Report on Tonix Pharmaceuticals

Based in Chatham, New Jersey, Tonix Pharmaceuticals is the result of several corporate transactions, specifically a reverse merger between Tamandare and Krele Pharmaceuticals in 2011, with Seth Lederman appointed as CEO, a position he still holds today.

The company produces therapies for the central nervous system, immunology, and infectious diseases, with TNX-102 SL as its leading candidate, indicated for the management of fibromyalgia which is a condition characterized by extreme pain, fatigue, and sleep deprivation.

Despite its noble cause, the company has faced several challenges in the past, with its stock price falling below $1 USD, resulting in regulatory issues, and only returning 2.35% year-to-date (YTD). Constant underperformance does not change the fact that Tonmya (TNX-102 SL) has the potential to be a $1 billion drug, if we're being optimistic, or 500mln if we're realistic. Still, with the company trading at a $170 million market cap, this presents an asymmetric opportunity.

Financials

The financial position of the company is solid for its size. With two marketed drugs, it generates revenue — uncommon for small pharma companies in the early stages of drug development, particularly those with a market cap under $200 million. The company has no debt, and cash reserves are expected to last until Q2 2026 at the current burn rate.

However, financial modeling often takes a back seat in pharmaceutical companies, where value is derived primarily from the pipeline. Instead, we focus on a sum-of-the-parts approach. The main point of this thesis is simple: how much is Tonmya going to sell?

One thing that needs to be made clear is that TNXP's management has repeatedly failed to deliver consistent positive performance. As stated in the introduction, performance has been poor at best. Hence my focus is on Tonmya alone. Relying on the rest of the pipeline carries too much risk given management's track record. This also means that if the **PDUFA** date is not successful, this thesis will be invalidated until we can better understand when Tonmya might hit the market. Nevertheless, I am confident that the odds favor TNXP in the coming catalyst date, for reasons I will outline below, one of which is the condition Tonmya aims to treat.

What is FM?

Fibromyalgia (FM), a prototypic nociplastic syndrome, is caused by amplified sensory and pain signaling in the central nervous system (CNS). It is often associated with other pain states such as recovery from infectious diseases, cancer treatment, or endocrine stress, but it can also appear without any prior cause. The disease is characterized by chronic pain, non-restorative sleep, fatigue, and even brain fog. There is no known cure, and current treatments only manage symptoms. FM is said to affect around 10 million Americans, with the number likely higher given that 40% of long COVID patients have overlapping symptoms.

No new drugs have been developed for this condition in over a decade, posing an opportunity for approval even if the treatment is not novel or game-changing. Moreover, around 50% of patients are prescribed opioids within 18 months of diagnosis. Tonmya and other candidates would provide a safer alternative for a debilitating condition that affects a significant number of people and for which current market offerings are inadequate.

Competition/Treatment landscape

FM has been difficult to treat, with only three drugs ever approved specifically for FM:

Company	Name	Generic	Launch
PFE	Lyrica	Duloxetine	2004
LLY	Cymbalta	Pregabalin	2005
ABBV	Savella	Milnacipran	2009

Since then, no new treatment has been approved. Patents for Lyrica and Cymbalta expired in 2014 and 2019, respectively. With patients reporting reduced efficacy from generics, there is a clear need for new treatments.

Other clinical stage competitors:

- **IMC-1** (Dogwood Therapeutics, DWTX): an antiviral combination of famciclovir and celecoxib, currently in late-phase II trials.
- **TRP-8802** (Tryptamine Therapeutics, TYP AU): a psilocybin-based serotonergic agonist in phase II trials.
  While these are novel approaches, studies to date have been small-scale, and such unconventional mechanisms may face additional regulatory hurdles.

AXS-14 (Axsome Therapeutics, AXSM): Esreboxetine is a highly selective norepinephrine reuptake inhibitor (NRI). Pfizer previously discontinued development, but Axsome licensed it in 2020 along with phase II/III data. While the trials met primary endpoints,

the FDA rejected the NDA due to trial design concerns, requesting longer observation periods and fixed dosage regimens.

This is not to say TNX-102 SL is a groundbreaking compound. Cyclobenzaprine was FDA-approved in the 1970s as a muscle relaxant. Tonmya simply changes the timing (administered at night) and route (sublingual) to target non-restorative sleep, strongly correlated with pain in FM. Nevertheless, cyclobenzaprine HCl sublingual has met its primary endpoint in two out of three phase III trials conducted by Tonix

RALLY's Failure

When assessing the likelihood of TNX-102 SL's approval, one must address its failed phase III trial, RALLY. Enrollment occurred from September 2020 to March 2021, during major COVID-19 waves. The protocol allowed telephone visits and other pandemic accommodations, and Tonix later reported unusually high AE-related discontinuations. Out of 514 enrolled subjects, 115 (24%) failed to complete the trial. These pandemic-related disruptions likely increased missing data and variability, erasing modest drug/placebo differences.

Importantly, RELIEF (completed mid-2020) and RESILIENT (enrolled April 2022–August 2023) both met their primary endpoints. The NDA therefore relies on two positive phase III results, while RALLY appears to be a trial-specific failure caused by pandemic-related noise rather than a consistent lack of efficacy.

Efficacy comparison

AXS-14 and TNX-102 SL, despite tackling FM differently, have shown comparable efficacy. The table below summarizes the findings from Tonix's RESILIENT and Pfizer's phase III trial for AXS-14:

Administred drug	Change from baseline @ Week 14	
	Pain	FIQR
TNX-SL 102 5.6mg	-0.6 (0.000)	-7.6 (0.000)
AXS-14 4mg	-0.73 (0.000)	-7.11 (0.000)
AXS-14 8mg	-0.76 (0.000)	-6.67 (0.000)
AXS-14 10mg	-0.42 (0.025)	-3.87 (0.023)

P values in parentheses

The table displays the change from baseline in the control groups for pain and FIQR measures, both commonly used in trials measuring efficacy in treating FM. Notably, both indications show significant decrease in pain and FIQR scales. Interestingly, AXS-14 has no significant effect on the 10mg dosage, with AXS 4mg and 8mh showing marginal better results than TNX while the later yielded a better effect on the FIQR scale. In short, both are comparable in efficacy, but AXS-14 still needs an additional phase III trial to support an NDA. With a first mover advantage and clear improvements

to serious FM symptoms, I believe Tonmya could achieve peak sales close to $500 million USD.

This thesis is based on the approval of Tonmya on August 15. I assign a high conditional probability of approval based on:

- Accepted NDA + Two positive phase III trials + PDUFA = Reasonable likelihood of approval

Valuing Tonix

Based on analyst estimates and historical sales for Lyrica and Cymbalta, I estimate that Tonmya could generate ~$70 million in its launch year, with peak sales near $500 million, even after accounting for market share loss to AXS-14. For comparison's sake, Lyrica reached ~$1.5 billion in peak annual sales. This supports a conservative valuation of $70 per share for Tonix.

In my view, this is an opportunity to buy a proven-mechanism drug with an entire pipeline effectively for free. At the time of writing, the stock trades at $46.49, offering roughly 50% upside.

I have built a 5% position in the stock and will scale further if the PDUFA catalyst is positive. If not, the thesis is partially invalidated, and I will exit the position. TNXP's valuation depends heavily on Tonmya's approval timeline.

Bottomline

- We are buying a drug that could generate $1+ billion in sales at a $170 million market cap.
- Approval is likely given the strength of the trial data.
- This is an asymmetric opportunity — we get the rest of the pipeline at no additional cost.