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

FORM 8-K

Current Report

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 6, 2025**

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

Delaware	**001-36268**	**22-2983783**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

TNF Pharmaceuticals, Inc. **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**

855 N. Wolfe Street, Suite 623
Baltimore, MD 21205
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	TNFA	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 7.01 Regulation FD Disclosure.

On March 6, 2025, TNF Pharmaceuticals, Inc. (the "Company") held a telephonic conference call to discuss the Company's research and development progress with respect to the Company's lead compound, Isomyosamine. A transcript of the call is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing. Furthermore, the furnishing of information under Item 7.01 of this Current Report on Form 8-K is not intended to constitute a determination by the Company that the information contained herein, including the exhibits hereto, is material or that the dissemination of such information is required by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
10.1	Transcript of Conference Call, held March 6, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

TNF PHARMACEUTICALS, INC.

Date: March 10, 2025

By: */s/ Joshua Silverman*
Joshua Silverman
Director

TNF Pharmaceuticals
Investor Update Conference Call
March 6, 2025

Presenters

Mitchell Glass - Director, President and Chief Medical Officer

Operator

Good afternoon, everyone, and welcome to the TNF Pharmaceuticals Investor Conference call and Clinical Scientific Update. Today's call will be conducted by the Company's President and Chief Medical Officer, Dr. Mitchell Glass.

Before I turn the call over to Dr. Glass, I would like to remind everyone that any statements made on today's conference call that express a belief, expectation, projection, forecast, anticipation or intent regarding the Company's future events and performance may be considered forward-looking statements as defined by the Private Securities Litigation Reform Act. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any expected future results, performance or achievements. A discussion of important factors that could cause actual results to differ materially from those indicated by such forward-looking statements is included in the Company's Annual Report on Form 10-K and other reports that the Company files with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and TNF Pharmaceuticals disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise.

And with that, I'll turn the call over to Dr. Mitchell Glass. Please go ahead.

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

Welcome, and thank you for joining us today. The purpose of this conference call is to provide a more detailed scientific context for the research and development progress we are making with our lead compound, Isomyosamine.

I've been involved in pharmaceutical R&D for more than 35 years. I've led teams through more than 50 INDs, more than 20 drug candidates into later stage development, and my teams have brought six novel drugs to market across a range of indications and territories. I've been an executive in large pharmaceutical companies and in startups. TNF Pharmaceuticals represents a new opportunity to provide much needed cost-effective treatment for a range of disorders.

I joined last summer to guide the progress of Isomyosamine, a patented synthetic small molecule derived from a compound found in tobacco, into larger and more definitive trials and commercialization. We changed our company name to TNF Pharmaceuticals with the Nasdaq ticker symbol "TNFA". This new name reflects our primary focus on exploiting the science around TNF-alpha inhibition in diseases and disorders that are best served with daily therapy with a small molecule that is easily absorbed by mouth and can cross the blood brain barrier.

We believe that being available orally and being a small molecule are key differentiators between our molecule and the approved drugs, all of which require repeat dosing by injection and currently make up the $40 billion annual TNF-inhibitor market.

TNF has now corroborated our preclinical research into Isomyosamine with clinical data that show decreases of biomarkers associated with TNF-alpha activation in elderly patients with sarcopenia. Specifically, our data provide a strong rationale for oral dosing with Isomyosamine in elderly patients with sarcopenia to establish the dosing regimen for the duration of our Phase 2b trial and follow-up Phase 3 studies.

Let's consider each element of our development strategy.

Sarcopenia and frailty are our prioritized targets. These conditions present with increased frequency in elderly patients. They're marked by loss of muscle mass and loss of muscle function, and decreased bone density associated with increased evidence of mononuclear cell inflammation, chief of which is the TNF-alpha cascade. Elderly patients do poorly in the face of prolonged inflammation, such as has been reported after hip or long bone fracture.

The treatment of hip or femoral fractures in sarcopenic patients requires a potent anti-TNF drug, but one which does not cause systemic immunosuppression. Elderly patients with sarcopenia are poor candidates for biological TNF-alpha inhibitors, all of which cause systemic immune suppression.

In contrast, Isomyosamine has shown no immunosuppressive effect in our studies to date. To take this approach one step further, unique characteristics of Isomyosamine provide an optimal rationale for our regulatory strategy. Isomyosamine has several important distinctions from approved TNF-alpha inhibitors.

The target product profile of an ideal oral small molecule TNF-alpha inhibitor would include: (a) potency comparable to the biologicals; (b) ease of titration including dosing increase or interruption based on clinical response or biomarker levels; and (c) anti-inflammatory activity with minimal or no immunosuppression. Isomyosamine is unique among TNF-alpha inhibitors in satisfying each of these three criteria.

In a head-to-head comparison, Isomyosamine was shown to have pharmacological activity that outperforms Etanercept, marketed as Enbrel. Oral dosing of our compound enables dose adjustment based on clinical or biomarker findings. Most importantly, Isomyosamine has shown no immunosuppression in-vitro, in-vivo in animal studies or in our initial clinical studies. Acute and chronic animal safety studies conducted in accordance with FDA regulations have shown no barrier to acute or chronic dosing at clinically effective levels.

We've designed our Phase 2b trial, which we have now initiated, to extend our biomarker data into clinical outcomes such as return to the ability to walk unassisted and live independently. In our study, designed to compare Isomyosamine to standard of care with placebo, patients will be offered informed consent after a major hip or femoral fracture and surgery. We will test recovery based on the Short Physical Performance Battery, which provides a validated basis for comparison to standard of care, and which provides a statistical basis for calculating the sample size for our Phase 3 studies. Our multi-center Phase 2b trial will enroll at least 60 patients, with dosing up to 90 days. We would expect to see topline results within 12 months.

We recognize that there are challenges associated with a study in sarcopenia or frailty. There is no simple clinical or chemistry diagnostic for these conditions, which paradoxically makes these conditions that much more important to diagnose and treat. Only a small fraction of patients with frailty with sarcopenia have been diagnosed prior to a trauma or infection so that sarcopenia or frailty are rarely identified as a pre-existing condition. However, improving the quality of life and completeness of healing reinforces

the importance of treating these patients early and for a period of time sufficient to enable significant improvement. We'll use biomarkers in conjunction with clinical presentations to identify our target patient population and their dose response to treatment.

In parallel with this program, allow me to spend a few minutes to describe another key initiative.

An increasing body of evidence has associated muscle loss and inflammation with GLP-1 agonist treatments for obesity and diabetes. Evidence shows that up to 40% of total weight loss in GLP-1 patients is lean body mass including skeletal muscle mass, which may be difficult or impossible to recover.

TNF has established a research and development collaboration with Renova Health to identify this population of patients at risk who will benefit from treatment with Isomyosamine to prevent or reverse GLP-1 induced inflammation and muscle loss. We've begun a series of clinical studies to examine TNF-alpha levels in patients receiving Wegovy or Ozempic.

These studies, as well as the Phase 2b trial, are fully funded.

This is an exciting time at TNF Pharmaceuticals. We believe we now have a thoughtful clinical roadmap, and if we can show successful results in our Phase 2b trial, we will be well positioned with a clear message on the appropriate patient and dosing regimen to advance to a Phase 3 trial with the right population, right dose, and the right indication. We believe the opportunity to bring the first oral TNF inhibitor to market will be disruptive and create substantial value for our shareholders.

With that, I'll conclude my prepared remarks. We can move on to Q&A. Operator, please go ahead.

Operator

Thank you, Dr. Glass. Participants on today's call were invited to send in questions for management prior to the start of this event. We'll begin with the first question: Dr. Glass, can you talk about your interest in TNF Pharmaceuticals? What brought you to this company as opposed to the many other biotechs that are further along and may be less risky?

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

I'm glad to address that. First of all, my entire career has focused on serious unmet medical needs, including asthma, heart failure, lupus and rheumatoid arthritis, amongst other challenging targets. Oral TNF inhibition has been a challenge in the industry during my entire career, and I have always been interested in focusing on first-in-class drugs rather than me-too drugs. The Company has been now funded to complete a meaningful Phase 2b trial. That was important to me, and I think that I have brought together a team that has the skills to design and execute this challenging program through to success into Phase 3 and commercialization.

Operator

The next question has two parts: The first one, sarcopenia, is a relatively small market compared to rheumatoid arthritis and others. Why did you pick sarcopenia for your first target, and can you give us an update on your plans for rheumatoid arthritis?

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

I certainly can. First of all, I should point out that rheumatoid arthritis was thought to be a very small target market in 1995 when Enbrel was finally approved, and I have managed programs in RA, including four programs with the increasing demands from the FDA around this.

One of those programs was Auranofin. As a microcap biotech company, it required a close examination to determine that there would be adequate resources to get to a prioritized program and a lead indication for a lead drug, and we are there now. So taken together, this makes sense.

We have not abandoned rheumatoid arthritis, but the rheumatoid arthritis market is relatively well satisfied, whereas the sarcopenia and frailty market, which I should point out is every bit as large as the rheumatoid arthritis market, really has no appropriate drug therapy at this point.

Operator

The second part of that question reads: the market demand for GLPs is massive. If you are able to enter this market, what is a realistic estimate of your addressable market opportunity?

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

The multi-phase approach we are taking together with Renova Health provides us a very large patient population from which to identify which population or sub-population are most addressable for either the reversal or prevention of the condition associated with muscle loss. With that caveat, our initial estimates are definitely going to be in the millions of patients, given the rapid uptake of these drugs. So, we see this opportunity, which will also be taking advantage of machine learning and AI to define the appropriate patient population, and look forward to providing you some additional updates starting in the near future.

Operator

Next question: the Company's progress over the course of three years under the prior management team was costly and inefficient. Why do you think you can succeed, given the issues with the prior management team?

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

Well, we are definitely not that management team. I have run more than 50 new drug programs in early drug development through to approval. No program that I have run and determined was either ineffective or unsafe has ever subsequently achieved approval, so we have a very high bar when it comes to go/no-go decision making with respect to programs we take forward.

So at this point, I have assembled the right team, including two of my team members who are now CEOs in their own right of small companies, and we have added to that a group of experts so that every aspect of this program is geared to a very strong positive endpoint from this study.

Finally, I would point out that, in the teaching that I do, I use a simple mantra when it comes to interacting with the Food and Drug Administration, who in many ways, along with our investors, represent our primary customer. And that mantra is three simple words: listen, clarify and obey.

Operator

Next question: how long will Phase 2b take until you could potentially move forward into Phase 3? What is the hypothetical timeline to approval for a best-case scenario?

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

As I said earlier, we have initiated this study and are identifying centers of excellence that bring together these characteristics of a population with hip or femoral fracture, a population that is expert in gerontology, diseases and disorders of older patients, and the ability to run clinical trials. With that in mind, our target now is that we should have topline results for you within a year, and with a properly designed and executed study, we expect to be in front of the FDA within that year to identify our study population for our Phase 3 program.

Operator

And for the final question, can you give us an update on Supera-CBD? It seems like that's on the sidelines since there haven't been any updates on that program for quite a while.

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

So job one, and job one on this call, was to walk you through a lot of science, specific drug characteristics and study design about Isomyosamine. The same issues around Supera-CBD would require a similar call with similar discussion. So Supera-CBD, having said that, is promising, and it is a luxury for this Company to have two promising assets. I would say that the team that we have assembled is absolutely expert enough to manage two programs in parallel if resources permit.

Operator

Great. That concludes today's question and answer session. Dr. Glass, please proceed with any closing remarks.

Dr. Mitchell Glass, Director, President and Chief Medical Officer, TNF Pharmaceuticals, Inc.

Thank you, everyone, for your participation today, your interest in TNF Pharmaceuticals. We look forward to being more consistent and more transparent with our progress, and I am happy to answer any questions or comments that you may have as we move forward. Thank you.

Operator

Thank you. Ladies and gentlemen, this does conclude today's conference call. Thank you for your participation, and have a wonderful day.