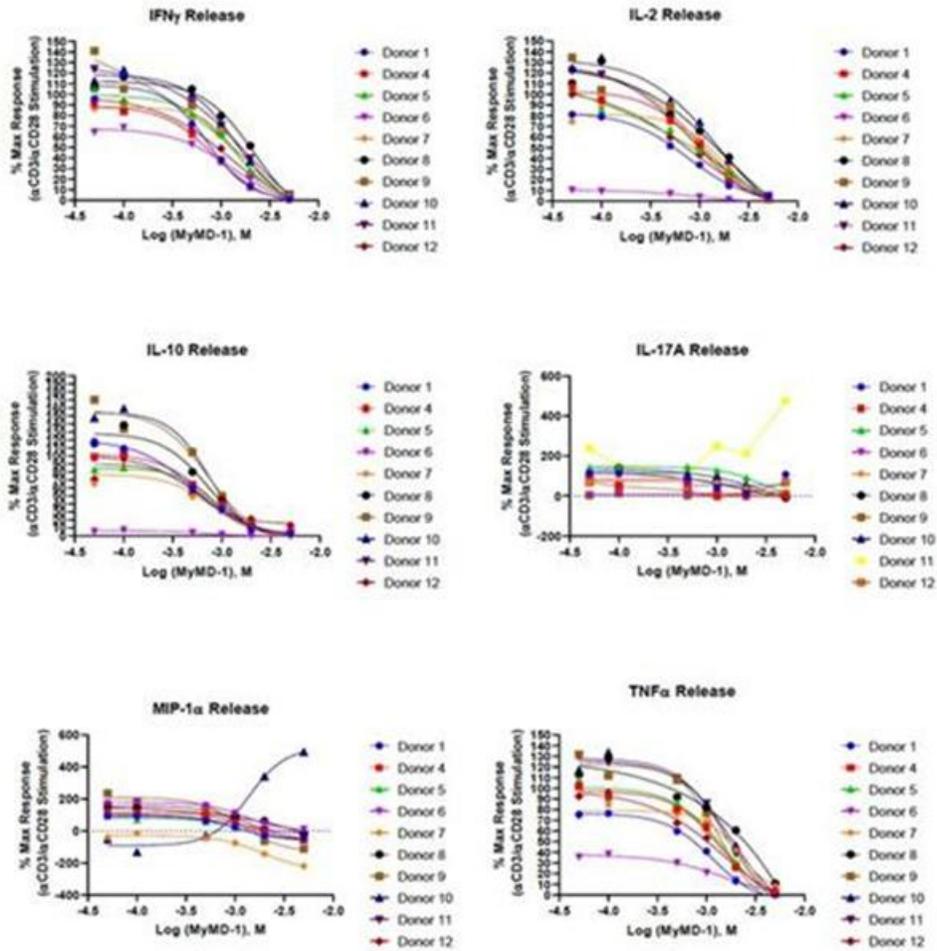
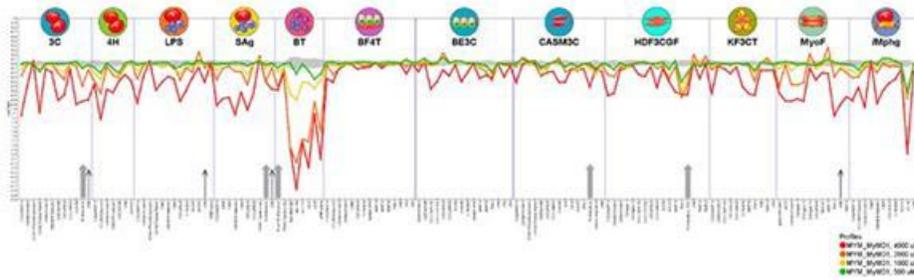


Figure 1. MYMD-1 modulates the release of a broad spectrum of cytokines.

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.

BioMAP Profile of MYM_MyMD1: All Concentrations



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

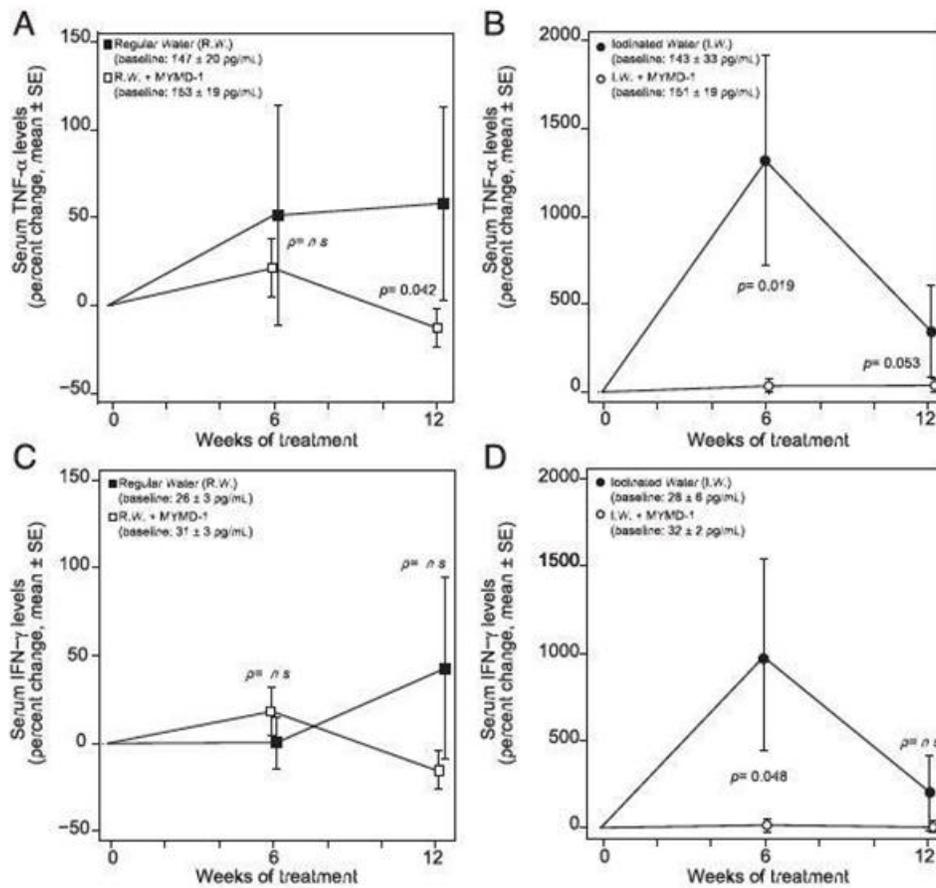


Figure 2. MYMD-1 decreases the serum levels TNF- α and INF- γ in NOD.H-2h4 mice. NOD.H-2h4 mice were treated with either regular water or iodinated water (500 mg/l of sodium iodide), and each group was treated or not treated with MYMD-1 (185 mg/l). Cytokines were measured at baseline and after 6 and 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 INF- γ 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 is designed to regulate the immunometabolic system to treat autoimmune diseases, including (but not limited to) multiple sclerosis, diabetes, rheumatoid arthritis, and 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 ("INF γ "). 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).

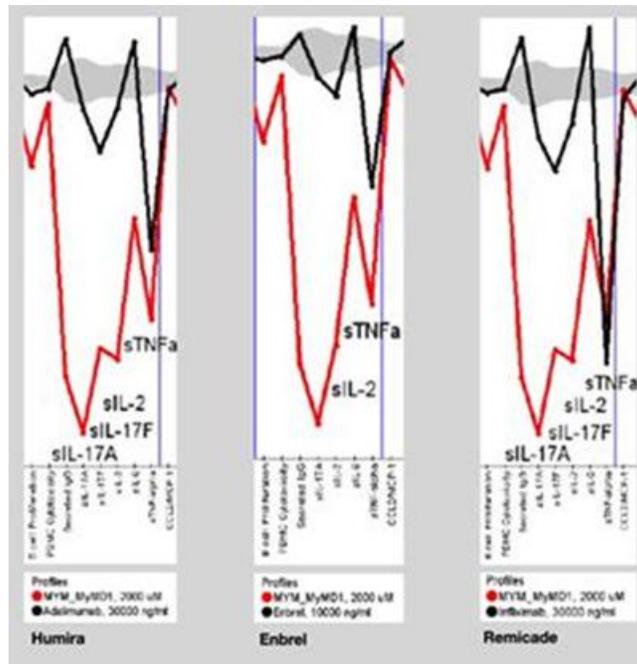


Figure 3. Comparison of inhibitory effect of MYMD-1 with other TNF- α blockers. MYMD-1 exhibits a dose-dependent reduction in release of several cytokine more effectively than Humira, Enbrel and Remicade.

Unlike currently marketed TNF- α blockers, MYMD-1 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. The selectivity of MYMD-1 in blocking TNF- α , therefore, might provide a much safer alternative to existing treatments for infectious, inflammatory, and autoimmune conditions, as well as simultaneously resulting in amelioration of immune mediated depression in such illnesses.

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 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.

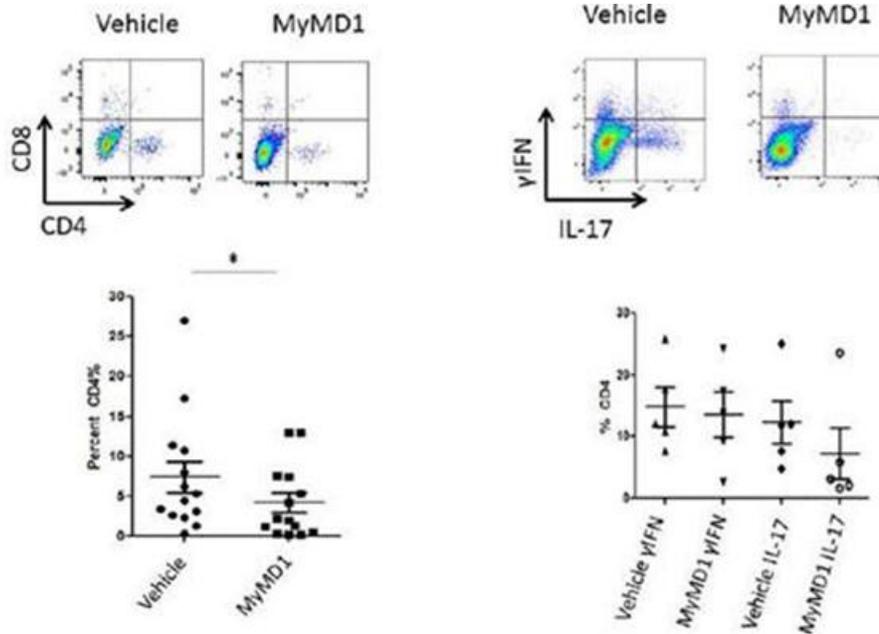


Figure 4. Effects of MYMD-1 on the influx of T cells into the CNS early in EAE. To assess the effects of MYMD-1 on the infiltration of T cells into the CNS, mice were immunized and treated with either vehicle control or 25 mg/mouse/day MYMD-1. Ten to 14 days later, mice were perfused and brains collected 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.

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 (NOD.H.2) mouse model. This study suggested that MYMD-1 suppresses 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.

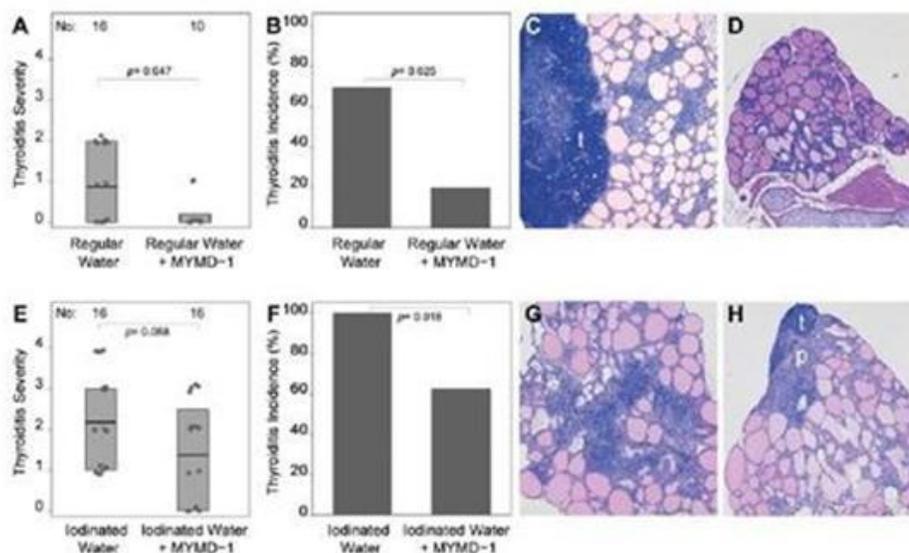


Figure 5. MYMD-1 decreases the incidence and severity of autoimmune thyroiditis in NOD.H-2h4 mice, as assessed by H&E histopathology. At 8 weeks old, 58 NOD.H-2h4 mice were divided into regular water and iodinated water groups. In the regular water group, 10 mice (7 M, 3 F) drank water that contained 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, which can reduce health span. 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 and elucidated MYMD-1's potential therapeutic effect on inflamm-aging and other age-related disorders.

MYMD-1 Commercialization Targets

MYMD-1 is being developed to address multiple autoimmune diseases and inflamm-aging. According to the U.S. Census Bureau, in 2019, there were approximately 54 million U.S. residents over 65 years of age. Thirty-four million Americans have diabetes with approximately 90% of the cases as type 2 diabetes (Centers for Disease Control and Prevention). Multiple sclerosis affects approximately one million Americans and approximately 2.5 million people worldwide. In 2021 there were an estimated 1.3 million adults with rheumatoid arthritis.

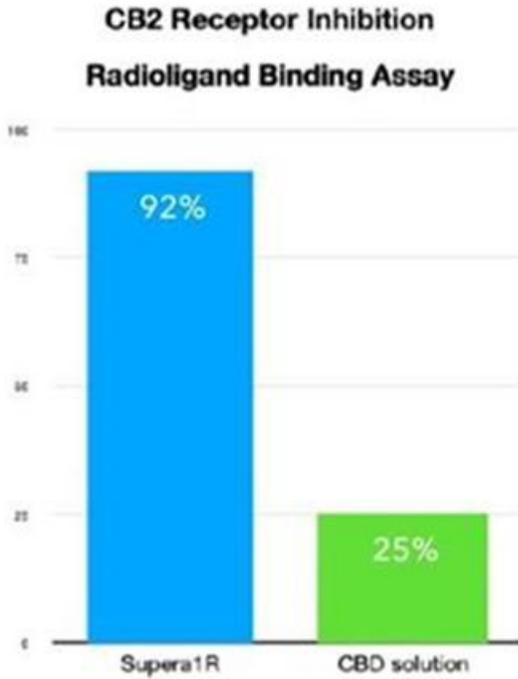
Supera-CBD

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 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.

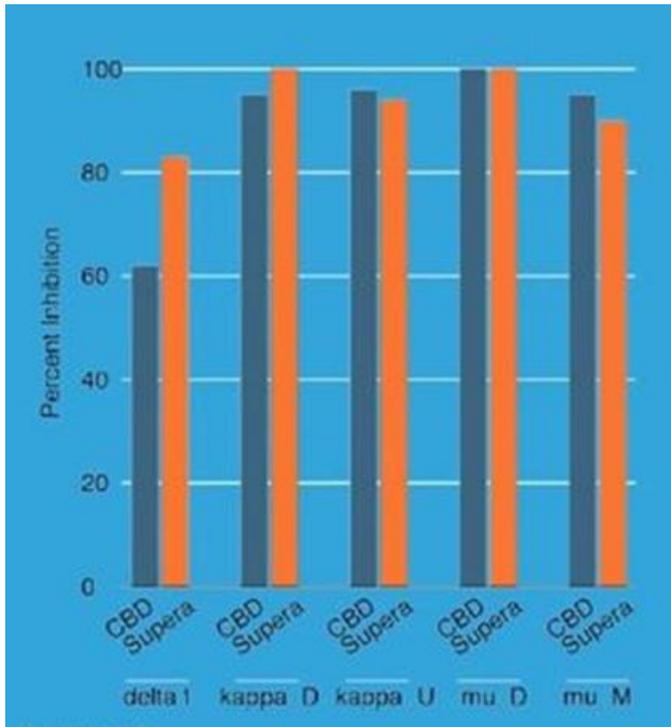
Overview

General Pharmacology and Therapeutic Profile

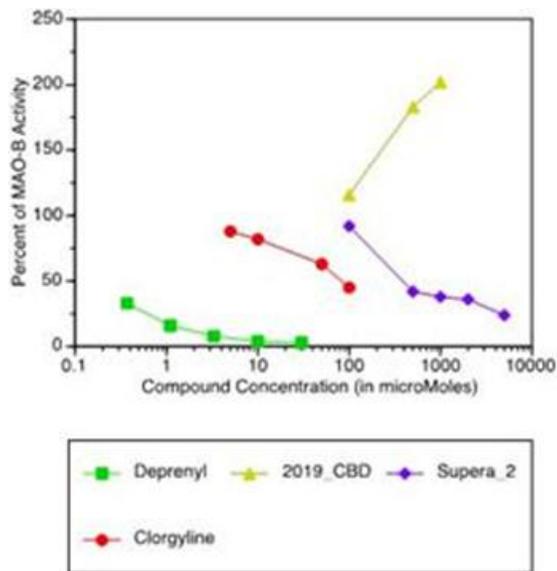
CBD inhibits a number of important receptors, including the CB2 receptor and opioid receptors, and can also inhibit MAO enzymes. In the immune system, one of the important functions of the CB2 receptor is in the regulation of cytokine release from immune cells. Antagonists targeting the CB2 receptor 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 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 Commercialization Targets

It is anticipated that initial commercialization efforts for Supera-CBD will focus on various existing CBD markets. These target markets are anticipated to include CBD sold as an FDA regulated and approved drug and CBD sold for a variety of conditions.

Currently, there is one FDA-approved drug based on CBD. 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. As a synthetic drug product, MYMD believes that Supera-CBD may mitigate a number of obstacles generally associated with growing and processing an active drug ingredient produced from naturally grown plant extracts.

Additionally, there are currently a number of over-the-counter CBD products marketed for pain, anxiety and sleep disorders. The regulatory status of these types of CBD products is not clear, but the FDA has taken the position that products containing CBD may not be lawfully marketed for such uses in the United States without first-obtaining FDA approval via the NDA process. However, these products are still marketed with various therapeutic claims, and the FDA has taken enforcement action against a number of CBD companies based on the claims being made about their products. CBD sales in the US reached \$4.6 billion in 2020 and have been projected to reach \$15 billion by 2025. MyMD believes that if Supera-CBD is approved by the FDA, it may have competitive advantages over currently marketed CBD products purified from cannabis, including cost and consistency. Additionally, we believe that Supera-CBD may also have competitive advantages over CBD products that have not been approved by FDA as drug products, as approved drugs are subject to ongoing FDA regulation and must, accordingly, have documented manufacturing processes that comply with applicable regulations, which provides assurances relating to, consistency and safety.

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 of MYMD-1. 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.

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) which collectively represented approximately \$29.3 billion in global sales in 2017. All of these existing TNF- α blocking drugs require injection, whereas MYMD-1 is being developed to be orally bioavailable.

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 preferable 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 15 issued U.S. patents, three pending U.S. patent applications and 25 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.

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 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 of 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 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 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 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 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 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.

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, 2021, MyMD had 9 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 2022

MYMD-1 Product Candidate

We are currently enrolling patients in the Phase II 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 I 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 II 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 II clinical trial on November 1, 2021.
 - We obtained IRB approval on November 16, 2021 which permitted us to start enrollment and dosing qualifying participants.

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. There were no treatment related gross pathology findings at Autopsy.
- 6-month Rat Study – completed on December 17, 2021: A 26-Week Toxicity and Toxicokinetic Study of MYMD-1 by Oral Gavage in Rats. There were no treatment related gross pathology findings at Autopsy.
- Studies produced guidance on dosing levels and overall safety in the human studies.

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 in the United States and abroad.

A scientific manuscript on MYMD-1 is under review:

- “MYMD-1 improves health span and prolongs lifespan in old mice and modulates aging-relevant biomarkers in vitro: A comparison to rapamycin and metformin.” Author: Johns Hopkins Medical School.
- The manuscript 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.

IND for Hashimoto’s Thyroiditis

- On July 26, 2021, 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 I 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 I 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 II 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.

The company plans to publish data from the Phase 1 dosing study for MYMD-1 as a treatment for aging. There was a statistically significant decrease in TNF-alpha 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 fourth quarter 2022. 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 third quarter 2022 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 2022. 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 2022.

The company expects to commence a [14C] MYMD-1 radiolabeled study in four healthy male volunteers in the fourth quarter 2022.

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 than capsules for long-term human trials.

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.

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.

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) 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.

The National Institutes of Health is planning to work on a grant for Supera-CBD in Epilepsy for the third quarter 2022.

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.

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.

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 will experience 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 receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the strategic and financial benefits currently anticipated from 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 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.

Prior to April 2021, there was no public market for the combined Company's common stock. The market price of the combined Company's common stock could 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 particularly 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 has resulted in significant financial market volatility and uncertainty in recent months. 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 anticipate 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 \$29,890,308 and \$9,810,157 for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of \$78,885,164. Substantially all of 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 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; 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.

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 our business, healthcare systems or the global economy as a whole. However, the effects have had and will likely continue to have a material impact on our operations, liquidity and capital resources, and we will continue to monitor the COVID-19 situation closely.

In response to public health directives and orders, we implemented and have continued to maintain work-from-home policies for many of our employees and the temporary modification of our operations to comply with applicable social distancing recommendations. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Similar health directives and orders are affecting third parties with whom we do business. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited, and may continue to limit, our ability to support our operations.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we may engage in connection with the development and testing of our 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 our ability to raise capital when needed through the sale of shares of common stock or other equity securities. Should these market conditions persist when we need to raise capital, and if we are able to sell shares of our common stock under then prevailing market conditions, we might have to accept lower prices for our 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 our shareholders.

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 \$1,265,306 related to this incident. Our management continues to investigate the incident together with our bank's fraud department and law enforcement authorities. 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 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 II 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 II 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 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.

The COVID-19 pandemic, or similar public health crises, 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. Initial studies indicate that MYMD-1 may have potential therapeutic effects on treatment of COVID-19. MyMD may not be successful in demonstrating the efficacy of this treatment before another, more effective drug enters the market. Furthermore, site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis for our planned clinical trials may be delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. Additionally, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our planned clinical trials. If the global effort to control the spread of COVID-19 and treat COVID-19 patients continues on the current trajectory for an extended period of time, we risk a delay in activating sites and enrolling subjects as previously projected. 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.

We completed a dosing study in Tampa in 2021 that took four and a half months because of COVID-19. The facility could only dose four subjects a week instead of the planned eight subjects per week. Normally this study would have been completed in two months. That has delayed reporting of our results and the final report we needed to provide for an IND to the FDA for the next pivotal study.

Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. 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.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our planned clinical trials, healthcare systems or the global economy. However, these effects could have a material adverse impact on our business, financial condition and results of operations.

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. 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 may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. 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 uncertain and may not yield commercial results and is subject to significant regulatory risks.

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 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 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. For example, any changes that reduce, or impede the ability to obtain, reimbursement for any products we may commercialize in the future, if 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 the 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 Florida has 15 issued U.S. patents, eight foreign patents, three pending U.S. patent applications, one pending international application, and 23 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.

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.

General Risk Factors

An active trading market for our common stock may not be sustained.

The listing of our common stock on The Nasdaq Capital Market 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.

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 (U.S.) rules and regulations. Our management, including our chief executive officer and chief 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.

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. The declaration of dividends is 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 chief executive officer and chief 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. Property

The company leases as its corporate headquarters an office facility located at 855 North Wolfe Street, Suite 601, Baltimore, Maryland 20215. The current lease has a twelve-month term beginning on November 16, 2021, which term shall automatically renew thereafter until termination by either party upon 60 days’ notice. The monthly rent is approximately \$4,400 and will increase 3% on each anniversary of the November 16, 2021 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, 2021, 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."

Holder

As of March 31, 2022, there were approximately 750 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, 2021.

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 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”), (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 its NASDAQ trading symbol 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 expected to pursue 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.

Impact of the COVID-19 Pandemic on Our Business and Company Operations

The ultimate impact of the ongoing global COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to future developments. These include but are not limited to the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that regulators, or our board of directors or management of the Company, may determine are needed. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems or the global economy. We will continue to monitor the COVID-19 situation closely.

In response to public health directives and orders, we have implemented work-from-home policies for many of our employees and temporarily modified our operations to comply with applicable social distancing recommendations. The effects of the orders and our related adjustments in our business have in the past and may continue to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Similar health directives and orders are affecting third parties with whom we do business. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our operations.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we may engage in connection with the development and testing of our therapeutic targets.

To date, we have encountered delays in receiving critical clinical supplies from our manufacturer in India, which has impacted our ability to execute our development plan and the studies needed to advance product development have been delayed by the Company’s difficulty recruiting patients for the required clinical trials.

In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the continuation of the COVID-19 pandemic could materially affect our business and the value of our common stock.

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, 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
- 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
- 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 associated with our 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 Starwood line-of credit which was terminated upon the closing of the merger with Akers Biosciences and the related line-of-credit plus the accumulated interest due was paid in full.

Amortization of Intangible Assets

Amortization of our development of the MyMD.com website. Costs for future website development and maintenance are now recorded as expenses in the period they are incurred and included in general and administrative expenses.

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, 2021 and 2020

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, 2021 and 2020.

Description	For the Year Ended December 31,		Percent Change
	2021	2020	
Operating Expenses			
Research and Development	\$ 6,745,104	2,466,924	173.4
General and Administrative	6,420,092	2,946,703	117.9
Interest Expense & Accretion of Debt Discount	608,460	1,191,859	(48.9)
Amortization of Intangible Assets	-	18,334	(100.0)
Stock Based Compensation	-	855,000	(100.0)
Stock Option Modifications	15,036,051	2,009,145	648.4
Total Operating Expenses	28,809,707	9,487,965	203.6
Loss from Operations	(28,809,707)	(9,487,965)	203.6
Other Income (Expense), net	(1,079,338)	141	*
Net Loss	\$ (29,889,045)	\$ (9,487,824)	215.0

* Not meaningful

Revenue

We had no revenue from operations during the years ended December 31, 2021 and 2020.

Research and Development Expenses

The table below summarizes our research and development expenses for the year months ended December 31, 2021 and 2020 as well as the percentage of change year-over-year:

Description	For the Year Ended December 31,		Percent Change
	2021	2020	
Salaries and Wages	\$ 808,554	\$ 271,220	198.1
Development Programs	4,815,617	1,741,432	176.5
Professional Services	34,790	111,005	(68.7)
Regulatory Expenses	1,057,702	260,142	306.6
Other Research and Development Expenses	28,441	83,125	(65.8)
Total Research and Development Expenses	\$ 6,745,104	\$ 2,466,924	173.4

Salaries and wages increased \$537,334 for the year ended December 31, 2021. The increase is attributed to the addition of an additional staff position and the full year costs of two staff members added in November and December of 2020.

Development program costs include those associated with pre-clinical development, clinical trials and other material and development programs. Costs increased \$3,074,185 for the year ended December 31, 2021 related to the completion of pre-clinical toxicology studies, Phase I clinical trials and the acquisition of base compounds for current and future trails.

Professional services costs declined \$76,215 for the year ended December 31, 2021. These costs are primarily related to legal and patent related fees associated with the protection of our intellectual property.

Regulatory expenses increased \$797,560 for the year ended December 31, 2021.

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 \$54,684 for the year ended December 31, 2021. 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, 2021 and 2020 as well as the percentage of change year-over-year:

Description	For the Years Ended December 31,		Percent Change
	2021	2020	
Personnel Costs	\$ 1,396,375	\$ 612,056	128.1
Professional Service Costs	1,725,200	910,055	89.6
Stock Market & Investor Relations Costs	895,741	90,300	892.0
Other Administrative Costs	2,402,776	1,334,292	80.1
Total Administrative Expense	\$ 6,420,092	\$ 2,946,703	117.9

Personnel costs increased \$784,319 for the year ended December 31, 2021. Two additional staff members were acquired during the merger with Akers Biosciences and a 20% allocation for two research and development staff members has been made to account for their administrative duties.

Professional services costs increased \$815,145 during the year ended December 31, 2021. 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.

Stock market and investor relations costs increased \$805,441 during the year ended December 31, 2021. 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 and special shareholder meetings.

Other administrative expenses increased 1,068,484 for the year ended December 31, 2021. These costs include Board expenses, business insurance, corporate travel and the settlement of shareholder litigation related to the merger.

Interest Expense and Accretion of Debt Discount

Interest expense and the accretion of the debt discount on the line-of-credit declined \$583,399 during the year ended December 31, 2021. 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 credit line. The line of credit also carried an annualized 5% interest rate.

The line of credit was terminated on April 16, 2021 in relation to the merger and was paid in full on April 28, 2021.

Amortization of Intangible Assets

Amortization of Intangible Assets included the amortization of the website for the year ended December 31, 2020. No amortization was recorded for the year ended December 31, 2021.

Stock-Based Compensation

During the year ended December 31, 2021, no stock options were issued.

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, 2021 and 2020 as well as the percentage of change year-over-year:

Description	For the Years Ended December 31,		Percent Change
	2021	2020	
Interest and Dividend Income	\$ (8,907)	\$ (141)	*
Gain on Debt Forgiveness	(180,257)	-	*
Loss on FMV of Equity Investments	42,793	-	*
Gain on Investments	(39,597)	-	*
Uninsured Casualty Loss	1,265,306	-	*
Total Other (Income)/Expense	\$ 1,079,338	\$ (141)	*

* Not meaningful

Other expenses, net of income, totaled \$1,079,338 for the year ended December 31, 2021, and other income, net of expenses, totaled \$141 for the year ended December 31, 2020.

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 has not identified any additional losses. Our management continues to investigate the 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. 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.

Income Taxes

As of December 31, 2021, and 2020, the Company had U.S. federal net operating loss carry forwards of approximately \$101.9 million and \$100.6 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, 2022 through 2037. The remaining U.S. federal net operating loss of approximately \$44.2 million does not expire, however it is limited to 80% of each subsequent year's net income. As of December 31, 2021, and 2020, the Company had U.S. state net operating loss carry forwards of approximately \$38.2 million and \$7.5 million, respectively, some of which expire beginning with the year ending December 31, 2022 through 2041.

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 immediate impact on our financial statements since we recorded a full valuation allowance for our deferred tax assets as of December 31, 2021 and 2020. (See Note 8 to the Consolidated Financial Statements)

Liquidity and Capital Resources

As of December 31, 2021, the Company's cash and cash equivalents on hand was \$555,967 and marketable securities were \$11,003,071. The Company has incurred net losses of \$29,889,045 and \$9,487,824 for the years ended December 31, 2021 and 2020, respectfully. As of December 31, 2021, the Company had working capital of \$11,625,519 and a stockholders' deficit of \$78,561,568. During the year ended December 31, 2021, cash flows used in operating activities were \$19,516,475, consisting primarily of a net loss from operations of \$29,889,045 and a decrease in trade and other payables of \$4,268,961 offset by non-cash stock option modification expenses of \$15,036,051. Since inception, the Company has met its liquidity requirements principally through the sale of its common stock in public and private placements.

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 condensed consolidated financial statements, are sufficient to fund its current operating budget and contractual obligations as of December 31, 2021 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 condensed consolidated financial statements.

Management has created an alternative plan providing that, in the event no financing consummated by September 30, 2022, management will slow down clinical efforts in order to maintain adequate cash reserves to maintain operations for an additional six months, providing additional time for the Company to complete a financing. Management believes a financing will occur prior to September 30, 2022.

Operating Activities

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.

Our net cash used by operating activities totaled \$4,663,546 during the year ended December 31, 2020. Net cash used consisted principally of the net loss from continuing operations of \$9,487,24 partially offset by non-cash amortization of the debt discount of \$1,191,859 and stock option expenses of \$2,009,145.

Investing Activities

Our net cash provided by investing activities totaled \$19,850,625 for the year ended December 31, 2021 as compared to cash provided by investing activities totaling \$0 during the year ended December 31, 2020. 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, 2021 was \$73,533 which consisted of the payoff of our lines of credit totaling \$3,062,444 offset by proceeds of \$120,000 from the line of credit and \$1,826,137 from the Promissory Note and net proceeds of \$1,189,840 from the exercise of warrants for common stock. Net cash provided by financing activities totaled \$4,677,331 during the year ended December 31, 2020 which consisted of proceeds from the line of credit of \$1,426,731, \$1,200,000 from the Promissory Note, \$1,980,000 from the issuance of common stock and \$70,600 from the Payroll Protection Program.

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, 2021 and 2020, 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, 2021 and 2020 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, 2021 and 2020. 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 2018 through 2021 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.

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, 2021.

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, 2021 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.	69	Director, President and Chief Medical Officer
Adam Kaplin, M.D., Ph.D.	55	Chief Scientific Officer
Paul Rivard, Esq.	51	Executive Vice President of Operations and General Counsel
Ian Rhodes	49	Interim Chief Financial Officer
Craig Eagle, M.D.	55	Director
Christopher Schreiber	57	Director
Joshua Silverman	51	Director, Chairman of the Board
Jude Uzonwanne	47	Director
Bill J. White	61	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.

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. Prior to joining MYMD Florida, Dr. Kaplin has served in a number of positions at Johns Hopkins University, including Principal Neuro-Psychiatric Consultant to the Johns Hopkins Multiple Sclerosis Center of Excellence, Director of the Johns Hopkins Ketamine Clinic and the Departments of Psychiatry & Neurology at Johns Hopkins University School of Medicine, positions he has held at various times from 2002 to present. In addition, since 2019, Dr. Kaplin has served as Adjunct Faculty at the George Mason University Department of Global and Community Health. Dr. Kaplin has also served as Co-Founder of numerous healthcare related startups, including, from 2018 to present, REWARD Pathways Inc., a company devoted to addiction treatment development focused on a combined eHealth and medicine approach to curing addiction, and from 2016 to present, Hollinger Kaplin Benjamin & Bond, an eHealth software development company. Dr. Kaplin’s research focuses on the investigation of the biological basis of immune mediated depression and cognitive impairment by using multiple sclerosis as the model. Dr. Kaplin has also been active for over a decade in the development and application of health information technology to mental health, combining this work with providing neuropsychiatric consultation and ongoing care of patients with multiple sclerosis spectrum disorders. Dr. Kaplin’s original research has been published over 40 times in several different publications, and he has authored or co-authored numerous review articles and textbooks. Dr. Kaplin received his B.S. in Biology from Yale University, graduating cum laude in 1988, and received his M.D. and Ph.D. from the Johns Hopkins University School of Medicine in 1996.

Paul Rivard, Esq. has been our 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 November 2021, Mr. Rivard also serves as President and General Counsel of MIRA1a Therapeutics, Inc., a privately held company developing a synthetic cannabinoid analog for treating chronic pain and anxiety. 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 Organisation 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 of directors of the combined company 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-imburement 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. He also volunteers on the board of directors for Fox Lane Youth Lacrosse, a community youth program. Mr. Schreiber is a graduate of Johns Hopkins University, where he received a bachelor’s degree in Political Science.

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., Protagenic Therapeutics, Synaptogenix, Inc and Petros Pharmaceutical, Inc., all 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.

Jude Uzonwanne has been our director since April 16, 2021. Mr. Uzonwanne is currently the Chief Business Officer for 54gene, Inc., a US based biopharmaceutical company focused on developing new genomic based drugs. Prior to 54gene, he was a Principal with ZS Associates, Inc., a consulting and professional services firm focusing on consulting, software and technology that provides services for clients in the private equity, healthcare, and technology industries, a position he has held since January 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. Since 2019, Mr. Uzonwanne has served as a member of the board of directors of Bonita Foods, a privately held emerging market specialty food and snacks company. 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. He currently serves as chief financial officer, treasurer and secretary of Intellicheck, Inc., a technology company listed on the NYSE MKT. Prior to working at Intellicheck, Inc., he served 11 years as the chief financial 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 over \$36 million in annual revenue in a five-year period. 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 of Directors, 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.

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 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 and 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 and recommending on an annual basis to the Board for its approval, the fees and equity compensation paid to the Company’s non-employee directors;
- 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 CEO 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 and making recommendations to the Board with respect to incentive-compensation programs and equity-based plans and the adoption of or material changes in material employee benefit, bonus, severance and other compensation plans;
- determining the need for and the appropriateness of 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.
- determining and approving the options and other equity-based compensation to be granted to executive officers, other than the Chief Executive Officer;
- recommending to the Board for approval options and other equity-based compensation to be granted to the Chief Executive Officer and non-employee directors; and
- in conjunction with the CEO, 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 Securities Exchange Act of 1934, as amended, 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 2021, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons with the following exceptions: following the Merger, Dr. Chapman, Dr. Kaplin, Mr. Schreiber, Mr. Uzonwanne, and Dr. Eagle filed Form 4's on April 21, 2021 disclosing the receipt of shares issued in connection with the Merger closing on April 16, 2021.

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 Chief Executive Officer and former Chief Executive Officer, (ii) the two most highly compensated executive officers other than the Chief Executive Officer who were serving as an executive officer at the end of the 2021 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 2021 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 2021 were as follows:

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

Summary Compensation Table

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 (the "Reverse Split") of the issued and outstanding shares of our common stock, at a ratio of one share for two shares. The stock awards listed below have been adjusted to give effect to the Reverse Split.

Name and Principal Position	Notes	Year	Salary	Bonus	Stock Awards ⁽¹⁾	Option Awards ⁽²⁾	All Other Compensation	Total
Christopher Chapman, M.D. ⁽³⁾ President, Chief Medical Officer		2021	\$ 165,000	\$ 121,540	\$ 4,854,000 ⁽⁷⁾	\$ -	\$ -	\$ 5,140,540
		2020	27,500	-	-	270,000 ⁽¹²⁾	-	297,500
Adam Kaplin, M.D., PhD ⁽⁴⁾ Chief Scientific Officer		2021	250,000	126,724	4,854,000 ⁽⁸⁾	-	-	5,230,724
		2020	20,833	100,000	-	240,000 ⁽¹³⁾	-	360,833
Christopher Schreiber ⁽⁵⁾ Former President and Chief Executive Officer		2021	300,000	-	1,213,500 ⁽⁹⁾	-	-	1,513,500
		2020	300,000	150,000	590,240 ⁽¹⁰⁾	-	57,618	1,097,858
Paul Rivard, Esq. ⁽⁶⁾ Executive Vice President of Operations and General Counsel		2021	165,000	60,000	1,618,000 ⁽¹¹⁾	-	-	1,843,000
		2020	55,000	-	-	120,000 ⁽¹⁴⁾	-	175,000

- (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) 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.
- (4) 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.
- (5) On January 24, 2020, Mr. Schreiber entered into an employment agreement, under which he would receive an annual salary of \$300,000. On November 20, 2020, Mr. Schreiber resigned from his position as Executive Chairman of the Company's Board of Directors and was appointed as the Company's Chief Executive Officer. Mr. Schreiber continued to serve in his position as President of the Company and his employment agreement with the Company remained in effect. Effective April 16, 2021, Mr. Schreiber resigned his position as the Company's President and Chief Executive Officer.
- (6) On April 16, 2021, Mr. Rivard entered into an employment agreement, under which he would receive an annual salary of \$165,000. 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 each director restricted stock units ("RSUs") to purchase shares of the Company's common stock, and Dr. Chapman was granted 600,000 RSUs.
- (8) On October 14, 2021, the Company granted each director RSUs to purchase shares of the Company's common stock, and Dr. Kaplin was granted 600,000 RSUs.
- (9) On October 14, 2021, the Company granted each director RSUs to purchase shares of the Company's common stock, and Mr. Schreiber was granted 150,000 RSUs.
- (10) On September 11, 2020, the Company granted each director RSUs to purchase shares of the Company's common stock, and Mr. Schreiber was granted 109,750 RSUs.
- (11) On October 14, 2021, the Company granted RSUs to purchase shares of the Company's common stock, and Mr. Rivard was granted 200,000 RSUs.
- (12) Consists of (i) a discretionary grant of options to purchase 77,180 shares of MyMD common stock at an exercise price of \$2.59 per share made to Dr. Chapman on August 2, 2020 and (ii) a grant of options to purchase 96,475 shares of MyMD common stock at an exercise price of \$2.59 per share made to Dr. Chapman on November 1, 2020 in connection with his appointment as President and Chief Medical Officer. All such options vested immediately upon grant and had an aggregate fair value on the date of grant of \$270,000.
- (13) Consists of a grant of options to purchase 400,000 shares of MyMD Florida common stock at an exercise price of \$1.00 per share made to Dr. Kaplin on December 18, 2020 in connection with his appointment as Chief Scientific Officer. All such options vested immediately upon grant and had an aggregate fair value on the date of grant of \$240,000. After giving effect to the Exchange Ratio and the Reverse 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.
- (14) Consists of a grant of options to purchase 200,000 shares of MyMD Florida common stock at an exercise price of \$1.00 per share made to Mr. Rivard on August 21, 2020. All such options vested immediately upon grant and had an aggregate fair value on the date of grant of \$120,000. After giving effect to the Exchange Ratio and the Reverse 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.

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 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 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.

Employment of Christopher C. Schreiber

On January 24, 2020, the Board independently reviewed and approved entering into an executive chairman agreement with Christopher C. Schreiber (the “Executive Chairman Agreement”). Pursuant to the Executive Chairman Agreement, Mr. Schreiber would continue to serve as the Executive Chairman of the Board as long as he was a member of the Board, or until termination of the Executive Chairman Agreement (as described below) or upon his earlier death, incapacity, removal, or resignation. Pursuant to the Executive Chairman Agreement, Mr. Schreiber was entitled to receive: (i) an annual base salary of \$300,000, payable monthly in equal installments, paid retroactively as of November 1, 2019 (it being agreed that such fee would be inclusive of any fees associated with Schreiber’s services as both a director of our company and in the capacity of Executive Chairman), (ii) employee benefits including health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in our 401(k) Plan, (iii) annual or other bonuses in cash and/or in securities of our company and/or otherwise, which bonuses, if any, shall be awarded in the complete discretion of the Board or a designated committee thereof and (iv) reimbursements for pre-approved reasonable business-related expenses incurred in good faith in the performance of Mr. Schreiber’s duties for us.

The Executive Chairman Agreement established an “at will” employment relationship pursuant to which Mr. Schreiber served as Executive Chairman. We had the right to terminate the Executive Chairman Agreement for any reason or no reason, and Mr. Schreiber had the right to voluntarily resign for any reason or no reason with sixty (60) days’ notice. The Executive Chairman Agreement also provided that Mr. Schreiber may not compete against us or solicit our employees or customers for a period of one (1) year after termination of the Executive Chairman Agreement or his association with us for any reason. On November 20, 2020, Mr. Schreiber resigned from his position as Executive Chairman of the Board and was appointed as the Chief Executive Officer, effective November 20, 2020, with Mr. Schreiber to continue serving as our principal executive officer and president. Mr. Schreiber’s Executive Chairman Agreement remained in effect, except for the title of his position, until on April 15, 2021, Mr. Schreiber tendered his resignation from his position as Chief Executive Officer of the Company, effective April 16, 2021, upon closing of the Merger. Since that date, Mr. Schreiber has served as a special advisor to the Company and received an annual base salary and employee benefits consistent with the terms of the Executive Chairman Agreement.

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 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.

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 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.

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, 2021:

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. President, Chief Medical Officer	38,590 ⁽³⁾	-	\$ 2.59	4/16/2023	-	\$ -
	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 Chief Scientific Officer	154,360 ⁽⁷⁾	-	2.59	4/16/2023	-	-
	-	-	-	n/a	600,000 ⁽²⁾	4,854,000
Christopher Schreiber Former President and Chief Executive Officer	-	-	-	n/a	150,000 ⁽²⁾	1,213,500
Paul Rivard, Esq Executive Vice President of Operations and General Counsel	77,180 ⁽⁸⁾	-	2.59	4/16/2023	-	-
	-	-	-	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 2021. All compensation paid to Dr. Chapman and Mr. Schreiber during 2021 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⁾	Total
Josh Silverman ⁽²⁾	\$ 216,000	\$ 4,854,000	\$ 5,070,000
Bill J. White ⁽³⁾	96,000	1,213,500	1,309,500
Robert Schroeder ⁽⁴⁾	64,000	-	64,000
Craig Eagle, M.D. ⁽⁵⁾	67,736	1,213,500	1,281,236
Jude Uzonwanne ⁽⁶⁾	67,736	1,213,500	1,281,236

(1) In accordance with SEC rules, this column reflects the aggregate fair value of stock awards granted during the fiscal year ended December 31, 2020, 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) As of December 31, 2021, Mr. Silverman had 673,776 outstanding RSUs.

(3) As of December 31, 2021, Mr. White had 223,776 outstanding RSUs.

(4) Mr. Schroeder passed away on September 1, 2021. As of December 31, 2021, Mr. Schroeder (or his heirs or devisees) had 29,837 outstanding RSUs.

(5) Dr. Eagle was appointed to the Board of Directors on April 16, 2021. As of December 31, 2021, Dr. Eagle had 150,000 outstanding RSUs.

(6) Mr. Uzonwanne was appointed to the Board of Directors on April 16, 2021. As of December 31, 2021, Mr. Uzonwanne had 150,000 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, 2021.

On September 11, 2020, the Compensation Committee of the Board approved the grant of 131,750 RSUs to Mr. Schreiber, 109,500 RSUs to each of Mr. Silverman and Mr. White; and 43,930 RSUs to Mr. Schroeder. 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 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 shall vest immediately upon the occurrence of (i) a change in control, provided that the grantee is employed or providing services to us and our affiliates on the closing date of such change in control, (ii) the grantee's termination of employment or services to us and our affiliates by reason of death or disability, or (iii) the grantee's termination of employment or services to us without cause. At our election, the vested RSUs may be settled for cash. On April 16, 2021, concurrently with the closing of the Merger, pursuant to the terms of the RSU Agreements between the Company and the four directors listed above, the 394,680 RSUs granted on September 11, 2020 under the 2018 Plan, as amended, that remained unvested accelerated and vested in full.

On November 23, 2020, we retained 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, we agreed to pay Taglich Brothers \$10,000 per month.

Mr. Schreiber is the managing director of capital markets at Taglich Brothers. This agreement was terminated without penalty effective August 31, 2021. Mr. Schroeder was the vice president of investment banking at Taglich Brothers until his death on September 1, 2021.

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 October 15, 2021, 4,433,184 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 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 Record Date, the Company had 8 employees, 0 contractors, and 5 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 November 12, 2021, options to purchase 4,188,315 shares of the Company’s common stock have been issued pursuant to the plan and 0 shares of 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 Akers 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 the Company’s common stock, at an exercise price per share of the Company’s 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 (“2013 Plan”). The 2013 Plan was amended by the our 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 October 15, 2021, 755 shares of common stock remain available for grants under the 2013 Plan.

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, 2020, grants of restricted stock and options to purchase totaling 1,532 shares of common stock have been issued pursuant to the 2017 Plan and as of October 15, 2021, 1,984 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 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 October 15, 2021, 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 Equity Compensation Plans as of the fiscal year ended December 31, 2021:

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)	6,983,315	\$ 4.79	4,732,960
Equity compensation plans not approved by security holders	-	-	-
Total	6,983,315	\$ 4.79	4,732,960

(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 31, 2022 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 36,058,245 shares of common stock issued and outstanding as of March 24, 2022. Percentage of Series D Preferred Stock ownership is based on 72,992 shares of Series D Preferred Stock issued and outstanding as of March 31, 2022.

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 31, 2022 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
<i>5% Beneficial Owner</i>					
Iroquois Capital Management LLC ⁽³⁾	1,418,665	3.62%	-	*	3.61%
Richard Abbe / Iroquois Capital Investment Group LLC ⁽³⁾	2,327,987	6.05%	-	*	6.05%
Caroline Williams / Starwood Trust ⁽⁴⁾	5,020,182	12.76%	-	*	12.75%
Premas Biotech PVT Ltd. ⁽⁵⁾	103,782	*	72,992	100%	*
<i>Named Executive Officers and Directors</i>					
Joshua Silverman ⁽⁶⁾	88,776	*	-	*	*
Bill J White ⁽⁷⁾	73,776	*	-	*	*
Craig Eagle, M.D. ⁽⁸⁾	482,375	1.25%	-	*	1.25%
Jude Uzonwanne ⁽⁹⁾	115,770	*	-	*	*
Christopher C Schreiber ⁽¹⁰⁾	88,238	*	-	*	*
Christopher Chapman, M.D. ⁽¹¹⁾	289,425	*	-	*	*
Adam Kaplin, M.D., PhD ⁽¹²⁾	154,360	*	-	*	*
Paul Rivard ⁽¹³⁾	169,360	*	-	*	*
All current executive officers and Directors as a group (9 persons)	1,462,080	3.70%	-	*	3.70%

* 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 24, 2022, 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 36,058,245 shares of common stock issued and outstanding as of March 24, 2022.
- (2) Shares of Series D Convertible Preferred Stock beneficially owned and convertible into common stock and the respective percentages of beneficial ownership of Series D Convertible 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 24, 2022, 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 24, 2022.
- (3) This information is based on a Schedule 13G/A filed with the SEC on February 22, 2022 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 Securities Exchange Act of 1934, as amended) of the securities held by Iroquois Capital and IMF. The shares included in the table report the number of shares that would be issuable giving effect to the 9.99% beneficial ownership blocker included in the Pre-Funded Warrants and the warrants. The percentage included in the table gives effect to the 9.99% beneficial ownership blocker included in the Pre-Funded Warrants and warrants.

IMF owns 260,366 shares of MyMD common stock, Pre-Funded Warrants to purchase 385,135 shares of MyMD common stock issued in connection with the MyMD Private Placement and warrants to purchase 773,164 shares of MyMD common stock.

Mr. Abbe 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 Securities Exchange Act of 1934, as amended) of the securities held by ICIG. ICIG owns 1,918,242 shares of common stock, Pre-Funded Warrants to purchase 135,135 shares of MyMD common stock issued in connection with the MyMD Private Placement and warrants to purchase 274,610 shares of MyMD common stock.

- (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 MyMD common stock and shared dispositive power for 3,747,210 shares of MyMD common stock. The MyMD 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 Securities Exchange Act of 1934, as amended) 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 MyMD common stock and options to purchase 1,275,731 shares of MyMD common stock.

Ms. Williams individually owns 1,272,972 shares of MyMD common stock as such is deemed to have beneficial ownership.

- (5) On March 23, 2020, Premas Biotech PVT., Ltd received 103,782 shares of MyMD common stock and 72,992 shares of MyMD Series D Convertible 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.

- (6) Represents (i) 15,000 shares of common stock 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 the Record Date.

- (7) Represents 73,776 RSU awards to Mr. White that are vested or scheduled to vest within 60 days of the Record Date.

- (8) Dr. Eagle individually owns 482,375 common stock options which vested immediately upon grant and expire April 16, 2023.

- (9) Represents 115,770 shares of common stock issuable upon the exercise of options held by Mr. Uzonwanne exercisable within 60 days of the Record Date.

- (10) Represents 88,238 RSU awards to Mr. Schreiber that are vested or scheduled to vest within 60 days of the Record Date.

- (11) Dr. Chapman individually owns 289,425 common stock options which vested immediately upon grant and expire on April 23, 2023.

- (12) Dr. Kaplin individually owns 154,360 common stock options which options vested immediately upon grant and expire April 16, 2023.

- (13) Mr. Rivard individually owns 15,000 shares of MyMD common stock and 77,180 common stock options which fully vested upon grant and expire on April 16, 2023. The Paul & Jennifer Rivard Revocable Living Trust (the “Rivard Trust”) owns 77,180 common stock options 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 Securities Exchange Act of 1934, as amended) 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 associates, 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 under “Item 11. Executive Compensation” herein, since January 1, 2020, 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 November 11, 2020, the Company entered into a Securities Purchase Agreement (the “Private Placement SPA”) with certain institutional and accredited investors (the “SPA Purchasers”), including Iroquois Master Fund Ltd. (“IMF”) and its affiliate, Iroquois Capital Investment Group, LLC (“ICIG”) Intracoastal Capital, LLC (“Intracoastal”) and Mainfield Enterprises Inc. (“Mainfield”), pursuant to which the Company agreed to issue and sell to the SPA Purchasers certain securities in a private placement (the “Private Placement”). In connection with the Private Placement, IMF and ICIG received an aggregate of 1,040,540 shares (520,270 after giving effect to the Reverse Split) of the Company’s common stock, 1,040,540 Pre-Funded Warrants (520,270 after giving effect to the Reverse Split) and 2,081,020 Investor Warrants (1,040,510 after giving effect to the Reverse Split); Intracoastal received 729,729 shares (364,865 after giving effect to the Reverse Split) of the Company’s common stock, and 729,729 Investor Warrants (364,865 after giving effect to the Reverse Split), and Mainfield received 1,081,081 shares (540,541 after giving effect to the Reverse Split) of the Company’s common stock, and 1,081,081 Investor Warrants (540,541 after giving effect to the Reverse Split)

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 Split, such shares of MyMD Florida common stock are equivalent to 13,096,639 shares of the Company’s 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 Split, such options to purchase MyMD Florida common stock are equivalent to options to purchase 12,078,670 shares of the Company's 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. The Starwood Trust is a trust for which Mr. Williams was the settlor/grantor; Mr. Williams did not have voting or investment power of the MyMD Florida shares held by the trust.

Item 14. Principal Accounting Fees and Services.

	2021	2020
Audit Fees	\$ 121,500	\$ 76,000
Audit-Related Fees	179,187	43,550
Tax Fees	26,000	17,200
All Other Fees	-	-
TOTAL	\$ 326,687	\$ 136,750

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 2021 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(1) Financial Statements

Report of Independent Registered Public Accounting Firm (PCAOB ID No: 00536)	F-2
Report of Independent Registered Public Accounting Firm (PCAOB ID No: 00677)	F-3
Consolidated Balance Sheets	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Changes in Shareholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7

(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).

- 4.1+ [Description of Securities](#)
- 4.2 [Form of Underwriters' Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the Securities Exchange Commission on November 18, 2013\).](#)
- 4.3 [Form of Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 10, 2017\).](#)
- 4.4 [Form of Purchaser Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017\).](#)
- 4.5 [Form of Placement Agent Warrant \(incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017\).](#)
- 4.6 [Form of Purchaser Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 13, 2017\).](#)
- 4.7 [Form of Underwriter's Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 15, 2017\).](#)
- 4.8 [Form of Common Stock Purchase Warrant \(incorporated herein by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 15, 2017\).](#)
- 4.9 [Form of Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018\).](#)
- 4.10 [Form of Series C Convertible Preferred Stock Warrant Certificate \(incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019\).](#)
- 4.11 [Form of Pre-Funded Warrant Certificate \(incorporated herein by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019\).](#)

- 4.12 [Form of Placement Agent Warrant Certificate.](#)
- 4.13 [Form of Placement Agent Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020\).](#)
- 4.14 [Form of Placement Agent Warrant \(incorporated herein by references to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020\).](#)
- 4.15 [Form of Placement Agent Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020\).](#)
- 4.16 [Form of Placement Agent Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 18, 2020\).](#)
- 4.17 [Rights Agreement dated as of September 9, 2020 between Akers Biosciences, Inc. and VStock Transfer, LLC as Rights Agent \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2020\).](#)
- 4.18 [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 \(incorporated herein by reference to Exhibit 4.19 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021\).](#)
- 4.19 [Form of Pre-Funded Warrant, of Akers Biosciences, Inc. \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020\).](#)
- 4.20 [Form of Investor Warrant, of Akers Biosciences, Inc. \(incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020\).](#)
- 10.1 [Amended License and Supply Agreement by and between the Company and Chubeworkx Guernsey Limited \(as successor to Sono International Limited \("Chubeworkx"\)\), \(EN\)10 \(Guernsey\) Limited \(formerly BreathScan International \(Guernsey\) Limited\) and \(EN\)10 Limited \(formerly BreathScan International Limited\), dated June 12, 2013 \(incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013\).](#)
- 10.2 [Share Purchase Agreement by and between the Company and Chubeworkx, dated June 12, 2013 \(incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013\).](#)
- 10.3 [Subscription Agreement by and between the Company and Chubeworkx, dated June 12, 2013 \(incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013\).](#)
- 10.4 [Subscription Agreement by and between the Company and Thomas J. Knox, dated September 14, 2012 \(incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013\).](#)
- 10.5 [Promissory Note entered into by Thomas J. Knox issued in favor of the Company, dated September 14, 2012 \(incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013\).](#)
- 10.6 [License and Supply Agreement by and among the Company, Sono International Limited \("SIL"\), BreathScan International \(Guernsey\) Limited and BreathScan International Limited, dated June 19, 2012 \(incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013\).](#)

- 10.7 [Distribution Agreement by and among the Company and Fisher Healthcare, and Amendment thereto, dated June 15, 2010 and May 1, 2012, respectively, \(incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013\).](#)
- 10.8 [National Brand Distribution Agreement by and among the Company and Cardinal Health 2000, and Amendment thereto, dated May 1, 2007 and June 1, 2008, respectively, \(incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013\).](#)
- 10.9# [2013 Incentive Stock and Award Plan \(incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013\).](#)
- 10.10# [Form of Nonqualified Stock Option Agreement \(Non-Employee\) \(incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013\).](#)
- 10.11# [Form of Nonqualified Stock Option Agreement \(Employee\) \(incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013\).](#)
- 10.12# [Form of Restricted Stock Agreement \(incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013\).](#)
- 10.13# [Form of Incentive Stock Option \(incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013\).](#)
- 10.14 [Letter Agreement, dated December 3, 2013, by and between the Company and Mr. Thomas Knox \(incorporated herein by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013\).](#)
- 10.15 [Joint Venture Agreement, dated October 24, 2014, by and between the Company, Hainan Savy Investment Management Ltd, and Thomas Knox \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2014\).](#)
- 10.16 [Amended and Restated 2013 Incentive Stock and Award Plan of the Company \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2015\).](#)
- 10.17 [Form of Lock Up Agreement of the Company \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2015\).](#)

- 10.18# [Employment Agreement between the Company and John J. Gormally, dated December 1, 2015. \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 3, 2015\).](#)
- 10.19 [First Amendment to the Amended and Restated 2013 Incentive Stock and Award Plan of the Company \(incorporated by referenced to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 12, 2016\).](#)
- 10.20 [Form of Placement Agency Agreement, dated March 30, 2017, by and between the Company and Joseph Gunnar and Co., LLC \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017\).](#)
- 10.21 [Form of Securities Purchase Agreement, dated March 30, 2017, by and between the Company and various purchasers. \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017\).](#)
- 10.22 [Form Registration Rights Agreement, dated March 30, 2017, by and between the Company and various purchasers \(incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017\).](#)
- 10.23# [the Company 2017 Equity Incentive Plan \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2017\).](#)
- 10.24 [Form Warrant Exercise Agreement, dated October 12, 2017 by and between the Company and various holders \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 13, 2017\).](#)
- 10.25# [Form of Resignation Agreement of the Company \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 11, 2018\).](#)
- 10.26 [Form of Securities Purchase Agreement, dated October 31, 2018, by and among the Company and the investors signatory thereto \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018\).](#)
- 10.27 [the Company 2018 Equity Incentive Plan \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2018\).](#)
- 10.28 [Form of Securities Purchase Agreement \(incorporated herein by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019\).](#)

- 10.30# [Offer of Employment to Christopher C. Schreiber, dated January 31, 2020 \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 31, 2020\).](#)
- 10.31 [Membership Interest Purchase Agreement, dated as of March 23, 2020, by and among the members of Cystron Biotech, LLC and the Company \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020\).](#)
- 10.32 [Support Agreement, dated as of March 23, 2020, by and among the Company and certain of its stockholders \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020\).](#)
- 10.33 [Registration Rights Agreement, dated as of March 23, 2020, by and among certain members of Cystron Biotech, LLC and the Company \(incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020\).](#)
- 10.34 [Amended and Restated License and Development Agreement by and among Premas Biotech PVT Ltd and Cystron Biotech, LLC \(incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020\).](#)
- 10.35 [Form of Securities Purchase Agreement \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020\).](#)
- 10.36 [Amendment No.1 to the Membership Interest Purchase Agreement, dated May 14, 2020 \(incorporated herein by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2020\).](#)
- 10.37 [Form of Securities Purchase Agreement \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020\).](#)
- 10.38# [CFO Consulting Agreement, dated as of July 21, 2020, between the Company and Brio Financial Group \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 22, 2020\).](#)
- 10.39 [Settlement Agreement and General Release, dated as of August 3, 2020, by and among the Company and ChubeWorkx Guernsey Limited \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 07, 2020\).](#)
- 10.40 [Leak-Out and Support Agreement, dated as of August 3, 2020, by and among the Company and ChubeWorkx Guernsey Limited \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 07, 2020\).](#)
- 10.41 [Form of Securities Purchase Agreement \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020\).](#)
- 10.42# [the Company 2018 Plan Amendment \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 28, 2020\).](#)
- 10.43 [Form of Lock-Up/Leak-Out Agreement \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020\).](#)
- 10.44 [The Secured Promissory Note, dated November 11, 2020, by and between the Company and MYMD Pharmaceuticals, Inc. \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020\).](#)

- 10.45 [Form of Securities Purchase Agreement, dated November 11, 2020, by and between the Company and purchasers named therein \(incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020\).](#)
- 10.46 [Form of Lock-Up and Support Agreement, dated November 11, 2020, by and between the Company and its stockholders named therein \(incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020\).](#)
- 10.47 [Contribution and Assignment Agreement, dated March 16, 2021, by and among Akers Biosciences, Inc., Cystron Biotech LLC, and Oravax Medical Inc. \(incorporated herein by reference to Exhibit 10.48 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021\).](#)
- 10.48 [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 \(incorporated herein by reference to Exhibit 10.49 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021\).](#)
- 10.49# [MyMD Pharmaceuticals, Inc. 2021 Equity Incentive Plan \(incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021\).](#)
- 10.50# [Form of Nonqualified Stock Option Agreement \(incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021\).](#)
- 10.51# [Form of Incentive Stock Option Agreement \(incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021\).](#)
- 10.52# [Form of Restricted Stock Award Agreement \(incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021\).](#)
- 10.53 [Asset Purchase Agreement, dated November 11, 2020, by and between MyMD Pharmaceuticals, Inc. and Supera Pharmaceuticals, Inc. \(incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.54# [MyMD Pharmaceuticals \(Florida\) Inc. Second Amendment to Amended and Restated 2016 Stock Incentive Plan, dated July 1, 2019 \(incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.55# [Amended and Restated Confirmatory Patent Assignment and Royalty Agreement dated November 11, 2020, by and between SRO Patent Holdings II, LLC and Supera Pharmaceuticals, Inc. \(incorporated herein by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.56# [Amended and Restated Confirmatory Patent Assignment and Royalty Agreement dated November 11, 2020, by and between SRO Patent Holdings, LLC and MyMD Pharmaceuticals, Inc. \(incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.57# [Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals \(Florida\), Inc., effective December 18, 2020 \(incorporated herein by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.58# [Amendment No. 1 to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals \(Florida\), Inc., dated February 11, 2021 \(incorporated herein by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.59# [Employment Agreement between Chris Chapman and MyMD Pharmaceuticals \(Florida\), Inc., effective November 1, 2020 \(incorporated herein by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.60# [Amendment No. 1 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals \(Florida\), Inc., dated December 18, 2020 \(incorporated herein by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.61# [Amendment No. 2 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals \(Florida\), Inc., dated January 8, 2021 \(incorporated herein by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)

10.62#	<u>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).</u>
10.63#	<u>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).</u>
10.64#	<u>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).</u>
10.65#	<u>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).</u>
10.66#+	<u>Amendment No. 4 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals, Inc., dated November 24, 2021.</u>
10.67#+	<u>Amendment No. 2 to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals, Inc., dated November 24, 2021.</u>
21.1+	<u>List of Subsidiaries of MyMD Pharmaceuticals, Inc.</u>
23.1+	<u>Consent of Morison Cogen LLP, Independent Registered Public Accounting Firm.</u>
23.2+	<u>Consent of Cherry Bekaert LP, Independent Registered Public Accounting Firm.</u>
31.1+	<u>Certification of the Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).</u>
31.2+	<u>Certification of the Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).</u>
32.1+	<u>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</u>
32.2+	<u>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</u>
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, 2022

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Christopher C. Chapman</u> Christopher C. Chapman, M.D.	President, Chief Medical Officer and Director (Principal Executive Officer)	March 31, 2022
<u>/s/ Ian Rhodes</u> Ian Rhodes	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2022
<u>/s/ Joshua Silverman</u> Joshua Silverman	Chairman of the Board	March 31, 2022
<u>/s/ Bill J. White</u> Bill J. White	Director	March 31, 2022
<u>/s/ Christopher C. Schreiber</u> Christopher C. Schreiber	Director	March 31, 2022
<u>/s/ Jude Uzonwanne</u> Jude Uzonwanne	Director	March 31, 2022
<u>/s/ Craig Eagle</u> Craig Eagle, M.D.	Director	March 31, 2022

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm (PCAOB ID No: 00536)	F-2
Report of Independent Registered Public Accounting Firm (PCAOB ID No: 00677)	F-3
Consolidated Balance Sheets	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Changes in Shareholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8

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 sheet of MyMD Pharmaceuticals, Inc. and Subsidiaries (the Company) as of December 31, 2021 and the related consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended 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, 2021 and the results of their operations and their cash flows for the year then ended 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit 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 audit, 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 audit 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 audit 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 audit provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was 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 matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

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, 2021 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.

/s/ Morison Cogen LLP

We have served as the Company's auditor since 2010.

Blue Bell, Pennsylvania

March 31, 2022

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 sheet of MyMD Pharmaceuticals, Inc. and Subsidiaries (the “Company”) as of December 31, 2020, and the related consolidated statements of comprehensive loss, changes in shareholders’ deficit, and cash flows for year then ended, and the related notes (collectively, referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Emphasis of a Matter

As discussed in Note 3 to the consolidated financial statements, the Company has incurred recurring losses from operations and negative cash flows from operating activities. Management’s plans in regard to these matters are also described in Note 3. Our opinion is not modified with respect to this matter.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that was communicated or required to be communicated to the Company’s Audit Committee and that (i) relates to accounts or disclosures that are material to the financial statements and (ii) involved especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

We served as the Company’s auditor from 2020 to 2022.

/s/ CHERRY BEKAERT LLP

Tampa, Florida
March 31, 2022

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2021 and 2020

	As of	
	2021	2020
ASSETS		
Current Assets		
Cash and Cash Equivalents	\$ 555,967	\$ 148,284
Marketable Securities	11,003,071	-
Prepaid expenses	1,106,347	1,218
Total Current Assets	12,665,385	149,502
Non-Current Assets		
Operating Lease Right-of-Use Asset	149,009	527,195
Goodwill	10,498,539	-
Investment in Oravax, Inc.	1,500,000	-
Total Non-Current Assets	12,147,548	527,195
Total Assets	\$ 24,812,933	\$ 676,697
LIABILITIES		
Current Liabilities		
Trade and Other Payables	\$ 986,626	\$ 1,104,801
Trade and Other Payables, related party	-	696,926
Operating Lease Liability	53,240	475,816
PPP Loan Payable	-	70,600
Total Current Liabilities	1,039,866	2,348,143
Non-Current Liabilities		
Due to MyMD Florida Shareholders	29,982	-
Line of Credit Payable– Related Party, net of discount	-	2,333,984
Notes Payable	-	1,200,000
Operating Lease Liability, net of current portion	95,911	51,602
Total Non-Current Liabilities	125,893	3,585,586
Total Liabilities	1,165,759	5,933,729
Commitments and Contingencies		
SHAREHOLDERS' EQUITY/(DEFICIT)		
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 and 0 shares issued and outstanding as of December 31, 2021 and 2020	144,524	-
Common stock, No par value, 500,000,000 shares authorized 37,673,110 and 0 issued and outstanding as of December 31, 2021 and 2020	102,064,218	-
Common stock, par \$0.0001, 100,000,000 shares authorized 0 and 28,553,307 issued and outstanding as of December 31, 2021 and 2020	-	4,004
Additional Paid in Capital	-	43,411,487
Accumulated Deficit	(78,561,568)	(48,672,523)
Total Shareholders' Equity/(Deficit)	23,647,174	(5,257,032)
Total Liabilities and Shareholders' Equity/(Deficit)	\$ 24,812,933	\$ 676,697

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,	
	2021	2020
Product Revenue	\$ -	\$ -
Product Cost of Sales	-	-
Gross Income	-	-
Administrative Expenses	6,420,092	2,946,703
Research and Development Expenses	6,745,104	2,466,924
Accretion of Debt Discount	608,460	1,191,859
Amortization of Intangible Assets	-	18,334
Stock Based Compensation	-	855,000
Stock Option Modification Expenses	15,036,051	2,009,145
Loss from Operations	(28,809,707)	(9,487,965)
Other (Income) Expenses		
Interest and Dividend Income	(8,907)	(141)
Gain on Sales of Marketable Securities	(39,597)	-
Unrealized Loss on Marketable Securities	42,793	-
Gain on Debt Forgiveness	(180,257)	-
Uninsured Casualty Losses	1,265,306	-
Total Other Income	1,079,338	(141)
Loss Before Income Tax	(29,889,045)	(9,487,824)
Income Tax Benefit	-	-
Net Loss	\$ (29,889,045)	\$ (9,487,824)
Basic and Dilutive net loss per common share	\$ (0.85)	\$ (0.34)
Weighted average basic and diluted common shares outstanding	35,017,244	28,188,438

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, 2021 and 2020

	Series D Convertible Preferred Stock		Common Stock				Accumulated Deficit	Total Equity
	Shares	Series D	Shares	Common Stock No Par	Common Stock Par \$0.0001	Additional Paid-In Capital		
	-	-	-	-	-	-		
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	<u>72,992</u>	<u>\$ 144,524</u>	<u>37,673,110</u>	<u>\$ 102,064,218</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ (78,561,568)</u>	<u>\$ 23,647,174</u>

	Series D Convertible Preferred Stock		Common Stock				Accumulated Deficit	Total Equity
	Shares	Series D	Shares	Common Stock No Par	Common Stock Par \$0.0001	Additional Paid-In Capital		
	-	-	-	-	-	-		
Balance at December 31, 2019	-	\$ -	27,785,366	-	\$ 3,806	\$ 36,848,063	\$ (39,184,699)	\$ (2,332,830)
Net loss	-	-	-	-	-	-	(9,487,824)	(9,487,824)
Private placement of common shares	-	-	767,941	-	198	1,979,802	-	1,980,000
Modification of the terms of 4,188,315 MyMD stock options	-	-	-	-	-	2,009,145	-	2,009,145
Stock-based compensation for borrowings	-	-	-	-	-	1,719,477	-	1,719,477
Stock-based compensation	-	-	-	-	-	855,000	-	855,000
Balance at December 31, 2020	<u>-</u>	<u>\$ -</u>	<u>28,553,307</u>	<u>\$ -</u>	<u>\$ 4,004</u>	<u>\$ 43,411,487</u>	<u>\$ (48,672,523)</u>	<u>\$ (5,257,032)</u>

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,	
	2021	2020
Cash flows from operating activities:		
Net loss from ongoing operations	\$ (29,889,045)	\$ (9,487,824)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued interest/dividends	(3,024)	177,556
Accretion of debt discount	608,460	1,191,859
Amortization of intangible assets	-	18,334
Gain on sale of marketable securities	(39,597)	-
Unrealized loss on marketable securities	42,793	-
Gain on forgiveness of debt	(180,258)	-
Stock based compensation:		
Stock option modification expense	15,036,051	2,009,145
Common stock options	-	855,000
Stock issued to non-employees	90,002	-
Change in assets and liabilities		
Prepaid expenses	(912,815)	16,254
Trade and other payables	(4,268,961)	557,286
Operating leases	(81)	(1,156)
Net cash used by operating activities	(19,516,475)	(4,663,546)
Cash flows from investing activities:		
Purchases of marketable securities	(13,403)	-
Proceeds from sale of marketable securities	18,483,176	-
Net cash received in business combination	1,380,852	-
Net cash provided by investing activities	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	1,426,731
Net proceeds from note payable	1,826,137	1,200,000
Net proceeds from issuance of common stock	-	1,980,000
Net proceeds from the Payroll Protection Program	-	70,600
Net proceeds from the exercise of warrants for common stock	1,189,840	-
Net cash provided by financing activities	73,533	4,677,331
Net increase in cash and cash equivalents	407,683	13,785
Cash and cash equivalents at beginning of year	148,284	134,499
Cash and cash equivalents at end of year	<u>\$ 555,967</u>	<u>\$ 148,284</u>
Supplemental cash flow information		
Cash paid for:		
Interest	\$ 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	\$ 141,387	\$ 527,195
Stock options issued and modified recorded as deferred financing charges	\$ -	\$ 1,719,477
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, 2021, 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 immunometabolic 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. Phase 2 clinical trials for autoimmune diseases are planned. MyMD Florida’s intellectual property portfolio consists of 15 U.S. granted patents and 28 pending applications (3 US, 25 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 its effectiveness in treating anxiety. The preclinical data was presented at the 4th Annual International Cannabinoid Summit describing the superior potency of Supera-CBD.

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”), (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’s 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’s Common Stock listed on The Nasdaq Capital Market, 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.

Note 2 – Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements for the years ended December 31, 2021 and 2020 have been prepared in accordance and in conformity with the accounting principles generally accepted in the United States of America (“U.S. GAAP”) and the applicable rules and regulations of the Securities and Exchange Commission (“SEC”) regarding consolidated financial information.

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, income 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 are included in the following notes for the 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 presented in U.S. Dollars 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 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.

(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.

Note 2 – Significant Accounting Policies (continued)

(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 has the ability to 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.

Following is a description of the valuation methodologies used for assets measured at fair value as of December 31, 2021 and December 31, 2020.

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, 2021	\$ 11,003,071	\$ -	\$ -
Marketable securities at December 31, 2020	\$ -	\$ -	\$ -

Marketable securities are classified as available for sale and are valued at fair market value. Maturities of the securities are less than one year.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies (continued)

As of December 31, 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, 2021 was of a loss of \$42,793 which was included in net loss from operations in the Consolidated Statements of Comprehensive Loss.

Gains resulting from the sales of marketable securities were \$39,597 and \$0 for the years ended December 31, 2021 and 2020, respectively

Proceeds from the sales of marketable securities in the years ended December 31, 2021 and 2020 were \$18,483,176 and \$0, respectively.

(g) Prepaid Expenses

Prepaid expenses represent expenses paid prior to the date that the related services are rendered or used and 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. At times, the Company's cash in banks is in excess of the Federal Deposit Insurance Corporation ("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, 2021.

Note 2 – Significant Accounting Policies (continued)

(i) Risk Management of Cash 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 value these investments using the cost method.

The investment in Oravax, Inc. is accounted for using the cost method.

Note 2 – Significant Accounting Policies (continued)

(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 to our Consolidated Statements of Comprehensive Loss.

Patents and Trade Secrets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person’s breath, blood, urine and saliva. Propriety protection for the Company’s products, technology and process is important to its competitive position. As of March 24, 2022, the Company has 15 issued U.S. patents, eight foreign patents, three pending U.S. patent applications, one pending international application, and 23 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.

Note 2 – Significant Accounting Policies (continued)

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 leases 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 houses 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 leased an aircraft under an operating lease (“Supera Aviation”) 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 leases 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 is provided. The initial term expires 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 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.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies (continued)

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 adoption of ASC 842 resulted in the recognition of operating lease ROU assets of \$1,014,636, operating lease liabilities for an operating leases of \$1,016,015 and an adjustment to accumulated deficit of \$1,379 on the Company’s Consolidated Balance Sheet as of January 1, 2020.

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 of 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 Supera Aviation, the Hyde Park, the 2020 Wolfe St and the 2021 Wolfe St. leases on the Consolidated Balance Sheet. The information related to these leases are presented below:

Balance Sheet Location	As of December 31, 2021					As of December 31, 2020				
	Supera Aviation	Hyde Park	2020 Wolfe Street	2021 Wolfe Street	Total	Supera Aviation	Hyde Park	2020 Wolfe Street	2021 Wolfe Street	Total
Operating Lease										
Lease Right of Use	\$ -	\$ 12,156	\$ -	\$ 136,853	\$ 149,009	\$ 431,809	\$ 34,722	\$ 60,664	\$ -	\$ 527,195
Lease Payable, current	-	12,164	-	41,076	53,240	431,809	25,120	18,887	-	475,816
Lease Payable - net of current	-	-	-	95,911	95,911	-	9,704	41,898	-	51,602

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 2 – Significant Accounting Policies (continued)

The following provides details of the Company's lease expense:

Lease Expenses	Year Ended December 31, 2021					Year Ended December 31, 2020				
	Supera Aviation	Hyde Park	2020 Wolfe Street	2021 Wolfe Street	Total	Supera Aviation	Hyde Park	2020 Wolfe Street	2021 Wolfe Street	Total
Operating Leases										
Lease Costs	\$ 150,000	\$ 25,026	\$ 22,667	\$ 4,533	\$ 202,226	\$ 600,000	\$ 25,026	\$ 4,121	\$ -	\$ 629,147

Other information related to leases is presented below:

Other Information	As of December 31, 2021				
	Supera Aviation	Hyde Park	2020 Wolfe Street	2021 Wolfe Street	Total
Operating Leases					
Operating cash used	\$ 150,000	\$ 25,120	\$ 22,060	\$ 4,400	\$ 201,580
Average remaining lease term	-	6	-	35	10
Average discount rate	10.0%	10.0%	10.0%	10.0%	10.0%

As of December 31, 2021, the annual minimum lease payments of the Company's operating lease liabilities were as follows:

For Years Ending December 31,	As of December 31, 2021				
	Supera Aviation	Hyde Park	2020 Wolfe Street	2021 Wolfe Street	Total
2022	\$ -	\$ 12,521	\$ -	\$ 52,932	\$ 65,453
2023	-	-	-	54,520	54,520
2024	-	-	-	51,348	51,348
Total future minimum lease payments, undiscounted	\$ -	\$ 12,521	\$ -	\$ 158,800	\$ 171,321
Less: Imputed interest	-	357	-	21,813	22,170
Present value of future minimum lease payments	\$ -	\$ 12,164	\$ -	\$ 136,987	\$ 149,151

Note 2 – Significant Accounting Policies (continued)

(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, 2021 and 2020, 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, 2021 and 2020 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.

Note 2 – Significant Accounting Policies (continued)

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, 2021 and 2020. 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 2018 through 2021 remain subject to examination by federal and state jurisdictions.

(r) Stock-based Payments

The Company accounts for stock-based compensation under the provisions of FASB 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. 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.

(s) 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 and dilutive potential common stock outstanding during the period.

As the Company reported a net loss for the years ended December 31, 2021 and 2020, common stock equivalents were anti-dilutive.

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,	
	2021	2020
Stock Options	4,176,739	4,188,315
Warrants to purchase Common Stock	5,074,489	-
Pre-funded Warrants to purchase Common Stock	520,270	-
Warrants to purchase Series C Preferred Stock	27,500	-
Unvested Restricted Stock Units	2,795,000	-
Series D Convertible Preferred Stock	36,496	-
Total potentially dilutive shares	12,630,494	4,188,315

(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.

Note 2 – Significant Accounting Policies (continued)

(u) Reclassifications

Certain reclassifications were made to the reported amounts in these consolidated financial statements as of December 31, 2020 to conform to the presentation as of December 31, 2021.

(v) Recently Issued Accounting Pronouncements

Recently Issued Accounting Pronouncements Adopted

In August 2020, the FASB issued ASU No. 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* (the “2020 Update”). The amendments in the 2020 Update affect entities that issue convertible instruments and/or contracts in an entity’s own equity. For convertible instruments, the instruments primarily affected are those issued with beneficial conversion features or cash conversion features because the accounting models for those specific features are removed. However, all entities that issue convertible instruments are affected by the amendments to the disclosure requirements in the 2020 Update. For contracts in an entity’s own equity, the contracts primarily affected are freestanding instruments and embedded features that are accounted for as derivatives under the current guidance because of failure to meet the settlement conditions of the derivatives scope exception related to certain requirements of the settlement assessment. The settlement assessment was simplified by removing the requirements (1) to consider whether the contract would be settled in registered shares, (2) to consider whether collateral is required to be posted, and (3) to assess shareholder rights. Those amendments also affect the assessment of whether an embedded conversion feature in a convertible instrument qualifies for the derivatives scope exception. Additionally, the amendments in this Update affect the diluted EPS calculation for instruments that may be settled in cash or shares and for convertible instruments. The amendments in the 2020 Update are effective for public business entities that meet the definition of a Securities and Exchange Commission (SEC) filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. An entity should adopt the guidance as of the beginning of its annual fiscal year. Entities are allowed to adopt the guidance through either a modified retrospective method of transition or a fully retrospective method of transition. The Company adopted this standard as of January 1, 2021 and the adoption did not have a material impact on its financial statements.

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 condensed consolidated financial statements upon the adoption of this ASU.

Note 2 – Significant Accounting Policies (continued)

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 Company is assessing the impact of this ASU on its financial statements and related disclosure.

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 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").

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 common stock of the Company 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).

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 – Recent Developments, Liquidity and Management’s Plans (continued)

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 is 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.

	<u>Valuation Analysis</u>
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.

Note 3 – Recent Developments, Liquidity and Management’s Plans (continued)

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.

Liquidity

As of December 31, 2021, the Company’s cash on hand was \$555,967 and marketable securities were \$11,003,071. The Company has incurred a net loss from operations of \$29,889,045 for the year ended December 31, 2021. As of December 31, 2021, the Company had working capital of \$11,625,519, stockholders’ equity of \$23,647,174 including an accumulated deficit of \$78,561,568. During the year ended December 31, 2021, cash flows used in operating activities were \$19,516,475, consisting primarily of a net loss of \$29,889,045 and a decrease in trade and other payables of \$4,268,961 offset by non-cash share-based compensation of \$15,036,051. 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, 2021 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.

Management created an alternative plan that in the event a financing was not consummated by September 30, 2022, management would slow down clinical efforts and defer other general and administrative costs as needed in order to maintain adequate cash reserves to maintain operations for an additional six months, providing additional time to complete a financing. Management believes a financing will occur prior to September 30, 2022.

Accordingly, management has since reevaluated the Company’s liquidity and financial condition and determined that sufficient capital exists to sustain operations one year from the date the financial statement is issued and therefore substantial doubt has been alleviated.

Note 4 – Trade and Other Payables

Trade and other payables consist of the following:

	As of December 31,	
	2021	2020
Accounts Payable – Trade	\$ 867,518	\$ 1,104,801
Accrued Expenses	119,108	-
Accounts Payable – Trade – Related Party	-	477,042
Accounts Payable – Other – Related Party	-	14,577
Accrued Expenses – Related Party	-	175,679
Interest Payable – Related Party	-	29,628
	<u>\$ 986,626</u>	<u>\$ 1,801,727</u>

See Note 10 for related party information.

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, 2021 and 2020, MyMD had advanced MyMD Florida \$3,000,000 and \$1,200,000, respectively, under the Bridge Loan Note plus accrued interest totaling \$26,137. The balance of \$3,026,137 as of December 31, 2021 was eliminated on consolidation.

Note 6 - Stock - based Compensation

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, 2021, grants of restricted stock and options to purchase 1,407 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, 2021, 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, 2021, grants of restricted stock and options to purchase 1,532 shares of Common Stock have been issued pursuant to the 2017 Plan, and 1,984 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, 2021, grants of RSUs 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, 2021, grants of RSUs to purchase 2,795,000 shares of Common Stock have been issued pursuant to the 2021 Plan, and 4,433,184 shares of Common Stock remain available for issuance.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 6 - Stock-based Compensation, continued

Stock Options

The following table summarizes the activities for MyMD stock options for the year ended December 31, 2021:

	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, 2020	4,188,315	\$ 2.59	\$ 2.59	2.37	\$ 5,805,667
Granted	-	-	-	-	-
Exercised	(11,576)	2.59	2.59	1.29	-
Forfeited	-	-	-	-	-
Canceled/Expired	-	-	-	-	-
Balance at December 31, 2021	4,176,739	\$ 2.59	\$ 2.59	1.29	\$ 14,493,284
Exercisable as of December 31, 2021	4,176,739	\$ 2.59	\$ 2.59	1.29	\$ 14,493,284

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$6.06 for the Company's common shares on December 31, 2021 and the closing stock price of \$3.98 for the Company's common shares on December 31, 2020.

All of the Company's outstanding stock options are fully vested and exercisable.

During the years ended December 31, 2021 and 2020, the Company incurred stock option expenses totaling \$15,036,051 and \$2,864,145, 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 September 30, 2021, options to purchase 4,188,315 shares of common stock have been issued pursuant to the plan and 0 shares of 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 ended 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.

Adoption of 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 Company Common Stock. At the effective time of the Merger, the number of shares of Company Common Stock that are reserved for issuance pursuant to awards under the 2021 Plan is 7,228,184 shares (post-Reverse Stock Split). As of December 31, 2021, 4,433,184 shares remain available for issuance.

The 2021 Plan will terminate on April 16, 2031, the tenth anniversary of its effective date. No award may be made under the 2021 Plan after its expiration date. In connection with the 2021 Plan, the Board adopted forms of (i) a Nonqualified Stock Option Agreement, (ii) an Incentive Stock Option Agreement and (iii) a Restricted Stock Award Agreement.

Pursuant to the Incentive Stock Option Agreement, participants will be granted options to purchase shares of Company Common Stock at a price equal to the fair market value per share of the Company Common Stock on the date of grant or 110% of such fair market value, in the case of a ten percent (10%) or more stockholder as provided in Section 422 of the United States Internal Revenue Code of 1986. Options granted pursuant to the Incentive Stock Option Agreement will expire on the date immediately preceding the tenth anniversary of the date of grant (or the date immediately preceding the fifth anniversary of the date of grant, in the case of a ten percent (10%) or more stockholder, as provided in Section 422 of the Code), unless terminated earlier.

Pursuant to the Nonqualified Stock Option Agreement, participants will be granted options to purchase shares of Company Common Stock at a price equal to the fair market value per share of the Company Common Stock on the date of grant. The options issued pursuant to the Nonqualified Stock Option Agreement will expire on the date immediately preceding the tenth anniversary of the date of grant, unless terminated earlier.

Pursuant to the Restricted Stock Award Agreement, participants will be granted restricted stock subject to such restrictions, price and vesting requirements set forth at the discretion of the Compensation Committee of the Company's Board of Directors or such other committee appointed or designated by the Company's Board of Directors to administer the 2021 Plan (the "Committee"). Restricted stock granted to participants pursuant to the Restricted Stock Award Agreement may be converted into the number of shares of Company Common Stock equal to the number of restricted stock units at such time as such units are no longer subject to restrictions as established by the Committee.

Note 6 - Stock-based Compensation, continued

Restricted Stock Units

On March 29, 2019, the Compensation Committee of the Board of Directors approved the grant of 2,601 Restricted Stock Units (“RSU”) to each of the three directors. Each RSU had a grant date fair value of \$46.56 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 and vested on January 1, 2020. Upon vesting, such RSUs shall be settled with the issuance of common stock.

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 the date of this filing, 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.

The following is the status of outstanding restricted stock units outstanding as of December 31, 2021 and changes for the year ended December 31, 2021:

	Number of RSUs	Weighted Average Grant Date Fair Value
<i>Balance at December 31, 2020</i>	-	\$ -
Granted	2,795,000	8.09
Exercised	-	-
Forfeited	-	-
Vested	-	-
Canceled/Expired	-	-
<i>Balance at December 31, 2021</i>	\$ 2,795,000	\$ 8.09
<i>Exercisable as of December 31, 2021</i>	\$ -	\$ -

As of December 31, 2021 and 2020, the unamortized value of the RSUs was \$22,611,550 and \$0, respectively.

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, 2021, 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 “Certificate of Designation”) with the Secretary of State of the State of New Jersey. Pursuant to the 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 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 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, 2021, 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 the Company’s 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 the Company’s common stock at an exercise price of \$2.59 per common share. The net proceeds of \$29,982 is recorded as a non-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.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 7 – Equity, continued

Common Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2021:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2020	-	\$ -	-	\$ -
Assumed from Merger	5,363,547	5.19	5.02	-
Granted	-	-	-	-
Exercised	(289,058)	4.12	4.38	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2021	<u>5,074,489</u>	<u>\$ 5.25</u>	4.34	<u>\$ 9,554,827</u>
Exercisable as of December 31, 2021	<u>5,074,489</u>	<u>\$ 5.25</u>	4.34	<u>\$ 9,554,827</u>

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards 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.

During the year ended December 31, 2021, warrant holders exercised 289,058 Common Stock Warrants for 289,058 shares of the Company's common stock generating net proceeds of \$1,189,840.

Pre-funded Common Stock Warrants

The table below summarizes the pre-funded warrant activity for the year ended December 31, 2021:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2020	-	\$ -	-	\$ -
Assumed from Merger	986,486	0.002	-	-
Granted	-	-	-	-
Exercised	(466,216)	0.002	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2021	<u>520,270</u>	<u>\$ 0.002</u>	-	<u>\$ 3,151,796</u>
Exercisable as of December 31, 2021	<u>520,270</u>	<u>\$ 0.002</u>	-	<u>\$ 3,151,796</u>

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 \$6.06 for the Company's common shares on December 31, 2021.

On February 16, 2022, a warrant holder exercised 385,135 pre-paid equity forward contracts for 385,135 shares of the Company's common stock.

Series C Convertible Preferred Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2021:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2020	-	\$ -	-	\$ -
Assumed from Merger	27,500	8.00	3.65	-
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2021	<u>27,500</u>	<u>\$ 8.00</u>	2.94	<u>\$ -</u>
Exercisable as of December 31, 2021	<u>27,500</u>	<u>\$ 8.00</u>	2.94	<u>\$ -</u>

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards 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.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 8 – Income Taxes

The values represented in the tables below for the year ended December 31, 2020 are for Akers Biosciences, Inc as pre-merger MyMD Florida and Supera were pass through entities for income tax purposes.

The Company's income tax (benefit)/provision is as follows:

	Years Ended December 31,	
	2021	2020
Current	\$ -	\$ -
Deferred	(6,219,000)	(1,958,000)
Change in Valuation Allowance	6,219,000	1,958,000
Income Tax Benefit	<u>\$ -</u>	<u>\$ -</u>

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, 2020 and 2019 are as follows:

	Years Ended December 31,	
	2021	2020
Statutory U.S. Federal Income Tax Rate	(21.0)%	(21.0)%
New Jersey State income taxes, net of U.S. Federal tax effect	(9.0)%	(5.1)%
Adjustment to deferred tax assets	9.3%	10.2%
Other	(0.1)%	4.8%
Change in Valuation Allowance	20.8%	11.1%
Net	<u>0.0%</u>	<u>0.0%</u>

As of December 31, 2021, and 2020, the Company had U.S. federal net operating loss carry forwards of approximately \$101.9 million and \$100.6 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, 2022 through 2037. The remaining U.S. federal net operating loss of approximately \$44.2 million does not expire, however it is limited to 80% of each subsequent year's net income. As of December 31, 2021, and 2020, the Company had U.S. state net operating loss carry forwards of approximately \$38.2 million and \$7.5 million, respectively, some of which expire beginning with the year ending December 31, 2022 through 2041. 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 immediate impact on the Company's financial statements since the Company recorded a full valuation allowance for the deferred tax assets as of December 31, 2021 and 2020.

The principal components of the deferred tax assets and related valuation allowances as of December 31, 2021 and 2020 are as follows:

	Years Ended December 31,	
	2021	2020
Reserves and other	\$ 179,000	\$ 51,000
Net operating loss carry-forwards	23,526,000	21,514,000
Research and development tax credit	610,000	455,000
Share-based compensation	4,021,000	97,000
Valuation Allowance	(28,336,000)	(22,117,000)
Net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

Note 8 - Income Tax Expense, continued

The valuation allowance for deferred tax assets increased by approximately \$6.2 million and \$2.0 million, for the years ended December 31, 2021 and 2020, 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, 2021 and 2020. 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 the Board regarding current and planned research and development programs, (ii) advise the Board regarding the scientific merit of technology or products involved in licensing and acquisition opportunities and (iii) provide strategic advice to the Board regarding emerging science and technology issues and trends. During the years ended December 31, 2021 and 2020, the Company incurred costs of \$174,000 and \$0, respectively. These expenses are included in Research and Development Expenses on the Consolidated Statement of Comprehensive Loss.

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.

In response to public health directives and orders, the Company has implemented and continues to maintain work-from-home policies for many of the Company's employees and temporarily modified the Company's operations to comply with applicable social distancing recommendations. The effects of the orders and the Company's related adjustments in its business are likely to negatively impact productivity, disrupt its business and delay the Company's timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on its ability to conduct its business in the ordinary course. Similar health directives and orders are affecting third parties with whom we do business. Further, restrictions on the Company's ability to travel, stay-at-home orders and other similar restrictions on its business have limited and may continue to limit its ability to support its operations.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 9 – Commitments and Contingencies, continued

Severe and/or long-term disruptions in the Company's operations will 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 will 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

Litigation Related to the Merger with MYMD Florida

Between January 22, 2021 and March 18, 2021, nine alleged MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.) stockholders filed separate actions in the state and federal courts of New York, New Jersey, and Pennsylvania against MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.) and the members of its board of directors, respectively captioned as follows: (i) *Douglas McClain v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 650497/2021 (Sup. Ct., N.Y. Cty.); (ii) *Owen Murphy v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 650545/2021 (Sup. Ct., N.Y. Cty.); (iii) *Sue Gee Cheng v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 1:21-cv-01110 (S.D.N.Y.); (iv) *Danny Lui v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. GLO-C-000006-21 (N.J. Super. Ct., Ch. Div.); (v) *Alan Misenheimer v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 1:21-cv-02310 (D.N.J.); (vi) *Robert Wilhelm v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 1:21-cv-04616 (D.N.J.); (vii) *Adam Franchi v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 1:21-cv-04696 (D.N.J.); (viii) *Cody McBeath v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 2:21-cv-01151 (E.D. Pa.); and (ix) *Ray Craven v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 1:21-cv-05762 (D.N.J.) (collectively, the "MYMD Merger Complaints"). The *Lui* action is styled as a putative class action brought on behalf of the plaintiff and other similarly situated stockholders, while the other eight actions are brought solely on behalf of the individual stockholders. The MYMD Merger Complaints generally assert that MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.) and its board of directors failed to disclose allegedly material information in the joint proxy and consent solicitation statement/prospectus and seek an order enjoining or unwinding the consummation of the Merger Agreement and awarding damages.

As reflected on page 61 of the Company's Amendment No. 1 to Form S-4, Registration No. 333-252181, filed on March 19, 2021 (the "Amended S-4"), each of the nine MYMD Merger Complaints sought an order enjoining or unwinding consummation of the Merger Agreement on the basis of alleged material omissions in the Company's preliminary S-4 filed on January 15, 2021. The Amended S-4 contains, among other things, supplemental disclosures addressing these purported material omissions. Prior to the April 15, 2021 special meeting of MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.)'s stockholders to approve the proposed merger, none of the plaintiffs sought to enjoin the transaction, which was approved at the special meeting. As of November 11, 2021, all of the Merger Complaints have been voluntarily dismissed.

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") 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.

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 SRE 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, 2021 and 2020.

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 totaled \$0 and \$14,577 as of December 31, 2021 and December 31, 2020. This debt 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. As of December 31, 2021 and 2020, the Company had a balance due of \$0 and \$477,042. The Company incurred expenses totaling \$150,000 for the year ended December 31, 2021 and \$600,000 for the year ended December 31, 2020.

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. The balance of \$109,658 was forgiven and is recorded as a gain on debt forgiveness on the Consolidated Statement of Comprehensive Loss for the year ended December 31, 2021.

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. As of December 31, 2021 and December 31, 2020, the principal balance totaled \$0 and \$599,747.

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. As of December 31, 2021 and December 31, 2020, the unamortized debt discount totaled \$0 and \$1,457,882 and the principal balance totaled \$0 and \$3,192,119. The Company recorded amortization of the debt discount totaling \$608,460 and \$1,191,859 during the years ended December 31, 2021 and 2020, respectively.

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%.

During the years ended December 31, 2021 and 2020, the Company made matching contributions to the 401(k) Plan of \$16,414 and \$0, 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 Condensed 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.

**DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934**

As of March 31, 2022, MyMD Pharmaceuticals, Inc., a New Jersey corporation (“we,” “our” and the “Company”) has our common stock, no par value per share registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The description of our capital stock included herein is intended as a summary and is qualified in its entirety by reference to our amended and restated certificate of incorporation (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 this 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 500,000,000 are common stock, without par value, and 50,000,000 are 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”), and 100,000 of which have been designated as Series E Junior Participating Preferred Stock. As of March 31, 2022, there were 38,058,245 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 31, 2022, there were 72,992 shares of Series D Preferred Stock issued and outstanding and warrants to purchase Series C Preferred Stock convertible into 27,500 shares of common stock 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 Action Stock Transfer Corporation, 2469 E. Fort Union Blvd., Suite 214, Salt Lake City, UT 84121.

Options, Warrants and RSUs

As of March 31, 2022, 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 31, 2022, Akers had 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 share 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.

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.

PLACEMENT AGENT COMMON STOCK PURCHASE WARRANT

AKERS BIOSCIENCES, INC.

Warrant Shares: _____

Issue Date: December 9, 2019

Initial Exercise Date: December 9, 2019

THIS PLACEMENT AGENT COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date set forth above (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on December 5, 2024 (the "Termination Date") but not thereafter, to subscribe for and purchase from Akers Biosciences, Inc., a New Jersey corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of the Company's Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant is being issued pursuant to that certain engagement letter, by and between H.C. Wainwright & Co., LLC and the Company, dated as of September 6, 2019.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Board of Directors" means the board of directors of the Company.

"Commission" means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, no par value, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time shares of Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Purchase Agreement” means that certain Securities Purchase Agreement, dated as of December 5, 2019, by and among the Company and the purchasers signatory thereto.

“Registration Statement” means the Company’s registration statement on Form S-1 (File No. 333-234447), and the related registration statement on Form S-1 (File No. 333-235359) filed pursuant to Rule 462(b) promulgated under the Securities Act, including the final prospectus filed in connection with the transaction contemplated by the Purchase Agreement.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Subsidiary” means Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means VStock Transfer, LLC, the current transfer agent of the Company, with a mailing address of 18 Lafayette Place, Woodmere, NY 11598, and any successor transfer agent of the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be **\$5.00**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance or resale of the Warrant Shares to or by the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing $[(A-B) (X)]$ by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b)(68) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (A) the earlier of (i) two (2) Trading Days and (ii) the number of days comprising the Standard Settlement Period, in each case after the delivery to the Company of the Notice of Exercise and (B) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by the Warrant Share Delivery Date. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (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 Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue 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 Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one (1) Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend (other than cash) or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Fundamental Transaction. If, at any time while this Warrant 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, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group 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 "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), 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 "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity, as of the date of consummation of such Fundamental Transaction, the same type or form of consideration (and in the same proportion), at the Black Scholes Value (as defined below) of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365-day annualization factor) as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the greater of (i) the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (ii) the greater of (x) the last VWAP immediately prior to the public announcement of such Fundamental Transaction and (y) the last VWAP immediately prior to the consummation of such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds within five (5) Trading Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Pursuant to FINRA Rule 5110(g)(1), neither this Warrant nor any Warrant Shares issued upon exercise of this Warrant shall be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which this Warrant is being issued, except the transfer of any security:

- i. by operation of law or by reason of reorganization of the Company;
- ii. to any FINRA member firm participating in the offering and the officers and partners thereof, if all securities so transferred remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period;
- iii. if the aggregate amount of securities of the Company held by the Holder or related person do not exceed 1% of the securities being offered;
- iv. that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or

- v. the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period.

Subject to the foregoing restriction, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Issue Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Warrant Shares on a "cashless exercise," and to receive the cash payments contemplated pursuant to Sections 2(d)(i) and 2(d)(iv), in no event will the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that the right to exercise this Warrant terminates on the Termination Date. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at [], Attention: [], email address: [], facsimile: [], or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

AKERS BIOSCIENCES, INC.

By: _____
Name: _____
Title: _____

NOTICE OF EXERCISE

TO: **AKERS BIOSCIENCES, INC.**

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

(4) The time of day this Notice of Exercise is being executed is:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____



ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____, _____

Holder's Signature:

Holder's Address:



FOURTH AMENDMENT TO EMPLOYMENT AGREEMENT

This **FOURTH AMENDMENT TO EMPLOYMENT AGREEMENT** (this "**Amendment**"), is entered into as of November 24, 2021 (the "**Effective Date**"), by and between Chris Chapman, M.D. ("**Employee**") and MYMD Pharmaceuticals, Inc. (the "**Company**"), for the purpose of amending that certain Employment Agreement, dated as of November 1, 2020, and as amended on December 18, 2020, January 8, 2021, and February 10, 2021, by and between Employee and the Company (the "**Agreement**"). Terms used in this Amendment with initial capital letters that are not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, Section 16 of the Agreement provides that no waiver or modification of any provision of the Agreement will be enforceable unless it is agreed to in writing by the party against which enforcement would be sought; and

WHEREAS, the Parties mutually desire to modify certain provisions that would otherwise apply to Bonus Compensation potentially payable to Employee pursuant to the Agreement.

NOW, THEREFORE, pursuant to Section 16 of the Agreement, in consideration of the mutual provisions, conditions, and covenants contained herein, and other good and valuable consideration, the adequacy of which is hereby acknowledged, the Parties hereby agree as follows:

1. The performance criteria applicable to the Bonus Compensation potentially payable upon achievement of Item 1 listed on Exhibit "B" of the Agreement is hereby waived and, therefore, deemed by the Company to have been achieved such that the \$100,000 of Bonus Compensation attributable thereto (the "**Initial Performance Bonus Payment**") shall be payable to Employee in accordance with the applicable terms and conditions of the Agreement.

2. Together with the Initial Performance Bonus Payment, the Company shall also pay Employee an additional amount equal to the applicable federal, state, and local income and employment taxes required to be withheld from the Initial Performance Bonus Payment (the "**Gross Up Amount**").

3. Employee acknowledges and agrees that the Gross Up Amount shall also be subject to applicable federal, state, and local income and employment taxes.

4. Except as expressly amended by this Amendment, the Agreement shall remain in full force and effect in accordance with the provisions thereof.

*[Remainder of the Page Intentionally Left Blank;
Signature Page Follows]*

IN WITNESS WHEREOF, the Parties have executed this Agreement to be effective as of the Effective Date.

EMPLOYEE:

/s/ Chris Chapman, M.D.

Chris Chapman, M.D.

THE COMPANY:

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

Name: Chris Chapman, M.D.

Title: President

SECOND AMENDMENT TO EMPLOYMENT AGREEMENT

This **SECOND AMENDMENT TO EMPLOYMENT AGREEMENT** (this "**Amendment**"), is entered into as of November 24, 2021 (the "**Effective Date**"), by and between Adam Kaplin, M.D. ("**Employee**") and MYMD Pharmaceuticals, Inc. (the "**Company**"), for the purpose of amending that certain Employment Agreement, dated as of December 18, 2020, and as amended on February 10, 2021, by and between Employee and the Company (the "**Agreement**"). Terms used in this Amendment with initial capital letters that are not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, Section 17 of the Agreement provides that no waiver or modification of any provision of the Agreement will be enforceable unless it is agreed to in writing by the party against which enforcement would be sought; and

WHEREAS, the Parties mutually desire to modify certain provisions that would otherwise apply to Bonus Compensation potentially payable to Employee pursuant to the Agreement.

NOW, THEREFORE, pursuant to Section 17 of the Agreement, in consideration of the mutual provisions, conditions, and covenants contained herein, and other good and valuable consideration, the adequacy of which is hereby acknowledged, the Parties hereby agree as follows:

1. The performance criteria applicable to the Bonus Compensation potentially payable upon achievement of Item 1 listed on Exhibit "B" of the Agreement is hereby waived and, therefore, deemed by the Company to have been achieved such that the \$100,000 of Bonus Compensation attributable thereto (the "**Initial Performance Bonus Payment**") shall be payable to Employee in accordance with the applicable terms and conditions of the Agreement.

2. Together with the Initial Performance Bonus Payment, the Company shall also pay Employee an additional amount equal to the applicable federal, state, and local income and employment taxes required to be withheld from the Initial Performance Bonus Payment (the "**Gross Up Amount**").

3. Employee acknowledges and agrees that the Gross Up Amount shall also be subject to applicable federal, state, and local income and employment taxes.

4. Except as expressly amended by this Amendment, the Agreement shall remain in full force and effect in accordance with the provisions thereof.

*[Remainder of the Page Intentionally Left Blank;
Signature Page Follows]*

IN WITNESS WHEREOF, the Parties have executed this Agreement to be effective as of the Effective Date.

EMPLOYEE:

/s/ Adam Kaplin

Adam Kaplin, M.D.

THE COMPANY:

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

Name: Chris Chapman, M.D.

Title: President

Subsidiaries of the Registrant¹

Name of Company	Jurisdiction of Organization
Akers Acquisition Sub, Inc.	New Jersey
Bout Time Marketing Corporation	New Jersey
MyMD Pharmaceuticals (Florida), Inc.	Florida
XYZ Merger Sub Inc.	Florida

¹ This information is as of March 31, 2022.

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) and Form S-3 (File No. 333-217390, 333-234449, 333-238631, 333-248095 and 333-254698) of MyMD Pharmaceuticals, Inc. of our report dated March 31, 2022 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ MORISON COGEN LLP

Blue Bell, Pennsylvania
March 31, 2022

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (333-234447 and 333-235359) and Form S-3 (333-217390, 333-234449, 333-238631, 333-248095 and 333-254698) of our report dated March 31, 2022 included in this Annual Report on Form 10-K of MyMD Pharmaceuticals, Inc. and Subsidiaries (the "Company"), relating to the consolidated financial statements of the Company as of and for the year ended December 31, 2020.

/s/ CHERRY BEKAERT LLP

Tampa, Florida
March 31, 2022

**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, 2022

By: /s/ Christopher C. Chapman, M.D.

Christopher C. Chapman, M.D.
President and Chief Medical Officer (Principal Executive Officer)

**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, 2022

By: /s/ Ian Rhodes

Ian Rhodes
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

**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, 2021 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, 2022

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.

**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, 2021 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, 2022

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.
