

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

FORM 10-Q

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

For the quarterly period ended: **September 30, 2021**

OR

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

For the transition period from _____ to _____

Commission File No. 001-36268

MyMD Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

New Jersey

(State or other jurisdiction
of incorporation)

22-2983783

(IRS Employer
Identification No.)

855 N. Wolfe Street, Suite 623

Baltimore, MD 21205

(Address of principal executive offices and zip code)

(856) 848-8698

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, no par value per share	MYMD	The NASDAQ Capital Market

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 past 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 such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 5, 2021, there were 37,639,912 shares outstanding of the registrant's common stock.

EXPLANATORY NOTE

This report is the Quarterly Report on Form 10-Q for the quarter ended September 30, 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

PART I – FINANCIAL INFORMATION

Item 1.	Financial Statements	3
Item 2.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	34
Item 4.	Controls and Procedures	34

PART II – OTHER INFORMATION

Item 1.	Legal Proceedings	35
Item 1A.	Risk Factors	35
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	60
Item 3.	Defaults Upon Senior Securities	60
Item 4.	Mine Safety Disclosures	60
Item 5.	Other Information	60
Item 6.	Exhibits	61
	Signatures	63

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
September 30, 2021 and December 31, 2020

	As of	
	September 30, 2021 (unaudited)	December 31, 2020 (restated)
ASSETS		
Current Assets		
Cash	\$ 1,375,014	\$ 148,284
Marketable Securities	14,002,767	-
Prepaid expenses	569,825	1,218
Total Current Assets	15,947,606	149,502
Non-Current Assets		
Operating Lease Right-of-Use Asset	64,231	527,195
Goodwill	10,498,539	-
Investment in Oravax, Inc.	1,500,000	-
Total Non-Current Assets	12,062,770	527,195
Total Assets	\$ 28,010,376	\$ 676,697
LIABILITIES		
Current Liabilities		
Trade and Other Payables	\$ 2,053,542	\$ 1,801,729
Notes Payable	-	1,200,000
Operating Lease Liability	38,932	481,049
PPP Loan Payable	-	70,600
Total Current Liabilities	2,092,474	3,553,378
Non-Current Liabilities		
Line of Credit Payable – Related Party, net of discount	\$ -	\$ 2,333,984
Operating Lease Liability, net of current portion	25,978	46,369
Total Non-Current Liabilities	25,978	2,380,353
Total Liabilities	2,118,452	5,933,731
Commitments and Contingencies		
STOCKHOLDERS' EQUITY		
Preferred Stock, no par value, 50,000,000 total preferred shares authorized	-	-
Series C Convertible Preferred Stock, 1,990,000 shares designated, no par value and a stated value of \$4.00 per share, 0 and 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020	-	-
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 September 30, 2021 and December 31, 2020	144,524	-
Series E Junior Participating Preferred Stock, 100,000 shares designated, no par value and a stated value of \$0.001 per share, 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020	-	-
Common stock, no par value, 500,000,000 shares authorized 37,419,774 and 0 issued and outstanding as of September 30, 2021 and December 31, 2020	101,069,246	-
Common stock, par \$0.001, 100,000,000 shares authorized 0 and 28,553,307 issued and outstanding as of September 30, 2021 and December 31, 2020	-	4,004
Additional Paid in Capital	-	43,411,487
Accumulated Deficit	(75,321,846)	(48,672,525)
Total Stockholders' Equity (Deficit)	25,891,924	(5,257,034)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 28,010,376	\$ 676,697

See accompanying notes to the condensed consolidated financial statements

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Comprehensive Loss
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Product Revenue	\$ -	\$ -	\$ -	\$ -
Product Cost of Sales	-	-	-	-
Gross Income	-	-	-	-
Administrative Expenses	1,640,540	884,529	4,601,853	2,045,422
Research and Development Expenses	2,767,663	908,119	5,437,147	1,435,696
Interest Expense and Debt Discount	-	213,648	701,090	582,458
Amortization of Intangible Assets	-	4,583	-	9,167
Stock Option Modification Expenses	-	1,112,156	15,036,051	1,127,156
Loss from Operations	<u>(4,408,203)</u>	<u>(3,123,035)</u>	<u>(25,776,141)</u>	<u>(5,199,899)</u>
Other (Income) Expenses				
Interest and Dividend Income	(1,714)	(135)	(7,355)	(141)
(Gain)/Loss on Sale of Marketable Securities	1,100	-	(40,347)	-
Unrealized Loss on Marketable Securities	848	-	42,295	-
Loss on Currency Conversions	758	-	758	-
Uninsured Casualty Loss	1,058,086	-	1,058,086	-
Gain on Debt Forgiveness	-	-	(180,257)	-
Total Other (Income) Expense	<u>1,059,078</u>	<u>(135)</u>	<u>873,180</u>	<u>(141)</u>
Loss Before Income Tax	(5,467,281)	(3,122,900)	(26,649,321)	(5,199,758)
Income Tax Benefit	-	-	-	-
Net Loss	<u>\$ (5,467,281)</u>	<u>\$ (3,122,900)</u>	<u>\$ (26,649,321)</u>	<u>\$ (5,199,758)</u>
Basic and Diluted loss per common share	<u>\$ (0.15)</u>	<u>\$ (0.11)</u>	<u>\$ (0.78)</u>	<u>\$ (0.19)</u>
Weighted average basic and diluted common shares outstanding	<u>37,634,747</u>	<u>28,269,692</u>	<u>34,064,914</u>	<u>28,066,574</u>

See accompanying notes to the condensed consolidated financial statements

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Stockholders' Equity
For the Nine Months Ended September 30, 2021 and 2020

	Series D		Common Stock					Accumulated Deficit	Total Equity
	Convertible Preferred Stock		Shares	Common Stock No Par	Common Stock Par \$0.0001	Additional Paid-In Capital			
	Shares	Series D							
Balance at December 31, 2020 (restated)	-	\$ -	28,553,307		\$ 4,004	43,411,487	\$ (48,672,525)	\$ (5,257,034)	
Net loss	-	-	-	-	-	-	(3,089,704)	(3,089,704)	
Balance at March 31, 2021 (unaudited)	-	\$ -	28,553,307	\$ -	\$ 4,004	\$ 43,411,487	\$ (51,762,229)	\$ (8,346,738)	
Reverse merger with Akers Biosciences Inc effective April 16, 2021	72,992	144,524	8,335,627	85,748,325	(4,004)	(43,411,487)	-	42,477,358	
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 prepaid equity forward contracts for common stock	-	-	466,716	-	-	-	-	-	
Net loss	-	-	-	-	-	-	(18,092,336)	(18,092,336)	
Balance at June 30, 2021 (unaudited)	72,992	144,524	37,355,650	100,784,376	-	-	(69,854,565)	31,074,335	
Stock based compensation for services	-	-	16,826	90,002	-	-	-	90,002	
Exercise of warrants for common stock	-	-	47,298	194,868	-	-	-	194,868	
Net loss	-	-	-	-	-	-	(5,467,281)	(5,467,281)	
Balance at September 30, 2021 (unaudited)	<u>72,992</u>	<u>\$ 144,524</u>	<u>37,419,774</u>	<u>\$ 101,069,246</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ (75,321,846)</u>	<u>\$ 25,891,924</u>	

	Series D		Common Stock					Accumulated Deficit	Total Equity
	Convertible Preferred Stock		Shares	Common Stock No Par	Common Stock Par \$0.0001	Additional Paid-In Capital			
	Shares	Series D							
Balance at December 31, 2019 (restated)	-	\$ -	14,688,726	\$ -	\$ 3,806	\$ 36,848,063	\$ (38,578,232)	\$ (1,726,363)	
Common shares issued for the acquisition of Supera Pharmaceuticals, Inc. a company under common control	-	-	13,096,640	-	-	-	(605,089)	(605,089)	
Effect of the adoption of Topic 842 effective as of January 1, 2019	-	-	-	-	-	-	(1,379)	(1,379)	
Balance at December 31, 2019 (restated)	-	\$ -	27,785,366	\$ -	\$ 3,806	\$ 36,848,063	\$ (39,184,700.00)	\$ (2,332,831.00)	
Private placement of common shares	-	-	250,835	-	-	650,000	-	650,000	
Net loss	-	-	-	-	-	-	(981,949)	(981,949)	
Balance at March 31, 2020 (unaudited)	-	\$ -	28,036,201	-	3,806	37,498,063	\$ (40,166,649)	\$ (2,664,780)	
Stock based compensation for services	-	-	1,930	-	-	14,800	-	14,800	
Stock options issued for debt issuance	-	-	-	-	-	693,450	-	693,450	
Net loss	-	-	-	-	-	-	(1,094,909)	(1,094,909)	
Balance at June 30, 2020 (unaudited)	-	-	28,038,131	-	3,806	38,206,313	(41,261,558)	(3,051,439)	
Private placement of common shares	-	-	513,248	-	-	1,330,000	-	1,330,000	
Stock options issued for services	-	-	-	-	-	804,588	-	804,588	
Stock options issued for debt issuance	-	-	-	-	-	273,935	-	273,935	
Net loss	-	-	-	-	-	-	(3,122,900)	(3,122,900)	
Balance at September 30, 2020 (unaudited)	<u>-</u>	<u>\$ -</u>	<u>28,551,379</u>	<u>-</u>	<u>3,806</u>	<u>40,614,836</u>	<u>\$ (44,384,458)</u>	<u>\$ (3,765,816)</u>	

See accompanying notes to the condensed consolidated financial statements

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2021 and 2020
(unaudited)

	For the Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (26,649,321)	\$ (5,199,758)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued interest/dividends	4,496	88,248
Amortization of debt discount	608,460	371,206
Amortization of intangible assets	-	13,750
Gain on sale of marketable securities	(40,347)	-
Unrealized loss on marketable securities	42,295	-
Gain on forgiveness of debt	(180,258)	-
Stock based compensation		
Options modification expense	15,036,051	804,588
Options issued for debt issuance	-	514,437
Shares issued for services	90,002	14,800
Change in assets and liabilities		
Prepaid Expenses	(382,543)	4,721
Trade and Other Payables	(3,233,299)	(26,142)
Operating Leases	456	(1,214)
Net cash used by operating activities	<u>(14,704,008)</u>	<u>(3,415,364)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(11,851)	-
Proceeds from sale of marketable securities	15,483,176	-
Net cash received in business combination	1,380,852	-
Net cash provided by investing activities	<u>16,852,177</u>	<u>-</u>
Cash flows from financing activities		
Consumed by the payoff of the line of credit – related party	(3,062,444)	-
Net proceeds from line of credit - related party	120,000	1,277,249
Net proceeds from note payable	1,826,137	-
Net proceeds from the Payroll Protection Program	-	70,600
Net proceeds from the exercise of warrants	194,868	-
Net proceeds from issuance of common stock	-	1,980,000
Net cash (used in)/provided by financing activities	<u>(921,439)</u>	<u>3,327,849</u>
Net increase (decrease) in cash	1,226,730	(87,515)
Cash at beginning of period	148,284	134,499
Cash at end of period	<u>\$ 1,375,014</u>	<u>\$ 46,984</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	\$ -	\$ 527,195
Investment in Oravax, Inc.	\$ 1,500,000	\$ -

See accompanying notes to the condensed consolidated financial statements

MYMD PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

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 September 30, 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 12 granted patents (11 US and 1 foreign), 35 pending applications (6 US, 28 foreign, and 1 international application).

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 derivative of naturally grown cannabidiols. Substantially all of Supera’s research and development activities in 2019 and 2020 were related to intellectual property development and securing patents, along with product manufacturing and planning initial pre-clinical development activities. During the three months ended September 30, 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 Condensed Consolidated Financial Statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

Certain information and note disclosures normally included in the financial statements prepared in accordance with US GAAP have been condensed. As such, the information included in these financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 2020 and 2019 included in the Company's 2020 Form 10-K, as filed on March 1, 2021. In the opinion of the Company's management, these condensed consolidated financial statements include all adjustments, which are only of a normal and recurring nature, necessary for a fair statement of the financial position of the Company as of September 30, 2021 and its results of operations for the three and nine months ended September 30, 2021 and 2020 and cash flows for the nine months ended September 30, 2021 and 2020. The results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the full fiscal year ending December 31, 2021.

The unaudited condensed combined balance sheet as of December 31, 2020 combines the audited balance sheets of pre-Merger MyMD Florida and Supera as of December 31, 2020, giving effect to the Supera Purchase and the adoption of ASU No. 2016-02, Leases, as if they were consummated on January 1, 2020.

The unaudited combined consolidated statement of comprehensive loss for the three and nine months ended September 30, 2020 combines the unaudited condensed statements of comprehensive loss for the three and nine months ended September 30, 2020 of MyMD Florida and Supera giving effect to the Supera Purchase and the adoption of ASU no. 2016-02, Leases, as if they were consummated on January 1, 2020.

The unaudited condensed consolidated balance sheet as of September 30, 2021 comprises the unaudited balance sheets of MyMD Florida, Supera and MyMD as of September 30, 2021, giving effect to the Supera Purchase as if they were consummated on January 1, 2020 and the reverse merger with MyMD on April 16, 2021 with all material intercompany balances eliminated and recording goodwill upon consolidation.

The unaudited condensed consolidated statement of comprehensive loss for the three and nine months ended September 30, 2021 comprises the unaudited statements of comprehensive loss of MyMD Florida and Supera for the three and nine months ended September 30, 2021 and the statement of comprehensive loss for MyMD for the post-acquisition period April 17, 2021 through September 30, 2021.

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 Quarterly Report on Form 10-Q, including the condensed 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 is included in the following notes related to business combinations, loss contingencies and the valuation of share-based payments.

(c) Functional and Presentation Currency

These condensed consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information has been rounded to the nearest dollar.

(d) Comprehensive Loss

The Company follows Financial Accounting Standards Board Accounting Standards Codification (“FASB ASC”) 220 in reporting comprehensive loss. Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income. Since the Company has no items of comprehensive income, comprehensive loss is equal to net loss.

(e) Cash and Cash Equivalents

The Company considers all highly liquid investments, which include short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal date or use, to be cash equivalents.

(f) Fair Value of Financial Instruments

The Company’s financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities.

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

Level 1 Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company 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.

(f) Fair Value of Financial Instruments, continued

The following is a description of the valuation methodologies used for assets measured at fair value as of September 30, 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 September 30, 2021	\$ 14,002,767	\$ -	\$ -
Marketable securities at December 31, 2020	\$ -	\$ -	\$ -

Marketable securities are classified as available for sale and are valued at fair market value.

As of September 30, 2021, the Company held certain mutual funds, which, under FASB ASC 321-10, were considered equity investments.

Gains and losses resulting from the sales of marketable securities were a realized loss of \$1,100 for the three months ended September 30, 2021 and a realized gain of \$40,347 for the nine months ended September 30, 2021. Gains and losses resulting from the sales of marketable securities were \$0 for the three and nine months ended September 30, 2020.

Proceeds from the sales of marketable securities in the three and nine months ended September 30, 2021 were \$5,500,000 and \$15,483,176, respectively and \$0 for the three and nine months ended September 30, 2020.

(g) Prepaid Expenses

Expenses paid prior to the date that the related services are rendered or used are recorded as prepaid expenses which are comprised principally of various insurance 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.

(i) Risk Management of Cash and Investments

It is the Company's policy to minimize the Company's capital resources to investment risks, prioritizing the preservation of capital over investment returns. Investments are maintained in securities, primarily publicly traded, short-term money market funds based on highly rated federal, state and corporate bonds, that minimize the risk to the Company's capital resources and provide ready access to funds.

The Company's investment portfolios are regularly monitored for risk and are held with a 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.

(k) 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.

(l) 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. As of September 30, 2021, and December 31, 2020, no liability for unrecognized tax benefits was required to be reported.

There is no income tax benefit for the losses for the three and nine months ended September 30, 2021 and 2020 since management has determined that the realization of the net deferred assets is not assured and has created a valuation allowance for the entire amount of such tax benefits.

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 three and nine months ended September 30, 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 2017 through 2020 remain subject to examination by federal and state jurisdictions.

(m) 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 three and three months ended September 30, 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 Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock Options	4,188,315	3,821,710	4,188,315	3,821,710
Warrants to purchase common stock	5,316,249	-	5,316,249	-
Pre-funded Warrants to purchase common stock	520,270	-	520,270	-
Series D Preferred Convertible Stock	36,496	-	36,496	-
Warrants to purchase Series C Preferred stock	27,500	-	27,500	-
Total potentially dilutive shares	<u>10,088,830</u>	<u>3,821,710</u>	<u>10,088,830</u>	<u>3,821,710</u>

(n) 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.

(o) Reclassifications

Certain prior year amounts have been reclassified to conform to the current year's presentation.

(p) Right-of-Use Assets

The Company leases a facility in Tampa, Florida (the "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 took effect on October 26, 2018 for a term of 36 months to expire on September 26, 2021. The Company cancelled the Supera Aviation in April 2021 without penalty.

The Company leases a facility in Baltimore, Maryland (the "N Wolfe St.") under an operating lease ("Baltimore Lease") with annual rentals of \$24,000 to \$25,462 plus certain operating expenses. The Baltimore Lease took effect on November 9, 2020 for a term of 36 months to expire on November 9, 2023.

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 and the N Wolfe St. Condensed Consolidated Balance Sheet information related to its leases are presented below:

Balance Sheet Location	As of September 30, 2021				As of December 31, 2020			
	Supera Aviation	Hyde Park	N Wolfe Street	Total	Supera Aviation	Hyde Park	N Wolfe Street	Total
Operating Leases								
Lease Right of Use	\$ -	\$ 18,010	\$ 46,221	\$ 64,231	\$ 431,809	\$ 34,722	\$ 60,664	\$ 527,195
Lease Payable, current	-	18,022	20,910	38,932	431,809	25,120	24,120	481,049
Lease Payable - net of current	-	-	25,978	25,978	-	9,704	36,665	46,369

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

Lease Expenses	Three Months Ended September 30, 2021				Nine Months Ended September 30, 2021			
	Supera Aviation	Hyde Park	N Wolfe Street	Total	Supera Aviation	Hyde Park	N Wolfe Street	Total
Operating Leases								
Lease Costs	\$ -	\$ 6,257	\$ 6,000	\$ 12,257	\$ 150,000	\$ 16,830	\$ 19,455	\$ 186,285

Other information related to leases is presented below:

Other Information	As of September 30, 2021			
	Supera Aviation	Hyde Park	N Wolfe Street	Total
Operating Leases				
Operating cash used	\$ -	\$ 150,000	\$ 16,830	\$ 186,285
Weighted-average remaining lease term	-	9	25	17
Weighted-average discount rate	10.0%	10.0%	10.0%	10.0%

As of September 30, 2021, the annual minimum lease payments of the Company's operating lease liabilities were as follows:

For Years Ending September 30,	As of September 30, 2021			
	Supera Aviation	Hyde Park	N Wolfe Street	Total
2022	\$ -	\$ 18,782	\$ 24,660	\$ 43,442
2023	-	-	25,400	25,400
2024	-	-	2,122	2,122
Total future minimum lease payments, undiscounted	\$ -	\$ 18,782	\$ 52,182	\$ 70,964
Less: Imputed interest	-	12	667	679
Present value of future minimum lease payments	\$ -	\$ 18,770	\$ 51,515	\$ 70,285

(q) Recently Issued Accounting Pronouncements

Recently Issued Accounting Pronouncements Adopted

In February 2016, the FASB issued ASU 2016-02—Leases (Topic 842) (“ASU-2016-02”), which requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-02 offers specific accounting guidance for a lessee, a lessor, and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company has adopted ASU-2016-02, effective January 1, 2019, and, as a result of this implementation, has recorded an operating lease right-of-use asset and an operating lease liability as of December 31, 2019.

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.

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”).

On April 16, 2021, the parties consummated the Contribution Transaction. 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. 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. The investment in Oravax is accounted for under the cost method. The Company's obligation to Oravax of \$1,500,000 was paid on July 1, 2021 (Note 5).

As of September 30, 2021, \$300,000 is included in Trade and Other Payables on the Condensed Consolidated Balance Sheet for amounts due to Premas under the Contribution Agreement and deferred to a future date to be determined by Premas. (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).

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.

Under the terms of the Merger Agreement, the Company has agreed to pay contingent consideration to MyMD Florida stockholders in the form of the Milestone Payments. The Milestone Payments are payable in the dollar amounts set forth in the chart below upon the achievement of the milestone events set forth opposite such dollar amount during the Milestone Period as follows:

Milestone Event	Milestone Payment
Market capitalization of the Company for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period is equal to or greater than \$500 million (the "First Milestone Event").	\$20 million.
For every \$250 million incremental increase in market capitalization of the 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 billion market capitalization of the Company.	\$10 million per each incremental increase (it being understood, however, that, if such incremental increase results in market capitalization equal to \$1 billion, such \$20 million payment in respect of such incremental increase shall be payable without duplication of any amount payable in respect of a Second Milestone Event).
Market Capitalization of the Company for at least 10 trading days during any 20 consecutive trading day period is equal to or greater than \$1 billion (the "Second Milestone Event").	\$25 million.
For every \$1 billion incremental increase in market capitalization of the 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 million per each incremental increase.

Each milestone payment will be payable in shares of Company Common Stock (the "Milestone Shares"), with the number of Milestone Shares to be issued determined by dividing the applicable Milestone Payment amount by the volume-weighted average price of a share of the Company's common stock during the 10 trading days immediately preceding the achievement of the milestone event; provided, however, that in no event shall the price of a share of Company Common Stock used to determine the number of Milestone Shares to be issued be deemed to be less than \$5.00 per share (as adjusted for stock splits, stock dividends, reverse stock splits, and the like occurring after the closing date). Notwithstanding the foregoing, the number of Milestone Shares payable by the Company shall not exceed 32,741,622 shares of Company Common Stock issued to MyMD Florida stockholders at the closing in connection with the Merger. As of the date of this report, the first milestone event has not been met.

Liquidity

As of September 30, 2021, the Company's cash on hand was \$1,375,014 and marketable securities were \$14,002,767. The Company has incurred a net loss from operations of \$26,649,321 for the nine months ended September 30, 2021. As of September 30, 2021, the Company had working capital of \$13,855,132, stockholders' equity of \$25,891,924 including an accumulated deficit of \$75,321,846. During the nine months ended September 30, 2021, cash flows used in operating activities were \$14,704,008, consisting primarily of a net loss of \$26,649,321 and a decrease in trade and other payables of \$3,233,299 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 condensed consolidated financial statements, are sufficient to fund its current operating budget and contractual obligations as of September 30, 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.

Note 4 – Unaudited Condensed Combined Balance Sheet as of December 31, 2020

The acquisition of Supera by pre-Merger MyMD Florida was accounted for as a business combination under common control in accordance with ASC 805 and is being presented as if the acquisition had been consummated and ASC 842 had been adopted on January 1, 2020.

The audited Balance Sheets as of December 31, 2020 of pre-Merger MyMD Florida and Supera is presented below with the adjustments required to eliminate inter-company transactions, implement ASC 842 for reporting leasing transactions and reclassify certain balances to conform with the classification in the Condensed Consolidated Balance Sheet as of September 30, 2021.

	MyMD Pharmaceuticals Inc. (audited)	Supera Pharmaceuticals Inc. (audited)	Adjustments	AJE #	Restated Total (unaudited)
ASSETS					
Current Assets					
Cash	\$ 133,733	\$ 14,551	-		\$ 148,284
Prepaid expenses	1,218	-	-		1,218
Due from affiliate	-	24,600	(24,600)	1	-
Total Current Assets	134,951	39,151	(24,600)		149,502
Non-Current Assets					
Operating Lease Right-of-Use Assets	-	-	527,195	3	527,195
Intangible Assets, net	-	-	-		-
Total Non-Current Assets	-	-	527,195		527,195
Total Assets	\$ 134,951	\$ 39,151	\$ 502,595		\$ 676,697
LIABILITIES					
Current Liabilities					
Trade and Other Payables	\$ 1,025,063	\$ 556,781	\$ 219,885	1,2	\$ 1,801,729
Due to Related Party	39,177	-	(39,177)	2	-
Interest Payable, related party	175,679	-	(175,679)	2	-
Loan Payable	1,200,000	-	-		1,200,000
Operating Lease Payable	-	-	481,049	3	481,049
Paycheck Protection Program Loan	54,000	16,600	-		70,600
Total Current Liabilities	2,493,919	573,381	486,078		3,553,378
Non-Current Liabilities					
Line of Credit Payable – related party, net of discount	1,734,237	599,747	-		2,333,984
Interest Payable, related party	-	29,628	(29,628)	2	-
Operating Lease Liability, net of current	-	-	46,369	3	46,369
Total Non-Current Liabilities	1,734,237	629,375	16,741		2,380,353
Total Liabilities	\$ 4,228,156	\$ 1,202,756	\$ 502,819		\$ 5,933,731
Commitments and Contingencies					
STOCKHOLDERS' DEFICIT					
Common stock, par \$0.0001, 100,000,000 shares authorized and 73,991,413 issued and outstanding as of December 31, 2020					
	4,004	-	-		4,004
Additional Paid in Capital	43,411,488	-	(1)	2	43,411,487
Accumulated Deficit	(47,508,697)	(1,163,605)	(223)	3	(48,672,525)
Total Stockholders' Deficit	(4,093,205)	(1,163,605)	(224)		(5,257,034)
Total Liabilities and Stockholders' Deficit	\$ 134,951	\$ 39,151	\$ 502,595		\$ 676,697

The following is an explanation of the adjusting entries that were recorded to arrive at the restated Condensed Consolidated Balance Sheet as of December 31, 2020:

AJE #	Account	Debit	Credit
1	Trade and Other Payables	24,600	
	Due from Affiliate		24,600
	To eliminate inter-company transactions		
2	Due to Related Party	39,177	
	Interest Payable, related party	175,679	
	Interest Payable, related party	29,628	
	Additional Paid-In Capital	1	
	Trade and Other Payables		244,485
	To reclassify account balances to conform with the classification on the September 30, 2021 Condensed Consolidated Balance Sheet		
3	Operating Lease Right-of-Use	527,195	
	Accumulated Deficit	223	
	Operating Lease Payable		481,049
	Operating Lease Payable, net of current portion		46,369
	To implement ASC 842 for the accounting of operating leases		

Note 5 - Trade and Other Payables

Trade and other payables consist of the following:

	September 30, 2021	December 31, 2020
Accounts Payable – Trade	\$ 1,914,672	\$ 1,104,803
Accounts Payable – Trade – related party	-	477,042
Accrued Expenses	138,870	205,307
Accounts Payable – Other - related party	-	14,577
	<u>\$ 2,052,542</u>	<u>\$ 1,801,729</u>

See Note 10 for related party information.

Note 6 – 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 September 30, 2021 and December 31, 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 September 30, 2021 was eliminated on consolidation upon the consummation of the Merger on April 16, 2021 (Notes 1 and 3).

Note 7 - Share-based Payments

The following is the status of outstanding stock options outstanding as of September 30, 2021 and changes for the nine months ended September 30, 2021:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2020	4,188,315	\$ 2.59	2.29	\$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance as of September 30, 2021	4,188,315	\$ 2.59	1.54	\$ 19,308,132
Exercisable as of September 30, 2021	4,188,315	\$ 2.59	1.54	\$ 19,308,132

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$7.20 for the Company's Common Stock on September 30, 2021. All options were vested on date of grant.

All stock options outstanding are fully vested and exercisable.

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 three and three months ended September 30, 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 September 30, 2021, 7,228,184 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.

Restricted Stock Units

On March 29, 2019, the Compensation Committee of the Board of Directors approved grants totaling 7,803 Restricted Stock Units to three of the Company's then-current 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. The Company Common Stock underlying these RSUs is subject to a lock-up/leak-out agreement for a period of 180 days from the effective date of the Merger with MyMD Florida (Note 3).

On September 11, 2020, the Compensation Committee of the Board of Directors approved grants totaling 394,680 RSUs to the Company's four then-current 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 was to vest on the first anniversary date of the grant and the remaining fifty percent (50%) was to 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.

2013 Stock Incentive Plan

On January 23, 2014, MyMD 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 September 30, 2021, grants of 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. As of April 16, 2021, the effective date of the Merger, and September 30, 2021 there are no outstanding options under the 2013 Plan.

2017 Stock Incentive Plan

On August 7, 2017, the shareholders approved, and MyMD 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 September 30, 2021, grants of 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. As of April 16, 2021, the effective date of the Merger, and September 30, 2021 there are no outstanding options under the 2017 Plan.

2018 Stock Incentive Plan

On December 7, 2018, the shareholders approved, and MyMD adopted the 2018 Stock Incentive Plan (“2018 Plan”). The 2018 Plan initially provided for the issuance of up to 39,063 shares of the Company’s common stock. On August 27, 2020, the stockholders approved an amendment to the 2018 Plan increasing the number of shares available for issuance by an additional 521,000 shares to a total of 560,063 shares of the Company’s common stock.

As of September 30, 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. As of April 16, 2021, the effective date of the Merger, and September 30, 2021 there are no outstanding options under the 2018 Plan.

Note 8 - Equity

Series D Convertible Preferred Stock

On March 24, 2020, the Company 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 us.

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.

The exchange ratio for the Preferred Stock was adjusted to two-for-one due to the effects of the Reverse Stock Split.

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.

On February 11, 2021, 466,216 shares of common stock issued pursuant to that certain Securities Purchase Agreement, dated November 11, 2020, by and between the Company and certain institutional and accredited investors were cancelled and 466,216 prefunded warrants (as defined therein) were issued at the request of a shareholder.

On May 18, 2021, 466,216 prefunded warrants were exercised in exchange for 466,716 shares of common stock.

On August 5, 2021, the Company issued 16,826 shares of common stock with a fair market value of \$90,002 in exchange for services.

Common Stock Warrants

The table below summarizes the warrant activity for the nine months ended September 30, 2021:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2020	-	\$ -	-	\$ -
Assumed from Merger	5,363,547	5.19	5.02	-
Granted	-	-	-	-
Exercised	(47,298)	4.12	4.63	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-

Balance as of September 30, 2021	5,316,249	\$ 5.19	4.59	\$ 15,905,538
Exercisable as of September 30, 2021	<u>5,316,249</u>	<u>\$ 5.19</u>	4.59	\$ 15,905,538

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$7.20 for the Company's Common Stock on September 30, 2021. All warrants were vested on date of grant.

During the three months ended September 30, 2021, 47,298 common stock warrants were exercised by the warrant holders, generating proceeds of \$194,868.

The warrants outstanding as of September 30, 2021 represent 5,316,249 underlying shares of Company Common Stock.

Pre-funded Common Stock Warrants

The table below summarizes the pre-funded warrant activity for the nine months ended September 30, 2021:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2020	-	\$ -	-	\$ -
Assumed from Merger	986,486	0.002	-	-
Granted	-	-	-	-
Exercised	466,216	0.002	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance as of September 30, 2021	<u>520,270</u>	<u>\$ 0.002</u>	-	\$ 3,744,903
Exercisable as of September 30, 2021	<u>520,270</u>	<u>\$ 0.002</u>	-	\$ 3,744,903

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$7.20 for the Company's Common Stock on September 30, 2021. All pre-funded warrants were vested on the date of grant and are exercisable at any time.

The pre-funded warrants outstanding as of September 30, 2021 represent underlying shares of Company Common Stock of 520,270.

Warrants for the purchase of Series C Convertible Preferred Stock

The table below summarizes the activity during the nine months period ended September 30, 2021 for warrants issued in December 2019 for the purchase of Series C Convertible Preferred Stock:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as December 31, 2020	-	\$ -	-	\$ -
Assumed from Merger	27,500	8.00	3.65	-
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance as of September 30, 2021	27,500	\$ 8.00	3.19	\$ -
Exercisable as of September 30, 2021	27,500	\$ 8.00	3.19	\$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$7.20 for the Company's Common Stock on September 30, 2021. All warrants to purchase Series C Convertible Preferred Stock were vested on the date of grant.

The warrants for the of Series C Convertible Preferred Stock outstanding as of September 30, 2021 represent underlying shares of Company Common Stock of 27,500.

Note 9 – Commitments and Contingencies

COVID-19

The ultimate impact of the 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 the Company's Board of Directors or management of the Company, may determine are needed. The Company does not yet know the full extent of potential delays or impacts on the Company's business, product development efforts, healthcare systems or the global economy as a whole. The Company will continue to monitor the COVID-19 situation closely.

In response to public health directives and orders, the Company has implemented 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 its ability to support its operations.

Severe and/or long-term disruptions in the Company's operations will negatively impact its 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 development and testing.

To date, the Company has 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 the Company's ability to access capital, which could in the future negatively affect its liquidity. A recession or market correction resulting from the continuation of the COVID-19 pandemic could materially affect the Company's business and the value of its common stock.

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 May 17, 2021, eight of the nine MYMD Merger Complaints have been voluntarily dismissed (the remaining pending case is *Ray Craven v. MyMD Pharmaceuticals, Inc. (p/k/a Akers Biosciences, Inc.), et al.*, No. 1:21-cv-05762 (D.N.J.)).

The defendants believe that the claims asserted in the remaining MYMD Merger Complaint are without merit and intend to appropriately defend themselves against them. Accordingly, the Company does not expect that these claims will have a material adverse effect on its financial condition or results of operations.

Raymond Akers Action

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 “Raymond Akers Action”). Mr. Akers asserts one common law whistleblower retaliation claim against the Company. The Company has not yet been served with the Complaint in the Raymond Akers Action and, therefore, has not yet responded to the Complaint.

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.” To date, Mr. Akers has not filed another complaint.

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. The Company recorded \$20,000 and \$50,000 for these services during the three and nine months ended September 30, 2021, which is included in administrative expenses on the Condensed Consolidated Statement of Comprehensive Loss. There were no amounts owing to Taglich Brothers as of September 30, 2021 and December 31, 2020. The agreement was terminated effective August 31, 2021 without penalty.

The Secretary of the Company is the managing director of capital markets at Taglich Brothers.

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 September 30, 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 September 30, 2021 and December 31, 2020, the Company had a balance due of \$0 and \$477,042. The Company incurred expenses totaling \$0 and \$150,000 for the three and nine months ended September 30, 2021 and \$150,000 and \$450,000 for the three and nine months ended September 30, 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 Condensed Consolidated Statement of Comprehensive Loss for the three and nine months ended September 30, 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 September 30, 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 September 30, 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 \$0 and \$608,460 during the three and nine months ended September 30, 2021 and \$139,342 and \$278,685 during the three and nine months ended September 30, 2020.

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 Code covering substantially all qualified employees of the Company (the “401(k) Plan”). Under the 401(k) Plan, the Company matches 100% up to a 3% contribution, and 50% over a 3% contribution, up to a maximum of 5%.

The Company made matching contributions to the 401(k) Plan totaling \$4,244 and \$7,132 for the three and nine months ended September 30, 2021 and \$0 for the three and nine months ended September 30, 2020.

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.

Note 14—Subsequent events

On October 14, 2021, the Compensation Committee of the Board of Directors 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.

On October 26, 2021, the Company discovered it had been a victim of wire fraud due to a compromised electronic mail account. The Company has engaged a third-party forensic technology company to investigate the fraud and to recommend methods of preventing future attacks. For the three and nine months ended September 30, 2021, the Company has identified losses totaling \$1,058,086 which are included as other expenses on the Statement of Comprehensive Loss. Additional losses totaling \$207,220 occurred during October 2021. The Company’s internal review of disbursements made during the period of the incident is continuing and additional losses may be identified.

Item 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations.

This quarterly report on Form 10-Q and other reports filed by MyMD Pharmaceuticals, Inc. ("MyMD," "we" or 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.

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States (“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 report.

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 will be evaluated in patients with depression due to COVID-19 related to the release of cytokines. 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 derivative 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 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”). 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 Unaudited Condensed 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 Unaudited Condensed Consolidated Financial Statements.

Impact of the COVID-19 Pandemic on Our Business

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.

RESULTS OF OPERATIONS

Summary of Statements of Operations for the Three Months Ended September 30, 2021 and 2020

We are focused on developing and commercializing two therapeutic platforms based on well-defined therapeutic targets, MyMD-1 and Supera-CBD.

Product Revenue

We had no product revenue from operations during the three months ended September 30, 2021 and 2020.

Research and Development Expenses

Research and Development expenses for the three months ended September 30, 2021 totaled \$2,767,663 as compared to \$908,119 for the three months ended September 30, 2020.

The table below summarizes our research and development expenses for the three months ended September 30, 2021 and 2020 as well as the percentage of change year-over-year:

Description	For the Three Months Ended September 30,		Percent Change
	2021	2020	
Salaries and Wages	\$ 3,732	\$ 3,739	-%
Development Programs	2,102,575	865,346	143%
Professional Services	20,450	57,595	(65)%
Regulatory Expenses	640,906	10,200	6,183%
Other Research and Development Expenses	-	(28,761)	(100)%
Total Research and Development Expenses	<u>\$ 2,767,663</u>	<u>\$ 908,119</u>	<u>205%</u>

Research and Development Expenses totaled \$2,767,663 (2020: \$908,119), an increase of 321%. Generally, the overall increases are due to our ability to implement our long-term development program as a result of the financial resources available upon consummation of the Merger.

The increased costs in our clinical development programs include costs for active pharmaceutical ingredients, optimization and pre-clinical toxicology studies.

Professional services are primarily related to legal and patent related fees associated with protecting our intellectual property.

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.

Administrative Expenses

Administrative expenses for the three months ended September 30, 2021 totaled \$1,640,540 as compared to \$884,529 for the three months ended September 30, 2020.

The table below summarizes our administrative expenses for the three months ended September 30, 2021 and 2020 as well as the percentage of change year-over-year:

Description	For the Three Months Ended September 30,		Percent Change
	2021	2020	
Personnel Costs	\$ 509,121	\$ 180,458	182%
Professional Service Costs	405,463	232,077	75%
Stock Market & Investor Relations Costs	206,183	57,570	258%
Other Administrative Costs	519,773	414,424	25%
Total Administrative Expense	\$ 1,640,540	\$ 884,529	86%

Administration expenses totaled \$1,640,540 for the three months ended September 30, 2021 and \$884,529 for the three months ended September 30, 2020. The increased costs include additional personnel added at the time of the Merger, legal and accounting fees associated with the Merger, investor relations firm fees, NASDAQ listing fees, printing and other Merger-related costs.

Interest Expense and Debt Discount

Interest Expense and Debt Discount for the three months ended September 30, 2021 and September 30, 2020 totaled \$0 and \$213,648, which includes interest expense and the amortization of the debt discount.

Amortization of Intangible Assets

Amortization of Intangible Assets includes the amortization of the website for the three months ended September 30, 2020. No amortization was recorded for the three months ended September 30, 2021 as the intangible assets were fully amortized as of December 31, 2020.

Other Income / Expense

Other expenses, net of income, for the three months ended September 30, 2021 totaled \$1,059,078. Other income, net of expenses totaled \$135 for the three months ended September 30, 2020.

The table below summarizes our other income and expenses for the three months ended September 30, 2021 and 2020, as well as the percentage of change year-over-year:

Description	For the Three Months Ended September 30,		Percent Change
	2021	2020	
Realized Loss on Investments	\$ 1,100	\$ -	-%
Equity Investments Losses	848	-	-%
Interest and Dividend Income	(1,714)	(135)	1,170%
Currency Conversion Losses	758	-	-%
Uninsured Casualty Losses	1,058,086	-	-%
Total Other (Income)/Expense	\$ 1,059,078	\$ (135)	(784,602)%

For the three months ended September 30, 2021, we have identified an uninsured casualty loss of \$1,058,086 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.

We have engaged a forensic technology firm to investigate the incident and to recommend improvements to our systems to prevent future attacks.

Summary of Statements of Operations for the Nine Months Ended September 30, 2021 and 2020

Product Revenue

We had no product revenue from operations during the nine months ended September 30, 2021 and September 30, 2020.

Research and Development Expenses

Research and Development expenses for the nine months ended September 30, 2021 totaled \$5,437,147 as compared to \$1,436,696 for the nine months ended September 30, 2020.

The table below summarizes our research and development expenses for the nine months ended September 30, 2021 and 2020 as well as the percentage of change year-over-year:

Description	For the Nine Months Ended September 30,		Percent Change
	2021	2020	
Salaries and Wages	\$ 11,235	\$ 11,230	-%
Development Programs	4,374,072	1,073,120	308%
Professional Services	44,715	77,840	(43)%
Regulatory Expenses	984,221	249,142	295%
Other Research and Development Expenses	22,904	24,364	(6)%
Total Research and Development Expenses	<u>\$ 5,437,147</u>	<u>\$ 1,436,696</u>	<u>279%</u>

Research and Development expenses totaled \$5,437,147 (2020: \$1,436,696), an increase of 279% during the nine months ended September 30, 2021. Generally, the overall increases are due to our ability to implement our long-term development program as a result of the financial resources available upon consummation of the Merger.

The increased costs in our clinical development program include costs for active pharmaceutical ingredients, optimization, pre-clinical toxicology studies and a Phase 1 Multiple Ascending Dose / Single Ascending Dose study.

Professional services are primarily related to legal and patent related fees associated with the protection of our intellectual property.

The increased costs in regulatory expenses include clinical research organizations (CRO) and regulatory consulting fees associated with Phase 2 clinical study design, protocol preparation and updating of the investigator brochure.

Administrative Expenses

Administrative expenses for the nine months ended September 30, 2021 totaled \$4,601,853 as compared to \$2,045,422 for the nine months ended September 30, 2020.

The table below summarizes our administrative expenses for the nine months ended September 30, 2021 and 2020 as well as the percentage of change year-over-year:

Description	For the Nine Months Ended September 30,		Percent Change
	2021	2020	
Personnel Costs	\$ 1,260,878	\$ 476,999	164%
Professional Service Costs	1,327,465	546,135	143%
Stock Market & Investor Relations Costs	546,154	57,570	849%
Other Administrative Costs	1,467,356	964,718	52%
Total Administrative Expense	\$ 4,601,853	\$ 2,045,422	125%

Administration expenses totaled \$4,601,853 for the nine months ended September 30, 2021 and \$2,045,422 for the nine months ended September 30, 2020. The increased costs include additional personnel added at the time of the Merger, legal and accounting fees associated with the Merger, investor relations firm fees, NASDAQ listing fees, printing and other Merger-related costs.

Interest Expense and Debt Discount

Interest Expense and Debt Discount for the nine months ended September 30, 2021 and September 30, 2020 totaled \$701,090 and \$582,458 which includes interest expense and the amortization of the debt discount.

Amortization of Intangible Assets

Amortization of Intangible Assets includes the amortization of the website for the nine months ended September 30, 2020. No amortization was recorded for the nine months ended September 30, 2021 as the intangible assets were fully amortized as of December 31, 2020.

Stock Option Modification Expenses

During the nine months ended September 30, 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. During the nine months ended September 30, 2020, we recorded \$1,127,156 in stock-based compensation for services.

Other Income and Expense

Other expenses, net of income, for the nine months ended September 30, 2021 totaled \$873,180. Other income, net of expense, for the nine months ended September 30, 2020 totaled \$141.

The table below summarizes our other income and expenses for the nine months ended September 30, 2021 and 2020, as well as the percentage of change year-over-year:

Description	For the Nine Months Ended September 30,		Percent Change
	2021	2020	
Realized Gains on Investments	\$ (40,347)	-	-\$ -%
Equity Investments Losses	42,295	-	-%
Interest and Dividend Income	(7,355)	(141)	5,116%
Currency Exchange Losses	758	-	-%
Uninsured Casualty Loss	1,058,086	-	-%
Gain on Debt Forgiveness	(180,257)	-	-%
Total Other Income, net of expenses	\$ 873,180	\$ (141)	131,039%

Other expenses, net of income, totaled \$873,180 for the nine months ended September 30, 2021, and other income, net of expenses, totaled \$141 for the nine months ended September 30, 2020. The gain on debt forgiveness is associated with the negotiated settlement of an outstanding debt on a lease totaling \$109,657 and the forgiveness of our Payroll Protection Program loans totaling \$70,600.

For the nine months ended September 30, 2021, we have identified an uninsured casualty loss of \$1,058,086 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.

We have engaged a forensic technology firm to investigate the incident and to recommend improvements to our systems to prevent future attacks.

Liquidity and Capital Resources

As of September 30, 2021, our cash on hand totaled \$1,375,014 and marketable securities totaled \$14,002,767. We incurred a net loss from operations of \$26,649,321 for the nine months ended September 30, 2021. As of September 30, 2021, we had working capital of \$13,855,132 and stockholders' equity of \$25,891,924, including an accumulated deficit of \$75,321,846. During the nine months ended September 30, 2021, cash flows used in operating activities were \$14,704,008, consisting primarily of a net loss of \$26,649,321 and a decrease in trade and other payables of \$3,233,299. Since our inception, we have met our liquidity requirements principally through the sale of our common stock in public offerings and private placements.

Concurrently with the Merger Agreement, on November 11, 2020, we entered into the Securities Purchase Agreement, by and between us and certain institutional and accredited investors (the "SPA Purchasers"), pursuant to which we agreed to issue and sell to the SPA Purchasers in a private placement (i) an aggregate of 4,882,980 shares of our Common Stock, at an offering price of \$3.70 per share or, at the election of each investor, Prefunded Warrants (as defined therein), and (ii) for each share of our Common Stock (or for each Prefunded Warrant, as applicable) purchased in the private placement, a common warrant to purchase one share of our Common Stock, for gross proceeds of approximately \$18.1 million before the deduction of placement agent fees and expenses and estimated offering expenses.

We believe that that our current financial resources as of the date of the issuance of these condensed consolidated financial statements are sufficient to fund our current twelve-month operating budget, and satisfying our estimated liquidity needs for twelve months from the issuance of these condensed consolidated financial statements.

Operating Activities

Our net cash used by operating activities totaled \$14,704,008 during the nine months ended September 30, 2021. Net cash used consisted principally of the net losses from operations of \$26,649,321 and a decrease in trade and other payables of \$3,233,299 partially offset by non-cash option modification expenses of \$15,036,051.

Our net cash used by operating activities totaled \$3,415,364 during the nine months ended September 30, 2020. Net cash used consisted principally of the net loss from continuing operations of \$5,199,758 partially offset by non-cash stock option expenses of \$1,127,156.

Investing Activities

Our net cash provided by investing activities totaled \$16,852,177 for the nine months ended September 30, 2021 as compared to cash provided by investing activities totaling \$0 during the nine months ended September 30, 2020. During the nine months ended September 30, 2021 we purchased securities totaling \$11,851 (2020: \$0) and sold securities totaling \$15,483,176 (2020: \$0) and received \$1,380,852 from the merger.

Financing Activities

Net cash consumed by financing activities during the nine months ended September 30, 2021 was \$921,439 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. Net cash provided by financing activities totaled \$3,327,849 during the nine months ended September 30, 2020 which consisted of proceeds from the line of credit of \$1,277,249, \$1,980,000 from the issuance of common stock and \$70,600 from the Payroll Protection Program.

Critical Accounting Policies

See accounting policies in Note 2 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this report.

Off-Balance Sheet Arrangements

We have no significant known off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. 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 Quarterly Report on Form 10-Q, 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 file 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 officer as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Except as noted above, there were no changes in our internal controls over financial reporting that occurred during the three months ended September 30, 2021 that have materially affected, or are reasonably likely to affect, our internal control over financial reporting.

Due to the recent cybersecurity incident reported elsewhere herein, we are continuing to review our established controls and procedures that involve cybersecurity matters to determine any other material impacts to our financial results, operations, and/or reputation to insure such incidents are immediately reported by management to the Board of Directors, or individual members or committees thereof, as appropriate, in accordance with our escalation framework and insure we have established procedures to ensure that management responsible for overseeing the effectiveness of disclosure controls is informed in a timely manner of known cybersecurity risks and incidents that may materially impact our operations and that timely public disclosure is made as appropriate.

PART II - OTHER INFORMATION

Item 1. 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 description of certain legal proceedings, please read Note 9 to the interim condensed consolidated financial statements, which information is incorporated herein by reference.

Item 1A. Risk Factors

The following description of risk factors includes any material changes to, and supersedes the description of, risk factors associated with our business, financial condition and results of operations previously disclosed in “Item 1A. Risk Factors” of our 2020 10-K, as filed with the SEC on March 1, 2021. 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-Q. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, “Financial Statements” and Part I, Item 2, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Form 10-Q.

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 risk factors 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 Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, 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 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 derivative 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 Quarterly Report on Form 10-Q and Item 1A of our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2020.

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.

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 derivative. 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.

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, 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.

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 20% 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.

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.

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.

The stockholder rights agreement adopted by our Board of Directors may impair an attempt to acquire control of the Company.

On September 9, 2020, our Board of Directors entered into that certain Rights Agreement, dated as of September 9, 2020, between the Company and VStock Transfer, LLC, as Rights Agent (the “Rights Agreement”) and declared a dividend of one preferred share purchase right (a “Right”) for each outstanding share of our common stock to stockholders of record on September 21, 2020. Each Right is transferred with common stock and entitles the registered holder, subject to the terms of the Rights Agreement to purchase from us one one-thousandth of a share of our Series E Junior Participating Preferred Stock at \$15.00, subject to certain adjustments. 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, subject to certain adjustments. The Rights Agreement remained in effect following the consummation of the Merger pursuant to the Merger Agreement, and the Rights Agreement could make it more difficult for a third party to acquire control of the Company or a large block of our common stock without the approval of our Board of Directors.

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 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.

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.

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.

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

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

- if Oravax is not successful in developing the COVID-19 vaccine candidate, we may not realize any value out of our ownership of Oravax shares; and
- costs and expenses associated with any undisclosed or potential liabilities.

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

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. While we are continuing to investigate, we believe 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 approximately \$1,265,000 related to this incident. While our management continues to investigate the incident and has engaged a third-party forensic technology company to investigate the fraud and to recommend methods of preventing future attacks, such cyber-attacks against us or our third-party providers and business partners remain a serious issue. The pervasiveness of cybersecurity incidents in general and the risks of cyber-crime 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, cyber-attacks or cyber-intrusions 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 cyber-attacks or cyber intrusion, 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

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 efforts 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.

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, MyMD-1, Supera-CBD and our other product candidates must be approved by the FDA pursuant to an NDA in the U.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 planned Phase 2 clinical trial for MyMD-1 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 recently completed a dosing study in Tampa 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. The FDA 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. If we promote our product candidates 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 investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

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 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 derivative 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 derivative 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. 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.

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

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.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. 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 may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act (“ACA”), was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. As implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase MyMD’s regulatory burdens and operating costs.

From time-to-time efforts have been made by different branches of the U.S. federal government to, modify, repeal or otherwise replace certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act (the “TCJA”), was enacted, effective January 1, 2019, and included, among other things, a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” There have been subsequent challenges to the constitutionality of the ACA following the repeal of the individual mandate. In June 2021, the U.S. Supreme Court held that the plaintiffs lacked standing to challenge the individual mandate provision, thus leaving the ACA in effect without ruling on the constitutionality of the individual mandate. In addition, there may be other efforts to challenge, repeal or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020 implemented under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) which was signed into law on March 27, 2020, unless additional Congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our financial operations.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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.

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 eleven issued U.S. patents, one foreign patent, six pending U.S. patent applications, one pending international application, and 28 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 its relationship 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.

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 or selling 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, 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 or 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 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-to-file” patent system. Under a “first-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-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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There were no unregistered sales of the Company’s equity securities during the three months ended September 30, 2021, other than those previously reported in a Current Report on Form 8-K.

Item 3. Defaults Upon Senior Securities

There has been no default in the payment of principal, interest, sinking or purchase fund installment, or any other material default, with respect to any indebtedness of the Company.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description
2.1**	<u>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 herein 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).</u>
2.2	<u>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 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).</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>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).</u>
4.1	<u>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).</u>
10.1	<u>Contribution and Assignment Agreement, dated March 18, 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).</u>
10.2	<u>Termination and Release Agreement, dated March 18, 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).</u>
10.3	<u>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).</u>
10.4#	<u>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).</u>
10.5#	<u>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).</u>
10.6#	<u>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).</u>
10.7#	<u>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).</u>

- 10.8# [MyMD Pharmaceuticals \(Florida\) Inc. Second Amendment to Amended and Restated 2016 Stock Incentive Plan, dated July 1, 2019 \(incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.9 [Amended and Restated Confirmatory Patent Assignment and Royalty Agreement dated November 11, 2020, by and between SRQ Patent Holdings II, LLC and Supera Pharmaceuticals, Inc. \(incorporated herein by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.10 [Amended and Restated Confirmatory Patent Assignment and Royalty Agreement dated November 11, 2020, by and between SRO Patent Holdings, LLC and MyMD Pharmaceuticals, Inc. \(incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.11# [Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals \(Florida\), Inc., effective December 18, 2020 \(incorporated herein by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.12# [Amendment No. 1 to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals \(Florida\), Inc., dated February 11, 2021 \(incorporated herein by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.13# [Employment Agreement between Chris Chapman and MyMD Pharmaceuticals \(Florida\), Inc., effective November 1, 2020 \(incorporated herein by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.14# [Amendment No. 1 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals \(Florida\), Inc., dated December 18, 2020 \(incorporated herein by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.15# [Amendment No. 2 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals \(Florida\), Inc., dated January 8, 2021 \(incorporated herein by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.16# [Amendment No. 3 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals \(Florida\), Inc., dated February 11, 2021 \(incorporated herein by reference to Exhibit 10.16 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.17# [Employment Agreement between Paul Rivard and MyMD Pharmaceuticals \(Florida\), Inc., dated September 21, 2020 \(incorporated herein by reference to Exhibit 10.17 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.18# [Amendment No. 1 to Employment Agreement between Paul Rivard and MyMD Pharmaceuticals \(Florida\), Inc., dated November 24, 2020 \(incorporated herein by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 10.19# [Amendment No. 2 to Employment Agreement between Paul Rivard and MyMD Pharmaceuticals \(Florida\), Inc., dated December 18, 2020 \(incorporated herein by reference to Exhibit 10.19 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021\).](#)
- 31.1* [Certification of Principal Executive Officer required by Rule 13a-14\(a\) or Rule 15d-14\(a\).](#)
- 31.2* [Certification of Principal Financial Officer required by Rule 13a-14\(a\) or Rule 15d-14\(a\).](#)
- 32.1* [Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2* [Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101* Interactive Data Files of Financial Statements and Notes.
- 104* Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Management contract or compensatory plan or arrangement.

* Filed herewith.

** 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

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MYMD PHARMACEUTICALS, INC.

Date: November 12, 2021

By: /s/ Chris Chapman

Name: Chris Chapman

Title: President, Chief Medical Officer, and Director
(Principal Executive Officer)

Date: November 12, 2021

By: /s/ Ian Rhodes

Name: Ian Rhodes

Title: Chief Financial Officer
(Principal Financial 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, Chris Chapman, President, Chief Medical Officer, and Director, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 12, 2021

By: /s/ Chris Chapman

Chris Chapman, M.D.

President, Chief Medical Officer, and Director (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, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 12, 2021

By: /s/ Ian Rhodes

Ian Rhodes
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 quarterly report on Form 10-Q of MyMD Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Chris Chapman, as the President, Chief Medical Officer, and Director 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: November 12, 2021

By: /s/ Chris Chapman

Chris Chapman, M.D.

President, Chief Medical Officer, and Director (*Principal Executive 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 quarterly report on Form 10-Q of MyMD Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Ian Rhodes, as the Chief Financial Officer, 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: November 12, 2021

By: */s/ Ian Rhodes*

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