Zacks Small-Cap Research

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Tonix Pharmaceuticals

(TNXP-NASDAQ)

TNXP: Upgrading to Buy Based on Clinical and Financial Progress

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	7/23/12
Current Price (11/13/13)	$4.18
Target Price	**$10.00**

In recent months Tonix has achieved several key milestones including the completion of a one-for-20 reverse stock split in May, raising gross proceeds of $20 million in cash from a secondary offering of 2.68 million units in August, and up-listing to the NASDAQ the same month. Adding to these achievements, on September 16, 2013 the company announced the initiation of enrollment of the Phase 2b BESTFIT trial of its proprietary reformulation of cyclobenzaprine, TNX-102SL in fibromyalgia.

Based on these positive steps and on the strong need for new medications to improve treatment and reduce treatment costs in fibromyalgia, we are upgrading Tonix to Buy from our previous rating of Neutral. We see $10 as fair-value.

SUMMARY DATA

52-Week High	**$0.35**
52-Week Low	**$0.29**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**1,516**
Shares Outstanding (mil)	**N/A**
Market Capitalization ($mil)	**$11**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	0 A	0 A	0 A	0 A	0 A
2013	0 A	0 A	0 A	0 E	0 E
2014					0 E
2015					10.0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$1.27 A	-$1.79 A	-$1.01 A	-$1.49 A	-$5.58 A
2013	-$0.93 A	-$0.95 A	-$0.87 A	-$0.65 E	-$2.31 E
2014					-$2.15 E
2015					-$0.28 E

WHAT'S NEW

Upgrading to Buy

Tonix Pharmaceuticals (TNXP) is developing TNX-102SL, a sublingual formulation of cyclobenzaprine for the treatment of fibromyalgia syndrome. Fibromyalgia is a complex and poorly understood disorder characterized by tender points, widespread muscular pain, sleep disruption, and chronic fatigue. It is most commonly treated with multi-drug cocktails, which incorporate various combinations of the approved fibromyalgia drugs Lyrica, Savella and Cymbalta, along with off-label use of generic drugs including benzodiazepines, opioid painkillers, antidepressants, and muscle relaxants. Although published treatment guidelines universally recommend against their use, addictive and habituating medicines such as opioids and benzodiazepines are the most highly rated medicines for providing symptom relief in patient surveys. These surveys further indicate that only a small minority of patients find satisfactory symptomatic relief with currently prescribed branded medications. The unmet medical need in this population is further documented by the poor agreement among published treatment guidelines regarding standard of care.

Over the last several years, there have been two high profile commercial failures of reformulated generic drugs that were developed for the treatment of insomnia. One of these, Silenor, is a low dose form of the generic drug doxipen. The other, Intermezzo, is a sublingual formulation of the generic sleep aid zolpidem. While the poor commercial performances of these two products may give investors pause in investing in a reformulated product for fibromyalgia, we believe that this is a vastly different market from that for insomnia drugs. Specifically, fibromyalgia, in addition to being poorly treated with currently available therapies, is a profoundly disabling condition. The incredible breadth and diversity of off-label drug use in this indication, including high risk drugs such as opiates and benzodiazepines, speaks to desperation for new therapeutic options that are not present in the insomnia market. The cost of these patients to the healthcare system, which various studies suggest is 3x to 4x that of demographically matched individuals without fibromyalgia, incentivizes third party payers to reimburse new medical treatments in order to reduce the costs of large numbers of physician office visits and non-pharmacological therapies such as physical therapy, massage, psychotherapy, and hydrotherapy. Lastly, as fatigue and sleep disruption are two of the most disabling aspects of the disorder, a new agent that provides assistance in sleep onset without increasing daytime sedation is expected to represent an important therapeutic advance in the treatment of fibromyalgia.

In recent months, Tonix has achieved several key milestones that we previously identified as paramount to strengthening the case for investing in the company's shares. These include the completion of a 1-for-20 reverse stock split in May 2013, and raising gross proceeds of $20 million in cash from a secondary offering of 2.68 million units and simultaneous up-listing to the NASDAQ in August 2013. On September 16, 2013, the company announced the initiation of enrollment of the Phase 2b BESTFIT trial of its proprietary reformulation of cyclobenzaprine, TNX-102SL in fibromyalgia.

Based on these positive steps and on the strong need for new medications to improve treatment and reduce healthcare costs in fibromyalgia, we are upgrading shares of Tonix Pharmaceuticals to Buy from our previous rating of Neutral.

INVESTMENT THESIS

Tonix Pharmaceuticals is a specialty pharmaceutical company focused on developing new pharmaceutical products for central nervous system (CNS) conditions that may be safer and more effective than currently available treatments. The company uses ongoing advances in science and medicine to search for potential therapeutic solutions among already existing prescription pharmaceutical agents that have been successfully used in patients for other conditions. The goal is to create new dose formulations for these agents with the intent to developing products that are optimized for the new therapeutic uses or indications.

Fibromyalgia Syndrome

Fibromyalgia Syndrome (FM) is a complex medical disorder characterized by widespread musculoskeletal pain, fatigue, lack of sleep, and mood and memory issues. The pain associated with FM is often described as a constant dull ache or burning sensation, typically arising from the muscles along the back, neck and shoulders. FM tender points are identified by applying pressure to specific areas of the body, including the back of the head, between the shoulders, along the neck, the upper chest, the hips, and the knees.

The FM diagnostic criteria, established by the American College of Rheumatology (ACR) in 1990, includes a history of widespread pain in all four quadrants of the body for a minimum duration of three months, and pain in at least 11 of the 18 designated tender points when a specified amount of pressure is applied (Figure 1).

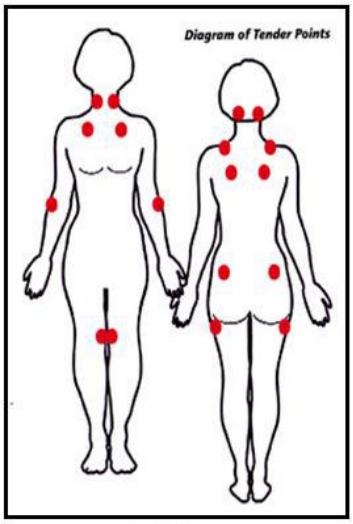


Figure 1

Besides the dull aching pain and fatigue, patients with FM often also experience mood and psychological disorders such as anxiety and depression. Many people who have fibromyalgia also have tension headaches and temporomandibular joint disorders. The symptoms are often worse in cold or damp weather.

People with FM tend to wake up with body aches and stiffness. For some patients, pain improves during the day and gets worse at night. However, fatigue and sleep problems are common in almost all patients. The National Pain Foundation estimates that 90% of all FM patients have sleep problems. Patients with FM often report waking up tired, even after sleeping a long period of time. Others report frequent awakenings due to pain, sleep apnea, and restless leg syndrome in the middle of the night. Almost all FM patients report memory and concentration problems associated with the lack of sleep and distracting pain.

These sleep and concentration problems, referred to as "fibro-fog", severely affect many FM patients to the point where employment is difficult to obtain and/or maintain. Approximately 20% of FM patients file some form of disability claim. Approximately 70% of FM patients report difficulty in conducting normal daily tasks, such as light housework. Chronic fatigue syndrome (CFS) has similar characteristics to FM, and patients are often diagnosed as having both FM and CFS.

...Causes...

The causes of FM are largely idiopathic, but common comorbid conditions include hypothyroidism, Lyme disease, endometriosis and irritable bowel syndrome. Physical trauma, surgery, infection, and psychological stress may bring about the onset of FM. In fact, stress is thought to play a significant role in the development of FM. There is a high correlation (approximately 42%) between the development of FM and post-traumatic stress disorder (PTSD).

...Medical & Psychiatric Comorbidity...

Medical	Prevalence	Psychiatric	Prevalence
Chronic Fatigue Syndrome	20-80%	Major Depressive Disorder	62%
Irritable Bowel Syndrome	32-80%	Bipolar Disorder	11%
Temporomandibular Disorder	75%	Panic Disorder	29%
Tension / Migraine Headaches	10-80%	Post-Traumatic Stress Disorder	21%
Chemical Sensitivities	33-35%	Social Phobias	19%
Interstitial Cystitis	13-21%	Obsessive Compulsive Disorder	7%
Chronic Pelvic Pain	18%		

Source: Aaron LA, et al. *BestPract Res Clin Rheumatol.* 2003;17:563-574; & Arnold LM, et al. *J Clin Psychiatry.* 2006;67:1219-1225.

There is evidence that genetic factors may also play a role in the development of FM. Research has demonstrated that FM is potentially associated with polymorphisms of genes in the serotoninergic, dopaminergic and catecholaminergic systems. Many researchers and physicians believe that dopamine dysfunction is centrally responsible for the symptoms associated with FM. Others believe that decreased serotonin levels are involved in the pathophysiology of FM. Increasing attention is being devoted to irregularities of the central nervous system as the underlying mechanism of FM. Patients with FM commonly have elevated corticotrophin releasing hormone (CRH) and elevated Substance P in the cerebrospinal fluid, and increased activated mast cells and chemokines (MCP-1 and IL-8) in the blood.

...Epidemiology...

The National Institutes of Health (NIH) estimates that FM affects approximately 5 million adult Americans, or roughly 2% of the general population. The American Fibromyalgia Syndrome Association (AFSA) pegs the prevalence higher, at approximately 3 to 5% of the general population. These statistics are in agreement with the National Fibromyalgia Association (NFA), which estimates approximately 10 million Americans with FM.

Diagnosis is usually made between the ages of 20 and 50 years, and incidence tends to rises with age. In fact, by age 80, approximately 8% of adults meet the ACR classification of FM. Diagnosis is often done by a rheumatologist (~42% of the time) or general practitioner (~35% of the time).

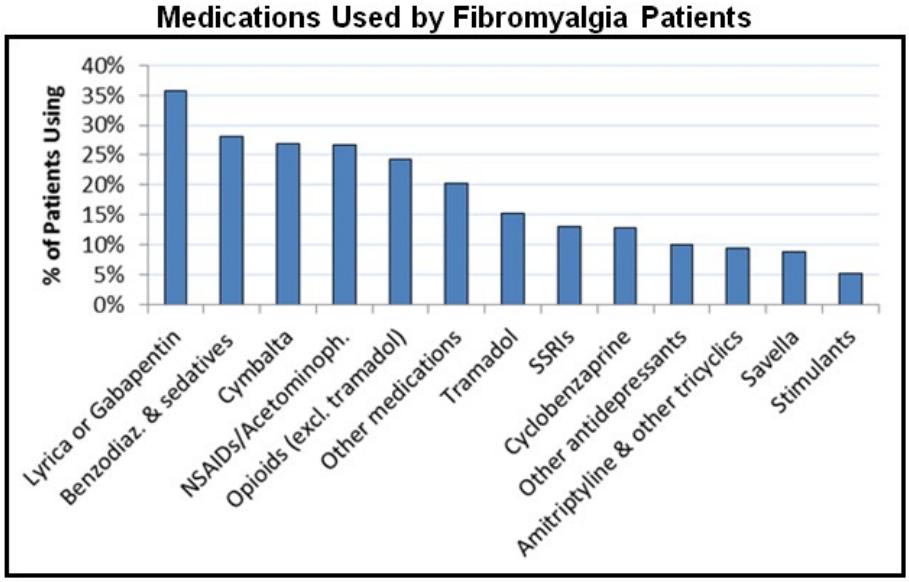
Women outnumber men diagnosed with FM by 9 to 1. Many female FM patients report flare-ups associated with their menstrual cycle. As noted above, there is a high correlation of FM and endometriosis. FM is often seen in families, among siblings or mothers and their children as well. Risk in developing FM increased by 8.5x if a first-degree family member has been diagnosed with FM.

…Treatment Options...

FM is a relatively new diagnosis. Prior to the 1990s it was often incorrectly diagnosed as osteoarthritis or chronic fatigue syndrome. In fact, a survey conducted by Russell K. Portenoy, MD, Chairman and Gerald J. Friedman Chair in Pain Medicine and Palliative Care at the Departments of Pain Medicine and Palliative Care, Beth Israel Medical Center, New York, NY, in 2007 found that 46% of newly diagnosed FM patients (n=2,596) consulted between 3 and 6 physicians before being finally being diagnosed with FM.

There is no cure for FM. Treatment typically consists of symptom management. Beside cognitive behavioral therapy and physical therapy, data suggests that FM patients are high pharmacological treatment seekers. Over 50% of FM patients visit their treatment physician over five times a year. Contrast this with the insomnia market, for example, where only roughly 10% seek pharmacological help. For FM therapy seekers, nearly three-fourths spend between $100 and $500 per month on OTC medications and nearly two-thirds spend the same amount on prescription medications.

FM is a highly complex disease, with manifestation of pain, mood and psychological disorders, and sleep disturbances. The NFA notes healthcare practitioners should, "Establish a multifaceted and individualized approach ..." for each specific patient depending on the severity of the symptoms in pain, mood, and sleep. There is no universally accepted standard-of-care. As such, multi-pharmacology is the norm for treating patients with FM. A recent paper by Robinson et al. (2012) describes a prospective study of treatment modalities and burden of disease in 1700 fibromyalgia patients recruited from rheumatology, primary care, physical medicine, and other practices believed representative of the distribution of physician types seen by fibromyalgia patients. The average number of medications taken per patient was 2.6, with the most common as shown in the Figure below.



The strengths and limitations of some key drugs widely used in the treatment of fibromyalgia are summarized below:

Lyrica: There were no FDA approved medications for FM until 2007 when the U.S. FDA approved Pfizer's Lyrica (pregabalin). Lyrica is a second-generation alpha-2-delta ligand calcium channel blocker that decreases the release of neurotransmitters including glutamate, noradrenaline, substance P and calcitonin gene-related peptide. Pfizer designed the drug as a more potent successor to gabapentin. The approval of Lyrica was a major step forward for the treatment of FM associated pain. The drug replaced the use of off-label analgesics, including gabapentin, but does little to address the mood or sleep-related issues associated with FM. Pfizer sold $4.2 billion worth of Lyrica worldwide in 2012. U.S. sales of Lyrica totaled $1.8 billion. FDA approvals include neuropathic pain and fibromyalgia. We estimate that around 1/3rd of Lyrica prescriptions, or around 3.2 million prescriptions annually in the U.S. accounting for roughly $500 million in sales, are in FM.

Benzodiazepines and non-Benzodiazapine Hypnotics/Sedatives: Benzodiazepines such as clonazepam are widely used in the treatment of fibromyalgia, both for pain control and to address issues of disturbed, un-refreshing sleep. However, a recent Cochrane Review (Corrigan 2012) found no controlled clinical trials supporting their efficacy in the treatment of this disorder. Tolerance, dose escalation, and dependence are important risks. Studies of the benzodiazepine alprazolam in healthy volunteers show that these drugs decrease the amount of time spent in slow wave (deep) sleep, suggesting the potential to aggravate the problem of non-restorative sleep in fibromyalgia.

Cymbalta and Savella: In 2008, the U.S. FDA approved Eli Lilly's Cymbalta (duloxetine), a serotonin-norepinephrine reuptake inhibitor (SNRI) for the treatment of FM. Cymbalta has been shown to address pain and mood / psychological disorders associated with FM. The drug has only a modest benefit on improvement in quality (restorative) sleep. Still, however, the approval of Cymbalta facilitated the replacement of older generation and off-label use of anti-depressants for the treatment of FM. Lilly sold $4.2 billion worth of Cymbalta worldwide in 2012. U.S. sales of Cymbalta totaled $1.7 billion. FDA approvals include major depressive disorder, diabetic peripheral neuropathic pain, general anxiety disorder, and fibromyalgia and chronic musculoskeletal pain. We estimate that around 1/5th of U.S. Cymbalta sales, or around 3.5 million tablets annually in the U.S. accounting for roughly $550 million in sales, are in FM. In 2009, the U.S. FDA approved Forest Labs Savella (milnacipran), a serotonin-norepinephrine reuptake inhibitor (SNRI) for the treatment of FM. Savella is only indicated for the treatment of FM. Sales were approximately $104 million in 2012.

NSAIDS and Acetaminophen: NSAIDs and acetaminophen are widely used in fibromyalgia both as prescription medications and as over the counter remedies. However, there is no evidence supporting their utility in fibromyalgia, and several studies have concluded that they offer no benefit. Fibromyalgia appears to be a disorder of hyper-reactivity of the central nervous system. NSAIDs and acetaminophen are believed to exert their activity primarily or exclusively in the periphery.

Tramadol and other Opioids: Opioid use is common for the treatment of severe pain. In fact, almost 40% of all FM patients will try opioids as a treatment option for managing the pain associated with FM. However, opioids carry significant side effects and addiction risk, so they should be used with caution. Opioids may also worsen mood (increase depression) and have little to no effectiveness in restorative sleep.

Tramadol is a centrally acting analgesic with atypical opioid and anti-depressant-like activity. The drug is moderately effective in treating FM pain. Effects on mood and restorative sleep are less predictable. Side effects included constipation, drowsiness, nausea, headache, and dizziness. In addition, long- term use of tramadol may be associated with physical dependence and withdrawal syndrome.

Naltrexone, an opioid antagonist, at very low dosage has been found to be effective in reducing fibromyalgia symptoms in a small controlled trial. Naltrexone also acts at very low dosage to inhibit microglia cells thereby reducing pro-inflammatory cytokines and neurotoxic superoxides. The use of other opioids for the treatment of chronic pain conditions is controversial, and subject to increasing regulatory oversight in most jurisdictions.

Antidepressants: In addition to the SNRI antidepressants Cymbalta and Savella (described above), tricyclic antidepressants and SSRIs have also been used for the treatment of fibromyalgia. These drugs are used in a multi-modal manner to treat pain, sleep disturbances, and the emotional co-morbidities commonly found in fibromyalgia including anxiety and depression. The tricyclics are regarded by many as being more effective for the treatment of pain and sleep disturbances than SSRIs, but they also produce more severe side effects such as dry mouth, sedation, and constipation.

Cyclobenzaprine: Cyclobenzaprine, developed by Merck as a muscle relaxant, it structurally a close homologue of the tricyclic antidepressant amitriptyline. Most commonly it is used taken at bed time, with the goal of enhancing onset and quality of sleep. We discuss cyclobenzaprine in greater detail below.

...Treatment Guidelines...

The extent of the unmet medical need in fibromyalgia is illustrated in part by the lack of any real consensus on how it should be best treated. This is illustrated in the table below, which shows the high degree of divergence among published meta analyses and treatment guidelines.

Treatment Guidelines & Systemic Reviews

	Canadian Guideline [a]	German Guideline [b]	Spanish Guideline [c]	JAMA Practice Guideline [d]	Uni of Portland Systematic Review [e]
Lyrica	Recommended	Recommended for short term use only	Recommended	Modest evidence for efficacy	Evidence supports efficacy in pain & sleep disturbances
Benzodiazepines / Sedatives	Not Recommended	Not Recommended	Not Recommended	No evidence for efficacy	
Cymbalta / Savella	Recommended	Recommended if comorbid depression or GAD for short term use	Recommended if comorbid depression or GAD	Modest evidence for efficacy	Evidence supports efficacy in pain, mood, and sleep disturbances
Acetominophen / NSAIDs	Recommended	Not Recommended	Not Recommended	No evidence for efficacy	
Tramadol	Recommended in select patients		Recommended	Modest evidence for efficacy	
Other Opioids	Not Recommended	Not Recommended	Not Recommended	No evidence for efficacy	
Tricyclics	Recommended	Recommended for short term use only	Recommended	Strong evidence for efficacy	Evidence supports effects on pain & fatigue
SSRIs	Recommended	Recommended for short term use only	Recommended if comorbid depression or GAD	Modest evidence for efficacy	Evidence supports efficacy in pain, sleep problems. Fatigue[f]
Cyclobenzaprine	Recommended	Not Recommended	Recommended	Strong Evidence for Efficacy	Modest evidence for effect on pain, sleep disturbances

[a] Fitzcharles 2012
[b] Sommer 2012
[c] de Miquel 2010
[d] Goldenberg 2004
[e] Smith-B 2011
[f] Efficacy finding mostly specific to fluoxetine

Separate from these academic studies, which attempt to evaluate the strength of evidence for specific treatment modalities based in part on the number of clinical trials that have been performed, are surveys of patient experience. A paper by Bennett (2007) describes an internet survey of 2,596 fibromyalgia patients. This study unfortunately occurred before Lyrica, Cymbalta, or Savella were approved in this indication, but is informative regarding patient perceptions of relative effectiveness of the other drugs. The scatterplot below shows the responses of patients to questions regarding the effectiveness of various drug treatments as well as what drugs they are currently taking.

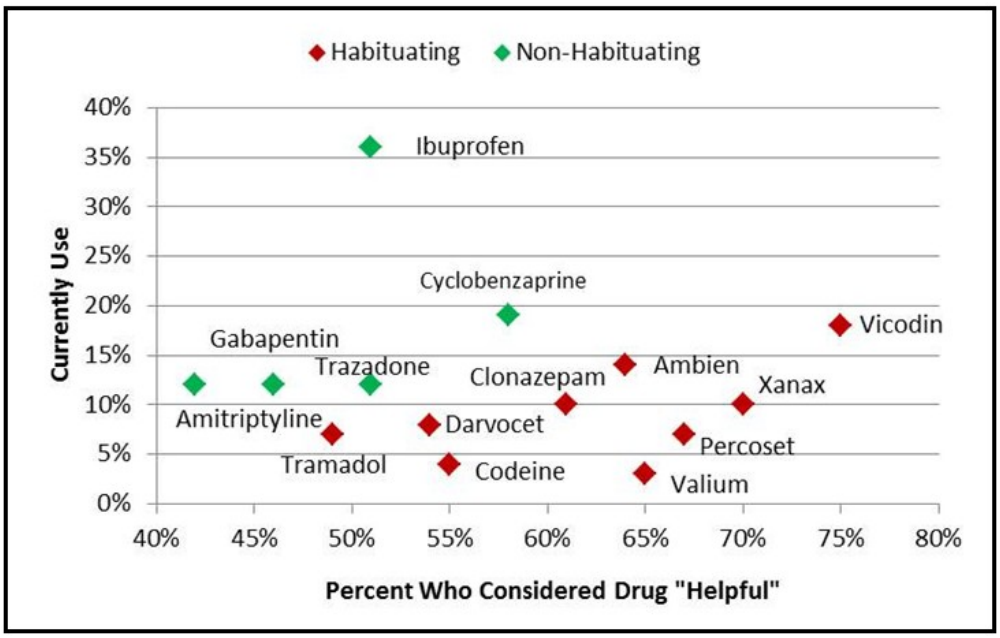
Several factors stand out:

- Ibuprofen is widely used but not being considered exceptionally effective. This outcome likely reflects prescriber perceptions of a relatively benign side effect profile for this drug.

- Medications receiving the highest effectiveness ratings from patients include:
  - → The narcotic painkillers Vicodin and Percoset;
  - → Anxiolytic benzodiazepines such as Xanax, Clonzaepam, Valium, and
  - → The sleep aid Ambien, which in many patients loses effectiveness over time

The medications most widely regarded as effective by patients are not the most widely used, as they tend to be those which raise prescriber concerns regarding the potential for habituation or need for escalating doses to maintain the same level of efficacy (tachyphylaxis). Among the medications with limited habituation and tolerance liabilities, cyclobenzaprine stands out as being perceived as effective by the highest percentage of patients.

Current Medication Use Vs. Patient-Percieved Effectiveness



...Market Size...

Frost & Sullivan conducted a market study on behalf of Tonix Pharmaceuticals that concluded the total prescription market for FM was approximately $1.2 billion in 2010. Frost & Sullivan concluded that the market has grown at a compound annual growth rate of 18% since 2007. Decision Resources estimates that approximately $1.1 billion of the $1.3 billion market in 2011 was on-label sales of Lyrica (~$450M), Cymbalta (~$550M), and Savella (~$100M), with the other $0.2 billion coming from off-label use of drugs like Tramadol, naltrexone, and cyclobenzaprine. We note that sales of off-label cyclobenzaprine are muted by the low cost of the generic molecules. In actual prescription numbers, Tonix management estimates that cyclobenzaprine is third most commonly prescribed drug for FM.

Cyclobenzaprine Shows Efficacy in Fibromyalgia Pain, Tenderness, Depression, and Sleep Disruption

Sleep disturbances in fibromyalgia are believed to contribute to exaggerated pain sensitivity. Cyclobenzaprine and amitriptyline each have sedating and sleep modulating profiles, and have widely been prescribed for use before bedtime to enhance sleep. Tonix is developing low dose cyclobenzaprine for the treatment of sleep disruption and pain in fibromyalgia.

In December 2011, data from a phase 2a study with a low dose formulation of cyclobenzaprine was published by the Sleep Disorders Clinics of the Centre for Sleep and Chronobiology, University of Toronto, Ontario, Canada (supported by Tonix Pharmaceuticals Inc.) in the Journal of Rheumatology (38(12):2653-63). The paper is called, "Effects of bedtime very low dose cyclobenzaprine on symptoms and sleep physiology in patients with fibromyalgia syndrome: a double-blind randomized placebo-controlled study."

The trial was a randomized, double-blind, placebo-controlled, dose-escalating, parallel-design study in patients with FM and disrupted sleep. A total of 36 patients (1:1 very low dose (VLD) cyclobenzaprine vs. placebo) were treated for 8 weeks. Doses were taken between dinner and bedtime. The dosage was 1 mg for the first 7 days, after which, if clinically indicated and according to tolerability, the daily dose could be increased up to 4 mg (mean dose was 3.1 mg at week 8). We present the key findings form the data below.

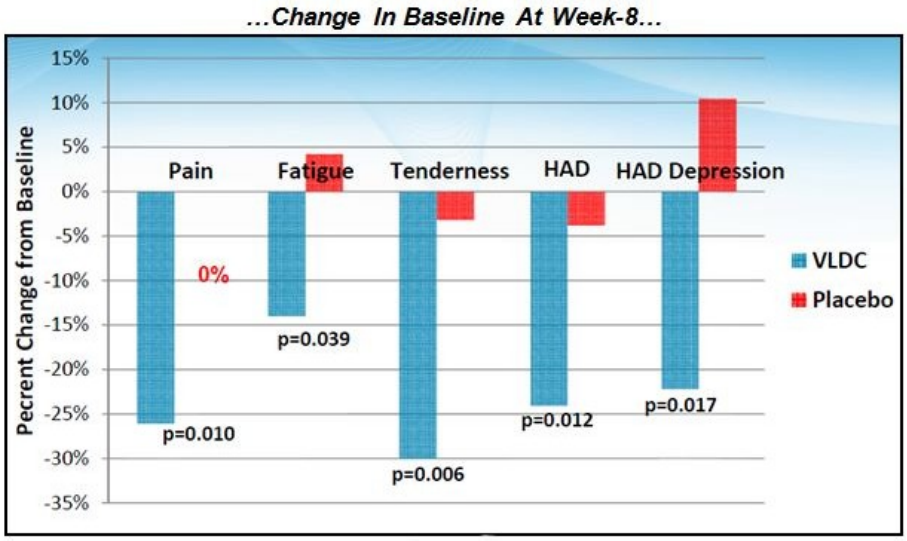
Tolerability: VLD cyclobenzaprine was well tolerated, with only 1 severe AE (headache) compared to five SAEs in the placebo group. The most common treatment related adverse events can be found in Figure 4, and was comparable between VLD cyclobenzaprine and the placebo. There were no serious adverse events in either group.

Pain: Musculoskeletal pain was rated on a 7-point scale (0 - 6) and showed patients on VLD cyclobenzaprine had a 26% reduction at week 8 (1.7 vs. 2.3, p=0.010) vs. no change for the placebo (p=0.044 vs. placebo).

Fatigue: Fatigue was rated on a 7-point scale (1 - 7) and showed patients on VLD cyclobenzaprine had a 14% reduction at week 8 (4.3 vs. 5.0, p=0.039) vs. a 4% (not significant) worsening for the placebo (4.9 vs. 4.7) (p=0.126 vs. placebo).

Tenderness: Application pressure was applied to specific body regions to assess tenderness. Patients on VLD cyclobenzaprine showed a 30% improvement in tenderness (18.6 vs. 14.3, p=0.006) vs. 1% (not significant) for the placebo (16.1 vs. 15.6) (p=0.029 vs. placebo).

Mood: Mood scores were assessed by the Hospital Anxiety and Depression Scale (HAD). Patients on VLD cyclobenzaprine showed a 24% reduction in hAd score (10.4 vs. 13.7, p=0.012) and 22% reduction in HAD depression (4.9 vs. 6.3, p=0.017) vs. a 4% reduction in HAD score (15.1 vs. 15.7) and 10.4% worsening in depression (7.4 vs. 6.7) for the placebo at week-8. Scores for HAD (p=0.067) and HAD depression (p=0.023) vs. placebo showed encouraging trends.



Effects On Sleep: Effects on sleep were assessed by using polysomnogram (PSG) recordings. PSG was performed at screening, at baseline, and typically at Weeks 2, 4, and 8. In the VLD cyclobenzaprine group from baseline to Week 8, total time awake decreased 38.5% (0.8 to 1.3 hrs, p=0.011), while total sleep time increased 12.3% (5.7 to 6.4 hrs, p=0.005), and sleep efficiency 15.6% (73.6% to 85.1%, p=0.023). In contrast, placebo treatment did not result in statistically significant changes in any of these measures. Compared to placebo, VLD cyclobenzaprine treatment did not significantly change total time awake, total sleep time, or sleep. Within the VLD cyclobenzaprine group from baseline to Week 8, VLD cyclobenzaprine treatment did not significantly change the percentages of Stage 1, 2, 3, or 4 or REM sleep (Figure 6).

To conduct a more thorough analysis of sleep quality, the authors assessed cyclic alternating pattern (CAP), an objective physiological measure of electroencephalographic (EEG) activity within non-REM sleep - essentially a measure of sleep maintenance and fragmentation. CAP in sleep has been shown to reflect disturbed sleep and may give a more accurate picture of sleep quality. A CAP sequence consists of two or more CAP cycles each having an A and B phase lasting between 2 and 60 seconds. Subtype A1 may occur when the brain is trying to maintain sleep. The other two subtypes A2 and A3 may occur due to central nervous system arousal. The higher the A1 phase the better the sleep stability. The higher the A2+A3 phase, the greater the sleep disturbance. Patients with FM have been shown to demonstrate significantly higher levels of A2+A3 (Cyclic alternating pattern: A new marker for sleep alteration in patients with fibromyalgia? J. Rheumatol 2004;31:1193-9).

Sleep EEG	VLDC	Placebo	p
$CAP_{A2+A3(Norm)}$ ≤33%	72%	33%	0.019

	VLDC $CAP_{A2+A3(Norm)}$ Correlation	
Variable	r	p
Fatigue	0.617	0.006
HAD score	0.505	0.033
HAD depression subscore	0.556	0.017
Patient-rated change in fatigue	0.614	0.007
Clinician-rated change in fatigue	0.582	0.011

The phase 2a data show that patients receiving VLD cyclobenzaprine had a meaningful and statistically significant reduction in A2+A3 phase (72% of treated patients had a reduction of 33% or more vs. only 33% for the placebo group, p=0.019) (Figure 7). Increased levels of A2+A3 have a high correlation to other symptoms of FM, including fatigue and depression (Cyclic alternating pattern: A new marker for sleep alteration in patients with fibromyalgia? J. Rheumatol 2004;31:1193-9).Based on the data seen in this trial, and results described in a comparative summary of Cymbalta, Savella, and Lyrica performed by the American Pain Society (Hauser 2010) the efficacies of these three drugs and VLD cyclobenzaprine can be summarized as shown below:

	Pain	Fatigue	Sleep Disruption	Depression
Cymbalta	Yes	No	Yes	Yes
Savella	No	Yes	No	Yes
Lyrica	Yes	Yes	Yes	No
LD Cyclobenzaprine	Yes	Yes	Yes	Yes

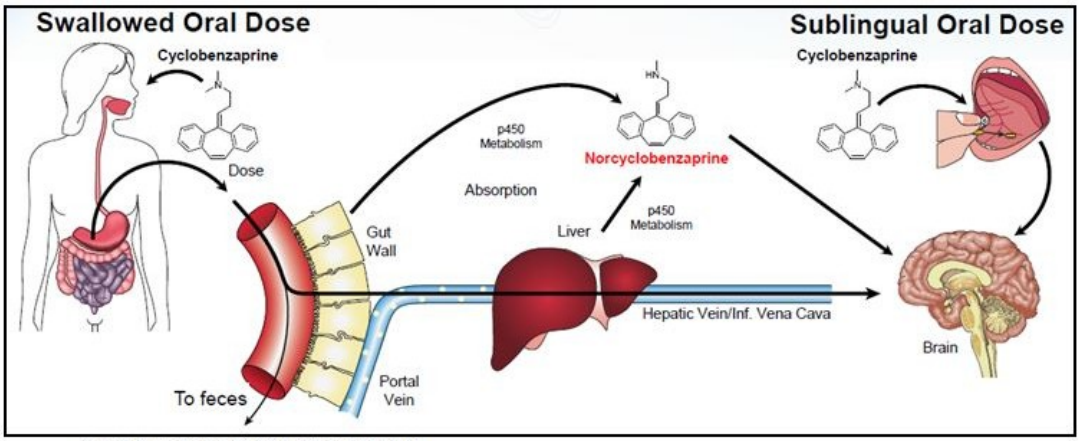
...Sublingual Administration Provides a Pharmacokinetic Profile Ideal for Bedtime Dosing...

In order to obtain a pharmacokinetic profile that is optimized for addressing sleep disruption in fibromyalgia, Tonix is developing a sublingual very low dose cyclobenzaprine formulation, TNX-102-SL. This novel sublingual formulation is designed specifically for bedtime dosing in patients with FM. TNX-102-SL is a novel formulation with rapid absorption and minimal next-day somnolence.

When cyclobenzaprine is administered by the traditional oral route, the time to peak serum concentrations is delayed due in part to the time required for the drug to travel through the digestive system to the intestines. It must then cross the lining of the intestine and be absorbed into the blood flow of the portal vein. It then travels into the liver before entering the general circulation.

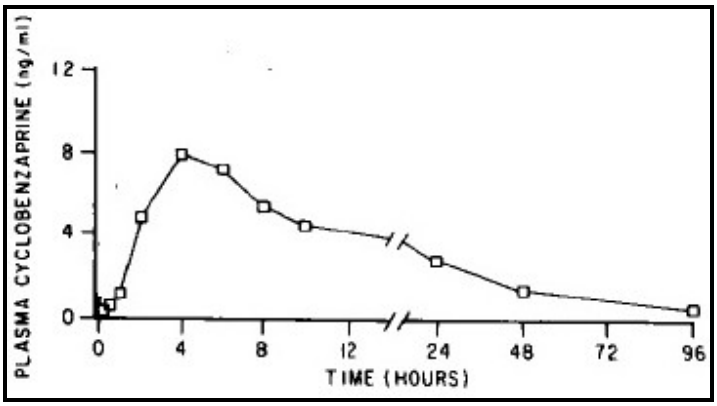
Within the liver cyclobenzaprine encounters drug metabolizing enzymes and is in part converted to des-methyl norepinephrine, a metabolite with similar biological activity and an extended serum half-life of 31 hours. A portion of the cyclobenzaprine is also excreted into the bile and thus back into the intestine. A fraction of this excreted material may be reabsorbed in a process called enterohepatic recirculation. This slows the transfer of drug from the intestines to the general circulation, such that a full four hours passes between taking the drug and peak serum levels.

Overall, oral administration of cyclobenzaprine leads to a lengthy delay until peak serum levels are achieved, and once established, high serum levels persist for up to a full day. Furthermore, a long-lived biologically active metabolite is formed that exacerbates the effects of the persistently high serum levels of the parent drug. For rapid sleep onset, the patient must remember to take a tablet several hours before bedtime. She may then remain groggy and sedated around the clock due to the slow absorption of the drug and the extended half-life of the nor-methyl metabolite. Daytime sedation is particularly problematic for FM patients, who already struggle with chronic fatigue.



Source: Tonix Inc Investor Presentation (Sept. 2012)

The pharmacokinetic profile of orally dosed cyclobenzaprine is shown in the Figure below. As noted above, 4 hours are needed to achieve maximum serum levels. Twenty-four hours after administration, serum levels remain close to one-third their maximum level.



Source: Till (1982)

In late July 2012, Tonix completed a comparative bioavailability study testing a new 2.4 mg sublingual (SL) formulation of TNX-102. The phase 1b open-label trial enrolled 23 healthy volunteers looking at measures of cyclobenzaprine (and norcyclobenzaprine) in plasma and urine at various time points over a 72 hour period. Tonix also assessed the safety and tolerability of TNX-102-SL over a month long period.

Arms	Assigned Interventions
Experimental: SL TNX-102 at pH 3.5 2.4 mg TNX-102 sublingual solution (2.4 mg/mL) in PBS at pH 3.5	Drug: SL TNX-102 2.4 mg at pH 3.5 1 dose of 2.4 mg TNX-102 sublingual solution (2.4 mg/mL) in PBS at pH 3.5, administered as 1 mL held under the tongue for 90 seconds without swallowing
Experimental: SL TNX-102 at pH 7.1 2.4 mg TNX-102 sublingual solution (2.4 mg/mL) in PBS at pH 7.1	Drug: SL TNX-102 2.4 mg at pH 7.1 1 dose of 2.4 mg TNX-102 sublingual solution (2.4 mg/mL) in PBS at pH 7.1, administered as 1 mL held under the tongue for 90 seconds without swallowing
Active Comparator: Cyclobenzaprine tablets 5 mg cyclobenzaprine tablet once	Drug: Cyclobenzaprine Tablet 1 x 5 mg cyclobenzaprine tablet, swallowed with 240 mL of room-temperature water
Active Comparator: Cyclobenzaprine IV 2.4 mg cyclobenzaprine USP in PBS (0.6 mg/mL) at pH 7.4	Drug: Cyclobenzaprine IV 1 dose of 2.4 mg cyclobenzaprine USP in PBS (0.6 mg/mL) at pH 7.4, administered intravenously as a 4 mL bolus injection over 30 seconds

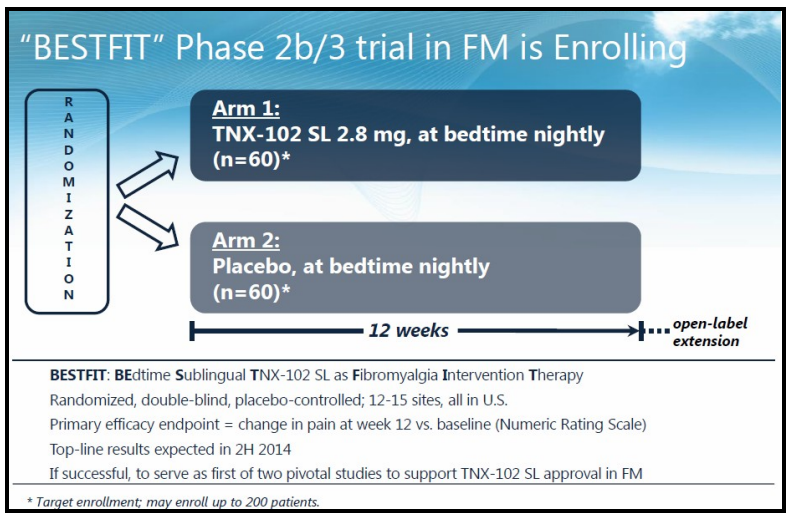
The PK results demonstrated that the solution formulation of TNX-102-SL delivered cyclobenzaprine to the systemic circulation more efficiently than the sublingual solution of a simulated crushed tablet and faster than the ingested oral tablet. We believe this translates to more rapid effects compared with current generic cyclobenzaprine products, increased dosage precision and decreased potential for morning grogginess / residual effect.

The Development Plan for TX-102

Tonix held an End-of Phase 2/Pre-Phase 3 meeting with the FDA to discuss its proposed NDA plan for TNX-102 SL in February 2013. Official FDA meeting minutes indicate FDA acceptance of the clinical program and provide clear direction to achieve a successful NDA filing of TNX-102-SL in fibromyalgia.

...Registrational Trials...

The registrational clinical trials will consist of two randomized, double-blind, placebo-controlled 12-week safety and efficacy studies in fibromyalgia patients who will take either a TNX-102 SL (cyclobenzaprine HCl 2.8 mg) tablet or placebo at bedtime. The primary endpoint of both trials will be the change in pain from baseline to Week 12 as measured by the Numeric Rating Scale (NRS). The company plans to conduct these trials in sequence, and has begun dosing in the first of these, called BESTFIT, as of September 2013. This trial will enroll approximately 120 fibromyalgia patients, and top-line data are anticipated to become available in late 2014.



We note the primary endpoint planned for these trials is similar to that utilized by Pfizer and Eli Lilly to gain approval for Lyrica and Cymbalta, respectively, for the treatment of fibromyalgia syndrome. Placebo response will be a key issue to watch. Tonix plans to include a 1-2 week wash-out period prior to randomization. We note the Pfizer phase 3 study with Lyrica showed a placebo response rate of nearly 50%. The company will also collect information on secondary endpoints, including NRS scores at other time points during the 12 week study, the Fibromyalgia Impact Questionnaire (FIQ), and the Patient Global Impression of Change (PGIC). We suspect that the trial will take about 12 months to enroll and report top-line data, at an all-in cost of around $3-4 million.

...Pharmacokinetic Reference Study...

Along with the phase 2b study noted above, Tonix plans to conduct a multi-dose pharmacokinetic study with TNX-102-SL in comparison to generic cyclobenzaprine in a multiple-day dosing (once daily) study. In the study, peak and trough blood levels of cyclobenzaprine will be measured in subjects that receive either TNX-102-SL or generic cyclobenzaprine immediate release for 4-5 consecutive days. The goal of the study is to show a bridge between 2.8 mg TNX-102-SL and generic 5 mg cyclobenzaprine that will allow for use of the generic tablet as a reference product in the planned 505(b)(2) NDA submission. We estimate the cost here at around $0.5 million.

...Next Day Drowsiness / Cognitive Effects Study...

In order to differential TNX-102-SL from the readily available generic cyclobenzaprine, Tonix plans to conduct a small study designed to evaluate next morning drowsiness and other cognitive measures following the bedtime dosing of either TNX-102-SL or generic cyclobenzaprine immediate release. We believe it is imperative for Tonix to clearly show a benefit to dosing 2.8 mg TNX-102-SL versus generic 5 mg cyclobenzaprine on measures such as next morning drowsiness and on other cognitive functions for else market penetration for the product will be negligible. We estimate the cost here at around $0.5 million.

...Safety Extension Study...

Following the completion of the double-blind randomized portion of these studies, patients may be eligible to enroll in open-label extension studies of TNX-102-SL. The FDA agreed that the safety database needed to support a 505(b)(2) NDA submission for TNX-102-SL would contain a total exposure of at least 300 fibromyalgia patients, with at least 100 patients receiving TNX-102-SL for six months and at least 50 patients for one year.

Intellectual Property

Management has stated that they have applied for patent protection for the unique pharmacokinetic profile of very low dose cyclobenzaprine administered sublingually, and for the eutectic mixture that makes this formulation possible. We believe that these applications have a high probability of being granted and that they will be highly defensible. A eutectic mixture is a mixture of two compounds that is low melting, and thus rapidly-dissolving. Such mixtures are typically found by serendipity, and it would be very difficult for a competitor to identify an alternative mixture with similar properties. The pharmacokinetic application covers the actual rate and extent of absorption of the drug substance into the bloodstream. Thus the very profile required by the FDA for an ANDA filing is protected by the IP, even if a generic competitor is able to produce a non-infringing formulation that is bioequivalent. Purdue Pharma used this type of patent to protect its lucrative OxyContin franchise for many years, and it withstood multiple Paragraph IV challenges.

Other pending applications include U.S. application 13/157,270, “Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine”, which was filed in 2011. Given its 2010 priority date, this application is expected to provide protection through 2030. Granted U.S. patents are listed in the table below. We believe the granted patents are less critical than the applications described above. The granted patents have early priority dates, and thus provide only a limited period of protection. Similar patents have been granted internationally.

Number	Name	Expiration
US 6,541,523	Methods for Treating or Preventing Fibromyalgia Using Very Low Doses of Cyclobenzaprine - USA	August 11, 2020
US 6,395,788	Methods and Compositions for Treating or Preventing Sleep Disturbances and Associated Illnesses Using Very Low Doses of Cyclobenzaprine - USA	August 11, 2020
US 6,358,944	Methods and Compositions for Treating Generalized Anxiety Disorder - USA	August 11, 2020

Reimbursement and Generic Competition

Important concerns for any company seeking to develop a reformulation of a generic drug are those of competition from the original formulation and the willingness of payers to reimburse for the new one. Recent examples in which reformulations failed to get traction with physicians and/or payers include the insomnia drugs Intermezzo, a sublingual reformulation of zolpidem for sleep maintenance insomnia, and Silenor, a low dose reformulation of doxepin for sleep onset insomnia. Launched in the first quarter of 2010, Silenor achieved revenues of only $7.7 million in the first three quarters of 2013, and Intermezzo sales were considerably lower.

The commercial failure of Silenor (3 mg or 6 mg doxepin) is a direct result of the lack of differentiation between Silenor and generic 5 mg or 10 mg doxepin. To date, sales of Intermezzo (1.75 mg or 3.5 mg zolpidem tartrate SL) have been a significant disappointment to Transcept Pharmaceuticals and commercial partner, Purdue Pharma L.P. We believe this creates a significant perception hurdle for Tonix with investors, because Transcept did studies to show differentiation between Intermezzo 3.5 mg and generic 10 mg zolpidem (Ambien®), and uptake is still far below what both Transcept and Purdue had hoped.

We believe, however, that there are several important differences between the insomnia market and the fibromyalgia market. First, very few fibromyalgia patients describe their symptomatic relief as adequate in spite of taking an average of 2.5 medications supplemented by various forms of non-pharmacological therapy. These patients are profoundly ill, and the lack of satisfactory treatment options creates a tremendous driving force to try new therapies, even in the case of physicians who might normally regard reformulated drugs with skepticism. Furthermore, the ability to enhance sleep with drug formulation that provides minimal daytime exposure is a powerful marketing message in a therapeutic area in which fatigue is one of the most prominent patient complaints.

A second strong differentiator from the situation encountered by reformulated drugs for insomnia is that while the insomnia patient bears the great majority of the burden of inadequately treatment on their own, the costs of inadequately treated fibromyalgia are borne to a significant extent by payors. The cost of treating patients with fibromyalgia was examined in a Spanish study reported by Rivera et al (2012). Two hundred thirty two patients referred to rheumatology clinics with a diagnosis of fibromyalgia were evaluated at baseline for to determine their recent healthcare utilization. They were compared to a demographically matched control group of 110 healthy patients selected from clinic staff or accompanying relatives, both before and after optimization of medicinal therapies by a rheumatologist. The study found that at baseline, total healthcare expenditures for the fibromyalgia patients averaged €423 per month, approximately 3.6-fold that of the healthy controls. At baseline, these expenses consisted primarily of physician visits and non-pharmacological therapies such as physical therapy, hydrotherapy, and psychotherapy. After three months of optimized medical therapy, total average expenditures fell to €335, a decrease of 21%.

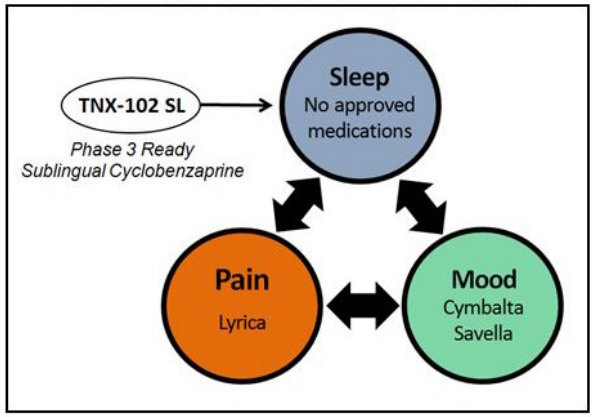
The final differentiator is the willingness of the patient to seek pharmacological help. Above we noted that over 50% of FM patients visit their treatment physician over five times a year. Contrast this with the insomnia market where only roughly 10% seek pharmacological help, and the majority are satisfied with generic zolpidem. For FM therapy seekers, nearly three-fourths spend between $100 and $500 per month on OTC medications and nearly two-thirds spend the same amount on prescription medications.

Revenue Model

Averaging the data obtained from the NIH, AFSA, and NFA, we estimate there are approximately 8 million Americans living with FM. Over 90% of these patients have sleep problems. Approximately 70% of FM patients report difficult in conducting normal daily tasks, such as light housework due to chronic fatigue. According to Decision Resources, U.S. sales of prescription drugs specifically for the treatment of FM totaled $1.4 billion in 2011. This figure includes sales of Cymbalta, Lyrica, and Savella of $595 million, $504 million, and $110 million, respectively.

Despite the availability of FDA approved products, we believe the current treatment options for FM continue to leave many patients dissatisfied. Existing approved FM medications such as Lyrica and Cymbalta, which focus on reducing FM-associated pain and mood disorder, respectively, do little to improve sleep quality. Insomnia medications such as Ambien and Lunesta improve total sleep time, but do little to improve the chronic fatigue associated with FM.

...TNX-102SL Aims To Fill A Market Void...



If Tonix can gain approval for TNX-102-SL in FM using standardized pain (NRS) endpoints in its phase 2b and phase 3 program, while also demonstrating improvement in symptoms of fatigue and sleep quality, we believe a meaningful market opportunity exists. Frost & Sullivan estimate that 50 million tablets of cyclobenzaprine were sold specifically for FM in 2010. We believe at least a third of FM patients would actively seek out prescription therapy, either as a monotherapy or an adjunctive therapy to Lyrica or Cymbalta, with their physicians support, and try a novel sublingual formulation of very low dose cyclobenzaprine. Tonix has successfully designed a superior 2.4 mg sublingual formulation of cyclobenzaprine to the readily available oral 10 mg generic. Does that mean there will be no, or even limited, generic substitution or competition once TNX-102-SL hits the market? No.

Based on the generic market, the target population for Tonix with TNX-102-SL is over 2 million patients. We think that the sublingual formulation clearly contains meaningful advantages over the generic oral formulation. These include rapid absorption and minimal next-day residual effects ideal for a bedtime dose, and avoidance of first pass metabolism and build-up of norcyclobenzaprine ideal for chronic dosing. Of course, all this will need to be confirmed in clinical trials.

For the purpose of our model, we assume Tonix (and its partner) can capture 5% share – that's one out of every twenty patients currently on generic oral cyclobenzaprine for FM switching to TNX-102-SL. At a cost of $6-7 per pill ($2,500 per year by 2020), with decent tier-2 and tier-3 coverage, we see TNX-102-SL as a $250 million peak drug. We expect that by 2017, both Lyrica and Cymbalta will be generic, and that Tonix commercial partner will have one of the only (if not the only) branded prescription medications for FM available.

Upgrading to Buy

FM is a complex medical disorder characterized by widespread musculoskeletal pain, fatigue, lack of sleep, and mood and memory issues. The National Pain Foundation estimates that 90% of all FM patients have sleep problems. Tonix is developing a sublingual formulation of cyclobenzaprine designed specifically for bedtime dosing in order to help patients improve quality (restorative) sleep and reduce the next-day pain and fibro-fog that is persistent with FM.

We believe this is a meaningful opportunity for Tonix, mainly because currently approved FM medications, such as Pfizer s Lyrica (pregabalin) and Lilly s Cymbalta (duloxetine), do little to improve sleep quality. Plus, cyclobenzaprine is a well-known and commonly used medication already for FM. Market research conducted by Frost & Sullivan found that cyclobenzaprine was the third most commonly prescribed medication for FM behind Lyrica and Cymbalta in 2011. Decision Resources estimates that approximately 50 million cyclobenzaprine tablets were taken by FM patients, off-label, in 2011 - That is 5% of the cyclobenzaprine market.

In recent months Tonix has achieved several key milestones including the completion of a 1-for-20 reverse stock split in May, raising gross proceeds of $20 million in cash from a secondary offering of 2.68 million units in August, and up-listing to the NASDAQ the same month. Adding to these achievements, on September 16, 2013, the company announced the initiation of enrollment of the Phase 2b BESTFIT trial of its proprietary reformulation of cyclobenzaprine, TNX-102SL in fibromyalgia.

These are all important steps which provide the firm with financial stability, a wider range of potential investors, the ability to fund its clinical development program, and which create a concrete timeline for approval of TNX-102-SL. Based on these positive steps and on the strong need for new medications to improve treatment and reduce treatment costs in fibromyalgia, we are upgrading Tonix to 'Buy' from our previous rating of 'Neutral'. We believe the stock is significantly under-valued at $4.18 per share. This price equates to a market capitalization of only $20 million, with a cash balance at the end of September 2013 of $7.4 million.

We have conducted a DCF analysis based on peak sales of TNX-102-SL at around $250 million in the U.S. and arrive at a fair-value price of $10 per share. This equates to 3x our peak sales estimate in 2022, discounted back to present day at a very aggressive rate of 40%.

PROJECTED FINANCIALS

Tonix Pharma
Income Statement

Tonix Pharmaceuticals	2011 A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E
TNX-102SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
TNX-102SL (PTSD)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Pipeline	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Research & Collaborations	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$10.0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$10.0**
YOY Growth	*100.0%*	-	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$1.2	$2.6	$0.7	$0.9	$1.6	$1.8	$5.1	$5.0	$5.0
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$2.2	$4.1	$1.3	$1.1	$1.5	$1.3	$5.2	$5.0	$5.5
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($3.4)	($6.7)	($2.0)	($2.1)	($3.1)	($3.1)	($10.3)	($10.0)	($0.5)
Operating Margin	*#DIV/0!*	-	-	-	-	-	-	-	-
Interest & Other Income	($0.1)	($2.8)	$0.0	$0.0	$0.0	($0.1)	($1.5)	($1.2)	($1.0)
Pre-Tax Income	($3.5)	($9.4)	($2.0)	($2.1)	($3.1)	($3.2)	($11.8)	($11.2)	($1.5)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($3.5)	($9.4)	($2.0)	($2.1)	($3.1)	($3.2)	($11.8)	($11.2)	($1.5)
Net Margin	*#DIV/0!*	-	-	-	-	-	-	-	-
Reported EPS	**($3.24)**	**($5.58)**	**($0.93)**	**($0.95)**	**($0.87)**	**($0.65)**	**($2.31)**	**($2.15)**	**($0.28)**
YOY Growth	*#REF!*	*72.3%*	-	-	-	-	*-58.6%*	*-6.7%*	*-86.9%*
Basic Shares Outstanding	1.07	1.69	2.16	2.20	3.54	4.90	5.10	5.20	5.30

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

HISTORICAL ZACKS RECOMMENDATIONS

INSERT CHART

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