SCLX: Leading Pain Product Company; Initiating Coverage With a Buy Rating and $14 Price Target

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Stock Data

Rating	Buy
Price Target	14.00
Exchange	NASDAQ
Price	1.53
52-Week High	16.20
52-Week Low	0.90
Cash (M)	4
Market Cap (M)	254
Shares Outstanding (M)	166
3 Month Avg Volume	928,359

Estimates

	2022A	2023A	2024E
			(Curr.)
Revenue (M) | $ | Year end: December			
Q1	-	10.6A	15.7E
Q2	-	12.6A	20.9E
Q3	-	10.1A	31.3E
Q4	-	13.5A	47.0E
FY	38.0A	46.7A	115E
EPS | $ | Year end: December			
Q1	-	(0.22)A	(0.11)E
Q2	-	(0.19)A	(0.02)E
Q3	-	(0.63)A	0.05E
Q4	-	(0.25)A	0.15E
FY	(0.17)A	(0.88)A	0.08E

One Year Performance Chart

KEY POINTS

Initiating coverage of Scilex with a Buy rating and a $14/share 12-month price target. Scilex is commercializing three non-opioid products for the management of pain. The company has three additional drug candidates in development.

Our Buy thesis on the shares of Scilex is based on the following:

Stop the Epidemic: Over the last two decades, the United States has faced a mounting crisis related to substance abuse and addiction. Since the year 2000, the annual count of overdose deaths linked to various drugs in the US has surged almost sixfold. A substantial portion of these fatalities, around 80,000, were connected to opioids. To combat this opioid epidemic, the CDC now advises against prescribing opioids for noncancerous pain management, advocating instead for non-opioid therapies for both acute and chronic pain. This shift has spurred growing demand for effective non-opioid medications.

Dedicated to Pain Management: Scilex is dedicated to the development and commercialization of non-opioid pain management solutions. The company has three commercial products, ZTlido, Gloperba and ELYXYB, along with three products in the pipeline, SP-102, SP-103 and SP-104. Its leading product, ZTlido (lidocaine topical system) 1.8%, is an approved prescription lidocaine topical product by the FDA in 2018 for alleviating pain associated with postherpetic neuralgia. The product incorporates innovative delivery and adhesion technology, aiming to overcome limitations observed in existing prescription lidocaine patches.

The company has also obtained approval from the FDA for two additional non-opioid pain products, ELYXYB and Gloperba. ELYXYB is indicated for the immediate treatment of migraines with or without aura in adults while Gloperba is prescribed for preventing gout flares in adults. ELYXYB was launched in the US in April 2023, and the company aims to bring Gloperba to the market in 1H24.

Early Commercial Success: ZTlido generated $145M in gross sales in 2023. The three approved products combined could allow the company to turn cash flow positive in 2H24. The extension of the label of ELYXYB to acute pain could help turn the drug into a blockbuster, generating over $1B in sales by 2031.

Valuation & Risks: We arrive at our twelve-month price target of $14/share by assessing the after-tax, risk adjusted NPV of potential future cash flows from the company's ZTlido, ELYXYB and Gloperba programs, in addition to the estimated value of pipeline assets. For commercial-stage assets, the probability-adjusted, fully taxed (21%) NPV (15% discount rate) of potential cash flows through 2036 is ~$1.2B or $11/share, according to our forecasts. We estimated that the value of pipeline assets to be $300M, or $3/share. The combined total NPV of all the assets is ~$1.5B or $14/share, corresponding to our 12-month price target. Significant factors that could impede shares from reaching our price target include the failure of ELYXYB's label expansion into acute pain and lower-than-estimated sales. In addition, the company may not be able to raise additional funds to repay debt and to complete development of drug candidates.

BACKGROUND

Pain Management

In the US, experiencing pain is one of the most common reasons adults seek medical care. According to International Association for the Study of Pain (IASP)[1], pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." Typically stemming from a specific cause, sudden onset **acute pain** is characterized by its sharp quality[2]. This type of pain is usually short-lived, usually not extending beyond six months, and dissipates once the underlying cause is resolved. Lasting beyond a period of six months, **chronic pain** persists even after the resolution of the initial injury or illness[3]. Pain signals remain active in the nervous system for an extended duration, ranging from weeks to months or even years. Some individuals experience chronic pain without a discernible past injury or evident bodily harm. Experiencing moderate to severe acute pain increases the likelihood of developing chronic pain[4].

Prescription opioids such as hydrocodone, oxycodone, and morphine are among the various choices available for addressing intense, short-term pain. While effective in alleviating pain during brief usage, these medications pose significant danger, including the risk of addiction and potential overdose, leading to fatalities when taken over extended periods or in high doses[5].

History: Opioid Crisis

Over the last two decades, the United States has faced a mounting crisis related to substance abuse and addiction, particularly evident in the significant increase in fatalities resulting from drug overdose[6]. Since the year 2000, the annual count of overdose deaths linked to various drugs in the US has surged almost sixfold[7]. A substantial portion of these fatalities, around 80,000, was connected to opioids, encompassing heroin, prescription pain medications, and notably, synthetic opioids, such as fentanyl in recent years[8]. In 2021, fentanyl and similar synthetic opioids independently contributed to approximately 71,000 drug overdose deaths, playing a role in most fatalities associated with methamphetamine, cocaine, and prescription opioid overdose — the next most prevalent substances linked to such deaths[9].

Mid-to-Late 1990s: The origin of the opioid crisis can be traced back three decades ago, with the "Pain as the 5th Vital Sign" initiative and the approval of Purdue Pharma's highly successful OxyContin by the FDA, prompting a surge in the prescription of opioid painkillers within the US healthcare system. Over the next decade, opioid prescriptions soared, leading to widespread addiction. Opioid over-prescription became commonplace, contributing to a rapid rise in overdose deaths. Multiple pharmaceutical companies, including Purdue Pharma, engaged in aggressive marketing strategies, downplaying the risks of addiction.

Turning Point – 2011: For over a decade after the approval of OxyContin, the upward trend in overdose fatalities linked to prescription opioids went largely unnoticed. However, in 2011 the Centers for Disease Control and Prevention (CDC) officially labeled deaths resulting from prescription painkillers as an "epidemic" and introduced guidelines to mitigate risky prescribing practices, and various states implemented legal restrictions. In the subsequent years, efforts were made within the US healthcare and public health systems to curb the prescription of opioid painkillers. Many healthcare providers started to adopt more cautious approaches in prescribing opioid painkillers. As

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a result, the number of prescription opioid overdose deaths started to stabilize, but did not experience a significant or sustained decline.

2011-2014 Transition to Illicit Opioids: During the period when deaths from prescription opioids reached their peak, the landscape of the opioid crisis underwent a noticeable transformation.

Initially, the rise in deaths was attributed to heroin, an illicit opioid trafficked by criminal enterprises for years, followed by an increase in fatalities from fentanyl and similar synthetic opioids, which also became part of trafficking efforts. Heroin gained popularity as individuals who were dependent on prescription opioids suddenly faced restrictions on access, leading them to seek alternative substances. Exploiting the expanding market for illicit opioids, traffickers eventually shifted their focus to fentanyl due to its ease of large-scale production, higher potency, and more convenient and cost-effective smuggling compared to heroin. Consequently, death rates from heroin began to decline, while those from fentanyl continued to rise.

2015 & Beyond: Ongoing Consequences and Legal Actions. The opioid crisis continues to have a profound societal impact, with escalating death tolls, strained healthcare resources, and legal actions against pharmaceutical companies, including Purdue Pharma, which face bankruptcy and lawsuits. Other pharmaceutical companies, including Johnson & Johnson, Endo Pharmaceuticals, McKesson, AmerisourceBergen, and Cardinal Health are experiencing legal consequences for their role in the crisis.

Pain Management to Alleviate the Opioid Crisis

The misuse of illicit opioids for chronic pain poses a significant public health challenge, prompting healthcare regulators to implement stringent policies to control prescription practices. In March 2016, the CDC released guidelines for opioid prescription, offering various cautions on prescribing. In 2022, the CDC updated the guideline, with 12 recommendations. Three principles stand out as crucial for enhancing patient care and safety:

- Nonopioid therapy is the preferred option for chronic pain, excluding cases of active cancer, palliative, and end-of-life care.
- In situations where opioids are prescribed, the dosage should be the lowest effective amount to minimize the risks of opioid use disorder and overdose.
- Prescribing opioids requires caution, and clinicians should diligently monitor all patients under opioid treatment.

As a result of restricting the prescription of opioid for noncancerous pain management, CDC recommended the usage of non-opioid therapies for both acute and chronic pain management, driving an increasing demand for effective **non-opioid medications.**

Overview of the Pain Management Market

The market is segmented by the mode of pain management, including pharmaceutical drugs (opioids and non-narcotic analgesics), neurostimulation devices, and the combination of devices and drugs such as analgesics infusion pumps. According to Mordor Intelligence, the pain management market in the US is estimated to be $78B in 2024, and could grow to $93B by 2029, increasing at a CAGR of 3.6%. The current market is progressively embracing a greater utilization of non-opioid drugs to mitigate the dependence on opioids and other widely used pain relievers in the industry.

PAIN INDICATIONS

Postherpetic Neuralgia-Related Pain

Disease Overview. **Shingles** is a viral infection that results in a painful rash[10]. Typically, it manifests as a single stripe of blisters. It is caused by varicella-zoster virus, the same virus responsible for chickenpox. After experiencing chickenpox, the virus remains dormant in the body throughout one's life, with the potential to reactivate as shingles years later. Around 1M instances of herpes zoster arise each year in the US, with one out of every three individuals experiencing herpes zoster at some point in their lifetime[11].

While shingles is not life-threatening, it can cause significant pain. The primary complication is **postherpetic neuralgia (PHN)**, a painful condition that prolongs shingles pain well after the blisters have healed[12]. It is a neuropathic pain condition persisting for months to years after the herpes zoster rash has resolved. This pain results from harm to peripheral and central neurons, potentially arising from the immune/inflammatory response triggered by the reactivation of the varicella-zoster virus[13]. Individuals affected by postherpetic neuralgia often express a diminished quality of life and disruption in their daily activities[14].

Treatment Options. Strategies for managing postherpetic neuralgia involve 1) preventing herpes zoster through vaccination or antiviral treatment and 2) using specific medications to address pain. Current guidelines suggest a stepwise approach to treating PHN, with priority given to calcium channel α2-δ ligands (including gabapentin and pregabalin), tricyclic antidepressants (including amitriptyline, nortriptyline, or desipramine), or topical lidocaine patches as first-line medications, and opioids and topical capsaicin patch or cream as second- or third-line treatment options.

Consideration may be given to topical treatments involving capsaicin and lidocaine for individuals experiencing mild to moderate localized pain from PHN or for those who prefer not to undergo oral drug therapy. In a meta-analysis of four randomized and controlled trials, patients with PHN treated with a single application of 8% topical capsaicin exhibited significantly better efficacy outcomes compared to those treated with 0.014% topical capsaicin[15]. However, pivotal trials revealed notable administration site reactions associated with the capsaicin 8% patch, along with transient increases in pain are frequently observed on the day of treatment. The utilization of 5% lidocaine patches (Dermalid and Lidoderm) has demonstrated, both in clinical practice and various trials, an enhancement in the quality of life and a reduction in pain for patients, especially when combined with other established analgesics for PHN[16].

Migraine

Disease Overview. **Migraine** is defined as “an episodic headache associated with certain features, such as sensitivity to light, sound, or movement” or “a recurring syndrome of headache associated with other symptoms of neurologic dysfunction in varying admixtures”[17]. It can be classified into two types: 1) resistant migraines, defined as those that have not responded to at least three classes of migraine preventatives, leading to at least eight disabling headache days per month for a continuous three-month period without improvement; and 2) refractory migraines, characterized by the failure of all available preventatives and enduring at least eight debilitating headache days per month for a continuous six-month period[18].

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Migraine is a challenging condition that affects an individual's financial status, family connections, and engagement in work and educational responsibilities[19]. In the US, individuals with migraine experience a notably greater economic burden compared to those without migraine. Migraine stands as one of the most prevalent neurological conditions globally, with an estimated 1.1B individuals affected. The worldwide occurrence of migraine has markedly risen in the past thirty years[20].

Treatment Options for Acute Migraine. The objective of acute migraine treatment is to swiftly alleviate migraine attacks, manage the dosage of medication effectively, and deter the onset of chronic migraine. Healthcare professionals have various classes of acute medications for prescribing to address migraine, including non-opioid analgesics, opioid analgesics, ergot derivatives, triptans, and rescue medications[21]. For mild to moderate migraine, initial treatments typically involve non-opioid analgesics such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), while triptans are preferred for managing moderate to severe migraines. Despite their effectiveness, triptans can be costly. In the case of refractory migraine or for specific patients, second- or third-line therapy may involve medications like ergot (such as dihydroergotamine), rescue medications and opioids.

Treatment Options for Chronic Migraine. The management of chronic migraine emphasizes preventive measures aimed at decreasing both the frequency and intensity of headaches, with the goal of reducing reliance on acute treatments[22]. A variety of oral medications are employed for preventive treatment of chronic migraine, including antihypertensives such as beta-blockers and calcium-channel blockers, antidepressants like tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), and noradrenergic and specific serotonergic antidepressants, as well as anticonvulsants. However, the effectiveness of these medications is often supported by limited evidence, leading to discontinuation of treatment due to perceived lack of efficacy or poor tolerability.

Injectables, including topiramate, onabotulinumtoxinA (BOTOX), and monoclonal antibodies targeting calcitonin gene-related peptide (CGRP), have demonstrated effectiveness of relieving chronic migraine. Topiramate, a broad-spectrum antiepileptic medication[23], received approval for migraine prevention in adults in Europe in 2003 and in the USA in 2004. CGRP monoclonal antibodies, including erenumab, galcanezumab, fremanezumab, and eptinezumab that blocks CGRP transmission in the trigeminovascular system, a key pathway involved in headache[24], have been approved since 2018 for treating chronic migraine.

OnabotulinumtoxinA (BOTOX) gained approval in the EU in 2010 for alleviating symptoms of chronic migraine and in the US for preventing headaches in adult chronic migraine patients. In those patients, onabotulinumtoxinA is administered at multiple sites in the head and neck muscles where sensory nerve endings are located[25]. By inhibiting these nerve endings, it reduces the transmission of pain signals to the brain and prevents the activation and sensitization of central neurons implicated in chronic migraine. OnabotulinumtoxinA disrupts vesicle trafficking and pain transmission in both motor and sensory nerves and reduces the exocytosis of pro-inflammatory and excitatory neurotransmitters and neuropeptides, such as substance P, calcitonin gene-related peptide, and glutamate, from nociceptive fibers.

Gout

Gout is a systemic condition arising from the accumulation of monosodium urate crystals (MSU) in tissues, with elevated level of serum uric acid (SUA) surpassing a specific threshold[26]. MSU crystals can lead to the formation of tophi, stone-like deposits. Gout is an intensely painful arthritis triggered by the body's natural immune reactions to the

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accumulation of MSU in affected joints and nearby tissues[27]. The predominant symptom of gout is the flare-up experienced in the impacted joint. Flares typically improve within one to two weeks, with symptom-free intervals in between[28]. Untreated gout can lead to more frequent and prolonged flares over time[29].

Despite hyperuricemia being the primary pathogenic factor in gout, not everyone with elevated uric acid levels develops gout or forms uric acid crystals. It affects approximately 1–4% of the overall population[30]. The global occurrence of gout is progressively rising, attributed to aging population, unhealthy dietary patterns such as fast-food consumption, insufficient physical activity, and an increased prevalence of obesity and metabolic syndrome[31].

Treatment Options. The treatment of gout encompasses two primary objectives: easing the pain and inflammation associated with acute gout attacks and implementing long-term management strategies concentrated on reducing SUA levels to mitigate the likelihood of future attacks[32]. As the first-line therapy, the American College of Rheumatology recommends pharmacologic therapy, complemented using topical ice and rest as necessary[33]. Three primary first-line therapies include NSAIDs or COX-2 inhibitors, colchicine, or systemic glucocorticoids[34]. Usually, monotherapy is suitable when dealing with mild-to-moderate pain affecting two or fewer joints of any size. In case of severe pain or attacks involving multiple joints, initial combination therapy may be advantageous.

Colchicine, derived from plants belonging to the *Colchicum genus*, has a well-established history of therapeutic application in conditions including gout and familial Mediterranean fever[35]. Colchicine influences multiple pro- and anti-inflammatory pathways associated with gouty arthritis[36]. By impeding microtubule assembly, colchicine disrupts inflammasome activation, inflammatory cell chemotaxis based on microtubules, the production of leukotrienes and cytokines, and the process of phagocytosis.

SCILEX - LEADER IN NON-OPIOID PAIN THERAPEUTICS

Company Overview

Scilex is dedicated to the development and commercialization of non-opioid pain management solutions. The company has three commercial products, ZTlido, GLOPERBA and ELYXYB, along with three products in the pipeline, SP-102, SP-103 and SP-104 (Figure 1).

Its leading product, **ZTlido®** (lidocaine topical system) 1.8%, is an approved prescription lidocaine topical product by the FDA in 2018 for alleviating pain associated with PHN. The product incorporates innovative delivery and adhesion technology, aiming to overcome limitations observed in existing prescription lidocaine patches.

The company has also obtained approval from the FDA for two additional non-opioid pain products, **GLOPERBA®** and **ELYXYB®**. GLOPERBA® is prescribed for preventing gout flares in adults, while ELYXYB® is indicated for the immediate treatment of migraines with or without aura in adults. ELYXYB® was launched in the US in April 2023, and the company aims to bring GLOPERBA® to the market in 2024.

Besides commercial products, the company also has three product candidates listed below: two in late-stage and one under early-stage clinical development.

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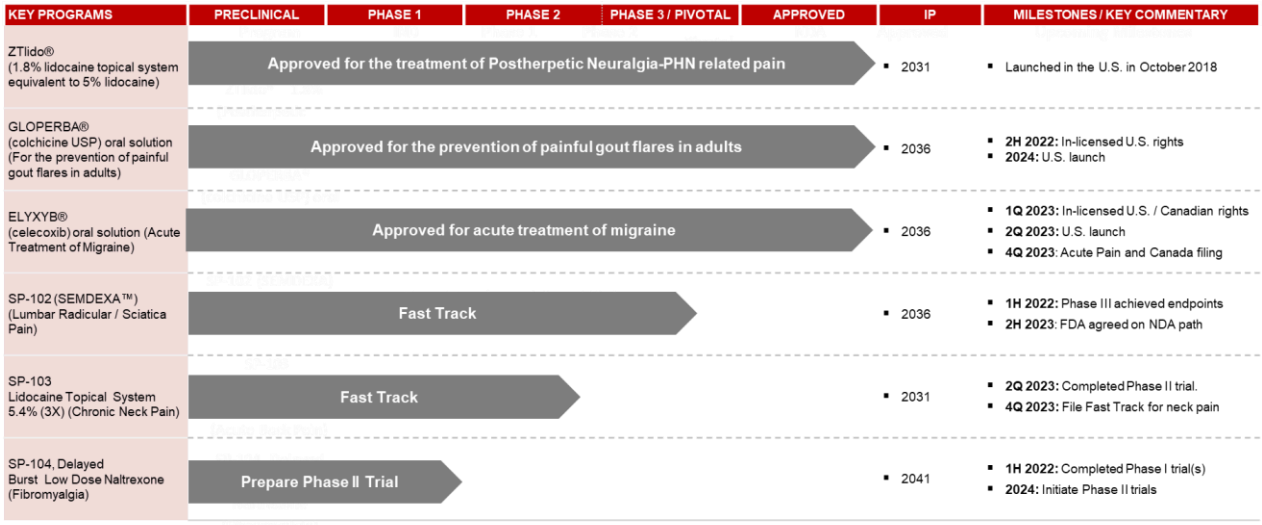
Figure 1: Products & Pipeline Overview



Source: Scilex Company Presentation, March 2024

ZTlido - FDA Approved for Relief of PHN Pain

Product Overview. **ZTlido** is an FDA-approved therapeutic product used for alleviating the pain associated with PHN caused by shingles. It is a transdermal non-opioid anesthetic topical patch with 1.8% lidocaine. It incorporates exclusive patch non-aqueous adhesion technology, ensuring a 12-hour wear time, and facilitating efficient lidocaine delivery, even during physical exercise. Its active ingredient, lidocaine, is classified as an amide-type local anesthetic agent that stabilizes neuronal membranes by impeding the ionic fluxes essential for initiating and conducting impulses. ZTlido requires only 36mg per patch, as opposed to 700mg for Lidoderm (5% lidocaine patch), to attain an equivalent therapeutic drug dose based on comparative pharmacokinetic studies.

Efficacy of Pain Relief. Patients experiencing persistent PHN pain often find that gabapentinoids (gabapentin and pregabalin) do not offer sufficient relief from their discomfort while incorporating other oral pain relievers to enhance the efficacy comes with side effects. Topical treatments including lidocaine transdermal patch help pain relief without the concerns of oral analgesics. Lidocaine transdermal patch is available with either a prescription (Dermalid, Lidoderm, ZTlido) or without a prescription (Absorbine Jr, Aspercreme, Lidocare, Salonpas, among others). About 5M of lidocaine patch prescriptions were filled, and around 170M lidocaine patches were sold in the US in 2022[37]. As mentioned earlier, Lidoderm and Dermalid (5% lidocaine patches) are part of the first-line standard of care for PHN, showing effectiveness in pain management when used in conjunction with other established analgesics[38].

A Phase 3, two-stage randomized, open-label study has been conducted to compare ZTlido with pregabalin monotherapy in patients with PHN (Figure 2A). The study demonstrated that adding ZTlido to pregabalin doubled the pain relief effect of pregabalin.

In Stage One, 98 individuals experiencing PHN with pain intensity exceeding 4/10 on the pain numeric rating scale (NRS) were randomly assigned to receive four weeks of monotherapy, with the option of either Pregabalin or ZTlido. The dose of pregabalin was adjusted based on its effectiveness, that all patients in pregabalin group were initially given 150mg/day in the first week, followed by an increase to 300mg/day in the second week. For those experiencing inadequate relief (NRS >4) at the end of the second week, the dose was further increased to 600mg/day. For those patients in the ZTlido group, each received a dosage of up to three patches per day, each worn for 12 hours followed by a 12-hour off period. By the end of Stage One, pain relief for all patients was evaluated using NRS to identify individuals who did not attain adequate pain relief.

During Stage Two, patients who achieved satisfactory treatment with monotherapy (NRS≤4) during Stage One continued with the same medication for a duration of eight weeks. On the other hand, those who did not experience sufficient improvement with monotherapy (NRS>4) were administered a combination of both drugs for eight weeks. The analysis primarily focuses on the patients who did not achieve adequate relief with pregabalin monotherapy.

The combination therapy of pregabalin and ZTlido was well-tolerated, with no serious adverse events (AEs) reported. The incidence of drug-related AEs was 5.9%, most of which were associated with pregabalin. The results indicate that during Stage Two combination treatment, the addition of ZTlido to pregabalin led to a 48% reduction in pain intensity (Figure 2B) and an improvement in PGIC score compared to pregabalin alone. Additionally, NRS score and quality of life showed improvement. The rescue usage of acetaminophen was also reduced by 49% compared to pregabalin alone.

Product Differentiation - Adhesion. Issues with adhesion are the most widely reported quality defects of transdermal patches (Figure 3A). ZTlido is the only lidocaine transdermal patch that delivers a 12-hour adhesion in a non-opioid therapy of PHN. ZTlido's non-aqueous adhesive is applied onto a non-woven polyester felt backing and is then overlaid with a release liner made of polyethylene terephthalate film. The release liner is perforated at the center and is taken off before applying the patch to the skin (Figure 3B).

In clinical trials assessing adhesion scores after the 12-hour period, 91% (49 out of 54) of participants achieved a score of 0 (≥ 90% adhered; essentially no detachment from the skin), while five subjects received a score of 1 (≥ 75% to <90% adhered; some edges lifting off the skin). In a separate adhesion study involving 44 participants, ZTlido exhibited statistically significant superior adhesion ($p<0.0001$) compared to Lidoderm at three hours, and this superiority continued to improve over the 12-hour administration period.

[37] Symphony Healthcare
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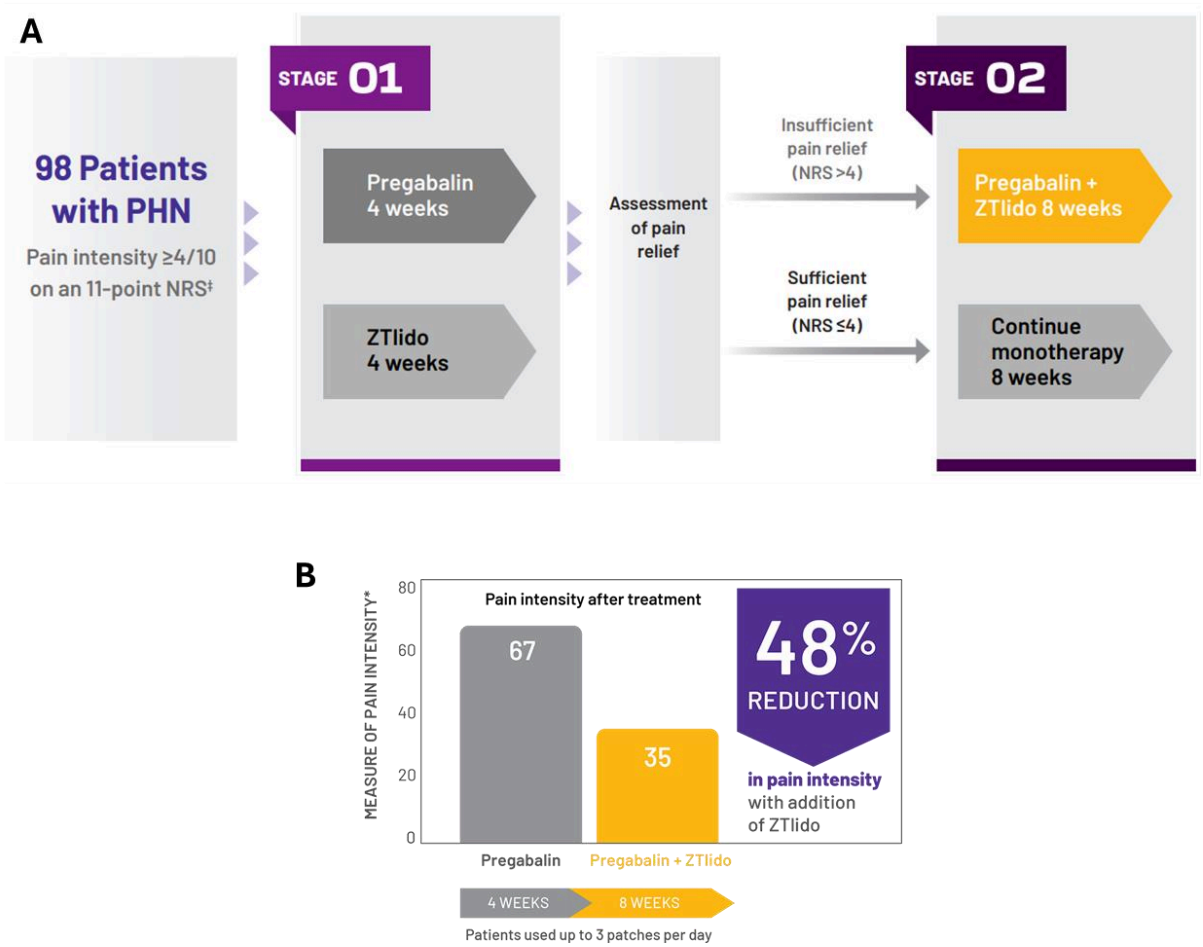
Figure 2: ZTlido Doubles Pain Relief Effect of Pregabalin Alone

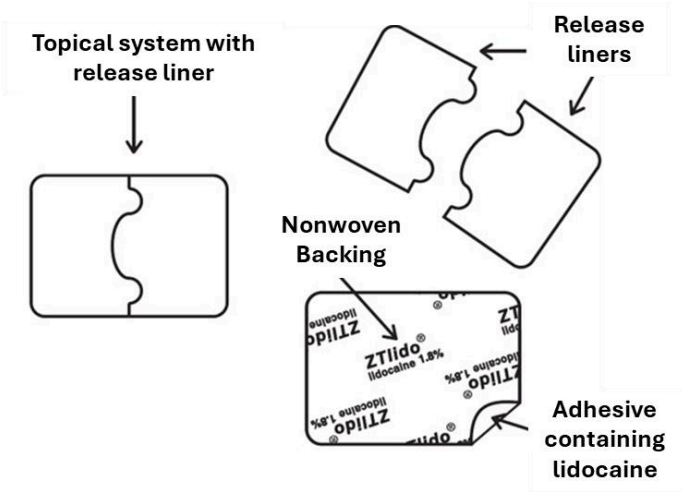


Source: Scilex Company Website, March 2024

Figure 3: 12-Hour Adhesion with ZTlido

A

B



C

Properties	Lidoderm (5%)	ZTlido (1.8%)
Bioavailability	~3 ± 2%	~45%
Weight	14 grams	2 grams
Thickness	1.6 millimeters	0.8 millimeters
Lidocaine Content	700 milligrams	36 milligrams
Adhesion	Water-based	Non-aqueous

Source: Scilex Company Presentation and Website, March 2024

Revenue Growth Supported by Affordable Prescription and Favorable Payer Coverage

ZTlido is covered by both Medicare and Medicaid (Figure 4A) and is preferred by many key commercial payers over lidocaine patches (Figure 4B).

ZTlido also provides a savings and support system that simplifies the process for PHN patients to access affordable monthly prescriptions. After securing ZTlido prescriptions from their doctor, PHN patients can request complimentary samples. With these prescriptions, patients can present the co-pay savings card to the pharmacist, potentially paying as little as zero for the prescriptions depending on their insurance coverage.

As a result of dedicated commercial efforts, ZTlido has achieved significant milestones since its introduction in October 2018. Over the last year, the average daily prescriptions have grown by 35% (Figure 4C). Over 1M patients are estimated to have received treatment with ZTlido since its launch, as indicated by Symphony Health prescription data. It has become the leading prescribed non-opioid branded pain medication among pain specialists in the US. Patients expressed an 89% satisfaction rate with ZTlido, rating their experience as "completely" or "mostly" satisfied with ZTlido treatment, based on a 2023 patient survey conducted by Scilex[39].

The company recorded ZTlido gross sales for the fiscal year ending December 31, 2023, of over $145M, marking a growth of >50% compared to $96M in the previous fiscal year. Additionally, ZTlido net sales for the fiscal year ended December 31, 2023, were ~$46M, exhibiting a growth ~21% compared to $38M in the fiscal year ended December 31, 2022.

Commercial Strategy - ZTlido as Add-on to Gabapentinoids

The company has launched a new campaign designed to allow ZTlido to achieve its true potential by repositioning from the benefits due to adhesion to efficacy. As discussed earlier, ZTlido possesses a unique ability to enhance the effectiveness of gabapentinoids, doubling their efficacy without the associated side effects commonly found in other oral analgesic options. With this Phase 3 combination efficacy data, the company aims to actively promote ZTlido by increasing awareness of the combination therapy among healthcare professionals. This campaign enables the company to enter the gabapentinoids market, which is significantly larger (ten times bigger) than the previous lidocaine patch market[40].

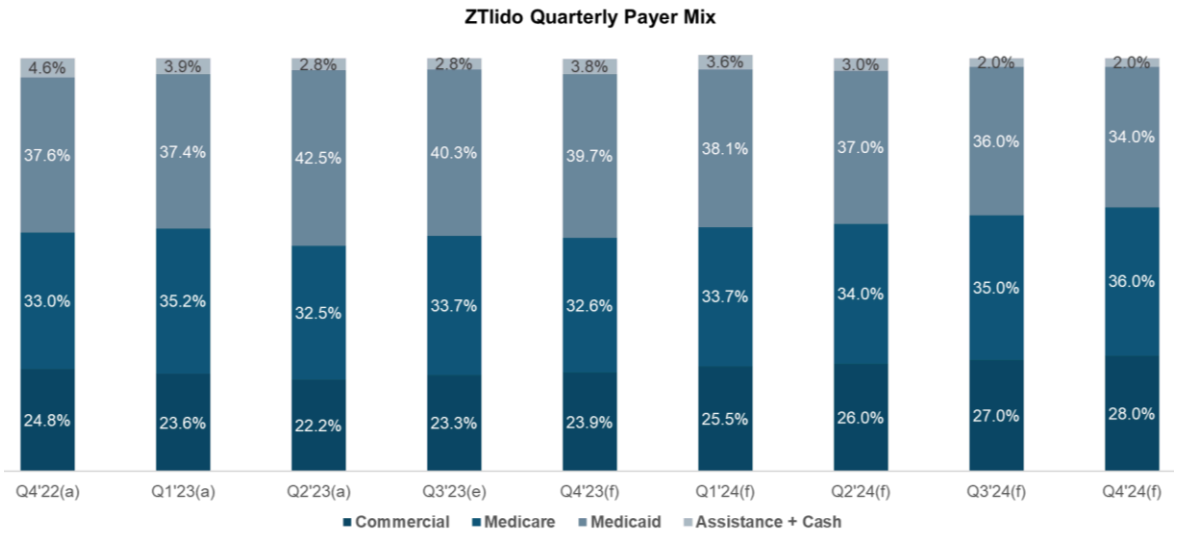
ZTlido - Planned Commercial Expansion

The company has partnered with CH Trading Group, and AD Port for a territorial distribution agreement to enhance the commercial presence of ZTlido in the Middle East and North Africa (MENA). This agreement includes a minimum five-year purchase commitment of $105M (first commitment: $11.5M; second commitment: $19M; third commitment: $22.5M; fourth commitment: $27M; fifth commitment: $30M), with the initial purchase order expected in 2024.

[39] Scilex company announcement. Source: https://www.scilexholding.com/archives/33611
[40] *Scilex Company Presentation, March 2024*

Figure 4: Commercial Success Driven by Favorable Payer Coverage

A



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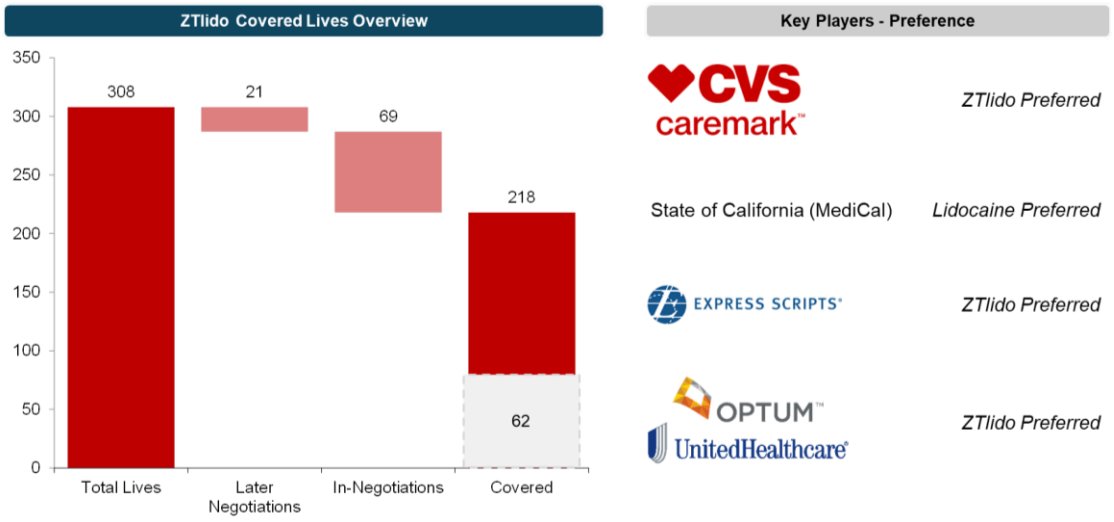

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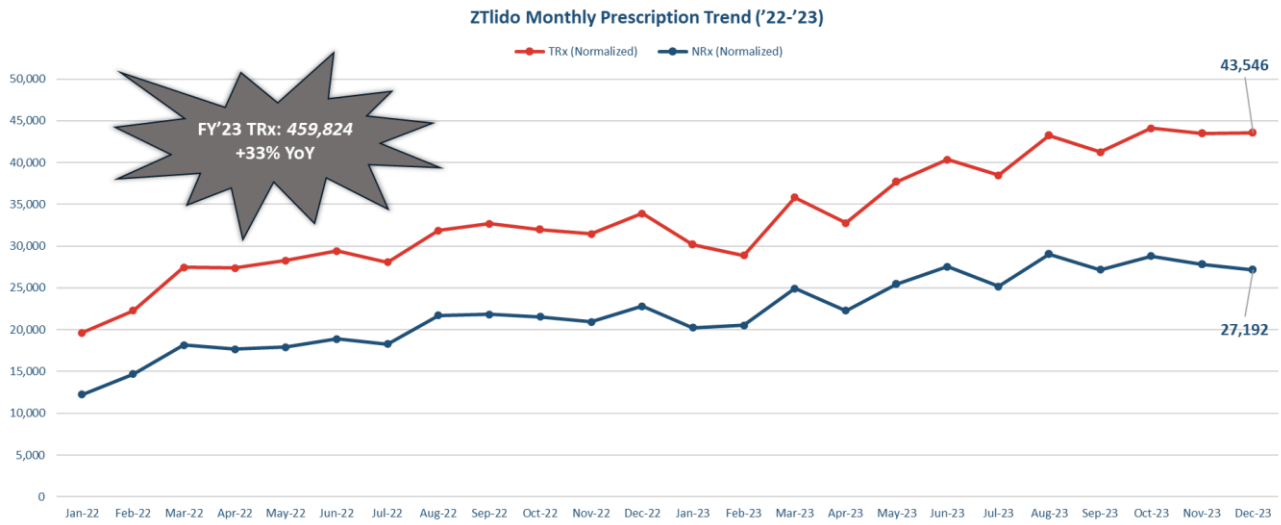

Source: Scilex Company Presentation and Website, March 2024

Elyxyb – Newest Addition to Scilex Non-Opioid Portfolio Addressing a Fast-Growing Market

Product Overview. **Elyxyb** (celecoxib) oral solution is a prescription NSAID indicated for the acute treatment of migraine with or without aura in adults. Its active ingredient, celecoxib, effectively reduces inflammation and alleviates pain by inhibiting cyclooxygenase-2 (COX-2), which is responsible for converting arachidonic acid into prostaglandin, a substance involved in inflammation. Although initially accessible in capsule form (Celebrex) since 1998, the FDA approved Elyxyb as an oral solution in 2020. The Elyxyb oral solution utilizes a self-micro emulsifying drug delivery system, enhancing the absorption and expediting the effectiveness of celecoxib. It is designed to deliver fast and long-lasting migraine relief.

NSAIDs are commonly prescribed to address pain management[41]. They exhibit analgesic effect through the inhibition of the cyclooxygenase enzymes (COX)[42]. COX presents two isoforms, COX-1 and COX-2, exhibiting variations in their expression and functions. COX-1 is consistently expressed, producing prostaglandins essential for regular cellular activities such as gastrointestinal (GI) mucosal protection and vascular maintenance[43]. On the other hand, COX-2 is an inducible isoform that contributes to inflammation and pain[44]. Traditional NSAIDs, including aspirin, ibuprofen, and naproxen, inhibit both isoforms and may lead to GI toxicity associated with COX-1 inhibition[45], rendering them unsuitable for chronic usage in migraine management. As a result, selective COX-2 inhibitors were created to deliver comparable analgesic effects while circumventing the gastrointestinal toxicity linked to traditional NSAIDs[46].

Celecoxib functions as a reversible and selective COX-2 inhibitor, is the only selective COX-2 inhibitor available in the US. In contrast to non-selective NSAIDs, celecoxib consistently demonstrates equivalent pain relief but with fewer gastrointestinal adverse effects[47]. In a large study involving 24,081 participants undergoing long-term treatment for osteoarthritis and rheumatoid arthritis, celecoxib exhibited a significantly reduced risk of GI events compared to naproxen or ibuprofen and a notably reduced risk of renal events compared to ibuprofen[48] [49].

Elyxyb is an oral liquid solution of celecoxib designed for the immediate treatment of migraines in adults. In contrast to the oral capsule formulation of celecoxib under fasting conditions, Elyxyb exhibited a quicker median time to peak concentration T_{max} (within one hour compared to 2.5 hours)[50]. This faster attainment of maximum plasma concentration may lead to a more rapid onset of pain relief, addressing a crucial treatment need for individuals with migraine[51]. Furthermore, Elyxyb demonstrated a relative bioavailability of 144%, 44% higher than 400mg dose of celecoxib oral capsules[52]. This increased bioavailability could potentially necessitate lower doses, contributing to enhanced GI safety and tolerability.

[41] Noor N, LaChute C, Root M, Rogers J, Richard M, Varrassi G, Urits I, Viswanath O, Khater N, Kaye AD. A Comprehensive Review of Celecoxib Oral Solution for the Acute Treatment of Migraine. Health Psychol Res. 2022 Apr 26;10(2):34265. doi: 10.52965/001c.34265. PMID: 35783664; PMCID: PMC9242839.
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[48] Moore RA, Derry S, Makinson GT, McQuay HJ. Tolerability and adverse events in clinical trials of celecoxib in osteoarthritis and rheumatoid arthritis: systematic review and meta-analysis of information from company clinical trial reports. Arthritis Res Ther. 2005;7(3):R644-65. doi: 10.1186/ar1704. Epub 2005 Mar 24. Erratum in: Arthritis Res Ther. 2006;8(1):401. PMID: 15899051; PMCID: PMC1174947.
[49] Nissen SE, Yeomans ND, Solomon DH, Lüscher TF, Libby P, Husni ME, Graham DY, Borer JS, Wisniewski LM, Wolski KE, Wang Q, Menon V, Ruschitzka F, Gaffney M, Beckerman B, Berger MF, Bao W, Lincoff AM; PRECISION Trial Investigators. Cardiovascular Safety of Celecoxib, Naproxen, or Ibuprofen for Arthritis. N Engl J Med. 2016 Dec 29;375(26):2519-29. doi: 10.1056/NEJMoa1611593. Epub 2016 Nov 13. PMID: 27959716.
[50] Pal A, Shenoy S, Gautam A, Munjal S, Niu J, Gopalakrishnan M, Gobburru J. Pharmacokinetics of DFN-15, a Novel Oral Solution of Celecoxib, Versus Celecoxib 400-mg Capsules: A Randomized Crossover Study in Fasting Healthy Volunteers. Clin Drug Investig. 2017 Oct;37(10):937-946. doi: 10.1007/s40261-017-0548-6. PMID: 28748412; PMCID: PMC5602059.
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Efficacy in Pain Relief. The effectiveness of Elyxyb for the immediate treatment of migraines in adults, with or without aura, was established in two randomized, double-blind, placebo-controlled clinical trials. A total of 1,253 patients underwent screening in two Phase 3 trials, one study involved 622 patients and the other one included 631 patients. The co-primary endpoints measured the percentage of patients achieving pain freedom and freedom from the most bothersome migraine symptom (MBS) two hours after the dose. The MBS, selected from nausea, photophobia, or phonophobia, was identified during screening.

In Study One, at two hours post-dose based on last observation carried forward (LOCF) analysis, Elyxyb (DFN-15) demonstrated significant superiority over the placebo for pain freedom (35.6% vs 21.7%), with an odds ratio of 2.00[53]. For MBS, Elyxyb also showed significantly better efficacy than the placebo (57.8% vs 44.8%), with an odds ratio of 1.68 (Figure 5). The most common AEs were dysgeusia and nausea. Similar results have been obtained for the observed case analysis. No DFN-15-treated subjects reported severe or withdrawal-inducing TEAEs, and there were no serious TEAEs, or deaths reported in the study.

In Study Two, Elyxyb exhibited significantly higher two-hour post-dose pain freedom response rates compared to the placebo (32.8% vs 23.5%)[54]. For two-hour post-dose freedom from the MBS, response rates were significantly elevated in the celecoxib oral solution group compared to the placebo (58.1% vs 43.9%) (Figure 6). Adverse events were reported by 10.7% (31/289) of patients using celecoxib oral solution and 9.9% (28/283) of those on placebo. Drug-related adverse events were reported by 7.3% (21/289) of celecoxib oral solution patients and 7.4% (21/283) of placebo patients.

Commercial Strategy of Elyxyb

Scilex positions Elyxyb as an acute treatment for migraine with features that are fast-acting and long-lasting (Figure 7). The product was officially launched in the US in March 2023, with continued growth in prescriptions and market share (Figure 8). In December 2023, the company announced the completion of an insurance coverage agreement with one of the top three national Pharmacy Benefit Managers (PBMs) for its Medicare population. This agreement has the potential to significantly expand Elyxyb coverage, broadening the patient base and fostering increased market adoption.

Indication Expansion of Elyxyb

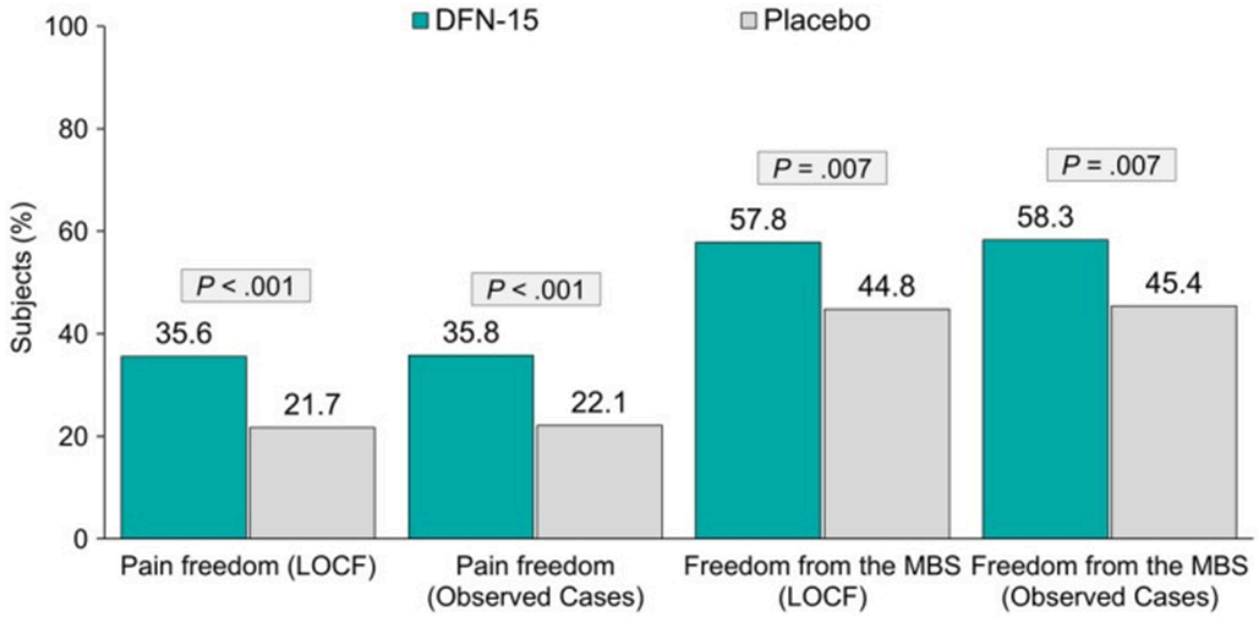
With the successful launch of Elyxyb for migraine, the company is planning to expand its indication to include acute pain. It is estimated that approximately 100M Americans experience various forms of acute pain, with over 20M of them requiring prescription drugs for pain management.[55] Elyxyb has the potential to address the unmet medical demand for fast-acting, safe, and effective non-opioid treatment options.

The company is on track of filing acute pain indication for Elyxyb with FDA in 2024. Celebrex, the oral capsules of celecoxib, is approved for treatment of acute pain. Therefore, in the supplement filing, the primary efficacy and safety data will involve PK modeling between Elyxyb and Celebrex. This data will be used to determine the dose and dosing regimen, providing a 505(b)(2) pharmaceutical bridge between Elyxyb and Celebrex. No additional clinical or nonclinical studies are needed, and no changes are required in CMC since there is no alteration in drug composition or product formulation/manufacturing process.

The company is also seeking to file for the pediatric migraine indication. The supplementary New Drug Application (sNDA) needs to include an initial Pediatric Study Plan (iPSP) agreed upon by the FDA. The company will request a waiver of pediatric studies due to the lack of prevalence in these populations and the availability of other therapies. The iPSP has been submitted, and all information requests by the FDA have been submitted as well. If the waiver is not approved, the company aims to conduct a post-approval PK study in age groups of 6 to <17 years. The status of the sNDA has been prepared and is being published. The company is on track for a 2024 submission pending iPSP agreement with the FDA.

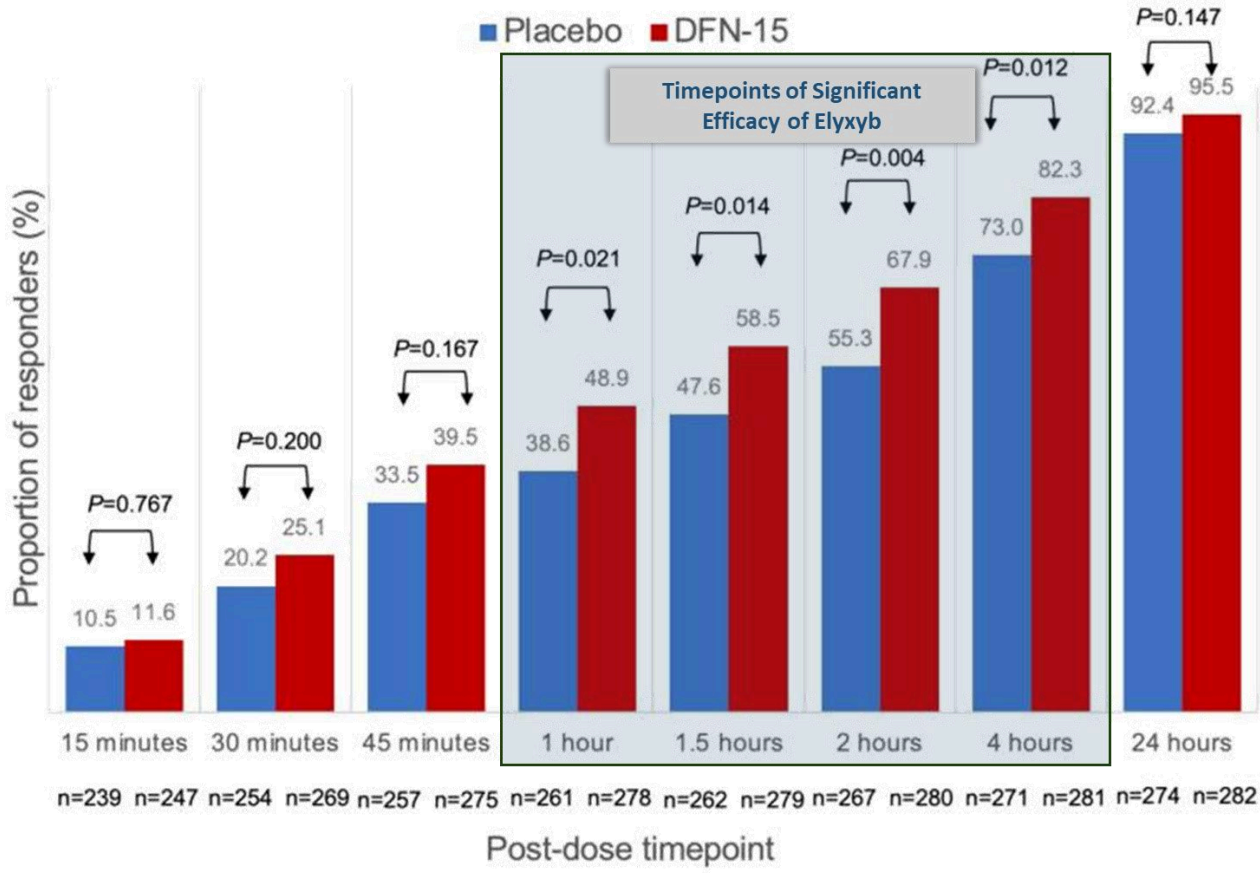
[53] Lipton RB, Munjal S, Brand-Schieber E, Tepper SJ, Dodick DW. Efficacy, Tolerability, and Safety of DFN-15 (Celecoxib Oral Solution, 25 mg/mL) in the Acute Treatment of Episodic Migraine: A Randomized, Double-Blind, Placebo-Controlled Study. Headache. 2020 Jan;60(1):58-70. doi: 10.1111/head.13663. Epub 2019 Oct 24. PMID: 31647577; PMCID: PMC7003821.
[54] Lipton RB, Munjal S, Tepper SJ, Iaconangelo C, Serrano D. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy, Tolerability, and Safety of Celecoxib Oral Solution (ELYXYB) in Acute Treatment of Episodic Migraine with or without Aura. J Pain Res. 2021 Aug 19;14:2529-2542. doi: 10.2147/JPR.S322292. PMID: 34447267; PMCID: PMC8382884.
[55] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5732548/

Figure 5: Elyxyb (DFN-15) Efficacy vs Placebo at Two Hours Post-Dose



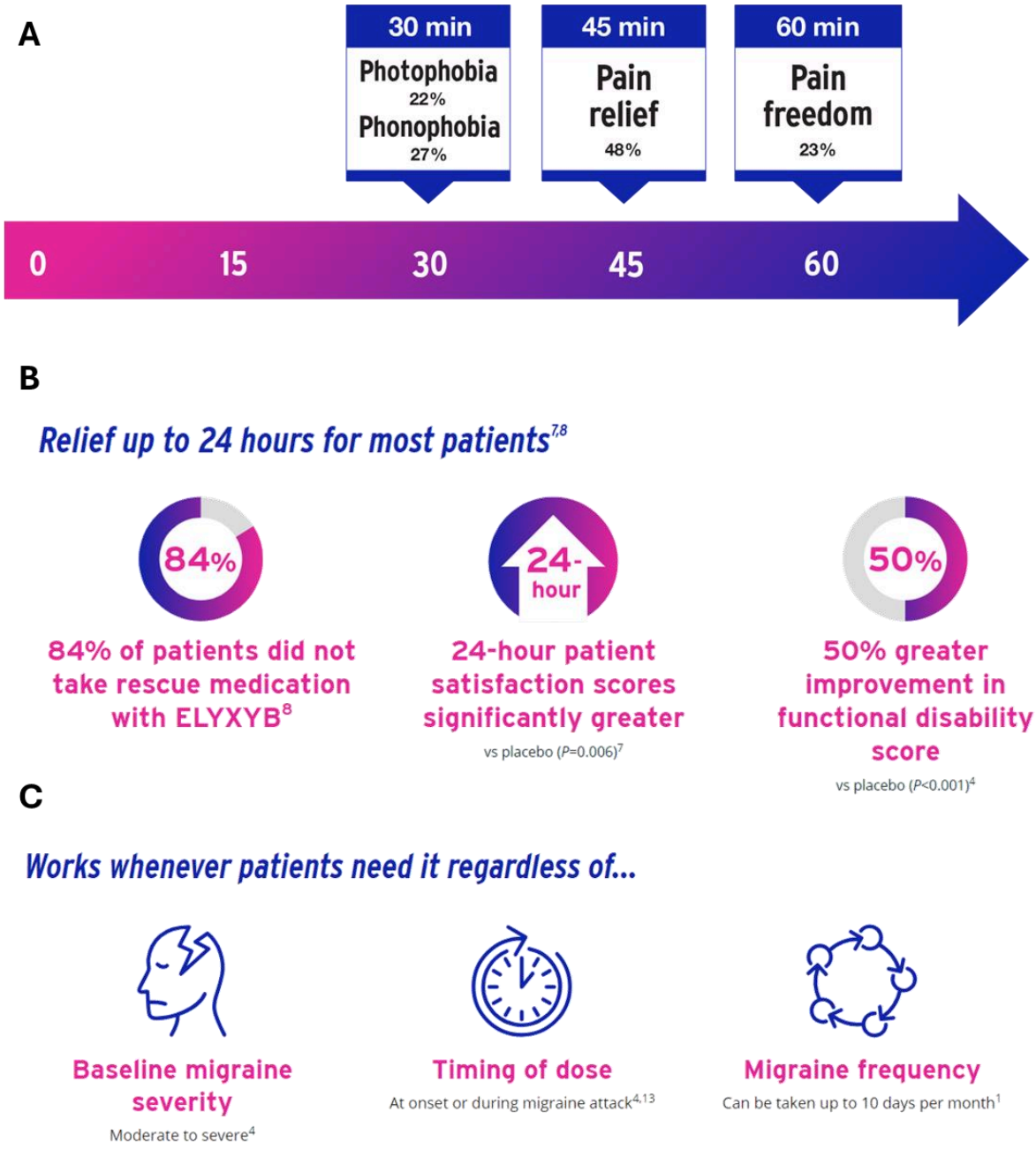
Source: Lipton et al., 2019

Figure 6: Proportion of Patients with Headache Pain Relief by Post-Dose Timepoint



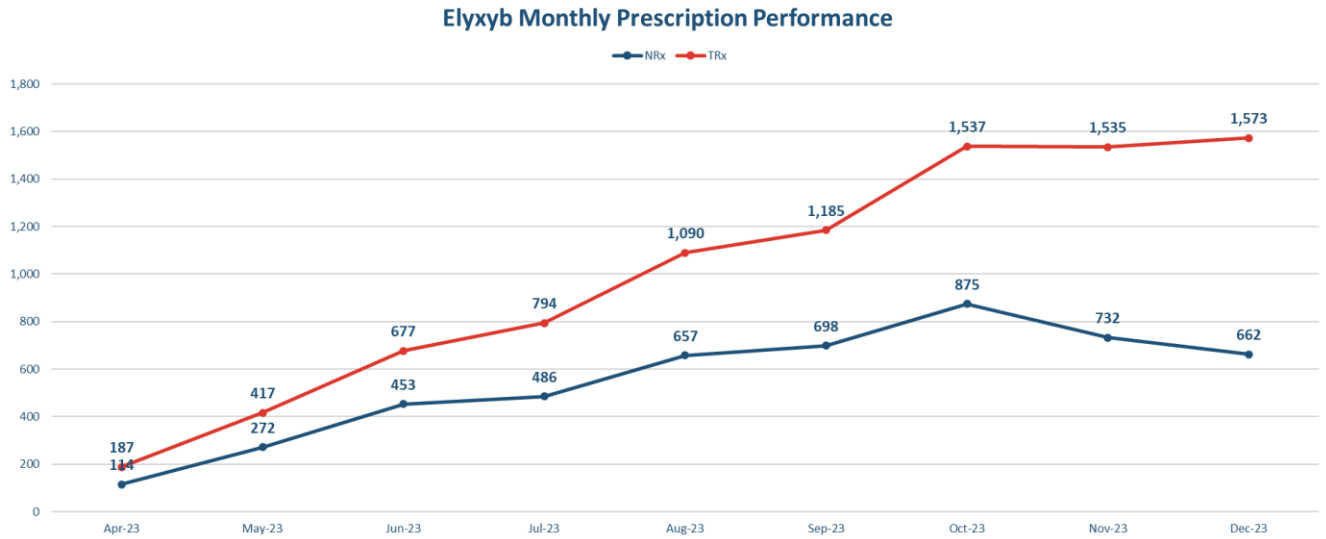
Source: Lipton et al., 2021

Figure 7: Elyxyb Commercial Positioning



Source: Scilex Company Presentation and Website, March 2024

Figure 8: Growing Prescriptions Since Launch in 2023



Source: Scilex Company Presentation, March 2024

Gloperba – Gout Treatment Addressing Unmet Demand

Product Overview. Gloperba is an FDA-approved colchicine oral solution for the prevention of painful gout flares in adults. It addresses a crucial aspect of treatment for patients who face challenges in swallowing pills and offers greater flexibility in dosing, allowing for titration and dose reduction, particularly beneficial for specific populations such as gout patients with renal or hepatic impairment. Romeg Therapeutics' Gloperba (colchicine) oral solution received FDA approval on January 31, 2019, for the prophylaxis of gout flares in adults. The company has announced the successful completion of the commercial manufacturing process for Gloperba, and the anticipated launch in the US is set for the second quarter of 2024.

Licensing Agreement with Romeg Therapeutics. On June 14, 2022, the company entered into a license and commercialization agreement with Romeg Therapeutics for the exclusive right to market and distribute Gloperba in the US. Under the License Agreement, Romeg granted Scilex the following rights: (a) a transferable license, inclusive of sublicense rights, to utilize specified patents and know-how and to commercialize such products; and to manufacture Gloperba; (b) an exclusive, transferable license, inclusive of sublicense rights, to utilize the trademark GLOPERBA and associated logos, designs, translations, and modifications thereof for the marketing of the Initial Licensed Product solely within the US.

In exchange for the license granted under the License Agreement, Scilex has committed to pay Romeg (a) an initial payment of $2M, (b) certain milestone payments totaling up to $13M upon Scilex achieving specific net sales milestones, and (c) royalties ranging from mid-single digit to low-double digit percentages based on annual net sales.

Efficacy in Gout. As discussed above, colchicine is a standard of care for gout. Besides Gloperba, colchicine is available in both branded and generic forms, including capsules (Mitigare®) and tablets (Colcrys®). The safety and effectiveness of Gloperba for addressing acute gout flares in the context of prophylaxis have not been investigated. Instead, the effectiveness of colchicine in individuals with chronic gout is supported by information found in published literature.

Two randomized clinical trials investigated the effectiveness of colchicine at a dosage of 0.6mg twice daily for preventing gout flares in patients with gout who were starting urate-lowering therapy. In both trials, the use of colchicine resulted in a reduction in the occurrence of gout flares.

The initial randomized controlled trial investigating the efficacy of colchicine in acute gout was conducted by Ahern *et al.,* in 1987[56]. In this trial, 43 patients with crystal-confirmed acute gout were randomly assigned to receive either colchicine (1mg loading dose followed by 0.5mg every two hours until symptom relief) or a placebo. The study revealed that 73% of joints in the colchicine group exhibited a 50% or greater improvement in pain at the 48-hour mark after initiating treatment, compared to 36% of joints in the placebo group (Figure 9A & B). Additionally, pain relief occurred sooner among patients in the colchicine group; however, all 22 patients in the colchicine group developed diarrhea.

More recently, Terkeltaub *et al*.[57] conducted a double-blind, placebo-controlled trial involving 575 patients with acute gout. The patients were randomly assigned to receive either a high dose of colchicine (1.2mg loading dose, followed by 0.6mg every hour for 6 hours), a low dose of colchicine (1.2mg loading dose, followed by 0.6mg 1 hour later), or a placebo. Participants were instructed to begin their medication within 12 hours of symptom onset, and 185 patients experienced an eligible gout flare during the study duration. After 24 hours of follow-up, a similar percentage of patients in the high-dose and low-dose colchicine groups achieved a ≥50% improvement in joint pain (32.7% in the high-dose group and 37.8% in the low-dose group), while a significantly smaller percentage of patients in the placebo group (15.5%) showed improvement (Figure 9C & D). However, 19.2% of patients in the high-dose colchicine group encountered diarrhea, whereas the incidence of diarrhea or other adverse effects in the low-dose colchicine group did not significantly differ from the placebo group.

Aligned with real-life practice and previous clinical studies, physicians generally express contentment with colchicine treatment for gout. Nevertheless, they recognize that colchicine's potential to induce GI adverse events, coupled with the caution required when prescribing it to patients with comorbidities, underscores the need for novel formulations with markedly enhanced safety profiles. With Gloperba, physicians can easily modify colchicine dosages for the management of toxicity profiles in patients with renal and liver impairment, side effects, common drug-to-drug interactions.

Regulatory and Commercial Strategy for Gloperba

The company aims to target gout patients who require adjustments to the colchicine dosage, including those with CKD Stage 3/4/5, GI tolerability issues, at risk of drug-to-drug interactions, or difficulty swallowing. Scilex is in the process of seeking FDA approval for an updated label of Gloperba to include a warning that patients with mild or moderate renal or hepatic impairment should be considered for dose adjustment, for patients with severe renal impairment the starting dose should be 0.3mg/day and for those who are undergoing dialysis the total recommended dose should be 0.3mg twice a week. The rate limiting step for label adjustment was Takeda's (TAK; NR) filing of a complaint against Scilex for infringement of specific Orange Book listed patents covering Takeda's colchicine product, Colcrys. Takeda sought a court order stipulating that any FDA approval of label revision be delayed until after the expiration date of the asserted patents listed in the Orange Book. In March 2024 Scilex announced a settlement agreement with Takeda, paving the way for the official adjustment of the prescription label of Gloperba.

Scilex intends to introduce Gloperba to the market in the first half of 2024, setting the launch price at $595 per 150ml bottle of liquid colchicine formulation.

The company is confident in its ability to effectively market and distribute Gloperba in the US. Scilex possesses a direct distribution network covering national and regional wholesalers as well as pharmacies across the US. The company also boasts a seasoned commercial and managed care team, which has demonstrated success in launching and expanding market access for multiple commercial products within the company.

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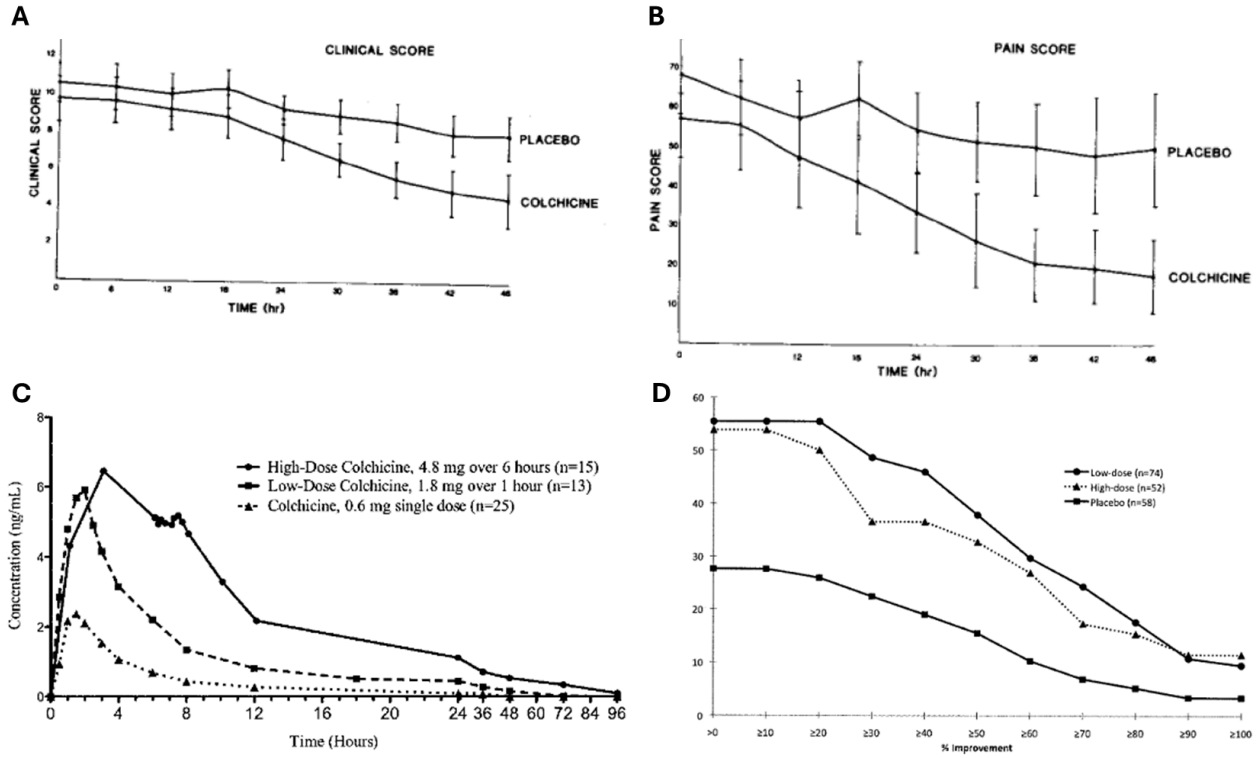
Figure 9: Clinical Evidence Supporting the FDA Approval of Gloperba



Source: Ahern et al. 1987 & Terkeltaub et al. 2010

PIPELINE PRODUCT

SP-102 (SEMDEXA) – Treatment for Chronic Low Back Pain

Disease Overview. Low back pain (LBP) poses a significant challenge to public and occupational health, presenting substantial professional, economic, and social implications[58]. It is estimated that up to 84% of the general population will encounter an episode of LBP at some point in their lives, with recurrent occurrences being common[59]. Non-specific LBP is characterized by axial/non-radiating pain primarily localized in the back, devoid of indications of a serious underlying condition[60]. Depending on the duration of symptoms, LBP may be categorized as acute (lasting less than two to four weeks), subacute (persisting from four to 12 weeks), or chronic (lasting beyond 12 weeks). Sciatica, a common type of back pain, is a condition characterized by pain that radiates along the path of the sciatic nerve, which branches from the lower back through hips and buttocks and down each leg[61]. It is often caused by compression or irritation of the sciatic nerve, commonly due to a herniated disk, bone spur on the spine, or narrowing of the spine. Symptoms of sciatica may include pain, numbness, tingling, or weakness in the affected leg or foot.

Non-pharmacological treatments of lower back pain include exercise therapy, physiotherapy, psychological treatment, and pharmacological treatments include NSAIDs, topical treatments such as lidocaine patch, and epidural steroid injections[62]. Approximately 60% of individuals suffering from chronic back pain utilize opioid pain medications[63], leading to the emergence of numerous new persistent opioid users each year. This trend also contributes to the annual rise in cases of opioid use disorder, underscoring the significant role of opioid use in addressing low back pain and its association with the broader opioid epidemic in the US.

Epidural steroid injections (ESIs) are frequently used to address various types of lower back pain and leg pain[64]. Named for the anatomical area of target, epidural steroid injections entail the direct administration of a local anesthetic and steroid medication into the epidural space surrounding the spinal cord and nerve roots. They are deemed essential in the nonsurgical treatment of sciatica and lower back pain.

Product Overview. SP-102 (SEMDEXA) is a non-opioid injectable therapeutic designed for alleviating low back pain. It represents a groundbreaking development as the initial non-opioid injectable corticosteroid gel formulation aimed at addressing lumbar radicular pain. Remarkably, it is devoid of preservatives, surfactants, solvents, or particulates. Following the completion of pivotal Phase 3 clinical trials, SP-102 received Fast Track Designation from the FDA.

SP-102 is targeting a significant market for back pain, with over 12M epidural steroid injections administered annually in the US. It benefits from an established reimbursement pathway as one of the most frequently performed pain procedures. The product employs an innovative viscous biologic gel formulation optimized for epidural injection, with its unique biocompatible excipient enabling rapid and durable local efficacy. SP-102 is stable at refrigerated temperatures in a prefilled syringe, which can be delivered epidurally through minimally invasive procedures conducted in outpatient pain clinics.

Clinical Status. SP-201 has completed its pivotal Phase 3 clinical trial and is on track to be the first and only FDA-approved epidural steroid product. Currently used products are off-label and contain preservatives, particulates, surfactants, or solvents. Its Phase 3 trial, known as the C.L.E.A.R. trial program, involved 401 randomized patients with lumbosacral radicular pain/sciatica across 40 sites spanning 25 states in the US. This trial stands as the largest double-blind randomized controlled clinical trial of epidural steroid injections for sciatica conducted to date.

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The study successfully achieved its primary endpoint, demonstrating a highly significant reduction in average daily leg pain among patients treated with SP-201 compared to those receiving a placebo. The median time to require a repeat injection was 58 days for the placebo group and 84 days for the SP-102. The safety analysis revealed a favorable safety profile, with no identified safety concerns and established the safety of repeat injections.

The key secondary endpoint assessed using the Oswestry Disability Index—an established measure for evaluating disability and estimating quality of life—demonstrated a notable 23% improvement at four weeks among patients treated with SP-102 compared to baseline.

Next Step. The company has confirmed the NDA 505(b)(2) application of SP-102 with the FDA and agreed with the FDA regarding the next steps for the NDA. Simultaneously, the company is engaging in discussions with various parties regarding distribution plans, aiming for a product launch in 2026.

SP-103 for Treatment of Acute Back Pain

Disease Overview. Neck pain is a complex condition that poses a significant challenge in contemporary society[65]. It ranks among the prevalent musculoskeletal conditions[66], with an age-standardized prevalence rate of 27.0 per 1000 population. In 2016, neck pain, along with low back pain, accounted for the highest healthcare expenditure among 154 conditions in the United States, totaling an estimated $134.5B[67]. Additionally, in 2012, neck pain contributed to absenteeism among 25.5M Americans, resulting in an average of 11.4 days of missed work per individual[68].

No single definitive treatment exists for neck pain. Nonetheless, various pharmacological and non-pharmacological interventions have been recommended[69]. NSAIDs are commonly prescribed to mitigate pain by diminishing inflammation and serve as the conventional approach for pharmacological treatment of neck pain[70]. Topical lidocaine products are often used off-label for treating neck and lower back pain[71]. However, the current low dosage strength may not always provide adequate pain relief. Increasing the concentration of lidocaine per patch area could potentially enhance efficacy.

Product Overview. SP-103, a triple-strength formulation of lidocaine (5.4%), is currently under clinical development as an investigational non-aqueous topical system for neck pain and acute low back pain. Leveraging insights from Scilex's FDA-approved product, ZTlido (a topical lidocaine system 1.8%), SP-103 utilizes the same adhesive drug delivery formulation and manufacturing technology. If granted approval, SP-103 has the potential to be the first FDA-approved lidocaine topical product indicated for neck and acute low back pain.

Clinical Status. On September 15, 2023, the company concluded a Phase 2 trial investigating SP-103 for managing acute lower back pain (LBP). The objective of this multi-center, parallel-group, placebo-controlled, double-blind, randomized study was to assess the safety and tolerability of SP-103 in individuals experiencing moderate to severe acute LBP. Subjects applied topical systems to the area of greatest tenderness in the lower back following a 12-hour ON/12-hour OFF regimen.

In the preliminary analysis, SP-103 exhibited favorable safety and tolerability profiles, with no instances of serious AEs reported. Patients receiving the higher lidocaine concentration of SP-103 (5.4%) did not display any signs of systemic toxicity compared to those using ZTlido 1.8%. Additionally, a subset of patients experiencing more severe muscle spasms demonstrated pain reduction during the initial week of treatment.

Next Step. The company has planned a Phase 2/3 trial of SP-103 for chronic non-radicular neck pain in 2024.

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SP-104 for Treatment of Fibromyalgia (FM)

Disease Overview. Fibromyalgia (FM) is a chronic condition associated with pain, stiffness, and tenderness of the muscles, tendons, and joints[72]. Additionally, it also causes restless sleep, tiredness, fatigue, anxiety, depression, and irregularities in bowel function. The affected painful tissues do not exhibit inflammation[73]. As a result, individuals with fibromyalgia, despite experiencing potentially incapacitating bodily pain, do not undergo tissue damage or deformation[74].

There is no cure for fibromyalgia, while various pain medications are beneficial in managing the symptoms of fibromyalgia[75]. While paracetamol and NSAIDs are commonly prescribed, they often prove ineffective in alleviating pain associated with the condition. Acetaminophen, however, may provide some relief from the pain and stiffness caused by fibromyalgia. Additionally, antidepressants, anticonvulsants, dopamine agonists, and growth hormones are among the drugs used to manage symptoms alongside analgesics. There is an unmet medical demand for novel, safe, and efficient treatments that can enhance the care provided to approximately 10MM fibromyalgia patients in the US and over 200M worldwide.

Naltrexone is an opioid receptor antagonist used to treat alcohol and opioid dependence, with typical daily dosages ranging between 50 and 100mg[76]. At these high doses, naltrexone can block activity across mu-, delta-, and kappa-opioid receptors[77]. At low doses (daily dose of 1 to 5mg; LDN), naltrexone appears to have paradoxical analgesic and anti-inflammatory systemic effects[78], causing transient blockade of opioid receptors centrally resulting in a rebound of endorphin function which may attenuate pain in fibromyalgia[79]. In a systemic review, LDN was found to be effective in the symptomatic management of FM, and of the 78% of included studies that evaluated for safety, no severe adverse events were reported[80].

Currently, there are no available formulations of naltrexone in doses lower than 5mg. Physicians rely on high-dose tablets commercially available (naltrexone hydrochloride 50mg) and have compounding pharmacies divide these doses into smaller amounts for patients. However, pharmacy compounding lacks precision and does not involve analyses to ensure the divided product contains the intended drug level. This lack of consistency can result in dosing errors and difficulties with dosage adjustment. Both commercial and pharmacy-compounded products release the drug immediately in the stomach, leading to potential compliance issues due to severe side effects, including hyperalgesia, dysphoria, insomnia, and anxiety.

Product Overview. SP-104 is a novel, patented, fixed dosage form with delayed burst release containing low-dose naltrexone (4.5mg), developed for FM treatment, aiming to minimize the adverse effects linked with immediate-release naltrexone formulations and the burden of FM disease. SP-104 employs delayed burst release technology, delivering the drug directly to the upper intestine rather than the stomach. By taking SP-104 before bedtime, peak drug levels are reached during sleep, minimizing the patient's awareness of hyperalgesia and other side effects. This combination of delayed-release and nighttime administration may enhance efficacy, as most endorphin/enkephalin release occurs during sleep, optimizing the product's potential to trigger a compensatory response. Data from the Phase 1 clinical trial indicated that SP-104 administered to healthy volunteers resulted in fewer adverse events compared to volunteers treated with immediate release naltrexone at the same dose (4.5mg).

Scilex plans to continue development of the program, once external non-dilutive capital is available.

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PRICING, MARKET POTENTIAL, NPV

ZTlido for PHN Pain

Typically, PHN patients are likely to remain on ZTlido for six months to a year, with rare cases extending to years. Each patient receives a prescription ranging from 30 to 90 patches, averaging 45 patches per patient, with each patch cost $11.70. ZTlido's patent is set to expire in 2031, implying an eight-year product lifecycle in the US. Based on our projections, peak US gross sales of ~$300M could be reached by 2031 (Figure 10). Net revenue also includes the five-year MENA purchase commitments mentioned earlier.

Elyxyb

Migraine. On average, a patient experiences between two to four migraine attacks per month. Elyxyb is available in a pack of six bottles, with each pack lasting for two months. Therefore, we estimate that the average annual cost per patient would be ~$5,000.

Acute Pain. The management has not provided guidance on pricing of Elyxyb for acute pain. We estimate it to be ~$500 per bottle, which could last seven to ten days.

Elyxyb patents will expire in 2036 for both migraine and acute pain. Therefore, we have assumed a twelve-year life cycle for the product in the US. Based on our estimate, peak US gross sales of ~$180M for migraine and ~$1.2B for acute pain could be achieved by 2036 (Figure 11 & 12).

Gloperba

Typically, a gout patient is likely to remain on Gloperba for six months. Each bottle of Gloperba lasts for 45 days per patient. Gloperba is expected to have its patent expiration in 2036, therefore, we assume a twelve-year life cycle for the product in the US. According to our estimate, peak sales of ~$400M could be achieved by 2036 in the US. (Figure 13).

The combined risk adjusted NPV of all commercial assets, with a 90% probability of success for Elyxyb's indication expansion in acute pain, is ~$1.2B ($11 per share), according to our model (Figure 14).

Figure 10: Market Model of ZTlido

PHN-Related Pain - U.S.		2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
($ in thousands except price)										
Total Population U.S. (in thousands) *		334,234	335,905	337,585	339,272	340,969	342,674	344,387	346,109	347,840
Population with Shingles**		111,411	111,968	112,528	113,091	113,656	114,225	114,796	115,370	115,947
Patients Suffering from PHN***		15,598	15,676	15,754	15,833	15,912	15,991	16,071	16,152	16,233
Patients with PHN Receiving Prescription		12,478	12,540	12,603	12,666	12,730	12,793	12,857	12,921	12,986
Total Patients Treated with ZTlido		275	364	454	456	458	461	463	465	467
% of market penetration		*2.2%*	*2.9%*	*3.6%*	*3.6%*	*3.6%*	*3.6%*	*3.6%*	*3.6%*	*3.6%*
Total Patches		12,353	16,365	20,417	20,519	20,622	20,725	20,829	20,933	21,037
Average Number of Patches per Patient	45									
Price per Patch ($)		$12	$12	$12	$13	$13	$14	$14	$14	$15
Gross Revenue		**$144,533**	**$197,218**	**$253,428**	**$262,336**	**$271,557**	**$281,102**	**$290,983**	**$301,211**	**$311,799**
Net U.S. Sales		$46,251	$88,748	$126,714	$131,168	$135,779	$140,551	$145,492	$150,606	$155,899
MENA Purchase Commitment			$11,500	$19,000	$22,500	$27,000	$30,000			
Total Net Revenue		**$46,251**	**$100,248**	**$145,714**	**$153,668**	**$162,779**	**$170,551**	**$145,492**	**$150,606**	**$155,899**

** The U.S. population is projected to be 334,233,854, growing by 0.5% annually going forward. Source: Census.gov*

*** In the U.S., about 1/3 people developes Shingles in their life times. Source: Census.gov*

****About 9 to 14.3% of shingle patients develop PHN. Source: https://www.ncbi.nlm.nih.gov/books/NBK493198/*

Source: Historical SEC Filings; Rodman & Renshaw estimates

Figure 11: Market Model for Elyxyb for Treating Migraine

Migraine - U.S.	2023A****	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
($ in thousands)														
Migraine Prevalence (in thousands) *	39,391	39,588	39,786	39,985	40,185	40,386	40,588	40,791	40,994	41,199	41,405	41,612	41,821	42,030
Patients Receive Acute Treatment **	9,060	9,105	9,151	9,197	9,242	9,289	9,335	9,382	9,429	9,476	9,523	9,571	9,619	9,667
Patients on NSAIDs ***	6,233	6,264	6,296	6,327	6,359	6,391	6,423	6,455	6,487	6,519	6,552	6,585	6,618	6,651
Patients on Non-Aspirin / Ibuprofen NSAIDs	3,958	3,978	3,998	4,018	4,038	4,058	4,078	4,099	4,119	4,140	4,161	4,181	4,202	4,223
Patients treated with Elyxyb for Migraine	1.2	4	10	17	20	22	22	23	23	23	23	23	23	23
% of Market Penetration	*0.03%*	*0.10%*	*0.24%*	*0.42%*	*0.50%*	*0.55%*	*0.55%*	*0.55%*	*0.55%*	*0.55%*	*0.55%*	*0.55%*	*0.55%*	*0.55%*
Treatment Cost Per Year	$5,244	$5,401	$5,563	$5,730	$5,902	$6,079	$6,262	$6,449	$6,643	$6,842	$7,047	$7,259	$7,477	$7,701
Gross Revenue	**$6,227**	**$21,486**	**$53,379**	**$96,696**	**$119,161**	**$135,684**	**$140,453**	**$145,390**	**$150,501**	**$155,791**	**$161,267**	**$166,935**	**$172,803**	**$178,877**
Net U.S. Revenue for Migraine	**$498**	**$8,594**	**$21,351**	**$38,678**	**$47,664**	**$54,274**	**$56,181**	**$58,156**	**$60,200**	**$62,316**	**$64,507**	**$66,774**	**$69,121**	**$71,551**

** About 39 million patients suffering from migraine headaches in the U.S. Source: Migraine Research Foundation & DRG*

*** About 43% of patients were treated acutely with migraine. Source: Migraine Research Foundation & DRG*

**** About 69% of patients treated acutely received NSAIDs; Among those patients, 64% of those patients received non-aspirin / ibuprofen NSAIDs. Source: The Journal of Headache and Pain*

***** As the first year of launch, promotion effort comes with lower gross-to-net ratio*

Source: Historical SEC Filings; Rodman & Renshaw estimates

Figure 12: Market Model for Elyxyb for Treating Acute Pain

Acute Pain - U.S.	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
($ in thousands)														
Total Population U.S. (in thousands) *	334,234	335,905	337,585	339,272	340,969	342,674	344,387	346,109	347,840	349,579	351,327	353,083	354,849	356,623
Adult Population **	260,368	261,670	262,978	264,293	265,615	266,943	268,278	269,619	270,967	272,322	273,683	275,052	276,427	277,809
Patients with Acute Pain ***	93,733	94,201	94,672	95,146	95,621	96,099	96,580	97,063	97,548	98,036	98,526	99,019	99,514	100,011
Patients Diagnosed with Acute Pain	46,866	47,101	47,336	47,573	47,811	48,050	48,290	48,531	48,774	49,018	49,263	49,509	49,757	50,006
Patients Receive Prescriptions	21,090	21,195	21,301	21,408	21,515	21,622	21,730	21,839	21,948	22,058	22,168	22,279	22,391	22,503
Patient Compliance with Prescriptions	10,545	10,598	10,651	10,704	10,757	10,811	10,865	10,920	10,974	11,029	11,084	11,140	11,195	11,251
Patients on Elyxyb for Acute Pain			128	300	506	811	1,087	1,365	1,646	1,654	1,663	1,671	1,679	1,688
% of Market Penetration			*1.20%*	*2.80%*	*4.70%*	*7.50%*	*10.00%*	*12.50%*	15.00%	15.00%	15.00%	15.00%	15.00%	15.00%
Treatment Cost Per Year			$500	$515	$530	$546	$563	$580	$597	$615	$633	$652	$672	$692
Gross Revenue			**$63,904**	**$154,350**	**$268,194**	**$443,013**	**$611,446**	**$791,173**	**$982,779**	**$1,017,324**	**$1,053,083**	**$1,090,099**	**$1,128,416**	**$1,168,080**
Net U.S. Revenue for Acute Pain			**$21,088**	**$65,940**	**$107,278**	**$199,356**	**$275,151**	**$356,028**	**$442,251**	**$457,796**	**$473,887**	**$490,544**	**$507,787**	**$525,636**

** The U.S. population is projected to be 334,233,854, growing by 0.5% annually going forward. Source: Census.gov*

*** More than 75% (77.9%) of U.S. population are adults. Source: Census.gov*

**** Prevalence of acute pain in adult population is about 36%, with 50% of them receive diagnosis, 45% of whom receive prescription drugs, with 50% of compliance rate.*

***** As the first year of launch, promotion efforts result in lower gross-to-net ratio*

Source: Historical SEC Filings; Rodman & Renshaw estimates

Figure 13: Market Model for Gloperba

Gout - U.S.	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
($ in thousands)														
Total Population U.S. (in thousands) *	334,234	335,905	337,585	339,272	340,969	342,674	344,387	346,109	347,840	349,579	351,327	353,083	354,849	356,623
Adult Population **	260,368	261,670	262,978	264,293	265,615	266,943	268,278	269,619	270,967	272,322	273,683	275,052	276,427	277,809
Patients with Gout ***	10,154	10,205	10,256	10,307	10,359	10,411	10,463	10,515	10,568	10,621	10,674	10,727	10,781	10,835
Patients Receive Colchicine ****	1,805	1,814	1,823	1,832	1,842	1,851	1,860	1,869	1,879	1,888	1,898	1,907	1,917	1,926
Patients in Need of Dose Adjustment (renal or hepatic impairment)	1,264	1,270	1,276	1,283	1,289	1,296	1,302	1,309	1,315	1,322	1,328	1,335	1,342	1,348
Patients on Gloperba for Dose Adjustment		4	17	43	69	82	96	96	96	97	97	98	98	99
% of Market Penetration		*0.3%*	*1.3%*	*3.3%*	*5.3%*	*6.3%*	*7.3%*	*7.3%*	*7.3%*	*7.3%*	*7.3%*	*7.3%*	*7.3%*	*7.3%*
Patient with GI Toxicity		308	310	312	313	315	316	318	319	321	323	324	326	327
Patient on Gloperba for Reducing GI Toxicity		2	6	10	11	12	13	13	13	13	13	13	13	13
% of Market Penetration		*0.7%*	*1.9%*	*3.1%*	*3.6%*	*3.9%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Total Patients on Gloperba		6	23	52	80	94	108	109	109	110	110	111	112	112
Treatment Cost Per Year		$2	$2	$3	$3	$3	$3	$3	$3	$3	$3	$3	$3	$3
Gross Revenue		$15,156	$56,094	$132,280	$208,052	$252,598	$298,710	$309,210	$320,078	$331,329	$342,975	$355,031	$367,510	$380,428
Net U.S. sales		**$6,062**	**$22,438**	**$52,912**	**$83,221**	**$101,039**	**$119,484**	**$123,684**	**$128,031**	**$132,532**	**$137,190**	**$142,012**	**$147,004**	**$152,171**

Source: Historical SEC Filings; Rodman & Renshaw estimates

Figure 14: NPV Model

ZTlido U.S. + MENA	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Total Net Revenue *($ in thousands)*	**$46,251**	**$100,248**	**$145,714**	**$153,668**	**$162,779**	**$170,551**	**$145,492**	**$150,606**	**$155,899**
Cost of Sales (27%)	$15,500	$27,067	$39,343	$41,490	$43,950	$46,049	$39,283	$40,664	$42,093
Gross Profit	**$30,751**	**$73,181**	**$106,371**	**$112,178**	**$118,828**	**$124,502**	**$106,209**	**$109,942**	**$113,807**

Elyxyb Migraine U.S.	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
Total Net Revenue in U.S. *($ in thousands)*	**$498**	**$8,594**	**$21,351**	**$38,678**	**$47,664**	**$54,274**	**$56,181**	**$58,156**	**$60,200**	**$62,316**	**$64,507**	**$66,774**	**$69,121**	**$71,551**
Cost of Sales (2024-2026: 27%; 2027 & Onward: 16%)	$135	$2,320	$5,765	$10,443	$7,626	$8,684	$8,989	$9,305	$9,632	$9,971	$10,321	$10,684	$11,059	$11,448
Gross Profit	**$364**	**$6,274**	**$15,587**	**$28,235**	**$40,038**	**$45,590**	**$47,192**	**$48,851**	**$50,568**	**$52,346**	**$54,186**	**$56,090**	**$58,062**	**$60,103**

Elyxyb Acute Pain U.S.	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
Total Net Revenue in U.S. *($ in thousands)*			**$21,088**	**$65,940**	**$107,278**	**$199,356**	**$275,151**	**$356,028**	**$442,251**	**$457,796**	**$473,887**	**$490,544**	**$507,787**	**$525,636**
Cost of Sales (2024-2026: 27%; 2027 & Onward: 16%)			$5,694	$17,804	$17,164	$31,897	$44,024	$56,964	$70,760	$73,247	$75,822	$78,487	$81,246	$84,102
Gross Profit			**$15,394**	**$48,136**	**$90,113**	**$167,459**	**$231,127**	**$299,063**	**$371,491**	**$384,548**	**$398,065**	**$412,057**	**$426,541**	**$441,534**
Probability of success 90%			*90%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*
Probability-adjusted Gross Profit			**$13,855**	**$43,323**	**$81,102**	**$150,713**	**$208,014**	**$269,157**	**$334,342**	**$346,094**	**$358,259**	**$370,852**	**$383,887**	**$397,381**

Gloperba U.S.	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
Total Net Revenue in U.S. *($ in thousands)*		**$6,062**	**$22,438**	**$52,912**	**$83,221**	**$101,039**	**$119,484**	**$123,684**	**$128,031**	**$132,532**	**$137,190**	**$142,012**	**$147,004**	**$152,171**
Cost of Sales (25%)		$1,516	$5,609	$13,228	$20,805	$25,260	$29,871	$30,921	$32,008	$33,133	$34,298	$35,503	$36,751	$38,043
Gross Profit		**$4,547**	**$16,828**	**$39,684**	**$62,416**	**$75,779**	**$89,613**	**$92,763**	**$96,024**	**$99,399**	**$102,893**	**$106,509**	**$110,253**	**$114,128**

NPV Calculation		2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
Total Net Revenue		$46,749	$114,905	$210,591	$311,198	$400,941	$525,220	$596,308	$688,473	$786,382	$652,644	$675,584	$699,331	$723,912	$749,358
Total Gross Profit		$31,062	$84,002	$152,641	$223,419	$302,384	$396,585	$451,028	$520,713	$594,740	$497,838	$515,337	$533,451	$552,202	$571,612
R&D		$12,746	$5,000	$10,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000
SG&A		$119,641	$64,000	$74,000	$84,000	$94,000	$104,000	$118,076	$136,326	$155,713	$129,232	$133,774	$138,476	$143,344	$148,382
Operating Income (EBIT)		($101,325)	$15,002	$68,641	$134,419	$203,384	$287,585	$327,952	$379,387	$434,027	$363,607	$376,563	$389,975	$403,858	$418,230
Tax Expense	*21%*						$60,393	$68,870	$79,671	$91,146	$76,357	$79,078	$81,895	$84,810	$87,828
Free Cash Flow		($101,325)	$15,002	$68,641	$134,419	$203,384	$227,192	$259,082	$299,716	$342,881	$287,249	$297,485	$308,080	$319,048	$330,402
Discount rate	*15%*														
NPV of FCF	**$1,197,191**														
Shares Outstanding in Thousands	114,576														
NPV of FCF per Share	**$11**														

In millions except per share values

Source: Historical SEC Filings; Rodman & Renshaw estimates

FINANCIALS

As of December 31, 2023, Scilex holding reported $4M in cash, cash equivalents, and investments. On March 5, 2024, the company announced the closing of a public offering of 5,882,353 shares of common stock and accompanying common warrants to purchase up to 5,882,353 shares of common stock, at a combined public offering price of $1.70, with gross proceeds of approximately $10M.

As of December 31, 2023, Scilex had nearly $129M in indebtedness (Figure 15). In March 2024 the company paid off the remaining balance of the Convertible Debentures and made a $15M payment on the Oramed Note. Beginning on June 21, 2024 Scilex is due make $20M quarterly payments on the note, concluding with a $26M payment by March 21, 2025.

Figure 15: Indebtedness, as of December 31, 2023

	December 31, 2023
Oramed Note (Outstanding Principal Balance: $96.9 million)	$ 104,089
Convertible Debentures (Outstanding Principal Balance: $4.4 million)	4,340
Revolving Facility	17,038
Deferred Consideration with Romeg	3,386
Total indebtedness	$ 128,853

Source: Historical SEC Filings

In addition to the shares (preferred and common) listed in Figure 16 and mentioned above (private placement in March), the company also has 33MM stock option shares issuable.

Figure 16: Capitalization Table

Preferred stock, $0.0001 par value, 45,000,000 shares authorized; 29,057,097 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively
Common stock, $0.0001 par value, 740,000,000 shares authorized; 160,084,250 shares issued and 100,015,665 shares outstanding as of December 31, 2023; 141,348,856 shares issued and outstanding as of December 31, 2022

	Warrants	Exercise Price	Expiration Date	Notes
SPAC Warrants				
Oramed	4,000,000	$11.50 per share	November 2027	
Scilex Holding Company	490,617	$11.50 per share	November 2027	
Other Spac warrants	6,467,692	$11.50 per share	November 2027	
Total	10,958,309			
New issued warrants				
Oramed initial	4,500,000	$0.01 per share	October 2028	
Oramed March 2024	2,125,000	$0.01 per share	October 2028	If Oramed debt fully paid before March 2024, Scilex will not need to issue additional 2.125mm warrants
Oramed June 2024	2,125,000	$0.01 per share	October 2028	If Oramed debt fully paid before June 2024, Scilex will not need to issue additional 2.125mm warrants
Oramed Septmeber 2024	2,125,000	$0.01 per share	October 2028	If Oramed debt fully paid before September 2024, Scilex will not need to issue additional 2.125mm warrants
Oramed December 2024	2,125,000	$0.01 per share	October 2028	If Oramed debt fully paid before December 2024, Scilex will not need to issue additional 2.125mm warrants
Total	13,000,000	$0.01 per share		

Source: Historical SEC Filings

MANAGEMENT

Jaisim Shah – Chief Executive Officer & President

Jaisim Shah has over 30 years industry success in leading product development & commercializing innovative therapies and creating companies with documented success in development and commercialization of some of today's most recognized pharmaceutical brands. He is a seasoned life science executive and board director with extensive accomplishments at Bristol-Myers Squibb, Roche, PDL Biopharma, Sorrento, Pfizer/Upjohn, Scilex, and start-ups Elevation and Semnur Pharmaceuticals. Mr. Shah has been CEO and President of Semnur Pharmaceuticals (acquired by Scilex Pharmaceuticals) since its inception in 2013. He has served as CEO and President of Scilex Holding and Scilex Pharmaceuticals since March 2019 and serves on the board of directors of Sorrento Therapeutics Inc. and Scilex Holding. Most recently, Mr. Shah served as Chief Business Officer of Elevation Pharmaceuticals where he focused on financing, mergers and acquisitions, and business development. He led the sale of Elevation to Sunovion Pharmaceuticals in 2012. At Facet Biotech and PDL BioPharma, he served from 2000 to 2009 as Chief Business Officer and held the position of senior vice president of marketing and medical affairs. During this time, he completed numerous licensing/partnering and strategic transactions including with Roche, Bristol-Myers Squibb, Otsuka, and Biogen Idec. His leadership in marketing and leading the commercial enterprise helped the company make large improvements to meet its profitability potential. At Bristol-Myers Squibb, as vice president of global marketing from 1997 to 2000, Mr. Shah received the "Presidents Award" for completing one of the most significant collaborations in the company's history. Prior to working with Bristol-Myers Squibb, Mr. Shah led international marketing for oncology and virology and was global business leader for corporate alliances at Roche from 1991 to 1997 with Genentech and IDEC, and prepared products for worldwide launch and pre-launch at F. Hoffman-La Roche AG in Switzerland. He has played a key role in the formulation of long-range plans and pre-launch and launch strategies for such brands as Abilify®, Pegasys®, and Rituxan/MabThera®, each of which have generated well over $1B in sales. Mr. Shah holds an M.A. in Economics from the University of Akron and an M.B.A. from University of Oklahoma.

Henry Ji, Ph.D. – Co-Founder and Executive Chairman of the Board

Henry Ji brings 25+ years of experience in the biotechnology and life sciences industry. Dr. Ji has been Chairman of Scilex from March 2019 to August 2023 and served as the CEO of Scilex Pharmaceuticals from November 2016 to March 2019. Dr. Ji co-founded Sorrento Therapeutics, Inc. and has served as a director since 2006, as its CEO and President since September 2012, and as Chairman of its board of directors since 2017. During his tenure at Sorrento, he has engineered and led a phenomenal growth of Sorrento through acquisition and mergers including Bioserv, Scilex Pharmaceuticals, Concortis Biotherapeutics, Levena Biopharma, LACEL, TNK Therapeutics, Virttu Biologics, Ark Animal Health, and Sofusa Lymphatic Delivery Systems. Dr. Ji has served as Sorrento's Chief Scientific Officer from November 2008 to September 2012 and as its Interim CEO from April 2011 to September 2012. Prior to Sorrento, he held senior executive positions at CombiMatrix, Stratagene, co-founded Stratagene Genomics, a subsidiary of Stratagene, and served as its President & CEO and a member of the board of directors. Henry Ji received a doctorate from the University of Minnesota and an undergraduate degree from Fudan University.

Suketu D. Desai, Ph.D. – Chief Technical Officer & Senior Vice President

Suketu D. Desai, Ph.D. has 25+ years of experience in the Biologics and Pharmaceutical Industry. Dr. Desai is Chief Technical Officer and Senior Vice President, Chemistry, Manufacturing and Controls, Regulatory CMC, and Quality Assurance at Scilex Pharmaceuticals (2015 – present). Prior to Scilex, Dr. Desai was Vice President of Biologics Development and Manufacturing for biologics drug substance and drug product, technical due diligence and commercial technical operations at Allergan, Inc. (2014-2015), which was acquired by Actavis, plc. Before Allergan, Dr. Desai was a CMC consultant in 2013. Dr. Desai was Vice President, Biotechnology Technical Operations for biologics drug substance and drug product, analytical, manufacturing, and technical due diligence at Cephalon, Inc. (2010-2012), which was acquired by Teva Pharmaceuticals. During 2007-2010, Dr. Desai was Ception Therapeutics, Inc., Vice President, Chemistry, Manufacturing and Controls and Quality Assurance responsible for biologics drug substance and drug product development, analytical, manufacturing, quality, regulatory CMC, and technical due diligence for business development. Ception was acquired by Cephalon (2010). Suketu was Principal Scientist, Process Sciences/Technical Operations for late-stage and commercial biologics drug substance and drug product at Centocor, Inc., a Johnson & Johnson subsidiary (2003-2006); Assoc. Director, Pharmaceutical and Biologic Formulations at AAI Pharma Development Services (2001-2003); Director/Sr. Manager at Aronex Pharmaceuticals, Inc. (1996-2001); and Senior Scientist II/I at Novartis

Pharmaceuticals, formerly Alcon Labs, Inc., (1992-1996). Dr. Desai has contributed to several commercial biologic products (Botox, Cinquair, Simponi, Remicade, ReoPro, Retavase, and Eprex) and pharmaceutical products (Azopt and Volfenol) and late-stage development products including placulumab, abicipar pegol/DARPin, and Innotox. Dr. Desai received his Ph.D. in Pharmaceutical Sciences from the University of Arizona, Tucson, AZ and master's in pharmacology and bachelor's in pharmacy from the University of Mumbai, Mumbai, India.

Dmitri Lissin, MD – Chief Medical Officer & Senior Vice President

Dmitri Lissin currently serves as Chief Medical Officer and Senior Vice President, Clinical Development and Medical Affairs of Scilex/Semnur Pharmaceuticals (2015 – present). Prior to Semnur, from 2011-2015, Dr. Lissin was Vice President of Clinical Development at Xenoport, responsible for conduct of multiple clinical research programs in neurology and dermatology. From 2006-2011 Dr. Lissin directed a clinical research team and served as member of the Executive Committee at DURECT Corporation, designing and executing clinical trials in chronic nociceptive, neuropathic, and acute post-operative pain, which led to successful licensing deals and NDA filings. From 1998-2006 Dr. Lissin managed various clinical R&D programs at Titan Pharmaceuticals, Aerogen, and Synarc. Dr. Lissin has a broad expertise with proprietary drug-delivery technologies applied to therapeutic products spanning numerous clinical areas including pain and neurological disorders. Most of his experience involves clinical development of novel oral, transdermal, implantable, and injectable formulations containing existing active pharmaceutical ingredients, using 505(b)(2) drug approval pathway. He has participated in many pre-IND, end of Phase 1, end of Phase 2, and pre-NDA meetings, negotiating clinical development programs with the FDA Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), Division of Neurology Products, and Division of Dermatology and Dental Products. He received his post-doctoral training at the University of California San Francisco, and his medical degree through an exchange program between Russian National Medical University and Harvard Medical School.

Suresh Khemani – Chief Commercial Officer & Senior Vice President

Mr. Khemani brings more than 25 years of global pharmaceutical experience to Scilex, a privately held clinical development and commercial company based in Palo Alto, California. Mr. Khemani has been SVP Chief Commercial Officer of Scilex since March 2019. He manages Scilex sales, sales operations, marketing, market research, and managed care operations, including its US promotional role and interactions with overseas partners, commercial development, and international operations. In addition to his 25 years of senior management experience in the industry, he successfully launched specialty and large market products including Zelmac / Zelnorm for IBS-D, readiness for Dexpramipexole (dex) in ALS and Parkinson's Disease, Cubicin, an injectable antibiotic in EU and developed launch plans for Pulminique, an inhaled cyclosporine, for US and EU, and Abilify a $7B product. His therapeutic areas include pain, neurology, oncology, immunology, and CV. He worked prior to Scilex at executive-level positions at Bristol Myers Squibb, Chiron, PDL Biopharmaceuticals, Facet Biotech, and Knopp Biosciences. He holds a bachelor's degree in pharmacy from Bombay University.

Steve Lincoln – General Counsel & Chief Compliance Officer

Steve Lincoln serves as General Counsel, Chief Compliance Officer for Scilex Holding Company. Mr. Lincoln has been involved in the biopharma industry for more than 21 years. Most recently, he was Counsel to the law firm of Brown Gee & Wenger, where his corporate practice included several publicly traded and private biopharma companies. Before that, Mr. Lincoln served in in-house counsel roles at SciClone Pharmaceuticals (acquired by GL Capital), Kosan Biosciences (acquired by Bristol Myers Squibb), SuperGen (now Astex Pharmaceuticals, a subsidiary of Otsuka), and Protein Design Labs (later Facet Biotech, acquired by AbbVie). Mr. Lincoln is a graduate of Brown University and the Boston University School of Law.

Stephen Ma – Chief Financial Officer & Senior Vice President

Stephen Ma has served as the Company's Chief Accounting Officer since November 2022 and previously served as its Vice President of Finance from January 2022 to November 2022. Mr. Ma has more than 15 years of finance and operational expertise across pharmaceuticals and venture backed biotechnology companies. He most recently served as Director of Finance and Operations for Anwita Biosciences, Inc., a clinical stage company, from August 2019 to January 2022. Prior to that, from May 2016 to August 2019, he served as Sr. Director of Finance and Controller for Semnur Pharmaceuticals, a specialty pharmaceutical company focused on the clinical and commercial development of innovative products that meet the needs of pain management practitioners and

their patients, which was acquired by the Company in March 2019. Prior to that, he served as Controller for Globavir and part of the management team that worked on its IPO process. He also served as the Controller for Ardelyx, which went public in 2014. Prior to that, Mr. Ma served in various finance positions at PDL BioPharma and Hyperion Therapeutics. Mr. Ma began his career with more than 10 years in high technology companies and has a wealth of experience in finance, strategic planning, commercial launching, debt financing, public offerings, and M&A transactions. Mr. Ma holds a B.S. in Finance and M.A. in Economics from San Jose State University.

Elaine K Chan, PharmD – Executive Director and Head of Medical Affairs

Dr. Elaine Chan heads Medical Affairs at Scilex since 2022. Prior to joining Scilex, Dr. Chan was Senior Director at Genentech Inc (a member of the Roche group), one of the world's leading pharmaceutical companies, from 2009 to 2021, where she held wide-ranging roles in Medical Affairs, Business Operations and Strategy, Pharmacovigilance, Marketing, and new product planning. While at Genentech, Dr. Chan was involved in the development and launch of several market-leading brands, including Gazyva (Obinutuzumab) and Susvimo (Ranibizumab injection for Ocular Implant). Dr. Chan has over a decade of experience working at small-midsize biotech companies, including PDL BioPharma (now Abbvie) and Chiron (now Novartis International AG), where she led Marketing and Product Strategy for Phase 3 Molecules in Hepatology and Lung Transplantation, two niche and underserved markets. Dr. Chan participated in four product pre-launches, two as leads (Terlipressin and Tenecteplase), and has a proven track record of delivering successful outcomes for patients and stakeholders. Dr. Chan holds a Doctor of Pharmacy (PharmD) from the University of California, San Francisco (UCSF), where she received extensive training in Clinical Pharmacology and Therapeutics.

Gigi DeGuzman – Executive Director of Administrative Operations and Head of Human Resources

Gigi DeGuzman is a seasoned professional with over 25 years of experience in human resources, operations management, facilities management, event planning, executive coordination, and administrative operations. She has played a significant role over the years, working in pharmaceuticals, biotechnology, medical devices, medical aesthetics, high-tech, and solar firms. Over her career, Ms. DeGuzman has demonstrated leadership and expertise. She is now Scilex Holding's Executive Director of Administrative Operations. Prior to joining Scilex Holding, Ms. DeGuzman became Business Office Manager at Semnur Pharmaceuticals in 2016, a pain treatment specialist pharmaceutical firm acquired by Scilex Holding in March 2019. Ms. DeGuzman accelerated her career by taking on more essential engagements at Scilex Holding. Strategic leadership, operational efficiency, and unrelenting excellence have defined her time at Scilex Holding. Her experience in executive coordinating, event planning, facility operations, and building a dynamic human resources environment has yielded results. She has demonstrated remarkable results with her blend of experience in various industries. She holds a B.S. in Hospitality and Tourism from Cal State East Bay, UC Davis facilities management training, and pursuit of SHRM certification; Ms. DeGuzman is committed to human resources excellence.

Mike Ciaffi – National Sales Director

Mr. Ciaffi has over 25 years in the pharmaceutical industry. Mr. Ciaffi currently serves as the National Sales Director at Scilex Holding Company. Mr. Ciaffi joined Scilex in 2018 as a Regional Business Director to build a sales team to launch ZTLido (Lidocaine Topical System) 1.8%. Mr. Ciaffi was appointed Area Business Director in 2019 and National Sales Director at Scilex in 2020. Prior to Scilex, Mr. Ciaffi spent 18 years with Purdue Pharma in sales, field sales training and development, and sales leadership roles earning multiple awards during his tenure at Purdue. Mr. Ciaffi successfully led sales teams through multiple product launches in the non-opioid and opioid pain space as well as an OTC line of products. Mr. Ciaffi's most notable therapeutic areas of experience include Pain Management, Dermatology, Rheumatology, Allergy, Asthma, & Immunology, and Gastroenterology. Mr. Ciaffi earned a Bachelor of Science Degree in Business Administration from Delaware Valley College.

Sumant Rajendran – Executive Director of Marketing

Sumant Rajendran heads up the Marketing department and brings over 20 years' experience to Scilex. He has been at the company since mid-2019 and has overseen the growth of our marketed portfolio from one product (ZTlido) to three (with the addition of Elyxyb and Gloperba). Besides this, Mr. Rajendran is closely involved in advancing our clinical portfolio in a rational manner to set our pipeline products up for commercial success. Mr. Rajendran is the architect of the novel ZTlido campaign ("the perfect partner to gabapentinoids") that has helped spark rapid brand growth from 2023, and of the impending Gloperba launch campaign ("precision, lowered dosing

of colchicine"). His industry experience spans both biologics and small molecules, at companies large (Amgen), mid-sized (Eisai) and small (Depomed); and therapeutic areas including Pain, Oncology, Metabolic Disease, Rheumatology and Dermatology. He has worked on best-in-class products such as Enbrel (etanercept) and Aloxi (palonosetron), as well as lead and grown multiple specialty products, including Pain brands such as Gralise (once daily gabapentin) and Zipsor (diclofenac potassium). Mr. Rajendran was selected and recognized by PM360 magazine in 2021 as an "Elite Strategist" in the pharmaceutical industry. Sumant holds an MBA from the University of Southern California, an MS from the University of the Ryukyus, Okinawa, Japan and BS from Loyola College, Chennai, India.

RISKS

Scilex is a commercial-stage pharmaceutical company with several clinical-stage assets. The investment is subject to risks, including but are not limited to:

- **Operational Risk**: The company is relying on the preliminary commercial success of ZTlido, since Elyxyb is in its initial stage of commercialization. Consequently, there is a possibility that the company may not generate adequate revenue to sustain its operations of commercializing ZTlido, Elyxyb and Gloperba.

- **Supplier Risk:** The company is relying on single-source suppliers and manufacturers for the commercial supply of certain products, clinical supply of product candidates, and some raw materials used in its product candidates. Should the company lose any of these suppliers or manufacturers, or fail to comply with FDA regulations, finding an alternative source on commercially reasonable terms, if at all, may prove challenging. The company also depends on third parties to conduct its clinical trials and plans to continue relying on them for all future clinical trials. Failure by these third parties to fulfill their contractual obligations, adhere to regulatory requirements, or meet expected deadlines could hinder the company's ability to obtain regulatory approval for its product candidates.

- **Product Risk:** The commercial products, ZTlido, ELYXYB, and Gloperba, may have undesirable properties or side effects that could lead to significant negative consequences. This could affect their commercial performance and ability to generate revenue.

- **Intellectual Property Risks:** The company relies on intellectual property licensed from Oishi and Itochu for ZTlido and SP-103. Losing the right to license this intellectual property or termination of the Product Development Agreement would negatively impact our ability to commercialize ZTlido and develop SP-103. Its agreement with Romeg is critical for commercialization of Gloperba in the US Patent protection for ZTlido, Gloperba, ELYXYB, and its product candidates is crucial for maintaining its competitiveness in the market.

    - On June 22, 2022, the company initiated legal action against Aveva and Apotex in the US District Court for the Southern District of Florida. This legal action, known as the ZTlido Patent Litigation, accuses Apotex of infringing certain Orange Book listed patents that cover ZTlido. The litigation was prompted by Apotex's submission of an abbreviated new drug application aiming to obtain approval for marketing a generic version of ZTlido before the expiration of the ZTlido Patents. Trial in the ZTlido Patent Litigation has been scheduled for July 8, 2024. If the generic version of ZTlido is approved, the company may have to reduce the price to maintain market share.

- **Clinical trial risk:** Scilex has completed multiple clinical studies for SP-103 and SP-102. Early data are encouraging and warrant further development. These drugs were safe and without any serious adverse events. However, going forward, in larger clinical trials the drug may not be deemed safe and effective.

- **Regulatory risk:** The FDA and European regulators may require additional data or clinical trials beyond the ones Scilex currently anticipates.

- **Financing risk:** The cash position of Scilex was around $4M (December 2023). The company may need to raise additional equity capital or debt. The terms of the Oramed Note restrict the operational and financial flexibility of the company. Financing may not be available under favorable terms, or at all. Specifically, the company may not be able to replace short-term debt with an instrument of longer duration.

Income Statements

Scilex Holdings — Elemer Piros, Ph.D. 212-540-4425 epiros@rodm.com

				2023A					2024E				
($ In thousands, except per share data)	**2020A**	**2021A**	**2022A**	**1QA**	**2QA**	**3QA**	**4QA**	**2023A**	**1QE**	**2QE**	**3QE**	**4QE**	**2024E**
Net revenue	**$23,560**	**$31,317**	**$38,034**	$10,582	$12,582	$10,117	$13,462	**$46,743**	$15,669	$20,892	$31,338	$47,007	**$114,905**
Cost of Revenue	**$2,149**	**$3,634**	**$10,797**	$3,591	$4,177	$3,392	$4,521	**$15,681**	$4,214	$5,619	$8,428	$12,642	**$30,903**
Gross Profit	**$21,411**	**$27,683**	**$27,237**	$6,991	$8,405	$6,725	$8,941	**$31,062**	$11,455	$15,273	$22,910	$34,364	**$84,002**
% Gross margin	*91%*	*88%*	*72%*	*66%*	*67%*	*66%*	*66%*	*66%*	*73%*	*73%*	*73%*	*73%*	*73%*
Operating Expenses													
Research and development	**$9,961**	**$9,201**	**$9,054**	$2,736	$3,204	$4,072	$2,734	**$12,746**	$1,500	$1,250	$1,250	$1,000	**$5,000**
Selling, general and administrative	**$42,970**	**$50,582**	**$64,895**	$28,701	$26,989	$40,431	$23,520	**$119,641**	$20,000	$15,000	$14,000	$15,000	**$64,000**
Intangible amortization	**$3,738**	**$3,738**	**$3,922**	$1,027	$1,026	$1,027	$1,026	**$4,106**	$1,050	$1,050	$1,050	$1,050	**$4,200**
Loss from operations	**($35,258)**	**($35,838)**	**($50,634)**	($25,473)	($22,814)	($38,805)	($18,339)	**($105,431)**	($11,095)	($2,027)	$6,610	$17,314	**$10,802**
Other (income) expense:													
(Gain) loss on derivative liability	**($800)**	**$300**	**($8,310)**	$5,253	$82	($4,245)	($578)	**$512**	$0	$0	$0	$0	**$0**
Change in fair value of debt and liability instruments	**$0**	**$12,463**	**($28,634)**	$0	$3,748	$449	$2,992	**$7,189**	$0	$0	$0	$0	**$0**
Gain on debt extinguishment, net	**$0**	**$28,000**	**$0**	$0	$0	$0	$0	**$0**	$0	$0	$0	$0	**$0**
Interest expense, net	**$13,116**	**$11,764**	**$9,604**	($1)	$5	$513	$551	**$1,068**	$600	$600	$600	$600	**$2,400**
Loss (gain) on foreign currency exchange	**($2)**	**$54**	**$66**	$20	$3	$7	$88	**$118**	$0	$0	$0	$0	**$0**
Total other (income) expense	**$12,314**	**$52,581**	**($27,274)**	$5,272	$3,838	($3,276)	$3,053	**$8,887**	$600	$600	$600	$600	**$2,400**
(Loss) income before income taxes	**($47,572)**	**($88,419)**	**($23,360)**	($30,745)	($26,652)	($35,529)	($21,392)	**($114,318)**	($11,695)	($2,627)	$6,010	$16,714	**$8,402**
Income tax expense (benefit)	**($53)**	**$5**	**$4**	$8	($3)	$0	$8	**$13**	$0	$0	$0	$0	**$0**
Net (loss) income	**($47,519)**	**($88,424)**	**($23,364)**	($30,753)	($26,649)	($35,529)	($21,400)	**($114,331)**	($11,695)	($2,627)	$6,010	$16,714	**$8,402**
Weighted average number of shares outstanding	**132,891**	**132,858**	**134,226**	141,660	142,626	139,808	130,298	**130,298**	107,968	110,127	112,330	114,576	111,250
Net loss per share	($0.36)	($0.67)	($0.17)	($0.22)	($0.19)	($0.63)	($0.25)	($0.88)	($0.11)	($0.02)	$0.05	$0.15	$0.08

Source: Scilex Holding SEC filings, Rodman & Renshaw estimates

Valuation and Risks

We arrive at our twelve-month price target of $14/share by assessing the after-tax, risk adjusted NPV of potential future cash flows from the company's ZTlido, ELYXYB and Gloperba programs, in addition to the estimated value of pipeline assets. For commercial-stage assets, the probability-adjusted, fully taxed (21%) NPV (15% discount rate) of potential cash flows through 2036 is ~$1.2B or $11/share, according to our forecasts. We estimated that the value of pipeline assets to be $300M, or $3/share. The combined total NPV of all the assets is ~$1.5B or $14/share, corresponding to our 12-month price target. Significant factors that could impede shares from reaching our price target include the failure of ELYXYB's label expansion into acute pain and lower-than-estimated sales. In addition, the company may not be able to raise additional funds to repay debt and to complete development of drug candidates.

Company description

Scilex Holding Company focuses on acquiring, developing, and commercializing non-opioid pain management products for the treatment of acute and chronic pain. Its commercial products include ZTlido (lidocaine topical system) 1.8%, a prescription lidocaine topical product for the relief of neuropathic pain associated with postherpetic neuralgia (PHN), which is a form of post-shingles nerve pain; ELYXYB, a ready-to-use oral solution for the acute treatment of migraine with or without aura in adults; and Gloperba, a liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults. The company is also developing three product candidates, including SP-102 (10 mg dexamethasone sodium phosphate viscous gel) (SEMDEXA), a novel viscous gel formulation of a used corticosteroid for epidural injections, which has completed a Phase 3 study to treat lumbosacral radicular pain or sciatica; SP-103 (lidocaine topical system) 5.4% (SP-103), a formulation of ZTlido for the treatment of chronic neck pain and low back pain (LBP) that has completed a Phase 2 trial; and SP-104 (4.5 mg low-dose naltrexone hydrochloride delayed-release capsules) (SP-104), a novel low-dose delayed-release naltrexone hydrochloride, which has completed Phase 1 trials for the treatment of fibromyalgia. The company is headquartered in Palo Alto, California.

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RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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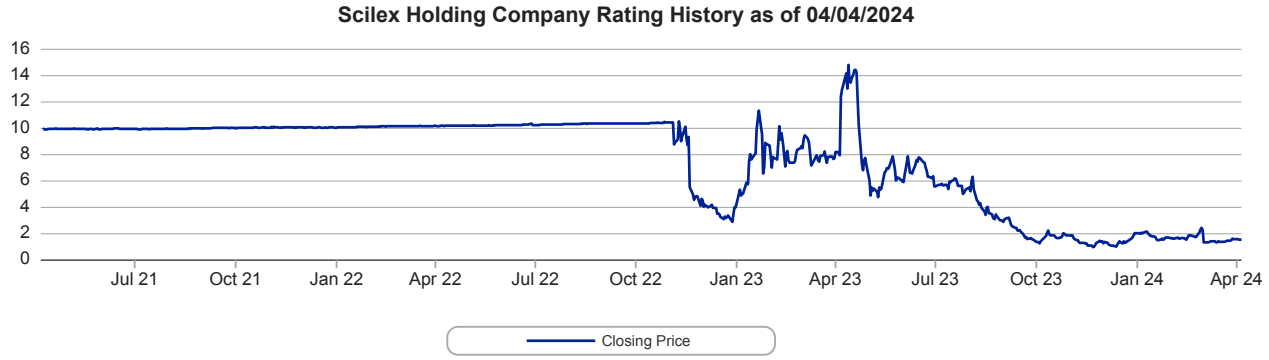

Distribution of Ratings Table as of April 08, 2024				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
BUY	8	100.00%	4	50.00%
HOLD	0	0.00%	0	0.00%
SELL	0	0.00%	0	0.00%
NOT RATED	0	0.00%	0	0.00%

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