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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

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

For the transition period from _____ to _____

Commission file number: 001-36268

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

Delaware	**22-2983783**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
1185 Avenue of the Americas, Suite 249 New York, NY	10036
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of Each Class:	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered:**
Shares of Common Stock, par value $0.001 per share	**TNF**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2024, based on a closing price of $1.84, was $3.788 million.

As of April 4, 2025, the registrant had 10,132,619 shares of its Common Stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

On July 22, 2024, the Company changed its name from MyMD Pharmaceuticals, Inc. to TNF Pharmaceuticals, Inc. by filing a certificate of amendment to its certificate of incorporation with the Secretary of State of Delaware. In addition, effective before the open of market trading on July 24, 2024, the Company's common stock, par value $0.001 per share ("Common Stock") ceased trading under the ticker symbol "MYMD" and began trading on the Nasdaq Stock Market under the ticker symbol "TNFA."

At the Company's annual meeting of stockholders held on July 31, 2023, the stockholders approved a plan to merge the Company with and into a newly formed wholly owned subsidiary, MyMD Pharmaceuticals, Inc., a Delaware corporation ("MyMD Delaware"), with MyMD Delaware being the surviving corporation, for the purpose of changing the Company's state of incorporation from New Jersey to Delaware (the "Reincorporation"). The Reincorporation was effected as of March 4, 2024. In connection with the Reincorporation to Delaware, the par value of the Company's Common Stock and preferred stock was changed to $0.001 per share.

MyMD Delaware is deemed to be the successor issuer of MyMD New Jersey under Rule 12g-3 of the Securities Exchange Act of 1934, as amended.

The Reincorporation did not result in any change in the Company's name, business, management, fiscal year, accounting, location of the principal executive offices, assets or liabilities. Holders of shares of the Company's Common Stock did not have to exchange their existing MyMD New Jersey stock certificates for MyMD Delaware stock certificates.

As of the Effective Date of the Reincorporation, the rights of the Company's stockholders are governed by the Delaware General Corporation Law, the MyMD Delaware Certificate of Incorporation and the Bylaws of MyMD Delaware.

On February 14, 2024, the Company effected a 1-for-30 reverse stock split (the "Reverse Stock Split"). Simultaneously with the Reverse Stock Split, the number of shares of the Company's Common Stock authorized for issuance was reduced from 500,000,000 shares to 16,666,666 shares, and our authorized capital stock was reduced from 550,000,000 shares to 66,666,666 shares. The Reverse Stock Split reduced the total number of issued and outstanding shares of Common Stock, including shares held by the Company as treasury shares. All share amounts have been retroactively adjusted for the Reverse Stock Split, unless stated otherwise.

On July 25, 2024, the Company increased the number of authorized shares of the Company's Common Stock from 16,666,666 to 250,000,000 and made a corresponding change to the number of authorized shares of the Company's capital stock by filing a Certificate of Amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Share Increase"). The Share Increase was approved by the Company's stockholders at the Company's special meeting of stockholders held on July 24, 2024.

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

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") and the documents we have filed with the Securities and Exchange Commission (which we refer to herein as the "SEC") that are incorporated by reference herein contain "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of forward-looking terms such as "anticipates," "assumes," "believes," "can," "could," "estimates," "expects," "forecasts," "future," "guides," "intends," "is confident that,", "may," "plans," "seeks," "projects," "targets," and "would" or the negative of such terms or other variations on such terms or comparable terminology. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements.

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

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

- fluctuation and volatility in the 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 stockholders;
- the impact of our ability to meet the continued listing requirements of the Nasdaq Capital Market;
- the availability of and our 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 Isomyosamine (formerly named 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 potential future public health emergencies 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 our product candidates;

- the impact of potential future public health emergencies 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;
- 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;
- changes in the market acceptance of our products and services;
- our compliance with all laws, rules, and regulations applicable to our business and drug product candidates;
- risks of mergers and acquisitions including the time and cost of implementing transactions and the potential failure to achieve expected gains, revenue growth or expense savings;
- other risks, including those described in the "Risk Factors" section of this Annual Report.

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

PART I

Item 1. Business.

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

- Isomyosamine is a clinical stage small molecule that regulates the immunometabolic system to treat autoimmune disease, including (but not limited to) sarcopenia, frailty, adverse effects of drugs used to treat diabetes and obesity, rheumatoid arthritis, and inflammatory bowel disease. The first indication for which Isomyosamine is being developed is to treat age-related frailty and sarcopenia. Isomyosamine works by regulating the release of numerous pro-inflammatory cytokines, such as TNF-α, interleukin 6 ("IL-6") and interleukin 17 ("IL-17").

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

The rights to Supera-CBD™ were previously owned by Supera Pharmaceuticals, Inc. ("Supera") and were acquired by MyMD Florida (as defined below) immediately prior to the closing of the Merger (as defined below) that occurred in 2021.

TNF Background and Corporate History

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

During the period 2016 through October of 2020, the Company's principal business activities consisted of the execution and completion of *in vitro* assays, *in vivo* pre-clinical animal studies, and genotoxicity and toxicology studies relating to Isomyosamine (as further described below). On June 25, 2019, the Company commenced a Phase 1 trial in healthy volunteers for pharmacokinetics and tolerability studies, and in December of 2019, the Company filed an IND for Isomyosamine for treatment of Hashimoto thyroiditis. The Phase 1 trial was completed on January 30, 2020, after which the Company commenced preparation of a Phase 2 clinical trial for Isomyosamine. The Company has also commenced a Phase 2 clinical trial for patients with sarcopenia, with dosing that began in the first quarter of 2022. The last patient visit took place on June 6, 2023.

Additionally, the Company together with h Charles River Laboratories has conducted a study titled "A 13 Week Electroencephalogram Safety Study of MYMD-1 by Oral Gavage Administration in Beagle Dog." Analysis and reporting were completed in December 2024 and the results have been favorably received by the FDA.

2021 Merger and Corporate Transactions

On April 16, 2021, pursuant to an Agreement and Plan of Merger and Reorganization, dated November 11, 2020 (as subsequently amended, the "Merger Agreement"), by and among the Company, previously known as Akers Biosciences, Inc., XYZ Merger Sub, Inc., 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"). The Merger consideration included potential milestone payments to the pre-Merger MyMD Florida stockholders (the "Milestone Payments") payable in shares of the Company's Common Stock upon the achievement of certain market capitalization milestone events during the 36-month period immediately following the closing of the Merger (the "Milestone Period"). On April 16, 2024, the Milestone Period expired and accordingly, the pre-Merger MyMD Florida stockholders are no longer entitled to any potential Milestone Payments pursuant to the Merger Agreement.

On November 11, 2020, in connection with entering into the Merger Agreement, MyMD Florida entered into an Asset Purchase Agreement with Supera, pursuant to which, MyMD Florida agreed to acquire from Supera substantially all of the assets (including all rights to Supera-CBD) and certain obligations of Supera in consideration of the issuance of an aggregate of 13,096,640 shares of MyMD Florida Common Stock to Supera. As partial consideration for such an assignment, Supera granted to SRQ Patent Holdings II, LLC a royalty with respect to product sales and other consideration arising from the assigned intellectual property.

The Company previously owned, through its subsidiary Cystron Biotech, LLC ("Cystron"), an exclusive license from Premas Biotech PVT Ltd. ("Premas") with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other coronavirus infections. On April 16, 2021, pursuant to a 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 Company caused Cystron to contribute substantially all of the assets associated with its business of developing and manufacturing Cystron's COVID-19 vaccine candidate to Oravax (the "Contribution Transaction"). Oravax is pursuing the development of the COVID-19 vaccine candidate. The Company's interest in Oravax consists of 13% of Oravax's outstanding shares of capital stock and the rights to a 2.5% royalty on all future net sales. The Company has evaluated several options with respect to its interest in Oravax, including a potential distribution of Oravax shares to the Company's stockholders. This would make Oravax a publicly held company. In addition, TNF currently has the right to designate a member of the board of directors of Oravax, pursuant to which Mr. Joshua Silverman, our Chairman of the Board, has been designated to serve as a director of Oravax.

Reincorporation and Name Change

On July 22, 2024, the Company changed its name from MyMD Pharmaceuticals, Inc. to TNF Pharmaceuticals, Inc. by filing a certificate of amendment to its certificate of incorporation with the Secretary of State of Delaware. In addition, effective before the open of market trading on July 24, 2024, the Company's common stock, par value $0.001 per share ("Common Stock") ceased trading under the ticker symbol "MYMD" and began trading on the Nasdaq Stock Market under the ticker symbol "TNFA."

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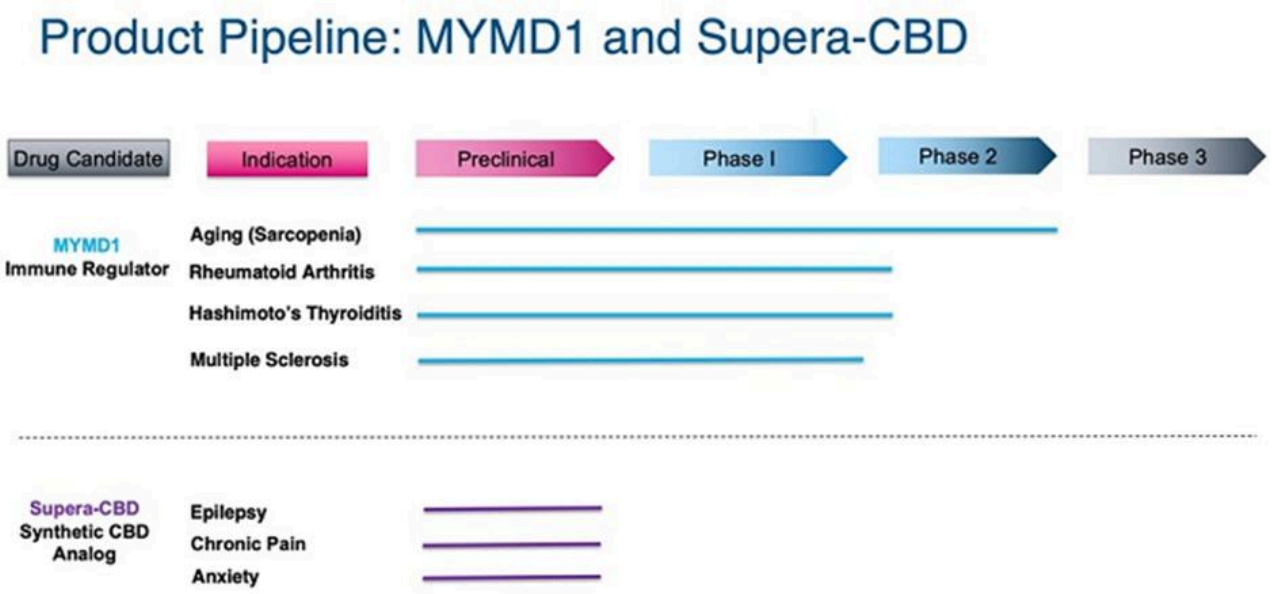
MyMD Delaware is deemed to be the successor issuer of MyMD New Jersey under Rule 12g-3 of the Securities Exchange Act of 1934, as amended.

The Reincorporation did not result in any change in the Company's name, business, management, fiscal year, accounting, location of the principal executive offices, assets or liabilities. Holders of shares of the Company's Common Stock did not have to exchange their existing MyMD New Jersey stock certificates for MyMD Delaware stock certificates.

As of the Effective Date of the Reincorporation, the rights of the Company's stockholders are governed by the Delaware General Corporation Law, the MyMD Delaware Certificate of Incorporation and the Bylaws of MyMD Delaware.

Drug Development

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



Strategy

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

- Completed a 28-day Phase 2 clinical trial in sarcopenia (i.e., age-related muscle loss) in the second quarter of 2023, which showed safety and tolerability of Isomyosamine at clinically effective doses;
- Initiated a 90-day Phase 2 clinical trial in sarcopenia to evaluate improvement in clinical outcomes in older sarcopenic patients who have sustained a hip or femur fracture;
- Advance Isomyosamine into Phase 2 clinical trials for rheumatoid arthritis and deleterious effects of drugs (GLP-1 agonists) used in patients with Type II diabetes to assist in weight loss;
- Execute on IND-enabling studies of Supera-CBD to enable submission of an IND for a Phase 1 clinical trial in healthy volunteers followed by Phase 2 clinical trials in epilepsy, addiction and anxiety disorders;
- Identify and validate additional novel targets and utilize translational platforms to develop a pipeline of product candidates for aging and other autoimmune disease;
- Maintain broad commercial rights to TNF's product candidates; and
- Continue to strengthen and expand TNF's intellectual property portfolio.

ISOMYOSAMINE

Overview

Isomyosamine is a clinical stage drug that targets the immune system by inhibiting the release of pro-inflammatory cytokines, such as TNF-α. Cytokines are a broad category of molecules involved in immune system coordination("Immunometabolic regulation"). By affecting the initial triggers that drive autoimmunity, Isomyosamine targets the underlying cause of these diseases rather than just their symptoms. TNF has completed a 28-day Phase 2 clinical trial for sarcopenia (age-related muscle loss) that showed safety and tolerability at clinically meaningful doses, without dose-limiting side effects or immunosuppression. TNF has initiated a Phase 2b clinical trial to evaluate clinical outcome improvements in sarcopenic patients who have sustained a hip or femur fracture. TNF has an active IND with the Endocrinology Division at the FDA for other autoimmune diseases. Studies have been completed on the mechanisms of action and efficacy of Isomyosamine in several pre-clinical models of autoimmune diseases (i.e., experimental autoimmune encephalomyelitis ("EAE") that models multiple sclerosis and autoimmune thyroiditis), and these studies have been published in peer reviewed journals. TNF plans to pursue these indications.

Isomyosamine*: A TNF-a inhibitor without immunosuppressive liability*

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

The goal of Isomyosamine is to target immune cells that overproduce pro-inflammatory cytokines, such as TNF-α, without preventing normal immune cell function. TNF-α is a cytokine that is released by immune cells that plays a key role in acute and chronic inflammation, autoimmune diseases and aging.

Isomyosamine is a novel small molecule orally available "immunometabolic" regulator that has demonstrated *in vitro* and *in vivo* activity to regulate the release of multiple cytokines from immune cells, including TNF-α. Isomyosamine is being developed to treat chronic inflammatory diseases, with the initial priority of complications of sarcopenia and frailty, which together affect more than 1,000,000 patients in the US.

Isomyosamine Regulates Multiple Cytokines

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

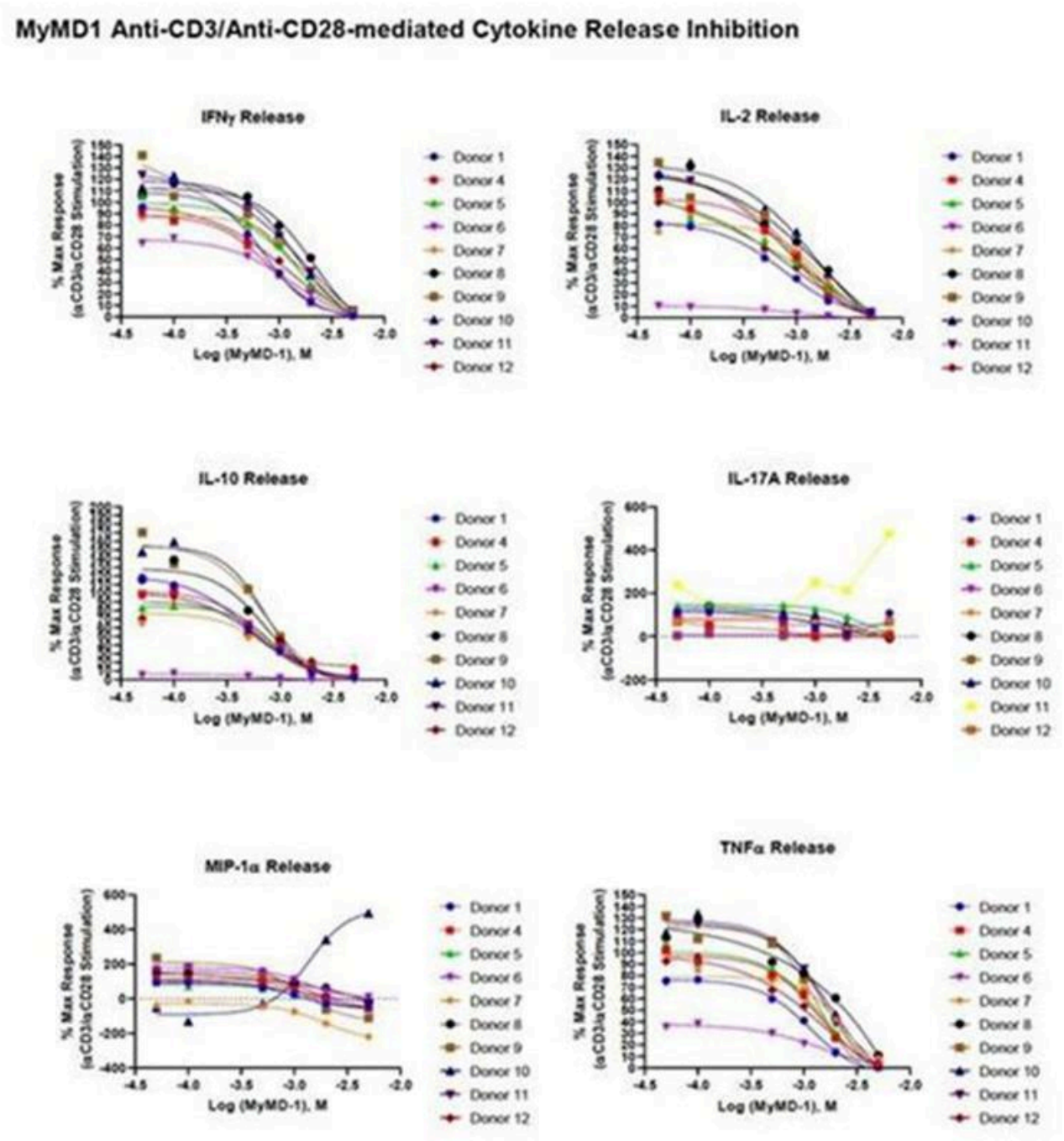
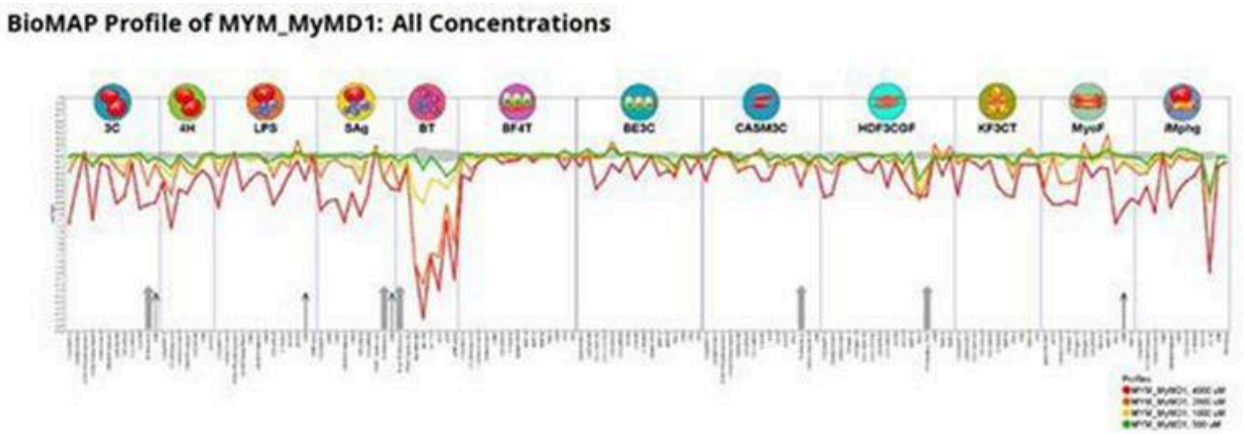


Figure 1. Isomyosamine *modulates the release of a broad spectrum of cytokines.*

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



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

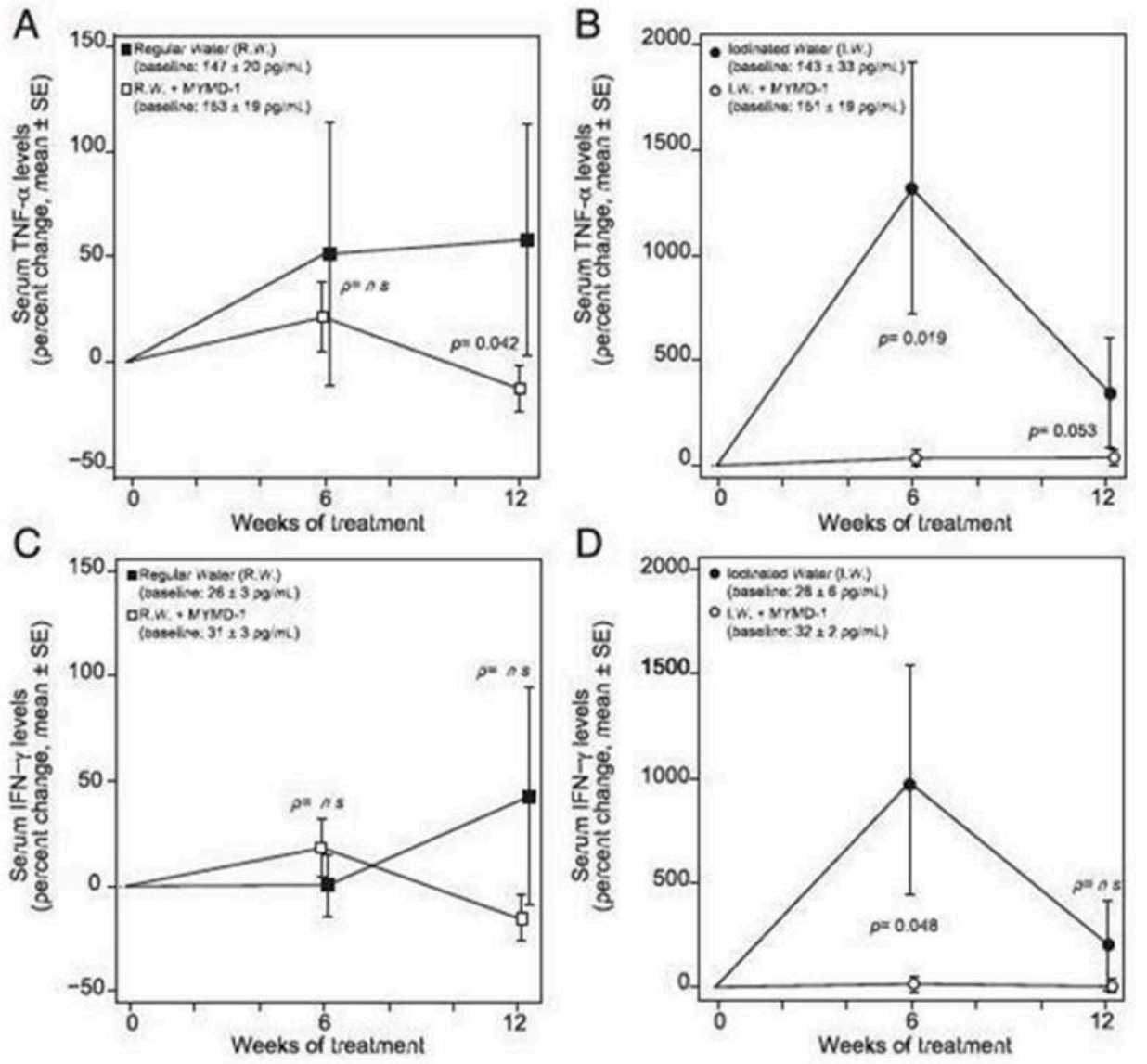


Figure 2. Isomyosamine decreases the serum levels TNF-α and IFN-g in NOD.H-2h4 mice. NOD.H-2h4 mice were treated with either regular water or iodinated water (500 mg/l of sodium iodide), and each group was treated or not treated with Isomyosamine (185 mg/l). Cytokines were measured at baseline and after 6 and 12 weeks of treatment using a multiplex magnetic bead array. (A and B) Isomyosamine significantly decreased serum TNF-α levels in the regular water group and tended to decrease it in the

iodinated water group. (C and D) Isomyosamine showed a modest effect on serum IFN-g in the iodinated water group. The results are from three independent experiments. Statistical comparisons were made by longitudinal data analysis with generalized estimating equations.

Isomyosamine Targets Autoimmune Diseases

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

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

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

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

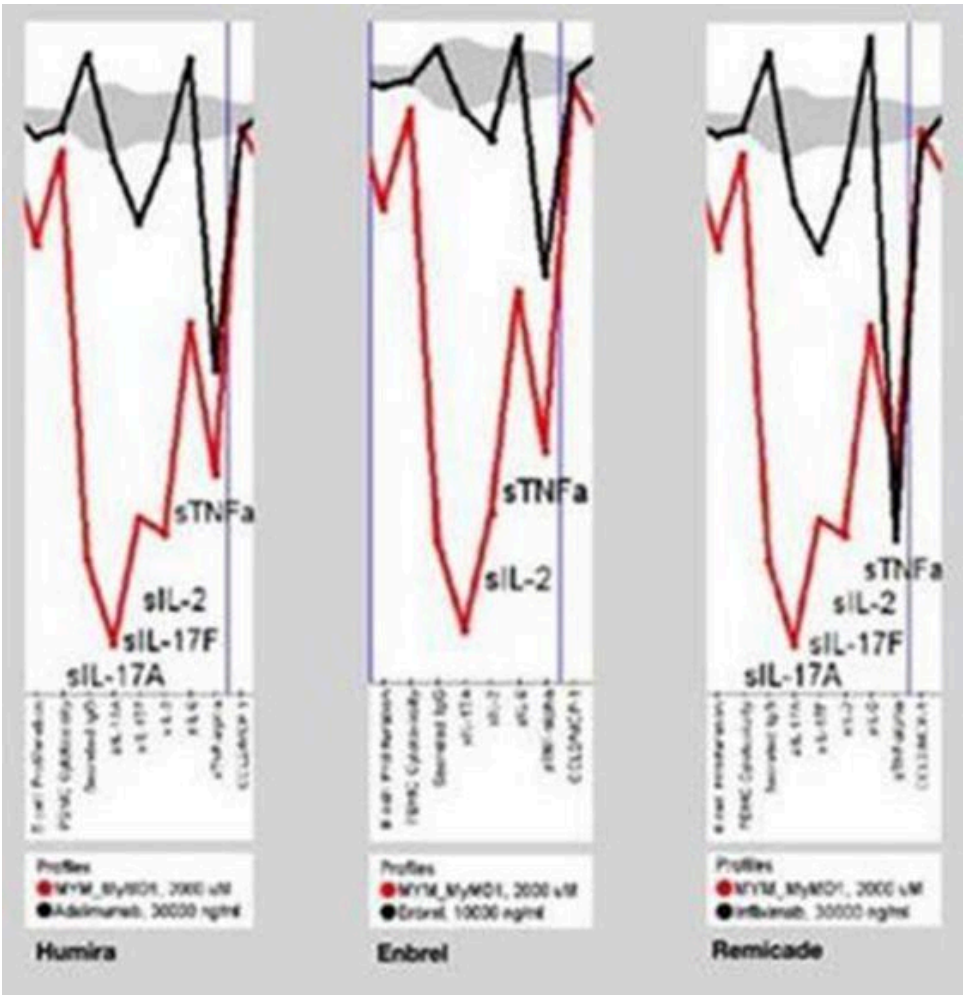


Figure 3. Comparison of inhibitory effect of Isomyosamine with other TNF-α blockers. Isomyosamine exhibits a dose-dependent reduction in release of several cytokine more effectively than Humira, Enbrel and Remicade.

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

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

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

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

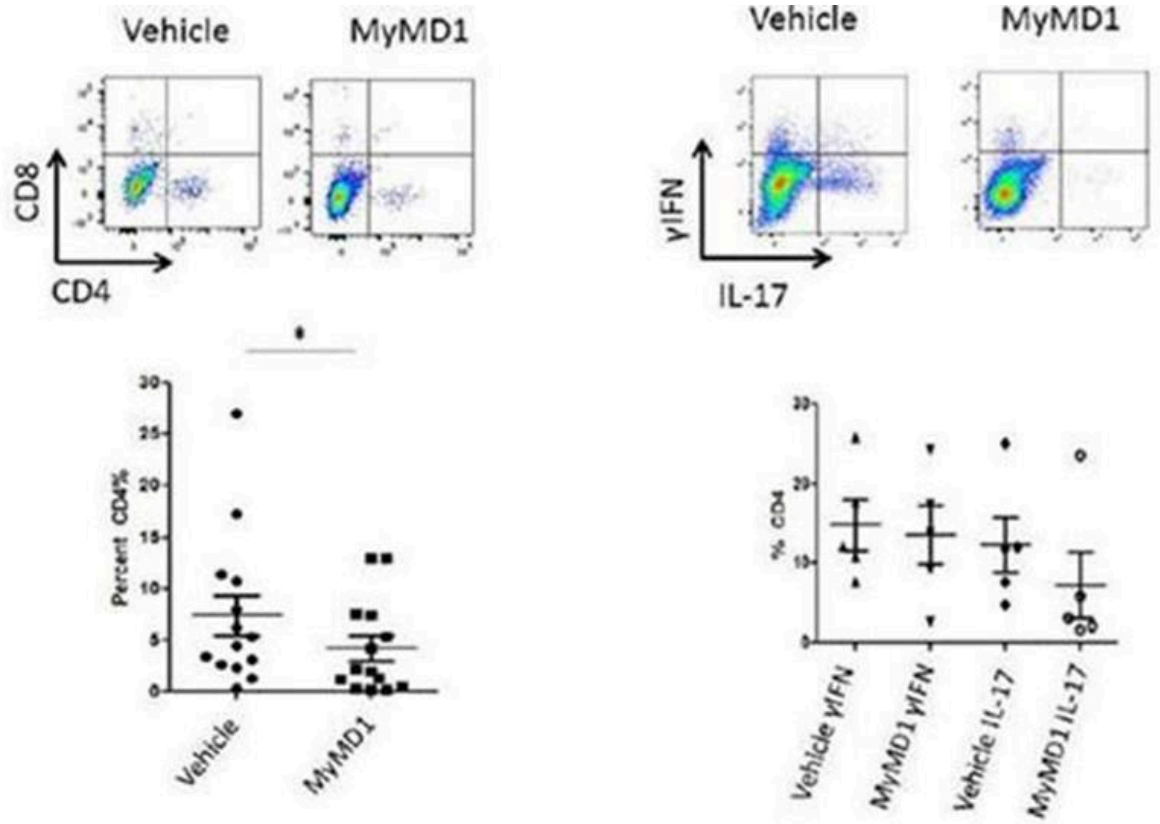


Figure 4. Effects of Isomyosamine on the influx of T cells into the CNS early in EAE. To assess the effects of Isomyosamine on the infiltration of T cells into the CNS, mice were immunized and treated with either vehicle control or 25 mg/mouse/day Isomyosamine. Ten to 14 days later, mice were perfused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

Isomyosamine In Vivo Study of Autoimmune Thyroiditis (NODH.2 Mouse Model)

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

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

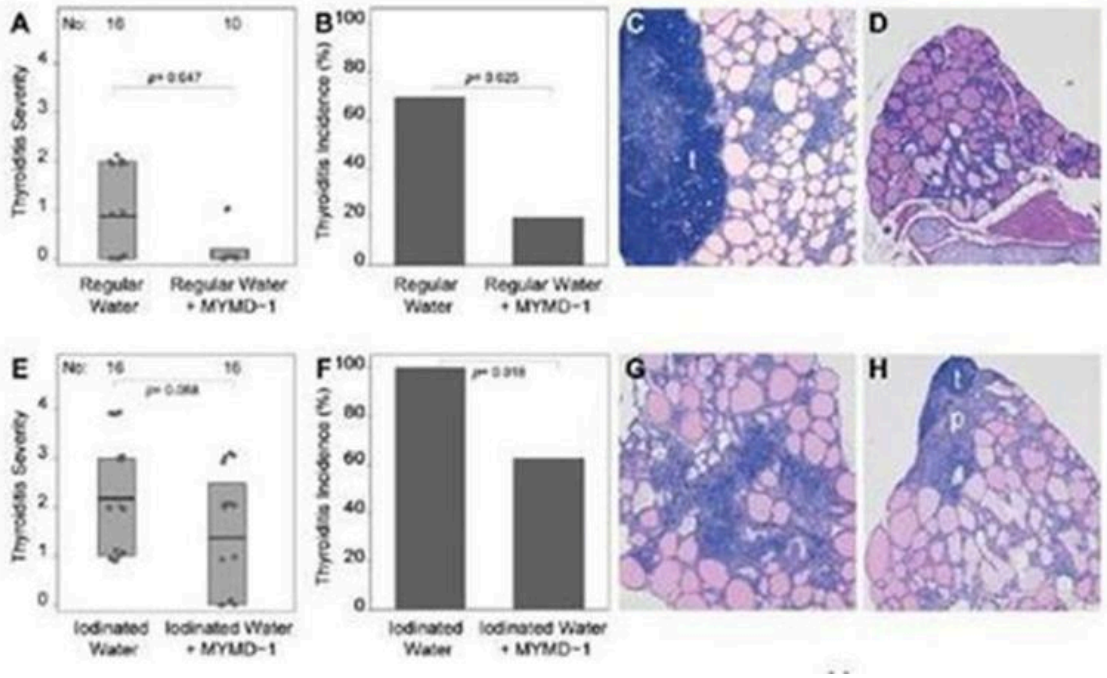

A
No: 16 10
p= 0.047
Thyroiditis Severity
Regular Water
Regular Water + MYMD-1
B
p= 0.025
Thyroiditis Incidence (%)
Regular Water
Regular Water + MYMD-1
C
t
D
E
No: 16 16
p= 0.068
Thyroiditis Severity
Iodinated Water
Iodinated Water + MYMD-1
F
p= 0.318
Thyroiditis Incidence (%)
Iodinated Water
Iodinated Water + MYMD-1
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Figure 5. Isomyosamine decreases the incidence and severity of autoimmune thyroiditis in NOD.H-2h4 mice, as assessed by H&E histopathology. At 8 weeks old, 58 NOD.H-2h4 mice were divided into regular water and iodinated water groups. In the regular water group, 10 mice (7 M, 3 F) drank water that contained Isomyosamine (185 mg/l), and 16 mice (10 M, 6 F) drank water without it. In the iodinated water group, the water was supplemented with 500 mg/l of sodium iodide and contained (16 mice: 10 M, 6 F) or did not contain (16 mice: 10 M, 6 F) Isomyosamine (185 mg/l). After 12 weeks of treatment, thyroids were removed and divided in half. (A and B) Thyroiditis severity and incidence assessed by histopathology in the regular water group. (C) A representative thyroid from a mouse in the regular water group, showing a severity score of 2. (D) A representative thyroid from a mouse in the regular water group treated with Isomyosamine, showing thyroid follicle preservation and an overall normal glandular size (severity score of 0). (E and F) Thyroiditis incidence and severity scores assessed by histopathology in the iodinated water group. (G) A representative thyroid from a mouse in the iodine group, showing marked lymphocytic infiltration, follicular enlargement, and architectural disruption (severity score of 4). (H) A representative thyroid from a mouse in the iodine plus Isomyosamine group (severity score of 2). Results represent the summary of 10 independent experiments, each analyzing 4 to 6 mice, for a total of 58 mice.

Isomyosamine Targets Inflamm-Aging and Related Disorders

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

Isomyosamine Commercialization Targets

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

Supera-CBD

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

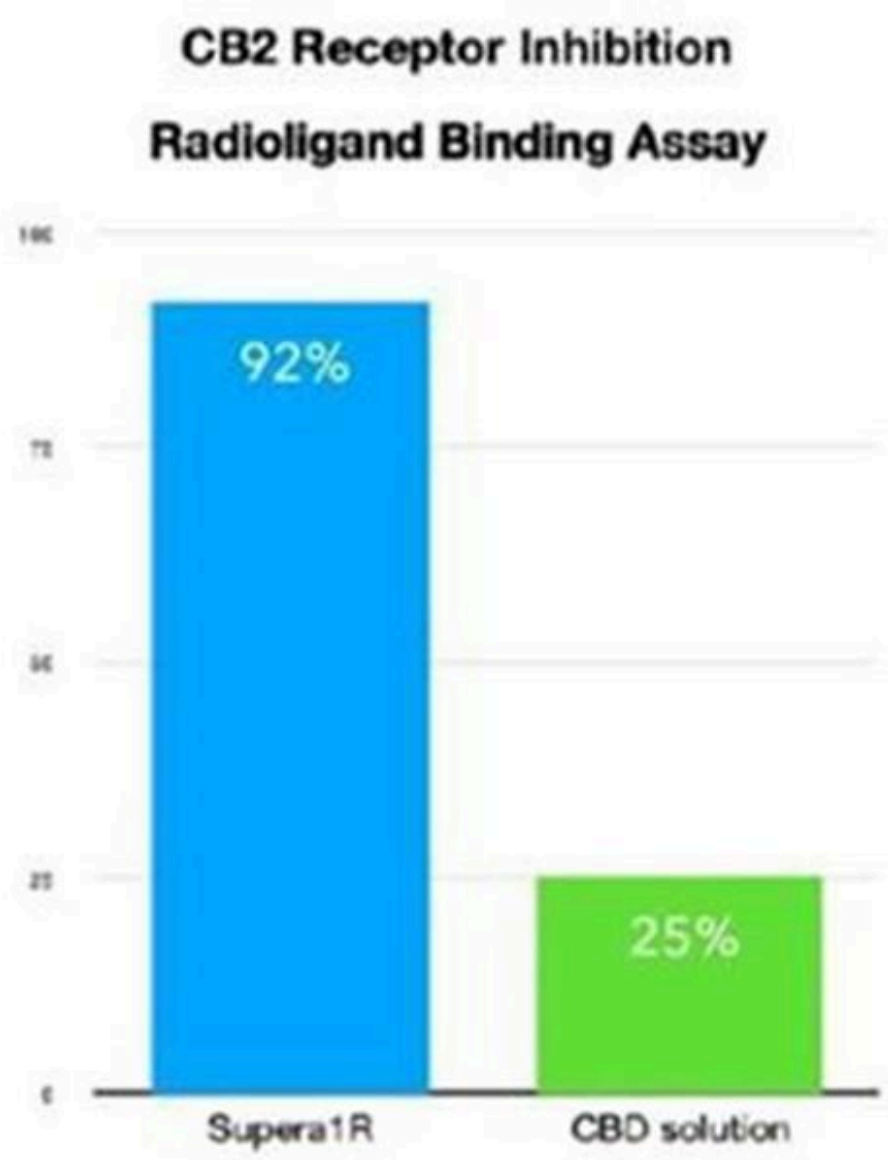
[1] U.S. Department of Health and Human Services. 2020 Profile of Older Americans. May 2021 Page 3.

[2] The Arthritis Foundation. Rheumatoid Arthritis: Causes, Symptoms, Treatments and More.

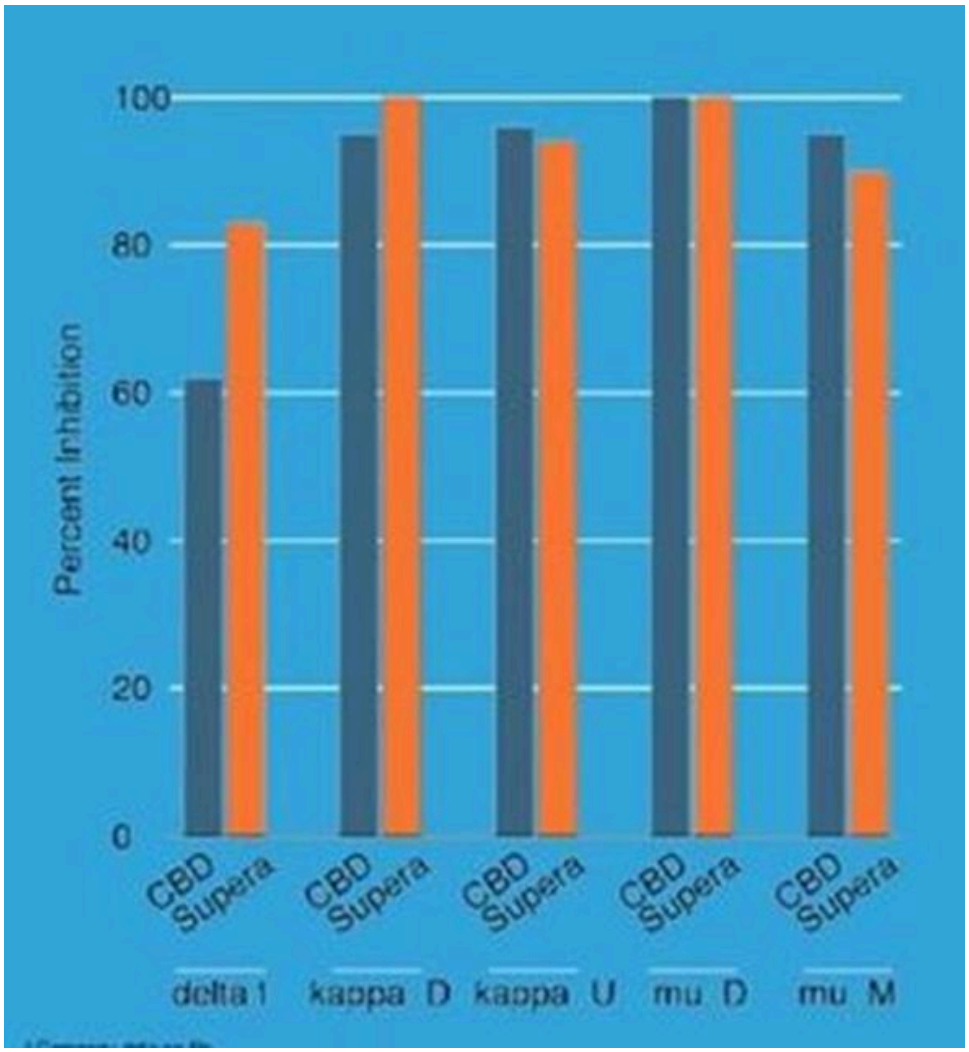
Overview

General Pharmacology and Therapeutic Profile

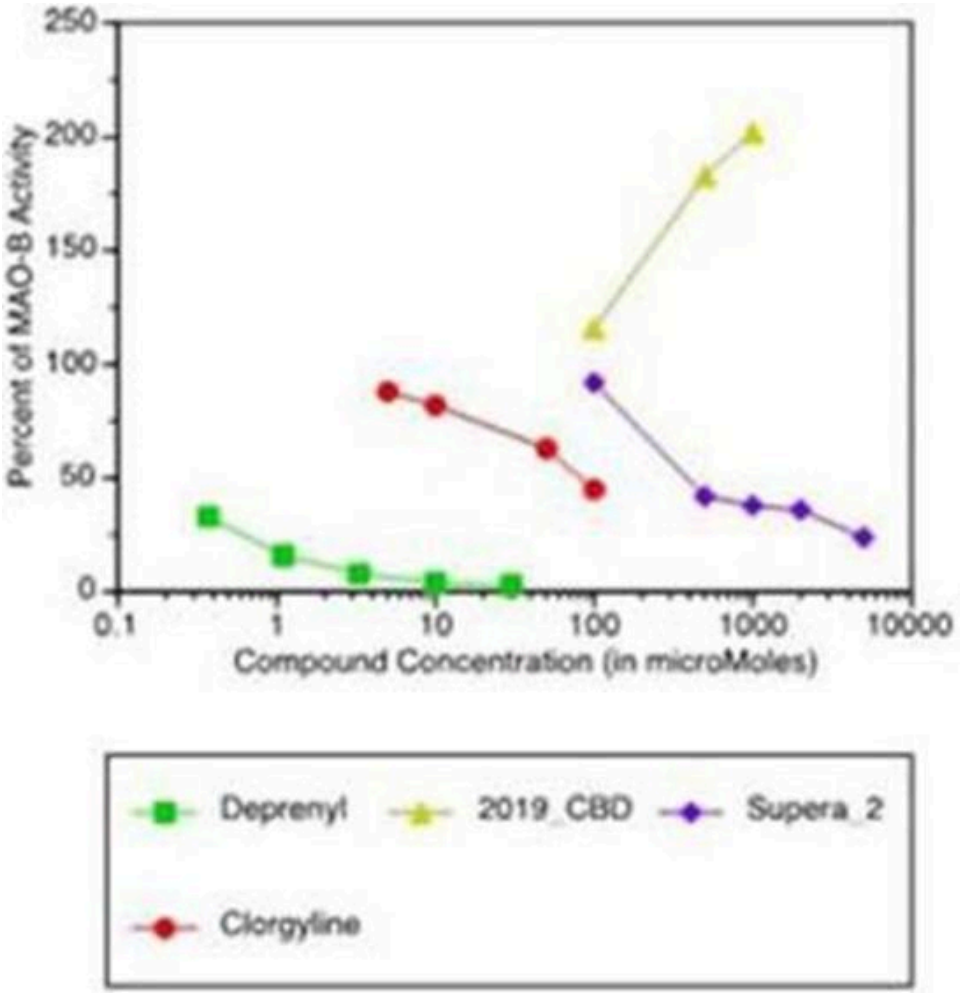
CBD inhibits a number of important receptors, including the CB2 receptor and opioid receptors, and can also inhibit MAO enzymes. In the immune system, one of the important functions of the CB2 receptor is in the regulation of cytokine release from immune cells. Antagonists targeting the CB2 receptor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



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


100
80
60
40
20
0
Percent Inhibition
CBD
Supera
CBD
Supera
CBD
Supera
CBD
Supera
CBD
Supera
delta 1
kappa D
kappa U
mu D
mu M

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



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

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

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

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

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

Sales and Marketing

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

Competition

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

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

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

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

Intellectual Property

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

TNF's patent portfolio includes protection for TNF's lead product candidates, Isomyosamine and Supera-CBD. Currently, there are multiple patent families relating to (i) age reversal and treatments of age-related disorders including sarcopenia; (ii) reduction of TNF-α levels and treatments of autoimmune disorders; (iii) addiction treatments; and (iv) methods of increasing hair growth. As of the date of this document, TNF has 18 issued U.S. patents, one pending U.S. patent application, 69 issued foreign patents, and 5 foreign patent applications pending in such jurisdictions as Canada, China, Israel, and Japan which, if issued, are expected to expire between 2036 and 2041.

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

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

Assignment and Royalty Agreements

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

Government Regulation

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

FDA Approval Process

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

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

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

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

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

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

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

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $4.3 million for fiscal year 2025 and $4 million for fiscal year 2024 (for applications containing clinical data), which increased from $3.2 million for fiscal year 2023. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved NDA is also subject to annual program fees, currently $416,734 for fiscal year 2024 for each prescription product and $403,889 for fiscal year 2025. for each prescription product. The FDA adjusts the user fees on an annual basis, and the fees typically increase annually.

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

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

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

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

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

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

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

Disclosure of Clinical Trial Information

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

Expedited Development and Review Programs

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

Fast-Track Designation

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

Breakthrough Therapy Designation

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

Priority Review Designation

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

Accelerated Approval

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

Post-marketing Requirements

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

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

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

Other Regulatory Matters

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

Other Healthcare Laws

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

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

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

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

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

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

- The federal Physician Payment Sunshine Act of 2021 ("PPSA"), enacted as part of the Patient Protection and Affordable Care Act ("ACA"), imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners.

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

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

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

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

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

Current and Future Healthcare Reform Legislation

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

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

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

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

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

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

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

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, former President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, on August 16, 2022, former President Biden signed into law the Inflation Reduction Act of 2022, which aims to lower prescription drug pricing by, among other things, allowing Medicare to negotiate prices for certain high-cost prescription drugs covered under Medicare Part D and Part B after the drugs have been on the market for a certain number of years and requiring on drug manufacturers to pay rebates if they increase drug prices "faster than inflation." Additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States or the effect of any future legislation or regulation. Furthermore, we cannot assess the impact that President Trump's second term will have on healthcare programs and regulations or the pharmaceutical industry in general. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for our product candidates approved for commercialization in the United States, if any, or any other drug products we may commercialize in the future or that reduce medical procedure volumes could adversely affect our operations and/or future business plans.

Packaging and Distribution in the United States

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

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

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

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

Reimbursement

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

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

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

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

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

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

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

Employees

As of December 31, 2024, TNF had two full-time employees and no part-time employees. TNF has not experienced any work stoppages. None of TNF's employees are represented by a labor union or covered by collective bargaining agreements, and TNF considers its relationship with its employees to be good.

Clinical Studies

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

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

TNF is preparing a Phase 2 study protocol, "Double blind placebo-controlled parallel group study of safety and efficacy of Isomyosamine in treating sarcopenia after hip or femoral fracture in gerontological population" for submission to the FDA. This study will expand upon the prior 28-day dosing study and will evaluate functional improvements in subjects after Isomyosamine dosing of up to 90 days.

A phase II study for rheumatoid arthritis, "A double-blind, randomized, placebo-controlled multicenter Phase II proof-of-concept study to evaluate the efficacy, safety, biological activity, and pharmacokinetics of MYMD-1™ added to methotrexate in patients with moderate-to-severe active rheumatoid arthritis" IND application was reviewed and approved by the FDA to begin clinical trials on August 9, 2023.

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

IND for Autoimmune Diseases

Animal Studies

- 10-month Dog Study – completed on December 20, 2021: A 39-Week Toxicity and Toxicokinetic Study of Isomyosamine by Oral Gavage in Beagle Dogs.
- 6-month Rat Study – completed on December 17, 2021: A 26-Week Toxicity and Toxicokinetic Study of Isomyosamine by Oral Gavage in Rats.
- 5-Day Mouse Study – Completed May 2020 with results pending: A Preliminary Introductory Traumatic Optic Neuropathy (TON) in a Mouse study
- Studies produced guidance on dosing levels and overall safety in human studies.
- TNF in collaboration with Charles River Laboratories completed "A 90-Day Oral Gavage Electroencephalogram Safety Study of A Test Item In The Beagle Dog". Dosing began on December 19, 2023, and ended around March 20, 2024. All animals completed the study and there was no treatment related adverse events reported. A final study report was provided to FDA in December 2024.
- Bascom Palmer in collaboration with TNF completed a study "TNF in Traumatic Optic Neuropathy (TON) in a Rat Pilot Study Vehicle versus TNFalpha". The crush injury raised levels of TNF-α. After being dosed with Isomyosamine, TNF-α levels were brought down in crush injury compared to controls, but the decrease did not meet statistical significance ($p=0.095$). Likely cause of the result not reaching $p<0.05$ may be attributed to rebound (e.g. TNF-α levels would have gone up when Isomyosamine stopped; daily dosing may need to me adjusted. The initial data was promising and will guide a longer study in the future.

Publications

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

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

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

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

TNF with its partner Frontage Laboratories plans to submit an abstract to the 39th Japanese Society for the Study of Xenobiotics (JSSX) and 26th North American Meeting of International Society for the Study of Xenobiotics (ISSX) in Honolulu, Hawaii; September 15-18, 2024. Identification of the Major Circulating Norcotinine and Elucidation of the Mechanism of Clearance of MYMD-1 in Humans. Role of Aldehyde Oxidase and CYP2A6.

On December 7, 2024, TNF presented at The Society on Sarcopenia, Cachexia, & Wasting Disorders (SCWD) 17th International Conference in Washington, D.C. The title of the presentation was, "Isomyosamine for the Treatment of Sarcopenia in Elderly Population."

All publications and abstracts support the continued development of Isomyosamine® across various indications.

IND for Hashimoto's Thyroiditis

- On February 18, 2022, we submitted an Annual Report to the FDA for the previously opened Hashimoto's Thyroiditis IND. Another Annual Report was submitted to the FDA on November 22. 2023.
- In April 2021, the FDA gave clearance for a Phase 1 dosing study in normal healthy volunteers; Institutional Review Board (IRB) approval was obtained on April 4, 2021. The clinical trial was conducted by The Clinical Research of West Florida Phase 1 unit with a closeout visit taking place on November 22, 2021.
- Analyses of laboratory parameters, vital sign, ECG, and physical findings did not reveal any clinically relevant effect of Isomyosamine. In one dose group, there was a decrease in TNF-α levels found in Isomyosamine treated subjects, but no change in the levels in subjects given placebo. In one dose group, there was a decrease in TNF-α levels found in Isomyosamine treated subjects, but no change in the levels in subjects given placebo.
- The data from the Phase 1 clinical trial was submitted to the FDA on September 14, 2021 as part of the Annual IND update for Hashimoto's Thyroiditis IND. The FDA responded by providing guidance on moving forward with Phase 2 clinical trials.
- This data was also included in a new commercial IND to the FDA on September 22, 2021.

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

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

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

In November 2022, the Company published data from the Phase 1 dosing study for Isomyosamine as a treatment for aging.

On August 5, 2021, our lead product candidate Isomyosamine was shown to suppress cytokines, which are the major cause of death in COVID-19 patients, in a human cell study. TNF may also seek additional FDA guidance on depression in MS patients under an Orphan Drug Designation (ODD).

On October 3, 2023, Charles River Laboratories provided a final report titled, "A Dose Range-Finding Embryo-fetal Development Study of MYMD-1 by Oral (Gavage) in Rats." The results of this study found that there were no drug-related fetal malformations or variations at any of the evaluated doses.

We have an active IND to start a Phase 2 study for the indication Hashimoto's Thyroiditis.

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

We have received domestic patent protection for Isomyosamine, including its use in methods of extending lifespan and treating arthritis, autoimmune diseases, and inflammatory and age-related disorders including sarcopenia. We will continue to prosecute patents to protect intellectual property for Isomyosamine in the United States and abroad. Patent Issued March 26, 2024: US Application 17/851,862: Method of Treating Diseases of the Visual System.

Supera-CBD Product Candidate

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

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

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

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

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

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

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

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

An example of our continued efforts include:

- the JHM Research, which is conducting a study with Isomyosamine and L/R-Supera-CBD for Depression and Anxiety;
- Forced Swim Test;
- Tail suspension;
- Elevated Plus Maze and Fear Conditioning;
- Dose response study;
- Supera-CBD open field and Y maze study; and
- Isomyosamine LPS induced depression.

Management Plans for 2025

TNFA plans to launch a Phase 2b clinical trial of isomyosamine's efficacy in sarcopenia early in the first quarter of 2025. The study will further explore the drug's efficacy in sarcopenia/frailty following statistically significant positive results from an earlier Phase 2 clinical study.

On October 19 2024, the Company announced that it has entered into a collaborative agreement with Renova Health for a planned trial of its TNF-alpha (TNF-α) inhibitor drug Isomyosamine as a treatment for GLP-1-induced sarcopenia and frailty. The fully funded study is expected to evaluate TNF-α levels in patients receiving GLP-1 agonist Wegovy or Ozempic who show signals for increased inflammation associated with sarcopenia.

Available information

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

Item 1A. Risk Factors.

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

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

Risk Factor Summary

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

Risks Related to our Business

- Our financial statements have been prepared on a going concern basis; we must raise additional capital to fund our operations in order to continue as a going concern.
- 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 will likely limit the ability of our stockholders to influence corporate matters.
- 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.
- Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security or those of third-party providers.

Risks Related to our Product Development and Regulatory Approval

- If we are unable to develop, obtain regulatory approval for and commercialize Isomyosamine, 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 Isomyosamine, 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.

- Potential future public health crises could have a material adverse impact the execution of our planned clinical trials.

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

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

Risks Related to Commercialization and Manufacturing

- The commercial success of our product candidates, including Isomyosamine 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 Isomyosamine, 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 Isomyosamine, Supera-CBD or our other product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.

Risks Related to Government Regulation

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

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

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

Risks Related to Our Intellectual Property

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

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

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

Risks Related to Our Preferred Stock

- Our Series F Convertible Preferred Stock (the "Series F Preferred Stock") and Series F-1 Convertible Preferred Stock ("Series F-1 Preferred Stock") provides for the payment of dividends in cash or in shares of our Common Stock. If we pay such dividends in shares of Common Stock, it may result in dilution to existing investors.

- Holders of our Series F Preferred Stock, Series F-1 Preferred Stock and Series G Convertible Preferred Stock ("Series G Preferred Stock") are entitled to certain payments under the Certificate of Designation that may be paid in cash or in shares of Common Stock depending on the circumstances. If we make these payments in cash, it may require the expenditure of a substantial portion of our cash resources. If we make these payments in Common Stock, it may result in substantial dilution to the holders of our Common Stock.

- The certificate of designation for the Series F Preferred Stock, Series F-1 Preferred Stock, Series G Preferred Stock and the warrants issued concurrently therewith contain anti-dilution provisions that may result in the reduction of the conversion price of the Series F Preferred Stock or the exercise price of such warrants in the future. These features may result in an indeterminate number of shares of Common Stock being issued upon conversion of the Series F Preferred Stock, Series F-1 Preferred Stock, Series G Preferred Stock or exercise of the warrants.

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

Risks Related to our Business

Our financial statements have been prepared on a going concern basis; we must raise additional capital to fund our operations in order to continue as a going concern.

In its report dated April 1, 2024, Morison Cogen LLP, our independent registered public accounting firm, expressed substantial doubt about our ability to continue as a going concern as we have suffered recurring losses from operations and have insufficient liquidity to fund our future operations. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. As of December 31, 2024, we had approximately $8.5 million of cash and marketable securities. In order to have sufficient cash to fund our operations in the future, we will need to raise additional equity or debt capital and cannot provide any assurance that we will be successful in doing so. If are unable to raise sufficient capital to fund our operations, 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 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 Isomyosamine and Supera-CBD and potentially commercialize these product candidates. We expect increased spending levels in connection with our clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to commercial launch, product sales, medical affairs, regulatory, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations before any commercial revenue may occur.

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

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

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

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

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

The market price of our Common Stock has been and could continue to be subject to significant fluctuation following. Market prices for securities of life sciences and biopharmaceutical companies in particular have historically been volatile and have shown extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our Common Stock, regardless of the actual operating performance of the combined company. Some of the factors that may cause the market price of our Common Stock to fluctuate include:

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

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

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

We have incurred net losses in each year since our inception. We incurred net losses attributable to shareholders of $27,161,219 and $8,218,163 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $129,080,851. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in the company incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.

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

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

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

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

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

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

Our largest stockholder maintains the ability to significantly influence all matters submitted to our stockholders for approval.

As of April 4, 2025, our largest stockholder, PharmaCyte Biotech, Inc. ("Pharmacyte") beneficially owns approximately 88.64% of the issued and outstanding Common Stock of the Company. As a result, if Pharmacyte may be able to significantly influence all matters submitted to the Company's stockholders for approval, as well as the Company's management and affairs. For example, Pharmacyte could significantly influence the election of directors or the approval of any merger, consolidation or sale of all or substantially all of the Company's assets. This concentration of voting power could delay or prevent an acquisition of the Company on terms that other

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 Isomyosamine, Supera-CBD and our other product candidates. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

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

We operate in a highly competitive industry.

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

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

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

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

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

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

In the ordinary course of our business, we and our third-party providers rely on electronic communications and information system to conduct our operations. We and our third-party providers have been, and may continue to be, targeted by parties using fraudulent e-mails and other communications in attempts to misappropriate bank accounting information, passwords, or other personal information or to introduce viruses or other malware to our information systems. On July 20, 2023, we experienced a cybersecurity incident. A third-party forensic technology company's investigation confirmed that we were a victim of wire fraud due to a compromised electronic mail account. As of the date of this filing, we have identified losses totaling $78,198 related to this incident, net of amounts recovered. Following the incident, we have taken measures to enhance our electronic mail security and have modified our internal procedures to ensure the authenticity of payment instructions and we continue to evaluate additional measures for improving cybersecurity. Despite these prophylactic measures, the risk of such cyber-attacks against us or our third-party providers and business partners remains a serious issue. Cybersecurity incidents are pervasive, and the risks of cybercrime are complex and continue to evolve. Although we are making significant efforts to maintain the security and integrity of our information systems and are exploring various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging.

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

Risks Related to our Product Development and Regulatory Approval

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

Potential Risks

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

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

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

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

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

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

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

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

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

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

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

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organization ("CRO") and clinical trial sites;
- delays in opening clinical trial sites or obtaining required IRB or independent ethics committee approval at each clinical trial site;
- actual or perceived lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues, such as drug interactions, including those which cause confounding changes to the levels of other concomitant medications;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects for the entire duration of applicable clinical studies (as study subjects may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- inadequacy of or changes in its manufacturing process or product candidate formulation;
- delays in obtaining regulatory authorization s, such as INDs and any others that must be obtained, maintained, and/or satisfied to commence a clinical trial, the imposition of "clinical holds" or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- changes in applicable regulatory policies and regulation, including changes to requirements imposed on the extent, nature or timing of studies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- delay or failure to supply products for use in clinical trials which conforms to regulatory specification , or otherwise do not comply with required manufacturing obligations, such as cGMPs;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- failure of its CROs, or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- Our failure, or the failure of any individuals, entities, or organizations involved in one or more aspects of our clinical development activities, to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- regulatory concerns and additional difficulties associated with cannabinoid products, generally;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow its clinical protocols; or
- difficulty in maintaining contact with patients during or after treatment, which may result in incomplete data.

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

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

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

Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of Isomyosamine, 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. Isomyosamine 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.

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

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

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

Success in pre-clinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, including our Phase 2 clinical trial for Isomyosamine, 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, this 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 this 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 Isomyosamine and Supera-CBD, to the satisfaction of the FDA or foreign regulatory authorities, then the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld or withdrawn.

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

Prior to commercialization in the United States, Isomyosamine, Supera-CBD and our other product candidates must be approved by the FDA pursuant to an NDA for their respective target indication(s). The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market Isomyosamine, 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 Isomyosamine, 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 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.

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 cGMPs, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

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

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

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

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

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

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

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

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

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

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

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

Further, the success of our prospective Supera-CBD candidate, if any, is subject to a number of constantly-evolving state and federal laws, regulations, and enforcement policies pertaining to the use of 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 local jurisdictions have also established controlled substance laws and regulations, which may differ from U.S. federal law. States have also developed CBD-specific laws and regulations that govern a wide range of CBD-related activities, from cultivation to processing to marketing. There is substantial variation among states' CBD laws, and we will have to devote substantial time, expenses, and resources toward compliance, and such laws are also subject to ongoing evolution and, thus, must be actively monitored. We or our business partners may be required to obtain separate state or country registrations, permits or licenses in order to be able to develop produce, sell, store and transport cannabinoids.

Compliance is Complex and Costly. Complying with laws and regulations relating to cannabinoids is evolving, complex and expensive, and may divert management's attention and resources from other aspects of our business. Failure to maintain compliance with such laws and regulations may result in regulatory action that could have a material adverse effect on our business, results of operations and financial condition. The DEA, FDA or state agencies may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. Additionally, to the extent we are able to successfully commercialize any of our currently contemplated CBD products, including Supera-CBD, the presence of CBD as an active or inactive ingredient may give rise to heightened regulatory scrutiny and greater risk of consumer litigation, either of which could further restrict the permissible scope of our marketing claims about such products or our ability to sell them in the U.S. at all.

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

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

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

Risks Related to Commercialization and Manufacturing

The commercial success of our product candidates, including Isomyosamine 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 Isomyosamine, 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 Isomyosamine, 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 third-party 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 Isomyosamine, 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 Isomyosamine, Supera-CBD or our other product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

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

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

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, former President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, in August 2022, the Inflation Reduction Act ("IRA") was signed into law, which will, among other things, allow U.S. Department of Health and Human Services ("HHS") to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services ("CMS") reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA also began penalizing drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. Additionally, in December, 2023, the Biden Administration announced further related initiatives under the IRA to lower prescription costs and increase competition with help from HHS, the DOJ, and the FTC.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S. or the effect of any future legislation or regulation. Furthermore, we cannot asses the impact that President Trump's second term will have on healthcare programs and regulations or the pharmaceutical industry in general. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the U.S. in the future, as applicable.

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

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

- fines, injunctions and civil penalties;
- recall, detention or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension or total shutdown of production;
- withdrawing approval of a marketing application; and
- criminal prosecution.

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

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

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

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the pharmaceutical industry. Recently, the U.S. Office of Management and Budget issued a memo that instructed agencies, including the FDA, to implement reductions in the workforce. If such reductions result in staffing cuts at the FDA, there may be delays in the review and approval of drug candidates, which may delay our ability to market any current or future drug candidates.

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.

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

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

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

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

On July 20, 2023, we experienced a cybersecurity incident. A third-party forensic technology company's investigation confirmed that we were a victim of wire fraud due to a compromised electronic mail account. As of the date of this filing, we have identified losses totaling $78,198 related to this incident, net of amounts recovered. Following the incident, we have taken measures to enhance our electronic mail security and have modified our internal procedures to ensure the authenticity of payment instructions and we continue to evaluate additional measures for improving cybersecurity. Despite these prophylactic measures, the risk of such cyber-attacks against us or our third-party providers and business partners remains a serious issue. Cybersecurity incidents are pervasive, and the risks of cybercrime are complex and continue to evolve.

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

Risks Related to Our Intellectual Property

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

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

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

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

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

Currently, TNF has 18 issued U.S. patents, 69 issued foreign patents, one pending U.S. patent applications, and five foreign patent applications pending in such jurisdictions as Canada, China, Israel, and Japan, which if issued are expected to expire between 2036 and 2041. Although we expect to obtain additional patents and in-licenses in the future, there is no guarantee that we will be able to successfully obtain such patents or in-licenses in a timely manner or at all. Further, any of our rights to existing patents, and any future patents issued to us, may be challenged, invalidated or circumvented. As such, any rights granted under these patents may not provide us with meaningful protection. Even if foreign patents are granted, effective enforcement in foreign countries may not be available. If our patents or rights to patents do not adequately protect our technology or processes, competitors may be able to offer products similar to our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing, selling or importing our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights or proprietary technology to us, which it is not required to do in the U.S. and certain other countries, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates;
- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Preferred Stock

Holders of our Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock are entitled to certain payments under the applicable Certificate of Designations that may be paid in cash, in shares of Common Stock or in additional shares of Series G Preferred Stock depending on the circumstances. If we make these payments in cash, it may require the expenditure of a substantial portion of our cash resources. If we make these payments in Common Stock, it may result in substantial dilution to the holders of our Common Stock.

Under the Series F Certificate of Designations and Series F-1 Certificate of Designations, we are required to redeem the shares of the shares of the Series F Preferred Stock and Series F-1 Preferred Stock in equal monthly installments commencing July 1, 2023, and December 1, 2024, respectively. Such holders are also entitled to receive dividends, payable in arrears monthly, and dividends payable on installment dates shall be paid as part of the applicable installment amount. Installment amounts are payable, at the Company's election, in shares of Common Stock or, subject to certain limitations, in cash. Installment amounts paid in cash must be paid in the amount of 105% of the applicable payment amount due.

Our ability to make payments due to the holders of our Series F Preferred Stock and Series F-1 Preferred Stock using shares of Common Stock is subject to certain limitations set forth in the applicable Certificate of Designations. If we are unable to make installment payments in shares of Common Stock, we may be forced to make such payments in cash. Additionally, the holders of the Series G Preferred Stock are entitled to dividends of 10% per annum, compounded monthly, which are payable in arrears monthly, at the holder's sole discretion, in cash, or "in kind" in the form of additional Series G Preferred Stock, or a combination thereof. If we do not have sufficient cash resources to make these payments, we may need to raise additional equity or debt capital, and we cannot provide any assurance that we will be successful in doing so. If are unable to raise sufficient capital to meet our payment obligations, we may need to delay, reduce or eliminate certain research and development programs or other operations, sell some or all of our assets or merge with another entity.

Our ability to make payments due to the holders of our Series F Preferred Stock, Series G Preferred Stock, Series F-1 Preferred Stock using cash is also limited by the amount of cash we have on hand at the time such payments are due as well as certain provisions of the Delaware General Corporation Law (the "DGCL"). Further, we intend to make the installment payments due to holders of Series F Preferred Stock and Series F-1 Preferred Stock in the form of Common Stock to the extent allowed under the applicable Certificate of Designation and applicable law in order to preserve our cash resources. The issuance of shares of Common Stock to the holders of our Series F Preferred Stock and Series F-1 Preferred Stock with increase the number of shares of Common Stock outstanding and could result in substantial dilution to the existing holders of our Common Stock.

The Certificate of Designations for the Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock and the warrants issued concurrently therewith contain anti-dilution provisions that may result in the reduction of the conversion price of the applicable preferred stock or the exercise price of such warrants in the future. These features may increase the number of shares of Common Stock being issuable upon conversion of the Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock or upon the exercise of the warrants.

The Series F Certificate of Designations, Series F-1 Certificate of Designations and Series G Certificate of Designations and the warrants issued concurrently therewith, contain anti-dilution provisions, which provisions require the lowering of the applicable conversion price or exercise, as then in effect, to the purchase price of equity or equity-linked securities issued in subsequent offerings. If in the future, while any of our Series F Preferred Stock, Series F-1 Preferred Stock, Series G Preferred Stock, Series F Warrants, Series F-1 Warrants or Series G Warrants are outstanding, we issue securities for a consideration per share of Common Stock (the "New Issuance Price") that is less than the applicable conversion price of our preferred stock or the exercise price of the Series F Warrants, Series F-1 Warrants or Series G Warrants, as then in effect, we will be required, subject to certain limitations and adjustments as provided in the applicable Certificate of Designations or the applicable warrants, to reduce the conversion price or the exercise price to be equal to the New Issuance Price, which will result in a greater number of shares of Common Stock being issuable upon conversion or exercise, as applicable, which in turn will increase the dilutive effect of such conversion or exercise on existing holders of our Common Stock. It is possible that we will not have a sufficient number of shares available to satisfy the conversion of the Series F Preferred Stock, Series F-1 Preferred Stock or Series G Preferred Stock or the exercise of the Series F Warrants, Series F-1 Warrants or Series G Warrants if we enter into a future transaction that reduces the applicable conversion price or exercise price. If we do not have a sufficient number of available shares for any such conversions or any such warrant exercises, we may need to seek stockholder approval to increase the number of authorized shares of our Common Stock, which may not be possible and will be time-consuming and expensive. The potential for such additional issuances may depress the price of our Common Stock regardless of our business performance and may make it difficult for us to raise additional equity capital while any of our Series F Preferred Stock, Series F-1 Preferred Stock, Series G Preferred Stock or Series F Warrants, Series F-1 Warrants or Series G Warrants are outstanding.

Under the February 2023 SPA, the Series F-1 Purchase Agreement and Series G Purchase Agreement we are subject to certain restrictive covenants that may make it difficult to procure additional financing.

The February 2023 SPA, pursuant to which we issued the Series F Preferred Stock, contains, among others, the following restrictive covenants: (i) until all of the Series F Warrants are exercised, we agreed not to enter into any variable rate transactions; and (ii) until the later of no shares of Series F Preferred Stock being outstanding and the maturity date of the Series F Preferred Stock, the opportunity to participate in any subsequent securities offerings by us. The Series F-1 Purchase Agreement, pursuant to which we issued the Series F-1 Preferred Stock, contains, among others, the following restrictive covenants: (i) until all of the Series F-1 Warrants are exercised, we agreed not to enter into any variable rate transactions; and (ii) until the later of no shares of Series F-1 Preferred Stock being outstanding and the maturity date, the opportunity to participate in any subsequent securities offerings by us. The Series G Purchase Agreement, pursuant to which we issued the Series G Preferred Stock, contains, among others, the following restrictive covenants: (i) until all of the Series G Warrants are exercised, we agreed not to enter into any variable rate transactions; and (ii) until the later of no shares of Series G Preferred Stock being outstanding and the second anniversary of the Series G Closing Date, the opportunity to participate in any subsequent securities offerings by us.

If we require additional funding while these restrictive covenants remain in effect, we may be unable to effect a financing transaction while remaining in compliance with the terms of the February 2023 SPA or Purchase Agreements, or we may be forced to seek a waiver from the investors party to the February 2023 SPA and Purchase Agreements.

General Risk Factors

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

Sales of a significant number of shares of our Common Stock in the public market could harm the market prices of our Common Stock and make it more difficult for us to raise funds through future offerings of Common Stock or other securities. Our stockholders and the holders of our options and warrants may sell substantial amounts of our Common Stock in the public market. In addition, we may be required to issue shares of Common Stock to the holders of our Series F Preferred Stock, Series F-1 Preferred Stock or Series G Preferred Stock upon conversion of such shares of our Series F Preferred Stock and the payment of the dividends thereunder in Common Stock as a result of the full ratchet anti-dilution price protection in the Certificate of Designation if the effective Common Stock purchase price in a subsequent offering is less than the then current conversion price, which in turn will increase the number of shares of Common Stock available for sale. See "Risk Factors—Risks Related to Our Series F Preferred Stock—The Certificate of Designations for the Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock and the warrants issued concurrently therewith contain anti-dilution provisions that may result in the reduction of the conversion price of the applicable preferred stock or the exercise price of such warrants in the future. These features may increase the number of shares of Common Stock being issuable upon conversion of the Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock or upon the exercise of the warrants."

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

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

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

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

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

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

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

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

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum stockholders' equity of $2.5 million and a minimum closing bid price of $1.00 per share or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from The Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

As previously disclosed, on March 17, 2025, we received a written notice (the "Notice") from the Listing Qualifications Department of the Nasdaq Stock Market indicating that for the last 30 consecutive business days, the bid price for our Common Stock had closed below the minimum $1.00 per share requirement for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The letter also indicated that the Company will be provided with a compliance period until September 15, 2025 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

Effective as of 4:05 p.m. Eastern Standard Time on February 14, 2024, we effected the Reverse Stock Split of our common stock at a ratio of one-for-thirty. Simultaneously with the Reverse Stock Split, number of shares of our common stock authorized for issuance was reduced from 500,000,000 shares to 16,666,666 shares, and our authorized capital stock was reduced from 550,000,000 shares to 66,666,666 shares. Our common stock continued to be traded on the Nasdaq Capital Market under the symbol TNF and began trading on a split-adjusted basis at market open on February 15, 2024. On March 4, 2024, we were notified by Nasdaq that we had regained compliance with all Nasdaq listing requirements and the matter was closed.

There is no assurance that we will maintain compliance with such minimum listing requirements. If our common stock were delisted from Nasdaq, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

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.

In addition, we may be required to issue an indeterminate number of shares of Common Stock to the holders of our Series F Preferred Stock, Series F-1 Preferred Stock, Series G Preferred Stock and related warrants upon the conversion or exercise of either, as applicable. See "Risk Factors—Risks Related to Our Preferred Stock—Holders of our Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock are entitled to certain payments under the applicable Certificate of Designations that may be paid in cash, in shares of Common Stock or in additional shares of Series G Preferred Stock depending on the circumstances. If we make these payments in cash, it may require the expenditure of a substantial portion of our cash resources. If we make these payments in Common Stock, it may result in substantial dilution to the holders of our Common Stock.." and "Risk Factors—Risks Related to Our Preferred Stock—The Certificate of Designations for the Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock and the warrants issued concurrently therewith contain anti-dilution provisions that may result in the reduction of the conversion price of the applicable preferred stock or the exercise price of such warrants in the future. These features may increase the number of shares of Common Stock being issuable upon conversion of the Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock or upon the exercise of the warrants."

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

We have never declared or paid cash dividends on our Common Stock and do not expect to do so in the foreseeable future. So long as any shares of Series F Preferred Stock, Series F-1 Preferred Stock or Series G Preferred Stock are outstanding, as they are at this time, we are not able to declare or pay any cash dividend or distribution on any of our capital stock (other than as required by the respective Certificate of Designations) without the prior written consent of the Required Holders (as defined in the respective Certificate of Designations). The declaration of dividends is further subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant our board of directors. You should not rely on an investment in us if you require dividend income from your investment in us. The success of your investment will likely depend entirely upon any future appreciation of the market price of our Common Stock, which is uncertain and unpredictable. There is no guarantee that our Common Stock will appreciate in value.

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

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

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. These provisions also could limit the price that investors might be willing to pay in the future for our securities, thereby depressing the market price of our securities. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- authorize our board of directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholder meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law that may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

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

We have been subject to a number of litigations as described elsewhere in this Annual Report on Form 10-K and in Note 8 to our consolidated financial statements. In connection with certain of these litigations, we have entered into settlements of claims for significant monetary damages. We may also be subject to judgements or enter into additional settlements of claims for significant monetary damages for the securities litigations that we have yet to enter into settlement agreements. Defending against the current litigations is or can be time-consuming, expensive and cause diversion of our management's attention.

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

We operate as a pre revenue company in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees; violation of privacy laws and other litigation and legal risk; and reputational risk. We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats. Both our executive management team and our board of directors are involved in the assessment, identification, and management of such risks, including prevention, mitigation, detection, and remediation of cybersecurity incidents. We do not engage outside assessors, consultants, auditors or other third parties in connection with our assessment, identification and management of material risks associated with cybersecurity threats.

Our executive management team, including our president and chief financial officer, are responsible for day-to-day assessment, identification and management of material risks from cybersecurity threats, including the prevention, mitigation, detection, and remediation of cybersecurity incidents. The executive management team monitors current events in order to remain aware of current cybersecurity threats and is informed of cybersecurity incidents as they arise by our employees. Our president and chief financial officer are experienced business executives and as such have experience with regard to assessing and managing such cybersecurity risks. Our executive management team reports information about such cybersecurity risks to the board of directors.

Our board of directors is responsible for oversight of risks from cybersecurity threats in conjunction with our executive management team. Our board of directors receives updates from our management team with respect to risks from cybersecurity threats and are notified of any new significant cybersecurity threats or incidents as they arise. Additionally, our board of directors considers risks from cybersecurity threats as part of its overall assessment of risk management, including its general oversight of the Company's business strategy, risk management policies, and financials.

To date, no cybersecurity incident (or aggregation of incidents) or cybersecurity threat has materially affected our business strategy, results of operations or financial condition, and we are not aware of any cybersecurity incidents that are reasonably likely to materially affect the Company, including our business strategy, results of operations, or financial condition. For further information regarding the risks associated with cybersecurity incidents, see "Risk Factors—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 Item 1A of this Annual Report on Form 10-K.

Item 2. Properties.

The Company utilities a shared office and service provider as its current corporate headquarters located at 1185 Avenue of the Americas, Suite 249, New Yok, NY 10036. The Company's monthly service fee is $136.

The Company leased its former corporate headquarters at an office facility located at 855 North Wolfe Street, Suite 601, Baltimore, Maryland 20215 (the "Maryland Lease"). The Maryland Lease, as amended, had an initial twelve-month term beginning on May 1, 2024, which term automatically renewed thereafter until termination by either party upon 60 days' notice. The monthly rent of the Maryland Lease is $2,700 and automatically increases 3% on each anniversary date beginning May 1, 2025. On February 26, 2025, the Company provided notice of its intention not to renew the Maryland Lease, effective April 30, 2025.

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

Item 3. Legal Proceedings.

From time to time, we are a party to litigation and subject to claims incident to the ordinary course of business. Future litigation may be necessary to defend ourselves and our customers by determining the scope, enforceability, and validity of third-party proprietary rights or to establish our proprietary rights. For a discussion of material legal proceedings affecting us as of December 31, 2024, please read Note 8 to the consolidated financial statements under "Litigation and Settlements," which information is incorporated herein by reference.

Item 4. Mine Safety Disclosures.

Not Applicable.

Part II

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

Market Information

Our Common Stock began trading on the Nasdaq Capital Market under the symbol "AKER" on January 23, 2014. On April 19, 2021, the symbol for our Common Stock changed to "MYMD." On July 22, 2024, the symbol for our Common Stock changed to "TNF."

Holders

As of April 4, 2025, there were approximately 735 holders of record of our Common Stock.

Dividends

Except as described herein, we have never paid any cash or other dividends to our stockholders and we do not plan to declare or pay any cash or other dividends in the foreseeable future. On or around September 9, 2020, our Board declared a dividend of one preferred share purchase right for each share of our Common Stock outstanding held by stockholders of record on September 21, 2020.

We currently intend to retain earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board and will depend on such factors as earning levels, contractual restrictions, capital requirements, our overall financial condition and any other factors deemed relevant by the Board. In addition, so long as any shares of Series F Preferred Stock, Series F-1 Preferred Stock or Series G Preferred Stock are outstanding, we are not able to declare or pay any cash dividend or distribution on any of our capital stock (other than as required by the respective Certificate of Designations) without the prior written consent of the Required Holders (as defined in the respective Certificate of Designations).

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

We did not re-purchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2024.

Item 6. [Reserved]

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

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

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

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

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

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

- fluctuation and volatility in market price of our Common Stock due to market and industry factors, as well as general economic, political and market conditions;
- the impact of dilution on our stockholders;
- the outcome of litigation or other proceedings we may become subject to in the future;
- the impact of our ability to meet the continued listing requirements of the Nasdaq Capital Market;
- our availability and ability to continue to obtain sufficient funding to conduct planned research and development efforts and realize potential profits;
- our ability to develop and commercialize our product candidates, including Isomyosamine, 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 potential future impact of pandemics 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 future pandemics on our results of operations, business plan and the global economy;
- challenges we may face with respect to our product candidates achieving market acceptance by providers, patients, patient advocacy groups, third party payors and the general medical community;
- the impact of pricing, insurance coverage and reimbursement status of our product candidates;
- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain, maintain and protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on its proprietary rights;
- our ability to maintain adequate cyber security and information systems;
- our ability to achieve the expected benefits and costs of the transactions related to the acquisition of Supera Pharmaceuticals, Inc. ("Supera");
- our ability to effectively execute and deliver our plans related to commercialization, marketing and manufacturing capabilities and strategy;
- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain adequate financing in the future on reasonable terms, as and when we need it;
- challenges we may face in identifying, acquiring and operating new business opportunities;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate; and
- our compliance with all laws, rules, and regulations applicable to our business.

Overview

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

- Isomyosamine is a clinical stage small molecule that regulates the immunometabolic system to treat autoimmune disease, including (but not limited to) sarcopenia, frailty, adverse effects of drugs used to treat diabetes and obesity, rheumatoid arthritis, and inflammatory bowel disease. The first indication for which Isomyosamine is being developed is to treat age-related frailty and sarcopenia. Isomyosamine works by regulating the release of numerous pro-inflammatory cytokines, such as TNF-α, interleukin 6 ("IL-6") and interleukin 17 ("IL-17")

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

The rights to Supera-CBDTM were previously owned by Supera Pharmaceuticals, Inc. ("Supera") and were acquired by MyMD Florida (as defined below) immediately prior to the closing of the Merger (as defined below) that occurred in 2021.

Reduction in Workforce

During October 2023, the Company implemented a reduction in workforce, eliminating three of the Company's ten employees. Separated employees were granted a severance package equal to one-quarter of their annual salary.

On June 7, 2023, the Company granted the three separated employees' options to purchase an aggregate of 7,668 shares of Common Stock with an exercise price of $47.10 per share. As consideration for a waiver and release in their separation agreements, the Company amended the employees' respective June 7, 2023 option agreements to accelerate vesting of the portion of optioned shares that otherwise would have vested upon the first and second anniversaries of the date of grant. The options have an exercise period of twelve months from the date of separation.

Going Concern

As of December 31, 2024, the Company's cash on hand was $173,154 and marketable securities were $8,345,082. The Company has incurred a net loss attributable to shareholders of $27,161,219 for the year ended December 31, 2024. As of December 31, 2024, the Company had working capital of $2,710,626 and stockholders' equity of $9,789,740 including an accumulated deficit of $129,138,286. During the year ended December 31, 2024, cash flows used in operating activities were $8,976,347. The Company does not currently have sufficient available liquidity to fund its operations for at least the next 12 months. Such factors raise substantial doubt about our ability to sustain operations for at least one year from the issuance of the audited financial statements included in this Annual Report. The accompanying financial statements do not include any adjustments related to the carrying amounts of assets or liabilities.

In response to these conditions and events, we are evaluating various financing strategies to obtain sufficient additional liquidity to meet our operating and capital requirements for the next twelve months following the date of this Annual Report. The potential sources of financing that we are evaluating include one or any combination of secured or unsecured debt, convertible debt and equity in both public and private offerings. We also plan to finance near-term operations with our cash on hand, as well as by exploring additional ways to raise capital. The sources of financing described above that could be available to us and the timing and probability of obtaining sufficient capital depend, in part, on our further developing and commercializing our product candidates and on future capital market conditions. If our current assumptions regarding the pace of such development are incorrect, or if there are any other changes or differences in our current assumptions that negatively impact our financing strategy, we may have to reduce expenditures or significantly delay, scale back or discontinue the development or commercialization of our product candidates.

There is no assurance we will manage to raise additional capital or otherwise increase cash flows, if required. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Nasdaq Deficiency

On March 17, 2025, the Company received a letter from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of the Company's Common Stock for the 30 consecutive business days between January 30, 2025, to March 14, 2025, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). The letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until September 15, 2025 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with Nasdaq's minimum bid price requirement, the Company's Common Stock must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Compliance Period. In the event the Company does not regain compliance by the end of the Compliance Period, the Company may be eligible for an additional 180 calendar days to regain compliance. There can be no assurance that the Company will be eligible for the additional 180 calendar day compliance period, if applicable, or that the Nasdaq staff would grant the Company's request for continued listing subsequent to any delisting notification. In the event of such a notification, the Company may appeal the Nasdaq staff's determination to delist its securities.

Financial Operations Overview

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

We anticipate that our expenses will increase significantly as we:

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

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

Components of our Results of Operations

Revenue

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

Operating Expenses

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

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

Research and Development

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

- Contractual agreements with third parties including contract research organizations, preclinical activities and clinical trials;
- Outside consultants including fees and expenses;
- Laboratory supplies and equipment;
- Regulatory compliance; and
- Patent application and maintenance costs to protect our intellectual property.

None of our two employees are principally involved in research and development activities for either Isomyosamine or Supera-CBD. Their salaries, wages and benefits are captured as a component of research and development but not allocated to specific projects.

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

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

- Size and scope of pre-clinical trials;
- The phases of clinical development and the stage of our product candidates in the cycle;
- Per subject trial costs;
- The number of sites required for the trials and the availability of appropriate sites to perform the trials;
- The time that is required to enroll the appropriate number of trial participants; and
- The time required to achieve the approval of regulatory agencies.

General and Administrative

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

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

Stock Based Compensation

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

Other Income (Expense), net

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

Results of Operations

Summary of Statements of Operations for the Years Ended December 31, 2024 and 2023

We are focused on developing and commercializing two therapeutic platforms based on well-defined therapeutic targets, Isomyosamine and Supera-CBD. The following table summarized the results of operations for the years ended December 31, 2024 and 2023.

Description	For the Year Ended December 31, 2024	2023	Percent Change
Operating Expenses			
General and Administrative	$ 4,161,907	$ 5,442,886	(23.5)
Research and Development	3,441,010	7,867,795	(56.3)
Stock Based Compensation	1,057,271	3,049,537	(65.3)
Series F Warrant Issuance Expenses	-	762,834	(100.0)
Series F-1 Warrant Issuance Expenses	539,097	-	100.0
Series G Warrant Issuance Expenses	969,505	-	100.0
Total Operating Expenses	$ 10,168,790	$ 17,123,052	(40,6)
Loss from Operations	(10,168,790)	(17,123,052)	40.6
Other Income (Expense), net	(13,190,146)	13,123,102	(200.5)
Net Loss	$ (23,359,334)	$ (3,999,950)	(484.0)
Preferred Stock Dividends	3,801,885	4,218,213	(9.9)
Net Loss Attributable to Common Shareholders	$ (27,161,219)	$ (8,218,163)	(230.5)

Revenue

We had no revenue from operations during the years ended December 31, 2024 and 2023.

Administrative Expenses

The table below summarizes our administrative expenses for the years ended December 31, 2024, and 2023 as well as the percentage of change year-over-year:

Description	For the Years Ended December 31, 2024	2023	Percent Change
Personnel Costs	$ 651,100	$ 1,410,950	(53.9)
Professional Service Costs	1,249,297	1,043,247	19.8
Stock Market & Investor Relations Costs	798,583	901,079	(11.4)
Other Administrative Costs	1,462,927	2,087,610	(29.9)
Total Administrative Expense	$ 4,161,907	$ 5,442,886	(23.5)

Personnel costs decreased $759,850 during the year ended December 31, 2024. We reduced administrative staffing during the year ended December 31, 2023, from four full-time positions to two and renegotiated one staff members compensation during the year ended December 31, 2024. In addition, two research and development staff members had 20% of their salaries allocated to general administrative expenses to recognize their areas of responsibility. One of these staff members separated during the year ended December 31, 2023, and the other during the year ended December 31, 2024. As of December 31, 2024, we have two full-time administrative staff members.

Professional services costs increased $206,050 during the year ended December 31, 2024. These costs include the consulting fees for our Interim Chief Financial Officer and 20% of the consulting fees for our President and Chief Medical Officer. Other costs include legal, accounting and audit, and specialized consulting services related to the initial and quarterly calculation of the fair market value of the Series F Preferred Stock, Series F-1 Preferred Stock and Series G Preferred Stock and their components.

Stock market and investor relations costs decreased $102,496 during the year ended December 31, 2024. These costs include the annual Nasdaq listing fees, activities related to keeping the stockholder base informed through press releases, presentations and other communication efforts, transfer agent fees, and the costs of annual stockholder meetings. The decrease is attributed to a reduction in consulting fees and stockholder meeting expenses.

Other administrative expenses decreased $624,683 during the year ended December 31, 2024. These costs include Board expenses, business insurance, corporate travel, and other general business expenses. The decrease is attributable to decreases in Board expenses, business insurance expenses, facility leasing expense, and corporate travel expenses.

Research and Development Expenses

The table below summarizes our research and development expenses for the years ended December 31, 2024, and 2023 as well as the percentage of change year-over-year:

Description	For the Year Ended December 31, 2024	2023	Percent Change
Salaries and Wages	$ 705,914	$ 1,765,488	(60.0)
Development Programs	2,387,664	5,593,041	(57.3)
Professional Services	317,134	329,271	(3.7)
Regulatory Expenses	390	21,574	(98.2)
Other Research and Development Expenses	29,908	158,421	(81.1)
Total Research and Development Expenses	$ 3,441,010	$ 7,867,795	(56.3)

Salaries and wages decreased $1,059,574 during the year ended December 31, 2024. We reduced administrative staffing during the year ended December 31, 2023, from six full-time positions to four and the remaining full-time staff separated during the year ended December 31, 2024. Two research and development staff members had 20% of their salaries allocated to general administrative expenses to recognize their areas of responsibility. One of these staff members separated during the year ended December 31, 2023, and the other during the year ended December 31, 2024. As of December 31, 2024, we have no full-time research and development staff members.

Development program costs include those associated with pre-clinical development, clinical trials and other material and development programs. Costs decreased $3,205,377 during the year ended December 31, 2024, compared to the year ended December 31, 2023, a result of the completion of pre-clinical toxicology studies and the Phase 2 Sarcopenia clinical trial, the analysis of the Phase 2 Sarcopenia study results, and the acquisition of base compounds for use in on-going studies. During the year ended December 31, 2024, we engaged a new Contract Research Organization and began preparing materials for the Phase 2b Sarcopenia clinical trial.

Professional services costs decreased $12,137 during the year ended December 31, 2024, as compared to the year ended December 31, 2023. These costs include the 80% of the consulting fees for our President and Chief Medical Officer, other consulting services , and legal and patent related fees associated with the protection of our intellectual property.

Regulatory expenses decreased $21,184 during the year ended December 31, 2024, as compared to the year ended December 31, 2023. Regulatory expenses include clinical research organizations (CRO) and regulatory consulting fees associated with Phase 2 clinical study designs, protocol preparations and the maintenance of the investigator brochures.

Other research and development expenses decreased $128,513 during the year ended December 31, 2024, as compared to the year ended December 31, 2023. These expenses include laboratory supplies, training and travel while working with third-party trial sites. The decrease is attributable to specialized freight costs for materials and travel in support of the studies and data analysis of the Phase 2 Sarcopenia trial results.

Stock-Based Compensation

During the year ended December 31, 2024, stock-based compensation totaled $1,057,271. These expenses include stock options issued to directors, staff, and service providers. During the year ended December 31, 2023, stock-based compensation totaled $3,049,537 for stock options issued to staff and service providers, restricted stock units and Common Stock warrants issued for services.

During the year ended December 31, 2024, we did not issue any new stock options or restricted stock units to staff or service providers.

Other Income and Expense

The table below summarizes our other income and expenses for the years ended December 31, 2024 and 2023 as well as the percentage of change year-over-year:

	For the Years Ended December 31,		Percent
Description	2024	2023	Change
Interest and Dividend Income	$ 351,809	$ 455,570	(22.8)
Gain on Sale of Marketable Securities	976	416	134.6
Gain on changes in fair value of Marketable Securities	671	514	30.5
Gain/(Loss) on changes in fair value of Derivative Liabilities	(388,000)	3,088,800	(112.6)
Gain/(Loss) on changes in fair value of Warrant Liabilities	(4,410,000)	9,756,000	(145.2)
Loss on Issuance of Stock	(8,846,000)	-	100.0
Uninsured Casualty Gain/(Loss)	100,000	(178,198)	(156.1)
Total Other Income/(Expense)	$ (13,169,544)	$ 13,123,102	(200.5)

Other expenses, net of income, totaled $13.169,544 for the year ended December 31, 2024, and other income, net of expenses, totaled $13,123,102 for the year ended December 31, 2023.

During the year ended December 31, 2024 interest and dividend income, the changes in fair value of our investments and realized gains from the sale of investments are primarily the availability of funds available for investment and the fluctuation of interest rates due to market conditions.

During the year ended December 31, 2024, we recorded a loss of $388,000 related to the change in fair value of the derivative liabilities.

- For the Series F Derivative (as defined herein), we recorded a gain of $61,000 , We estimated the $0 fair value of the bifurcated embedded derivative at December 31, 2024 using a Monte Carlo simulation model, with the following inputs: the fair value of our common stock of $1.15 on the valuation date, estimated equity volatility of 105.0%, estimated traded volume volatility of 320.0%, the time to maturity of 0.5 years, a discounted market interest rate of 6.0%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 3.60%.

- For the Series F-1 Derivative (as defined herein), we recorded a loss of $449,000. We estimated the $1,303,000 fair value of the bifurcated embedded derivative at December 31, 2024 using a Monte Carlo simulation model, with the following inputs: the fair value of our common stock of $1.15 on the valuation date, estimated equity volatility of 105.0%, estimated traded volume volatility of 320.0%, the time to maturity of 0.5 years, a discounted market interest rate of 7.0%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 3.60%.

During the year ended December 31, 2023, we recorded a gain of $3,088,800 related to the change in fair value of the derivative liabilities. We estimated the $61,000 fair value of the bifurcated embedded derivative at December 31, 2023 using a Monte Carlo simulation model, with the following inputs: the fair value of our common stock of $0.26 ($7.80 post reverse split) on the valuation date, estimated equity volatility of 140.0%, estimated traded volume volatility of 150.0%, the time to maturity of 0.5 year, a discounted market interest rate of 6.40%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 3.90%.

During the year ended December 31, 2024, we recorded a loss of $4,410,000 related to the change in fair value of the warrant liabilities as follows:

- For the Series F Warrants (as defined herein), we recorded a loss of $7,094,000, The fair value of the Series F warrants of approximately $7,194,000 was estimated at March 31, 2024 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 3.90 years; equity volatility of 110.0%; and a risk-free interest rate of 4.31%.

- For the Series F-1 Short-Term Warrants (as defined herein), we recorded a gain of $646,000, The fair value of the Series F-1 Short-Term warrants of approximately $2,660,000 was estimated at July 25, 2024 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 1.33 years; equity volatility of 115.0%; and a risk-free interest rate of 4.70%.

- For the Series F-1 Long-Term Warrants (as defined herein), we recorded a gain of $322,000, The fair value of the Series F-1 Long-Term warrants of approximately $34,305,000 was estimated at July 25, 2024 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 4.83 years; equity volatility of 120.0%; and a risk-free interest rate of 4.10%.

- For the Series G Short-Term Warrants (as defined herein), we recorded a gain of $1,146,000, The fair value of the Series G Short-Term warrants of approximately $4,713,000 was estimated at July 25, 2024 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 1.33 years; equity volatility of 115.0%; and a risk-free interest rate of 4.70%.

- For the Series G Long-Term Warrants (as defined herein), we recorded a gain of $570,000, The fair value of the Series G Long-Term warrants of approximately $7,630,000 was estimated at July 25, 2024 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 4.83 years; equity volatility of 120.0%; and a risk-free interest rate of 4.10%.

During the year ended December 31, 2023, we recorded a gain of $9,756,000 related to the change in fair value of the warrant liabilities. The fair value of the Warrants of approximately $867,000 was estimated at December 31, 2023 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 4.15 years; equity volatility of 120.0%; and a risk-free interest rate of 3.91%.

During the year ended December 31, 2024, we recorded a loss associated with the issuance of the Series F-1 Preferred Stock totaling $3,737,000 and the Series G Preferred Stock totaling $5,109,000. The losses resulted from the fair market value of the warrants issued exceeding the sum of the gross proceeds, discount and derivative derived from the placement of the preferred shares.

For the year ended December 31, 2023, we identified a casualty loss of $178,198 related to wire fraud due to a compromised electronic mail account. This incident occurred on May 17, 2023 and was discovered on July 20, 2023 when the vendor notified us of a delinquent invoice. An investigation determined that the original invoice from the vendor, sent to our consultant on this project, was intercepted and resent with altered wring instructions from a domain name that varied from the actual vendor's domain by one character. We notified our cyber insurance carrier on November 9, 2023. The Company recovered $100,000 of this loss from the insurance carrier on July 2, 2024.

Income Taxes

As of December 31, 2024, and 2023, we had U.S. federal net operating loss carry forwards of approximately $116.5 million and $113.1 million, respectively. Approximately $47.1 million of the U.S. federal net operating loss generated in tax years beginning before January 1, 2018 expire beginning with the year ending December 31, 2025 through 2037. The remaining U.S. federal net operating loss of approximately $69.4 million does not expire, however it is limited to 80% of each subsequent year's net income. As of December 31, 2024, and 2023, we had U.S. state net operating loss carry forwards of approximately $55.7 million and $45.2 million, respectively, some of which expire beginning with the year ending December 31, 2025 through 2044.

Under Section 382 of the Code, use of our net operating loss carryforwards is limited if we experience a cumulative change in ownership of greater than 50% in a moving three-year period. We experienced an ownership change as a result of the Merger and therefore our ability to utilize our net operating loss carryforwards and certain credit carryforwards are limited. The limitation is determined by the fair market value of our common stock outstanding immediately prior to the ownership change, multiplied by the applicable federal rate. It is expected that the Merger caused our net operating loss carryforwards to be limited. However, the limitation had no impact on our financial statements since we recorded a full valuation allowance for our deferred tax assets as of December 31, 2024 and 2023 (See Note 7 to the Consolidated Financial Statements).

Liquidity and Capital Resources

As of December 31, 2024, the Company's cash on hand was $173,154 and marketable securities were $8,345,082. The Company has incurred a net loss attributable to shareholders of $27,161,219 for the year ended December 31, 2024. As of December 31, 2024, the Company had working capital of $2,710,626 and stockholders' equity of $9,789,740 including an accumulated deficit of $129,138,286. During the year ended December 31, 2024, cash flows used in operating activities were $8,976,347. Since inception, the Company has met its liquidity requirements principally through the sale of its common and preferred stock in public and private placements; however, there is no assurance that management will be able to obtain additional financing in the future.

As of December 31, 2023, the Company's cash on hand was $2,681,010 and marketable securities were $2,242,106. The Company has incurred a net loss attributable to shareholders of $8,218,163 for the year ended December 31, 2023. As of December 31, 2023, the Company had working capital of $828,253 and stockholders' equity of $12,369,572 including an accumulated deficit of $101,977,067. During the year ended December 31, 2023, cash flows used in operating activities were $12,980,625.

Operating Activities

Our net cash used by operating activities during the year ended December 31, 2024, were $8,976,347, consisting primarily of a net loss of $23,359,334 a decrease in trade and other payables of $814,114 and a decrease in deferred compensation payable of $100,538 offset by fair value adjustments for derivatives of $388,000, fair value adjustments for warrants of $4,410,000, non-cash losses on the issuance of preferred stock of $8,846,000, non-cash share-based compensation of $1,057,271, and non-cash compensation to a service provider of $600,000.

Our net cash used by operating activities during the year ended December 31, 2023, were $12,980,625, consisting primarily of a net loss of $3,999,950 and fair value adjustments of $3,088,800 for derivatives and $9,756,000 for warrants related to offering of preferred stock offset by non-cash share-based compensation of $3,049,537, an increase in trade and other payables of $1,042,997 and a decrease in prepaid expenses of $327,439.

Investing Activities

Our net cash used in investing activities totaled $6,101,329 for the year ended December 31, 2024, as compared to cash provided by investing activities totaling $1,845,726 during the year ended December 31, 2023. During the year ended December 31, 2024, we purchased securities totaling $12,851,809 and sold securities totaling $6,750,480. During the year ended December 31, 2023, we purchased securities totaling $13,454,304 and sold securities totaling $15,300,000.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2024, was $12,569,820 which consisted of $14,000,000 for the net proceeds from the sale of preferred stock offset by $73,472 for the redemption of preferred stock and dividends on preferred stock of $1,356,708. Net cash provided by financing activities during the year ended December 31, 2023, was $13,066,819 which consisted of 14,685,689 for the net proceeds from the sale of preferred stock offset by $89,635 for the redemption of Preferred Stock, $1,452,145 for dividends and $77,090 for premiums related to such shares.

February 2023 Offering

On February 21, 2023, the Company entered into a Securities Purchase Agreement (the "Series F Purchase Agreement") with certain accredited investors (the "Series F Investors"), pursuant to which it agreed to sell to the Investors (i) an aggregate of 15,000 shares of the Company's newly-designated Series F convertible preferred stock with a stated value of $1,000 per share, initially convertible into up to 6,651,885 shares (pre-split) of the Company's Common Stock at an initial conversion price (the "Series F Conversion Price") of $2.255 per share (pre-split), subject to adjustment (the "Series F Preferred Shares"), and (ii) warrants to acquire up to an aggregate of 6,651,885 shares (pre-split) of the Company's Common Stock, subject to adjustment (the "Series F Warrants") (collectively, the "February 2023 Offering").

Following the Reverse Stock Split, (i) the Series F Conversion Price was adjusted to $3.18 per share pursuant to the terms of the Series F Certificate of Designations, which was subsequently amended and restated by the filing of the Amended and Restated Certificate of Designations of Series F Convertible Preferred Stock, effective April 8, 2024 (as amended and restated, the "Series F Certificate of Designations") with the Secretary of State of the State of Delaware, and (ii) the exercise price of the Series F Warrants (the "Series F Exercise Price") was adjusted to $3.18 per share. In connection with the Private Placements (as defined herein), (i) the Series F Conversion Price was further adjusted to $1.816 per share pursuant to the full ratchet anti-dilution provisions contained in the Series F Certificate of Designations and, (ii) the Series F Exercise Price was further adjusted to $1.816 per share. As of December 31, 2024, in connection with the issuance of shares of Common Stock upon conversion of the Series F-1 Preferred Shares (as defined herein), (i) the Series F Conversion Price was equal to $1.30 per share pursuant to the full ratchet anti-dilution provisions contained in the Series F Certificate of Designations and, (ii) the Series F Exercise Price was equal to $1.30 per share and the number of shares of Common Stock issuable upon exercise of the Series F warrants was equal to 11,538,462 shares pursuant to the full ratchet anti-dilution provisions contained in the Series F Warrants.

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

As of December 31, 2024, there were 4,211 Series F Preferred Shares outstanding and Series F Warrants outstanding to purchase up to 8,259,911 shares of Common Stock. As of December 31, 2024, Series F Conversion Price was equal to $1.30 and on March 4, 2025, the Series F Conversion Price was adjusted to $0.364.

Series F Convertible Preferred Stock

Prior to the Series F Certificate of Amendment (as defined below), the Company was initially required to redeem the Series F Preferred Shares in 12 equal monthly installments, commencing on July 1, 2023. The amortization payments due upon such redemption are payable, at the Company's election, in cash, or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Series F Conversion Price then in effect and (ii) the greater of (A) 80% of the average of the three lowest closing prices of the Company's Series F Common Stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) a "Floor Price" of $6.60 on a post-split basis (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Stock Market.

On April 5, 2024, the Company entered into an Omnibus Waiver and Amendment (the "Omnibus Agreement") with the Required Holders (as defined in the Series F Certificate of Designations). Pursuant to the Omnibus Agreement, the Required Holders agreed (i) to defer payment of the monthly installment amounts due on March 1, 2024, and April 1, 2024 (the "Installments"), under Section 9(a) of the Series F Certificate of Designations, until May 1, 2024, and (ii) to waive any breach or violation of the Series F Purchase Agreement, the Series F Certificate of Designations, or the Series F Warrants resulting from missing the Installments. The Company may require holders to convert their Series F Preferred Shares into shares of Common Stock if the closing price of the Common Stock exceeds $6.765 per share (as adjusted for the Reverse Stock Split) (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock exceeds $3,000,000 per day during the same period and certain equity conditions described in the Series F Certificate of Designations are satisfied.

On May 20, 2024, the Company entered into an Omnibus Waiver, Consent, Notice and Amendment (the "May 2024 Series F Agreement") with the Required Holders (as defined in the Series F Certificate of Designations). Pursuant to the May 2024 Series F Agreement, the Required Holders agreed to (i) amend the Series F Purchase Agreement to amend certain terms relating to purchase rights thereunder, (ii) waive certain rights under the Series F Purchase Agreement and Series F Certificate of Designations in respect of the issuance of the Company's Series F-1 Convertible Preferred Stock, with a par value of $0.001 per share and a stated value of $1,000 per share ("Series F-1 Preferred Stock"), the Company's Series G Convertible Preferred Stock, with a par value of $0.001 per share and a stated value of $1,000 per share ("Series G Preferred Stock"), and entrance by the Company into the Purchase Agreements (as defined herein), (iii) waive the requirement that the Company reserve for issuance a sufficient number of shares of Common Stock as required by the Series F Certificate of Designations, the Series F Purchase Agreement and Series F Warrants, until such time as the Company obtains the Stockholder Approval (as defined herein), and (iv) consent to the issuance of the Series F-1 Preferred Stock and Series G Preferred Stock as required pursuant to certain terms of the Series F Certificate of Designations, the Series F Purchase Agreement and the Series F Warrants, as applicable. The Company and the Required Holders further agreed pursuant to the May 2024 Series F Agreement, to amend the Series F Certificate of Designations by filing a Certificate of Amendment to the Series F Certificate of Designations (the "Series F Certificate of Amendment") with the Secretary of State of the State of Delaware. The Series F Certificate of Amendment amends the Series F Certificate of Designations to (i) extend the maturity date to December 31, 2024, (ii) permit and modify certain procedures related to the payment of installment amounts with respect to the Installment Dates (as defined in the Series F Certificate of Designations) falling between (and including) July 1, 2024, and (and including) August 1, 2024, thereunder, and (iii) modify the schedule of Installment Dates.

On November 7, 2024, each holder of the Series F Preferred Shares agreed that payment by the Company of any Installment Amounts (as defined in the Series F Certificate of Designations) that are accrued and are unredeemed, unconverted and/or otherwise unpaid as of November 7, 2024, will be deferred until December 1, 2024.

On April 8, 2025, the Company entered into an Omnibus Amendment Agreement ("April 2025 Amendment Agreement") with the Required Holders (as defined in the Series F Certificate of Designations and Series F-1 Certificate of Designations), pursuant to which, the Required Holders agreed to amend (i) the Series F-1 Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F-1 Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F-1 Certificate of Amendment"), (ii) the Series F Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F Certificate of Amendment"), (iii) the Series F-1 Purchase Agreement, to amend the definition of "Excluded Securities" such that the definition includes the issuance of common stock issued after the date of the Seres F-1 Purchase Agreement pursuant to an Approved Stock Plan (as defined in the Series F-1 Purchase Agreement), which in the aggregate does not exceed more than 2% of the shares of common stock issued and outstanding as of the date of such issuance (the "Excluded Securities Modification"), and (iv) to amend the term of the Series F-1 Short-Term Warrants to be five years from the date of issuance. In addition, in consideration of the foregoing, the Company agreed to reduce the size of the board of directors of the Company to no more than six directors, no later than the Company's 2025 annual meeting of stockholders.

The April 2025 Series F Certificate of Amendment amends the Series F Certificate of Designations to (A) (i) extend the maturity date to June 30, 2025, and (ii) modify the schedule of Installment Dates (as defined in the Series F Certificate of Designations), in each case, effective as of December 31, 2024, and (B) subject to obtaining the approval of the Company's stockholders, effective January 1, 2025, increase the aggregate Stated Value of the Series F Preferred Stock outstanding to an amount equal to 110% of the aggregate Stated Value of the Series F Preferred Stock outstanding. The April 2025 Series F Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

The holders of the Series F Preferred Shares are entitled to dividends of 10% per annum, compounded monthly, which is payable in cash or shares of Common Stock at the Company's option, in accordance with the terms of the Series F Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F Certificate of Designations), the Series F Preferred Shares accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series F Preferred Shares are also entitled to receive a dividend make-whole payment. Except as required by applicable law, the holders of the Series F Preferred Shares are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F Preferred Shares is entitled to be calculated assuming a conversion price of $60.21 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series F Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series F Certificate of Designations. The Series F Certificate of Designations further provides that the holders of record of the Series F Preferred Shares, exclusively and as a separate class, shall be entitled to elect one director of the Company one time on or before June 30, 2024. Effective as of April 8, 2024, the Company appointed Dr. Mitchell Glass to serve as a member of the Company's board of directors, with Mr. Glass having been elected to such position by the holders of the Series F Preferred Share.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization and dividend make-whole payments using shares of Common Stock is subject to certain limitations set forth in the Series F Certificate of Designations. Further, the Series F Certificate of Designations contains a certain beneficial ownership limitation after giving effect to the issuance of shares of Common Stock issuable upon conversion of, or as part of any amortization payment or dividend make-whole payment under, the Series F Certificate of Designations or Series F Warrants.

Series F Common Stock Warrants

Pursuant to the February 2023 Offering, the Company issued to investors the Series F Warrants to purchase 4,716,904 shares of Common Stock, with an initial exercise price of $3.18 per share (subject to adjustment), for a period of five years from the date of issuance. The Series F Exercise Price and the number of shares issuable upon exercise of the Series F Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series F Exercise Price (subject to certain exceptions). Upon any such price-based adjustment to the exercise price, the number of shares issuable upon exercise of the Series F Warrants will be increased proportionately. As of December 31, 2024, the Series F Exercise Price was equal to $1.30 per share and the number of shares of Common Stock issuable upon exercise of the Series F Warrants was equal to 11,538,462 shares pursuant to the full ratchet anti-dilution provisions contained in the Series F Warrants.

On May 14, 2024, the Company entered into an Amendment (the "Series F Warrant Amendment") with the Series F Investors in the February 2023 Offering, effective as of March 31, 2024. The Series F Warrant Amendment modified certain terms of the Series F Warrants relating to the rights of the holders of the Series F Warrants to provide that, in the event of a Fundamental Transaction (as defined in the Series F Warrants) that is not within the Company's control, including the Fundamental Transaction not being approved by the Company's Board of Directors, the holder of the Series F Warrant shall only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of such Series F Warrant, that is being offered and paid to the holders of the Company's common stock in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the successor entity (which such successor entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. The modification resulted in the reclassification of the Series F Warrants to be considered equity classified as they were no longer in the scope of ASC 815. In accordance with ASC 815-40, the Company remeasured the Series F Warrant liabilities at $7,961,000 fair value as of March 31, 2024, the effective date of the modification, and recognized the $7,094,000 loss on the change in fair value and reclassified the $7,961,000 fair value of the Series F Warrants to additional paid-in capital as of March 31, 2024.

Series F-1 Private Placement

On May 20, 2024, the Company entered into a Securities Purchase Agreement (the "Series F-1 Purchase Agreement") with certain accredited investors (the "Series F-1 Investors") pursuant to which it agreed to sell to the Series F-1 Investors (i) an aggregate of 5,050 shares of the Company's newly-designated Series F-1 Preferred Stock, initially convertible into up to 2,780,839 shares of Common Stock at a conversion price (the "Series F-1 Conversion Price") of $1.816 per share, (ii) short-term warrants to acquire up to an aggregate of 2,780,839 shares of Common Stock (the "Series F-1 Short-Term Warrants") at an exercise price of $1.816 per share, and (iii) long-term warrants to acquire up to an aggregate of 2,780,839 shares of Common Stock (the "Series F-1 Long-Term Warrants," and collectively with the Series F-1 Short-Term Warrants, the "Series F-1 Warrants") at an exercise price of $1.816 per share (collectively, the "Series F-1 Private Placement"). The closing of the Series F-1 Private Placement occurred on May 23, 2024 (the "Series F-1 Closing Date").

As of December 31, 2024, in connection with the issuance of shares of Common Stock upon conversion of the Series F-1 Preferred Stock, (i) the Series F-1 Conversion Price was equal to $1.30 per share pursuant to the full ratchet anti-dilution provisions contained in the Series F-1 Certificate of Designations and, (ii) the exercise price of the Series F-1 Warrants was equal to $1.30 per share and the number of shares of Common Stock issuable upon exercise of the Series F-1 Warrants was equal to 7,769,230 shares pursuant to the full ratchet anti-dilution provisions contained in the Series F-1 Warrants.

We received net proceeds from the Series F-1 Private Placement of approximately $5.0 million, after deducting various fees and expenses. We intend to use the net proceeds from this offering for general corporate purposes.

As of December 31, 2024, there were 4,747 shares of Series F-1 Preferred Stock outstanding, Series F-1 Short-Term Warrants outstanding to purchase up to 3,884,615 shares of Common Stock and Series F-1 Long-Term Warrants outstanding to purchase up to 3,884,615 shares of Common Stock. As of December 31, 2024, the Series F-1 Conversion Price was equal to $1.30 and as of March 4, 2025, the Series F-1 Conversion Price was adjusted to $0.364.

Series F-1 Preferred Stock

The Series F-1 Preferred Stock became convertible upon issuance into Common Stock (the "Series F-1 Conversion Shares") at the election of the holder at any time at the initial conversion price of $1.816. The Series F-1 Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series F-1 Conversion Price (subject to certain exceptions).

The Company is required to redeem the Series F-1 Preferred Stock in seven (7) equal monthly installments, commencing on December 1, 2024. The amortization payments due upon such redemption are payable, at the Company's election, in cash at 105% of the applicable Installment Redemption Amount (as defined in the Series F-1 Certificate of Designations), or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Series F-1 Conversion Price then in effect and (ii) the greater of (A) 80% of the average of the three lowest closing prices of the Company's Common Stock during the thirty consecutive trading day period ending and including the trading day immediately prior to the date the amortization payment is due or (B) $0.364, which is 20% of the "Minimum Price" (as defined in Nasdaq Stock Market Rule 5635) on the date in which the Series F-1 Stockholder Approval (as defined herein) was obtained or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Capital Market, and, in each case, subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events, which amortization amounts are subject to certain adjustments as set forth in the Series F-1 Certificate of Designations (the "Series F-1 Floor Price").

The holders of the Series F-1 Preferred Stock are entitled to dividends of 10% per annum, compounded monthly, which are payable in arrears monthly in cash or shares of Common Stock at the Company's option, in accordance with the terms of the Series F-1 Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F-1 Certificate of Designations), the Series F-1 Preferred Stock will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series F-1 Preferred Stock are also entitled to receive a dividend make-whole payment. The holders of the Series F-1 Preferred Stock are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F-1 Preferred Stock is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series F-1 Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series F-1 Certificate of Designations.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization and dividend make-whole payments using shares of Common Stock is subject to certain limitations set forth in the Series F-1 Certificate of Designations. Further, the Series F-1 Certificate of Designations contains a certain beneficial ownership limitation after giving effect to the issuance of shares of Common Stock issuable upon conversion of, or as part of any amortization payment or dividend make-whole payment under, the Series F-1 Certificate of Designations or Series F-1 Warrants.

Series F-1 Warrants

Pursuant to the Series F-1 Private Placement, the Company issued to investors (i) the Series F-1 Long-Term Warrants to purchase 2,780,839 shares of Common Stock, with an initial exercise price of $1.816 per share (subject to adjustment), for a period of five years from the date of issuance and (ii) the Series F-1 Short-Term Warrants to purchase 2,780,839 shares of Common Stock, with an initial exercise price of $1.816 per share (subject to adjustment), for a period of eighteen months from the date of issuance.

The exercise price of the Series F-1 Warrants and the number of shares issuable upon exercise of the Series F-1 Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable exercise price (subject to certain exceptions). Upon any such price-based adjustment to the exercise price, the number of shares issuable upon exercise of the Series F-1 Warrants will be increased proportionately. As of December 31, 2024, the Series F Exercise Price was adjusted to $1.30 per share and the number of shares of Common Stock issuable upon exercise of the Series F Warrants was adjusted proportionally to 7,769,230 shares pursuant to the full ratchet anti-dilution provisions contained in the Series F Warrants.

On August 16, 2024, the Company entered into (i) an Amendment (the "Series F-1 Long Term Warrant Amendment") with the Series F-1 Investors, effective as of June 30, 2024 relating to the Series F-1 Long Term Warrants, and (ii) an Amendment (the "Series F-1 Short Term Warrant Amendment" and, together with the Series F-1 Long Term Warrant Amendment, the "Series F-1 Warrant Amendments") with the Series F-1 Investors, effective as of June 30, 2024 relating to the Series F-1 Short Term Warrants. The Series F-1 Warrant Amendments modified certain terms of the Series F-1 Warrants relating to the rights of the holders of the Series F-1 Warrants to provide that, in the event of a Fundamental Transaction (as defined in the Series F-1 Warrants) that is not within the Company's control, including the Fundamental Transaction not being approved by the Company's Board of Directors, the holder of the Series F-1 Warrant shall only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of such Series F-1 Warrant, that is being offered and paid to the holders of the Company's Common Stock in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the successor entity (which such successor entity may be the Company following such Fundamental Transaction). Additionally, the Series F-1 Warrant Amendments amend the definition of Black Scholes Value related to the volatility input which is now an expected volatility equal to the 30 day volatility, obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the trading day immediately following the earliest to occur of (1) the public disclosure of the applicable Fundamental Transaction and (2) the date of a holder's request. The modification resulted in the reclassification of the Series F-1 Warrants to be considered equity classified as they were no longer in the scope of ASC 815.

Series G Private Placement

On May 20, 2024, the Company entered into a Securities Purchase Agreement (the "Series G Purchase Agreement" and collectively with the Series F-1 Purchase Agreement, each a "Purchase Agreement" and collectively, the "Purchase Agreements") with certain accredited investors (the "Series G Investors" and collectively with the Series F-1 Investors, the "Investors"), with certain accredited investors (the "Series G Investors"), pursuant to which it agreed to sell to the Series G Investors (i) an aggregate of 8,950 shares of the Company's newly-designated Series G Preferred Stock, initially convertible into up to 4,928,416 shares of the Company's Common Stock, at an initial conversion price (the "Series G Conversion Price") of $1.816 per share (ii) short-term warrants to acquire up to an aggregate of 4,928,416 shares of Common Stock (the "Series G Short-Term Warrants") at an exercise price of $1.816 per share, and (iii) long-term warrants to acquire up to an aggregate of 4,928,416 shares of Common Stock (the "Series G Long-Term Warrants," and collectively with the Series G Short-Term Warrants, the "Series G Warrants") at an initial exercise price (the "Series G Exercise Price") of $1.816 per share (collectively, the "Series G Private Placement" and collectively with the Series F-1 Private Placement, each a "Private Placement" and collectively, the "Private

Placements"). The closing of the Series G Private Placement occurred on May 23, 2024 (the "Series G Closing Date" and collectively with the Series F-1 Closing Date, the "Closing Date").

As of December 31, 2024, in connection with the issuance of shares of Common Stock upon conversion of the Series F-1 Preferred Stock, (i) the Series G Conversion Price was equal to $1.30 per share due to the full ratchet anti-dilution provisions contained in the Series G Certificate of Designations and, (ii) the exercise price of the Series G Warrants was equal to $1.30 per share and the number of shares of Common Stock issuable upon exercise of the Series G Warrants was equal to 13,769,230 shares pursuant to the full ratchet anti-dilution provisions contained in the Series G Warrants.

We received net proceeds from the Series G Private Placement of approximately $8.9 million, after deducting various fees and expenses. We intend to use the net proceeds from this offering for general corporate purposes.

As of December 31, 2024, there were 8,884 shares of Series G Preferred Stock outstanding, Series G Short-Term Warrants outstanding to purchase up to 6,884,615 shares of Common Stock, and Series G Long-Term Warrants outstanding to purchase up to 6,884,615 shares of Common Stock. As of December 31, 2024, the Series G Conversion Price was equal to $1.30 and on March 4, 2025, the Series G Conversion Price was adjusted to $0.364.

Series G Preferred Stock

The Series G Preferred Shares became convertible upon issuance into Common Stock (the "Series G Conversion Shares") at the election of the holder at any time at an initial conversion price of $1.816 (the "Series G Conversion Price"). The Series G Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series G Conversion Price (subject to certain exceptions).

At any time after the issuance date of the Series G Preferred Shares, the Company has the option to redeem in cash all or any portion of the shares of Series G Preferred Shares then outstanding at a premium upon notice by the Company to all holders of the Series G Preferred Shares.

The holders of the Series G Preferred Shares will be entitled to dividends of 10% per annum, compounded monthly, which will be payable in arrears monthly, at the holder's options, (i) in cash, (ii) "in kind" in the form of additional shares of Series G Preferred Shares (the "PIK Shares"), or (iii) in a combination thereof, in each case, in accordance with the terms of the Certificate of Designations of the Series G Preferred Shares (the "Series G Certificate of Designations"). Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series G Certificate of Designations), the Series G Preferred Stock will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series G Preferred Shares are also entitled to receive a dividend make-whole payment. The holders of the Series G Preferred Shares will be entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series G Preferred Share is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series G Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series G Certificate of Designations. During the years ended December 31, 2024 and 2023, the Company recorded dividends totaling $559,032 and $0, respectively, which are reported as Series G Preferred Stock Dividends on the Consolidated Statements of Comprehensive Loss.

Notwithstanding the foregoing, the Company's ability to settle conversions and make dividend make-whole payments using shares of Common Stock is subject to certain limitations set forth in the Series G Certificate of Designations. Further, the Series G Certificate of Designations contains a certain beneficial ownership limitation, which applies to each Series G Investor, other than PharmaCyte Biotech, Inc., after giving effect to the issuance of shares of Common Stock issuable upon conversion of the Series G Preferred Shares or as part of any dividend make-whole payment under the Series G Certificate of Designations.

On June 17, 2024, the Company entered into an Amendment Agreement (the "Series G Amendment") with the Required Holders (as defined in the Series G Certificate of Designations). Pursuant to the Series G Amendment, the Required Holders agreed to amend the Series G Certificate of Designations by filing a Certificate of Amendment ("Series G Certificate of Amendment") to the Series G Certificate of Designations with the Secretary of State of the State of Delaware (the "Secretary of State") to increase the number of authorized shares of Series G Preferred Stock from 8,950 to 12,826,273, in order to authorize a sufficient number of shares of Series G Preferred Stock for the payment of PIK Shares. On June 17, 2024, the Company filed the Series G Certificate of Amendment with the Secretary of State, thereby amending the Series G Certificate of Designations. The Series G Certificate of Amendment became effective with the Secretary of State upon filing.

On August 8, 2024, the Company entered into an Amendment Agreement (the "August Series G Amendment") with the Required Holders (as defined in the Series G Certificate of Designations). Pursuant to the August Series G Amendment, the Required Holders agreed to amend the Series G Certificate of Designations by filing a Certificate of Amendment ("August Series G Certificate of Amendment") to the Series G Certificate of Designations with the Secretary of State to adjust the calculation of the PIK Shares. On August 8, 2024, the Company filed the August Series G Certificate of Amendment with the Secretary of State, thereby amending the Series G Certificate of Designations. The August Series G Certificate of Amendment became effective with the Secretary of State upon filing.

Series G Warrants

Pursuant to the Series G Private Placement, the Company issued to investors (i) the Series G Long-Term Warrants to purchase 4,928,416 shares of Common Stock, with an initial exercise price of $1.816 per share (subject to adjustment), for a period of five years from the date of issuance and (ii) the Series G Short-Term Warrants to purchase 4,928,416 shares of Common Stock, with an initial exercise price of $1.816 per share (subject to adjustment), for a period of eighteen months from the date of issuance. As of December 31, 2024, the Series G Exercise Price was adjusted to $1.30 per share and the number of shares of Common Stock issuable upon exercise of the Series G Warrants was adjusted proportionally to 13,769,230 shares pursuant to the full ratchet anti-dilution provisions contained in the Series G Warrants.

The exercise price of the Series G Warrants and the number of shares issuable upon exercise of the Series G Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable exercise price (subject to certain exceptions). Upon any such price-based adjustment to the exercise price, the number of shares issuable upon exercise of the Series G Warrants will be increased proportionately.

On August 16, 2024, the Company entered into (i) an Amendment (the "Series G Long Term Warrant Amendment") with the Series G Investors, effective as of June 30, 2024, relating to the Series G Long Term Warrants, and (ii) an Amendment (the "Series G Short Term Warrant Amendment" and, together with the Series G Long Term Warrant Amendment, the "Series G Warrant Amendments") with the Series G Investors, effective as of June 30, 2024, relating to the Series G Short Term Warrants. The Series G Warrant Amendments modified certain terms of the Series G Warrants relating to the rights of the holders of the Series G Warrants to provide that, in the event of a Fundamental Transaction (as defined in the Series G Warrants) that is not within the Company's control, including the Fundamental Transaction not being approved by the Company's Board of Directors, the holder of the Series G Warrant shall only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value (as defined in the Series G Warrants) of the unexercised portion of such Series G Warrant, that is being offered and paid to the holders of the Company's Common Stock in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the successor entity (which such successor entity may be the Company following such Fundamental Transaction). Additionally, the Series G Warrant Amendments amend the definition of Black Scholes Value related to the volatility input which is now an expected volatility equal to the 60 day volatility, obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the trading day immediately following the earliest to occur of (1) the public disclosure of the applicable Fundamental Transaction and (2) the date of a holder's request. The modification resulted in the reclassification of the Series G Warrants to be considered equity classified as they were no longer in the scope of ASC 815.

Registration Rights Agreements

In connection with the Series F-1 Private Placement, the Company entered into a Registration Rights Agreement with the Series F-1 Investors (the "Series F-1 Registration Rights Agreement,"), pursuant to which the Company agreed to file a resale registration statement (the "Series F-1 Registration Statement") with the SEC to register for resale (A) 200% of the Series F-1 Conversion Shares and (B) 200% of the Series F-1 Warrant Shares promptly following the Closing Date, but in no event later than 30 calendar days after the Closing Date, and to have such Series F-1 Registration Statement declared effective by the Effectiveness Deadline (as defined in the Series F-1 Registration Rights Agreement).

In connection with the Series G Private Placement, the Company entered into a Registration Rights Agreement with the Series G Investors (the "Series G Registration Rights Agreement" and, together with the Series F-1 Registration Rights Agreement, the "Registration Rights Agreements") pursuant to which the Company agreed to file a resale registration statement (the "Series G Registration Statement") with the SEC to register for resale (A) 200% of the Series G Conversion Shares, (B) 200% of the shares of Common Stock issuable upon conversion of the PIK Shares, and (C) 200% of the Series G Warrant Shares promptly following the Closing Date, but in no event later than 30 calendar days after the Closing Date, and to have such Series G Registration Statement declared effective by the Effectiveness Deadline (as defined in the Series G Registration Rights Agreement).

In connection with the Registration Rights Agreements, the Company filed a registration statement on Form S-3 covering such securities, which registration statement was filed on June 21, 2024, amended on August 8, 2024 and declared effective by the SEC on August 12, 2024. Under the Series F-1 Registration Rights Agreement, the Company is obligated to pay certain liquidated damages to the Series F-1 Investors if the Company, among other things, failed to file the Series F-1 Registration Statement when required, failed to file or cause the Series F-1 Registration Statement to be declared effective by the SEC when required, or fails to maintain the effectiveness of the Series F-1 Registration Statement.

Private Placement Warrants

In connection with the Private Placements, pursuant to (A) an engagement letter (the "GPN Agreement") with GP Nurmenkari Inc. ("GPN") and (B) an engagement letter (the "Palladium Agreement," and collectively with the GPN Agreement, the "Engagement Letters") with Palladium Capital Group, LLC ("Palladium," and collectively with GPN, the "Placement Agents"), the Company engaged the Placement Agents to act as non-exclusive placement agents in connection with each Private Placement, pursuant to which, the Company agreed to (i) pay the Placement Agents a cash fee equal to 3% of the gross proceeds of each Private Placement (including any cash proceeds realized by the Company from the exercise of the Series F Warrants), (ii) reimbursement and payment of certain expenses, and (iii) issue to the Placement Agents on the Closing Date, warrants to purchase up to an aggregate of 693,833 of shares of Common Stock to each Placement Agent, which is equal to 3% of the aggregate number of shares of Common Stock underlying the securities issued in each Private Placement, including upon exercise of any Series F Warrants, with terms identical to the Series G Long-Term Warrants and Series F-1 Long-Term Warrants.

Nasdaq Stockholder Approval

The Company's ability to issue Series F-1 Conversion Shares and Series G Conversion Shares and Series F-1 Warrant Shares and Series G Warrant Shares using shares of Common Stock is subject to certain limitations set forth in the Series F-1 Certificate of Designations and Series G Certificate of Designations, as applicable. Prior to the Nasdaq Stockholder Approval (as defined below), such limitations included a limit on the number of shares that could be issued until the time that the Company's stockholders have approved the issuance of more than 19.99% of the Company's outstanding shares of Common Stock in accordance with the rules of the Nasdaq Stock Market. Each Purchase Agreement requires the Company to hold a meeting of its stockholders no later than August 1, 2024, to seek approval (the "Stockholder Approval") (i) under Nasdaq Stock Market Rule 5635(d) for the issuance of shares of Common Stock in excess of 19.99% of the Company's issued and outstanding shares of Common Stock at prices below the "Minimum Price" (as defined in Rule 5635 of the Rules of the Nasdaq Stock Market) on the date of the applicable Purchase Agreement pursuant to the terms of the Series F-1 Preferred Shares and Series G Preferred Shares, as applicable, and the Series G Warrants and Series F-1 Warrants, as applicable, and (ii) to increase the number of authorized shares of the Company to ensure that the number of authorized shares of Common Stock is sufficient to meet the Required Reserve Amount (as defined in the Purchase Agreements) pursuant to the terms of each Purchase Agreement. The Company received the Nasdaq Stockholder Approval at a special meeting of stockholders held on July 24, 2024.

Critical Accounting Estimates

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

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

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

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

Income Taxes

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

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

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. For the years ended December 31, 2024 and 2023, no liability for unrecognized tax benefits was required to be reported.

There was no income tax benefit recorded for the losses for the years ended December 31, 2024 and 2023 since management determined that the realization of the net deferred tax assets is not more likely than not to be realized and has recorded a full valuation allowance on the net deferred tax assets.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the years ended December 31, 2024 and 2023. 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.

Since the Company had losses in the past, all prior years that generated net operating loss carryforwards are open and subject to audit examination in relation to the net operating loss generated from those years.

Share-based Compensation

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

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

Recent Developments

Reverse Stock Split

Effective as of 4:05 p.m. Eastern Standard Time on February 14, 2024, we effected the Reverse Stock Split of our common stock at a ratio of one-for-thirty. Simultaneously with the Reverse Stock Split, number of shares of our common stock authorized for issuance was reduced from 500,000,000 shares to 16,666,666 shares, and our authorized capital stock was reduced from 550,000,000 shares to 66,666,666 shares. All share and per share information in this report have been retroactively adjusted to reflect the Reverse Stock Split.

Share Increase

On July 25, 2024, the Company increased the number of authorized shares of the Company's Common Stock from 16,666,666 to 250,000,000 and made a corresponding change to the number of authorized shares of the Company's capital stock by filing a Certificate of Amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Share Increase"). The Share Increase was approved by the Company's stockholders at the Company's special meeting of stockholders held on July 24, 2024.

Delaware Reincorporation

On March 4, 2024, MyMD New Jersey merged with and into its wholly owned subsidiary, MyMD Delaware, with MyMD Delaware being the surviving corporation, pursuant to the Plan of Merger for the purpose of changing the Company's state of incorporation from New Jersey to Delaware. MyMD Delaware is deemed to be the successor issuer of MyMD New Jersey under Rule 12g-3 of the Securities Exchange Act of 1934, as amended.

The Reincorporation did not result in any change in the Company's name, business, management, fiscal year, accounting, location of the principal executive offices, assets or liabilities. In addition, the Company's common stock retains the same CUSIP number and continues to trade on the Nasdaq Capital Market under the symbol "MYMD." As of the Effective Date of the Reincorporation, the rights of the Company's stockholders are governed by the Delaware General Corporation Law, the MyMD Delaware Certificate of Incorporation, and the Bylaws of MyMD Delaware.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

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

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

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

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

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

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

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

Management evaluated the effectiveness of our internal control over financial reporting based on the 2013 framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation management concluded that our internal control over financial reporting was effective as of December 31, 2024.

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

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our last fiscal quarter ended December 31, 2024 that have materially affected, or are reasonably likely to affect, our internal control over financial reporting.

Item 9B. Other Information.

On April 8, 2025, the Company entered into the April 2025 Amendment Agreement with the Required Holders (as defined in the Series F Certificate of Designations and Series F-1 Certificate of Designations), pursuant to which, the Required Holders agreed to amend (i) the Series F-1 Certificate of Designations, as described below, by filing the April 2025 Series F-1 Certificate of Amendment with the Secretary of State of the State of Delaware, (ii) the Series F Certificate of Designations, as described below, by filing the April 2025 Series F Certificate of Amendment with the Secretary of State of the State of Delaware, (iii) the Series F-1 Purchase Agreement, to amend the definition of "Excluded Securities" such that the definition includes the issuance of common stock issued after the date of the Series F-1 Purchase Agreement pursuant to an Approved Stock Plan (as defined in the Series F-1 Purchase Agreement), which in the aggregate does not exceed more than 2% of the shares of common stock issued and outstanding as of the date of such issuance, and (iv) to amend the term of the Series F-1 Short-Term Warrants to be five years from the date of issuance. In addition, in consideration of the foregoing, the Company agreed to reduce the size of the board of directors of the Company to no more than six directors, no later than the Company's 2025 annual meeting of stockholders.

The April 2025 Series F Certificate of Amendment amends the Series F Certificate of Designations to (A) (i) extend the maturity date to June 30, 2025, and (ii) modify the schedule of Installment Dates (as defined in the Series F Certificate of Designations), in each case, effective as of December 31, 2024, and (B) subject to obtaining the approval of the Company's stockholders, effective January 1, 2025, increase the aggregate Stated Value of the Series F Preferred Stock outstanding to an amount equal to 110% of the aggregate Stated Value of the Series F Preferred Stock outstanding. The April 2025 Series F Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

The April 2025 Series F-1 Certificate of Amendment amends the Series F-1 Certificate of Designations to amend the definition of "Excluded Securities" substantially similar to the Excluded Securities Modification. The April 2025 Series F-1 Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

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

Not applicable.

PART III

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

Directors and Executive Officers

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

Name	Age	Position with the Company
Mitchell Glass, M.D.	73	Director, President and Chief Medical Officer
Ian Rhodes	52	Interim Chief Financial Officer
Craig Eagle, M.D.	57	Director
Christopher Schreiber	59	Director
Joshua Silverman	53	Director, Chairman of the Board
Jude Uzonwanne	49	Director
Bill J. White	64	Director
Stephen Friscia	54	Director

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

Dr. Mitchell Glass has been our director since April 8, 2024, and currently serves as our President and Chief Medical Officer, a position he has held since June 13, 2024. Dr. Glass is presently Chief Executive Officer of Chronic Airway Therapeutics, Chairman and Chief Executive Officer of ACCOLADE Pharma LLC and a principal at Broom Street Associates. Previously, Dr. Glass was director of pulmonary therapeutics at ICI/Zeneca and responsible world-wide for the development of zafirlukast ("Accolate®), the first successful antileukotriene for the treatment of asthma. Dr. Glass also served as Vice President at SmithKline Beecham beginning March, 1995, where he also held executive roles in the development of carvedilol (COREG®) for heart failure, eprosartan (TEVETEN®) for hypertension and led the worldwide portfolio development in cardiovascular, respiratory, renal and metabolic diseases and disorders. At Athrogenix, Dr. Glass led the development of AGI1067 to a successful end of phase 2 meeting with the FDA. After 2 years as the CSO of the University City Science Center in Philadelphia between 2005 and 2006, which included responsibility for 54 early-stage companies, Dr. Glass joined Aqumen Pharma KK ("Aqumen Pharma") in 2006 as Director Aqumen KK. Dr. Glass also served as Chief Executive Officer and Chief Medical Officer of Aqumen Pharma's U.S. subsidiary was responsible for the ophthalmic portfolio, the lead compound of which was successfully developed and marketed in the U.S. and served in such roles until 2011. Previously, Dr. Glass served as the Chief Medical Officer and Director at Invion Plc. (ASX IVN) ("Invion") beginning 2011 until 2019 and led the de-merger of Invion into Chronic Airway Therapeutics, the lead compound of which, nadolol, executed a positive proof of concept study in smokers with bronchitis. Dr. Glass graduated from the University of Chicago and is board certified in internal medicine, pulmonary and critical care medicine.

Ian Rhodes has been our Interim Chief Financial Officer since February 1, 2021. Since August 2024, Mr. Rhodes has been the Chief Financial Officer of Renatus Tactical Acquisition Corp I. Mr. Rhodes joined Brio Financial Group ("Brio") in January 2021. From March 2020 to December 2020, Mr. Rhodes served as the Interim Chief Financial Officer of Roadway Moving and Storage. From November 2018 to July 2019, he served as Interim CFO of Greyston Bakery and Foundation. From December 2016 to September 2018, Mr. Rhodes served as President, Chief Executive Officer and Director of GlyEco, Inc., and served as Chief Financial Officer of GlyEco, Inc. from February 2016 to December 2016. From May 2014 to January 2016, he served as Chief Financial Officer of Calmare Therapeutics. Mr. Rhodes began his career at PricewaterhouseCoopers, where he worked for 15 years. Mr. Rhodes holds a Bachelor of Science degree in Business Administration with a concentration in Accounting from Seton Hall University and is a licensed CPA in New York.

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

Christopher C. Schreiber has been our director since August 8, 2017 and he previously served as our Chief Executive Officer, President, and Executive Chairman of the Board at various times. Mr. Schreiber combines over 30 years of experience in the securities industry. Mr. Schrieber retired in 2023 from his position as the Managing Director of Capital Markets at Taglich Brothers, Inc., where Mr. Schreiber built upon his extensive background in capital markets, deal structures, and syndications. Prior to his time at Taglich Brothers, Inc., he was a member of the board of directors of Paulson Investment Company, a 40-year-old full-service investment banking firm. In 2023, Mr. Schrieber joined the Board of Directors of Sonon Group, a German based company that focuses on providing solar-powered mobility applications. In addition, Mr. Schreiber serves as a director and partner of Long Island Express North, an elite lacrosse training organization for teams and individuals. Mr. Schreiber is a graduate of Johns Hopkins University, where he received a bachelor's degree in political science. Mr. Schreiber's qualifications to sit on the Board include his financial expertise and his experience with the Company.

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

Jude Uzonwanne has been our director since April 16, 2021. Mr. Uzonwanne is currently an independent consultant at Miralogx LLC, where he previously served as Chief Operating Officer / Senior Adviser from June 2022 to December 2024. From June 2022 until April 2023, Mr. Uzonwanne served as the Chief Executive Officer for Mira Pharmaceuticals Inc. ("Mira"), a U.S. based biopharmaceutical company focused on developing an oral FDA approved marijuana analog. Prior to Mira, he was the Chief Business Officer at a genetics-based healthcare company, 54gene, from March 2021 to June 2022. Prior to 54gene, he was a Principal with ZS Associates, Inc. ("ZS Associates"), a consulting and professional services firm, a position he held from January 2021 to March 2021. Prior to joining ZS Associates, Mr. Uzonwanne was a Principal at IQVIA, Inc. ("IQVIA") from 2018 to 2020, where he served as the head of the firm's US Financial Investors Consulting practice and as management consulting lead for IQVIA's service to a global pharmaceutical company and select emerging biopharmaceutical companies. Prior to joining IQVIA, Mr. Uzonwanne served as Vice President (Associate Partner) at EY-Parthenon LLP from 2016 to 2018, where he managed teams advising corporate and private equity investors on a range of commercial due diligence targets in healthcare strategies and advised clients on growth accelerating strategies and investments. Prior to this role, Mr. Uzonwanne has worked for several other companies including Bain & Company, Dalberg Global Development Advisers, the Bill and Melinda Gates Foundation, and Monitor Group. Mr. Uzonwanne is a 1998 graduate of Swarthmore College (double Honors B.A in Economics and Political Science). Mr. Uzonwanne's qualifications to sit on the Board include his extensive life sciences advisory experience, as well as a deep corporate strategy and finance role across multiple markets globally.

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

Stephen Friscia has been our director since June 13, 2024. Mr. Friscia is the manager and co-founder of Kipps Capital, a family office established in 2016. Previously, Mr. Friscia was a managing director and portfolio manager for multiple institutional investment and asset management firms, with several focused in small and mid-cap value equities, including Iridian Asset Management LLC, MacKay Shields LLC, Bear Stearns Asset Management Inc., John A. Levin & Co., Inc., and Evergreen Investments LLC (Wachovia Corporation). Mr. Friscia received his B.A. from Pace University – Lubin School of Business. Mr. Friscia's qualifications to sit on the Board include his experience with small and mid-cap companies.

Family Relationships

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

Code of Ethics

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

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

Insider Trading Policy

The Company has adopted an Insider Trading Policy which governs trading policy and procedures governing the purchase, sale, and/or other dispositions of the Company's securities by directors, officers and employees that is designed to promote compliance with insider trading laws, rules and regulations, as well as procedures designed to further the foregoing purposes. A copy of the insider trading policy is included in Exhibit 14.1 to this Annual Report on Form 10-K. While the Company is not subject to the insider trading policy, the Company does not trade in its securities when it is in possession of material non-public information other than pursuant to previously adopted Rule 10b5-1 trading plans, if any.

Board Composition and Committees

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

Board Diversity

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

Director Independence

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

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

Board Committees

The Board delegates various responsibilities and authority to different Board committees. Committees regularly report on their activities and actions to the full Board. Currently, the Board has established an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee and a Risk and Disclosure Committee. Committee assignments are re-evaluated annually. Each of these committees operates under a charter that has been approved by our Board. The current charter of each of these committees is available on our website at www.tnfpharma.com in the "Corporate Governance" section under "Investors."

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

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

Audit Committee

Our Audit Committee is responsible for, among other matters:

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

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

Compensation Committee

Our Compensation Committee is responsible for, among other matters:

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

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

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

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

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

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

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

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

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

Nominating and Corporate Governance Committee

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

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

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

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

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

- reviewing the Board's committee structure and to recommend to the Board for its approval;

- reviewing recommendations received from stockholders for persons to be considered for nomination to the Board;

- monitoring compliance with our corporate governance guidelines;

- developing and implementing an annual self-evaluation of the Board, both individually and as a Board, and of its committees;

- reviewing and recommending changes to procedures whereby stockholders may communicate with the Board;

- assessing the independence of directors annually and reporting to the Board;

- recommending to the Board for its approval, the leadership structure of the Board, including whether the Board should have an executive or non-executive Chairman, whether the roles of Chairman and Chief Executive Officer should combine, and whether a Lead Director of the Board should be appointed; provided that such structure shall be subject to the bylaws of the Company then in effect.

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

Risk and Disclosure Committee

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

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

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

Involvement in Certain Legal Proceedings

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

Compliance with Section 16(a) of the Exchange Act

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

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, the Company believes that each person who, at any time during the year ended December 31, 2024, was a director, officer or beneficial owner of more than ten percent of the Company's common stock complied with all Section 16(a) filing requirements during such fiscal year with the following exceptions: a Form 3 for Mr. Glass Mitchell was filed late on May 16, 2024 and a Form 3 for Mr. Stephen Friscia was filed late on June 28, 2024.

Item 11. Executive Compensation.

The following is a discussion of the material components of the executive compensation arrangements of our named executive officers, comprised of (i) our principal executive officer, (ii) the two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of the 2024 fiscal year and whose salary, as determined by Regulation S-K, Item 402, exceeded $100,000 and (iii) up to two most highly compensated former executive officers who were no longer serving as an executive officer at the end of the 2024 fiscal year (the individuals falling within categories (i), (ii) and (iii) are collectively referred to as the "Named Executive Officers").

Our Named Executive Officers for 2024 were as follows:

- Mitchell Glass, M.D., President and Chief Medical Officer
- Ian Rhodes, CPA, Interim Chief Financial Officer
- Christopher Chapman, M.D., Former, President and Chief Medical Officer
- Adam Kaplin, M.D., Former Chief Scientific Officer

Effective as of 4:05 pm Eastern Time on February 14, 2024 we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a Reverse Stock Split of the issued and outstanding shares of our Common Stock, at a ratio of 1 for 30. The stock awards listed below have been adjusted to give effect to the Reverse Stock Split.

Summary Compensation Table

Name and Principal Position	Notes	Year	Salary	Bonus	Stock Awards	Option Awards[1]	All Other Compensation[2]	Total
Mitchell Glass, M.D.[3] President, Chief Medical Officer		2024	175,833	-	-	-	6,500[9]	182,333
Ian Rhodes, CPA.[4]		2024	162,000	-	-	-	-	162,000
Interim Chief Financial Officer		2023	162,000	-	-	-	-	162,000
Christopher Chapman, M.D.[5]		2024	269,231	-	-	-	151,154	420,385
Former President, Chief Medical Officer		2023	464,703	200,000	-	2,218,565[7]	1,058	2,884,326
Adam Kaplin, M.D., PhD[6]		2024	76,112	-	-	-	2,019	78,131
Former Chief Scientific Officer		2023	250,000	100,000		235,245[8]	8,750	593,995

(1) In accordance with SEC rules, this column reflects the aggregate fair value of option awards granted during the fiscal year ended December 31, 2024, computed as of their respective grant dates in accordance with FASB ASC Topic 718 for share-based compensation transactions.

(2) This column reflects the matching contribution paid to participants of the TNF Pharmaceuticals, Inc. 401(k) PS Plan (the "401(k) Plan") and amounts paid for personal time off and severance of separated employees.

(3) Dr. Glass was appointed President and Chief Medical Officer of TNF effective June 13, 2024. For further information regarding the terms of Dr. Glass' employment, see the section below titled "Narrative Disclosure to Summary Compensation Table—Employment of Mitchell Glass, M.D."

(4) Ian Rhodes serves as our interim Chief Financial Officer on the terms of a CFO Consulting Agreement, dated July 21, 2020, between the Company and Brio Financial Group. For further information regarding the terms of Mr. Rhodes' employment, see the section below titled "Narrative Disclosure to Summary Compensation Table—Employment of Ian Rhodes."

(5) Dr. Chapman was appointed President and Chief Medical Officer of TNF effective April 16, 2021. Prior to the Merger, Dr. Chapman served as the President and Chief Medical Officer of MyMD Florida effective November 1, 2020. On June 14, 2024, Dr. Chapman resigned from his position as President, Chief Medical Officer and member of the board of directors of the Company. For further information regarding the terms of Dr. Chapman's employment, see the section below titled "Narrative Disclosure to Summary Compensation Table—Employment of Chris Chapman, M.D." Dr. Glass is not entitled to any additional compensation for his service as President and Chief Medical Officer.

(6) Dr. Kaplin was appointed Chief Scientific Officer of TNF effective April 16, 2021. Prior to the Merger, Dr. Kaplin served as Chief Scientific Officer of MyMD Florida effective December 18, 2020. On April 15, 2024, Dr. Kaplin resigned from his role as an officer of the Company. For further information regarding the terms of Dr. Kaplin's employment, see the section below titled "Narrative Disclosure to Summary Compensation Table—Employment of Adam Kaplin, M.D., Ph.D."

(7) On April 16, 2021, Mr. Rivard entered into an employment agreement, under which he received an annual salary of $165,000. On March 22, 2023, Mr. Rivard was appointed as Chief Legal Officer and his annual salary was increased to $275,000, retroactively to January 1, 2023. Prior to the Merger, Mr. Rivard served as Executive Vice President of Operations and General Counsel of MyMD Florida effective September 21, 2020. Effective as of November 14, 2023, Mr. Rivard separated from his employment with the Company.

(8) On April 4, 2023, the Company granted 25,000 non-qualified stock options, on June 7, 2023, the Company granted 10,000 non-qualified stock options, and on September 6, 2023, the Company granted 33,334 non-qualified stock options to Dr. Chapman. Pursuant to the Chapman Severance Agreement (as defined herein), such options accelerated upon Dr. Chapman's resignation and Dr. Chapman was provided with three months following his resignation to exercise such options. Such options were not exercised within the prescribed period and, accordingly, were forfeited.

(9) On June 7, 2023, the Company granted 5,000 non-qualified stock options to Dr. Kaplin.

(10) Dr. Glass has served as a member of the Board of Directors since April 8, 2024. Dr. Glass' board fees totaled $6,500 for the year ended December 31, 2024.

Narrative Disclosure to Summary Compensation Table

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

Employment of Ian Rhodes

On July 21, 2020, the Company entered into a CFO Consulting Agreement (the "Consulting Agreement") with Brio Financial Group ("Brio"), pursuant to which, Brio would provide an Interim Chief Financial Officer for the Company. Effective as of January 29, 2021, the Company appointed Ian Rhodes as its interim Chief Financial Officer. Pursuant to the Consulting Agreement, the Company paid Brio an initial retainer fee of $7,500 and paid a fixed monthly payment of $13,500. The Consulting Agreement also provided that the Company would be billed for travel and other out-of-pocket costs. The Consulting Agreement expired on June 30, 2021. Since that time, Mr. Rhodes has continued to serve as the Company's interim Chief Financial Officer under the same terms set forth in the Consulting Agreement.

Employment of Chris Chapman, M.D.

Pre-Merger Employment Agreement

Effective November 1, 2020, MyMD Florida and Dr. Chapman entered into an employment agreement, which was subsequently amended by that certain First Amendment to Employment Agreement, dated December 18, 2020, that certain Second Amendment to Employment Agreement dated January 8, 2021, and that certain Third Amendment to Employment Agreement dated February 11, 2021 (such agreement, as amended, the "Chapman Employment Agreement"), pursuant to which Dr. Chapman was appointed President and Chief Medical Officer of MyMD Florida. Under the Chapman Employment Agreement, Dr. Chapman was entitled to an annual base salary of $165,000, payable monthly. Dr. Chapman was also eligible to receive bonus compensation in the form of lump-sum cash payments made within 30 days following the completion of certain specified "Bonus Events" (as defined in the Chapman Employment Agreement). The aggregate amount of bonus compensation payable to Dr. Chapman upon achievement of all specified Bonus Events was $800,000. In addition, Dr. Chapman was eligible to receive additional bonus compensation in connection with his annual performance, determined in the sole discretion of MyMD Florida's board of directors. Pursuant to and on the effective date of the Chapman Employment Agreement, Dr. Chapman was also granted options to purchase 250,000 shares of MyMD Florida Common Stock, at an exercise price of $1.00 per share, which was subsequently adjusted to options to purchase 3,215 shares of the Company's Common Stock at an exercise price of $77.10 in connection with the Merger and reverse stock split of the Company's Common Stock. Such options all vested immediately upon grant. The options had an original term of lasting until the earlier of (i) ten years from the date of grant or (ii) the second-year anniversary of the effective date of a "Reorganization Event" as defined in the MyMD Pharmaceuticals, Inc. Amended and Restated 2016 Equity Incentive Plan (as amended, the "MyMD Florida Incentive Plan") (the practical effect of which makes the term of such options expire on the second-year anniversary of the effective date of the merger, which occurred on April 16, 2021). MyMD Florida also agreed to provide and cover the cost of health insurance and disability policies for Dr. Chapman during the term of employment under the Chapman Employment Agreement.

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

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

On August 2, 2020, Dr. Chapman received a discretionary grant of options to purchase 200,000 shares of MyMD Florida Common Stock, at an exercise price of $1.00 per share which was subsequently adjusted to options to purchase 2,572 shares of Common Stock at an exercise price of $77.10 in connection with the Merger and reverse stock split of the Company's Common Stock. All such options vested immediately upon grant. The options had an original term of ten years from the date of grant, subject to certain events described in the applicable award agreement, including Dr. Chapman's, death, disability, retirement or an "Event of Cause" (as defined in the applicable award agreement). In connection with the Merger Agreement, certain terms of such options were amended. These options expired on April 16, 2023.

Post-Merger Employment Agreement

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

On November 24, 2021, the Company and Dr. Chapman entered into a Fourth Amendment to the Chapman Employment Agreement (the "Fourth Amendment"). The Fourth Amendment provided that certain performance criteria applicable to Dr. Chapman's bonus compensation under the Chapman Employment Agreement would be waived and deemed to have been achieved, and that Dr. Chapman would be entitled to a bonus payment of $100,000 as a result. On August 30, 2022, the Company and Dr. Chapman entered into a Fifth Amendment to the Chapman Employment Agreement to amend one of the performance criteria under the Chapman Employment Agreement, upon the achievement of which by the Company Dr. Chapman would be entitled to an additional bonus payment of $100,000. On February 1, 2023, the Company and Dr. Chapman entered into the Sixth Amendment to the Chapman Employment Agreement providing for Dr. Chapman's annual base salary to be set at $310,000, effective retroactively to January 1, 2023, and on September 8, 2023, the Company and Dr. Chapman entered into a Seventh Amendment to the Chapman Employment Agreement providing for Dr. Chapman's annual base salary to be set at $500,000, effective retroactively to January 1, 2023.

November 2023 Amendment

Effective November 13, 2023, the Company entered into the Eighth Amendment to the Chapman Employment Agreement providing for Dr. Chapman's annual base salary to be adjusted from $500,000 (the "Full Base Salary") to $250,000 in cash per annum, until payment of such Full Base Salary would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion. The amendment further provides that the remaining $250,000 of base salary per annum (the "Deferral Amount") shall be deferred until payment of the Deferral Amount would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time the Deferral Amount may be paid, at Dr. Chapman's election, in shares of Common Stock or in cash.

Effective June 14, 2024, the Company entered into a general release and severance agreement with Dr. Chapman ("Chapman Severance Agreement"). Pursuant to the Chapman Severance Agreement, Dr. Chapman was entitled to (i) payment in the amount of $125,000, less all lawful and authorized withholdings and deductions, to be paid in three (3) equal monthly installments, (ii) a one-time payment equal to $25,000, less all lawful and authorized withholdings and deductions, (iii) reimbursement for continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, for a period of up to three (3) months, and (iv) acceleration of certain unvested options granted to Dr. Chapman pursuant to those certain non-qualified stock option agreements, dated April 4, 2023 and June 7, 2023.

On June 14, 2024, the Company and Christopher Chapman, M.D. mutually agreed on the separation of Dr. Chapman from his position as President, Chief Medical Officer and member of the board of directors of the Company, effective as of June 14, 2024.

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

Pre-Merger Employment Agreement

Effective December 18, 2020, MyMD Florida and Dr. Kaplin entered into an employment agreement, which was subsequently amended by that certain First Amendment to Employment Agreement, dated February 11, 2021 (such agreement, as amended, the "Kaplin Employment Agreement"), pursuant to which Dr. Kaplin was appointed Chief Scientific Officer of MyMD Florida. Under the Kaplin Employment Agreement, Dr. Kaplin was entitled to an annual base salary of $250,000, payable monthly. Dr. Kaplin was also eligible to receive bonus compensation in the form of lump-sum cash payments made within 30 days following the completion of certain specified "Bonus Events" (as defined in the Kaplin Employment Agreement). The aggregate amount of bonus compensation payable to Dr. Kaplin upon achievement of all specified Bonus Events is $800,000. In addition, Dr. Kaplin was eligible to receive additional bonus compensation in connection with his annual performance, determined in the sole discretion of MyMD Florida's board of directors. On the effective date of the Kaplin Employment Agreement, Dr. Kaplin received a signing bonus in the form of a lump-sum cash payment in the amount of $100,000 and was also granted options to purchase 400,000 shares of MyMD Florida Common Stock, at an exercise price of $1.00 per share. (After giving effect to the Exchange Ratio and the Reverse Stock Split, such MyMD Florida options became options to purchase 5,145 shares of the Company's Common Stock at an exercise price of $77.10 per share.) Such options all vested immediately upon grant. The options had an original term of lasting until the earlier of (i) ten years from the date of grant or (ii) the second-year anniversary of the effective date of a "Reorganization Event" as defined in the MyMD Florida Incentive Plan (the practical effect of which made the term of such options expire on the second-year anniversary of the effective date of the merger, which occurred on April 16, 2021). MyMD Florida also agreed to provide and cover the cost of health insurance and disability policies for Dr. Kaplin during the term of employment under the Kaplin Employment Agreement.

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

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

Post-Merger Employment Agreement

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

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

November 2023 Amendment

Effective November 13, 2023, the Company entered into an amendment to the Fourth Kaplin Employment Agreement (the "Kaplin Fourth Amendment") providing that Dr. Kaplin's employment shall have an initial term of four months, which the parties may mutually agree to extend for additional consecutive terms of one month each. The Kaplin Fourth Amendment further provided that, in the event of termination without cause by the Company prior to the end of the initial term, Dr. Kaplin would receive his monthly base salary through the end of the initial term. The Kaplin Fourth Amendment further provided that all outstanding and unvested shares granted pursuant to the Nonqualified Stock Option Agreement, dated June 7, 2023, between the Company and Dr. Kaplin shall accelerate upon the termination of Dr. Kaplin's employment. The Kaplin Fourth Amendment further provided that, in the event of a termination for any reason prior to the end of the first renewal term following the end of the initial term, the Company would continue to cover the costs of Dr. Kaplin's health insurance coverage through the end of the first renewal term, subject to the execution and timely return of a release. The initial term ended on March 12, 2024, and the term of the Kaplin Employment Agreement was not extended. Dr. Kaplin served as the Company's Chief Scientific Officer and received a salary of $125,000 per annum and benefits without an employment agreement until he tendered his resignation from such role effective April 15, 2024.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning the outstanding equity awards that have been previously awarded to each of our Named Executive Officers and which remain outstanding as of December 31, 2024:

Named Executive Officer	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Option exercise price	Option expiration date[1]	Number of shares or units of stock that have not vested	Market value of shares or units of stock that have not vested
Mitchell Glass, M.D. President, Chief Medical Officer	-	-	$ -	-	-	$ -
Ian Rhodes, CPA Interim Chief Financial Officer	-	-	$ -	-	-	$ -
Christopher Chapman, M.D.	25,000(1)	-	$ 46.50	4/4/2028	-	$ -
Former President, Chief Medical Officer	10,000(2)	-	$ 49.80	6/7/2033	-	$ -
Adam Kaplin, M.D., PhD Former Chief Scientific Officer	1,667(2)	-	$ 49.80	6/7/2033	-	$ -

(1) Granted April 4, 2023. One third of the options awarded on such date vest immediately, one third vest on the first anniversary date of the grant date, and one third vest on the second anniversary of the grant date. Pursuant to the terms of the Separation Agreement, dated as of June 14, 2024, by and between the Company and Dr. Chapman (the "Separation Agreement"), in connection with Dr. Chapman's resignation from his position as President, Chief Medical Officer and member of the board of directors of the Company, the vesting of such options accelerated and Dr. Chapman had until September 14, 2024, to exercise such options. Such options were not exercised and were forfeited.

(2) Granted June 7, 2023. One third of the options awarded on such date vest immediately, one third vest on the first anniversary date of the grant date, and one third vest on the second anniversary of the grant date. Pursuant to the Separation Agreement, the vesting of such options accelerated and Dr. Chapman had until September 14, 2024, to exercise such options. Such options were not exercised and were forfeited.

Director Compensation

The following table presents the total compensation for each person who served as a member of our Board during 2024. All compensation paid to Dr. Chapman and Dr. Glass during 2024 is reported under the Summary Compensation Table. Other than as set forth in the table and described more fully below, we did not pay any compensation, reimburse any expense of, make any equity awards or non-equity awards to, or pay any other compensation to any of the other members of our Board in such period.

Name	Fees earned or paid in cash	Stock Awards[(1)]	All Other Compensation[(2)]	Total
Josh Silverman	$ 207,000	$ -	-	$ 207,000
Bill J. White	92,000	-	-	92,000
Craig Eagle, M.D	92,000	-	-	92,000
Jude Uzonwanne	92,000	-	-	92,000
Stephen Friscia	38,300	-	-	38,300
Christopher Schreiber[(3)]	-	-	244,800	244,800

(1) In accordance with SEC rules, this column reflects the aggregate fair value of stock awards granted during the fiscal year ended December 31, 2024, computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for share-based compensation transactions.
(2) This column includes salaries and matching contributions paid to participants of the 401(k) Plan for non-executive employee members of the Board.
(3) On January 24, 2020, Mr. Schreiber entered into an employment agreement with the Company, under which he would receive an annual salary of $300,000. Since then, he has served the Company in various positions, and his employment agreement with the Company remains in effect.

In connection with an overall reduction in compensation paid to the Company's directors implemented in November 2023, effective November 13, 2023, the Company entered into an amendment to the employment agreement of Mr. Schreiber providing for Mr. Schreiber's annual fee to be adjusted from $300,000 (the "Full Fee") to $60,000 in cash per annum, until payment of his Full Fee would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion. The amendment further provides that the remaining $240,000 of the fees per annum (the "Fee Deferral Amount") shall be deferred until payment of the Fee Deferral Amount would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time the Fee Deferral Amount may be paid, at Mr. Schreiber's election, in shares of Common Stock or in cash.

Narrative Disclosure to Director Compensation Table

As approved by the Compensation Committee of the Board on March 29, 2019, beginning in April 2019, each serving director who is not also holding a position as an executive officer is paid $8,000 per month. On or around May 2020, the Compensation Committee of the Board approved payments to Mr. Silverman of $18,000 per month, beginning in May 2020. All director fees were paid on a monthly basis.

On November 13, 2023, the Board approved certain adjustments to the director fees. Mr. Silverman's fees were decreased from $216,000 to $60,000 annually, with payment of the excess amount of $156,000 deferred until the date that payment of such amount would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time such amount may be paid, at Mr. Silverman's election, in shares of Common Stock or in cash. Messrs. Eagle's, Uzonwanne's, and White's fees were decreased from $96,000 to $60,000 annually, with payment of the excess amounts of $36,000 per director deferred until the date that payment of such amounts would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time such amounts may be paid, at each director's election, in shares of Common Stock or in cash.

On October 14, 2021, the Compensation Committee of the Board authorized the issuance of 93,166 restricted stock units with a fair market value of $242.70 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. As of December 31, 2024, none of the vesting milestones have been met.

On June 5, 2023, the Compensation Committee of the Board authorized the issuance, effective as of June 7, 2023, of options to purchase an aggregate of 66,498 shares of Common Stock with an exercise price of $49.80 per share to the directors and key employees of the Company. These options vested (i) one third on the date of grant; (ii) one third on the first anniversary of the date of grant; and (iii) one third on the second anniversary of the date of grant, provided that the holder remains employed by the Company or a subsidiary on the applicable vesting date.

Timing of Certain Equity Awards

We do not have any policies and practices on the timing of awards of stock options or other equity grants in relation to the disclosure of material nonpublic information. The Company grants stock options based on timelines in the normal course of business independent of the occurrence of these types of events (e.g., at a pre-established dates, such as on an employee's start date, at board of director meetings held once each year and following annual performance reviews). During the last completed fiscal year, we did not grant equity awards in anticipation of the release of material nonpublic information that is likely to result in changes to the price of our Common Stock and did not time the public release of such information based on award grant dates. During the last completed fiscal year, we have not made awards to any named executive officer during the period beginning four business days before and ending one business day after the filing of a period report on Form 10-Q or Form 10-K or the filing or furnishing of a current report on Form 8-K, and we have not timed the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Equity Compensation Plans

2021 Equity Incentive Plan

Pursuant to the Merger Agreement, at the effective time of the Merger, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"), which was approved by the Company's stockholders on April 15, 2021. The 2021 Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, and other awards which may be granted singly, in combination or in tandem, and which may be paid in cash or shares of Common Stock. At the effective time of the Merger, the number of shares of Common Stock that were reserved for issuance pursuant to awards under the 2021 Plan was 240,940 shares. On November 25, 2025, the Company's stockholders approved the First Amendment to the 2021 Plan to increase the aggregate number of shares of the Company's Common Stock available for the grant of awards under the 2021 Plan to a total of 2,500,000 shares of Common Stock. As of December 31, 2024, 2,349,184 shares remain available for issuance under the 2021 Plan.

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

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

Share Authorization. At the effective time of the Merger, the number of shares of Common Stock that were reserved for issuance pursuant to awards under the 2021 Plan was 240,940 shares, 100% of which may be delivered as incentive stock options. Shares to be issued may be made available from authorized but unissued shares of the Company's Common Stock, shares held by the Company in its treasury, or shares purchased by the Company on the open market or otherwise. During the term of the 2021 Plan, the Company will at all times reserve and keep enough shares available to satisfy the requirements of the 2021 Plan. If an award under the 2021 Plan is cancelled, forfeited, or expires, in whole or in part, the shares subject to such forfeited, expired, or cancelled award may again be awarded under the 2021 Plan. Awards that may be satisfied either by the issuance of Common Stock or by cash or other consideration shall be counted against the maximum number of shares that may be issued under the 2021 Plan only during the period that the award is outstanding or to the extent the award is ultimately satisfied by the issuance of shares. An award will not reduce the number of shares that may be issued pursuant to the 2021 Plan if the settlement of the award will not require the issuance of shares, as, for example, a stock appreciation right that can be satisfied only by the payment of cash. Shares of Common Stock that are otherwise deliverable pursuant to an award under the 2021 Plan that are withheld in payment of the option price of an option or for payment of applicable employment taxes and/or withholding obligations resulting from the award shall be treated as delivered to the award recipient and shall be counted against the maximum number of shares of our Common Stock that may be issued under the 2021 Plan. Only shares forfeited back to the Company or cancelled on account of termination, expiration, or lapse of an award shall again be available for grant of incentive stock options under the 2021 Plan but shall not increase the maximum number of shares described above as the maximum number of shares of the Company's Common Stock that may be delivered pursuant to incentive stock options.

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

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

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

Eligibility. Employees (including any employee who is also a director or an officer), contractors, and non-employee directors of the Company or any of its subsidiaries, whose judgment, initiative, and efforts contributed to or may be expected to contribute to the Company's successful performance, are eligible to participate in the 2021 Plan. As of December 31, 2024, the Company had 2 employees, 5 contractors, and 4 non-employee directors who would be eligible for awards under the 2021 Plan.

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

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

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

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

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

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

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

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

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

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

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

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

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

MyMD Florida Pre-Merger Plan

In 2016, pre-Merger MyMD Florida adopted the MyMD Pharmaceuticals, Inc. Amended and Restated 2016 Equity Incentive Plan (the "2016 Plan"). The MyMD Florida Incentive Plan provided for the issuance of up to 50,000,000 shares of pre-Merger MyMD Florida Common Stock. As of December 31, 2023, options to purchase 0 shares of Company Common Stock have been issued pursuant to the plan and 0 shares of Company Common Stock remain available for issuance.

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

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

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

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

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

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

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

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

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

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

Company Pre-Merger Plans

On December 21, 2016, the stockholders approved, and the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of up to 1,666,667 shares of the Company's common stock. As of December 31, 2024, grants of options to purchase 0 shares of Common Stock have been issued pursuant to the 2016 Plan, and 0 shares of Common Stock remain available for issuance.

On August 7, 2017, the stockholders approved, and the Company adopted the 2017 Stock Incentive Plan ("2017 Plan"). The 2017 Plan provides for the issuance of up to 118 shares of the Company's Common Stock. The purpose of the 2017 Plan is to provide additional incentive to those of our officers, employees, consultants and non-employee directors and our parents, subsidiaries and affiliates whose contributions are essential to the growth and success of our business. As of December 31, 2024, grants of restricted stock and options to purchase totaling 93 shares of Common Stock have been issued pursuant to the 2017 Plan and as of December 31, 2024, 25 shares of Common Stock remain available for grants under the 2017 Plan. The 2017 Plan provides for the issuance of shares of the Company's Common Stock through the grant of non-qualified options, incentive options, restricted stock and unrestricted stock to directors, officers, consultants, attorneys, advisors, and employees.

On December 7, 2018, the stockholders approved, and we adopted the 2018 Stock Incentive Plan (the "2018 Plan") and on August 27, 2020, the stockholders approved, and we adopted an amendment to the plan to increase the number of shares of Common Stock available for issuance pursuant to awards under the 2018 Plan by an additional 17,366 shares. The 2018 Plan, as amended, provides for the issuance of up to 18,670 shares of the Company's Common Stock. The purpose of the 2018 Plan is to provide additional incentive to those of our officers, employees, consultants and non-employee directors and to promote the success of our business. As of December 31, 2024, grants of RSUs to purchase 8,769 shares of Common Stock had been issued pursuant to the 2018 Plan, and 9,901 shares of Common Stock remained available for issuance. The 2018 Plan provides for the issuance of shares of the Company's Common Stock through the grant of options, restricted stock, stock appreciation rights, other stock-based awards, performance compensation awards to directors, officers, consultants, advisors, and employees. In addition, the 2018 Plan provides the Compensation Committee of the Board with discretion to accelerate the vesting and exercisability of outstanding awards upon the occurrence of a change of control (as defined in the 2018 Plan).

Equity Compensation Plan Information

The following table provides information regarding the number of securities to be issued under the 2013 Plan, the 2016 Plan, the 2017 Plan the 2018 Plan, and the 2021 Plan (collectively, the "Equity Compensation Plans") as of December 31, 2024:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options (b)	Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[(1)]	59,838	$ 49.03	2,399,943
Equity compensation plans not approved by security holders	-	-	-
Total	59,838	$ 49.03	2,399,943

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

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

The following table sets forth information regarding the beneficial ownership of our voting securities as of April 4, 2025 by (i) each person known to us to beneficially own five percent (5%) or more of any class of our voting securities; (ii) each of our Named Executive Officers and directors; and (iii) all of our directors and executive officers as a group.

The percentages of voting securities beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. Except as indicated in the footnotes to this table, to our knowledge and subject to community property laws where applicable, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned and each person's address is c/o TNF Pharmaceuticals, Inc., 1185 Avenue of the Americas, Suite 249, New York, NY 10036.

Percentage of Common Stock ownership is based on 7,392,565 shares of Common Stock issued and outstanding as of March 31, 2025. Percentage of Series D Convertible Preferred Stock (the "Series D Preferred Stock") ownership is based on 72,992 shares of Series D Preferred Stock issued and outstanding as of April 4, 2025. The Series F Preferred Stock ownership is based on approximately 3795.25 shares of Series F Preferred Stock outstanding as of April 4, 2025. The Series F-1 Preferred Stock ownership is based on approximately 2214.78 shares of Series F-1 Preferred Stock outstanding as of April 4, 2025. The Series G Preferred Stock ownership is based on 8,063 shares of Series G Preferred Stock outstanding as of April 4, 2025.

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

Beneficial ownership is determined in accordance with the rules of the SEC. For the purpose of calculating the number of shares beneficially owned by a stockholder and the percentage ownership of that stockholder, shares of Common Stock subject to options or warrants that are currently exercisable or exercisable within sixty (60) days of April 4, 2025 by that stockholder are deemed outstanding.

Name	Number of Shares of Common Stock Beneficially Owned (1)	Percentage of Class	Number of Shares of Series D Preferred Stock Beneficially Owned (2)	Percentage of Class	Number of Shares of Series F Preferred Stock Beneficially Owned (3)	Percentage of Class	Number of Shares of Series F-1 Preferred Stock Beneficially Owned (4)	Percentage of Class	Number of Shares of Series G Preferred Stock Beneficially Owned (5)	Percentage of Class	Total Voting Power
5% Beneficial Owner											
Richard Abbe / Iroquois Capital Investment Group, LLC (6)	387,911	4.99%	-	-	2,041.55	53.79%	496.80	22.43%	-	-	2.21%
Premas Biotech PVT Ltd. (8)	3,459	*	72,992	100%	-	-	-	-	-	-	*
Intracoastal Capital LLC (9)	388,264	4.99%	-	-	1,709.20	45.04%	1,703.06	76.90%	-	-	4.99%
PharmaCyte Biotech, Inc. (11)	57,692,313	88.64%	-	-	-	-	-	-	7,000	86.82%	26.30%
Five Narrow Lane LP (12)	388,264	4.99%	-	-	-	-	-	-	508	6.30%	1.91%
Named Executive Officers and Directors											
Joshua Silverman (14)	7,404	*	-	-	-	-	-	-	-	-	*
Bill J White (15)	5,792	*	-	-	-	-	-	-	-	-	*
Craig Eagle, M.D. (16)	10,556	*	-	-	-	-	-	-	-	-	*
Jude Uzonwanne (17)	3,333	*	-	-	-	-	-	-	-	-	*
Christopher C Schreiber (18)	6,274	*	-	-	-	-	-	-	-	-	*
Stephen Friscia	-	-	-	-	-	-	-	-	-	-	-
Mitchell Glass	-	-	-	-	-	-	-	-	-	-	-
Ian Rhodes	-	-	-	-	-	-	-	-	-	-	-
All current executive officers and Directors as a group (8 persons)	33,359	*	-	-	-	-	-	-	-	-	*

* Less than 1%.

(1) Percentage of Common Stock ownership is based on 7,392,565 shares of Common Stock issued and outstanding as of March 31, 2025.

(2) Percentage of Series D Preferred Stock ownership is based on 72,992 shares of Series D Preferred Stock issued and outstanding as of April 4, 2025.

(3) Percentage of Series F Preferred Stock ownership is based on approximately 3,795.25 shares of Series F Preferred Stock issued and outstanding as of April 4, 2025.

(4) Percentage of Series F-1 Preferred Stock ownership is based on 2,214.78 shares of Series F-1 Preferred Stock issued and outstanding as of April 4, 2025.

(5) Percentage of Series G Preferred Stock ownership is based on 8,063 shares of Series G Preferred Stock issued and outstanding as of April 4, 2025.

(6) This information is based on a Schedule 13G/A filed with the SEC on February 14, 2024, by Iroquois Capital Management, LLC ("Iroquois Capital") and on information available to the Company. The principal business office is 125 Park Avenue, 25th Floor, New York, NY 10017. Iroquois Capital is the investment advisor

for Iroquois Master Fund, Ltd. ("IMF"). As directors of IMF, Kimberly Page ("Ms. Page") and Richard Abbe ("Mr. Abbe") make voting and investment decisions on behalf of IMF. As a result of the foregoing, Ms. Page and Mr. Abbe may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by Iroquois Capital and IMF.

IMF owns (1) 6,248 shares of Common Stock, (2) 1,314.51 shares of Series F Preferred Stock, which are convertible into up to approximately 3,611,291 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (3) Series F Warrants to purchase up to 13,736,264 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (4) 303.77 Series F-1 Preferred Shares, which are convertible into up to approximately 834,533 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (5) Series F-1 Long-Term Warrants to purchase up to 3,846,154 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), and (6) Series F-1 Short-Term Warrants to purchase up to 3,846,154 shares of Common Stock (subject to a 4.99% beneficial ownership blocker).

Mr. Abbe also has voting control and investment discretion over securities held by Iroquois Capital Investment Group LLC ("ICIG"). As such, Mr. Abbe may be deemed to be the beneficial owner (as determined under Section 13(d) of the Exchange Act) of the securities held by ICIG. ICIG owns (1) 473 shares of Common Stock, (2) 727.04 shares of Series F Preferred Stock, which are convertible into up to 1,997,363 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (3) Series F Warrants to purchase up to 7,554,945 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (4) 193.03 Series F-1 Preferred Shares, which are convertible into up to 530,302 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (5) Series F-1 Long-Term Warrants to purchase up to 2,060,437 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), and (6) Series F-1 Short-Term Warrants to purchase up to 2,060,437 shares of Common Stock (subject to a 4.99% beneficial ownership blocker). In addition, by virtue of his position as a custodian or trustee of certain Accounts (The Samantha Abbe Irrevocable Trust, The Talia Abbe Irrevocable Trust and The Bennett Abbe Irrevocable Trust), Mr. Abbe may be deemed to be the beneficial owner of the 3,859 shares of Common Stock held in aggregate by such Accounts.

(7) On March 23, 2020, Premas Biotech PVT., Ltd received 103,782 (not adjusted for the Reverse Stock Split) shares of Common Stock and 72,992 shares of Series D Preferred Stock as partial compensation for their rights to Cystron.

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

(8) This information is based on certain information made available to the Company. Intracoastal Capital LLC owns (1) 1,709.20 shares of Series F Preferred Stock, which are convertible into up to 4,695,604 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (2) Series F Warrants to purchase up to 17,857,143 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (3) 1,703.06 Series F-1 Preferred Shares, which are convertible into up to 4,678,736 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (4) Series F-1 Long-Term Warrants to purchase up to 5,906,595 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), and (5) Series F-1 Short-Term Warrants to purchase up to 5,906,595 shares of Common Stock (subject to a 4.99% beneficial ownership blocker).

The principal business address of Intracoastal Capital LLC is 245 Palm Trail, Delray Beach, Florida 33483.

(9) This information is based on a Schedule 13D filed with the SEC on May 30, 2024, by PharmaCyte Biotech, Inc. ("PharmaCyte") and on information available to the Company. Consists of (i) 7,000 Series G Preferred Shares, which are convertible into up to 19,230,770 shares of Common Stock, (ii) Series G Long-Term Warrants to purchase up to 19,230,772 shares of Common Stock, and (iii) Series G Short-Term Warrants to purchase up to 19,230,772 shares of Common Stock.

The principal business address of PharmaCyte is PharmaCyte Biotech, Inc., 3960 Howard Hughes Parkway, Suite 500, Las Vegas, Nevada 89169.

(10) This information is based on certain information made available to the Company. Consists of (i) 508 Series G Preferred Shares, which are convertible into up to 1,395,604 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), (ii) Series G Long-Term Warrants to purchase up to 2,747,254 shares of Common Stock (subject to a 4.99% beneficial ownership blocker), and (iii) Series G Short-Term Warrants to purchase up to 2,747,254 shares of Common Stock (subject to a 4.99% beneficial ownership blocker).

The principal business address of Five Narrow Lane LP is 510 Madison Avenue, Suite 1400, New York, NY 10022.

(11) Represents (i) 2,959 shares of Common Stock held by Mr. Silverman and (ii) 4,445 shares of Common Stock issuable upon the exercise of options held by Mr. Silverman exercisable within 60 days of April 4, 2025.

(12) Represents (i) 2,459 shares of Common Stock held by Mr. White and (ii) 3,333 shares of Common Stock issuable upon the exercise of options held by Mr. White exercisable within 60 days of April 4, 2025.

(13) Represents 10,556 shares of Common Stock issuable upon the exercise of options held by Dr. Eagle exercisable within 60 days of April 4, 2025.

(14) Represents 3,333 shares of Common Stock issuable upon the exercise of options held by Mr. Uzonwanne exercisable within 60 days of April 4, 2025.

(15) Represents (i) 2,941 shares of Common Stock held by Mr. Schreiber and (ii) 3,333 shares of Common Stock issuable upon the exercise of options held by Mr. Schreiber exercisable within 60 days of April 4, 2025.

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

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

Other than compensation agreements, and other arrangements which are described below and under "Item 11. Executive Compensation" herein, since January 1, 2023, there has not been, and there is not currently proposed, any transaction or series of similar transactions to which we were or will be a party in which the amount involved exceeded or will exceed the lesser of $120,000 or the average of our total assets at year-end for the last two completed fiscal years and in which any director, executive officer, holder of 5% or more of any class of our capital stock, or any member of their immediate family had or will have a direct or indirect material interest.

On April 14, 2023, the Company issued a reimbursement payment to Mr. Jonnie Williams, Sr. in the amount $500,000. The payment represented reimbursement for expenses incurred by Mr. Williams meeting with potential strategic corporate partners on behalf of the Company as part of the Company's business development efforts. Mr. Williams is an immediate family member of a stockholder who beneficially holds more than 5% of our Common Stock.

Pursuant to the Series F Purchase Agreement, dated February 21, 2023, we issued to: (i) ICIG, 2,750 shares of our Series F Preferred Stock with a stated value of $1,000 per share and warrants to purchase up to 40,651 shares of Common Stock at an initial exercise price of $1.816 per share, and (ii) IMF, 5,000 shares of our Series F Preferred Stock with a stated value of $1,000 per share and warrants to purchase up to 73,910 shares of Common Stock at an initial exercise price of $1.816 per share. The aggregate gross proceeds from the February 2023 Offering were $15.0 million.

On May 23, 2024, pursuant to the Series F-1 Purchase Agreement, we issued to: (i) Iroquois Capital Investment Group LLC ("ICIG") 750 shares of our Series F-1 Preferred Stock, Long-Term Series F-1 Warrants to purchase up to 412,996 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series F-1 Warrants to purchase up to 412,996 shares of Common Stock at an initial exercise price of $1.816 per share; (ii) Iroquois Master Fund Ltd ("IMF") 1,400 shares of our Series F-1 Preferred Stock, Long-Term Series F-1 Warrants to purchase up to 770,926 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series F-1 Warrants to purchase up to 770,926 shares of Common Stock at an initial exercise price of $1.816 per share; (iii) Intracoastal Capital LLC 2,150 shares of our Series F-1 Preferred Stock, Long-Term Series F-1 Warrants to purchase up to 1,183,921 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series F-1 Warrants to purchase up to 1,183,921 shares of Common Stock at an initial exercise price of $1.816 per share; (iv) V4 Global, LLC 500 shares of our Series F-1 Preferred Stock, Long-Term Series F-1 Warrants to purchase up to 275,331 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series F-1 Warrants to purchase up to 275,331 shares of Common Stock at an initial exercise price of $1.816 per share; and (v) Mr. Scot Cohen 250 shares of our Series F-1 Preferred Stock, Long-Term Series F-1 Warrants to purchase up to 137,666 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series F-1 Warrants to purchase up to 137,666 shares of Common Stock at an initial exercise price of $1.816 per share. The aggregate gross proceeds from the Series F-1 Private Placement were $5.0 million.

On May 23, 2024, pursuant to the Series G Purchase Agreement, we issued to: (i) PharmaCyte, a Company controlled by Joshua Silverman, a director of the Company, 7,000 shares of our Series G Preferred Stock, Long-Term Series G Warrants to purchase up to 3,854,626 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series G Warrants to purchase up to 3,854,626 shares of Common Stock at an initial exercise price of $1.816 per share; (ii) Five Narrow Lane LP 750 shares of our Series G Preferred Stock, Long-Term Series G Warrants to purchase up to 412,996 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series G Warrants to purchase up to 412,996 shares of Common Stock at an initial exercise price of $1.816 per share; and (iii) Hewlett Fund LP 1,000 shares of our Series G Preferred Stock, Long-Term Series G Warrants to purchase up to 550,661 shares of Common Stock at an initial exercise price of $1.816 per share and Short-Term Series G Warrants to purchase up to 550,661 shares of Common Stock at an initial exercise price of $1.816 per share. The aggregate gross proceeds from the Series G Private Placement were $8.9 million.

On October 1, 2024, the Company entered into a Stock Purchase Agreement, dated as of October 1, 2024 (the "Prevail Purchase Agreement"), by and between the Company and Prevail Partners, LLC ("Prevail"), a beneficial owner of more than 4.99% of the Company's Common Stock, pursuant to which, the Company agreed to sell to Prevail 283,019 shares of Common Stock, at a price per share equal to $2.12, which was 120.0% of the dollar volume-weighted average price of the Company's Common Stock on the Nasdaq Stock Capital Market LLC for the thirty (30) trading days immediately preceding the date of the Prevail Purchase Agreement.

Director Independence

See "Item 10. Directors, Executive Officers, and Corporate Governance—Director Independence," above.

Item 14. Principal Accountant Fees and Services.

The following is a summary of the fees billed to us by Morison Cogen LLP, our former independent registered public accounting firm, for professional services rendered in the years ended December 31, 2024 and 2023. On September 30, 2024, in conjunction with its exit from providing audit services to publicly traded companies, Morison Cogen LLP resigned from its role as our independent registered public accounting firm. On October 3, 2024, the Audit Committee engaged Stephano Slack LLC as our independent registered public accounting firm for the fiscal year ended December 31, 2024, effective as of such date. Fees for year ended December 31, 2024, consisted of payments to Morison Cogen LLP and Stephano Slack LLC of $188,158 and $42,071, respectively.

	2024	2023
Audit Fees	$ 215,929	$ 150,492
Audit-Related Fees	-	-
Tax Fees	14,300	14,300
All Other Fees	-	-
TOTAL	$ 230,229	$ 169,136

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

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

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

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

Pre-Approval Policies and Procedures

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

All of the services rendered by Morison Cogen LLP and Stephano Slack LLC in 2024 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

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

(1) Financial Statements

(2) Financial Statements Schedule

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

(3) Exhibits

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

Item 16. Form 10-K Summary.

Not applicable

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
2.1**	Agreement and Plan of Merger and Reorganization, dated November 11, 2020, by and among Akers Biosciences, Inc., XYZ Merger Sub Inc., and MYMD Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
2.1.1	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated March 16, 2021, by and among Akers Biosciences, Inc., XYZ Merger Sub Inc., and MyMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.2 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021)
2.2	Agreement and Plan of Merger, dated March 4, 2024, by and between MyMD Pharmaceuticals, Inc., a New Jersey corporation, and MyMD Pharmaceuticals, Inc., a Delaware corporation (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 March 7, 2024).
3.1	Certificate of Incorporation of MyMD Pharmaceuticals, Inc., a Delaware corporation (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 March 7, 2024).
3.1.1	Certificate of Correction, dated March 25, 2024, to the Certificate of Incorporation of MyMD Pharmaceuticals, Inc., a Delaware corporation (incorporated herein by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K/A filed with the Securities and Exchange Commission on March 26, 2024).
3.1.2	Certificate of Amendment of Certificate of Incorporation of TNF Pharmaceuticals, Inc. (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 July 26, 2024).
3.1.3	Certificate of Amendment of Certificate of Incorporation of TNF Pharmaceuticals, Inc. (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 July 26, 2024).
3.2	Bylaws of MyMD Pharmaceuticals, Inc., a Delaware corporation (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 March 7, 2024).
3.3	Form of Series C Convertible Preferred Stock Warrant Certificate (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (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 March 24, 2020).
3.4.1	Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated herein by reference to Exhibit 4.1 to the Company's Form 8-3 filed with the Securities and Exchange Commission on May 22, 2020)
3.5	Form of Certificate of Designations of Series F Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2023).
3.5.1	Amended and Restated Certificate of Designations of Series F Convertible Preferred Stock of MyMD Pharmaceuticals, Inc. (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 8, 2024).
3.5.2	Certificate of Amendment of Amended and Restated Certificate of Designations of Series F Convertible Preferred Stock of MyMD Pharmaceuticals, Inc. (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 May 21, 2024).
3.5.3+	Certificate of Amendment of Amended and Restated Certificate of Designations of Series F Convertible Preferred Stock.

3.6	Certificate of Designations of Series F-1 Convertible Preferred Stock (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 May 23, 2024).
3.6.1+	Certificate of Amendment of Certificate of Designations of Series F-1 Convertible Preferred Stock.
3.7	Certificate of Designations of Series G Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 23, 2024).
3.7.1	Certificate of Amendment of Certificate of Designations of Series G Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2024).
3.7.2	Certificate of Amendment of Certificate of Designations of Series G Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 24, 2024).
3.7.3	Certificate of Amendment of Certificate of Designations of Series G Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2024).
4.1+	Description of Securities.
4.2	Form of Pre-Funded Warrant Certificate (incorporated herein by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
4.3	Form of Placement Agent Warrant Certificate (incorporated herein by reference to Exhibit 4.12 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022).
4.4	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020).
4.5	Form of Placement Agent Warrant (incorporated herein by references to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020).
4.6	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020).
4.7	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 18, 2020).
4.8	Rights Agreement dated as of September 9, 2020 between Akers Biosciences, Inc. and VStock Transfer, LLC as Rights Agent (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2020).
4.8.1	Amendment No. 1 to Rights Agreement, dated as of March 18, 2021, by and between Akers Biosciences, Inc. and VStock Transfer, LLC, as Rights Agent (incorporated herein by reference to Exhibit 4.19 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021).

4.9	Form of Pre-Funded Warrant. of Akers Biosciences, Inc. (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
4.10	Form of Investor Warrant. of Akers Biosciences, Inc. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
4.11	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 15, 2022).
4.12	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2023).
4.12.1	Form of Amendment to Series F Warrant, dated March 14, 2024, by and between TNF Pharmaceuticals, Inc. and the investors party thereto. (incorporated herein by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2024).
4.13	Form of Series G Long-Term Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2024).
4.13.1	Form of Amendment to Series G Long-Term Warrant (incorporated herein by reference to Exhibit 4.8 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 19, 2024).
4.14	Form of Series G Short-Term Warrant (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2024).
4.14.1	Form of Amendment to Series G Short Term Warrant (incorporated herein by reference to Exhibit 4.9 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 19, 2024).
4.15	Form of Series F-1 Long-Term Warrant (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2024).
4.15.1	Form of Amendment to Series F-1 Long-Term Warrant (incorporated herein by reference to Exhibit 4.6 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 19, 2024).
4.16	Form of Series F-1 Short-Term Warrant (incorporated herein by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2024).
4.16.1	Form of Amendment to Series F-1 Short-Term Warrant (incorporated herein by reference to Exhibit 4.7 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 19, 2024).

10.1	Form of Placement Agency Agreement, dated March 30, 2017, by and between the Company and Joseph Gunnar and Co., LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.2	Form of Securities Purchase Agreement, dated March 30, 2017, by and between the Company and various purchasers. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.3	Form Registration Rights Agreement, dated March 30, 2017, by and between the Company and various purchasers (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.4#	2017 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2017).
10.5	Form of Securities Purchase Agreement, dated October 31, 2018, by and among the Company and the investors signatory thereto (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018).
10.6#	2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2018).
10.7	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
10.8#	Offer of Employment to Christopher C. Schreiber, dated January 31, 2020 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 31, 2020).
10.9	Membership Interest Purchase Agreement, dated as of March 23, 2020, by and among the members of Cystron Biotech, LLC and the Company (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).

10.9.1	Amendment No.1 to the Membership Interest Purchase Agreement, dated May 14, 2020 (incorporated herein by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2020).
10.10	Support Agreement, dated as of March 23, 2020, by and among the Company and certain of its stockholders (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.11	Registration Rights Agreement, dated as of March 23, 2020, by and among certain members of Cystron Biotech, LLC and the Company (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.12	Amended and Restated License and Development Agreement by and among Premas Biotech PVT Ltd and Cystron Biotech, LLC (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.13	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020).
10.14	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020).
10.15#	CFO Consulting Agreement, dated as of July 21, 2020, between the Company and Brio Financial Group (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 22, 2020).
10.16	Settlement Agreement and General, Release, dated as of August 3, 2020, by and among the Company and ChubeWorkx Guernsey Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 07, 2020).
10.17	Leak-Out and Support Agreement, dated as of August 3, 2020, by and among the Company and ChubeWorkx Guernsey Limited (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 07, 2020).
10.18	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020).
10.19#	First Amendment to the Akers Biosciences, Inc., 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 28, 2020).
10.20	Secured Promissory Note, dated November 11, 2020, by and between the Company and MYMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
10.21	Form of Securities Purchase Agreement, dated November 11, 2020, by and between the Company and purchasers named therein (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020).
10.22	Contribution and Assignment Agreement, dated March 16, 2021, by and among Akers Biosciences, Inc., Cystron Biotech LLC, and Oravax Medical Inc. (incorporated herein by reference to Exhibit 10.48 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021).

10.23	Termination and Release Agreement, dated March 16, 2021, by and among Akers Biosciences, Inc., Cystron Biotech LLC, Premas Biotech Pvt. Ltd., and the other parties signatory thereto (incorporated herein by reference to Exhibit 10.49 to the Company's Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on March 19, 2021).
10.24#	MyMD Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
10.24.1#	First Amendment to the TNF Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 26, 2024).
10.25#	Form of Nonqualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
10.26#	Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
10.27#	Form of Restricted Stock Award Agreement (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2021).
10.28	Asset Purchase Agreement, dated November 11, 2020, by and between MyMD Pharmaceuticals, Inc. and Supera Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.29#	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).
10.30	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).
10.31	Amended and Restated Confirmatory Patent Assignment and Royalty Agreement dated November 11, 2020, by and between SRQ Patent Holdings, LLC and MyMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 18, 2021).
10.32#	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).
10.32.1#	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).

10.32.2#	Amendment No. 2 to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals, Inc., dated November 24, 2021 (incorporated herein by reference to Exhibit 10.67 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022)
10.32.3#	Third Amendment to Employment Agreement between Adam Kaplin and MyMD Pharmaceuticals, Inc., dated August 30, 2022 (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 November 10, 2022).
10.32.4#	Fourth Amendment to Employment Agreement, dated November 13, 2023, by and between MyMD Pharmaceuticals, Inc. and Dr. Adam Kaplin (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 November 14, 2023).
10.33#	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).
10.33.1#	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).
10.33.2#	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).
10.33.3#	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).
10.33.4#	Amendment No. 4 to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals, Inc., dated November 24, 2021 (incorporated herein by reference to Exhibit 10.66 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022).
10.33.5#	Fifth Amendment to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals, Inc., dated August 30, 2022 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 2022).
10.33.6#	Sixth Amendment to Employment Agreement between Chris Chapman and MyMD Pharmaceuticals, Inc., dated January 1, 2023 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 3, 2023).
10.33.7#	Seventh Amendment to Employment Agreement, dated September 6, 2023, by and between MyMD Pharmaceuticals, Inc. and Dr. Chris Chapman (incorporated herein by reference to Exhibit 10.58 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2024).
10.33.8#	Eighth Amendment to Employment Agreement, dated November 13 2023, by and between MyMD Pharmaceuticals, Inc. and Dr. Chris Chapman (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2023).

10.33.9	General Release and Severance Agreement, by and between MyMD Pharmaceuticals, Inc. and Christopher Chapman, dated as of June 14, 2024 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2024).
10.34	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 15, 2022).
10.35	Form of Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2023).
10.36#	First Amendment to Agreement, dated November 13, 2023, by and between MyMD Pharmaceuticals, Inc. and Christopher C. Schreiber (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2023).
10.37	Form of Omnibus Waiver and Amendment, dated April 5, 2024, by and between TNF Pharmaceuticals, Inc. and the investors party thereto (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2024).
10.38	Form of Amendment Agreement, dated as of June 17, 2024, by and among MyMD Pharmaceuticals, Inc. and the investors party thereto (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2024).
10.39	Form of Series G Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2024).
10.40	Form of Series F-1 Purchase Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2024).
10.41	Form of Series G Registration Rights Agreement (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 May 21, 2024).
10.42	Form of Series F-1 Registration Rights 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 May 21, 2024).
10.43	Form of Omnibus Waiver, Consent, Notice and Amendment, by and among MyMD Pharmaceuticals, Inc. and the investors party thereto (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 May 21, 2024).
10.44	Stock Purchase Agreement, dated as of October 1, 2024, by and between TNF Pharmaceuticals, Inc. and Prevail Partners, LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 7, 2024).
10.45+	Form of Omnibus Amendment Agreement, dated March 30, 2025, by and between TNF Pharmaceuticals, Inc. and the investors party thereto.
19.1+	TNF Pharmaceuticals, Inc. Insider Trading Policy.
21.1	List of Subsidiaries of TNF Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2023)
23.1+	Consent of Morison Cogen LLP, Independent Registered Public Accounting Firm.
31.1+	Certification of the Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2+	Certification of the Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1*	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	TNF Pharmaceuticals, Inc. Compensation Recovery Policy (incorporated herein by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2024).
101	Interactive Data Files of Financial Statements and Notes.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Filed herewith

* Furnished herewith.

Management contract or compensatory plan or arrangement.

** The schedules and exhibits to the Agreement and Plan of Merger and Reorganization have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TNF PHARMACEUTICALS, INC.

Date: April 11, 2025

By: */s/ Mitchell Glass*
Name: Mitchell Glass, M.D.
Title: President and Chief Medical Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Mitchell Glass Christopher C. Chapman, M.D.	President, Chief Medical Officer and Director (Principal Executive Officer)	April 11, 2025
/s/ Ian Rhodes Ian Rhodes	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 11, 2025
/s/ Joshua Silverman Joshua Silverman	Chairman of the Board	April 11, 2025
/s/ Bill J. White Bill J. White	Director	April 11, 2025
/s/ Christopher C. Schreiber Christopher C. Schreiber	Director	April 11, 2025
/s/ Jude Uzonwanne Jude Uzonwanne	Director	April 11, 2025
/s/ Craig Eagle Craig Eagle, M.D.	Director	April 11, 2025

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
TNF Pharmaceuticals. Inc. and Subsidiaries

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of TNF Pharmaceuticals. Inc. and Subsidiaries (the "Company") as of December 31, 2024 and the related consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has experienced a net loss and negative cash flows from operations for the year ended December 31, 2024, which raises substantial doubt about their ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of their internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of preferred stock and bifurcated embedded derivative

As discussed in Notes 1 and 2 to the consolidated financial statements, on February 21, 2023, the Company sold 15,000 shares of Series F Convertible Preferred Stock ("Series F Preferred Stock"), with various embedded features. The Preferred Stock was determined to be more akin to a debt-like host than an equity-like host. The Company concluded that the embedded features were not clearly and closely related to the debt host instrument and thus were deemed to be bifurcated embedded derivatives ("Embedded Derivative"). The Embedded Derivative liabilities are measured at fair value at inception and then are required to be re-measured and reported at fair value at each reporting period. Management's estimate of the Embedded Derivative liabilities as of December 31, 2024 was $0. On April 8, 2025, the Company entered into an Omnibus Amendment Agreement with the Series F Preferred Stock holders, which amended certain terms of the Certificate of Designations surrounding the Stated Value, the timing and amount of installment redemptions and the final maturity date of the Series F Preferred Stock. This amendment resulted in an extinguishment of the original instrument and reissuance of Series F Preferred Stock on December 31, 2024. The estimated fair value of the Series F Preferred Stock at December 31, 2024 reissuance was $4,930,000.

As discussed in Notes 1 and 2 to the consolidated financial statements, on May 20, 2024, the Company sold 5,050 shares of Series F-1 Convertible Preferred Stock ("Series F-1 Preferred Stock"), with various embedded features. The Preferred Stock was determined to be more akin to a debt-like host than an equity-like host. The Company concluded that the embedded features were not clearly and closely related to the debt host instrument and thus were deemed to be bifurcated embedded derivatives ("Embedded Derivative"). The Embedded Derivative liabilities are measured at fair value at inception and then are required to be re-measured and reported at fair value at each reporting period. Management's estimate of the Embedded Derivative liabilities at inception and as of December 31, 2024 was $854,000 and $1,303,000. The estimated fair value of the Series F-1 Preferred Stock at issuance was $9,323,000.

As discussed in Notes 1 and 2 to the consolidated financial statements, on May 20, 2024, the Company sold 8,950 shares of Series G Convertible Preferred Stock ("Series G Preferred Stock"). The estimated fair value of the Series G Preferred Stock at issuance was $22,260,000.

Management applies considerable judgment in selecting assumptions used to estimate the fair value of Preferred Stock and Embedded Derivative liabilities and changes in market conditions or variations in certain assumptions could result in significant fluctuations in the estimate. Management estimates the fair value of the Preferred Stock and Embedded Derivative liabilities using a Monte Carlo simulation model, with the following inputs: the fair value of the Company's common stock on the issuance date and re-measurement date, estimated equity volatility, estimated traded volume volatility, the time to maturity, a discounted market interest rate, a dividend rate, a penalty dividend rate, and probability of default. The fair value of the bifurcated derivative liabilities was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

Given the inherent uncertainty in selecting assumptions and the complexity of the calculations, we have determined that management's valuation of the Preferred Stock and Embedded Derivative liabilities is a critical audit matter which required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the judgments made and the reasonableness of the models and assumptions used in the valuation. The audit effort included the use of professionals with specialized skill and knowledge to assist in performing these procedures and evaluating the audit evidence obtained from these procedures.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- With the involvement of our fair value specialists, we developed an independent fair value estimate for a sample and compared our estimate to the Company's estimate and evaluated any differences. We developed our estimate by evaluating the observable and unobservable inputs used by management or developing independent inputs.

- With the involvement of our fair value specialists, we evaluated the methods, models, and judgments applied by management in the determination of principal assumptions and the calculations of fair value of Preferred Stock and Embedded Derivative liabilities.

- For the re-measurement at December 31, 2024, we evaluated management's ability to accurately estimate fair value by comparing management's fair value re-measurements at quarterly reporting dates during 2024 to their fair value re-measurement at December 31, 2024.

Goodwill - Assessment of Impairment

As of December 31, 2024, the Company's goodwill balance was approximately $10.5 million. As discussed in Note 2 to the consolidated financial statements, the Company tests goodwill for impairment annually, or more frequently if certain events or changes in circumstances indicate that the fair value of the reporting unit may be less than its carrying amount. The Company operates as a single reporting unit and performed its annual impairment test as of December 31, 2024, using both qualitative and quantitative approaches. The Company's assessment included consideration of a third-party valuation and a recent equity financing transaction. The results of these analyses, along with various mitigating factors, were evaluated to determine if goodwill impairment was necessary.

The principal considerations for our determination that performing procedures relating to the impairment assessment for goodwill is a critical audit matter is the significant judgment by management in making the qualitative and quantitative assessment of whether goodwill was impaired. This in turn led to significant auditor judgment in assessing whether the fair value of the reporting unit exceeded its carrying amount, particularly given the pre-revenue status of the Company, its reliance on ongoing research and development activities, and its low market capitalization relative to book value.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- Gaining an understanding of management's impairment testing process and verifying that the Company operates as a single reporting unit.
- Evaluation of management's qualitative assessment of whether events or changes in circumstances indicate potential of goodwill.
- Reviewing the third-party valuation report and other key documents used by management to assess the fair value of the reporting unit.
- Evaluating the recent equity financing transaction, including the investor composition and terms, and assessing its relevance in determining the fair value of the reporting unit.

Going Concern Assessment

As discussed in Note 3 to the consolidated financial statements, historically, the Company has incurred net losses. Since its inception, the Company has met its liquidity requirements principally through the sale of its preferred and common stock in public and private placements. The Company believes that its current financial resources as of the date of issuance of the consolidated financial statements are not sufficient to fund its current operating budget and contractual obligations as of December 31, 2024 as they fall due in the next twelve-month period, and as such have concluded that there are material uncertainties related to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern. In making such a determination, management prepared a short-term cash flow projection. Management used significant assumptions in preparing the short-term cash flow projection, which included operating costs and financing obligations.

The principal considerations for our determination that performing procedures relating to the going concern assessment is a critical audit matter are the significant judgments in management's plans to fund its operating budget and contractual obligations. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate management's conclusion that it is probable the Company's plans will be effectively implemented within twelve months after the date the consolidated financial statements are issued and will provide the necessary cash flows to fund the Company's operating budget and contractual obligations.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- Evaluation of the reasonableness of key assumptions and estimates used by the management in the short-term cash flow projection in the light of its existing operating requirements and plans.
- Evaluation of the reasonableness of management's plans on the cash flow requirements of the operations.
- Testing the completeness, accuracy, and relevance of underlying data in the short-term cash flow projection.
- Evaluation of the adequacy of the Company's disclosure of these circumstances in the consolidated financial statements.

Investment in Oravax, Inc. - Assessment of Impairment

As discussed in Note 2 to the consolidated financial statements, the Company has elected to measure its investment in Oravax Medical, Inc. as an equity security without a readily determinable fair value. Under this election, an equity security without a readily available fair value is reflected at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. At each reporting period, the Company is required to make a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. If deemed impaired, the Company is required to estimate the fair value of the investment and recognize an impairment loss equal to the difference between the fair value of the investment and its carry amount. As of December 31, 2024, the Company performed a qualitative assessment to evaluate whether the investment is impaired and determined that the investment was not impaired and thus no adjustment to fair market value was required as of December 31, 2024. In making such a determination, management prepared a detailed qualitative analysis considering various impairment indicators. Management used significant judgment in their qualitative assessment.

The principal considerations for our determination that performing procedures relating to the impairment assessment of investments in equity securities without readily determinable fair value is a critical audit matter is the significant judgment by management in making the qualitative assessment of whether investments in equity securities were impaired. This in turn led to significant auditor judgment and effort in performing procedures to evaluate the reasonableness of significant judgments management applied in determining whether events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- Analyzing management's detailed qualitative analysis considering various impairment indicators that may indicate that the carrying amount of the investment might not be recoverable for reasonableness.

- Reviewing management's assessment of events or changes in circumstances for reasonableness.

- Evaluating management's significant accounting policies related to the election to measure its investment in Oravax Medical, Inc. as an equity security without a readily determinable fair value.

/s/ Stephano Slack LLC
We have served as the Company's auditor since 2024.
Wayne, Pennsylvania
April 11, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
TNF Pharmaceuticals, Inc. (formerly, MyMD Pharmaceuticals, Inc.) and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of TNF Pharmaceuticals, Inc. (formerly, MyMD Pharmaceuticals, Inc.) and Subsidiaries (the Company) as of December 31, 2023 and the related consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for the year ended December 31, 2023 and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and the results of their operations and their cash flows for the year ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has experienced a net loss and negative cash flows from operations for the year ended December 31, 2023, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of bifurcated embedded derivative

As discussed in Note 2 to the consolidated financial statements, on February 21, 2023, the Company sold 15,000 shares of Series F Convertible Preferred Stock ("Preferred Stock"), with various embedded features. The Preferred Stock was determined to be more akin to a debt-like host than an equity-like host. The Company concluded that the embedded features were not clearly and closely related to the debt host instrument and thus were deemed to be bifurcated embedded derivatives ("Embedded Derivative"). The Embedded Derivative liabilities are measured at fair value at inception and then are required to be re-measured and reported at fair value at each reporting period. Management's estimate of the Embedded Derivative liabilities at inception and as of December 31, 2023 was $3,149,800 and $61,000. Management applies considerable judgment in selecting assumptions used to estimate the Embedded Derivative liabilities and changes in market conditions or variations in certain assumptions could result in significant fluctuations in the estimate. Management estimates the fair value of the Embedded Derivative liabilities using a Monte Carlo simulation model, with the following inputs: the fair value of the Company's common stock on the issuance date and re-measurement date, estimated equity volatility, estimated traded volume volatility, the time to maturity, a discounted market interest rate, a dividend rate, a penalty dividend rate, and probability of default. The fair value of the bifurcated derivative liabilities was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

Given the inherent uncertainty in selecting assumptions and the complexity of the calculations, we have determined that management's valuation of Embedded Derivative liabilities is a critical audit matter which required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the judgments made and the reasonableness of the models and assumptions used in the valuation. The audit effort included the use of professionals with specialized skill and knowledge to assist in performing these procedures and evaluating the audit evidence obtained from these procedures

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- With the involvement of our fair value specialists, we developed an independent fair value estimate for a sample and compared our estimate to the Company's estimate and evaluated any differences. We developed our estimate by evaluating the observable and unobservable inputs used by management or developing independent inputs.
- With the involvement of our fair value specialists, we evaluated the methods, models, and judgments applied by management in the determination of principal assumptions and the calculation of Embedded Derivative liabilities.
- For the re-measurement at December 31, 2023, we evaluated management's ability to accurately estimate fair value by comparing management's fair value re-measurements at quarterly reporting dates during 2023 to their fair value re-measurement at December 31, 2023.

Going Concern Assessment

As discussed in Note 3 to the consolidated financial statements, historically, the Company has incurred net losses. Since its inception, the Company has met its liquidity requirements principally through the sale of its preferred and common stock in public and private placements. The Company believes that its current financial resources as of the date of issuance of the consolidated financial statements are not sufficient to fund its current operating budget and contractual obligations as of December 31, 2023 as they fall due in the next twelve-month period, and as such have concluded that there are no material uncertainties related to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern. In making such a determination, management prepared a short-term cash flow projection. Management used significant assumptions in preparing the short-term cash flow projection, which included operating costs and financing obligations.

The principal considerations for our determination that performing procedures relating to the going concern assessment is a critical audit matter are the significant judgments in management's plans to fund its operating budget and contractual obligations. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate management's conclusion that it is probable the Company's plans will be effectively implemented within twelve months after the date the consolidated financial statements are issued and will provide the necessary cash flows to fund the Company's operating budget and contractual obligations.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- Evaluation of the reasonableness of key assumptions and estimates used by the management in the short-term cash flow projection in the light of its existing operating requirements and plans.
- Evaluation of the reasonableness of management's plans on the cash flow requirements of the operations.
- Testing the completeness, accuracy, and relevance of underlying data in the short-term cash flow projection.
- Evaluation of the adequacy of the Company's disclosure of these circumstances in the consolidated financial statements.

Assessment of Impairment for Investment in Oravax, Inc.

As discussed in Note 2 to the consolidated financial statements, the Company has elected to measure its investment in Oravax Medical, Inc. as an equity security without a readily determinable fair value. Under this election, an equity security without a readily available fair value is reflected at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. At each reporting period, the Company is required to make a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. If deemed impaired, the Company is required to estimate the fair value of the investment and recognize an impairment loss equal to the difference between the fair value of the investment and its carry amount. As of December 31, 2023, the Company performed a qualitative assessment to evaluate whether the investment is impaired and determined that the investment was not impaired and thus no adjustment to fair market value was required as of December 31, 2023. In making such a determination, management prepared a detailed qualitative analysis considering various impairment indicators. Management used significant judgment in their qualitative assessment.

The principal considerations for our determination that performing procedures relating to the impairment assessment of investments in equity securities without readily determinable fair value is a critical audit matter is the significant judgment by management in making the qualitative assessment of whether investments in equity securities were impaired. This in turn led to significant auditor judgment and effort in performing procedures to evaluate the reasonableness of significant judgments management applied in determining whether events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included the following:

- Analyzing management's detailed qualitative analysis considering various impairment indicators that may indicate that the carrying amount of the investment might not be recoverable for reasonableness.
- Reviewing management's assessment of events or changes in circumstances for reasonableness.
- Evaluating management's significant accounting policies related to the election to measure its investment in Oravax Medical, Inc. as an equity security without a readily determinable fair value.

/s/ Morison Cogen LLP

We served as the Company's auditor from 2010 to 2024.

Blue Bell, Pennsylvania
April 1, 2024

TNF PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2024 and 2023

	As of	
	December 31, 2024	**December 31, 2023**
ASSETS		
Current Assets		
Cash and Cash Equivalents	$ 173,154	$ 2,681,010
Marketable Securities	8,345,082	2,242,106
Prepaid Expenses	893,730	893,226
Total Current Assets	9,411,966	5,816,342
Non-Current Assets		
Operating Lease Right-of-Use Assets	10,579	47,389
Goodwill	10,498,539	10,498,539
Investment in Oravax, Inc.	1,500,000	1,500,000
Total Non-Current Assets	12,009,118	12,045,928
Total Assets	$ 21,421,084	$ 17,862,270
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$ 2,902,104	$ 3,716,218
Due to MyMD Florida Shareholders	29,982	29,982
Operating Lease Liability	10,579	48,870
Derivative Liabilities	1,303,000	61,000
Warrant Liabilities	-	867,000
Dividends Payable	2,455,675	265,019
Total Current Liabilities	6,701,340	4,988,089
Non-Current Liabilities		
Deferred Compensation Payable	-	100,538
Total Non-Current Liabilities	-	100,538
Total Liabilities	$ 6,701,340	$ 5,088,627
Commitments and Contingencies		
Mezzanine Equity		
Series F Convertible Preferred Stock, 15,000 shares designated, par value $0.001 and a stated value of $1,000 per share, 4,211 and 6,633 shares issued and outstanding as of December 31, 2024 and December 31, 2023. Liquidation preference of $4,211,000 plus dividends at 10% per annum of $1,600,807 as of December 31, 2024	4,930,004	6,500,278
Series F Convertible Preferred Stock – Discount	-	(4,702,023)
Series F Convertible Preferred Stock – Derivative	-	(1,394,184)
Series F-1 Convertible Preferred Stock, 5,050 shares designated, par value $0.001 and a stated value of $1,000 per share, 4,747 and 0 shares issued and outstanding as of December 31, 2024 and December 31, 2023. Liquidation preference of $4,747,000 plus dividends at 10% per annum of $295,836 as of December 31, 2024	4,744,101	-
Series F-1 Convertible Preferred Stock – Discount	(4,744,101)	-
Series G Convertible Preferred Stock, 12,826,273 shares designated, par value $0.001 and a stated value of $1,000 per share, 8,884 and 0 shares issued and outstanding as of December 31, 2024 and December 31, 2023. Liquidation preference of $8,884,000 plus dividends at 10% per annum of $559,032 as of December 31, 2024	8,884,000	-
Series G Convertible Preferred Stock – Discount	(8,884,000)	-
Total Mezzanine Equity	4,930,004	404,071
STOCKHOLDERS' EQUITY		
Preferred Stock, par value $0.001, 50,000,000 total preferred shares authorized		
Series D Convertible Preferred Stock, 211,353 shares designated, $0.001 par value and a stated value of $0.01 per share, 72,992 shares issued and outstanding as of December 31, 2024 and December 31, 2023	144,524	144,524
Common Stock, par value $0.001, 250,000,000 shares authorized, 3,363,603 and 2,018,857 shares issued and outstanding as of December 31, 2024 and December 31, 2023	3,364	2,019
Additional Paid in Capital	138,780,138	114,200,096
Accumulated Deficit	(129,138,286)	(101,977,067)
Total Stockholders' Equity	9,789,740	12,369,572
Total Liabilities and Stockholders' Equity	$ 21,421,084	$ 17,862,270

TNF PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Comprehensive Loss

	For the Years Ended December 31,	
	2024	**2023**
Product Revenue	$ -	$ -
Product Cost of Sales	-	-
Gross Income	-	-
Administrative Expenses	4,161,907	5,442,886
Research and Development Expenses	3,441,010	7,867,795
Stock Based Compensation	1,057,271	3,049,537
Series F Warrant Issuance Expenses	-	762,834
Series F-1 Warrant Issuance Expenses	539,097	-
Series G Warrant Issuance Expenses	969,505	-
Loss from Operations	(10,168,790)	(17,123,052)
Other (Income) Expenses		
Interest and Dividend Income	(351,809)	(455,570)
Gain on Sales of Marketable Securities	(976)	(416)
Unrealized Gain on Marketable Securities	(671)	(514)
Change in fair value of Derivatives Liabilities	388,000	(3,088,800)
Change in fair value of Warrant Liabilities	4,410,000	(9,756,000)
Loss on issuance of Series F-1 Convertible Preferred Stock	3,737,000	-
Loss on issuance of Series G Convertible Preferred Stock	5,109,000	-
Casualty Loss/(Gain)	(100,000)	178,198
Total Other (Income) Expenses	13,190,544	(13,123,102)
Loss Before Income Tax	(23,359,334)	(3,999,950)
Income Tax Benefit	-	-
Net Loss	$ (23,359,334)	$ (3,999,950)
Preferred Stock Dividends	3,801,885	4,218,213
Net Loss Attributable to Common Stockholders	$ (27,161,219)	$ (8,218,163)
Basic and Dilutive net loss per common share	$ (11.15)	$ (5.33)
Weighted average basic and diluted common shares outstanding	2,437,000	1,542,453

The accompanying notes are an integral part to these consolidated financial statements.

TNF PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statement of Changes in Stockholders' Equity
For the Years Ended December 31, 2024 and 2023

	Series F Convertible Preferred Stock		Series F-1 Convertible Preferred Stock		Series G Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Equity
	Shares	Series F	Shares	Series F-1	Shares	Series G	Shares	Series D	Shares	Common Stock Par Value $0.001			
Balance at December 31, 2023	6,633	$ 404,071	-	$ -	-	$ -	72,992	$ 144,524	2,018,857	$ 2,019	$114,200,096	$(101,977,067)	$ 12,369,572
Net loss	-	-	-	-	-	-	-	-	-	-	-	(23,359,334)	(23,359,334)
Issuance of common stock for vested restricted stock units	-	-	-	-	-	-	-	-	908	1	(1)	-	-
Issuance of common stock for services	-	-	-	-	-	-	-	-	283,019	283	599,717	-	600,000
Issuance of 5,050 shares of Series F-1 Convertible Preferred Stock, net of discount and offering costs of $35,252	-	-	5,050	-	-	-	-	-	-	-	-	-	-
Issuance of 8,950 shares of Series G Convertible Preferred Stock, net of discount and offering costs of $48,559	-	-	-	-	8,950	-	-	-	-	-	-	-	-
Redemption of 1,195 shares of stock	(1,195)	(73,472)	-	-	-	-	-	-	-	-	-	-	-
Accelerated Conversion of 1,251 shares of Series F Convertible Preferred Stock	(1,227)	(74,330)		-	-	-	-	-	747,283	747	292,404	-	293,151
Accelerated Conversion of 303 shares of Series F-1 Convertible Preferred Stock	-	-	(303)	-	-	-	-		262,768	263	35,437	-	35,700
Conversion of 66 shares of Series G Convertible Preferred Stock	-	-	-	-	(66)	-	-		50,768	51	(51)	-	-
Preferred Stock Dividends	-	-	-	-	-	-	-	-	-	-	-	(3,801,885)	(3,801,885)
Reclass of warrant liability upon warrant modiffication for Series F Convertible	-	-	-	-	-	-	-	-	-	-	7,961,000		7,961,000

Preferred Stock													
Reclass of warrant liability upon warrant modiffication for Series F-1 Convertible Preferred Stock	-	-	-	-	-	-	-	-	-	-	19,308,000		19,308,000
Modification of Series F Convertible Preferred Stock	-	4,673,735	-	-	-	-	-	-	-	-	(4,673,735)		(4,673,735)
Stock based compensation - stock options	-	-	-	-	-	-	-	-	-	-	1,057,271	-	1,057,271
Balance at December 31, 2024	4,211	$4,930,004	4,747	$ -	8,884	$ -	72,992	$ 144,524	3,363,603	$ 3,364	$138,780,138	$(129,138,286)	$ 9,789,740

	Series F Convertible Preferred Stock		Series F-1 Convertible Preferred Stock		Series g Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock				
	Shares	Series F	Shares	Series F-1	Shares	Series G	Shares	Series D	Shares	Common Stock Par Value $0.001	Additional Paid In Capital	Accumulated Deficit	Total Equity
Balance at December 31, 2022	-	$ -	-	$ -	-	$ -	72,992	$ 144,524	1,315,674	$ 1,316	$108,308,120	$ (93,758,904)	$14,695,056
Net loss	-	-	-	-	-	-	-	-	-	-	-	(3,999,950)	(3,999,950)
Round-up shares from the 1-for-30 reverse split effective February 23, 2024	-	-	-	-	-	-	-	-	65,960	66	(66)	-	-
Issuance of common stock for vested restricted stock units	-	-	-	-	-	-	-	-	7,861	8	(8)	-	-
Exercise of prepaid equity forward contract	-	-	-	-	-	-	-	-	4,505	4	(4)	-	-
Issuance of 15,000 shares of Series F Convertible Preferred Stock, net of discount and offering costs of $14,087,111	15,000	912,889	-	-	-	-	-	-	-	-	-	-	-
Conversion of 4,937 shares of Series F Convertible Preferred Stock, July 1, 2023 through October 1, 2023, monthly installments of $1,429,871 paid with common stock	(4,937)	(291,880)	-	-	-	-	-	-	204,457	205	981,805	-	982,010
Redemption of 1,389 shares of Series F Convertible Preferred Stock, November 1, 2023 through December 1, 2023, monthy linstallments of $1,429,871 paid with cash and common stock	(1,389)	(89,635)	-	-	-	-	-	-	-	-	-	-	-
Accelerated Conversion of 2,041 shares of Series F	(2,041)	(127,303)	-	-	-	-	-	-	335,077	335	427,965	-	428,300

Convertible Preferred Stock													
Deemed Dividend for the true-up of the August 1, 2023 installment for the Series F Convertible Preferred Stock paid with common stock	-	-	-	-	-	-	-	-	29,045	29	766,474	(766,503)	-
Deemed Dividend for the true-up of the October 1, 2023 installment for the Series F Convertible Preferred Stock paid with common stock	-	-	-	-	-	-	-	-	56,278	56	666,273	(666,329)	-
Preferred Stock Dividends	-	-	-	-	-	-	-	-	-	-	-	(2,785,381)	(2,785,381)
Stock based compensation - stock options	-	-	-	-	-	-	-	-	-	-	3,049,537	-	3,049,537
Balance at December 31, 2023	6,633	$ 404,071	-	$ -	-	$ -	72,992	$ 144,524	2,018,857	$ 2,019	$114,200,096	$(101,977,067)	$12,369,572

The accompanying notes are an integral part of these consolidated financial statements

TNF PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss from ongoing operations	$ (23,359,334)	$ (3,999,950)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of marketable securities	(976)	(416)
Change in fair value of marketable securities	(671)	(514)
Change in fair value of derivatives	388,000	(3,088,800)
Change in fair value of warrants	4,410,000	(9,756,000)
Loss on issuance of Series F-1 Convertible Preferred Stock	3,737,000	-
Loss on issuance of Series G Convertible Preferred Stock	5,109,000	-
Stock based compensation:		
Options issued to directors	476,563	944,834
Options issued to key employees	507,390	1,962,138
Options issued to non-employees	73,318	142,565
Shares issued for services	600,000	-
Change in assets and liabilities		
Prepaid expenses	(504)	(327,439)
Trade and other payables	(814,114)	1,042,997
Operating leases	(1,481)	(578)
Deferred compensation payable	(100,538)	100,538
Net cash used by operating activities	(8,976,347)	(12,980,625)
Cash flows from investing activities:		
Purchases of marketable securities	(12,851,809)	(13,454,304)
Proceeds from sale of marketable securities	6,750,480	15,300,030
Net cash (used in)/provided by investing activities	(6,101,329)	1,845,726
Cash flows from financing activities		
Net proceeds from the issuance of Series F Convertible Preferred Stock	-	14,685,689
Net proceeds from the issuance of Series F-1 Convertible Preferred Stock	5,050,000	-
Net proceeds from the issuance of Series G Convertible Preferred Stock	8,950,000	-
Redemption of Convertible Preferred Stock	(73,472)	(89,635)
Dividend on Convertible Preferred Stock	(1,356,708)	(1,452,145)
Premium on Convertible Preferred Stock	-	(77,090)
Net cash provided by financing activities	12,569,820	13,066,819
Net increase/(decrease) in cash and cash equivalents	(2,507,856)	1,931,920
Cash and cash equivalents at beginning of year	2,681,010	749,090
Cash and cash equivalents at end of year	$ 173,154	$ 2,681,010
Supplemental cash flow information		
Cash paid for:		
Interest	$ -	$ -
Income Taxes	$ -	$ -
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Initial fair value of warrant liabilities pursuant to the issuance of Series F Convertible Preferred Stock and Warrants	$ -	$ 10,623,000
Initial fair value of derivative liabilities pursuant to the issuance of Series F Convertible Preferred Stock and Warrants	$ -	$ 3,149,000
Initial fair value of warrant liabilities pursuant to the issuance of Series F-1 Convertible Preferred Stock and Warrants	$ 7,933,000	$ -
Initial fair value of derivative liabilities pursuant to the issuance of Series F-1 Convertible Preferred Stock and Warrants	$ 854,000	$ -
Initial fair value of warrant liabilities pursuant to the issuance of Series G Convertible Preferred Stock and Warrants	$ 14,059,000	$ -
Reclass of warrant liability to equity upon warrant modification for the Series F Warrants	$ 7,961,000	$ -
Reclass of warrant liability to equity upon warrant modification for the Series F-1 Warrants	$ 6,965,000	$ -
Reclass of warrant liability to equity upon warrant modification for the Series G Warrants	$ 12,343,000	$ -
Modification of Series F Convertible Preferred Stock	$ 4,673,735	$ -

The accompanying notes are an integral part to these consolidated financial statements.

Note 1 – Organization and Description of Business

TNF Pharmaceuticals, Inc. is a Delaware corporation ("TNF" or the "Company") that was incorporated in New Jersey prior to the Reincorporation (as defined below). On July 22, 2024, the Company changed its name from MyMD Pharmaceuticals, Inc. to TNF Pharmaceuticals, Inc. by filing a certificate of amendment to its certificate of incorporation with the Secretary of State of Delaware. In addition, effective before the open of market trading on July 24, 2024, the Company's common stock, par value $0.001 per share ("Common Stock") ceased trading under the ticker symbol "MYMD" and began trading on the Nasdaq Stock Market under the ticker symbol "TNFA."

These consolidated financial statements include two wholly owned subsidiaries as of December 31, 2024, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation (together, the "Company"). All material intercompany transactions have been eliminated in consolidation.

Isomyosamine (formerly MYMD-1) is an oral, next-generation TNF-α inhibitor with the potential to transform the way TNF-α based diseases are treated due to its selectivity and ability to cross the blood brain barrier. Its ease of oral dosing is a significant differentiator compared to currently available TNF-α inhibitors, all of which require delivery by injection or infusion. Isomyosamine has also been shown to selectively block TNF-α action where it is overactivated without preventing it from doing its normal job of responding to routine infection. Isomyosamine is doubly effective at inhibiting inflammation by blocking both TNF-a and IL-6 activity, whereas currently approved anti-TNF and anti-IL-6 treatments for rheumatoid arthritis ("RA") can only target one or the other. In addition, in early clinical studies it has not been associated with serious side effects known to occur with traditional immunosuppressive therapies that treat inflammation.

At the Company's annual meeting of stockholders held on July 31, 2023, the stockholders approved a plan to merge the Company with and into a newly formed wholly owned subsidiary, MyMD Pharmaceuticals, Inc., a Delaware corporation ("MyMD Delaware"), with MyMD Delaware being the surviving corporation, for the purpose of changing the Company's state of incorporation from New Jersey to Delaware (the "Reincorporation"). The Reincorporation was effected as of March 4, 2024. In connection with the Reincorporation to Delaware, the par value of the Company's Common Stock and preferred stock was changed to $0.001 per share.

MyMD Delaware is deemed to be the successor issuer of MyMD New Jersey under Rule 12g-3 of the Securities Exchange Act of 1934, as amended.

The Reincorporation did not result in any change in the Company's name, business, management, fiscal year, accounting, location of the principal executive offices, assets or liabilities. In addition, the Company's Common Stock retained the same CUSIP number and continued to trade on the Nasdaq Capital Market under the symbol "MYMD." Holders of shares of the Company's Common Stock did not have to exchange their existing MyMD New Jersey stock certificates for MyMD Delaware stock certificates.

As of the Effective Date of the Reincorporation, the rights of the Company's stockholders are governed by the Delaware General Corporation Law, the MyMD Delaware Certificate of Incorporation and the Bylaws of MyMD Delaware.

On February 14, 2024, the Company effected a 1-for-30 reverse stock split (the "Reverse Stock Split"). Simultaneously with the Reverse Stock Split, number of shares of the Company's Common Stock authorized for issuance was reduced from 500,000,000 shares to 16,666,666 shares, and our authorized capital stock was reduced from 550,000,000 shares to 66,666,666 shares. The Reverse Stock Split reduced the total number of issued and outstanding shares of Common Stock, including shares held by the Company as treasury shares. All share amounts have been retroactively adjusted for the Reverse Stock Split, unless stated otherwise.

On July 25, 2024, the Company increased the number of authorized shares of the Company's Common Stock from 16,666,666 to 250,000,000 and made a corresponding change to the number of authorized shares of the Company's capital stock by filing a Certificate of Amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Share Increase"). The Share Increase was approved by the Company's stockholders at the Company's special meeting of stockholders held on July 24, 2024.

Recent Events

The February 2023 Offering

On February 21, 2023, the Company entered into a Securities Purchase Agreement (the "Series F Purchase Agreement") with certain accredited investors (the "Series F Investors"), pursuant to which it agreed to sell to the Investors (i) an aggregate of 15,000 shares of the Company's newly-designated Series F convertible preferred stock with a stated value of $1,000 per share, initially convertible into up to 6,651,885 shares (pre-split) of the Company's Common Stock at an initial conversion price of $2.255 per share (pre-split), subject to adjustment (the "Series F Preferred Shares"), and (ii) warrants to acquire up to an aggregate of 6,651,885 shares (pre-split) of the Company's Common Stock, subject to adjustment (the "Series F Warrants") (collectively, the "February 2023 Offering"). Following the Reverse Stock Split, (i) the conversion price of the Series F Preferred Shares was adjusted to $3.18 per share pursuant to the terms of the Series F Certificate of Designations (as defined below), and (ii) the exercise price of the Series F Warrants was adjusted to $3.18 per share and the number of shares of Common Stock issuable upon exercise of the Series F Warrants was adjusted proportionately to 4,716,904 shares pursuant to the terms of the Series F Warrants.

In connection with the Private Placements (as defined herein), (i) the conversion price of the Series F Preferred Shares was adjusted to $1.816 per share pursuant to the full ratchet anti-dilution provisions contained in the Series F Certificate of Designations and, (ii) the exercise price of the Series F Warrants was adjusted to $1.816 per share and the number of shares of Common Stock issuable upon exercise of the Series F warrants was adjusted proportionally to 8,259,911 shares pursuant to the full ratchet anti-dilution provisions contained in the Series F Warrants.

Series F Convertible Preferred Stock

The Series F Preferred Shares became convertible upon issuance into Common Stock (the "Series F Conversion Shares") at the election of the holder at any time at an initial conversion price of $2.255 (pre-split) (as adjusted, the "Series F Conversion Price"). The Series F Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series F Conversion Price (subject to certain exceptions). Following the Reverse Stock Split, the Series F Conversion Price was adjusted to $3.18 per share pursuant to the terms of the Certificate of Designations of Series F Convertible Preferred Stock, which was subsequently amended and restated by the filing of the Amended and Restated Certificate of Designations of Series F Convertible Preferred Stock, effective April 8, 2024 (as amended and restated, the "Series F Certificate of Designations") with the Secretary of State of the State of Delaware. The Series F Conversion Price was further adjusted to $1.816 per share pursuant to the full ratchet anti-dilutive provisions contained in the Series F Certificate of Designations in connection with the Private Placements (as defined herein).

Prior to the Series F Certificate of Amendment (as defined below), the Company was initially required to redeem the Series F Preferred Shares in 12 equal monthly installments, commencing on July 1, 2023. The amortization payments due upon such redemption are payable, at the Company's election, in cash, or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Series F Conversion Price then in effect and (ii) the greater of (A) 80% of the average of the three lowest closing prices of the Company's Series F Common Stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) a "Floor Price" of $6.60 on a post-split basis (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Stock Market.

On April 5, 2024, the Company entered into an Omnibus Waiver and Amendment (the "Omnibus Agreement") with the Required Holders (as defined in the Series F Certificate of Designations). Pursuant to the Omnibus Agreement, the Required Holders agreed (i) to defer payment of the monthly installment amounts due on March 1, 2024, and April 1, 2024 (the "Installments"), under Section 9(a) of the Series F Certificate of Designations, until May 1, 2024, and (ii) to waive any breach or violation of the Series F Purchase Agreement, the Series F Certificate of Designations, or the Series F Warrants resulting from missing the Installments. The Company may require holders to convert their Series F Preferred Shares into shares of Common Stock if the closing price of the Common Stock exceeds $6.765 per share (as adjusted for the Reverse Stock Split) (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock exceeds $3,000,000 per day during the same period and certain equity conditions described in the Series F Certificate of Designations are satisfied.

On May 20, 2024, the Company entered into an Omnibus Waiver, Consent, Notice and Amendment (the "Series F Agreement") with the Required Holders (as defined in the Series F Certificate of Designations). Pursuant to the Series F Agreement, the Required Holders agreed to (i) amend the Series F Purchase Agreement to amend certain terms relating to purchase rights thereunder, (ii) waive certain rights under the Series F Purchase Agreement and Series F Certificate of Designations in respect of the issuance of the Company's Series F-1 Convertible Preferred Stock, with a par value of $0.001 per share and a stated value of $1,000 per share ("Series F-1 Preferred Stock"), the Company's Series G Convertible Preferred Stock, with a par value of $0.001 per share and a stated value of $1,000 per share ("Series G Preferred Stock"), and entrance by the Company into the Purchase Agreements (as defined herein), (iii) waive the requirement that the Company reserve for issuance a sufficient number of shares of Common Stock as required by the Series F Certificate of Designations, the Series F Purchase Agreement and Series F Warrants, until such time as the Company obtains the Stockholder Approval (as defined herein), and (iv) consent to the issuance of the Series F-1 Preferred Stock and Series G Preferred Stock as required pursuant to certain terms of the Series F Certificate of Designations, the Series F Purchase Agreement and the Series F Warrants, as applicable. The Company and the Required Holders further agreed pursuant to the Series F Agreement, to amend the Series F Certificate of Designations by filing a Certificate of Amendment to the Series F Certificate of Designations (the "Series F Certificate of Amendment") with the Secretary of State of the State of Delaware. The Series F Certificate of Amendment amends the Series F Certificate of Designations to (i) extend the maturity date to December 31, 2024, (ii) permit and modify certain procedures related to the payment of installment amounts with respect to the Installment Dates (as defined in the Series F Certificate of Designations) falling between (and including) July 1, 2024, and (and including) August 1, 2024, thereunder, and (iii) modify the schedule of Installment Dates.

On April 8, 2025, the Company entered into an Omnibus Amendment Agreement ("April 2025 Amendment Agreement") with the Required Holders (as defined in the Series F Certificate of Designations and Series F-1 Certificate of Designations), pursuant to which, the Required Holders agreed to amend (i) the Series F-1 Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F-1 Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F-1 Certificate of Amendment"), (ii) the Series F Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F Certificate of Amendment"), (iii) the Series F-1 Purchase Agreement, to amend the definition of "Excluded Securities" such that the definition includes the issuance of common stock issued after the date of the Seres F-1 Purchase Agreement pursuant to an Approved Stock Plan (as defined in the Series F-1 Purchase Agreement), which in the aggregate does not exceed more than 2% of the shares of common stock issued and outstanding as of the date of such issuance (the "Excluded Securities Modification"), and (iv) to amend the term of the Series F-1 Short-Term Warrants to be five years from the date of issuance. In addition, in consideration of the foregoing, the Company agreed to reduce the size of the board of directors of the Company to no more than six directors, no later than the Company's 2025 annual meeting of stockholders.

The April 2025 Series F Certificate of Amendment amends the Series F Certificate of Designations to (A) (i) extend the maturity date to June 30, 2025, and (ii) modify the schedule of Installment Dates (as defined in the Series F Certificate of Designations), in each case, effective as of December 31, 2024, and (B) subject to obtaining the approval of the Company's stockholders, effective January 1, 2025, increase the aggregate Stated Value of the Series F Preferred Stock outstanding to an amount equal to 110% of the aggregate Stated Value of the Series F Preferred Stock outstanding. The April 2025 Series F Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

The holders of the Series F Preferred Shares are entitled to dividends of 10% per annum, compounded monthly, which is payable in cash or shares of Common Stock at the Company's option, in accordance with the terms of the Series F Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F Certificate of Designations), the Series F Preferred Shares accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series F Preferred Shares are also entitled to receive a dividend make-whole payment. Except as required by applicable law, the holders of the Series F Preferred Shares are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F Preferred Shares is entitled to be calculated assuming a conversion price of $60.21 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series F Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series F Certificate of Designations. The Series F Certificate of Designations further provides that the holders of record of the Series F Preferred Shares, exclusively and as a separate class, shall be entitled to elect one director of the Company one time on or before June 30, 2024. Effective as of April 8, 2024, the Company appointed Dr. Mitchell Glass to serve as a member of the Company's board of directors, with Mr. Glass having been elected to such position by the holders of the Series F Preferred Shares. During the years ended December 31, 2024 and 2023, the Company recorded dividends totaling $2,927,803 and $4,218,213, respectively, which are reported as Preferred Stock Dividends on the Consolidated Statements of Comprehensive Loss.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization and dividend make-whole payments using shares of Common Stock is subject to certain limitations set forth in the Series F Certificate of Designations. Further, the Series F Certificate of Designations contains a certain beneficial ownership limitation after giving effect to the issuance of shares of Common Stock issuable upon conversion of, or as part of any amortization payment or dividend make-whole payment under, the Series F Certificate of Designations or Series F Warrants.

The Series F Preferred Shares are classified in temporary equity as the holder of the Series F Preferred Stock has the right to require the Company to redeem for cash all or any portion of such holder's shares upon the suspension from trading or the failure of the Common Stock to be trading or listed (as applicable) on an eligible market for a period of five (5) consecutive trading days. The Series F Preferred Stock is not unconditionally redeemable and is only conditionally puttable at the holder's option upon this trading suspension or failure. This would not be considered to be within the Company's control.

The Series F Preferred Shares were determined to be more akin to a debt-like host than an equity-like host. The Company identified the following embedded features that are not clearly and closely related to the debt host instrument: 1) make-whole interest upon a contingent redemption event, 2) make-whole interest upon a conversion event, 3) an installment redemption upon an Equity Conditions Failure (as defined in the Series F Certificate of Designations), and 4) variable share-settled installment conversion. These features were bundled together, assigned probabilities of being affected and measured at fair value. Subsequent changes in fair value of these features are recognized in the Consolidated Statements of Comprehensive Loss. The Company estimated at issuance the $3,149,800 fair value of the bifurcated embedded derivative using a Monte Carlo simulation model, with the following inputs; the fair value of our Common Stock of $1.90 on the issuance date, estimated equity volatility of 120.0%, estimated traded volume volatility of 190.0%, the time to maturity of 1.35 years, a discounted market interest rate of 6.8%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 0.5%. The fair value of the bifurcated derivative liabilities was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

The discount to the fair value is included as a reduction to the carrying value of the Series F Preferred Shares. The Company recorded a total discount of $14,087,111 upon issuance of the Series F Preferred Shares, which was comprised of the issuance date fair value of the associated embedded derivative of $3,149,800, stock issuance costs of $314,311 and the fair value of the Series F Warrants of $10,623,000.

During the years ended December 31, 2024 and 2023, the Company recorded gains of $61,000 and $3,088,800, respectively, related to the change in fair value of the derivative liabilities, which is recorded in other income (expense) on the Consolidated Statements of Comprehensive Loss. The Company estimated the $0 fair value of the bifurcated embedded derivative at December 31, 2024 using a Monte Carlo simulation model, with the following inputs; the fair value of the Company's Common Stock of $1.15 on the valuation date, estimated equity volatility of 105.0%, estimated traded volume volatility of 320.0%, the time to maturity of 0.5 years, a discounted market interest rate of 6.0%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 3.6%.

Series F Common Stock Warrants

Pursuant to the February 2023 Offering, the Company issued to investors the Series F Warrants to purchase 4,716,904 shares of Common Stock, with an initial exercise price of $3.18 per share (subject to adjustment), which was adjusted to $1.816 per share and the number of shares of Common Stock issuable upon exercise of the Series F warrants was adjusted proportionally to 8,259,911 shares pursuant to the full ratchet anti-dilution provisions contained in the Series F Warrants in connection with the Private Placements (as defined herein)(the "Series F Exercise Price"), for a period of five years from the date of issuance. The Series F Exercise Price and the number of shares issuable upon exercise of the Series F Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Exercise Price (subject to certain exceptions). Upon any such price-based adjustment to the exercise price, the number of shares issuable upon exercise of the Series F Warrants will be increased proportionately.

The Series F Warrants were determined to be within the scope of ASC 480-10 as they are puttable to the Company at Holders' election upon the occurrence of a Fundamental Transaction (as defined in the agreements). As such, the Company recorded the Series F Warrants as a liability at fair value with subsequent changes in fair value recognized in earnings. The Company utilized the Black Scholes Model to calculate the value of these warrants. The fair value of the Series F Warrants of $10,623,000 was estimated at the date of issuance using the following weighted average assumptions: dividend yield 0%; term of 5.0 years; equity volatility of 125.0%; and a risk-free interest rate of 4.09%.

Transaction costs incurred attributable to the issuance of the Series F Warrants of $762,834 were immediately expensed in accordance with ASC 480.

During the year ended December 31, 2024, the Company recorded a loss of $7,094,000 related to the change in fair value of the Series F Warrant liabilities through the March 31, 2024 reclassification of Series F Warrant liabilities to equity, which is recorded in other income (expense) on the Consolidated Statements of Comprehensive Loss (see below). The fair value of the Series F Warrants of $7,961,000 was estimated at March 31, 2024, utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 3.90 years; equity volatility of 110.0%; and a risk-free interest rate of 4.31%.

During the year ended December 31, 2023, the Company recorded a gain of $9,756,000 related to the change in fair value of the Series F Warrant liabilities, which is recorded in other income (expense) on the Consolidated Statements of Comprehensive Loss.

On May 14, 2024, the Company entered into an Amendment (the "Series F Warrant Amendment") with the Series F Investors in the February 2023 Offering, effective as of March 31, 2024. The Series F Warrant Amendment modified certain terms of the Series F Warrants relating to the rights of the holders of the Series F Warrants to provide that, in the event of a Fundamental Transaction (as defined in the Series F Warrants) that is not within the Company's control, including the Fundamental Transaction not being approved by the Company's Board of Directors, the holder of the Series F Warrant shall only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of such Series F Warrant, that is being offered and paid to the holders of the Company's common stock in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the successor entity (which such successor entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. The modification resulted in the reclassification of the Series F Warrants to be considered equity classified as they were no longer in the scope of ASC 815. In accordance with ASC 815-40, the Company remeasured the Series F Warrant liabilities at $7,961,000 fair value as of March 31, 2024, the effective date of the modification, and recognized the $7,094,000 loss on the change in fair value and reclassified the $7,961,000 fair value of the Series F Warrants to additional paid-in capital as of March 31, 2024.

On November 7, 2024, each holder of the Series F Preferred Shares agreed that payment by the Company of any Installment Amounts (as defined in the Series F Certificate of Designations) that are accrued and are unredeemed, unconverted and/or otherwise unpaid as of November 7, 2024, will be deferred until December 1, 2024.

Series F-1 Private Placement

On May 20, 2024, the Company entered into a Securities Purchase Agreement (the "Series F-1 Purchase Agreement") with certain accredited investors (the "Series F-1 Investors") pursuant to which it agreed to sell to the Series F-1 Investors (i) an aggregate of 5,050 shares of the Company's newly-designated Series F-1 Preferred Stock, initially convertible into up to 2,780,839 shares of Common Stock at a conversion price of $1.816 per share, (ii) short-term warrants to acquire up to an aggregate of 2,780,839 shares of Common Stock (the "Series F-1 Short-Term Warrants") at an exercise price of $1.816 per share, and (iii) long-term warrants to acquire up to an aggregate of 2,780,839 shares of Common Stock (the "Series F-1 Long-Term Warrants," and collectively with the Series F-1 Short-Term Warrants, the "Series F-1 Warrants") at an exercise price of $1.816 per share (collectively, the "Series F-1 Private Placement"). The closing of the Series F-1 Private Placement occurred on May 23, 2024 (the "Series F-1 Closing Date").

Series F-1 Preferred Stock

The Series F-1 Preferred Stock became convertible upon issuance into Common Stock (the "Series F-1 Conversion Shares") at the election of the holder at any time at an initial conversion price of $1.816 (the "Series F-1 Conversion Price"). The Series F-1 Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series F-1 Conversion Price (subject to certain exceptions).

The Company is required to redeem the Series F-1 Preferred Stock in seven (7) equal monthly installments, commencing on December 1, 2024. The amortization payments due upon such redemption are payable, at the Company's election, in cash at 105% of the applicable Installment Redemption Amount (as defined in the Series F-1 Certificate of Designations), or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Series F-1 Conversion Price then in effect and (ii) the greater of (A) 80% of the average of the three lowest closing prices of the Company's Common Stock during the thirty consecutive trading day period ending and including the trading day immediately prior to the date the amortization payment is due or (B) $0.364, which is 20% of the "Minimum Price" (as defined in Nasdaq Stock Market Rule 5635) on the date in which the Series F-1 Stockholder Approval (as defined herein) was obtained or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Capital Market, and, in each case, subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events, which amortization amounts are subject to certain adjustments as set forth in the Series F-1 Certificate of Designations (the "Series F-1 Floor Price").

On April 8, 2025, the Company entered into the April 2025 Amendment Agreement with the Required Holders (as defined in the Series F Certificate of Designations and Series F-1 Certificate of Designations), pursuant to which, the Required Holders agreed to amend (i) the Series F-1 Certificate of Designations, as described below, by filing the April 2025 Series F-1 Certificate of Amendment with the Secretary of State of the State of Delaware, (ii) the Series F Certificate of Designations, as described below, by filing the April 2025 Series F Certificate of Amendment, (iii) the Seres F-1 Purchase Agreement, to amend the definition of "Excluded Securities" such that the definition includes the issuance of common stock issued after the date of the Seres F-1 Purchase Agreement pursuant to an Approved Stock Plan (as defined in the Series F-1 Purchase Agreement), which in the aggregate does not exceed more than 2% of the shares of common stock issued and outstanding as of the date of such issuance, and (iv) to amend the term of the Series F-1 Short-Term Warrants to be five years from the date of issuance. In addition, in consideration of the foregoing, the Company agreed to reduce the size of the board of directors of the Company to no more than six directors, no later than the Company's 2025 annual meeting of stockholders.

The April 2025 Series F-1 Certificate of Amendment amends the Series F-1 Certificate of Designations to amend the definition of "Excluded Securities" substantially similar to the Excluded Securities Modification. The April 2025 Series F-1 Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

The holders of the Series F-1 Preferred Stock are entitled to dividends of 10% per annum, compounded monthly, which are payable in arrears monthly in cash or shares of Common Stock at the Company's option, in accordance with the terms of the Series F-1 Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F-1 Certificate of Designations), the Series F-1 Preferred Stock will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series F-1 Preferred Stock are also entitled to receive a dividend make-whole payment. The holders of the Series F-1 Preferred Stock are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F-1 Preferred Stock is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series F-1 Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series F-1 Certificate of Designations. During the year ended December 31, 2024, the Company recorded dividends totaling $315,410, which are reported as Preferred Stock Dividends on the Consolidated Statements of Comprehensive Loss.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization and dividend make-whole payments using shares of Common Stock is subject to certain limitations set forth in the Series F-1 Certificate of Designations. Further, the Series F-1 Certificate of Designations contains a certain beneficial ownership limitation after giving effect to the issuance of shares of Common Stock issuable upon conversion of, or as part of any amortization payment or dividend make-whole payment under, the Series F-1 Certificate of Designations or Series F-1 Warrants.

The Series F-1 Preferred Shares are classified as temporary equity as the holder of the Series F-1 Preferred Stock has the right to require the Company to redeem for cash all or any portion of such Holder's shares upon the suspension from trading or the failure of the Common Stock to be trading or listed (as applicable) on an eligible market for a period of five (5) consecutive Trading Days. The Series F-1 Preferred Stock is not unconditionally redeemable and is only conditionally puttable at the Holder's option upon this trading suspension or failure. This would not be considered to be within the Company's control.

The estimated fair value of the Series F-1 Preferred Stock on the issuance date of approximately $9.3 million, was determined utilizing Monte Carlo simulations. The estimated aggregate fair value of the Warrants of approximately $7.9 million was determined utilizing the Black Scholes Model. The aggregate fair value of the Warrants exceeds the aggregate gross proceeds from the transaction as the Warrants were issued in the money. Further, the fair value of the derivative liability related to the Series F-1 Preferred Stock was determined to be approximately $0.9 million on the date of issuance.

The approximately $5.1 million stock discount (contra-Preferred Stock) resulting from (i) approximately $4.2 million related to the difference between the gross proceeds and the allocated residual fair value of the Series F-1 Preferred Stock (i.e., $0), and (ii) approximately $0.9 million related to the stock derivative at issuance, is accounted for as a reduction to the carrying value of the Series F Preferred Stock and will be accreted from the issuance date to maturity in accordance with ASC 480-10-S99-3A as redemption is deemed probable pursuant to the Installment Redemption terms of the Series F-1 Certificate of Designations.

During the year ended December 31, 2024, the Company recorded a loss of $449,000, related to the change in fair value of the derivative liabilities, which is recorded in other income (expense) on the Consolidated Statements of Comprehensive Loss. The Company estimated the $1,303,000 fair value of the bifurcated embedded derivative at December 31, 2024 using a Monte Carlo simulation model, with the following inputs: the fair value of the Company's Common Stock of $1.15 on the valuation date, estimated equity volatility of 105.0%, estimated traded volume volatility of 320.0%, the time to maturity of 0.5 years, a discounted market interest rate of 7.0%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 3.6%.

Series F-1 Warrants

The Series F-1 Warrants were accounted for as liabilities based on the following analysis. The Series F-1 Preferred Shares were determined to be more akin to a debt-like host than an equity-like host. The Company identified the following embedded features that are not clearly and closely related to the debt host instrument: 1) make-whole interest upon a contingent redemption event, 2) make-whole interest upon a conversion event, 3) an installment redemption upon an Equity Conditions Failure (as defined in the Series F Certificate of Designations), and 4) variable share-settled installment conversion. These features were bundled together, assigned probabilities of being affected and measured at fair value. Subsequent changes in fair value of these features are recognized in the Consolidated Statements of Comprehensive Loss. The Company estimated at issuance the $3,149,800 fair value of the bifurcated embedded derivative using a Monte Carlo simulation model, with the following inputs: the fair value of our Common Stock of $1.90 on the issuance date, estimated equity volatility of 120.0%, estimated traded volume volatility of 190.0%, the time to maturity of 1.35 years, a discounted market interest rate of 6.8%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 0.5%. The fair value of the bifurcated derivative liabilities was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

Pursuant to the Series F-1 Private Placement, the Company issued to investors (i) the Series F-1 Long-Term Warrants to purchase 2,780,839 shares of Common Stock, with an exercise price of $1.816 per share (subject to adjustment), for a period of five years from the date of issuance and (ii) the Series F-1 Short-Term Warrants to purchase 2,780,839 shares of Common Stock, with an exercise price of $1.816 per share (subject to adjustment), for a period of eighteen months from the date of issuance.

The exercise price of the Series F-1 Warrants and the number of shares issuable upon exercise of the Series F-1 Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable exercise price (subject to certain exceptions). Upon any such price-based adjustment to the exercise price, the number of shares issuable upon exercise of the Series F-1 Warrants will be increased proportionately.

On August 16, 2024, the Company entered into (i) an Amendment (the "Series F-1 Long Term Warrant Amendment") with the Series F-1 Investors, effective as of June 30, 2024 relating to the Series F-1 Long Term Warrants, and (ii) an Amendment (the "Series F-1 Short Term Warrant Amendment" and, together with the Series F-1 Long Term Warrant Amendment, the "Series F-1 Warrant Amendments") with the Series F-1 Investors, effective as of June 30, 2024 relating to the Series F-1 Short Term Warrants. The Series F-1 Warrant Amendments modified certain terms of the Series F-1 Warrants relating to the rights of the holders of the Series F-1 Warrants to provide that, in the event of a Fundamental Transaction (as defined in the Series F-1 Warrants) that is not within the Company's control, including the Fundamental Transaction not being approved by the Company's Board of Directors, the holder of the Series F-1 Warrant shall only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of such Series F-1 Warrant, that is being offered and paid to the holders of the Company's Common Stock in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the successor entity (which such successor entity may be the Company following such Fundamental Transaction). Additionally, the Series F-1 Warrant Amendments amend the definition of Black Scholes Value related to the volatility input which is now an expected volatility equal to the 30 day volatility, obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the trading day immediately following the earliest to occur of (1) the public disclosure of the applicable Fundamental Transaction and (2) the date of a holder's request. The modification resulted in the reclassification of the Series F-1 Warrants to be considered equity classified as they were no longer in the scope of ASC 815. In accordance with ASC 815-40, the Company remeasured the Series F-1 Warrants at fair value as of July 25, 2024 ($6,965,000), and recognized the $6,000 change in fair value as a non-cash loss and reclassified the Series F-1 Warrants to additional paid-in capital as of July 25, 2024. For the year ended December 31, 2024, the Company recognized a non-cash gain on the change in fair value of $968,000.

Series G Private Placement

On May 20, 2024, the Company entered into a Securities Purchase Agreement (the "Series G Purchase Agreement" and collectively with the Series F-1 Purchase Agreement, each a "Purchase Agreement" and collectively, the "Purchase Agreements") with certain accredited investors (the "Series G Investors" and collectively with the Series F-1 Investors, the "Investors"), with certain accredited investors (the "Series G Investors"), pursuant to which it agreed to sell to the Series G Investors (i) an aggregate of 8,950 shares of the Company's newly-designated Series G Preferred Stock, initially convertible into up to 4,928,416 shares of the Company's Common Stock, at a conversion price of $1.816 per share (ii) short-term warrants to acquire up to an aggregate of 4,928,416 shares of Common Stock (the "Series G Short-Term Warrants") at an exercise price of $1.816 per share, and (iii) long-term warrants to acquire up to an aggregate of 4,928,416 shares of Common Stock (the "Series G Long-Term Warrants," and collectively with the Series G Short-Term Warrants, the "Series G Warrants") at an exercise price of $1.816 per share (collectively, the "Series G Private Placement" and collectively with the Series F-1 Private Placement, each a "Private Placement" and collectively, the "Private Placements"). The closing of the Series G Private Placement occurred on May 23, 2024 (the "Series G Closing Date" and collectively with the Series F-1 Closing Date, the "Closing Date").

Series G Preferred Stock

The Series G Preferred Shares became convertible upon issuance into Common Stock (the "Series G Conversion Shares") at the election of the holder at any time at an initial conversion price of $1.816 (the "Series G Conversion Price"). The Series G Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series G Conversion Price (subject to certain exceptions). At any time after the issuance date of the Series G Preferred Shares, the Company has the option to redeem in cash all or any portion of the shares of Series G Preferred Shares then outstanding at a premium upon notice by the Company to all holders of the Series G Preferred Shares.

The holders of the Series G Preferred Shares will be entitled to dividends of 10% per annum, compounded monthly, which will be payable in arrears monthly, at the holder's options, (i) in cash, (ii) "in kind" in the form of additional shares of Series G Preferred Shares (the "PIK Shares"), or (iii) in a combination thereof, in each case, in accordance with the terms of the Certificate of Designations of the Series G Preferred Shares (the "Series G Certificate of Designations"). Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series G Certificate of Designations), the Series G Preferred Stock will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series G Preferred Shares are also entitled to receive a dividend make-whole payment. The holders of the Series G Preferred Shares will be entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series G Preferred Share is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series G Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series G Certificate of Designations. During the year ended December 31, 2024, the Company recorded dividends totaling $559,393, which are reported as Preferred Stock Dividends on the Consolidated Statements of Comprehensive Loss.

Notwithstanding the foregoing, the Company's ability to settle conversions and make dividend make-whole payments using shares of Common Stock is subject to certain limitations set forth in the Series G Certificate of Designations. Further, the Series G Certificate of Designations contains a certain beneficial ownership limitation, which applies to each Series G Investor, other than PharmaCyte Biotech, Inc., after giving effect to the issuance of shares of Common Stock issuable upon conversion of the Series G Preferred Shares or as part of any dividend make-whole payment under the Series G Certificate of Designations.

On June 17, 2024, the Company entered into an Amendment Agreement (the "Series G Amendment") with the Required Holders (as defined in the Series G Certificate of Designations). Pursuant to the Series G Amendment, the Required Holders agreed to amend the Series G Certificate of Designations by filing a Certificate of Amendment ("Series G Certificate of Amendment") to the Series G Certificate of Designations with the Secretary of State of the State of Delaware (the "Secretary of State") to increase the number of authorized shares of Series G Preferred Stock from 8,950 to 12,826,273, in order to authorize a sufficient number of shares of Series G Preferred Stock for the payment of PIK Shares. On June 17, 2024, the Company filed the Series G Certificate of Amendment with the Secretary of State, thereby amending the Series G Certificate of Designations. The Series G Certificate of Amendment became effective with the Secretary of State upon filing.

The Series G Preferred Shares are classified as temporary equity as the holder of the Series G Preferred Stock has the right to require the Company to redeem for cash all or any portion of such Holder's shares upon the suspension from trading or the failure of the Common Stock to be trading or listed (as applicable) on an eligible market for a period of five (5) consecutive Trading Days. The Series G Preferred Stock is not unconditionally redeemable and is only conditionally puttable at the Holder's option upon this trading suspension or failure. This would not be considered to be within the Company's control.

The estimated fair value of the Series G Preferred Stock on the issuance date of approximately $22.3 million, was determined utilizing Monte Carlo simulations. The estimated aggregate fair value of the Warrants of approximately $14.1 million was determined utilizing the Black Scholes Model. The aggregate fair value of the Warrants exceeds the aggregate gross proceeds from the transaction as the Warrants were issued in the money.

The approximately $9.0 million stock discount (contra-Preferred Stock) resulting from the difference between the gross proceeds and the allocated residual fair value of the Series G Preferred Stock (i.e. $0) is accounted for as a reduction to the carrying value of the Preferred Stock and is not accreted until redemption becomes probable in accordance with ASC 480-10-S99-3A.

Since the fair value of the liabilities required to be subsequently measured at fair value exceeds the net proceeds received, the excess of the fair value over the net proceeds received is recognized as a loss in earnings. As such, the Company recognized a loss on the issuance of preferred stock of approximately $5.1 million.

On August 8, 2024, the Company entered into an Amendment Agreement (the "August Series G Amendment") with the Required Holders (as defined in the Series G Certificate of Designations). Pursuant to the August Series G Amendment, the Required Holders agreed to amend the Series G Certificate of Designations by filing a Certificate of Amendment ("August Series G Certificate of Amendment") to the Series G Certificate of Designations with the Secretary of State to adjust the calculation of the PIK Shares. On August 8, 2024, the Company filed the August Series G Certificate of Amendment with the Secretary of State, thereby amending the Series G Certificate of Designations. The August Series G Certificate of Amendment became effective with the Secretary of State upon filing.

Series G Warrants

The Series G Preferred Shares were determined to be more akin to a debt-like host than an equity-like host. The Company identified the following embedded features that are not clearly and closely related to the debt host instrument: 1) make-whole interest upon a contingent redemption event, 2) make-whole interest upon a conversion event, 3) an installment redemption upon an Equity Conditions Failure (as defined in the Series G Certificate of Designations), and 4) variable share-settled installment conversion. These features were bundled together, assigned probabilities of being affected and measured at fair value. Subsequent changes in fair value of these features are recognized in the Consolidated Statements of Comprehensive Loss. The Company estimated at issuance the $3,149,800 fair value of the bifurcated embedded derivative using a Monte Carlo simulation model, with the following inputs: the fair value of our Common Stock of $1.90 on the issuance date, estimated equity volatility of 120.0%, estimated traded volume volatility of 190.0%, the time to maturity of 1.35 years, a discounted market interest rate of 6.8%, dividend rate of 10.0%, a penalty dividend rate of 15.0%, and probability of default of 0.5%. The fair value of the bifurcated derivative liabilities was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

Pursuant to the Series G Private Placement, the Company issued to investors (i) the Series G Long-Term Warrants to purchase 4,928,416 shares of Common Stock, with an exercise price of $1.816 per share (subject to adjustment), for a period of five years from the date of issuance and (ii) the Series G Short-Term Warrants to purchase 4,928,416 shares of Common Stock, with an exercise price of $1.816 per share (subject to adjustment), for a period of eighteen months from the date of issuance.

The exercise price of the Series G Warrants and the number of shares issuable upon exercise of the Series G Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable exercise price (subject to certain exceptions). Upon any such price-based adjustment to the exercise price, the number of shares issuable upon exercise of the Series G Warrants will be increased proportionately.

On August 16, 2024, the Company entered into (i) an Amendment (the "Series G Long Term Warrant Amendment") with the Series G Investors, effective as of June 30, 2024, relating to the Series G Long Term Warrants, and (ii) an Amendment (the "Series G Short Term Warrant Amendment" and, together with the Series G Long Term Warrant Amendment, the "Series G Warrant Amendments") with the Series G Investors, effective as of June 30, 2024, relating to the Series G Short Term Warrants. The Series G Warrant Amendments modified certain terms of the Series G Warrants relating to the rights of the holders of the Series G Warrants to provide that, in the event of a Fundamental Transaction (as defined in the Series G Warrants) that is not within the Company's control, including the Fundamental Transaction not being approved by the Company's Board of Directors, the holder of the Series G Warrant shall only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value (as defined in the Series G Warrants) of the unexercised portion of such Series G Warrant, that is being offered and paid to the holders of the Company's Common Stock in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the successor entity (which such successor entity may be the Company following such Fundamental Transaction). Additionally, the Series G Warrant Amendments amend the definition of Black Scholes Value related to the volatility input which is now an expected volatility equal to the 60 day volatility, obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the trading day immediately following the earliest to occur of (1) the public disclosure of the applicable Fundamental Transaction and (2) the date of a holder's request. The modification resulted in the reclassification of the Series G Warrants to be considered equity classified as they were no longer in the scope of ASC 815. In accordance with ASC 815-40, the Company remeasured the Series G Warrants at fair value as of July 25, 2024 ($12,343,000) and recognized the $11,000 change in fair value as a non-cash loss and reclassified the Series G Warrants to additional paid-in capital as of July 25, 2024. For the year ended December 31, 2024, the Company recognized a non-cash gain on the change in fair value of $1,716,000.

Registration Rights Agreements

In connection with the Series F-1 Private Placement, the Company entered into a Registration Rights Agreement with the Series F-1 Investors (the "Series F-1 Registration Rights Agreement,"), pursuant to which the Company agreed to file a resale registration statement (the "Series F-1 Registration Statement") with the SEC to register for resale (A) 200% of the Series F-1 Conversion Shares and (B) 200% of the Series F-1 Warrant Shares promptly following the Closing Date, but in no event later than 30 calendar days after the Closing Date, and to have such Series F-1 Registration Statement declared effective by the Effectiveness Deadline (as defined in the Series F-1 Registration Rights Agreement).

In connection with the Series G Private Placement, the Company entered into a Registration Rights Agreement with the Series G Investors (the "Series G Registration Rights Agreement" and, together with the Series F-1 Registration Rights Agreement, the "Registration Rights Agreements") pursuant to which the Company agreed to file a resale registration statement (the "Series G Registration Statement") with the SEC to register for resale (A) 200% of the Series G Conversion Shares, (B) 200% of the shares of Common Stock issuable upon conversion of the PIK Shares, and (C) 200% of the Series G Warrant Shares promptly following the Closing Date, but in no event later than 30 calendar days after the Closing Date, and to have such Series G Registration Statement declared effective by the Effectiveness Deadline (as defined in the Series G Registration Rights Agreement).

In connection with the Registration Rights Agreements, the Company filed a registration statement on Form S-3 covering such securities, which registration statement was filed on June 21, 2024, amended on August 8, 2024 and declared effective by the SEC on August 12, 2024. Under the Series F-1 Registration Rights Agreement, the Company is obligated to pay certain liquidated damages to the Series F-1 Investors if the Company, among other things, failed to file the Series F-1 Registration Statement when required, failed to file or cause the Series F-1 Registration Statement to be declared effective by the SEC when required, or fails to maintain the effectiveness of the Series F-1 Registration Statement.

Private Placement Warrants

In connection with the Private Placements, pursuant to (A) an engagement letter (the "GPN Agreement") with GP Nurmenkari Inc. ("GPN") and (B) an engagement letter (the "Palladium Agreement," and collectively with the GPN Agreement, the "Engagement Letters") with Palladium Capital Group, LLC ("Palladium," and collectively with GPN, the "Placement Agents"), the Company engaged the Placement Agents to act as non-exclusive placement agents in connection with each Private Placement, pursuant to which, the Company agreed to (i) pay the Placement Agents a cash fee equal to 3% of the gross proceeds of each Private Placement (including any cash proceeds realized by the Company from the exercise of the Series F Warrants), (ii) reimbursement and payment of certain expenses, and (iii) issue to the Placement Agents on the Closing Date, warrants to purchase up to an aggregate of 693,833 of shares of Common Stock to each Placement Agent, which is equal to 3% of the aggregate number of shares of Common Stock underlying the securities issued in each Private Placement, including upon exercise of any Series F Warrants, with terms identical to the Series G Long-Term Warrants and Series F-1 Long-Term Warrants.

Nasdaq Stockholder Approval

The Company's ability to issue Series F-1 Conversion Shares and Series G Conversion Shares and Series F-1 Warrant Shares and Series G Warrant Shares using shares of Common Stock is subject to certain limitations set forth in the Series F-1 Certificate of Designations and Series G Certificate of Designations, as applicable. Prior to the Nasdaq Stockholder Approval (as defined below), such limitations included a limit on the number of shares that could be issued until the time that the Company's stockholders have approved the issuance of more than 19.99% of the Company's outstanding shares of Common Stock in accordance with the rules of the Nasdaq Stock Market. Each Purchase Agreement requires the Company to hold a meeting of its stockholders no later than August 1, 2024, to seek approval (the "Stockholder Approval") (i) under Nasdaq Stock Market Rule 5635(d) for the issuance of shares of Common Stock in excess of 19.99% of the Company's issued and outstanding shares of Common Stock at prices below the "Minimum Price" (as defined in Rule 5635 of the Rules of the Nasdaq Stock Market) on the date of the applicable Purchase Agreement pursuant to the terms of the Series F-1 Preferred Shares and Series G Preferred Shares, as applicable, and the Series G Warrants and Series F-1 Warrants, as applicable, and (ii) to increase the number of authorized shares of the Company to ensure that the number of authorized shares of Common Stock is sufficient to meet the Required Reserve Amount (as defined in the Purchase Agreements) pursuant to the terms of each Purchase Agreement. The Company received the Nasdaq Stockholder Approval at a special meeting of stockholders held on July 24, 2024.

Reduction in Workforce

During October and November 2023, the Company implemented a reduction in workforce, eliminating three of the Company's ten employees. Separated employees were granted a severance package equal to one-quarter of their annual salary.

On June 7, 2023, the Company granted the three employee's options to purchase an aggregate of 7,668 shares of Common Stock with an exercise price of $49.80 per share. As consideration for a waiver and release in their separation agreements, the Company amended the employees' respective June 7, 2023 option agreements to accelerate vesting of the portion of optioned shares that otherwise would have vested upon the first and second anniversaries of the date of grant. The options have an exercise period of twelve months from the date of separation. The Company recognized as compensation expense $168,496 which represented the remaining unamortized fair value of the original grant.

Executive Officer Contract Amendments and Separations

Effective November 13, 2023, the Company entered into an amendment to the employment agreement of Dr. Chris Chapman, its President and Chief Medical Officer, providing for Dr. Chapman's annual base salary to be adjusted from five hundred thousand dollars ($500,000) (the "Full Base Salary") to two hundred fifty thousand dollars ($250,000) in cash per annum, until payment of his Full Base Salary would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion. The amendment further provides that the remaining $250,000 of base salary per annum (the "Deferral Amount") shall be deferred until payment of the Deferral Amount would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time the Deferral Amount may be paid, at Dr. Chapman's election, in shares of Common Stock or in cash. As of December 31, 2024 and December 31, 2023, the Company had recognized a salary deferral of $149,038 and $28,846, respectively, which was paid to Dr. Chapman on June 27, 2024.

Dr. Chapman's employment agreement terminated June 14, 2024. Pursuant to a General Release and Severance Agreement (the "Separation Agreement"), dated as of June 14, 2024, Dr. Chapman is entitled to (i) payment in the amount of $125,000, less all lawful and authorized withholdings and deductions, to be paid in three (3) equal monthly installments, (ii) a one-time payment equal to $25,000, less all lawful and authorized withholdings and deductions, (iii) reimbursement for continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") for a period of up to three (3) months, and (iv) acceleration of certain unvested options granted to Dr. Chapman pursuant to those certain Nonqualified Stock Option Agreements, dated April 4, 2023 and June 7, 2023. The Company recognized $150,000 of salary expense and $197,427 of stock-based compensation during the yere ended December 31, 2024, which is included in the Consolidated Statement of Comprehensive Loss.

In connection with an overall reduction in compensation paid to the Company's directors implemented in November 2023, effective November 13, 2023, the Company entered into an amendment to the employment agreement of Christopher C. Schreiber, a Director and the Company's former Executive Chairman, providing for Mr. Schreiber's annual fee to be adjusted from three hundred thousand dollars ($300,000) (the "Full Fee") to sixty thousand dollars ($60,000) in cash per annum, until payment of his Full Fee would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion. The amendment further provides that the remaining $240,000 of the fees per annum (the "Fee Deferral Amount") shall be deferred until payment of the Fee Deferral Amount would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time the Fee Deferral Amount may be paid, at Mr. Schreiber's election, in shares of Common Stock or in cash. The amendment also clarified that Mr. Schreiber's title is "Director." As of December 31, 2024 and 2023, the Company had recognized a salary deferral of $175,385 and $27,692, respectively, which was paid to Mr. Schreiber on August 22, 2024.

Effective November 13, 2023, the Company entered into an amendment to the employment agreement of Dr. Adam Kaplin, its Chief Scientific Officer, providing that Dr. Kaplin's employment and had an initial term of four months, which the parties had the option to mutually agree to extend for additional consecutive terms of one month each. The amendment further provided that, in the event of termination without cause by the Company prior to the end of the initial term, Dr. Kaplin shall receive his monthly base salary through the end of the initial term. The amendment further provided that all outstanding and unvested shares granted pursuant to the Nonqualified Stock Option Agreement, dated June 7, 2023, between the Company and Dr. Kaplin shall accelerate upon the termination of Dr. Kaplin's employment. Dr. Kaplin's amendment further provided that, in the event of a termination for any reason prior to the end of the first renewal term following the end of the initial term, the Company will continue to cover the costs of Dr. Kaplin's health insurance coverage through the end of the first renewal term, subject to the execution and timely return of a release. Dr. Kaplin's employment was terminated effective April 15, 2024.

Effective November 13, 2023, the Company entered into a mutual employment separation agreement with Paul M. Rivard, its Chief Legal Officer. The separation agreement provides for a lump-sum severance payment equal to three months of his normal base salary in exchange for a waiver and release. The separation agreement further provides that Mr. Rivard will be deemed a contractor providing services to the Company for purposes of any awards previously granted to him under the 2021 Plan if at the relevant time(s) he is providing services to the Company while under the employ of a law firm representing the Company.

Director's Deferral of Board Service Fees

On November 13, 2023, the Board approved certain adjustments to the director fees. Mr. Silverman's fees were decreased from $216,000 to $60,000 annually, with payment of the excess amount of $156,000 deferred until the date that payment of such amount would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time such amount may be paid, at Mr. Silverman's election, in shares of Common Stock or in cash. Messrs. Eagle's, Uzonwanne's and White's fees were decreased from $96,000 to $60,000 annually, with payment of the excess amounts of $36,000 per director deferred until the date that payment of such amounts would no longer jeopardize the Company's ability to continue as a going concern, as determined by the Company in its sole discretion, at which time such amounts may be paid, at each director's election, in shares of Common Stock or in cash. Upon their appointment to the Board, Messrs. Friscia and Glass were also subject to this deferral. As of December 31, 2024 and 2023, the Company had recognized a board fee deferral of $209,800 and $44,000, respectively, which was paid to the respective Board member on August 21, 2024.

Note 2 – Significant Accounting Policies

(a) Basis of Presentation

The Consolidated Financial Statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

(b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. Information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements is included in the following notes for recording research and development expenses, impairment of intangible assets and the valuation of share-based payments.

(c) Functional and Presentation Currency

These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information has been rounded to the nearest dollar. Foreign Currency Transaction Gains or Losses, resulting from cash balances denominated in Foreign Currencies, are recorded in the Consolidated Statements of Comprehensive Loss.

(d) Comprehensive Income (Loss)

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

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and for the year ended December 31, 2024. The carrying amounts of cash equivalents, accounts receivable, other current assets, other assets, accounts payable, and accrued expenses approximated their fair values as of December 31, 2024 due to their short-term nature. The fair value of the bifurcated embedded derivative related to the convertible preferred stock was estimated using a Monte Carlo simulation model, which uses as inputs the fair value of the Company's Common Stock and estimates for the equity volatility and traded volume volatility of the Company's Common Stock, the time to maturity of the convertible preferred stock, the risk-free interest rate for a period that approximates the time to maturity, dividend rate, a penalty dividend rate, and the probability of default. The fair value of the warrant liabilities was estimated using the Black Scholes Model which uses as inputs the following weighted average assumptions: dividend yield, expected term in years; equity volatility; and risk-free interest rate.

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

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

Level 2 Inputs to the valuation methodology include:

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;
- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3 Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Valuation techniques maximize the use of relevant observable inputs and minimize the use of unobservable inputs.

(f) Fair Value of Financial Instruments, continued

The following is a description of the valuation methodologies used for assets measured at fair value as of December 31, 2024 and December 31, 2023.

Marketable Securities: Valued using quoted prices in active markets for identical assets.

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Quoted Prices for Similar Assets or Liabilities in Active Markets (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities at December 31, 2024	$ 8,345,081	$ -	$ -
Marketable securities at December 31, 2023	$ 2,242,106	$ -	$ -

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

As of December 31, 2024 and 2023, the Company held certain mutual funds, which, under FASB ASC 321-10, were considered equity investments. As such, the change in fair value in the year ended December 31, 2024 and 2023 were gains of $671 and $514, respectively.

Gains and losses resulting from the sales of marketable securities were gains of $976 and $416 for the years ended December 31, 2024 and 2023, respectively.

Proceeds from the sales of marketable securities were $6,750,480 and $15,300,030 in the years ended December 31, 2024 and 2023, respectively. Purchases of marketable securities were $12,851,809 and $13,454,304 during the years ended December 31, 2024 and 2023, respectively.

Fair Value on a Recurring Basis

The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The estimated fair value of the warrant liabilities and bifurcated embedded derivatives represent Level 3 measurements. The following table presents information about the Company's liabilities that are measured at fair value on a recurring basis as of December 31, 2024 and 2023, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

		As of December 31,	
Description	**Level**	**2024**	**2023**
Liabilities			
Warrant Liabilities	3	$ -	$ 867,000
Derivative Liabilities	3	$ 1,282,000	$ 61,000

The following table sets forth a summary of the change in the fair value of the warrant liabilities that is measured at fair value on a recurring basis for the years ended December 31, 2024 and 2023:

	As of December 31,	
Description	**2024**	**2023**
Balance on December 31, 2023 and 2022	$ 867,000	$ -
Issuance of warrants reported at fair value	-	10,623,000
Changes in fair value of warrant liabilities	7,094,000	(1,175,000)
Reclassification of warrant liability to equity upon warrant modification	(7,961,000)	
Balance on March 31,	-	9,448,000
Issuance of warrants reported at fair value	21,992,000	-
Changes in fair value of warrant liabilities	(2,701,000)	(1,635,000)
Balance on June 30,	19,291,000	7,813,000
Changes in fair value of warrant liabilities	17,000	(5,356,000)
Reclassification of warrant liability to equity upon warrant modification	(19,308,000)	-
Balance on September 30,	-	2,457,000
Changes in fair value of warrant liabilities	-	(1,590,000)
Balance on December 31,	$ -	$ 867,000

The following table sets forth a summary of the change in the fair value of the derivative liabilities that is measured at fair value on a recurring basis for the years ended December 31, 2024 and 2023:

	As of December 31,	
Description	**2024**	**2023**
Balance on December 31, 2023 and 2022	$ 61,000	$ -
Issuance of derivatives reported at fair value	-	3,149,800
Changes in fair value of derivative liabilities	(61,000)	120,700
Balance on March 31,	-	3,270,500
Issuance of derivatives reported at fair value	854,000	-
Changes in fair value of derivative liabilities	72,000	194,500
Balance on June 30,	926,000	3,465,000
Changes in fair value of derivative liabilities	356,000	(2,566,900)
Balance on September 30,	1,282,000	898,100
Changes in fair value of derivative liabilities	21,000	(837,100)
Balance on December 31,	$ 1,303,000	$ 61,000

There were no assets or liabilities measured on a non-recurring basis as of December 31, 2024 or December 31, 2023.

(g) Derivative Financial Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, "*Derivatives and Hedging*." If liability accounting is required, the Company's derivative instruments are recorded at fair value at the issuance date and re-valued at each reporting date, with changes in the fair value reported in the statements of operations. Derivative assets and liabilities are classified on the balance sheet as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within twelve (12) months of the balance sheet date.

The Company has determined that the Series F Convertible Preferred Stock warrants are derivatives that are required to be accounted for as liabilities. The Company has also determined that the following embedded features in the preferred stock are not clearly and closely related to the debt host instrument: 1) make-whole interest upon a contingent redemption event, 2) make-whole interest upon a conversion event, 3) an installment redemption upon an Equity Conditions Failure (as defined in the Certificate of Designation), and 4) variable share-settled installment conversion and as such are bifurcated from the preferred stock and accounted for as liabilities. The fair value of the warrants and embedded features are estimated using internal valuation models. The Company's valuation models utilize inputs and other assumptions and may not be reflective of the price at which they can be settled.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own Common Stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability classified and recorded at their initial fair value on the date of issuance and remeasured at fair value and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the Statements of Comprehensive Income (Loss).

Modification of warrants

The Company applies the guidance in ASC 815-40 to account for warrants that are liability classified that are subsequently modified resulting in a reclassification to equity. The warrants are remeasured at fair value on the modification date, the change in fair value is recognized as a non-cash gain or loss on the Statement of Comprehensive Income (Loss), and the warrants are reclassified to additional paid-in capital.

(h) Prepaid Expenses

Prepaid expenses represent expenses paid prior to the date that the related services are rendered or used are comprised principally of prepaid insurance and research and development expenses.

(i) Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash on deposit with financial institutions and accounts receivable. At times, the Company's cash in banks exceeds the FDIC insurance limit. The Company has not experienced any loss because of these cash deposits. These cash balances are maintained with two banks and do not exceed the FDIC limit as of December 31, 2024.

(j) Risk Management of Cash and Investments

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

The Company's investment portfolios are regularly monitored for risk and are held with one brokerage firm.

(k) Investments

Investments recorded using the cost method will be assessed for any decrease in value that has occurred that is other than temporary and the other than temporary decrease in value shall be recognized. As and when circumstances and facts change, the Company will evaluate the Company's ability to significantly influence operational and financial policy to establish a basis for converting the investment accounted for using the cost method to the equity method of valuation in accordance with FASB ASC 323.

In accordance with FASB ASC 323, the Company recognizes investments in joint ventures based upon the Company's ability to significantly influence the operational or financial policies of the joint venture. An objective judgment of the level of influence is made at the time of the investment based upon several factors including, but not limited to the following:

a) Representation on the Board of Directors
b) Participation in policy-making processes
c) Material intra-entity transactions
d) Interchange of management personnel
e) Technological dependencies
f) Extent of ownership and the ability to influence decision making based upon the makeup of other owners when the shareholder group is small.

The Company follows the equity method for valuating investments in joint ventures when the existence of significant influence over operational and financial policy has been established, as determined by management; otherwise, the Company will valuate these investments using the cost method.

In accordance with FASB ASC 321-10-35-2, the Company has elected to measure its investment in Oravax Medical, Inc. ("Oravax") (Note 3) as an equity security without a readily determinable fair value. Under this election, an equity security without a readily available fair value is reflected at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. At each reporting period, the Company is required to make a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. If deemed impaired, the Company is required to estimate the fair value of the investment and recognize an impairment loss equal to the difference between the fair value of the investment and its carry amount. As of December 31, 2024, the Company performed a qualitative assessment to evaluate whether the investment is impaired and determined that the investment was not impaired and thus no adjustment to fair market value was required as of December 31, 2024.

(l) Property, Plant and Equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized within "other (income)/expense" in the Consolidated Statements of Comprehensive Loss.

Depreciation is recognized over the estimated useful lives of the property, plant and equipment. Leased assets are depreciated over the shorter of the lease term or their useful lives.

The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Plant and equipment	5-12
Furniture and fixtures	5-10
Computer equipment & software	3-5
Leasehold Improvements	Shorter of the remaining lease or estimated useful life

Depreciation methods, useful lives and residual values are reviewed at each reporting date.

(m) Intangible Assets

The Company's long-lived intangible assets, other than goodwill, are assessed for impairment when events or circumstances indicate there may be an impairment. These assets were initially recorded at their estimated fair value at the time of acquisition and assets not acquired in acquisitions were recorded at historical cost. However, if their estimated fair value is less than the carrying amount, other intangible assets with indefinite lives are reduced to their estimated fair value through an impairment charge in the Consolidated Statements of Comprehensive Loss.

Patents and Trade Secrets

Propriety protection for the Company's products, technology and process is important to its competitive position. As of December 31, 2024, the Company has 18 issued U.S. patents, 69 issued foreign patents, one pending U.S. patent applications and five foreign patent applications pending in such jurisdictions as Canada, China, Israel, and Japan, which if issued are expected to expire between 2036 and 2041. Management intends to protect all other intellectual property (e.g. copyrights, trademarks, and trade secrets) using all legal remedies available to the Company.

The Company records expenses related to the application for and maintenance of patents as a component of research and development expenses on the Consolidated Statement of Comprehensive Loss.

Patent Costs and Trade Secrets

Patents may be purchased from third parties. The costs of acquiring the patent are capitalized as patent costs if it represents a future economic benefit to the Company. Once a patent is acquired it is amortized over its remaining useful life and assessed for impairment when necessary.

Other Intangible Assets

Other intangible assets that are acquired by the Company, which have definite useful lives, are measured at cost less accumulated amortization and accumulated impairment losses.

Amortization

Amortization is recognized on a straight-line basis over the estimated useful lives of intangible assets, other than goodwill, from the date that they are available for use. The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Patents and trademarks	12-17

(n) Goodwill

Goodwill is evaluated annually for impairment or whenever the Company identifies certain triggering events or circumstances that would more likely than not reduce the fair value below its carrying amount. Events or circumstances that might indicate an interim evaluation is warranted include, among other things, unexpected adverse business conditions, economic factors (for example, the loss of key personnel), supply costs, unanticipated competitive activities, and acts by governments and courts. No impairment was recorded for each of the years ended December 31, 2024 and 2023.

(o) Recoverability of Long-Lived Assets

In accordance with FASB ASC 360-10-35 "Impairment or Disposal of Long-lived Assets", long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable or that the useful lives of those assets are no longer appropriate. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment.

The Company determines the existence of such impairment by measuring the expected future cash flows (undiscounted and without interest charges) and comparing such amount to the carrying amount of the assets. An impairment loss, if one exists, is then measured as the amount by which the carrying amount of the asset exceeds the discounted estimated future cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value of such assets less costs to sell. Asset impairment charges are recorded to reduce the carrying amount of the long-lived asset that will be sold or disposed of to their estimated fair values. Charges for the asset impairment reduce the carrying amount of the long-lived assets to their estimated salvage value in connection with the decision to dispose of such assets.

(o) Right-of-Use Assets

The Company leased a facility in Baltimore, Maryland under an operating lease ("2021 Baltimore Lease") with annual rentals of $52,800 to $56,016 plus certain operating expenses. The 2021 Baltimore Lease took effect on November 17, 2021, for a term of 12 months with automatic renewals unless sixty-day notice is provided. The initial term expired on November 30, 2022. The lease renewed effective December 1, 2022, for a term of 12 months with automatic renewals unless a sixty-day notice is provided. The 2021 Baltimore Lease was terminated by the lessor on April 30, 2024.

The Company leased a facility in Tampa, Florida under an operating lease ("Platt Street Lease") with annual rentals of $22,030 to $23,259 plus certain operating expenses. The Platt Street Lease took effect on April 1, 2022, for a term of 36 months. The Platt Street Lease was cancelled without penalty effective October 31, 2023.

The Company leased a facility in Baltimore, Maryland under an operating lease ("2024 Baltimore Lease") with annual rentals of $32,400 plus certain operating expenses. The 2024 Baltimore Lease took effect on May 1, 2024, for a term of 12 months with automatic renewals unless sixty-day notice was provided. On February 26, 2025, the Company provided notice of its intention not to renew the Baltimore Lease, effective April 30, 2025.

In accordance with 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 guidance requires the recognition of the right-of-use ("ROU") assets and related operating and finance lease liabilities on the balance sheet.

The Company utilizes 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 operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments. The Company generally uses its incremental borrowing rate as the discount rate for leases, unless an interest rate is implicitly stated in the lease. The present value of the lease payments is calculated using the incremental borrowing rate for operating leases, which was determined using a portfolio approach based on the rate of interest that the Company would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term. The lease term for all the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend the lease that the Company is reasonably certain to exercise, or an option to extend the lease controlled by the lessor. All ROU assets are reviewed for impairment.

Lease expense for operating leases consists of the lease payments plus any initial direct costs and is recognized on a straight-line basis over the lease term.

The Company's operating leases are comprised of the 2024 Baltimore Lease, the 2021 Baltimore Lease and the Platt Street Lease on the Consolidated Balance Sheets. The information related to these leases are presented below:

	As of December 31, 2024				As of December 31, 2023		
Balance Sheet Location	**Platt Street Lease**	**2021 Baltimore Lease**	**2024 Baltimore Lease**	**Total**	**Platt Street Lease**	**2021 Baltimore Lease**	**Total**
Operating Lease							
Lease Right of Use	$ -	$ -	$ 10,579	$ 10,579	$ -	$ 47,389	$ 47,389
Lease Payable, current	-	-	10,579	10,579	-	48,870	48,870
Lease Payable - net of current	-	-	-	-	-	-	-

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

	For the Years Ended December 31, 2024				For the Years Ended December 31, 2023		
Lease Expenses	**Platt Street Lease**	**2021 Baltimore Lease**	**2024 Baltimore Lease**	**Total**	**Platt Street Lease**	**2021 Baltimore Lease**	**Total**
Operating Leases							
Lease Costs	$ -	$ 18,672	$ 21,600	$ 40,272	$ 18,868	$ 54,400	$ 73,268

Other information as of December 31, 2024 related to leases is presented below:

Other Information	Other Lease Information			
	Platt Street Lease	2021 Baltimore Lease	2024 Baltimore Lease	Total
Operating Leases				
Operating cash used	$ -	$ 18,672	$ 21,600	$ 40,272
Average remaining lease term	-	-	4	4
Average discount rate	10.0%	10.0%	10.0%	10.0%

As of December 31, 2024, the annual minimum lease payments of the Company's operating lease liabilities were as follows:

	Annual Minimum Lease Payments			
	Platt Street Lease	2021 Baltimore Lease	2024 Baltimore Lease	Total
For Years Ending December 31,				
2024	-	-	-	$ -
2025	-	-	10,800	10,800
Total future minimum lease payments, undiscounted	$ -	$ -	$ 10,800	$ 10,800
Less: Imputed interest	-	-	221	221
Present value of future minimum lease payments	$ -	$ -	$ 10,579	$ 10,579

(q) Revenue Recognition

The Company will recognize revenue under ASC 606, Revenue from Contracts with Customers. The core principle of the revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods and services transferred to the customer. The following five steps are applied to achieve that core principle:

1) Identify the contract with the customer
2) Identify the performance obligations in the contract
3) Determine the transaction price
4) Allocate the transaction price to the performance obligations in the contract
5) Recognize revenue when the company satisfies a performance obligation

(r) Income Taxes

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

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

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. For the years ended December 31, 2024 and 2023, no liability for unrecognized tax benefits was required to be reported.

There was no income tax benefit recorded for the losses for the years ended December 31, 2024 and 2023 since management determined that the realization of the net deferred tax assets is not more likely than not to be realized and has recorded a full valuation allowance on the net deferred tax assets.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the years ended December 31, 2024 and 2023. 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.

Since the Company had losses in the past, all prior years that generated net operating loss carryforwards are open and subject to audit examination in relation to the net operating loss generated from those years.

(s) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common stock 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 stock plus dilutive common share equivalents outstanding during the period. Potential common stock that would have the effect of increasing diluted earnings per share are considered anti-dilutive.

Diluted net loss per share is computed using the weighted average number of shares of Common Stock and dilutive potential Common Stock outstanding during the period.

As the Company reported a net loss for the years ended December 31, 2024 and 2023, Common Stock equivalents were anti-dilutive.

As of December 31, 2024 and 2023, the following securities are excluded from the calculation of weighted average dilutive common stock because their inclusion would have been anti-dilutive:

	For the Years Ended December 31,	
	2024	**2023**
Stock Options	45,226	47,286
Unvested Restricted Stock Units	48,334	88,668
Warrants to purchase Common Stock	33,293,640	4,933,622
Series C Preferred Convertible Warrants	-	918
Series D Preferred Convertible Stock	1,217	1,217
Series F Preferred Convertible Stock	3,239,231	3,318,626
Series F-1 Convertible Preferred Stock	3,651,538	-
Series G Convertible Preferred Stock	6,833,846	-
Total potentially dilutive shares	47,113,032	8,390,337

(t) Stock-based Payments

The Company accounts for stock-based compensation under the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, "Compensation - Stock Compensation", which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting (the "2018 Update"). The amendments in the 2018 Update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Prior to the 2018 Update, Topic 718 applied only to share-based transactions to employees. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied.

The Company has elected to account for forfeiture of stock-based awards as they occur.

(u) 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.

(v) Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose significant segment expenses and other segment items on an interim and annual basis and provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The ASU does not change how a public entity identifies its operating segments, aggregates them, or applies the quantitative threshold to determine its reportable segments. The new disclosure requirements are also applicable to entities that account and report as a single operating segment entity. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The Company adopted the guidance for the annual reporting period ended December 31, 2024. There was no impact on the Company's reportable segments identified and additional required disclosures have been included in Note 12, Segment Reporting.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as expanded disclosures on income taxes paid by jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact related to the adoption of ASU 2023-09 on their consolidated financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (Topic 220), which requires disclosure in the notes to financial statements about specific types of expenses included in the expense captions presented on the face of the statement of operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact related to the adoption of ASU 2024-03 on their consolidated financial statement disclosures.

Note 3 – Going Concern

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

As of December 31, 2024, the Company's cash on hand was $173,154 and marketable securities were $8,345,082. The Company has incurred a total net loss attributable to common stockholders of $27,161,219 for the year ended December 31, 2024. As of December 31, 2024, the Company had working capital of $2,710,626 and stockholders' equity of $9,789,740, including an accumulated deficit of $129,138,286. Since its inception, the Company has met its liquidity requirements principally through the sale of its Common Stock and Preferred Stock in public and private placements.

During the year ended December 31, 2024, the Company raised $12,487,399, net of offerings costs of $1,512,601, through the private placement of the Company's Series F-1 Preferred Stock and Series G Preferred Stock and warrants to purchase shares of the Company's Common Stock.

The Company evaluated the current cash requirements for operations in conjunction with management's strategic plan and believes that the Company's current financial resources as of the date of the issuance of these Consolidated Financial Statements are sufficient to fund its current operating budget and contractual obligations as of December 31, 2024 as they fall due within the next twelve-month period from the date of the issuance of these financial statements, alleviating any substantial doubt raised by the Company's historical operating results and satisfying its estimated liquidity needs for twelve months from the issuance of these consolidated financial statements.

Note 4 – Trade and Other Payables

Trade and other payables consist of the following:

	December 31, 2024	December 31, 2023
Accounts Payable – Trade	$ 2,515,421	$ 3,079,080
Accrued Expenses	386,683	637,138
	$ 2,902,104	$ 3,716,218

Note 5 – Stock-based Payments

Equity incentive Plans

2016 Stock Incentive Plan

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 the Company's Common Stock. As of December 31, 2024, no options were outstanding and no shares of Common Stock remain available for issuance under the 2016 Plan. 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 pre-Merger MyMD Florida's Second Amendment to Amended and Restated 2016 Incentive Plan together with the 2016 Plan, the "MyMD Florida Incentive Plan"), assuming all of pre-Merger MyMD Florida's rights and obligations with respect to the options issued thereunder (except that the term of each options was amended to expire on the second-year anniversary of the effective time of closing). All such options expired on April 16, 2023.

2017 Stock Incentive Plan

On August 7, 2017, the stockholders approved, and the Company adopted the 2017 Stock Incentive Plan ("2017 Plan"). The 2017 Plan provides for the issuance of up to 118 shares of the Company's Common Stock. As of December 31, 2024, grants of restricted stock and options to purchase 93 shares of Common Stock have been issued pursuant to the 2017 Plan, and 25 shares of Common Stock remain available for issuance.

2018 Stock Incentive Plan

On December 7, 2018, the stockholders approved, and the Company adopted the 2018 Stock Incentive Plan ("2018 Plan"). On August 27, 2020, the 2019 Plan was modified to increase the total authorized shares. The 2018 Plan, as amended, provides for the issuance of up to 18,670 shares of the Company's Common Stock. As of December 31, 2024, grants of RSUs and restricted stock to purchase 8,769 shares of Common Stock have been issued pursuant to the 2018 Plan, and 9,901 shares of Common Stock remain available for issuance.

2021 Stock Incentive Plan

On April 15, 2021, the stockholders approved, and the Company adopted the 2021 Stock Incentive Plan, as amended, ("2021 Plan"). The 2021 Plan provides for the issuance of up to 2,500,000 shares of the Company's Common Stock. As of December 31, 2024, grants of RSUs and stock options to purchase 109,983 shares of Common Stock have been issued pursuant to the 2021 Plan, and 2,390,017 shares of Common Stock remain available for issuance.

Stock Options

The following table summarizes the activities for the Company's stock options for the year ended December 31, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2023	139,840	$ 46.09	$ 42.34	8.17	$ -
Granted	-	-	-	-	-
Exercised	-	-	-	-	-
Forfeited	(80,002)	43.89	39.62	6.56	-
Canceled/Expired	-	-	-	-	-
Balance at December 31, 2024	59,838	49.03	45.97	7.98	$ -
Exercisable as of December 31, 2024	45,226	48.78	45.60	7.84	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.15 for the Company's Common Stock on December 31, 2024 and the closing stock price of $7.77 for the Company's Common Stock on December 31, 2023.

On April 4, 2023, the Company issued 25,000 options to a key employee. These shares had a grant date fair value of $39.00 per share or a cumulative fair market value of $978,675 as calculated using Black-Scholes (exercise price $46.50 per share, stock price $46.50 per share, volatility of 122.12%, discount rate of 3.39% and a five-year term). 1/3 of the options vested on the grant date, 1/3 vest on the first anniversary of the grant and 1/3 vest on the second anniversary of the grant. The 1/3rd of the fair-market value of the options was expensed on the grant date and the remaining 2/3rd is amortized over 24 month vesting.

On June 7, 2023, the Company issued 66,503 options to the directors and key employees. These shares had a grant date fair value of $47.10 per share or a cumulative fair market value of $3,128,759 as calculated using Black-Scholes (exercise price $49.00 per share, stock price $49.00 per share, volatility of 115.94%, discount rate of 3.79% and a ten-year term). 1/3 of the options vested on the grant date, 1/3 vest on the first anniversary of the grant and 1/3 vest on the second anniversary of the grant. The 1/3rd of the fair-market value of the options was expensed on the grant date and the remaining 2/3rd is amortized over 24 month vesting.

On July 19, 2023, the Company issued 1,667 options to a consultant for services. These shares had a grant date fair value of $29.18 per share or a cumulative fair market value of $48,643 as calculated using Black-Scholes (exercise price $34.80 per share, stock price $34.80 per share, volatility of 120.30%, discount rate of 3.98% and a five-year term). The options vested on the grant date. The fair-market value of the options was recorded immediately for services previously performed.

On September 6, 2023, the Company issued 33,334 options to a key employee. These shares had a grant date fair value of $23.10 per share or a cumulative fair market value of $769,700 as calculated using Black-Scholes (exercise price $24.30 per share, stock price $24.30 per share, volatility of 117.90%, discount rate of 4.44% and a ten-year term). The options will vest upon the achievement of specific performance goals. The fair-market value of the options will be recognized in the period the vesting event is achieved. As of December 31, 2023, none of the vesting events have occurred.

On September 6, 2023, the Company issued 3,334 options to a key employee. These shares had a grant date fair value of $23.10 per share or a cumulative fair market value of $76,970 as calculated using Black-Scholes (exercise price $24.30 per share, stock price $24.30 per share, volatility of 117.90%, discount rate of 4.44% and a ten-year term). ½ of the options vested on the grant date, ½ vest on the first anniversary of the grant. The fair-market value of the vested options was amortized upon the issuance of the grant and the remaining options will be amortized over the 12-month vesting cycle.

During the years ended December 31, 2024 and 2023, the Company recognized stock option expenses totaling $1,057,271 and $3,049,537, respectively.

The unamortized stock option expenses as of December 31, 2024 and 2023 totaled $148,583 and $2,418,338, respectively.

Restricted Stock Units

During the year ended December 31, 2023, the Company converted 261 vested RSUs issued in March 2019 and 7,600 vested RSUs issued in September 2020 to members of the Board of Directors into 7,861 shares of Common Stock of the Company. Expenses related to these RSUs had been recognized by pre-merger Akers Biosciences, Inc in 2021 and prior years.

On October 14, 2021, the Compensation Committee of the Board of Directors approved grants totaling 93,169 Restricted Stock Units to the Company's six directors and seven key employees. Each RSU had a grant date fair value of $242.70 which will be amortized upon vesting into administrative expenses within the Consolidated Statement of Comprehensive Loss. Such RSUs were granted under the 2021 Plan. Vesting of each RSU is:

- One-third (33%) of each RSU will vest when the Company's market capitalization is equal to or greater than $500,000,000 for at least ten (10) trading days during any twenty (20) consecutive trading day period ending on or after December 15, 2021 and the fair market value of the Common Stock equals or exceeds $150.00 during such trading day period.

- One-third (33%) of each RSU will vest when the Company's market capitalization is equal to or greater than $750,000,000 for at least ten (10) trading days during any twenty (20) consecutive trading day period ending on or after December 15, 2021 and the fair market value of the Common Stock equals or exceeds $150.00 during such trading day period.

- The remaining awarded units will vest when the Company's market capitalization is equal to or greater than $1,000,000,000 for at least ten (10) trading days during any twenty (20) consecutive trading day period ending on or after December 15, 2021 and the fair market value of the Common Stock equals or exceeds $150.00 during such trading day period.

- In the event that (i) a change in control occurs or (ii) the participant incurs a termination of service by the Company without cause or due to the participant's death or total and permanent disability, then all unvested units shall become vested units immediately upon the occurrence of such event.

As of December 31, 2024, none of the vesting milestones have been met.

For the year ended December 31, 2024 the Company converted 908 vested RSUs issued in September 2020 to a member of the Board of Directors, convertible into 908 shares of Common Stock of the Company. Expenses related to these RSUs had been recognized by pre-merger Akers Biosciences, Inc. in 2021 and prior years.

The following is the status of outstanding unvested restricted stock units outstanding as of December 31, 2024 and the changes for the year ended December 31, 2024:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at December 31, 2023	88,668	$ 242.70
Granted	-	-
Vested	-	-
Forfeited	(40,334)	242.70
Canceled/Expired	-	-
Balance at December 31, 2024	48,334	$ 242.70

As of December 31, 2024 and 2023, the unamortized value of the RSUs was $9,789,061 and $21,600,300, respectively.

Note 6 – Equity

Authorized Capital Stock

On July 24, 2024, the Company's stockholders approved the adoption of the Certificate of Amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of the Company's Common Stock from 16,666,666 to 250,000,000 ("Authorized Share Increase Amendment") and to make a corresponding change to the number of authorized shares of capital stock. On July 25, 2024, the Company filed the Authorized Share Increase Amendment with the Secretary of State of Delaware (the "Secretary of State"). On June 17, 2024, the Company filed a Certificate of Amendment to the Series G Certificate of Designations with the Secretary of State to increase the number of authorized shares of Series G Preferred Stock from 8,950 to 12,826,273.

As of December 31, 2024, the Company's authorized capital stock consisted of 300,000,000 shares, of which 250,000,000 are shares of Common Stock, and 50,000,000 are shares of preferred stock, $0.001 par value per share, 1,990,000 of which have been designated as Series C Convertible Preferred Stock (the "Series C Preferred Stock"), 211,353 of which have been designated as Series D Convertible Preferred Stock (the "Series D Preferred Stock"), 100,000 of which have been designated as Series E Junior Participating Preferred Stock, 15,000 of which have been designated as Series F Convertible Preferred Stock (the "Series F Preferred Stock") 5,050 of which have been designated as Series F-1 Convertible Preferred Stock and 12,826,273 of which have been designated as Series G Preferred Stock.

As of December 31, 2024 and December 31, 2023, there were 3,363,603 and 2,018,857 shares of Common Stock issued and outstanding, respectively. There were 72,992 shares of Series D Preferred Stock issued and outstanding and warrants to purchase Series C Preferred Stock convertible into 918 shares of Common Stock issued and outstanding as of December 31, 2024 and December 31, 2023. There were 4,211 and 6,633 shares of Series F Preferred Stock issued and outstanding as of December 31, 2024 and December 31, 2023, respectively. There were 4,747 and 0 shares of Series F-1 Preferred Stock issued and outstanding as of December 31, 2024 and December 31, 2023, respectively. There were 8,884 and 0 shares of Series G Preferred Stock issued and outstanding as of December 31, 2024 and December 31, 2023, respectively. There were no shares of Series C Convertible Preferred Stock or Series E Junior Participating Preferred Stock issued and outstanding as of December 31, 2024 and December 31, 2023.

Preferred Stock

The holders of preferred shares or preferred warrants are entitled to vote per share, as limited by the certificate of designation for each class of preferred shares or warrants, at meetings of the Company.

Series D Convertible Preferred Stock

The following are the principal terms of the Series D Preferred Stock:

Rank

The Series D Preferred Stock ranks (1) on parity with Common Stock on an "as converted" basis, (2) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series D Preferred Stock, (3) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series D Preferred Stock, and (4) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series D Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

Conversion Rights

A holder of Series D Preferred Stock is entitled at any time to convert any whole or partial number of shares of Series D Preferred Stock into shares of our Common Stock, determined by dividing the stated value equal to $0.01 by the conversion price of $0.01 per share. A holder of Series D Preferred Stock is prohibited from converting Series D Preferred Stock into shares of Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our Common Stock then issued and outstanding (with such ownership restriction referred to as the "Series D Beneficial Ownership Limitation") immediately after giving effect to the issuance of the shares of Common Stock issuable upon conversion of the Series D Preferred Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. The conversion rate of the Series D Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividend Rights

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series D Preferred Stock are entitled to receive dividends on shares of Series D Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends are payable on shares of Series D Preferred Stock.

Voting Rights

Subject to the Series D Beneficial Ownership Limitation, on any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of a meeting), each holder, in its capacity as such, shall be entitled to cast the number of votes equal to the number of whole shares of our Common Stock into which the Series D Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Series D Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of the Certificate of Designation of Series D Convertible Preferred Stock (the "Series D Certificate of Designation"), the holders of Series D Preferred Stock, in their capacity as such, shall vote together with the holders of our Common Stock and any other class or series of stock entitled to vote thereon as a single class.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series D Preferred Stock are entitled to receive, *pari passu* with the holders of Common Stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series D Preferred Stock been converted into Common Stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Series D Beneficial Ownership Limitation, as described above.

Exchange Listing

Series D Preferred Stock is not listed on the Nasdaq, any national securities exchange or other nationally recognized trading system. Our Common Stock issuable upon conversion of the Series D Preferred Stock is listed on the Nasdaq under the symbol "TNFA".

Failure to Deliver Conversion Shares

If we fail to timely deliver shares of Common Stock upon conversion of the Series D Preferred Stock (the "Series D Conversion Shares") within the time period specified in the Series D Certificate of Designation (within two trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), then we are obligated to pay to the holder, as liquidated damages, an amount equal to $25 per trading day (increasing to $50 per trading day on the third trading day and $100 per trading day on the sixth trading day) for each $5,000 of stated value of Series D Preferred Stock being converted which are not timely delivered. If we make such liquidated damages payments, we are also not obligated to make Series D Buy-In (as defined below) payments with respect to the same Series D Conversion Shares.

Compensation for Series D Buy-In on Failure to Timely Deliver Shares

If we fail to timely deliver the Series D Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the holder of the Series D Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Series D Buy-In"), then we are obligated to (A) pay in cash to such holder (in addition to any other remedies available to or elected by such holder) the amount, if any, by which (x) such holder's total purchase price (including any brokerage commissions) for the shares of Common Stock so purchased exceeds (y) the product of (1) the aggregate number of Series D Conversion Shares that such holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of such holder, either reissue (if surrendered) the shares of Series D Preferred Stock equal to the number of shares of Series D Preferred Stock submitted for conversion (in which case, such conversion shall be deemed rescinded) or deliver to such holder the number of Series D Conversion Shares that would have been issued if we had timely complied with its delivery requirements.

As of December 31, 2024 and December 31, 2023, the Company had 72,992 shares of Series D Convertible Preferred Stock outstanding which represent 1,217 underlying shares of the Company's Common Stock.

Series F Convertible Preferred Stock

The following are the principal terms of the Series F Preferred Stock:

Dividends

The holders of the Series F Preferred Stock are entitled to dividends of 10.0% per annum, compounded monthly, which are payable in cash or shares of Common Stock at the Company's option, in accordance with the terms of the certificate of designation of the Series F Preferred Stock (the "Series F Certificate of Designation"). Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F Certificate of Designation), shares of Series F Preferred Stock will accrue dividends at the rate of 15.0% per annum. Upon conversion or redemption, the holders of shares of Series F Preferred Stock are also entitled to receive a dividend make-whole payment.

Voting Rights

Except as required by law (including without limitation, the Delaware General Corporation Law (the "DGCL")), the holders of the Series F Preferred Stock are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F Preferred Stock is entitled to be calculated assuming a conversion price of $60.21 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series F Certificate of Designation. The Series F Certificate of Designation further provides that the holders of record of the Series F Preferred Stock, exclusively and as a separate class, shall be entitled to elect one director of the Company one time on or before June 30, 2024. To the extent that under the DGCL the vote of the holders of shares of Series F Preferred Stock, voting separately as a class or series, as applicable, is required to authorize a given action of the Company, the affirmative vote or consent of a majority of the outstanding shares of Series F Preferred Stock, voting together in the aggregate and not in separate series unless required under the DGCL, represented at a duly held meeting at which a quorum is presented or by written consent of such majority (except as otherwise may be required under the DGCL) shall constitute the approval of such action by both the class or the series, as applicable.

Liquidation

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, each holder of shares of the Series F Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount per share of Series F Preferred Stock equal to the greater of (A) 125% of the stated value of such share of Series F Preferred Stock (plus any applicable make-whole amount, unpaid late charge or other applicable amount) on the date of such payment and (B) the amount per share such holder would receive if such holder converted such share of Series F Preferred Stock into Common Stock immediately prior to the date of such payment. All shares of capital stock of the Company shall be junior in rank to all shares of Series F Preferred Stock with respect to the preferences as to payments upon the liquidation.

Optional Conversion

The Series F Preferred Stock can be converted at the option of the holder at any time and from time to time after the original issuance date. Holders shall effect conversions by providing us with the form of conversion notice (the "Series F Notice of Conversion") specifying the number of shares of Series F Preferred Stock to be converted, the number of shares of Series F Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable holder delivers by email such Series F Notice of Conversion to us.

Mandatory Conversion

If on any day after the issuance of the shares of Series F Preferred Stock the closing price of the Common Stock has exceeded $6.765 (as adjusted for the Reverse Stock Split) (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock has exceeded $3,000,000 per trading day during the same period and certain equity conditions described in the Series F Certificate of Designation are satisfied (the "Mandatory Conversion Date"), the Company shall deliver written notice of the Mandatory Conversion (as defined below) to all holders on the Mandatory Conversion Date and, on such Mandatory Conversion Date, the Company shall convert all of each holder's shares of Series F Preferred Stock into Conversion Shares at the then effective Conversion Price (the "Mandatory Conversion"). If any of the Equity Conditions shall cease to be satisfied at any time on or after the Mandatory Conversion Date through and including the actual delivery of all of the Conversion Shares to the holders, the Mandatory Conversion shall be deemed withdrawn and void ab initio.

Beneficial Ownership Limitation

The Series F Preferred Stock cannot be converted to Common Stock if the holder and its affiliates would beneficially own more than 4.99% or 9.99% at the election of the holder of the outstanding Common Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Series F-1 Preferred Stock

The following are the principal terms of the Series F-1 Preferred Stock:

Dividends

The holders of the Series F-1 Preferred Stock are entitled to dividends of 10% per annum, compounded monthly, which are payable in arrears monthly in cash or shares of Common Stock at our option, in accordance with the terms of the Series F-1 Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F-1 Certificate of Designations), the Series F-1 Preferred Stock will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series F-1 Preferred Stock are also entitled to receive a dividend make-whole payment.

Voting Rights

Except as required by law (including without limitation, the Delaware General Corporation Law (the "DGCL")), the holders of the Series F-1 Preferred Stock are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F-1 Preferred Stock is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series F-1 Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series F-1 Certificate of Designations. To the extent that under the DGCL the vote of the holders of shares of Series F-1 Preferred Stock, voting separately as a class or series, as applicable, is required to authorize a given action of the Company, the affirmative vote or consent of a majority of the outstanding shares of Series F-1 Preferred Stock, voting together in the aggregate and not in separate series unless required under the DGCL, represented at a duly held meeting at which a quorum is presented or by written consent of such majority (except as otherwise may be required under the DGCL) shall constitute the approval of such action by both the class or the series, as applicable.

Liquidation

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, each holder of shares of the Series F-1 Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount per share of Series F-1 Preferred Stock equal to the greater of (A) 125% of the stated value of such share of Series F-1 Preferred Stock (plus any applicable make-whole amount, unpaid late charge or other applicable amount) on the date of such payment and (B) the amount per share such holder would receive if such holder converted such share of Series F-1 Preferred Stock into Common Stock immediately prior to the date of such payment. All shares of capital stock of the Company shall be junior in rank to all shares of Series F-1 Preferred Stock with respect to the preferences as to payments upon the liquidation.

Exchange Cap

The Company was initially restricted from issuing shares of Common Stock upon conversion of the Series F-1 Preferred Stock and Series G Preferred Stock or exercise of the associated warrants in excess of 19.99% of the shares of Common Stock outstanding as of the date immediately prior to the issuance of the shares of Series F-1 Preferred Stock and Series G Preferred Stock and the associated warrants (the "Issuable Maximum") until the Company obtained stockholder approval for the issuance of shares of Common Stock in excess of the Issuable Maximum. The Company received the Stockholder Approval on July 24, 2024.

Optional Conversion

The Series F-1 Preferred Stock can be converted at the option of the holder at any time and from time to time after the original issuance date. Holders shall effect conversions by providing us with the form of conversion notice (the "Notice of Conversion") specifying the number of shares of Series F-1 Preferred Stock to be converted, the number of shares of Series F-1 Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable holder delivers by email such Notice of Conversion to us.

Mandatory Conversion

If on any day after the issuance of the shares of Series F-1 Preferred Stock the closing price of the Common Stock has exceeded $5.448 per share (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock has exceeded $3,000,000 per trading day during the same period and certain equity conditions described in the Series F-1 Certificate of Designation are satisfied (the "Mandatory Conversion Date"), the Company shall deliver written notice of the Mandatory Conversion (as defined below) to all holders on the Mandatory Conversion Date and, on such Mandatory Conversion Date, the Company shall convert all of each holder's shares of Series F-1 Preferred Stock into Conversion Shares at the then effective Conversion Price (the "Mandatory Conversion"). If any of the Equity Conditions shall cease to be satisfied at any time on or after the Mandatory Conversion Date through and including the actual delivery of all of the Conversion Shares to the holders, the Mandatory Conversion shall be deemed withdrawn and void ab initio.

Beneficial Ownership Limitation

The Series F-1 Preferred Stock cannot be converted to Common Stock if the holder and its affiliates would beneficially own more than 4.99% or 9.99% at the election of the holder of the outstanding Common Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Series G Preferred Stock

The following are the principal terms of the Series G Preferred Stock:

Voting Rights

Except as required by law (including without limitation, the Delaware General Corporation Law (the "DGCL")), the holders of the Series G Preferred Stock are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series G Preferred Stock is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the Series G Purchase Agreement, subject to certain beneficial ownership limitations as set forth in the Series G Certificate of Designations. To the extent that under the DGCL the vote of the holders of shares of Series G Preferred Stock, voting separately as a class or series, as applicable, is required to authorize a given action of the Company, the affirmative vote or consent of a majority of the outstanding shares of Series G Preferred Stock, voting together in the aggregate and not in separate series unless required under the DGCL, represented at a duly held meeting at which a quorum is presented or by written consent of such majority (except as otherwise may be required under the DGCL) shall constitute the approval of such action by both the class or the series, as applicable.

Liquidation

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, each holder of shares of the Series G Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount per share of Series G Preferred Stock equal to the greater of (A) 125% of the stated value of such share of Series G Preferred Stock (plus any applicable make-whole amount, unpaid late charge or other applicable amount) on the date of such payment and (B) the amount per share such holder would receive if such holder converted such share of Series G Preferred Stock into Common Stock immediately prior to the date of such payment. All shares of capital stock of the Company shall be junior in rank to all shares of Series G Preferred Stock with respect to the preferences as to payments upon the liquidation.

Exchange Cap

The Company was initially restricted from issuing shares of Common Stock upon conversion of the Series F-1 Preferred Stock and Series G Preferred Stock or exercise of the associated warrants in excess of 19.99% of the shares of Common Stock outstanding as of the date immediately prior to the issuance of the shares of Series F-1 Preferred Stock and Series G Preferred Stock and the associated warrants until the Company obtained stockholder approval for the issuance of shares of Common Stock in excess of the Issuable Maximum. The Company received the Stockholder Approval on July 24, 2024.

Optional Conversion

The Series G Preferred Stock can be converted at the option of the holder at any time and from time to time after the original issuance date. Holders shall effect conversions by providing us with the form of conversion notice (the "Notice of Conversion") specifying the number of shares of Series G Preferred Stock to be converted, the number of shares of Series G Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable holder delivers by email such Notice of Conversion to us.

Beneficial Ownership Limitation

The Series G Preferred Stock cannot be converted to Common Stock if the holder, other than PharmaCyte Biotech, Inc., and its affiliates would beneficially own more than 4.99% or 9.99% at the election of the holder of the outstanding Common Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Common Stock

The holders of Common Stock are entitled to one vote per share at meetings of the Company.

During the year ended December 31, 2023, the Company issued 7,861 shares of Common Stock for previously vested restricted stock units.

During the year ended December 31, 2023, 4,505 prefunded warrants were exercised in exchange for 4,505 shares of Common Stock.

During the year ended December 31, 2023 the Company issued 539,534 shares of Common Stock as installment conversions and 85,323 shares of Common Stock for make-whole adjustments for the Series F Preferred Stock.

During the year ended December 31, 2024, the Company issued 908 shares of Common Stock for previously vested restricted stock units.

During the year ended December 31, 2024, the Company issued 283,019 shares of Common Stock in exchange for services with a fair market value of $600,000.

During the year ended December 31, 2024 the Company issued 747,283 shares of Common Stock as installment conversions and 0 shares of Common Stock for make-whole adjustments for the Series F Preferred Stock.

During the year ended December 31, 2024 the Company issued 262,768 shares of Common Stock as installment conversions and 0 shares of Common Stock for make-whole adjustments for the Series F-1 Preferred Stock.

During the year ended December 31, 2024 the Company issued 50,768 shares of Common Stock for the exercise of the Series G Preferred Stock.

Common Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2024:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2023	4,933,622	$ 9.02	4.08	$ 21,650,589
Issued	21,538,460	1.30	2.82	-
Series F Modification				
Warrants issued February 23, 2023	(4,716,904)	3.18	3.15	-
Warrant modification November 6, 2024	11,538,462	1.30	3.15	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2024	33,293,640	$ 2.18	2.81	$ -
Exercisable as of December 31, 2024	33,293,640	$ 2.18	2.81	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.15 for the Company's Common Stock on December 31, 2024 and the closing stock price of $7.77 for the Company's Common Stock on December 31, 2023. All warrants were vested on date of grant.

Pursuant to the February 2023 Offering, the Company issued Warrants to investors to purchase 4,716,904 shares of Common Stock (as adjusted, and subject to further adjustment), with an exercise price of $3.18 per share (as adjusted, and subject to further adjustment), for a period of five years from the date of issuance. The Exercise Price and the number of shares issuable upon exercise of the Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Exercise Price (subject to certain exceptions). Upon any such price-based adjustment to the Exercise Price, the number of shares issuable upon exercise of the Warrants will be increased proportionally.

Pursuant to the Series F-1 Private Placement, the Company issued the Series F-1 Short-Term Warrants to investors to purchase 2,780,839 shares of Common Stock (as adjusted, and subject to further adjustment), with an initial exercise price of $1.816 per share (as adjusted, and subject to further adjustment), for a period of 18 months from the date of issuance and the Series F-1 Short-Long Warrants to investors to purchase 2,780,839 shares of Common Stock (as adjusted, and subject to further adjustment), with an initial exercise price of $1.816 per share (as adjusted, and subject to further adjustment), for a period of five years from the date of issuance. The Series F-1 Exercise Price and the number of shares issuable upon exercise of the Series F-1 Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series F-1 Exercise Price (subject to certain exceptions). Upon any such price-based adjustment to the Series F-1 Exercise Price, the number of shares issuable upon exercise of the Series F-1 Warrants will be increased proportionately.

Pursuant to the Series G Private Placement, the Company issued the Series G Short-Term Warrants to investors to purchase 4,928,416 shares of Common Stock (as adjusted, and subject to further adjustment), with an initial exercise price of $1.816 per share (as adjusted, and subject to further adjustment), for a period of 18 months from the date of issuance and the Series G Short-Long Warrants to investors to purchase 4,928,416 shares of Common Stock (as adjusted, and subject to further adjustment), with an initial exercise price of $1.816 per share (as adjusted, and subject to further adjustment), for a period of five years from the date of issuance. The Series G Exercise Price and the number of shares issuable upon exercise of the Series G Warrants are subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series G Exercise Price (subject to certain exceptions). Upon any such price-based adjustment to the Series G Exercise Price, the number of shares issuable upon exercise of the Series G Warrants will be increased proportionately.

Series C Convertible Preferred Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2024:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2023	918	$ 240.00	0.94	**$** -
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	(918)	240.00	-	-
Balance at December 31, 2024	-	$ -	-	$ -
Exercisable as of December 31, 2024	-	$ -	-	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.15 for the Company's Common Stock on December 31, 2024 and the closing stock price of $7.77 for the Company's Common Stock on December 31, 2023. All Series C Convertible Preferred Stock Warrants were vested on date of grant.

Note 7 – Income Taxes

The Company's income tax (benefit)/provision is as follows for the years ended December 31, 2024 and 2023:

	2024	2023
Current	$ -	$ -
Deferred	(5,446,000)	4,129,000
Change in Valuation Allowance	5,446,000	(4,129,000)
Income Tax Benefit	$ -	$ -

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2024 and 2023 are as follows:

	2024	2023
Statutory U.S. Federal Income Tax Rate	(21.0)%	(21.0)%
State income taxes, net of U.S. Federal tax effect	(7.5)%	45.5%
Adjustment to deferred tax assets	2.9%	82.8%
Tax credits	(1.6)%	-%
Non-deductible expenses	3.9%	-%
Change in Valuation Allowance	23.3%	(107.3)%
Net	0.0%	0.0%

As of December 31, 2024, and 2023, the Company had U.S. federal net operating loss carry forwards of approximately $116.5 million and $113.1 million, respectively. Approximately $47.1 million of the U.S. federal net operating loss generated in tax years beginning before January 1, 2018 expire beginning with the year ending December 31, 2025 through 2037. The remaining U.S. federal net operating loss of approximately $69.4 million does not expire, however it is limited to 80% of each subsequent year's net income. As of December 31, 2024, and 2023, the Company had U.S. state net operating loss carry forwards of approximately $55.7 million and $45.2 million, respectively, some of which expire beginning with the year ending December 31, 2025 through 2044. U.S. federal net operating losses of approximately $4.4 million expired during 2024. The timing and manner in which the Company can utilize operating loss carryforwards in any year may be limited by provisions of the Internal Revenue Code regarding changes in ownership of corporations. Such limitation may have an impact on the ultimate realization of its carryforwards and future tax deductions.

Under Section 382 of the Code, use of the Company's net operating loss carryforwards is limited if the Company experiences a cumulative change in ownership of greater than 50% in a moving three-year period. The Company experienced an ownership change as a result of the Merger and therefore the Company's ability to utilize its net operating loss and certain credit carryforwards are limited. The limitation is determined by the fair market value of the Company's common stock outstanding immediately prior to the ownership change, multiplied by the applicable federal rate. It is expected that the Merger caused the Company's net operating loss carryforwards to be limited. However, the limitation had no impact on the Company's financial statements since the Company recorded a full valuation allowance for the deferred tax assets as of December 31, 2024 and 2023.

The principal components of the deferred tax assets and liabilities, and related valuation allowances as of December 31, 2024 and 2023 are as follows:

	2024	2023
Reserves and other	$ 731,000	$ 796,000
Net operating loss carry-forwards	27,869,000	26,494,000
Capitalized research and development	3,894,000	3,946,000
Research and development tax credit	2,205,000	1,326,000
Share-based compensation	1,430,000	1,108,000
Warrant liability	-	(2,860,000)
Derivative liability	-	(688,000)
Valuation Allowance	(36,129,000)	(30,122,000)
Net deferred tax asset	$ -	$ -

The valuation allowance for deferred tax assets increased by approximately $5.4 million during the year ended December 31, 2024, due mainly to increases in the Company's deferred tax asset related to increases in the Company's cumulative deductible temporary differences and decreases in the Company's cumulative taxable temporary differences. The valuation allowance for deferred tax assets (decreased) by approximately $(4.1) million during the year ended December 31, 2023, due mainly to write-offs of the gross deferred tax asset related to share-based compensation, net of increases in the Company's deferred tax assets related to its net operating loss carryforward and capitalized research expenses. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets may be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating losses and temporary differences become deductible. Management considers projected future taxable income and tax planning strategies in making this assessment.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the years ended December 31, 2024 and 2023. The Company does not expect its uncertain tax position to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

The Company files U.S. federal income tax returns and state income tax returns. Since the Company had losses in the past, all prior years that generated net operating loss carryforwards are open and subject to audit examination in relation to the net operating loss generated from those years.

Note 8 – Commitments and Contingencies

Litigation and Settlements

Raymond Akers Actions

On April 14, 2021, Raymond F. Akers, Jr., Ph.D. filed a lawsuit against the Company (f/k/a Akers Biosciences, Inc.) in the Superior Court of New Jersey, Law Division, Gloucester County (the "First Raymond Akers Action"). Mr. Akers asserts one common law whistleblower retaliation claim against the Company.

On September 23, 2021, the Court granted the Company's Motion to Dismiss Plaintiff's Amended Complaint and dismissed Plaintiff's Amended Complaint. The Court indicated that Mr. Akers is "free to file another complaint, however, tort-based 'Pierce' allegations, and/or CEPA claims are barred by the statute of limitations."

On March 1, 2022, Mr. Akers filed a second action against the Company in the Superior Court of New Jersey, Law Division, Gloucester County (the "Second Raymond Akers Action") again asserting one common law whistleblower retaliation claim against the Company. The Company believes that the Second Raymond Akers Action was filed against the Court's specific admonition that Plaintiff does not attempt to circumvent the statute of limitations.

On May 27, 2022, the Court granted-in-part and denied-in-part the Company's Motion to Dismiss Plaintiff's Complaint. The Court reaffirmed the ruling in the First Raymond Akers Action that any tort-based Pierce claims are time-barred. However, the Court denied the Motion as it pertained to Plaintiff's contract-based Pierce claim and "Repayment of Monies Owed" claim. On July 29, 2022, the Company filed its Answer, which included affirmative defenses. As of December 31, 2024, the Second Raymond Akers Action is in the discovery phase.

All legal fees incurred were expensed as and when incurred. While no assurance can be provided, the Company does not believe that the current litigation will have a material impact on its financial condition or results of operations.

Note 9 – Related Parties

SRQ Patent Holdings and SRQ Patent Holdings II

The Company is a party to two Amended and Restated Confirmatory Patent Assignment and Royalty Agreements, both dated November 11, 2020, with SRQ Patent Holdings and SRQ Patent Holdings II, under which the Company (or its successor) will be obligated to pay to SRQ Patent Holdings or SRQ Patent Holdings II (or its designees) certain royalties on product sales or other revenue received on products that incorporate or are covered by the intellectual property that was assigned to the Company. The royalty is equal to 8% of the net sales price on product sales and, without duplication, 8% of milestone revenue or sublicense compensation. SRQ Patent Holdings and SRQ Patent Holdings II are affiliates of Mr. Jonnie Williams, Sr. No revenue has been recognized subject to these agreements for the year ended December 31, 2024 and 2023.

MIRA Pharmaceuticals Limited License Agreement

The Company is a party to an Amended and Restated Limited License Agreement, dated June 27, 2022 and amended on April 20, 2023, with MIRA Pharmaceuticals, Inc. (Nasdaq: MIRA), under which the parties agreed to share technical information and know-how pertaining to the synthetic manufacture and formulation of the parties' respective Supera-CBD™ and MIRA1a™ product candidates. The Company, which holds patent rights to MIRA1a™ in 22 foreign countries, was granted a perpetual, non-exclusive, royalty-free license to use improvements to MIRA1a™ made under the agreement, and MIRA was granted a limited, perpetual, worldwide, non-exclusive, royalty-free license to use Supera-CBD™ as a synthetic intermediate in the manufacture of MIRA1a™.

Series G Preferred Stock Issuance

On May 20, 2024, the Company entered into the Series G Purchase Agreement with the Series G Investors, including PharmaCyte Biotech, Inc. ("Pharmacyte"), pursuant to which it agreed to sell to the Series G Investors (i) an aggregate of 8,950 Series G Preferred Stock, initially convertible into up to 4,928,416 shares of the Company's Common Stock, at a conversion price of $1.816 per share (ii) Series G Short-Term Warrants to acquire up to an aggregate of 4,928,416 shares of Common Stock at an exercise price of $1.816 per share, and (iii) Series G Long-Term Warrants acquire up to an aggregate of 4,928,416 shares of Common Stock at an exercise price of $1.816 per share, for aggregate gross proceeds equaling approximately $8.9 million. The interim CEO, President and Director of PharmaCyte, Joshua Silverman, serves as the Company's Chairman of the Board.

Note 10 – Employee Benefit Plan

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code covering substantially all qualified employees of the Company (the "401(k) Plan"). Under the 401(k) Plan, the Company matches 100% up to a 3% contribution, and 50% over a 3% contribution, up to a maximum of 5%.

The Company made matching contributions to the 401(k) Plan during the years ended December 31, 2024 and 2023 of $22,142 and $44,942, respectively.

Note 11 – Patent Assignment and Royalty Agreement

In November 2016, the Company entered into an agreement with the holders of certain intellectual property relating to the Company's current product candidate. Under the terms of the agreement, the counterparty assigned its rights and interest in certain patents to the Company in exchange for future royalty payments based on a fixed percentage of future revenues, as defined. The agreement is effective until the later of (1) the date of expiration of the assigned patents or (2) the date of expiration of the last strategic partnership or licensing agreement including the assigned patents. No revenue has been received subject to these agreements as of December 31, 2024 and 2023.

Note 12 – Segment Reporting

The Company has one reportable segment focused on Isomyosamine (formerly MYMD-1). The Company's chief operating decision maker ("CODM"), who is responsible for evaluating financial performance and allocating resourses, is the President and Chief Medical Officer. The accounting policies of the single segment are the same as those described in the summary of significant accounting policies. The CODM does not use assets to assess the segment. The CODM assesses performance for the single segment and decides how to allocate resources based on net operating loss excluding stock-based compensation and warrant issuance expenses. The CODM uses a non-GAAP measure, net of operating loss excluding stock-based compensation and warrant issuance expenses, as the primary measure of operating performance and to monitor the Company's cash burn and adherence to budget.

To date, the Company has not generated any product revenue and has incurred losses and negative cash flows from operations since inception.

The following table presents certain financial data for the Company's reportable segment and a reconciliation to the Company's consolidated net loss.

	2024	2023
Product Revenue	$ -	$ -
Product Cost of Sales	-	-
Gross Income	-	-
Operating Expenses		
Administrative Expenses	4,161,907	5,442,886
Research and Development Expenses	3,441,010	7,867,795
Segment Net Loss	(7,602,917)	(13,310,681)
Reconcilement of Net Loss		
Adjustments and Reconciling Items		
Stock Based Compensation	1,057,271	3,049,537
Series F Warrant Issuance Expenses	-	762,834
Series F-1 Warrant Issuance Expenses	539,097	-
Series G Warrant Issuance Expenses	969,505	-
Interest and Dividend Income	351,809	455,570
Gains on Sales of Marketable Securities	976	416
Unrealized Gains on Marketable Securities	671	514
Change in Fair Value of Derivative Liabilities	(388,000)	3,088,800
Change in Fair Value of Warrant Liabilities	(4,410,000)	9,756,000
Loss on Issuance of Series F-1 Convertible Preferred Stock	(3,737,000)	-
Loss on Issuance of Series G Convertible Preferred Stock	(5,109,000)	-
Casualty Gain/(Loss)	100,000	(178,198)
Total Adjustments and Reconciling Items	(15,756,417)	9,310,731
Consolidated Net Loss	$ (23,359,334)	$ (3,999,950)

Segment assets are not reviewed by the CODM and, accordingly, asset information is not presented.

Note 13 – Subsequent Events

On March 5, 2025, in connection with the issuance of shares of Common Stock upon conversion of the Series F-1 Preferred Shares, (i) the Series F Conversion Price, Series F-1 Conversion Price and Series G Conversion Price was adjusted to $0.364 per share pursuant to the full ratchet anti-dilution provisions contained in the applicable Certificate of Designations and, (ii) the Series F Exercise Price, the Series F-1 Conversion Price and Series G Exercise Price was adjusted to $0.364 per share and the number of shares of Common Stock issuable upon exercise of such warrants was adjusted proportionally pursuant to the full ratchet anti-dilution provisions contained in the applicable warrants.

On April 8, 2025, the Company entered into an Omnibus Amendment Agreement ("April 2025 Amendment Agreement") with the Required Holders (as defined in the Series F Certificate of Designations and Series F-1 Certificate of Designations), pursuant to which, the Required Holders agreed to amend (i) the Series F-1 Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F-1 Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F-1 Certificate of Amendment"), (ii) the Series F Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F Certificate of Amendment"), (iii) the Series F-1 Purchase Agreement, to amend the definition of "Excluded Securities" such that the definition includes the issuance of common stock issued after the date of the Seres F-1 Purchase Agreement pursuant to an Approved Stock Plan (as defined in the Series F-1 Purchase Agreement), which in the aggregate does not exceed more than 2% of the shares of common stock issued and outstanding as of the date of such issuance (the "Excluded Securities Modification"), and (iv) to amend the term of the Series F-1 Short-Term Warrants to be five years from the date of issuance. In addition, in consideration of the foregoing, the Company agreed to reduce the size of the board of directors of the Company to no more than six directors, no later than the Company's 2025 annual meeting of stockholders.

The April 2025 Series F Certificate of Amendment amends the Series F Certificate of Designations to (A) (i) extend the maturity date to June 30, 2025, and (ii) modify the schedule of Installment Dates (as defined in the Series F Certificate of Designations), in each case, effective as of December 31, 2024, and (B) subject to obtaining the approval of the Company's stockholders, effective January 1, 2025, increase the aggregate Stated Value of the Series F Preferred Stock outstanding to an amount equal to 110% of the aggregate Stated Value of the Series F Preferred Stock outstanding. The April 2025 Series F Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

The April 2025 Series F Certificate of Amendment amends the Series F-1 Certificate of Designations to amend the definition of "Excluded Securities" substantially similar to the Excluded Securities Modification. The April 2025 Series F-1 Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

On March 17, 2025, the Company received a letter from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of the Company's Common Stock for the 30 consecutive business days between January 30, 2025, to March 14, 2025, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). The letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until September 15, 2025 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A). In order to regain compliance with Nasdaq's minimum bid price requirement, the Company's Common Stock must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Compliance Period. In the event the Company does not regain compliance by the end of the Compliance Period, the Company may be eligible for an additional 180 calendar days to regain compliance. There can be no assurance that the Company will be eligible for the additional 180 calendar day compliance period, if applicable, or that the Nasdaq staff would grant the Company's request for continued listing subsequent to any delisting notification. In the event of such a notification, the Company may appeal the Nasdaq staff's determination to delist its securities.

Exhibit 3.5.3

CERTIFICATE OF AMENDMENT OF
CERTIFICATE OF DESIGNATIONS OF
SERIES F CONVERTIBLE PREFERRED STOCK OF
TNF PHARMACEUTICALS, INC.

PURSUANT TO SECTION 242 OF THE
DELAWARE GENERAL CORPORATION LAW

This Certificate of Amendment to the Certificate of Designations of Series F Convertible Preferred Stock (the "**Amendment**") is dated as of April 8, 2025.

WHEREAS, the board of directors (the "**Board**") of TNF Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), pursuant to the authority granted to it by the Company's Certificate of Incorporation (as amended, the "**Certificate of Incorporation**") and Section 151(g) of the Delaware General Corporation Law (the "**DGCL**"), has previously fixed the rights, preferences, restrictions and other matters relating to a series of the Company's preferred stock, consisting of 15,000 authorized shares of preferred stock, classified as Series F Convertible Preferred Stock (the "**Preferred Stock**"), and the Amended and Restated Certificate of Designations of the Preferred Stock (as amended, the "**Certificate of Designations**") was initially filed with the Secretary of State of the State of Delaware on April 8, 2024 evidencing such terms;

WHEREAS, pursuant to Section 32(b) of the Certificate of Designations, the Certificate of Designations or any provision thereof may be amended by obtaining the affirmative vote at a meeting duly called for such purpose, or written consent without a meeting in accordance with the DGCL, of the holders of at least a majority of the outstanding shares of Preferred Stock (the "**Required Holders**"), voting separately as a single class, and with such other stockholder approval, if any, as may then be required pursuant to the DGCL and the Certificate of Incorporation;

WHEREAS, the Required Holders pursuant to the Certificate of Designations have consented, in accordance with the DGCL, on April 8, 2025, to this Amendment on the terms set forth herein; and

WHEREAS, the Board has duly adopted resolutions proposing to adopt this Amendment and declaring this Amendment to be advisable and in the best interest of the Company and its stockholders.

NOW, THEREFORE, this Amendment has been duly adopted in accordance with Section 242 of the DGCL and has been executed by a duly authorized officer of the Company as of the date first set forth above to amend the terms of the Certificate of Designations as follows:

1. Section 33(ii) of the Certificate of Designations is hereby amended and restated to read as follows:

(ii) "**Stated Value**" shall mean (i) if the Stated Value Stockholder Approval is not obtained, from July 1, 2023, until the Maturity Date, $1,000 per share, and (ii) following the Stated Value Stockholder Approval, from January 1, 2025, until the Maturity Date, $1,100 per share.

2. Section 33(nn) of the Certificate of Designations is hereby amended and restated to read as follows (emphasis added):

(nn) "**Installment Date**" means (i) July 1, 2023, and thereafter, the first Trading Day of each calendar month immediately following the previous Installment Date until February 1, 2024, (ii) July 1, 2024, and thereafter, the first Trading Day of each calendar month immediately following the previous Installment Date until December 31, 2024, (iii) <u>April 1, 2025, and thereafter, the first Trading Day of each calendar month immediately following the previous Installment Date until the Maturity Date</u>, and (iv) the Maturity Date.

3. Section 33(kk) of the Certificate of Designations is hereby amended and restated to read as follows (emphasis added):

(kk) "**Installment Schedule Amount**" means 882.35 Preferred Shares.

4. Section 33(tt) of the Certificate of Designations is hereby amended and restated to read as follows (emphasis added):

(tt) "**Maturity Date**" shall mean <u>June 30, 2025</u>; provided, however, the Maturity Date may be extended at the option of a Holder (i) in the event that, and for so long as, a Triggering Event shall have occurred and be continuing or any event shall have occurred and be continuing that with the passage of time and the failure to cure would result in a Triggering Event or (ii) through the date that is twenty (20) Business Days after the consummation of a Fundamental Transaction in the event that a Fundamental Transaction is publicly announced or a Change of Control Notice is delivered prior to the Maturity Date, provided further that if a Holder elects to convert some or all of its Preferred Shares pursuant to Section 4 hereof, and the Conversion Amount would be limited pursuant to Section 4(d) hereunder, the Maturity Date shall automatically be extended until such time as such provision shall not limit the conversion of such Preferred Shares.

5. Section 33 of the Certificate of Designations is hereby amended to include a new subsection (ttt) as follows:

(ttt) "**Stated Value Stockholder Approval**" means the approval of the Company's stockholders at an annual meeting of stockholders or special meeting of stockholders providing for the increase of the aggregate Stated Value of the Preferred Shares outstanding as of the record date for such meeting to an amount equal to 110% of the aggregate Stated Value of the Preferred Shares outstanding as of the record date of such meeting, in compliance with the rules and regulations of the Principal Market.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Company has caused this Amendment to be signed by its duly authorized officer this 8th day of April, 2025.

TNF PHARMACEUTICALS, INC.

By: */s/ Mitchell Glass*
Name: Mitchell Glass
Title: President and Chief Medical Officer

Exhibit 3.6.1

CERTIFICATE OF AMENDMENT OF
CERTIFICATE OF DESIGNATIONS OF
SERIES F-1 CONVERTIBLE PREFERRED STOCK OF
TNF PHARMACEUTICALS, INC.

PURSUANT TO SECTION 242 OF THE
DELAWARE GENERAL CORPORATION LAW

This Certificate of Amendment to the Certificate of Designations of Series F-1 Convertible Preferred Stock (the "**Amendment**") is dated as of April 8, 2025.

WHEREAS, the board of directors (the "**Board**") of TNF Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), pursuant to the authority granted to it by the Company's Certificate of Incorporation (as amended, the "**Certificate of Incorporation**") and Section 151(g) of the Delaware General Corporation Law (the "**DGCL**"), has previously fixed the rights, preferences, restrictions and other matters relating to a series of the Company's preferred stock, consisting of 5,050 authorized shares of preferred stock, classified as Series F-1 Convertible Preferred Stock (the "**Preferred Stock**"), and the Certificate of Designations of the Preferred Stock (the "**Certificate of Designations**") was initially filed with the Secretary of State of the State of Delaware on May 21, 2024, evidencing such terms;

WHEREAS, pursuant to Section 31(b) of the Certificate of Designations, the Certificate of Designations or any provision thereof may be amended by obtaining the affirmative vote at a meeting duly called for such purpose, or written consent without a meeting in accordance with the DGCL, of the holders of at least a majority of the outstanding shares of Preferred Stock (the "**Required Holders**"), voting separately as a single class, and with such other stockholder approval, if any, as may then be required pursuant to the DGCL and the Certificate of Incorporation;

WHEREAS, the Required Holders pursuant to the Certificate of Designations have consented, in accordance with the DGCL, on April 8, 2025, to this Amendment on the terms set forth herein; and

WHEREAS, the Board has duly adopted resolutions proposing to adopt this Amendment and declaring this Amendment to be advisable and in the best interest of the Company and its stockholders.

NOW, THEREFORE, this Amendment has been duly adopted in accordance with Section 242 of the DGCL and has been executed by a duly authorized officer of the Company as of the date first set forth above to amend the terms of the Certificate of Designations as follows:

1. Section 32(cc) of the Certificate of Designations is hereby amended and restated to read as follows (emphasis added):

(ii) "**Excluded Securities**" means (i) shares of Common Stock or standard options to purchase Common Stock issued or issuable to directors, officers, employees or other service providers of the Company for services rendered to the Company in their capacity as such pursuant to an Approved Stock Plan, provided that (A) all such issuances (taking into account the shares of Common Stock issuable upon exercise of such awards) after the Subscription Date pursuant to this clause (i) do not, in the aggregate, exceed more than 2% of the Common Stock issued and outstanding as of the date of such issuance and (B) the exercise price of any such options is not lowered and none of such options are amended to increase the number of shares issuable thereunder; (ii) shares of Common Stock issued or issuable upon the conversion or exercise of Convertible Securities (other than shares of Common Stock issued or issuable pursuant to an Approved Stock Plan that are covered by clause (i) above) issued prior to the Subscription Date, provided that the conversion price of any such Convertible Securities (other than standard options to purchase Common Stock issued pursuant to an Approved Stock Plan that are covered by clause (i) above) is not lowered (other than in accordance with the terms thereof in effect as of the Subscription Date) from the conversion price in effect as of the Subscription Date (whether pursuant to the terms of such Convertible Securities or otherwise), none of such Convertible Securities (other than those issued pursuant to an Approved Stock Plan that are covered by clause (i) above) are amended to increase the number of shares issuable thereunder and none of the terms or conditions of any such Convertible Securities (other than those issued pursuant to an Approved Stock Plan that are covered by clause (i) above) are otherwise materially changed in any manner that adversely affects any of the Buyers; (iii) the shares of Common Stock issuable upon conversion of the Preferred Shares or otherwise pursuant to the terms of this Certificate of Designations; (iv) the shares of Common Stock issuable upon exercise of the Warrants; and, (v) securities issued as consideration for the acquisition of another entity by the Company by merger, purchase of substantially all of the assets or other reorganization or bona fide joint venture agreement, provided that such issuance is approved by the majority of the disinterested directors of the Company and provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the Restricted Period (as defined in the Securities Purchase Agreement) and such issuance does not, in the aggregate, exceed more than 5% of the shares of Common Stock issued and outstanding immediately prior to the Subscription Date.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Company has caused this Amendment to be signed by its duly authorized officer this 8th day of April, 2025.

TNF PHARMACEUTICALS, INC.

By: */s/ Mitchell Glass*
Name: Mitchell Glass
Title: President and Chief Medical Officer

Exhibit 4.1

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXHANGE ACT OF 1934, AS AMENDED

This description of the capital stock of TNF Pharmaceuticals, Inc., a Delaware corporation ("we," "our" and the "Company") is intended as a summary and is qualified in its entirety by reference to our Certificate of Incorporation (the "Certificate of Incorporation") and the Bylaws (the "Bylaws") as currently in effect, copies of which are filed as exhibits to our Annual Report on Form 10-K and are incorporated herein by reference.

Authorized Capital Stock

Our authorized capital stock consists of 300,000,000 shares, of which 250,000,000 are shares of Common Stock, par value $0.001 per share (the "Common Stock"), and 50,000,000 are shares of preferred stock, par value $0.001 per share, 1,990,000 of which have been designated as Series C Convertible Preferred Stock (the "Series C Preferred Stock"), 211,353 of which have been designated as Series D Convertible Preferred Stock (the "Series D Preferred Stock"), 100,000 of which have been designated as Series E Junior Participating Preferred Stock, 15,000 of which have been designated as Series F Convertible Preferred Stock (the "Series F Preferred Stock"), 5,050 of which have been designated as Series F-1 Convertible Preferred Stock (the "Series F-1 Preferred Stock") and 12,826,273 of which have been designated as Series G Convertible Preferred Stock (the "Series G Preferred Stock").

Common Stock

Voting Rights

Each stockholder has one vote for each share of Common Stock held on all matters submitted to a vote of stockholders. A stockholder may vote in person or by proxy. Elections of directors are determined by a plurality of the votes cast and all other matters are decided by a majority of the votes cast by those stockholders entitled to vote and present in person or by proxy.

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of Common Stock will be able to elect all of our directors. Our Amended and Restated Certificate of Incorporation and Bylaws provide that stockholder actions may be affected at a duly called meeting of stockholders or pursuant to written consent of the majority of stockholders. A special meeting of stockholders may be called by the president, chief executive officer or the board of directors pursuant to a resolution approved by the majority of the board of directors.

Dividend Rights

The holders of outstanding shares of Common Stock are entitled to receive dividends out of funds legally available at the times and in the amounts that our board of directors may determine, provided that required dividends, if any, on preferred stock have been paid or provided for. So long as any shares of Series F Preferred Stock, Series G Preferred Stock or Series F-1 Preferred Stock are outstanding, as they are at this time, we are not able to declare or pay any cash dividend or distribution on any of our capital stock (other than as required by the Certificate of Designations of the Series F Preferred Stock (the "Series F Certificate of Designations"), Certificate of Designations of the Series F-1 Preferred Stock ("Series F-1 Certificate of Designations") and the Certificate of Designations of the Series G Preferred Stock ("Series G Certificate of Designations" and, together with the Series F Certificate of Designations and the Series F-1 Certificate of Designations, the "Certificate of Designations")) without the prior written consent of the Required Holders (as defined in the applicable Certificate of Designations).

To date we have not paid or declared cash distributions or dividends on our Common Stock and do not currently intend to pay cash dividends on our Common Stock in the foreseeable future. We intend to retain all earnings, if and when generated, to finance our operations. The declaration of cash dividends in the future will be determined by the board of directors based upon our earnings, financial condition, capital requirements and other relevant factors.

No Preemptive or Similar Rights

Holders of our Common Stock do not have preemptive rights, and Common Stock is not convertible or redeemable.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders and remaining after payment to holders of preferred stock of the amounts, if any, to which they are entitled, are distributable ratably among the holders of our Common Stock subject to any senior class of securities.

The Nasdaq Capital Market Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "TNFA".

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Securities Transfer Corporation, 2901 Dallas Pkwy Suite 380, Plano, TX 75093.

Preferred Stock

We may issue any class of preferred stock in any series. Our board of directors has the authority, subject to limitations prescribed under Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the Common Stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the Company and may adversely affect the market price of Common Stock and the voting and other rights of the holders of Common Stock.

Series C Convertible Preferred Stock

Rank

The Series C Preferred Stock ranks (1) on parity with Common Stock on an "as converted" basis, (2) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series C Preferred Stock, (3) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series C Preferred Stock, and (4) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series C Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

Conversion Rights

Each share of the Series C Preferred Stock is convertible into one (1) share of Common Stock, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of Common Stock if, as a result of such conversion, the holder would own more than 4.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of the shares of Common Stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of the shares of Common Stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividend Rights

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends are payable on shares of Series C Preferred Stock.

Voting Rights

Except as provided in the Certificate of Designation of Series C Convertible Preferred Stock (the "Series C Certificate of Designation") or as otherwise required by law, the holders of Series C Preferred Stock will have no voting rights. However, we may not, without the consent of holders of a majority of the outstanding shares of Series C Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock, or enter into any agreement with respect to the foregoing.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series C Preferred Stock are entitled to receive, *pari passu* with the holders of Common Stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into Common Stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the beneficial ownership limitation, as described above.

Exchange Listing

Akers does not plan on making an application to list the shares of Series C Preferred Stock on the Nasdaq, any national securities exchange or other nationally recognized trading system. Our Common Stock issuable upon conversion of the Series C Preferred Stock is listed on the Nasdaq under the symbol "TNF".

Failure to Deliver Conversion Shares

If we fail to timely deliver shares of Common Stock upon conversion of the Series C Preferred Stock (the "Series C Conversion Shares") within the time period specified in the Series C Certificate of Designation (within two trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), then we are obligated to pay to the holder, as liquidated damages, an amount equal to $50 per trading day (increasing to $100 per trading day after the third trading day and $200 per trading day after the tenth trading day) for each $5,000 of Series C Conversion Shares for which the Series C Preferred Stock being converted are not timely delivered. If we make such liquidated damages payments, we are not also obligated to make Series C Buy-In (as defined below) payments with respect to the same Series C Conversion Shares.

Compensation for Series C Buy-In on Failure to Timely Deliver Shares

If we fail to timely deliver the Series C Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the holder of the Series C Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Series C Buy-In"), then we are obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Series C Conversion Shares that we were required to deliver times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Series C Preferred Stock and equivalent number of Series C Conversion Shares for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of Common Stock that would have been issued had we timely complied with our conversion and delivery obligations.

Subsequent Rights Offerings; Pro Rata Distributions

If we grant, issue or sell any Common Stock equivalents pro rata to the record holders of any class of shares of Common Stock (the "Series C Purchase Rights"), then a holder of Series C Preferred Stock will be entitled to acquire, upon the terms applicable to such Series C Purchase Rights, the aggregate Series C Purchase Rights which the holder could have acquired if the holder had held the number of shares of Common Stock acquirable upon conversion of the Series C Preferred Stock (without regard to any limitations on conversion). If we declare or make any dividend or other distribution of our assets (or rights to acquire our assets) to holders of Common Stock, then a holder of Series C Preferred Stock is entitled to participate in such distribution to the same extent as if the holder had held the number of shares of Common Stock acquirable upon complete conversion of the Series C Preferred Stock (without regard to any limitations on conversion).

Fundamental Transaction

If, at any time while the Series C Preferred Stock is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each a "Series C Preferred Stock Fundamental Transaction"), then upon any subsequent conversion of Series C Preferred Stock, the holder will receive, for each Series C Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Series C Preferred Stock Fundamental Transaction (without regard to the beneficial ownership limitation), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Series C Preferred Stock Alternate Consideration") receivable as a result of such Series C Preferred Stock Fundamental Transaction by a holder of the number of shares of Common Stock for which the Series C Preferred Stock is convertible immediately prior to such Series C Preferred Stock Fundamental Transaction (without regard to the beneficial ownership limitation). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Series C Preferred Stock Alternate Consideration based on the amount of Series C Preferred Stock Alternate Consideration issuable in respect of one share of Common Stock in such Series C Preferred Stock Fundamental Transaction. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Series C Preferred Stock Fundamental Transaction, then the holder will be given the same choice as to the Series C Preferred Stock Alternate Consideration it receives upon automatic conversion of the Series C Preferred Stock following such Series C Preferred Stock Fundamental Transaction.

Series D Convertible Preferred Stock

Rank

The Series D Preferred Stock ranks (1) on parity with Common Stock on an "as converted" basis, (2) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series D Preferred Stock, (3) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series D Preferred Stock, and (4) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series D Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

Conversion Rights

A holder of Series D Preferred Stock is entitled at any time to convert any whole or partial number of shares of Series D Preferred Stock into shares of our Common Stock, determined by dividing the stated value equal to $0.01 by the conversion price of $0.01 per share. A holder of Series D Preferred Stock is prohibited from converting Series D Preferred Stock into shares of Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our Common Stock then issued and outstanding (with such ownership restriction referred to as the "Series D Beneficial Ownership Limitation") immediately after giving effect to the issuance of the shares of Common Stock issuable upon conversion of the Series D Preferred Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. The conversion rate of the Series D Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividend Rights

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series D Preferred Stock are entitled to receive dividends on shares of Series D Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends are payable on shares of Series D Preferred Stock.

Voting Rights

Subject to the Series D Beneficial Ownership Limitation, on any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of a meeting), each holder, in its capacity as such, shall be entitled to cast the number of votes equal to the number of whole shares of our Common Stock into which the Series D Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Series D Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of the Certificate of Designation of Series D Convertible Preferred Stock (the "Series D Certificate of Designation"), the holders of Series D Preferred Stock, in their capacity as such, shall vote together with the holders of our Common Stock and any other class or series of stock entitled to vote thereon as a single class.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series D Preferred Stock are entitled to receive, *pari passu* with the holders of Common Stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series D Preferred Stock been converted into Common Stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Series D Beneficial Ownership Limitation, as described above.

Exchange Listing

Series D Preferred Stock is not listed on the Nasdaq, any national securities exchange or other nationally recognized trading system. Our Common Stock issuable upon conversion of the Series D Preferred Stock is listed on the Nasdaq under the symbol "TNFA".

Failure to Deliver Conversion Shares

If we fail to timely deliver shares of Common Stock upon conversion of the Series D Preferred Stock (the "Series D Conversion Shares") within the time period specified in the Series D Certificate of Designation (within two trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), then we are obligated to pay to the holder, as liquidated damages, an amount equal to $25 per trading day (increasing to $50 per trading day on the third trading day and $100 per trading day on the sixth trading day) for each $5,000 of stated value of Series D Preferred Stock being converted which are not timely delivered. If we make such liquidated damages payments, we are not also obligated to make Series D Buy-In (as defined below) payments with respect to the same Series D Conversion Shares.

Compensation for Series D Buy-In on Failure to Timely Deliver Shares

If we fail to timely deliver the Series D Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the holder of the Series D Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Series D Buy-In"), then we are obligated to (A) pay in cash to such holder (in addition to any other remedies available to or elected by such holder) the amount, if any, by which (x) such holder's total purchase price (including any brokerage commissions) for the shares of Common Stock so purchased exceeds (y) the product of (1) the aggregate number of Series D Conversion Shares that such holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of such holder, either reissue (if surrendered) the shares of Series D Preferred Stock equal to the number of shares of Series D Preferred Stock submitted for conversion (in which case, such conversion shall be deemed rescinded) or deliver to such holder the number of Series D Conversion Shares that would have been issued if we had timely complied with its delivery requirements.

Series E Junior Participating Preferred Stock

In September 2020, our board of directors declared a dividend of one preferred share purchase right (a "Right") for each of our issued and outstanding shares of Common Stock, payable to the stockholders of record on September 21, 2020. Each such Right entitles the registered holder, subject to the terms of a Rights Agreement, dated as of September 9, 2020, between the Company and VStock Transfer, LLC (the "Rights Agreement"), to purchase from the Company one one-thousandth of a share of the Company's Series E Junior Participating Preferred Stock, with a stated value of $0.001 (the "Series E Preferred Stock"), at $15.00, subject to certain adjustments. Pursuant to the Agreement and Plan of Merger, dated November 11, 2020, by and among the Company, XYZ Merger Sub Inc., a wholly owned subsidiary of the Company, and MyMD Pharmaceuticals, Inc., we agreed to take any and all necessary action to terminate such shareholder rights plan prior to closing of the merger.

The Rights will not be exercisable until the earlier to occur of (i) the tenth business day following a public announcement or filing that a person has, or affiliates or associates of such person have, become an "Acquiring Person," which is defined as a person, or affiliates or associates of such person, who, at any time after the date of the Rights Agreement, has acquired, or obtained the right to acquire, Beneficial Ownership of 10% or more of our outstanding shares of Common Stock, subject to certain exceptions, or (ii) the tenth business day (or such later date as may be determined by action of our board of directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person becoming an Acquiring Person (the earlier of such dates being called the "Distribution Date"). Beneficial Ownership, as defined in the Rights Agreement, includes certain interests in securities created by derivatives contracts, which are beneficially owned, directly or indirectly, by a counterparty (or any of such counterparty's affiliates or associates) under any derivatives contract to which such person or any of such person's affiliates or associates is a receiving party (as such terms are defined in Rights Agreement), subject to certain limitations.

Until the Distribution Date, (i) the Rights will be evidenced by the Common Stock certificates (or, for uncertificated shares of Common Stock, by the book-entry account that evidences record ownership of such shares) and will be transferred with, and only with, such Common Stock, and (ii) new Common Stock certificates issued after September 21, 2020 will contain a legend incorporating the Rights Agreement by reference (for book entry Common Stock, this legend will be contained in the notations in book entry accounts). Until the earlier of the Distribution Date and the Expiration Date (defined below), the transfer of any shares of Common Stock outstanding on September 21, 2020 will also constitute the transfer of the Rights associated with such shares of Common Stock. As soon as practicable after the Distribution Date, VStock Transfer, LLC (the "Rights Agent") will send by first-class, insured, postage prepaid mail, to each record holder of the Common Stock as of the close of business on the Distribution Date separate rights certificates evidencing the Rights ("Right Certificates"), and such Right Certificates alone will evidence the Rights. We may choose book entry in lieu of physical certificates, in which case, references to "Rights Certificates" shall be deemed to mean the uncertificated book entry representing the Rights.

The Rights, which are not exercisable until the Distribution Date, expire upon the earliest to occur of (i) the close of business on September 8, 2021; (ii) the time at which the Rights are redeemed or exchanged pursuant to the Rights Agreement; and (iii) the time at which the Rights are terminated upon the closing of any merger or other acquisition transaction involving the Company pursuant to a merger or other acquisition agreement that has been approved by our board of directors prior to any person becoming an Acquiring Person (the earliest of (i), (ii), and (iii) is referred to as the "Expiration Date").

Each share of Series E Preferred Stock will be entitled to a preferential per share dividend rate equal to the greater of (i) $0.001 and (ii) the sum of (1) 1,000 times the aggregate per share amount of all cash dividends, plus (2) 1,000 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions other than certain dividends or subdivisions of the outstanding shares of Common Stock. Each shares of Series E Preferred Stock will entitle the holder thereof to a number of votes equal to 1,000 on all matters submitted to a vote of our stockholders. In the event of any merger, consolidation or other transaction in which shares of Common Stock are exchanged, each share of Series E Preferred Stock will be entitled to receive 1,000 times the amount received per one share of Common Stock. Pursuant to the Rights Agreement, the preferential rates noted above may be adjusted in the event that we (i) pay dividends in Common Stock, (ii) subdivide the outstanding Common Stock or (iii) combine outstanding Common Stock into a smaller number of shares.

The purchase price payable, and the number of shares of Series E Preferred Stock or other securities or property issuable, upon exercise of the Rights are subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend, or a subdivision, combination or reclassification of the Series E Preferred Stock, (ii) if the holders of the Series E Preferred Stock are granted certain rights, options or warrants to subscribe for the applicable Series E Preferred Stock or securities convertible into the applicable Series E Preferred Stock at less than the current market price of the applicable Series E Preferred Stock, or (iii) upon the distribution to holders of Series E Preferred Stock of evidences of indebtedness, cash (excluding regular quarterly cash dividends), assets (other than dividends payable in Series E Preferred Stock) or subscription rights or warrants (other than those referred to in (ii) immediately above). The number of outstanding Rights and the number of one one-thousandths of a shares of Series E Preferred Stock issuable upon exercise of each Right are also subject to adjustment in the event of a stock split, reverse stock split, stock dividends and other similar transactions.

With some exceptions, no adjustment in the purchase price relating to a Right will be required until cumulative adjustments amount to at least one percent (1%) of the purchase price relating to the Right. No fractional shares of Series E Preferred Stock are required to be issued (other than fractions which are integral multiples of one one-thousandth of a share of Series E Preferred Stock) and, in lieu of the issuance of fractional shares, we may make an adjustment in cash based on the market price of the Series E Preferred Stock on the trading date immediately prior to the date of exercise.

In the event that a person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right will thereafter have the right to receive, upon exercise, Common Stock (or, in certain circumstances, other securities, cash or other assets of the Company) having a value equal to two (2) times the exercise price of the Right. Notwithstanding any of the foregoing, following the occurrence of a person becoming an Acquiring Person, all Rights that are, or (under certain circumstances specified in the Rights Agreement) were, beneficially owned by any Acquiring Person (or by certain related parties) will be null and void and any holder of such Rights (including any purported transferee or subsequent holder) will be unable to exercise or transfer any such Rights. However, Rights are not exercisable following the occurrence of a person becoming an Acquiring Person until the Distribution Date.

In the event that, after a person or a group of affiliated or associated persons has become an Acquiring Person, the Company is acquired in a merger or other business combination transaction, or 50% or more of the Company's assets or earning power are sold, proper provision will be made so that each holder of a Right will thereafter have the right to receive, upon the exercise of a Right that number of shares of Common Stock of the person with whom the Company has engaged in the foregoing transaction (or its parent) that at the time of such transaction have a market value of two (2) times the exercise price of the Right.

At any time before any person or group of affiliated or associated persons becomes an Acquiring Person, our board of directors may redeem the Rights in whole, but not in part, at a price of $0.001 per Right (subject to certain adjustments) (the "Redemption Price"). The redemption of the Rights may be made effective at such time, on such basis and with such conditions as our board of directors in its sole discretion may establish. Immediately upon the action of the board of directors electing to redeem or exchange the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price.

Our board of directors may, at its option, at any time after the first occurrence of a Flip-in Event (as defined in the Rights Agreement), exchange all or part of the then outstanding and exercisable Rights for shares of Common Stock at an exchange ratio of one share of Common Stock per Right, appropriately adjusted to reflect any stock split, stock dividend or similar transaction occurring after the effective date. However, the board of directors shall not effect such an exchange at any time after any person, together with all affiliates and associates of such person, becomes a beneficial owner of 50% or more of the outstanding shares of Common Stock. Immediately upon the action of our board of directors to exchange the Rights, the Rights will terminate and the only right of the holders of Rights will be to receive the number of shares of Common Stock equal to the number of Rights held by such holder multiplied by the exchange ratio.

Until a Right is exercised or exchanged, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

Our board of directors may amend or supplement the Rights Agreement without the approval of any holders of Rights at any time so long as the Rights are redeemable. At any time the Rights are no longer redeemable, no such supplement or amendment may (i) adversely affect the interests of the holders of Rights (other than an Acquiring Person or an affiliate or associate of an Acquiring Person), (ii) cause the Rights Agreement to become amendable other than in accordance with Section 27 of the Rights Agreement, or (iii) cause the Rights again to become redeemable.

Series F Convertible Preferred Stock

The following are the principal terms of the Series F Preferred Stock:

Dividends

The holders of the Series F Preferred Stock will be entitled to dividends of 10.0% per annum, compounded monthly, which will be payable in cash or shares of Common Stock at the Company's option, in accordance with the terms of the certificate of designation of the Series F Preferred Stock (the "Series F Certificate of Designation"). Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F Certificate of Designation), shares of Series F Preferred Stock will accrue dividends at the rate of 15.0% per annum. Upon conversion or redemption, the holders of shares of Series F Preferred Stock are also entitled to receive a dividend make-whole payment.

Voting Rights

Except as required by applicable law, the holders of the Series F Preferred Shares are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F Preferred Shares is entitled to be calculated assuming a conversion price of $60.21 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the purchase agreement executed in connection with the issuance of the Series F Preferred Stock, subject to certain beneficial ownership limitations as set forth in the Series F Certificate of Designations.

Liquidation

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the each holder shares of the Series F Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount per share of Series F Preferred Stock equal to the greater of (A) 125% of the stated value of such share of Series F Preferred Stock (plus any applicable make-whole amount, unpaid late charge or other applicable amount) on the date of such payment and (B) the amount per share such holder would receive if such holder converted such share of Series F Preferred Stock into Common Stock immediately prior to the date of such payment. All shares of capital stock of the Company shall be junior in rank to all shares of Series F Preferred Stock with respect to the preferences as to payments upon the liquidation.

Conversion

The Series F Preferred Stock is convertible into shares of Common Stock (the "Conversion Shares"). The initial conversion price, subject to adjustment as set forth in the Series F Certificate of Designation, was $2.255 (pre-split) (the "Conversion Price"). The Conversion Price can be adjusted as set forth in the Series F Certificate of Designation for stock dividends and stock splits or the occurrence of a fundamental transaction (generally including any reorganization, recapitalization or reclassification of the Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the outstanding Common Stock). The Conversion Price is also subject to "full ratchet" price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Conversion Price (subject to certain exceptions).

Following the Reverse Stock Split, the Conversion Price was adjusted to $3.18 per share pursuant to the terms of the Series F Certificate of Designations. As of December 31, 2024, Series F Conversion Price was equal to $1.30.

If any shares of Series F Preferred Stock are converted or reacquired by us, such shares shall resume the status of authorized but unissued shares of Series F Preferred Stock of the Company and shall no longer be designated as Series F Preferred Stock.

The Company is required to redeem the shares of Series F Preferred Stock in 12 equal monthly installments, commencing on July 1, 2023. The amortization payments due upon such redemption are payable, at the company's election, in cash, or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Conversion Price then in effect and (ii) the greater of (A) a 80% of the average of the three lowest closing prices of the Company's Common Stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) the Floor Price (as defined below). For purposes of the Series F Certificate of Designation, the "Floor Price" means $6.60 (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Stock Market; provided that if the amount set forth in clause B is the lowest effective price, the Company will be required to pay the amortization payment in cash.

On April 5, 2024, the Company entered into an Omnibus Waiver and Amendment (the "Omnibus Agreement") with the Required Holders (as defined in the Series F Certificate of Designations). Pursuant to the Omnibus Agreement, the Required Holders agreed (i) to defer payment of the monthly installment amounts due on March 1, 2024, and April 1, 2024 (the "Installments"), under Section 9(a) of the Series F Certificate of Designations, until May 1, 2024, and (ii) to waive any breach or violation of the Series F Purchase Agreement, the Series F Certificate of Designations, or the Series F Warrants resulting from missing the Installments. The Company may require holders to convert their Series F Preferred Shares into shares of Common Stock if the closing price of the Common Stock exceeds $6.765 per share (as adjusted for the Reverse Stock Split) (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock exceeds $3,000,000 per day during the same period and certain equity conditions described in the Series F Certificate of Designations are satisfied.

On May 20, 2024, the Company entered into an Omnibus Waiver, Consent, Notice and Amendment (the "May 2024 Series F Agreement") with the Required Holders (as defined in the Series F Certificate of Designations). Pursuant to the May 2024 Series F Agreement, the Required Holders agreed to (i) amend the Series F Purchase Agreement to amend certain terms relating to purchase rights thereunder, (ii) waive certain rights under the Series F Purchase Agreement and Series F Certificate of Designations in respect of the issuance of the Company's Series F-1 Convertible Preferred Stock, with a par value of $0.001 per share and a stated value of $1,000 per share ("Series F-1 Preferred Stock"), the Company's Series G Convertible Preferred Stock, with a par value of $0.001 per share and a stated value of $1,000 per share ("Series G Preferred Stock"), and entrance by the Company into the Purchase Agreements (as defined herein), (iii) waive the requirement that the Company reserve for issuance a sufficient number of shares of Common Stock as required by the Series F Certificate of Designations, the Series F Purchase Agreement and Series F Warrants, until such time as the Company obtains the Stockholder Approval (as defined herein), and (iv) consent to the issuance of the Series F-1 Preferred Stock and Series G Preferred Stock as required pursuant to certain terms of the Series F Certificate of Designations, the Series F Purchase Agreement and the Series F Warrants, as applicable. The Company and the Required Holders further agreed pursuant to the May 2024 Series F Agreement, to amend the Series F Certificate of Designations by filing a Certificate of Amendment to the Series F Certificate of Designations (the "Series F Certificate of Amendment") with the Secretary of State of the State of Delaware. The Series F Certificate of Amendment amends the Series F Certificate of Designations to (i) extend the maturity date to December 31, 2024, (ii) permit and modify certain procedures related to the payment of installment amounts with respect to the Installment Dates (as defined in the Series F Certificate of Designations) falling between (and including) July 1, 2024, and (and including) August 1, 2024, thereunder, and (iii) modify the schedule of Installment Dates.

On November 7, 2024, each holder of the Series F Preferred Shares agreed that payment by the Company of any Installment Amounts (as defined in the Series F Certificate of Designations) that are accrued and are unredeemed, unconverted and/or otherwise unpaid as of November 7, 2024, will be deferred until December 1, 2024.

On April 8, 2025, the Company entered into an Omnibus Amendment Agreement ("April 2025 Amendment Agreement") with the Required Holders (as defined in the Series F Certificate of Designations and Series F-1 Certificate of Designations), pursuant to which, the Required Holders agreed to amend (i) the Series F-1 Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F-1 Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F-1 Certificate of Amendment"), (ii) the Series F Certificate of Designations, as described below, by filing a Certificate of Amendment to the Series F Certificate of Designations with the Secretary of State of the State of Delaware (the "April 2025 Series F Certificate of Amendment"), (iii) the Series F-1 Purchase Agreement, to amend the definition of "Excluded Securities" such that the definition includes the issuance of common stock issued after the date of the Seres F-1 Purchase Agreement pursuant to an Approved Stock Plan (as defined in the Series F-1 Purchase Agreement), which in the aggregate does not exceed more than 2% of the shares of common stock issued and outstanding as of the date of such issuance (the "Excluded Securities Modification"), and (iv) to amend the term of the Series F-1 Short-Term Warrants to be five years from the date of issuance. In addition, in consideration of the foregoing, the Company agreed to reduce the size of the board of directors of the Company to no more than six directors, no later than the Company's 2025 annual meeting of stockholders.

The April 2025 Series F Certificate of Amendment amends the Series F Certificate of Designations to (A) (i) extend the maturity date to June 30, 2025, and (ii) modify the schedule of Installment Dates (as defined in the Series F Certificate of Designations), in each case, effective as of December 31, 2024, and (B) subject to obtaining the approval of the Company's stockholders, effective January 1, 2025, increase the aggregate Stated Value of the Series F Preferred Stock outstanding to an amount equal to 110% of the aggregate Stated Value of the Series F Preferred Stock outstanding. The April 2025 Series F Certificate of Amendment was filed with the Secretary of State of the State of Delaware, effective as of April 8, 2025.

Exchange Cap

The Series F Certificate of Designations provided that the Series F Preferred Stock would not be convertible into shares of Common Stock in excess of 19.99% of the shares of Common Stock outstanding as of the date immediately prior to the date of the prospectus supplement under which the shares of Series F Preferred Stock were registered (the "Issuable Maximum") except in the event that the Company (A) obtained the stockholder approval for issuances of shares of Common Stock in excess of the Issuable Maximum or ("Stockholder Approval") or (B) obtained a written opinion from outside counsel to the Company that such approval is not required. Until such approval or such written opinion was obtained, no holder of Series F Preferred Stock would be issued in the aggregate more shares of Common Stock than such holder's pro rata share of the Issuable Maximum. In the event that after July 1, 2023, the Company had not obtained the Stockholder Approval or was not otherwise permitted to issue shares in excess of the Issuable Maximum, then a holder of Series F Preferred Stock could elect to have his or her shares of Series F Preferred Stock redeemed for cash. The Company received the Stockholder Approval on July 31, 2023.

Optional Conversion

The Series F Preferred Stock can be converted at the option of the holder at any time and from time to time after the original issuance date. Holders shall effect conversions by providing us with the form of conversion notice (the "Notice of Conversion") specifying the number of shares of Series F Preferred Stock to be converted, the number of shares of Series F Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable holder delivers by email such Notice of Conversion to us.

Mandatory Conversion

If on any day after the issuance of the shares of Series F Preferred Stock the closing price of the Common Stock has exceeded 300% of the Conversion Price per share (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock has exceeded $3,000,000 per trading day during the same period and certain equity conditions described in the Series F Certificate of Designation are satisfied (the "Mandatory Conversion Date"), we shall deliver written notice of the Mandatory Conversion (as defined below) to all holders on the Mandatory Conversion Date and, on such Mandatory Conversion Date, we shall convert all of each holder's shares of Series F Preferred Stock into Conversion Shares at the then effective Conversion Price (the "Mandatory Conversion"). If any of the Equity Conditions shall cease to be satisfied at any time on or after the Mandatory Conversion Date through and including the actual delivery of all of the Conversion Shares to the holders, the Mandatory Conversion shall be deemed withdrawn and void ab initio.

Beneficial Ownership Limitation

The Series F Preferred Stock cannot be converted to Common Stock if the holder and its affiliates would beneficially own more than 4.99% or 9.99% at the election of the holder of the outstanding Common Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Series F-1 Convertible Preferred Stock

The following are the principal terms of the Series F-1 Preferred Stock:

Dividends

The holders of the Series F-1 Preferred Stock are entitled to dividends of 10% per annum, compounded monthly, which are payable in arrears monthly in cash or shares of Common Stock at the Company's option, in accordance with the terms of the Series F-1 Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series F-1 Certificate of Designations), the Series F-1 Preferred Stock will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series F-1 Preferred Stock are also entitled to receive a dividend make-whole payment.

Voting Rights

Except as required by applicable law, the holders of the Series F-1 Preferred Shares are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F-1 Preferred Shares is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the purchase agreement executed in connection with the issuance of the Series F-1 Preferred Stock, subject to certain beneficial ownership limitations as set forth in the Series F-1 Certificate of Designations.

Liquidation

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, each holder of shares of the Series F-1 Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount per share of Series F-1 Preferred Stock equal to the greater of (A) 125% of the stated value of such share of Series F-1 Preferred Stock (plus any applicable make-whole amount, unpaid late charge or other applicable amount) on the date of such payment and (B) the amount per share such holder would receive if such holder converted such share of Series F-1 Preferred Stock into Common Stock immediately prior to the date of such payment. All shares of capital stock of the Company shall be junior in rank to all shares of Series F-1 Preferred Stock with respect to the preferences as to payments upon the liquidation.

Conversion

The Series F-1 Preferred Stock became convertible upon issuance into Common Stock (the "Series F-1 Conversion Shares") at the election of the holder at any time at the initial conversion price of $1.816. The Series F-1 Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series F-1 Conversion Price (subject to certain exceptions). As of December 31, 2024, Series F Conversion Price was equal to $1.30.

The Company is required to redeem the Series F-1 Preferred Stock in seven (7) equal monthly installments, commencing on December 1, 2024. The amortization payments due upon such redemption are payable, at the Company's election, in cash at 105% of the applicable Installment Redemption Amount (as defined in the Series F-1 Certificate of Designations), or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Series F-1 Conversion Price then in effect and (ii) the greater of (A) 80% of the average of the three lowest closing prices of the Company's Common Stock during the thirty consecutive trading day period ending and including the trading day immediately prior to the date the amortization payment is due or (B) $0.364, which is 20% of the "Minimum Price" (as defined in Nasdaq Stock Market Rule 5635) on the date in which the Series F-1 Stockholder Approval (as defined herein) was obtained or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Capital Market, and, in each case, subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events, which amortization amounts are subject to certain adjustments as set forth in the Series F-1 Certificate of Designations (the "Series F-1 Floor Price").

The Company is required to redeem the shares of Series F Preferred Stock in 12 equal monthly installments, commencing on July 1, 2023. The amortization payments due upon such redemption are payable, at the company's election, in cash, or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the Conversion Price then in effect and (ii) the greater of (A) a 80% of the average of the three lowest closing prices of the Company's Common Stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) the Floor Price (as defined below). For purposes of the Series F Certificate of Designation, the "Floor Price" means $6.60 (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) or, in any case, such lower amount as permitted, from time to time, by the Nasdaq Stock Market; provided that if the amount set forth in clause B is the lowest effective price, the Company will be required to pay the amortization payment in cash.

Exchange Cap

The Company was initially restricted from issuing shares of Common Stock upon conversion of the Series F-1 Preferred Stock and Series G Preferred Stock or exercise of the associated warrants in excess of 19.99% of the shares of Common Stock outstanding as of the date immediately prior to the issuance of the shares of Series F-1 Preferred Stock and Series G Preferred Stock and the associated warrants (the "Issuable Maximum") until the Company obtained stockholder approval for the issuance of shares of Common Stock in excess of the Issuable Maximum. The Company received the Stockholder Approval on July 24, 2024.

Optional Conversion

The Series F-1 Preferred Stock can be converted at the option of the holder at any time and from time to time after the original issuance date. Holders shall effect conversions by providing us with the form of conversion notice (the "Notice of Conversion") specifying the number of shares of Series F-1 Preferred Stock to be converted, the number of shares of Series F-1 Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable holder delivers by email such Notice of Conversion to us.

Mandatory Conversion

If on any day after the issuance of the shares of Series F-1 Preferred Stock the closing price of the Common Stock has exceeded $5.448 per share (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 20 consecutive trading days and the daily dollar trading volume of the Common Stock has exceeded $3,000,000 per trading day during the same period and certain equity conditions described in the Series F-1 Certificate of Designation are satisfied (the "Mandatory Conversion Date"), the Company shall deliver written notice of the Mandatory Conversion (as defined below) to all holders on the Mandatory Conversion Date and, on such Mandatory Conversion Date, the Company shall convert all of each holder's shares of Series F-1 Preferred Stock into Conversion Shares at the then effective Conversion Price (the "Mandatory Conversion"). If any of the Equity Conditions shall cease to be satisfied at any time on or after the Mandatory Conversion Date through and including the actual delivery of all of the Conversion Shares to the holders, the Mandatory Conversion shall be deemed withdrawn and void ab initio.

Beneficial Ownership Limitation

The Series F-1 Preferred Stock cannot be converted to Common Stock if the holder and its affiliates would beneficially own more than 4.99% or 9.99% at the election of the holder of the outstanding Common Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Series G Convertible Preferred Stock

The following are the principal terms of the Series G Preferred Stock:

Dividends

The holders of the Series G Preferred Shares will be entitled to dividends of 10% per annum, compounded monthly, which will be payable in arrears monthly, at the holder's options, (i) in cash, (ii) "in kind" in the form of additional shares of Series G Preferred Shares (the "PIK Shares"), or (iii) in a combination thereof, in each case, in accordance with the terms of the Certificate of Designations of the Series G Preferred Shares (the "Series G Certificate of Designations"). Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series G Certificate of Designations), the Series G Preferred Stock will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, the holders of the Series G Preferred Shares are also entitled to receive a dividend make-whole payment.

Voting Rights

Except as required by applicable law, the holders of the Series G Preferred Shares are entitled to vote with holders of the Common Stock on as as-converted basis, with the number of votes to which each holder of Series F-1 Preferred Shares is entitled to be calculated assuming a conversion price of $2.253 per share, which was the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) applicable immediately before the execution and delivery of the purchase agreement executed in connection with the issuance of the Series G Preferred Stock, subject to certain beneficial ownership limitations as set forth in the Series G Certificate of Designations.

Liquidation

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, each holder of shares of the Series G Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount per share of Series G Preferred Stock equal to the greater of (A) 125% of the stated value of such share of Series G Preferred Stock (plus any applicable make-whole amount, unpaid late charge or other applicable amount) on the date of such payment and (B) the amount per share such holder would receive if such holder converted such share of Series G Preferred Stock into Common Stock immediately prior to the date of such payment. All shares of capital stock of the Company shall be junior in rank to all shares of Series G Preferred Stock with respect to the preferences as to payments upon the liquidation.

Optional Conversion

The Series G Preferred Stock can be converted at the option of the holder at any time and from time to time after the original issuance date. Holders shall effect conversions by providing us with the form of conversion notice (the "Notice of Conversion") specifying the number of shares of Series G Preferred Stock to be converted, the number of shares of Series G Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable holder delivers by email such Notice of Conversion to us.

Exchange Cap

The Company was initially restricted from issuing shares of Common Stock upon conversion of the Series F-1 Preferred Stock and Series G Preferred Stock or exercise of the associated warrants in excess of 19.99% of the shares of Common Stock outstanding as of the date immediately prior to the issuance of the shares of Series F-1 Preferred Stock and Series G Preferred Stock and the associated warrants (the "Issuable Maximum") until the Company obtained stockholder approval for the issuance of shares of Common Stock in excess of the Issuable Maximum. The Company received the Stockholder Approval on July 24, 2024.

Beneficial Ownership Limitation

The Series G Preferred Stock cannot be converted to Common Stock if the holder, other than PharmaCyte Biotech, Inc., and its affiliates would beneficially own more than 4.99% or 9.99% at the election of the holder of the outstanding Common Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Anti-Takeover Provisions

The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of the Company.

These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

In addition, the anti-takeover provisions of Section 203 of the DGCL. In general, the statute prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale, or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who, together with affiliates and associates, owns (or within three years prior thereto, did own) 15% or more of the corporation's voting stock.

Exhibit 10.45

OMNIBUS AMENDMENT AGREEMENT

This Omnibus Amendment Agreement (this "Agreement"), dated as of April 8, 2025, is by and between TNF Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and the investor listed on the signature page attached hereto (the "Investor").

WITNESSETH

WHEREAS, the Company and the Investor are party to that certain Securities Purchase Agreement, dated as of February 21, 2023 (the "Series F Purchase Agreement"), pursuant to which the Company sold to the Investor shares of the Company's Series F Convertible Preferred Stock, par value $0.001 per share (the "Series F Preferred Stock"), the terms of which are set forth in the Amended and Restated Certificate of Designations of the Series F Convertible Preferred Stock (as amended, the "Series F Certificate of Designations"), and a warrant (the "Series F Warrant," and, together with the Series F Purchase Agreement and the Series F Certificate of Designations, the "Transaction Documents") to purchase shares of the Company's common stock, par value $0.001 per share ("Common Stock");

WHEREAS, the Company and the Investor are party to that that certain Securities Purchase Agreement, by and among the Company and each of the investors listed on the Schedule of Buyers attached thereto, dated as of May 20, 2024 (the "Series F-1 Purchase Agreement"), pursuant to which the Company issued to the Investor (i) shares of the Company's Series F-1 Convertible Preferred Stock, par value $0.001 per share ("Series F-1 Preferred Stock"), the terms of which are set forth in the Certificate of Designations of the Series F-1 Convertible Preferred Stock (the "Series F-1 Certificate of Designations"), (ii) accompanying warrants to purchase shares of the Company's Common Stock with a term of five (5) years from the date of issuance, and (iii) accompanying warrants to purchase shares of the Company's Common Stock with a term of eighteen (18) months from the date of issuance (the "Short-Term Warrant" and, together with the Series F-1 Certificate of Designations and the Series F-1 Purchase Agreement, the "Series F-1 Transaction Documents") to purchase shares of the Company's Common Stock;

WHEREAS, the Investor, together with certain other investors party to Series F Purchase Agreement and/or Series F-1 Purchase Agreement and entering into similar Omnibus Amendment Agreements of even date hereof, collectively hold at least a majority of the outstanding shares of Series F Preferred Stock and the Series F-1 Preferred Stock and, in each case, thereby constitute the Required Holders (as defined in the Series F Certificate of Designations and Series F-1 Certificate of Designations); and

WHEREAS, the Company and the Investor desire to amend certain provisions of the Transaction Documents and Series F-1 Transaction Documents.

NOW, THEREFORE, in consideration of the premises and mutual covenants and obligations hereinafter set forth, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Definitions. Capitalized terms used herein but not otherwise defined herein shall have the respective meanings given such terms in the Series F Certificate of Designations and Series F-1 Certificate of Designations, as applicable.

2. Amendment to the Certificate of Designations. The parties hereto hereby agree to amend the terms of the Series F Preferred Stock as set forth in the Certificate of Amendment to Certificate of Designations of the Series F Preferred Stock in the form attached hereto as Exhibit A (the "Amendment"), with such Amendment being effective as of December 31, 2024. The Company shall promptly file the Amendment with the Secretary of State of the State of Delaware and provide a copy thereof to each Investor promptly after such filing.

3. Amendment to the Series F-1 Certificate of Designations. The parties hereto hereby agree to amend the terms of the Series F-1 Preferred Stock as set forth in the Amendment to Series F-1 Certificate of Designations in the form attached hereto as Exhibit B (the "Series F-1 Amendment"), with such Series F-1 Amendment being effective as of the date hereof. The Company shall promptly file the Series F-1 Amendment with the Secretary of State of the State of Delaware and provide a copy thereof to each Investor promptly after such filing.

4. Amendment to Short-Form Warrant. The parties hereto hereby agree to amend the terms of the Short-Form Warrant such that the Short-Form Warrant shall have a term of five (5) years from the date of issuance.

5. Amendment to the F-1 Purchase Agreement. The parties hereto hereby agree that clause (i) of Section 4(l) of the Series F-1 Purchase Agreement is hereby amended and restated as follows (emphasis added):

> (i) shares of Common Stock or standard options to purchase Common Stock issued or issuable to directors, officers, employees or other service providers of the Company in their capacity as such pursuant to an Approved Stock Plan (as defined below), provided that (1) all such issuances (taking into account the shares of Common Stock issuable upon exercise of such awards) after the date hereof pursuant to this clause (i) do not, in the aggregate, exceed more than 2% of the shares of Common Stock issued and outstanding as of the date of such issuance and (2) the exercise price of any such options is not lowered and none of such options are amended to increase the number of shares issuable thereunder

6. Reduction to Board Size. In consideration of the foregoing, the Company hereby agrees to reduce the size of the board of directors of the Company to no more than six directors, no later than the Company's 2025 annual meeting of stockholders.

7. Counterparts; Facsimile Execution. This Agreement may be executed in one or more counterparts (including by electronic mail, in PDF or by DocuSign or similar electronic signature), all of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other parties. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

8. Governing Law; Jurisdiction; Jury Trial. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in The City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Nothing contained herein shall be deemed or operate to preclude the Investor from bringing suit or taking other legal action against the Company in any other jurisdiction to collect on the Company's obligations to the Investor or to enforce a judgment or other court ruling in favor of the Investor.

9. EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE TO, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR UNDER ANY OTHER TRANSACTION DOCUMENT OR IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT, OR ANY TRANSACTION CONTEMPLATED HEREBY OR THEREBY.

10. Terms and Conditions of the Transaction Documents and the Series F-1 Transaction Documents. Except as modified and amended herein, all of the terms and conditions of the Transaction Documents and the Series F-1 Transaction Documents shall remain in full force and effect.

[*Signature pages follow immediately*.]

[*Company Signature Page to Amendment Agreement*]

IN WITNESS WHEREOF, the undersigned has executed and delivered this Agreement as of the date first above written.

Company:

TNF PHARMACEUTICALS, INC.

By: _____
Name:
Title:

[*Investor Signature Page to Amendment Agreement*]

IN WITNESS WHEREOF, the undersigned has executed and delivered this Agreement as of the date first above written.

Name of Investor:

By: _____
Name of signatory:
Title:

Exhibit A

Form of Amendment to Certificate of Designations

Exhibit B

Form of Amendment to Series F-1 Certificate of Designations

Exhibit 19.1

Insider Trading

This statement sets forth the policies of TNF Pharmaceuticals on trading and causing the trading of securities while in possession of material non-public information. Sections 1 through 3 and Section 5 applies to all persons associated with the Corporation including consultants. The entire policy applies to the following "Covered Persons": (i) all directors of the Corporation; and (ii) all officers of the Corporation and its subsidiaries at the level of Vice President and above.

1. The Basic Policy—No Trading or Causing Trading While in Possession of Material Non-Public Information

(a) No person associated with the Corporation may purchase or sell any security, whether or not issued by the Corporation, while in possession of material non-public information concerning the security. (The terms "material" and non-public" are defined in Section 2 below.)
(b) No person associated with the Corporation who knows of material non-public information may communicate that information to any other person if he or she has reason to believe that the information may be improperly used in connection with securities trading.
(c) Covered Persons and certain related persons must "preclear" all trading in securities of the Corporation in accordance with the procedures set forth in Section 4 below.

2. The Law Against "Insider Trading"

One of the principal purposes of the federal securities laws is to prohibit so-called insider trading. In recent years this has become a major focus of the enforcement program of the Securities and Exchange Commission and of criminal prosecutions brought by United States Attorneys.

(a) Application to Non-Insiders and to Securities Other Than Securities of the Corporation

Prohibitions against "insider trading" apply to trades, tips, and recommendations by virtually any person—including all persons associated with the Corporation—if the information involved is "material" and "non-public." Thus, for example, the prohibitions would apply if you trade on the basis of material non-public information you obtain regarding the Corporation, its borrowers, customers, suppliers, or other corporations with which the Corporation has contractual relationships or may be negotiating transactions. For compliance purposes, you should never trade, tip, or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that you have reason to believe is material and non-public unless you first consult with, and obtain the advance approval of, the Legal Department.

(b) Materiality

Insider trading restrictions come into play only if the information you possess is "material." Materiality, however, involves a relatively low threshold.

Information is generally regarded as "material" if it has market significance, that is, if its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision.

Information dealing with the following subjects is reasonably likely to be found material in particular situations:

- Significant changes in the Corporation's prospects;
- Significant write-downs in assets or increases in reserves;
- Developments regarding significant litigation or government agency investigations;
- Liquidity problems;
- Changes in earnings estimates or unusual gains or losses in major operation;
- Major changes in management;
- Changes in dividends;
- Extraordinary borrowings;
- Award or loss of a significant contract;
- Changes in debt ratings;
- Proposals, plans, or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets;
- Public offerings; and
- Pending statistical reports (e.g., consumer price index, money supply and retail figures, interest rate developments).

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition, or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular non-public information is material, exercise caution. Consult the Legal Department before making a decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates.

(c) Non-Public Information

Insider trading prohibitions come into play only when you possess information that is material and "non-public." The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally. Even after public disclosure of information regarding the Corporation, you generally must wait a period of two or three days for the information to be absorbed by public investors before you can treat the information as public.

Non-public information may include:

- Information available to a select group of analysts or brokers or institutional investors;
- Undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and
- Information that has been entrusted to the Corporation on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two or three days).

As with questions of materiality, when in doubt about whether information is non-public call the Legal Department or assume that the information is "non-public" and, therefore, treat it as confidential.

3. Severe Penalties for Violating Insider Trading Laws

Penalties for trading on or communicating material non-public information are severe, both for individuals involved in such unlawful conduct and their employers and supervisors. A person who violates the insider trading laws can be sentenced to a substantial jail term and required to pay a penalty of several times the amount of profits gained or losses avoided.

Moreover, Congress has passed insider trading legislation that, in a significant departure from prior law, explicitly empowers the Securities and Exchange Commission to seek substantial penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation." Such persons may be held liable for up to the greater of $1 million or three times the amount of the profit gained or loss avoided. Thus, even for violations that result in a small or no profit, the Securities and Exchange Commission can seek a minimum of $1 million from the Corporation and various management and supervisory personnel.

Given the severity of the potential penalties, compliance with the policies set forth in Section 1 of this Statement is absolutely mandatory, and noncompliance is a ground for dismissal. Exceptions to these policies, if any, may only be granted by the Legal Department and must be provided before any activity contrary to the above policies takes place.

4. Preclearance of Securities Transactions

Because Covered Persons are likely to obtain material non-public information on a regular basis, the Corporation requires all such persons to preclear all purchases and sales of the Corporation's securities in accordance with the following procedures:

(a) Subject to the exemption in part "(d)" below, no Covered Person may, directly or indirectly, purchase or sell any security issued by the Corporation without first obtaining prior approval from the Legal Department. These procedures also apply to transactions by such person's spouse, other persons living in such person's household and minor children, and to transactions by entities over which such person exercises control.

(b) The Legal Department shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days following the day on which it was granted.

(c) Requests are most likely to be approved for trading that is to occur in the following "window periods":

(i) Commencing at the close of trading on the second full business day following the date of public disclosure of the financial results for a particular fiscal quarter or year and continuing until the eleventh business day of the third month of the next fiscal quarter. For example, if public disclosure occurs on Monday, May 14th, trading requests would likely be approved from Thursday, May 17th through Thursday, June 14th;
(ii) Following the wide dissemination of information on the status of the Corporation and current results; or
(iii) At those times when there is relative stability in the Corporation's operations and the market for its securities.

(d) Preclearance is not required for purchases and sales of securities under a preexisting written plan, contract, instruction, or arrangement that is adopted pursuant to Securities and Exchange Commission Rule 10b5-1(c) (17 C.F.R. § 240.10b5-1(c)) and approved in writing by our Legal Department and counsel with respect to TNF Pharmaceuticals concerns. Generally, Rule 10b5-1(c) trading plans are developed in consultation with individual counsel and not the responsibility of the Legal Department or our counsel. These concerns include:

(i) That the plan was entered into in good faith by the Covered Person at a time when the Covered Person was not in possession of material non-public information about the Company; and
(ii) The plan either

(e) Gives a third party the discretionary authority to execute such purchases and sales, outside the control of the Covered Person, so long as such third party does not possess any material non-public information about the Company; or

(f) Explicitly specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions.

With respect to any purchase or sale under a pre-arranged trading plan as described above, the third party effecting transactions on behalf of the Covered Person should be instructed to send duplicate confirmations of all such transactions to the Legal Department.

5. Prohibited Transactions

Persons associated with the Corporation, including such person's spouse, other persons living in such person's household, and minor children and entities over which such person exercises control, is prohibited from engaging in the following transactions in securities of the Corporation unless advance approval is obtained from the Legal Department:

(a) Short-term trading. Persons associated with the Corporation who purchase its securities must retain such securities for at least six months.
(b) Short sales. Persons associated with the Corporation may not sell the Corporation's securities short.
(c) Options trading. Persons associated with the Corporation may not buy or sell puts or calls on the Corporation's securities.
(d) Trading on margin. Persons associated with the Corporation may not trade on the margin on the Corporation's securities.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-234447 and 333-235359), Form S-3 (File No. 333-217390, 333-238631, 333-248095 and 333-254698) and Form S-8 (File No. 333-266019) of TNF Pharmaceuticals, Inc. (formerly, MyMD Pharmaceuticals, Inc.) and Subsidiaries of our report dated April 1, 2024 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ Morison Cogen LLP

Blue Bell, Pennsylvania
April 11, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Mitchell Glass, President and Chief Medical Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of TNF 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: April 11, 2025

By: */s/ Mitchell Glass, M.D.*
Mitchell Glass, M.D.
President and Chief Medical Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Ian Rhodes, Interim Chief Financial Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of TNF Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 11, 2025

By: */s/ Ian Rhodes*
Ian Rhodes
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of TNF Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Mitchell Glass, M.D., as the President of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 11, 2025

By: */s/ Mitchell Glass, M.D.*
Mitchell Glass, M.D., President and Chief Medical Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of TNF Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Ian Rhodes, as the Interim Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 11, 2025

By: */s/ Ian Rhodes*
Ian Rhodes, Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.