

# Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

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## Scilex Holding Company (SCLX-NASDAQ)

### SCLX: Initiating Coverage-Providing Better Pain Relief

SCLX is developing pain relief products that don't involve opioids. We currently value SCLX at \$4.75 using a 10% discount ratio with the belief that estimate will rise as new products come to market.

### OUTLOOK

SCLX is filling a much-needed area of the health care sector, that of developing non-opioid pain relief products. The company already has commercialized products that are proven to improve patients' lives.

We believe SCLX is at the beginning of a rapid ramp higher, with new products in the pipeline and a dedicated sales team and manufacturing facility already in place.

Current Price (10/25/23) \$2.03  
Valuation \$4.75

### SUMMARY DATA

52-Week High \$14.80  
52-Week Low \$1.26  
One-Year Return (%) -80.57  
Beta 0.80  
Average Daily Volume (sh) 909,576

Shares Outstanding (mil) 150  
Market Capitalization (\$mil) \$305  
Short Interest Ratio (days) N/A  
Institutional Ownership (%) 78  
Insider Ownership (%) 8

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 2023 Estimate N/A

P/E using 2024 Estimate N/A

Risk Level Medium  
Type of Stock Small-Growth  
Industry N/A

### ZACKS ESTIMATES

#### Revenue

(in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	N/A	N/A	N/A	N/A	38.0 A
2023	10.6 A	12.6 A	13.4 E	13.7 E	50.3 E
2024	19.0 E	20.9 E	24.2 E	28.0 E	92.1 E
2025	28.5 E	29.0 E	30.0 E	30.9 E	118.4 E

#### Earnings

(per share)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	N/A	N/A	N/A	N/A	-0.17 E
2023	-0.22 E	-0.19 E	-0.17 E	-0.17 E	-0.75 E
2024	-0.15 E	-0.10 E	-0.08 E	-0.05 E	-0.38 E
2025	-0.08 E	-0.07 E	-0.06 E	-0.06 E	-0.27 E

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## INITIATION REPORT

We are pleased to be initiating coverage of Scilex Holding Company (SCLX) with a valuation of \$4.75.

Scilex Holding Company is a revenue-generating company that is focused on addressing one of the biggest issues facing humanity today—that of the overuse of opioids. Scilex is focused on developing non-opioid pain management products that provide the relief patients so desperately need, while avoiding the debilitating addiction that often comes with the use of opioids. Roughly 80,000 Americans died in 2022 from the overuse of opioids and there is no doubt that a good number of those started their opioid use to reduce physical pain of various types.

Scilex recognizes this problem and is committed to developing and commercializing solutions. And this isn't a clinical stage company, although Scilex has several exciting products in the development pipeline. Scilex currently has one major product on the market—ZTlido, which is a topical pain-relieving patch that has better adhesion and better proven pain reduction than comparable products. Sales of ZTlido are increasing as more doctors become aware of the product and its benefits.

The company isn't just resting on the success that ZTlido is showing, but pushing to get more pain-relieving products into the market to help patients that need pain relief. One of the major characteristics of this company that we appreciate and believe adds to the value proposition in the infrastructure already in place for ZTlido that can easily accommodate future pain-relieving solutions. The company has a national sales force in place that will target many of the same doctors and distributors for all its products, meaning that won't have to add substantially to labor costs with the launch of each new product into the market. Additionally, the company has its manufacturing facility with its partner in Japan in place already with ZTlido. And that facility has seen the potential for added demand from Scilex and added capacity to meet future demand. This ability to scale up production and marketing without adding to costs in a substantive way leads us to believe that SCLX is poised to move higher as margins and profitability grow.

The final thing we want to highlight in this summary section is the management team guiding Scilex. We have long believed that management is crucial to company success, and even more so in the drug development industry due to the regulatory hurdles. At the top of this team are CEO Jaisim Shah and Executive Chairman Henry Ji. Between these two leaders, the company benefits from over 60 years of global biopharmaceutical and biotechnology experience, including stints at companies such as Bristol-Myers Squibb, Biogen and Pfizer, among others. We don't believe that management means everything, but it often proves to be the difference between a financially successful company and one that isn't.

Details of the pipeline follow but we'll summarize by urging investors to take a look at SCLX. A company that has a growing revenue stream and a growing portfolio of products that provide desperately needed relief to millions of patients, without the problems associated with opioids is one that we believe has solid current prospects and excellent future ones.

## THE PRODUCTS

### ZTLIDO

As mentioned, the company's lead product ZTlido (lidocaine topical system) 1.8%, is a prescription lidocaine topical patch product approved by the U.S. Food and Drug Administration for the relief of pain associated with Post-Herpetic Neuralgia (PHN), which is a form of post-shingles nerve pain. Post-herpetic neuralgia (PHN) is a painful and often debilitating condition that can develop as a complication of herpes zoster, commonly known as shingles. Shingles is caused by the varicella-zoster virus (VZV), which also causes chickenpox. After a person recovers from chickenpox, the virus remains dormant in the nervous system. Later in life, it can reactivate and cause shingles.

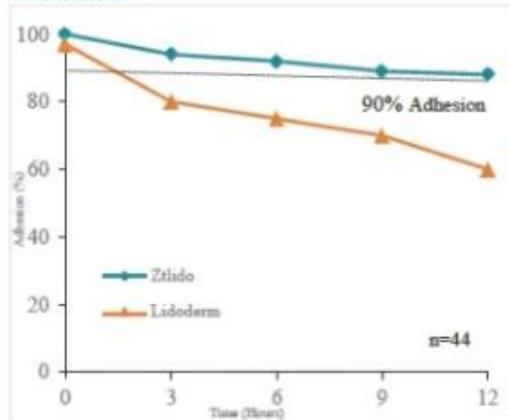
Here's a detailed explanation of post-herpetic neuralgia:

1. **Herpes Zoster Infection:** Shingles typically begins with a painful rash and blisters that appear in a specific dermatomal pattern (a specific area of the skin supplied by a single nerve). The rash is often accompanied by symptoms such as itching, burning, and sharp or shooting pain.
2. **Acute Phase:** Initially, during the active phase of shingles, the pain is attributed to the inflammation and damage caused by the virus as it travels along nerve pathways. Most people recover from shingles within a few weeks as the rash and pain subside.
3. **Development of PHN:** In up to 18% of shingles patients, the pain persists long after the rash has healed. This lingering pain is termed post-herpetic neuralgia. PHN is defined as pain that persists for more than three months after the shingles rash has disappeared. It results from damage to the nerves during the acute phase of shingles.
4. **Symptoms:** PHN is characterized by severe, burning, or stabbing pain in the affected area. The pain can be constant or intermittent and is often described as excruciating. It can be extremely sensitive to touch, temperature changes, or even the slightest breeze. The condition can last for weeks, months, or even years.

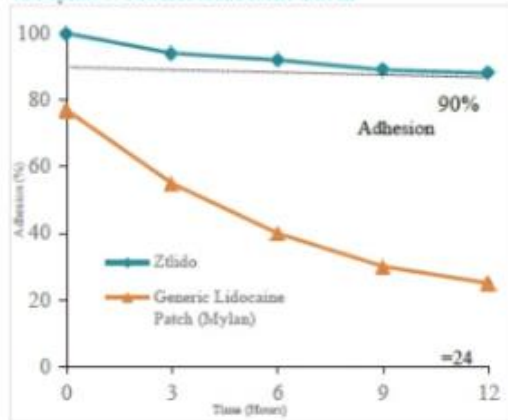
It's easy to see why patients suffering from the above condition benefit from a patch that relieves pain. The important thing here is that the Scilex patch, ZTlido, is a better patch than others on the market. Scilex employs anhydrous, single-layer, drug-in-adhesive, topical delivery system technology to keep its patches thin, light, and drug delivery locally targeted. Also, that single-layer system allows the patch to be easily cut into smaller sizes and it is designed to be flexible to fit and adhere to the various contours of the human body.

A patch, no matter how good the design, won't help much if it doesn't adhere to the area experiencing pain in a variety of situations. According to studies done by the company, ZTlido has 3.5 times greater average adhesion compared to a generic lidocaine patch. ZTlido also stayed attached following biking tests lasting two hours and continued to adhere even after being exposed to water, something that can't be said about conventional lidocaine patches. And studies initiated by the company versus a couple of major competitors dramatically show how the adhesion of ZTlido is superior:

**ZTlido Demonstrated Superior Adhesion Compared to Lidoderm**



**ZTlido Demonstrated Superior Adhesion Compared to Mylan's Generic Lidocaine Patch**



Source: Scilex Holding Company

This better adhesion also allows for more efficient delivery of the needed pain-relieving medication. For example, ZTlido has 1.8% lidocaine (by weight), while its major competitor has 5% lidocaine. Studies have shown, however, that the same amount of lidocaine is delivered to the patient due to the superior formulation and adhesion qualities. These superior qualities also likely contribute to ZTlido being the preferred branded lidocaine patch product for Pharmacy Benefit Managers (PBMs) and Managed Health Care Organizations.

And while the PHN market is a vital one and will benefit from ZTlido, lidocaine patches including ZTlido are used for many other painful conditions, like low back pain, neuropathic pain, and diabetic neuropathies. For example, the company has seen stellar results when pairing ZTlido with gabapentinoids with the company reporting that ZTlido, when combined with gabapentinoids, provide almost 50% additional pain relief compared to gabapentinoids alone.

There are several current treatment uses for gabapentinoids:

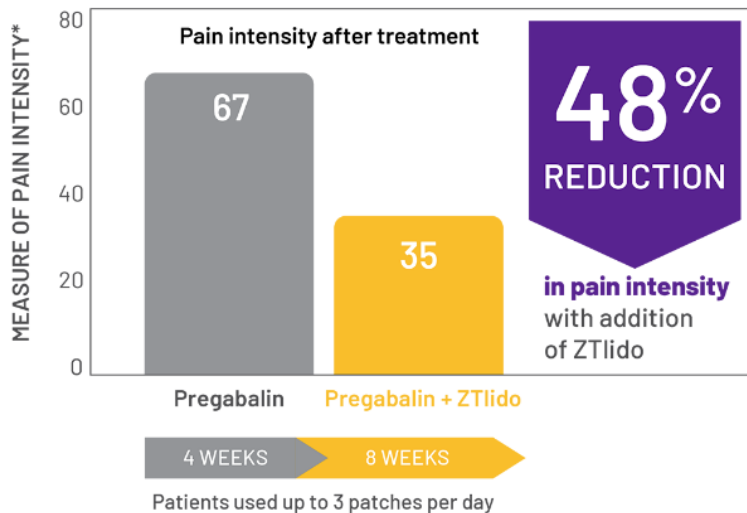
Gabapentinoids are a class of medications that are primarily used to treat chronic neuropathic pain, which is a type of pain that results from damage or dysfunction of the nerves. The two main drugs in this class are gabapentin and pregabalin. These medications are believed to work by affecting certain neurotransmitters in the brain and spinal cord, ultimately reducing abnormal electrical activity in nerve cells and helping to alleviate neuropathic pain. Here's an overview of gabapentinoids and their use in treating chronic neuropathic pain:

1. **Gabapentin (Neurontin) and Pregabalin (Lyrica):** These are the two most commonly prescribed gabapentinoids. While they have similar mechanisms of action, pregabalin is considered to have a more predictable and efficient absorption in the body.
2. **Mechanism of Action:** Gabapentinoids work by binding to a specific subunit of voltage-gated calcium channels in the central nervous system. By doing so, they reduce the release of certain neurotransmitters, such as glutamate, which play a role in transmitting pain signals.
3. **Conditions Treated:** Gabapentinoids are primarily used to treat chronic neuropathic pain associated with various conditions, including:
  - Diabetic neuropathy: Nerve pain resulting from diabetes.
  - Post-herpetic neuralgia: Pain that persists after a shingles outbreak.
  - Peripheral neuropathy: Nerve damage often related to conditions like HIV, chemotherapy, or certain infections.
  - Fibromyalgia: A chronic pain disorder characterized by widespread pain and tender points.
  - Neuropathic pain associated with spinal cord injury.

- Generalized anxiety disorder (pregabalin only): Pregabalin is also approved to treat generalized anxiety disorder.

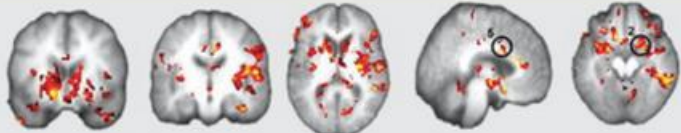
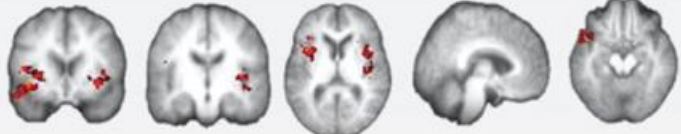

4. **Dosage and Administration:** Gabapentinoids are usually taken orally in the form of capsules or tablets. The dosage and frequency of administration depend on the specific condition being treated, the individual's response to the medication, and other factors. The dosage is often started at a low level and gradually increased to find the most effective and tolerable dose. Many patients never reach the minimum dose level needed to relieve pain due to the side effects.
5. **Effectiveness:** Gabapentinoids are considered effective in many cases of neuropathic pain, particularly when other pain management strategies, such as over-the-counter pain relievers or physical therapy, have been ineffective. However, their efficacy varies among individuals, and not everyone responds positively to these medications.
6. **Side Effects:** Common side effects of gabapentinoids can include dizziness, drowsiness, fatigue, and difficulty with coordination. These side effects can limit their use, especially in situations where activities such as driving or operating heavy machinery are necessary. Some individuals may also experience weight gain, edema, or mood changes.
7. **Dependency and Withdrawal:** There have been reports of dependency and withdrawal symptoms associated with gabapentinoids, particularly with pregabalin. It is important to use these medications as prescribed and under the guidance of a healthcare provider.

It is clear to us that the more a topical treatment can reduce the use of the above treatments, or at least provide more relief to the patient, the greater the benefit to the patient and that's where ZTlido comes in. Studies conducted by the company have shown that patients that pair lidocaine patches like ZTlido with existing gabapentinoids experience better results:



Source: Scilex Holding Company

ZTlido starts working immediately and provides relief locally. When used daily, 12 hours on and 12 hours off for at least 2 weeks, product shows central effect as seen in the MRI scans below. ZTlido can also reduce the pain areas in the brain:

SESSION	FMRI SHOWING MODULATION OF BRAIN ACTIVITY FOR SPONTANEOUS PAIN OF PHN BY ZTLIDO THERAPY	PAIN INTENSITY (0-10 SCALE)
Pretreatment		4.9
After 6 hours' ZTlido use		3.7
After 2 weeks' ZTlido use		2.9

The above results demonstrate the brain activity for spontaneous PHN pain is decreasing with treatment.

Source: Scilex Holding Company

Finally, patient market research studies have shown using ZTlido to the existing treatment plan resulted in improved patient functioning:



Source: Scilex Holding Company

In an effort to get the word out about the benefit of ZTlido, the company is ramping up the advertising for using ZTlido in conjunction with gabapentinoids based on the additional benefits seen in studies. Company management believes represents a market 10 times larger opportunity than the lidocaine patch market. As noted in the summary Scilex has an experienced sales force of over 65 people targeting over 10,000 primary care physicians, pain specialists, neurologists and palliative care physicians to promote ZTlido over other comparable treatments and how their patient could benefit.

And the company is able to meet the projected increase in demand as the manufacturing facility in Japan that the company contracts with recently upgraded capacity and is currently running at roughly 10% capacity according to Scilex management, which leaves plenty of room for production expansion. In addition, the company holds worldwide rights to ZTlido, excepting only Japan, and has partnered with distributors in the Middle East/North Africa region, where it expects to be selling ZTlido as soon as next year.

## GLOPERBA

The company is not resting on its ZTlido laurels, however, and continues to pursue non-opioid pain treatments. In that vein, Scilex in-licensed the exclusive right to commercialize Gloperba (colchicine USP) oral solution, an FDA-approved prophylactic treatment for painful gout flares in adults, in the U.S. Scilex is planning to commercialize Gloperba in 2024.

Gout flares, also known as gout attacks or acute gouty arthritis, are sudden and intensely painful episodes that occur in individuals with gout, a type of arthritis. Gout is characterized by the

accumulation of uric acid crystals in joints, which leads to inflammation and severe joint pain. Gout flares typically have the following characteristics:

1. **Sudden Onset:** Gout flares often come on suddenly, without warning. A person may be relatively symptom-free for extended periods between flares, and then suddenly experience intense pain in one or more joints.
2. **Severe Pain:** The hallmark of a gout flare is severe pain. The affected joint becomes extremely tender and sensitive to touch. The pain is often described as excruciating, throbbing, and unbearable. It can be so intense that even the slightest movement of the joint can be agonizing.
3. **Location:** Gout commonly affects the joint at the base of the big toe, although it can occur in other joints as well. Other frequently affected joints include the ankle, knee, and smaller joints in the hands and feet. The pain is usually localized to one joint at a time.
4. **Inflammation:** In addition to pain, gout flares are characterized by significant joint inflammation. The affected joint becomes red, swollen, and warm to the touch.
5. **Limited Mobility:** Due to the pain and inflammation, individuals experiencing a gout flare often have limited mobility in the affected joint. They may have difficulty walking or using the affected limb.
6. **Duration:** Gout flares can last anywhere from a few days to several weeks if left untreated. The duration of a flare can vary from person to person and may depend on the severity of the attack and how quickly it is treated.

According to research cited by the company, there are roughly 9 million gout sufferers in the US. The company acknowledges that there are already effective treatments for gout, primarily involving colchicine. However, the existing treatments have some potentially uncomfortable gastrointestinal side effects, that can become so severe for some patients that they quit taking colchicine. This is the market that Scilex believes their product can positively affect as Gloperba has been proven to have fewer and less severe side effects than existing treatments. Colchicine is not used for patients with chronic kidney disease (CKD) due to risk of toxicities with accumulation. Literature shows there can be as high as 70% of patients suffering from gout with some level of kidney disease. Gloperba can be given to those patients with CKD by reducing the dose of colchicine. Because Gloperba is a prophylactic treatment, it is used as a preventive measure before gout flares can occur. As such, it complements existing acute gout treatments.

## ELYXYB

The latest addition to the company's non-opioid pain management portfolio is Elyxyb (celecoxib oral solution) for treatment of acute migraine. Scilex is planning to continue the commercialization of Elyxyb in 2023 and beyond.

An acute migraine is a neurological condition characterized by recurrent, severe headaches that can be accompanied by other symptoms. Migraine attacks are typically episodic and can significantly impact a person's daily life. Here's an explanation of acute migraines:

1. **Pain:** The primary symptom of an acute migraine is a severe headache, which is often described as throbbing or pulsating. The pain is typically unilateral, meaning it affects one side of the head, but it can sometimes occur on both sides. The headache is usually intense and can last from a few hours to several days.
2. **Aura (in some cases):** About one in four people with migraines experience an aura before the headache phase. An aura is a series of sensory disturbances that typically develop gradually over a few minutes and can last for up to an hour. Common aura symptoms include visual disturbances like flashing lights or

zigzag lines, sensory changes, or even difficulty speaking. The aura phase is usually followed by the headache phase.

- 3. Other Symptoms:** Migraine attacks are often accompanied by other symptoms, which can vary from person to person and even from one episode to another. These may include nausea, vomiting, sensitivity to light (photophobia), and sensitivity to sound (phonophobia). Some individuals also experience neck pain, dizziness, or visual disturbances without a full aura.
- 4. Triggers:** Migraines can be triggered by various factors, which differ among individuals. Common triggers include stress, certain foods (e.g., aged cheeses, caffeine, alcohol), hormonal changes (such as menstrual periods), changes in sleep patterns, strong odors, and weather changes.
- 5. Duration and Frequency:** The duration of a migraine attack can vary widely, but most last from 4 to 72 hours if left untreated. The frequency of migraines also varies from person to person. Some people experience them only occasionally, while others have them more frequently, sometimes even multiple times a week.

According to the Migraine Research Foundation, there are approximately 39 million people suffering from migraines in the US, although that number could be higher due to unreported cases. Approximately 9 million of those people are being treated acutely and those are the patients that the company is targeting in the ongoing initial commercialization stage. Elyxyb studies have shown that the drug works quickly for many patients, a critical unmet need for Migraine patients. Elyxyb starts working in 30 minutes and within one hour almost a quarter of patients experienced pain freedom. At 2 hours, 34% of patients were pain free.

#### Time Elapsed and Percent of Patients Experiencing Relief from Elyxyb



Source: Scilex Holding Company

One of the other advantages of Elyxyb is that it can be used by the patient at any time during the migraine and in any place due to the small bottle the product is sold in, providing great flexibility for migraine sufferers.

The above products are the already approved drugs that are in the commercialization stage, but the company also has an impressive pipeline of drugs moving through the FDA approval process that we believe will enhance revenue and benefit patients in the coming years.

## THE PIPELINE

### SP-102

Furthest along the approval process is SP-102, which goes by the name of Semdexa, and is being developed for the treatment of low back pain and sciatica.

Sciatica is a term used to describe a set of symptoms rather than a specific medical condition. It refers to pain that radiates along the path of the sciatic nerve, which is the longest nerve in the human body. The sciatic nerve runs from the lower back, through the buttocks, and down each leg. Sciatica typically affects only one side of the body.



The most common cause of sciatica is compression or irritation of the sciatic nerve, often due to a herniated or slipped disc in the lumbar spine (lower back). Other potential causes of sciatica include spinal stenosis (narrowing of the spinal canal), spondylolisthesis (a condition where one vertebra slips over another), piriformis syndrome (compression of the sciatic nerve by the piriformis muscle in the buttocks), or even injury to the nerve itself.

The primary symptom of sciatica is pain, which can vary in intensity and location but usually follows the path of the sciatic nerve. Common symptoms and characteristics of sciatica include:

1. **Sharp or shooting pain:** This pain can be severe and may feel like an electric shock.
2. **Constant pain:** Sciatica pain can be continuous or intermittent, and it often worsens with movements like coughing or sneezing.
3. **Numbness and tingling:** People with sciatica may experience numbness, tingling, or a "pins and needles" sensation in the affected leg or foot.
4. **Weakness:** Some individuals with sciatica may also experience weakness in the leg or foot on the affected side, making it difficult to move or bear weight.

Treatment for sciatica depends on its underlying cause and the severity of symptoms. Common approaches to managing sciatica include:

- **Conservative measures:** Rest, over-the-counter pain medications, hot or cold therapy, and physical therapy exercises to improve strength and flexibility can often help alleviate mild to moderate sciatica symptoms.
- **Medications:** In some cases, prescription medications like muscle relaxants or corticosteroids may be used to manage pain and inflammation.
- **Injections:** Epidural steroid injections can be administered around the affected nerve root to reduce inflammation and provide pain relief.
- **Surgery:** If conservative treatments are ineffective and the cause of sciatica is a severe structural issue like a herniated disc or spinal stenosis, surgical intervention may be necessary to relieve pressure on the nerve.

Multiple medical organizations recommend multi-modal analgesia for chronic pain management, including the American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia (ASRA) & the American Academy of Orthopedic Surgeons.

Multi-modal analgesia is a pain management approach that combines different techniques and medications to provide more effective pain relief while minimizing the potential for side effects and complications. The goal of multi-modal analgesia is to address pain from multiple angles and to provide better pain control with lower doses of individual medications. This approach is commonly used in various medical settings, including postoperative care, chronic pain management, and in the treatment of acute pain conditions.

Here are some key components and principles of multi-modal analgesia:

1. **Combination of Therapies:** Instead of relying solely on a single type of pain relief, multi-modal analgesia combines various interventions, such as medications, physical therapies, nerve blocks, and non-pharmacological approaches, to manage pain effectively.

2. **Diverse Medications:** Multi-modal analgesia may include different classes of medications, such as opioids, non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, local anesthetics, and adjuvant medications (e.g., anticonvulsants or antidepressants), each targeting different aspects of pain pathways.
3. **Customized Treatment:** Healthcare providers tailor the multi-modal approach to each patient's specific needs and the nature of their pain. Factors like the cause and location of pain, the patient's medical history, and potential side effects are considered when designing the treatment plan.
4. **Reduced Opioid Dependence:** One of the primary goals of multi-modal analgesia, especially in postoperative and acute pain management, is to reduce reliance on opioids. This can help minimize the risk of opioid-related side effects, addiction, and opioid-related complications.
5. **Improved Pain Control:** By addressing pain through multiple mechanisms, multi-modal analgesia often leads to more effective pain relief. Combining medications that work through different pathways can result in additive or synergistic effects.
6. **Fewer Side Effects:** Since multi-modal analgesia typically involves lower doses of individual medications, it can lead to fewer side effects and a lower risk of complications.
7. **Faster Recovery:** Improved pain control can lead to faster recovery times and better patient outcomes, particularly after surgery or during the management of acute pain conditions.

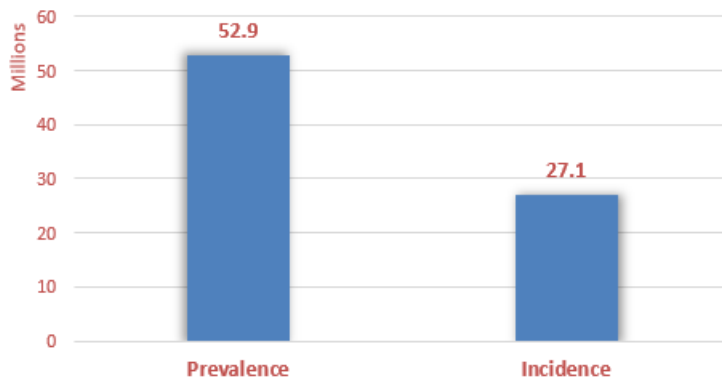
As part of this model, the ASA and ASRA note that “members strongly agree that epidural steroid injections with or without local anesthetics should be used for radicular pain or radiculopathy,” which is where Semdexa comes into play. There are over 12 million epidural steroid injections used per year in the US. Clinical trials have shown that patients receiving Semdexa injections experienced extended and durable pain relief that continued for over 12 weeks when compared with a placebo. Those same trials also showed that the treatment was safe for both single and repeat injections and can be conducted in outpatient pain clinics. Existing steroid formulations are used despite warning in the label that these formulations should not be used in the epidural space. There are no double-blind placebo-controlled trials conducted to prove safety and efficacy of these formulations.

Scilex believes that Semdexa can be a crucial piece to this treatment method and provide safer, more effective relief and is currently in discussions with the FDA on the next step to an NDA. The existing epidural steroid injections are all used off-label by physicians. If approved, Semdexa could be the first FDA-approved epidural steroidal treatment for sciatica.

### **SP-103**

The next drug in the pipeline for Scilex is related to the first product this report referenced in ZTlido. SP-103 is the next generation of the company's primary drug, with triple the amount of lidocaine delivered and the same superior adhesion and efficient delivery as ZTlido. This investigational product gained the Fast Track designation from the FDA in August 2022 and results from Phase 2 trials are expected to be released soon. SP-103 is being developed to initially treat pain related to cervicalgia, or neck pain, as well as the related condition of lower back pain. According to the National Institute of Health, NIH, roughly 53 million Americans suffer from neck pain, which equals about 20% of the adult population.

## Neck Pain: U.S. Epidemiology



Source: Scilex Holding Company

There is also an economic impact to this condition, with the Journal of the American Medical Association reporting that neck pain is responsible for job absences of 25.5 million Americans who miss an average of 11 days of work per year. The Journal also reports that the US market for the treatment of low back and neck pain was over \$134 billion in 2020.

As anyone with the condition or who knows someone with the condition understands, there is no definitive treatment for neck pain.

The choice of treatment for neck pain depends on the underlying cause, severity, and individual factors. Here are some common treatments for neck pain:

1. Over-the-Counter Pain Medications:
  - Non-prescription pain relievers such as ibuprofen (Advil), naproxen (Aleve), or acetaminophen (Tylenol) is the standard of care for pharmacological therapy and can help alleviate pain and reduce inflammation.
2. Heat and Cold Therapy:
  - Applying ice or cold packs to the affected area can help reduce inflammation and numb the pain.
  - Heat therapy in the form of warm compresses or heating pads can relax tense muscles and improve blood circulation.
3. Physical Therapy:
  - Physical therapy involves exercises and stretches designed to strengthen the neck muscles, improve posture, and increase range of motion. A physical therapist can provide guidance on proper techniques.
4. Neck Braces or Collars:
  - In some cases, wearing a neck brace or collar for a short period can help stabilize the neck and reduce strain on the affected area. However, prolonged use is generally discouraged, as it can lead to muscle weakening.
5. Massage:
  - Professional massage therapy can help relax tight muscles, improve blood flow, and reduce pain. It can be especially useful for muscle-related neck pain.
6. Chiropractic Care:
  - Chiropractors may perform spinal adjustments to alleviate neck pain. These manual manipulations aim to restore proper alignment of the spine and relieve pressure on nerves.

7. Acupuncture:
  - Acupuncture involves inserting thin needles into specific points on the body to promote pain relief and relaxation. Some people find it effective for managing neck pain.
8. Medications:
  - In some cases, your healthcare provider may prescribe stronger pain medications or muscle relaxants for short-term relief. These are typically used for more severe neck pain.
9. Injections:
  - Corticosteroid injections can be administered into the neck to reduce inflammation and alleviate pain, particularly when the pain is related to conditions like herniated discs or spinal stenosis.
12. Surgical Intervention:
  - Surgery is typically considered a last resort when conservative treatments have failed, and there is an underlying structural issue, such as a herniated disc or spinal instability. Common surgical procedures for neck pain include discectomy, fusion, and decompression.

In our view, adding a patch that adheres well to the skin and stays adhered and delivers a powerful but non-opioid pain reliever to the impacted area would fit very well into this menu of treatments and may eventually move to the forefront of treatment options. The Phase 2 trial was completed in 2Q 2023 and results are expected to be released soon and will measure the amount of pain relief in 80 patients who apply the investigational product for 12 hours per day for 28 days. Given the results seen in ZTlido, we are expecting a positive announcement and are looking forward to seeing the results.

#### **SP-104**

The final drug in the Scilex pipeline, at least at the current time and with more likely to come, is one that is being studied to treat fibromyalgia, which, according to the CDC, impacts an estimated 4 million Americans, with women twice as likely as men to suffer from the condition.

Fibromyalgia is a chronic pain condition characterized by widespread musculoskeletal pain, fatigue, and tenderness in specific areas of the body. While the exact cause of fibromyalgia is not fully understood, it is believed to involve a complex interplay of genetic, environmental, and neurological factors. Here's an overview of the causes, symptoms, and treatments for fibromyalgia:

**Causes:** The precise cause of fibromyalgia is not known, but several factors may contribute to its development:

1. Genetic Predisposition: Some individuals may be genetically predisposed to fibromyalgia, as it tends to run in families.
2. Abnormal Pain Processing: Fibromyalgia is associated with an abnormal pain processing system in the central nervous system, which amplifies pain signals.
3. Trauma or Infections: Physical or emotional trauma, as well as certain infections, may trigger the onset of fibromyalgia in susceptible individuals.
4. Hormonal Factors: Hormonal imbalances, such as low levels of serotonin and elevated levels of substance P (a neurotransmitter associated with pain), are thought to play a role.

Symptoms: Fibromyalgia symptoms can vary from person to person but typically include the following:

1. **Widespread Pain:** Chronic, widespread pain and tenderness in specific areas, known as tender points or trigger points. These may include the neck, shoulders, back, hips, and other locations.
2. **Fatigue:** Profound, unrelenting fatigue, often described as "fibro fog," which can lead to difficulties with concentration and memory.
3. **Sleep Disturbances:** Sleep problems, such as insomnia, restless leg syndrome, and sleep apnea, which contribute to fatigue and worsen pain.
4. **Cognitive Issues:** Difficulties with memory and concentration, often referred to as "fibro fog."
5. **Headaches:** Frequent tension headaches or migraines.
6. **Irritable Bowel Syndrome (IBS):** Many individuals with fibromyalgia also experience gastrointestinal symptoms like IBS.
7. **Sensitivity to Temperature and Sensory Stimuli:** Heightened sensitivity to temperature changes, loud noises, bright lights, and strong odors.
8. **Depression and Anxiety:** A higher risk of developing depression and anxiety due to the chronic nature of the condition and its impact on daily life.

Treatments: There is no cure for fibromyalgia, but several treatment approaches can help manage the condition and improve quality of life:

1. **Medications:**
  - Pain relievers, such as over-the-counter analgesics or prescription medications.
  - Antidepressants to help manage pain and improve sleep.
  - Anticonvulsant medications, like gabapentin or pregabalin, for pain management.
2. **Physical Therapy:**
  - Exercise programs and physical therapy can improve strength, flexibility, and reduce pain.
3. **Cognitive-Behavioral Therapy (CBT):**
  - CBT can help individuals manage the psychological and emotional aspects of fibromyalgia and develop coping strategies.
4. **Lifestyle Changes:**
  - Stress management techniques, such as relaxation exercises and mindfulness.
  - Getting regular, good-quality sleep.
  - Making dietary changes to manage IBS symptoms.
  - Maintaining a balanced exercise routine, which may include low-impact activities like swimming or walking.

Scilex is aiming to add to these treatment options with the introduction of SP-104, which is designed as a delayed-burst, low-dose naltrexone.

Low-dose naltrexone (LDN) is a medication that has gained attention in recent years for its potential therapeutic effects in treating various medical conditions. Naltrexone, in standard doses, is an opioid receptor antagonist used primarily to treat opioid addiction and alcohol dependence. However, when used in much smaller doses, typically ranging from 1 to 5 mg per day, it is referred to as low-dose naltrexone, and it is being investigated for a range of off-label uses.

The concept behind LDN is that at these lower doses, it may exert different effects on the body than at higher, therapeutic doses. Some proponents of LDN claim that it can modulate the immune system and have anti-inflammatory properties, potentially benefiting individuals with certain autoimmune diseases and chronic conditions.

Conditions for which low-dose naltrexone is sometimes considered include:

1. **Autoimmune Diseases:** LDN has been explored as a potential treatment for conditions like multiple sclerosis (MS), rheumatoid arthritis, Crohn's disease, and lupus.
2. **Chronic Pain:** Some people with fibromyalgia, neuropathic pain, or other chronic pain conditions have reported benefits from LDN.
3. **Mood Disorders:** There is some interest in the use of LDN for mood disorders, although the evidence is limited.

Possible side effects of low-dose naltrexone can include sleep disturbances, vivid dreams, and mood changes. Scilex believes that developing a delayed-burst, low-dose version of naltrexone will limit the side effects of the treatment but still have the positive impact desired, because the naltrexone is released in the body after the patient is asleep, when possible side effects are less noticeable. The company is currently planning on taking SP-104 through Phase 2 trials, which are projected to be initiated in 2024. We, and the millions suffering from this condition, are anxiously awaiting results from those trials.

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## VALUATION

Scilex is a company with a growing revenue stream that has the potential to come from an increasing number of sources. Obviously, we can't know the future but from the history of the company and the management we are confident that the products in development will get to the commercialization stage and that the company will introduce treatments that aren't in the current pipeline. As we have mentioned many times, our valuation strategy uses conservative elements in order to give investors the best chance of seeing upside performance. In that vein, we are using the four treatments that are either commercialized or close to commercialization with the understanding that as the other two existing treatments in trials move along, we'll likely add those to the mix. Another assumption is that the existing sales force the company has in place won't have to be greatly expanded due to the many of the same providers being targeted for each of the treatment options, allowing for the company to scale the revenue component, while keeping costs relatively stable.

We also assume that the R&D budget will grow with inflation, but not expand or decrease substantially due to the company being in a seeming constant state of development. As for the revenue component, we are fairly conservative and believe there is a decent chance Scilex outperforms our expectations. We assume that ZTlido will grow by 10% annually for the next two years, helped along by more aggressive marketing, and then grow at a 5% annual rate after that. As for Gloperba, we don't have initial sales data projections, but we assume that revenue will start coming in in 2024, roughly equal to 0.01% of the US gout market, with is estimated by Grand View Research to be roughly \$12.7 billion. After that we assume sales of Gloperba will rise by 3% per year. Moving on to Elyxyb, we also lack sales projections but assume that the year will have minimal revenue but that in 2024 the drug will get 0.05% of the US migraine market, which is projected to be roughly \$4.8 billion in 2024 in data cited by the company. Sales will then grow at 3% annually—again with a good potential in our view to exceed those expectations. Finally, SP-102, which targets sciatica—an estimated \$2 billion market annually according to the NIH, starts being a revenue generator in 2025 and starts with 0.01% of the market and grows that at 3% annually.

We then apply a discount rate of 10% to Scilex, which we believe is appropriate given the current revenue stream that the company has and the number of treatments at advanced stages in the pipeline. Additionally, with a sales team and manufacturing facility with abundant capacity already in place we believe a slightly lower discount rate to what we might normally apply to a small cap stock is appropriate. Applying all of these assumptions to SCLX gives us a current valuation of \$4.75 per share, which represents a premium to recent trading history, but we believe is still a conservative estimate for the reasons given above.

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## RISKS

- Scilex could see current drugs in the company's pipeline not approved for commercialization.
- Competitors could introduce better treatment options for the conditions being targeted by Scilex.
- Doctors could be slow to add Scilex products to their treatment recommendations.
- The company will likely lose money for at least the next several years and obtaining the needed financing could prove difficult.
- We've mentioned that one of the positive factors for Scilex is its management team, which could depart—leading to a leadership vacuum in the company.
- Sales growth could be slower than anticipated.
- Insurance companies could fail to add certain Scilex products to their covered treatment lists.

## PROJECTED INCOME STATEMENT & BALANCE SHEET

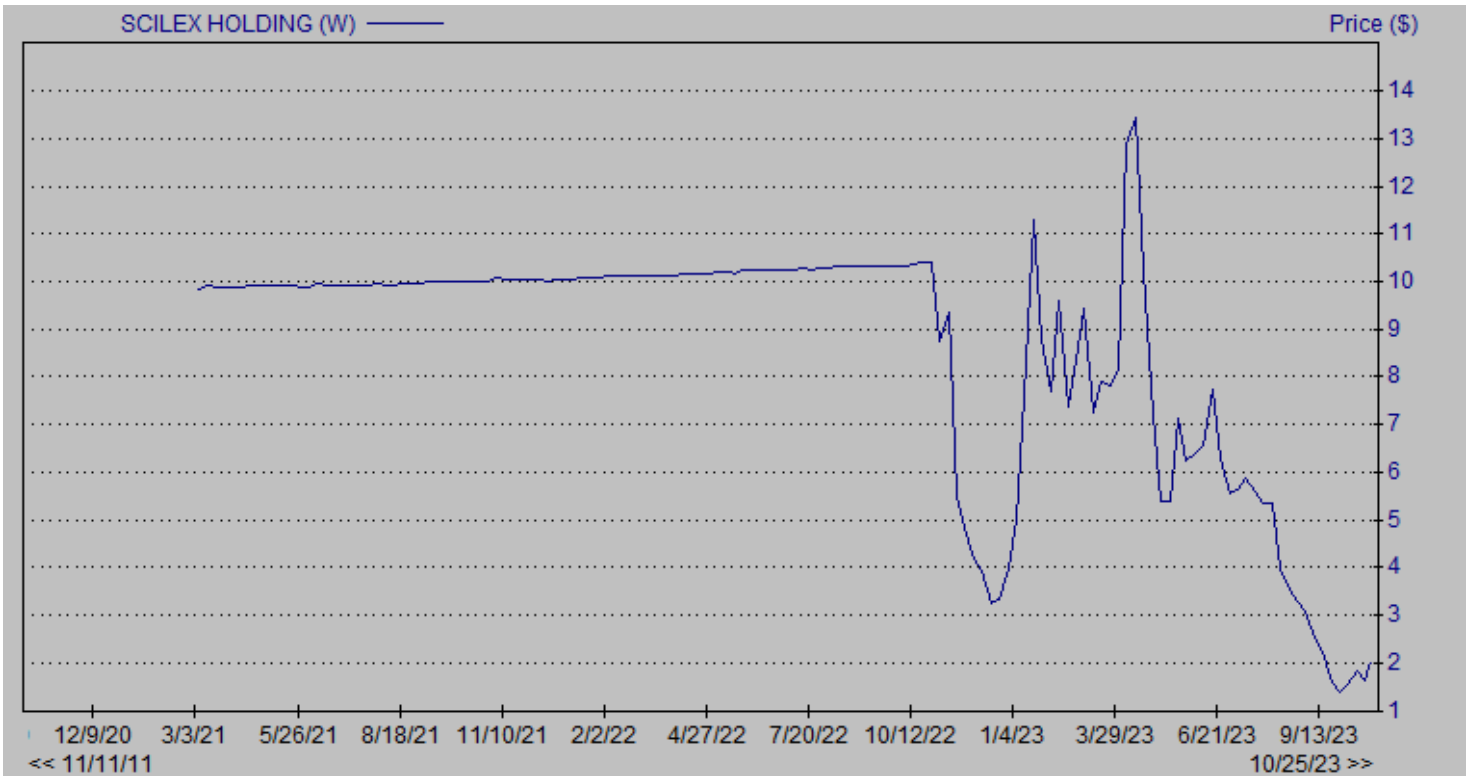
### Scilex Holding Company Income Statement and Balance Sheet

(in thousands, except for per share data)

	2022A	1Q2023A	2Q2023A	3Q2023E	4Q2023E	2024E	2025E
Revenue	38,034	10,582	12,582	13,418	13,686	92,090	118,399
Operating Costs							
Cost of revenue	10,797	3,591	4,177	4,025	4,106	27,627	35,520
Research and development	9,054	2,736	3,204	3,236	3,268	9,507	9,982
Selling, general and admin.	64,895	28,701	26,989	27,259	27,531	110,480	111,585
Intangible amortization	3,922	1,027	1,026	1,016	1,006	3,844	3,882
Total Operating Costs	88,668	36,055	35,396	35,536	35,911	151,458	160,969
Gain/(loss) from operations	(50,634)	(25,473)	(22,814)	(22,118)	(22,225)	(59,367)	(42,570)
Other (income)/expense							
Interest expense	9,604	(1)	5	0	0	0	0
Other (gain)	(36,878)	5,273	3,833	3,910	3,988	0	0
Total other (income)/expense	(27,274)	5,272	3,838	3,910	3,988	0	0
Gain/(loss) before income taxes	(23,360)	(30,745)	(26,652)	(26,028)	(26,213)	(59,367)	(42,570)
Income tax expense/(benefit)	4	8	(3)	(3)	(3)	(3)	(3)
Net gain/(loss)	(23,364)	(30,753)	(26,649)	(26,025)	(26,210)	(59,364)	(42,567)
Net gain/(loss) per share	\$ (0.17)	\$ (0.22)	\$ (0.19)	\$ (0.17)	\$ (0.17)	\$ (0.38)	\$ (0.27)
Wtd avg. shares outstanding--basic and diluted	134,226	141,660	142,626	149,757	152,752	154,280	155,823
Current assets:							
Cash and cash equivalents	2,184	5,069	34,122	32,416	30,795	29,255	27,793
Accounts rec., net	21,236	19,244	27,568	27,844	28,122	28,403	28,687
Inventory	1,378	2,275	3,110	3,141	3,173	3,204	3,236
Other	4,810	4,516	4,447	4,491	4,536	4,582	4,628
Total current assets	29,608	31,104	69,247	67,892	66,626	65,445	64,344
Property and equipment	772	762	760	752	745	737	730
Other long-term assets	56,147	54,185	56,457	57,022	57,592	58,168	58,749
Total Assets	86,527	86,051	126,464	125,666	124,963	124,350	123,823
Current liabilities:							
Accounts payable	8,450	9,817	11,412	11,526	11,641	11,758	11,875
Accrued rebates and fees	30,893	35,629	47,779	48,257	48,739	49,227	49,719
Other current liabilities	5,499	19,156	44,392	44,836	45,284	45,737	46,194
Total current liabilities	44,842	64,602	103,583	104,619	105,665	106,722	107,789
Long-term debt	3,387	0	0	0	0	0	0
Other long-term liabilities	2,059	10,373	12,464	12,589	12,715	12,842	12,970
Total liabilities	50,288	74,975	116,047	117,207	118,380	119,563	120,759
Stockholder equity:							
Common and preferred stock	17	18	18	18	18	18	18
Additional paid-in capital	412,136	417,725	443,715	448,152	452,634	457,160	461,732
Accumulated deficit	(375,914)	(406,667)	(433,316)	(439,711)	(446,068)	(452,391)	(458,686)
Total stockholders' equity/(deficit)	36,239	11,076	10,417	8,459	6,583	4,787	3,064
Total liabilities and stockholders' equity/(deficit)	86,527	86,051	126,464	125,666	124,963	124,350	123,823



# HISTORICAL STOCK PRICE



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