

## Scilex Holding Company (SCLX - \$1.94\*)

Healthcare: Biotech Buy; \$4.00 PT; \$289.2M Market Cap

Coverage Initiated Friday, October 13, 2023

## No Pain, Non-Opioid Gain: SCLX Entering a New Era of Growth—Initiate at Buy, \$4 PT

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Shareholders' Equity

\$ in millions.

	STOCK DA	TA					
Market Cap (m 52-Week Range 3-Month ADTV	•	\$1.23	\$289.2 1–\$16.90 758,902				
Shares Outstan Float (%) Short Interest Fiscal Year-End	ding (mil)	149.1 57.5 3,275,669 December					
FINANCIAL DATA							
FY <b>EPS</b>	2022A \$(0.17)	2023E \$(0.83)					
BAI	ANCE SHEE	T DATA					
Cash & Equivale	ents		2Q23 \$34.1				
Current Assets Total Assets Total Liabilities			\$69.2 \$126.5 \$116.0				

### **Summary and Recommendation**

We are initiating coverage of Scilex Holding Company (SCLX) with a Buy rating and 12-month PT of \$4/share. SCLX is a revenue-generating biopharma company focused on the development and commercialization of innovative, non-opioid pain therapeutics, including (1) ZTlido, a 1.8% lidocaine topical system that generates ~\$130/\$43M in annual gross/net sales (~50%/~25% growth Y/Y), offering improved bioavailability and superior adhesion vs. market-leading patch Lidoderm 5%; (2) Gloperba, an FDA-approved prophylactic treatment for painful gout flares in adults; and (3) Ph. III clinically de-risked SP-102 for lower back pain (sciatica), undergoing a LT safety follow-up study to become the first FDA-approved epidural steroid product, which could exceed \$237M in risk-adjusted peak sales by 2030. Recent developments pertaining to Elyxyb commercialization in the acute migraine market and SP-103 mid-stage development in acute back/neck pain represent potential upside to our mid- to long-term estimates. SCLX has prudently built a targeted, experienced sales force efficiently supportive of an expanding product portfolio. SCLX came to public markets via a 4Q22 de-SPAC process that, unfortunately, has delayed its capital-raising efforts and pressured the stock. We believe the stock trading at <3x projected 2026E revenues aptly bakes in any inherent balance sheet risks.

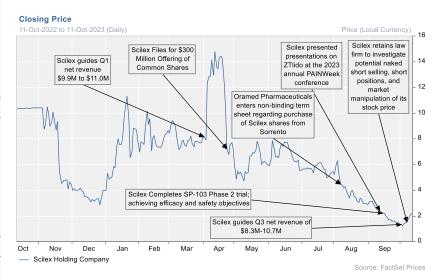
### **Key Points**

- ZTlido growth resumes with improving customer mix and renewed sales campaign targeted at gabapentin market. Over the past 4 years, ZTlido has gained meaningful share in a steadily growing lidocaine patch market (~5M unit volume/year), primarily driven by strong payer coverage, spanning 220M+ covered lives across Medicare and major commercial plans. Recent volume gains coming within the Medicaid segment have adversely impacted grossto-net, trending closer to 70%, which SCLX anticipates improving with its recently launched sales campaign focused on utilization in the gabapentin combination setting (~50M unit volume/year) that is supported by clinical data reaffirming the mechanistic rationale for driving stronger analgesia via a non-opioid treatment regimen for the relief of neuropathic pain associated with postherpetic neuralgia (PHN).
- Ph. III stage SP-102 clinical de-risking underway to become the first FDA-approved epidural steroid injection (ESI) product for sciatica, providing a safe, effective and durable solution in a disease with a lifetime incidence of 10%–40% in the U.S. SCLX recently generated positive primary and secondary efficacy data from the pivotal Ph. III C.L.E.A.R. randomized placebo-controlled study, positioning SP-102 favorably to capture a market of 12M+ ESI unit volume, with lumbar radiculopathy/sciatica procedures comprising ~88%, and likely to play a material role in driving U.S. opioid prescriptions down. The 400-subject study demonstrated a statistically significant reduction in average daily pain in the affected leg over 4 weeks, with comparably clinically meaningful improvement noted on disability index (ODI) and multitude of pain scores. The time to repeat injections, 84 vs. 58 days (p=0.001), implies reduced physician and patient burden, which translates to significant healthcare cost savings.
- Recent corporate actions aimed at protecting SCLX shareholders indicate a renewed focus on business fundamentals and specific NT catalysts that we believe could elevate SCLX's positioning in a relatively underfollowed biopharma space, where we see the potential for peer VRTX's Ph. III NaV1.8 inhibitor, VX548, dataset in acute and neuropathic pain to drive a renaissance of investor interest. SCLX recently purchased all SCLX common shares, preferred shares, and warrants owned by prior parent company, Sorrento Therapeutics, Inc., thereby fending off an auction process that led to \$110M in senior secured notes issued by SCLX. Separately, SCLX has an eCapital AR revolving loan arrangement and a SEPA/ELOC in place to serve capital needs on the path to profitability, which management expects as early as 2026.

\$10.4

## Leading the Vanguard as an Innovative Leader in Non-Opioid Pain Therapeutics

Key Financial Metrics									
Rating Buy									
Price Targe	t	\$4							
Last Price		\$1.94							
52-wk	High	\$16.90							
range	Low	\$1.21							
Market Cap	(M)	\$289.17							
Enterprise \	Value	\$280.30							
Volume (av	g. 90 days)	724,763							
Shares Out	standing (M)	149.06							
% institutio	nal Ownership	14.27							
Short	% of float	3.8							
Interest	Days to cover	3.9							
Cash Burn	(M); est. 12 months	(\$38.5)							



Source: FactSet and B. Riley Securities Research

## Recent De-SPAC with Attractive Fundamentals That Have Yet to Catch the Street's Attention

As of	November 2022	October 2023
Buy	0	1
Hold		
Sell		

Source: FactSet and B. Riley Securities Research

## Key Modeling Assumptions Focused on ZTlido, SP-102, Gloperba, and Elyxyb

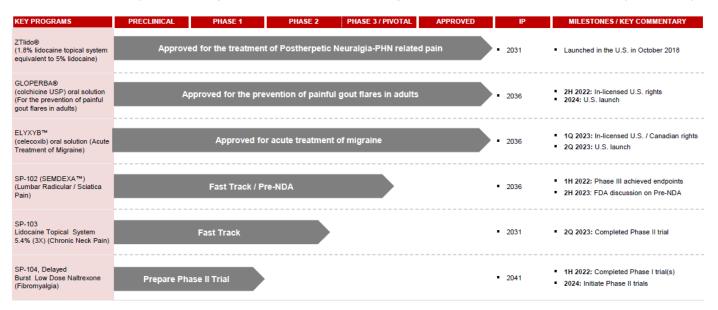
Product Modeling Metrics	Total Addressable Market (WW, Launch year)	Peak Penetration	Probability of Success	WW Projected Peak Sales
ZTILIDO	55M (Scripts; Approved)	7%	100%	\$101M
SP-102	2.2M (2026)	20%	65%	\$237M
GLOPERBA	1.5M (2024)	2%	100%	\$29M
ELYXYB	23.56M (2023)	4.5%	100%	\$39M

Source: FactSet and B. Riley Securities Research

## Pursuing a Diversified Portfolio of Acute and Chronic Pain Management Products

Scilex Holding Company is a commercial-stage CNS biotechnology company focused on the development of innovative, non-opioid pain therapeutics for small- and large-prevalence indications to meaningfully improve upon the current underwhelming standard-of-care options. SCLX was founded as a majority-owned subsidiary of Sorrento Therapeutics (SRNE) and completed a merger with Vickers Vantage Corp. The company's pipeline is built around three commercial-stage products: (1) ZTlido, a 1.8% lidocaine topical system that was approved in 1Q18 and offers improved bioavailability and superior adhesion at a lower lidocaine content than market-leading patch Lidoderm 5%, (2) Gloperba (colchicine USP), an FDA-approved prophylactic treatment for painful gout flares in adults, which was in-licensed from ROMEG Therapeutics in June 2022 and which we believe is well positioned for a successful 2024 launch, and (3) ELYXYB (celecoxib), an FDA-approved oral solution for acute treatment of migraines, for which Scilex acquired Canadian and U.S. rights in February 2023, both of which we view as leveraging SCLX's direct distribution network to national and regional wholesalers and pharmacies, as well as its experienced commercial and managed care team that has successfully launched and grown market access for ZTlido to >200M covered lives in the U.S. We believe that SCLX's pipeline products offer near- and long-term opportunities for value creation centered on NDA-ready SP-102 (SEMDEXA), a nonopioid injectable therapeutic for low back pain (sciatica), which would be the first FDA-approved epidural steroid product and would establish a significant improvement over off-label products that contain neurotoxic preservatives, particulates, surfactants, and solvents and have been implicated in >100 serious, including fatal, neurological events in the past few decades. The remainder of the pipeline includes SP-103, a 5.4% lidocaine topical system (3x the strength of ZTlido) for acute back pain, and SP-104, a delayed low-dose burst formulation of naltrexone for fibromyalgia.

SCLX's Pain-Focused Pipeline Looking to Shift the Treatment Paradigm toward More Effective, Safe, Non-Opioid Therapeutics



Source: SCLX company filings

As reformulations, SCLX's ZTlido, Gloperba, and Elyxyb marketed products were approved via the 505(b)2 pathway, and SCLX's clinical-stage pipeline offers the chance for first-in-indication approvals for multiple pain conditions. The 505(b)2 pathway is a capital-efficient, streamlined regulatory process intended for molecules that have been previously approved by the FDA as safe and effective. 505(b)(2) products have the advantage of potentially much lower development costs and shorter development timelines versus traditional new molecular entities, as an extensive characterization of the safety and efficacy profile of the active molecule has been completed in both preclinical and clinical models. A key feature of the 505(b)(2) pathway is that it allows a manufacturer to submit a product for FDA review by including data and/or study results generated by the original drug manufacturer. Additionally, products gaining approval through the 505(b)(2) pathway are eligible for three to five years of market exclusivity, a significant advantage over the abbreviated NDA pathway, which enables a generic product to gain six months of market exclusivity if it is the first variation approved. As such, the 505(b)(2) pathway has gained traction in recent years, with the FDA's Center for Drug Evaluation and Research (CDER) approving 75 and 64 drugs in 2018 and 2019, respectively, representing 56% of all CDER approvals in 2019; 45% of all 505(b)(2) approvals in 2019 represented new formulations or manufacturers.

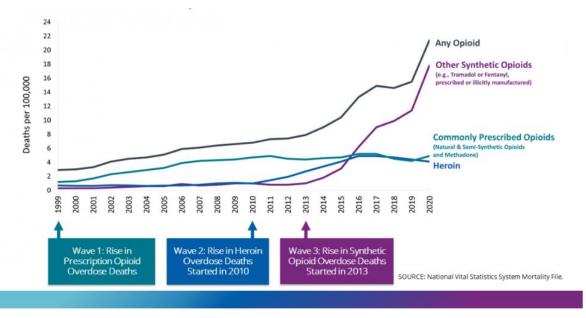
The FDA has granted Fast Track designation to SCLX's SP-102 program, and the company plans to leverage its successful Phase III data from the C.L.E.A.R. trial to pursue a U.S. NDA filing for the high-unmet-need sciatica indication for which no treatments have been approved in the U.S. SCLX's SP-103 non-aqueous lidocaine topical system has an adhesive drug delivery formulation and manufacturing technology that is similar to that of ZTlido, but at 3 times the drug load, i.e., 108 mg vs. 36 mg, and is designed to deliver a localized dose of lidocaine that is three-fold greater than any currently marketed lidocaine topical product. SCLX management recently received guidance from the FDA to conduct an additional Phase III open-label safety and efficacy trial enrolling ~700 subjects that would help meet the 1,000-subject exposure requirement for the safety database prior to NDA filing. The trial follow-up period is estimated to be 6 months, with up to 3 repeat injections, which essentially lays the ground for how SP-102 will be used in the real world.

SP-104 is a novel low-dose delayed-release naltrexone hydrochloride formulation that is designed for the treatment of fibromyalgia, which affects ~8M–10M individuals in the U.S. Currently approved treatments (e.g., duloxetine, pregabalin, and milnacipran) come with poor response rates, i.e., 27%–40% with immediate-release formulations, and are associated with unpleasant adverse events (AEs), such as hyperalgesia, dysphoria, nausea, anxiety, and insomnia, and patients are often required to supplement their treatment with off-label products with abuse potential. Low-dose naltrexone (LDN) has been used off-label to treat multiple types of chronic pain, complex regional pain, and other indications, including fibromyalgia, but complications with dose titration and risk of dysphoric effects with incorrectly dosed naltrexone have limited the uptake in the compounding pharmacy supply. In contrast, SP-104 has demonstrated a favorable safety profile in early Phase I studies with a significantly lower number of subjects with treatment-related adverse events (TEAEs) of special interest relative to the immediate-release 4.5 mg naltrexone comparator.

## Opioid Crisis Underscoring the Need to Shift an Outdated Treatment Paradigm

Despite interventions from Congress, the CDC, and additional regulatory and governing bodies, the opioid epidemic persists in the U.S., with debilitating downstream consequences at the physician, patient, healthcare system, financial, and familial levels. While there is little debate surrounding the use case of opioids in the acute pain setting given the wealth of data published on the efficacy of approved therapeutics, opioids have been progressively prescribed more and more for chronic non-cancer-related pain, despite inadequate data on the long-term sequalae that we have started to see come to fruition in clinical practice. Chronic, non-cancer pain (CNCP) is defined as any ailment that lasts for more than 3 months and may have an overwhelming impact physically, psychologically, socially, and/or economically, necessitating medical intervention. (2) CNCP is a worldwide public health challenge affecting 8%–50% of adults across different geographies—e.g., impacting nearly one-third of the U.K. population. Patients are typically exposed to opioid use for 90+ days, often as a result of aggressive prescribing practices of medical practitioners, widespread opioid misuse, and increasing rates of prescription refills, all of which are particularly exacerbated in western economies such as North America.

Opioid Overdose Deaths on the Rise, Presenting in Three Waves since 1999



Source: CDC.aov

According to the CDC, there were nearly 71,000 drug overdose deaths in 2019, most of which involved a prescription or illicit opioid. Overuse of prescription opioids has also led to an increase in the illicit use of non-prescription opioids (10x–14x from 2010 onwards relative to prior decades), and mortality rates due to heroin overdoses in the U.S. more than tripled from 2010 to 2014; drug overdoses exceeded automobile accidents as the chief cause of accidental death for the first time in 2014.<sup>(2)</sup> From 1999 to 2019, nearly 814,000 people died from a drug overdose, and ~187 people die on a daily basis from an overdose of opioids, 50% of which are not a result of an opioid product from a prescription. To further compound the problem, the economic liability of opioid misuse has been projected to be more than \$78B annually in the U.S. The first wave of the epidemic dates back to 1999 with the availability of natural and semi-synthetic opioids and became the crisis we are grappling with today beginning in 2010, with rapid increases due to the overuse of heroin. In 2013, the CDC began to see increases in overdose deaths involving synthetic opioids, particularly those involving illicitly manufactured fentanyl.

In response to the opioid overdose epidemic and drug overdose deaths topping 100,000 for the first time in 2021, the CDC has launched many opioid awareness campaigns, including the Overdose Data to Action (OD2A), a 4-year cooperative agreement through which the CDC funds health departments in 47 states for surveillance and prevention efforts, including the tracking of nonfatal and fatal drug overdoses, improving toxicology to better track polysubstance-involved deaths, enhancing access to care for people with opioid use disorder and at risk for opioid overdose, improving prescription drug monitoring programs, implementing health system interventions, partnering with public safety, and implementing other innovative surveillance and prevention activities.<sup>(3)</sup> Separately, the Opioid Rapid Response Program (ORRP) is a coordinated federal effort to help mitigate overdose risks among patients who lose access to a prescriber of opioids; medications for opioid use disorder; or other controlled substances, such as benzodiazepines. The program was designed to address care continuity and risk reduction for patients by alerting state health agencies about law enforcement events that might disrupt patients' access to care and supporting state and local capacity building to prepare for and respond to disruptions in care that may otherwise result in patients pursuing off-label or illicit treatment options to manage their chronic pain. In 2014, the DEA announced the rescheduling of Vicodin (hydrocodone/acetaminophen) from a Schedule III to Schedule II drug, prompting a series of regulations on prescribing patterns in the primary care setting for chronic care management, both for oral and topical pharmacologic agents.

DEA Drug Classification List Provides an Overview of Risk Stratification for Drugs with Abuse Potential

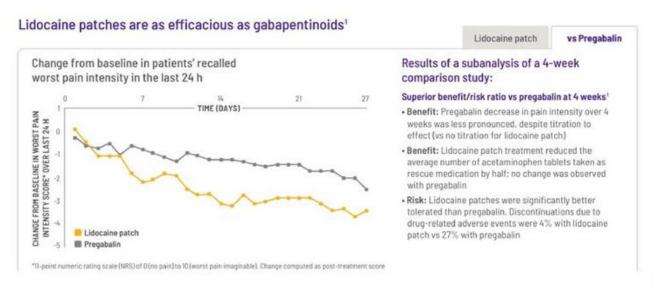
Classification	Examples	Description					
Schedule I	- Marijuana - LSD - Eestasy (MDMA) - Heroin	Schedule 1 drugs as classified as substances that have a high potential for abuse and no accepted medical use and are not safe to use under medical supervision					
Schedule II	- Cocaine - Opium - High Grade Morphine - Oxycodone - Methamphetamines (i.e. Adderall)	Schedule II drugs are classified as substances that have a high potential for abuse, despite having an accepted medicinal use in the U.S.					
Schedule III	- Low-Grade Morphine - Anabolic Steroids - Ketamine - Certain Codeine Mixtures	Schedule III drugs are classified as substances that have less potential for abuse than Schedule I or II but abuse can lead to moderate physical dependence or high psychological dependence.					
Schedule IV	- Ambien - Soma - Valium - Darvon - Xanax - Darvocet - Rohypnol - Ativan - Zolpidem - Talwin	Schedule IV drugs are classified as substances that have less potential for abuse than Schedule III and has accepted medical use in the U.S. but abuse of the drug may lead to limited physical or psychological dependence compared to those of Schedule III					
Schedule V	- Cough Syrup (less than 200 mg) - Lomotil - Motofen - Lyrica - Parepectolin	Schedule V drugs are classified as substances with limited quantities of certain narcotics that have less potential for abuse than Schedule IV and have accepted medical use in the U.S. with limited risk of physical/psychological dependency.					

Source: CompassDetox adapted from DEA Diversion, U.S. DOJ.gov

In response to the increasing scrutiny of opioid-related products, innovation in drug development for non-opioid alternatives has garnered significant industry, investment, and strategic interest, including for topical analgesics. Figures from the American Academy of Pain Medicine (AAPM) suggest that chronic pain affects nearly one-third of the U.S. population and places a significant burden on the healthcare system on the order of hundreds of billions of dollars. Within the chronic setting, origins of pain can be defined as somatic, i.e., localized pain that originates from damage to the skin, skeletal system, or joints, or visceral, i.e., diffuse pain from internal organs carrying a greater emotional burden. Within the etiology of pain, there are three main forms of clinical presentation: (1) nociceptive pain results from damage to a somatic source, e.g., musculoskeletal system; (2) neuropathic pain results from damage to the peripheral or central nervous system, e.g., in the setting of postherpetic neuralgia (PHN); and (3) a combination of nociceptive and neuropathic pain with heterogenous symptomatology. Given the risks and difficulties associated with the chronic use of oral or IV opioid treatment, topical therapies have been increasingly used in the clinical setting, particularly for the management of musculoskeletal and peripheral neuropathic pain. (4)

While oral pain medications have cemented their place in the treatment paradigm, systemic absorption increases the risk of both AEs and increased dependence and potential abuse. Relative to oral formulations, buccal, sublingual, topical, transdermal, rectal, intranasal, subcutaneous, and IV medications have been used to curb the risks of off-target effects and/or dependency to provide local analgesia and, in the case of topical and transdermal patches, to bypass major organ systems. Although fentanyl has been implicated in the most recent wave of opioid-related death overdoses, the transdermal formulation is able to provide significant analgesia while bypassing absorption in the GI system and limiting the risk of nausea, vomiting, and diarrhea with significantly lower systemic exposure. The two leading topical pain medications, diclofenac and lidocaine, are able to avoid absorption with limited first-pass metabolism and are used often in the clinic today. Diclofenac sodium is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits its action via cyclooxygenase (COX) enzyme inhibition with a higher selectivity to COX-2 that is implicated in the regulation of inflammatory processes. The diclofenac 1.3% patch and topical solution have been used for a variety of pain indications, including osteoarthritis of the knee, but both come with shortcomings e.g., they should not be worn in wet conditions and cannot be used with heat or occlusive coverings. The more common product used for peripheral neuropathic pain relief is the lidocaine 5% patch, which acts by interrupting the transmission of signaling along afferent nerve fibers to the central nervous system (CNS) through reversible inhibition of sodium-potassium channels. Similar to diclofenac, lidocaine contact with water and/or use with occlusive dressings is also to be avoided, and removal of the patch is necessary after 12 hours to prevent elevated blood concentrations that may result in serious adverse events such as cardiac dysrhythmia and methemoglobinemia. Per Symphony Healthcare, despite some of the issues with adhesion and adherence to treatment, more than 3.9M prescriptions were written, and 147M prescription lidocaine patches were sold in the U.S. in 2021 for relief of pain associated with PHN.

Lidocaine Patches Have Demonstrated Continuous Improvements in Pain Control over 4 Weeks Relative to Gabapentinoids



Source: SCLX company filings

Endo Pharmaceuticals' Lidoderm 5% lidocaine patch was the first product to receive FDA approval for the relief of pain associated with PHN in 1999. Lidoderm 5% is an adhesive patch containing 700 mg of lidocaine that acts by penetrating the skin in sufficient concentration to stabilize neuronal membranes by inhibiting the ionic fluxes required for the initiation and conduction of impulses but less than the amount necessary to produce a complete sensory block. Interestingly, at its recommended dose, 95% of the lidocaine remains in the used patch, while ~3%–5% of the dose applied is expected to be absorbed with a mean peak blood concentration of 0.13 μg/mL, which is ~1/10 the therapeutic concentration required to treat cardiac arrhythmias. In clinical studies, Lidoderm demonstrated (1) statistically significant improvements in analgesia relative to a nonmedicated vehicle patch over 4–12 hours; (2) significant improvements in time to exit from trial, i.e., 3.8 days for treated patients relative to 14 days on vehicle; (3) improved daily average pain relief; and (4) concomitant medication required in ~50% of patients receiving the Lidoderm patch. On safety, Lidoderm application may result in generally mild blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, and pruritus. As a patch, however, systemic adverse reactions are infrequently observed and limited to transient excitatory CNS reactions, e.g., lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, and respiratory depression and arrest. (5)

While Lidoderm 5% Has Experienced Commercial Success, SCLX's ZTlido May Offer a Superior Alternative

Properties	ZTlido® 1.8%	Lidoderm® 5%
Bioavailability	~45%	~3±2%
Weight	2 g	14 g
Thickness	0.8 mm	1.6 mm
Lidocaine content	36 mg	700 mg
Adhesive	Non-aqueous	Water-based

Source: SCLX company filings

# **ZTlido: A Transformative Non-Opioid Alternative for PHN Pain Management**

PHN is the most common complication of shingles infection caused by a reactivation of the varicella-zoster virus, the same virus that causes chickenpox and remains dormant in afflicted patients. Shingles results in painful lesions presenting in a banded pattern that initially start as rashes before progressing to blisters. While the rash-associated pain from shingles typically resolves after a few weeks, the pain caused by the nerve injury can persist for months to years in the affected area. While nearly all Americans over the age of 40 have had chickenpox, approximately one in three people will develop shingles in their lifetime, and of these patients, ~20% will develop postherpetic neuralgia with a bias toward the elderly population, immunocompromised patients, patients with severe shingles cases, and patients with a particularly debilitating itch associated with their shingles virus. It is estimated that more than 1M cases of herpes zoster occur annually in the U.S., and PHN itself is caused by damage to nerve fibers during herpes zoster infection that send amplified pain signals to the brain. PNH presents as (1) burning, sharp, or aching pain in the area where the shingles rash appeared; (2) itchiness or numbness at or near the area of the former rash; (3) constant or intermittent flares; and (4) tender skin that causes pain even at a light touch that gets worse at night or in hot or cold temperatures. (6) A hallmark of the infection is that it typically presents as unilateral, and in most cases, only a single dermatome is affected. The erythematous maculopapular rash is usually accompanied by pain and dysesthesia and progresses to clear vesicles similar to the original chickenpox outbreak before pustules form over a period of 48–72 hours that ulcerate and eventually scab over. (7)

While PHN may be relatively well managed if caught in the initial stages of its outbreak, long-term chronic treatment has proved more difficult given the shortcomings of existing lidocaine patches. PHN can be preventable by avoiding infection with herpes zoster virus, which was made possible with the introduction of the varicella vaccine in 1995. However, for adults and non-vaccinated children that did contract chickenpox during childhood, reactivation of herpes zoster can be accomplished with a live attenuated shingles vaccine, marketed as Zostavax and Shingrix by Merck and GSK, respectively. Notably, despite its relatively lower efficacy to Shingrix—i.e., 51% reduction in shingles with Zostavax relative to 90%+ observed with Shingrix—a study evaluating 38,500 patients vaccinated against herpes zoster with Zostavax showed a 61.1% reduction in herpes zoster—related complications, e.g., PHN following vaccination. Additionally, less than 30% of adults older than 60 reported receiving the vaccination in a 2014 survey.<sup>(7)</sup> Zostavax was originally licensed by the FDA in 2006 but was pulled from the U.S. market in 4Q20, and the CDC now recommends that adults 50 years and older get two doses of the vaccine to receive the 90% risk reduction against shingles and PHN, with immunity typically staying strong for at least 7 years post-vaccination. Following the

demerger of GSK's consumer health business, sales of GSK's suite of products have rapidly accelerated, including a near doubling in Shingrix sales to \$882M in 2Q22 relative to prior quarters impacted by COVID-19. GSK also presented data at Infectious Disease Week 2022 in the form of an interim analysis of the ZOSTER-049 extension study showing that the vaccine provides durable production for up to 10 years post-vaccination and 80% overall efficacy at 6–10 years post-vaccination.

Although Shingrix's Market Share Has Demonstrated Consistent Sequential Growth, PHN Remains a Significant Unmet Need

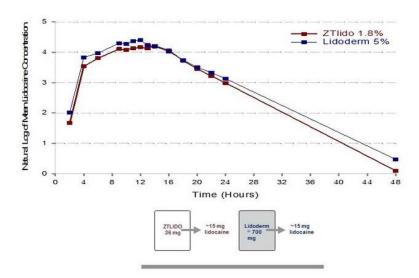


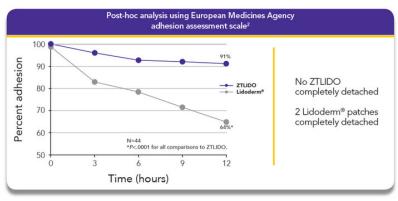
Source: SCLX company filings

SCLX's proprietary non-opioid 1.8% lidocaine topical system ZTlido received FDA approval in 2018, having demonstrated superior bioavailability, adhesion to the skin, and drug delivery efficiency relative to the U.S. reference product, Lidoderm 5%. Similar to Lidoderm, ZTlido is applied to the intact skin once every 12 hours to provide localized, targeted analgesia to areas of pain associated with PHN but is able to provide sufficient analgesia at a 36 mg dose relative to 700 mg with Lidoderm (and at 1.8% lidocaine relative to 5%) and drives 45% bioavailability relative to 3%–5% observed with Lidoderm. Other key points of differentiation include no clinically relevant differences in systemic absorption under exercise conditions and a study in 12 healthy volunteers showing no effect on ZTlido pharmacokinetics when the topical system is applied to the administration site after external heat exposure. (8) ZTlido's superior adhesion properties were also highlighted in a 54-subject trial with patient-reported scores; 47 subjects (87%) had adhesion scores of 0 (≥ 90% adhered) for all evaluations performed every 3 hours during the 12 hours of administration, 7 subjects (13%) had adhesion scores of 1 (≥ 75% to < 90% adhered) for at least one evaluation, and no subjects had scores of 2 or greater. (8) More recently, ZTlido was evaluated in the first-ever study under water stress conditions in a 24-patient Phase I study, with data indicating that wet topical ZTlido systems can be reapplied and do not increase lidocaine plasma levels. The FDA consequently approved SCLX's sNDA application, providing a significant competitive advantage over water-based or hydrogel-based formulations that cannot be used when wet and must be removed prior to water exposure.

## ZTlido 1.8% Has Shown Proven Bioequivalence to Lidoderm 5% with Superior Adhesion Properties

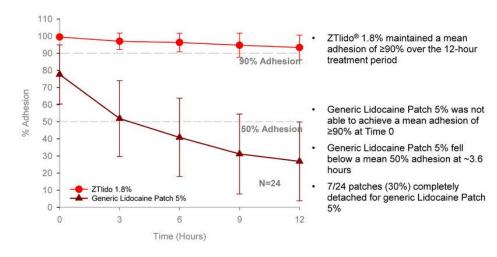
Y-Axis: Natural Log of Mean Lidocaine Concentration; X-Axis Time (Hours)





Source: SCLX company filings

## ZTlido Has Also Shown Superior Adhesion to Generic Competition, Including Mylan's Lidocaine Patch

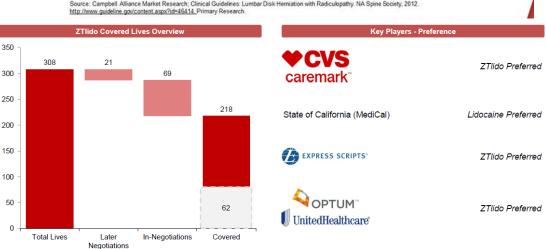


Source: SCLX company filings

SCLX has extensively invested in commercial infrastructure and a strong, targeted sales force for the ZTlido franchise, which the company expects to also leverage for its future drug launches. As part of the ZTlido commercial team, SCLX has built a dedicated field sales force of 100 experienced sales representatives targeting 10,000+ PCPs, pain specialists, neurologists, and palliative care physicians. The team has successfully targeted the top plans in the U.S. responsible for the majority of prescriptions with a strong copay assistance program and is using a multi-channel marketing strategy, e.g., print, digital, and PR, to expand awareness and utilization of ZTlido. Coverage today spans national and regional pharmacy benefit managers, health maintenance organizations, and Medicare and Medicaid plans for over 200M covered lives with the goal of reaching 300M–325M covered lives for ZTlido. ZTlido is able to address the 2 key issues in the lidocaine patch market of lack of adhesion and use in wet conditions and has been able to garner market share and grow the overall patch market, as Lidoderm and generic lidocaine patches are not actively marketed in the U.S. For the market as a whole, >3.9M prescriptions for lidocaine patches were written in 2021, with nearly 150M patches sold, underscoring a significant TAM in which SCLX has demonstrated the ability to garner incremental market share. In its first year of launch in 2019, ZTlido generated ~\$20M in revenue, which grew to \$38.5M for the January–October time frame for 2020 and \$51.8M for the same period in 2021. We expect the product to demonstrate continued sequential growth that may be particularly accelerated with the sNDA approval enabling use in wet conditions.

### SCLX's Targeted Commercial Strategy and Expanded Market Access for ZTlido and Its CNS-Focused Portfolio

15,000-20,000 Target Physicians Consist of a Mix of Health Care Specialists, Focus in High Volume Clinics Physicians treating neuropathic and chronic back pain Neurology Significant concentration Orthopedic in high volume clinics surgeons Anesthesiologists ~3,000 pain clinics (<1,000 interventional) Pain 329 Medicine Sales team in 2021 of 65+ 27% Physical Interventional Medicine& **Pain Management** Rehab **Specialists** Specialists Source: Campbell Alliance Market Research: Clinical Guidelines: Lumbar Disk Herniation with Radiculopathy, NA Spine Society, 2012 ww.guideline.gov/content.aspx?id=46414. Primary Research 308 21



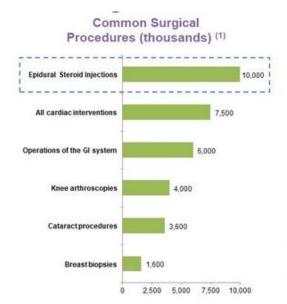
Source: SCLX company filings

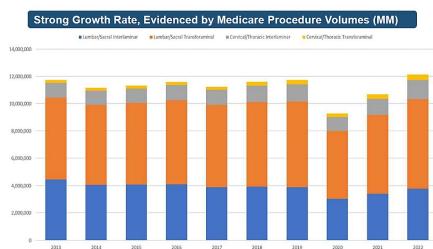
## SP-102: On Track to Become the First FDA-Approved Epidural Steroid for Sciatica

Sciatica is a debilitating condition resulting from disturbances to sciatic nerve root pathology in which patients experience severe pain and paresthesia in the sciatic nerve distribution or associated lumbosacral nerve root. (9) Sciatica falls under the general umbrella of lower back or radicular leg pain but specifically implicates the sciatic nerve pathology spanning from L4 to S2 that provides direct motor function to hamstrings and lower extremity adductors and indirect motor function to calves, anterior lower leg muscles, and intrinsic foot muscles. The vast majority of cases are due to inflammation resulting in irritation of the sciatic nerve; however, in some cases, more severe motor dysfunction may occur if the nerve is directly compressed entirely. The most common cause of sciatica is a herniated or bulging lumbar intervertebral disc, with the etiology of some cases related to spondylolisthesis or a relative misalignment of one vertebra relative to another. (9) Sciatica has a peak incidence in patients age 40 to 50, with an overall annual incidence of 1%–5%, and while there is generally no gender predominance, individuals subject to chronic time in physically awkward positions, e.g., machine operators, truck drivers, and desk jobs, may be at higher risk. (10) Treatment is currently limited to a short course of oral NSAIDs for more benign cases, opioid and non-opioid analgesics and muscle relaxants for mild to moderate cases, and if these are insufficient, a course of oral or localized corticosteroid injection therapy is recommended.

Epidural steroid injections (ESIs) have become one of the most common medical procedures (and the top pain procedure) in the U.S., with widespread reimbursement despite a history of documented serious spinal adverse events associated with their use. As part of the initiative to move away from prescription opioid use and a focus on non-narcotic pain management, the use of ESIs has skyrocketed as the American Society of Anesthesiologists, American Society of Regional Anesthesia, and American Academy of Orthopedic Surgeons has recommended a multi-modal approach to pain management. As it relates to lower back and radicular pain specifically, opioids may not even provide clinically meaningful pain relief, and patients have been encouraged to turn to ESIs. However, importantly, despite being one of the more popular procedures done in the U.S., no product has been granted a label to treat sciatica, and a retrospective analysis performed by Racoosin et al. indicated that there were 90 serious, including fatal, neurologic events following ESIs documented from 1997 to 2014. Separately, >70 deaths were reported in 2012 due to fungal contamination of compounded ESIs, prompting the FDA to issue a warning for all injectable corticosteroid product labels.

ESIs Have Become One of the Most Common Surgical Procedures in the U.S. with a Strong Growth Rate and No Signs of Slowing





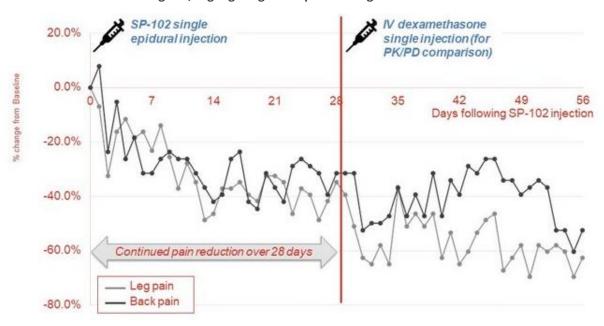
Source: SCLX company filings

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We believe SP-102 is well positioned to emerge as the first novel epidural steroid formulation with an FDA-approved label to treat sciatica with a meaningfully improved profile over commercially available steroid products, e.g., Kenalog, Depo-Medrol, and Decadron. Key differentiating characteristics for SP-102 relative to the 10M+ ESIs administered annually in the U.S. include its (1) design as a non-particulate steroid, i.e., injectable dexamethasone sodium phosphate viscous gel; (2) pre-filled syringe for epidural use; (3) gel formulation for extended local release and improved magnitude of pain relief; (4) ability to be well-tolerated based on the use of a key viscous excipient that has been extensively de-risked in preclinical and clinical studies; (5) rapid onset of action and improved targeted delivery to limit off-target effects; (6) design with no preservatives, surfactants, or particulates with no opioid properties; and (7) projected 24-month shelf-life. SCLX recently reported overwhelmingly positive results from the Phase III C.L.E.A.R. study in which SP-102 met all primary and secondary endpoints with statistical significance over placebo and achieved all study objectives with up to 3 months of therapeutic effect after a single injection.

SCLX initially evaluated SP-102 in a hydrodynamic animal study, revealing (1) the implementation of the viscosity excipient results in an increase of time of drug in epidural space in a dose-dependent manner; (2) an epidural residency half-life of >110 minutes relative to ~15 minutes with commercially injectable steroid products; and (3) accomplishing targeted, localized delivery to the infection site, with spread limited to 1 vertebrate relative to 6–7 vertebrae with competitive alternatives. The drug candidate was also evaluated in multiple preclinical toxicology studies, including in both dogs and pigs, based on FDA guidance prior to IND submission, with no notable liabilities in either species with single or repeat dosing. Further, no local or systemic toxicities were observed with QW dosing in a 4-week cycle with clean histopathology at a no observed adverse effect level (NOAEL) of 10 mg. The drug was cleared within 24 hours from the plasma and cerebrospinal fluid (CSF) and upon direct injection into the vertebral artery of pigs resulted in no vessel occlusion or macroscopic brain injury.

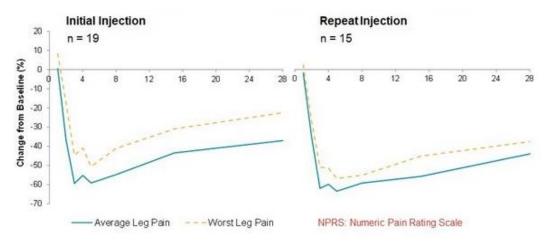
SP-102 Built on a Robust Clinical Program, Highlighting a Competitive Edge over Steroid Alternatives



Source: SCLX company filings

Upon receiving IND clearance, SP-102 was tested in multiple clinical settings, beginning with a 12-patient Phase I/II PK/PD bridging study. In addition to demonstrating a well-tolerated safety profile in humans, patients reported significant changes from baseline in pain scores following SP-102 injection, with continued pain reductions over 28 days and a more attractive PK/PD profile and nearly 60% reduction in leg and back pain out to D56. Similar results were observed in a Phase II repeat dosing study (n=19; NCT03613662) with primary outcome measures of change in plasma cortisol, blood glucose levels, and white blood cell count from baseline and secondary endpoints of changes in pain rating scale over 12 weeks. Notably, more than 50% pain reduction was reported for average leg pain that was amplified with a second dose, and cortisol suppression time was constant (i.e., not extended with repeat dosing). There was also no interference in making the decision to administer a second dose.

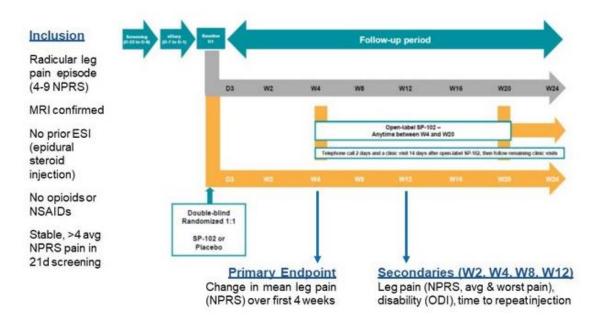
Repeat Dosing of SP-102 Drives Incremental Efficacy with No Material Impact on Safety or Cortisol Suppression



Source: SCLX company filings

Pivotal 12-week Phase III C.L.E.A.R. study SP-102 study results highly de-risking of the NDA filing, in our view. SP-102 was initially granted Fast Track designation by the FDA, enabling more frequent issuer interactions with the FDA and making the drug candidate eligible for accelerated and/or priority review if applicable or for a rolling NDA review. Having generated a highly compelling dataset, SCLX has continued to take advantage of the flexibility with the regulatory process and is nearing an NDA submission plan as part of ongoing FDA correspondence that requires conduct of an additional Phase III open-label safety study in approximately 700 subjects. The C.L.E.A.R. study was designed to evaluate the analgesic effect of SP-102 on average leg pain relative to an intramuscular placebo injection over 4 weeks, with secondary objectives of evaluating the degree of disability on the Oswestry Disability Index (ODI), changes in radiculopathy symptoms on imaging and patient-reported forms, and assessing the safety and tolerability of repeat SP-102 injections.

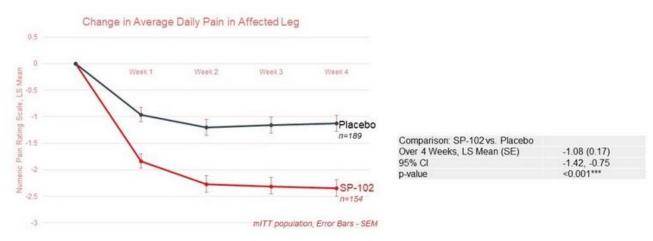
SP-102 Phase III Corticosteroid Lumbar Epidural Analgesia for Radiculopathy (C.L.E.A.R.) Trial Design



Source: SCLX company filings

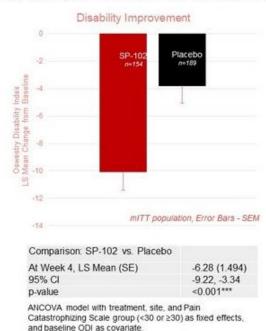
The trial enrolled more than 400 low back pain subjects with unilateral intervertebral disc herniation in the lumbosacral spine resulting in radicular pain symptoms of moderate to severe leg pain to account for an expected 15% drop rate and was 90% powered to demonstrate a 1-point difference in mean numerical pain rating scale (NPRS) daily pain scores relative to baseline over 4 weeks. Initial top-line results revealed statistical significance on the primary endpoint of reduction in pain rating scale, with a 1.08 point difference relative to placebo on average (p<0.001), and two key secondary endpoints demonstrated a 28% (6.28 point) improvement on ODI relative to placebo at week 4 (p<0.001). Additionally, following the initial 4-week observation period, during which subjects with moderate to severe radicular pain could receive an open-label repeat injection of SP-102, repeat injections were administered to 67% of subjects who initially received placebo treatment and to 46% of subjects who initially received active treatment. On safety, SP-102 was well tolerated with no notable liabilities or AEs of special interest, e.g., paraplegia and hematoma, that are known to be associated with epidural steroid injections.

### SP-102 Overwhelmingly Achieved Primary and Secondary Endpoints of Pain Reduction in the Phase III C.L.E.A.R. Trial



The analysis used a restricted maximum likelihood (REML) based mixed model for repeated measures (MMRM) with fixed effects for treatment (SP-102 or placebo), week, site, Pain Catastrophizing Scale group (<30 or ≥30), baseline averaged daily leg pain score, and treatment-by-week interaction.

Sensitivity analysis using pattern mixture model (PMM) of Mean Change from Baseline to Week 4 showed the same results.



Source: SCLX company filings

## Days to Open-Label Repeat Injection

	SP-102 (N=154)	Placebo (N=189)
Number of subjects with repeat injection of SP-102(%)	70 (46%)	126 (67%)
Time (days) to Repeat Injection		
25th quantile (95% CI)	50 (43, 62)	36 (34, 39)
50th quantile (95% CI)	NE (78, NE)	57 (49, 67)
75th quantile (95% CI)	NE (NE, NE)	NE (85, NE)
Comparison to Placebo		
Hazard Ratio (95% CI)	0.49 (0.36, 0.65)	
p-value	<0.001***	

Quartiles estimated using Kaplan-Meier estimation. A Cox proportional hazards model adjusting for site and Pain Catastrophizing Scale (<30 or ≥30).

NE - Not estimable.

Furthermore, SP-102 showed continued reduction of pain beyond one month, and the median time to repeat injection was 99 days. To put this in context, off-label injectable steroids typically provide pain relief for periods ranging from less than a week and up to one month, at which point repeat injections are often required and can carry additional safety risks. To this end, SCLX demonstrated that patients with moderate to severe pain that required repeat injections between week 4 and week 23 had a comparable safety profile to patients that required only a single administration.

SP-102 Was Well Tolerated with No Meaningful Differences in Safety Between Single and Repeat Dosing Cohorts

	SP-102/SF	-102	PBO/SP-	102	SP-102/n	one	PBO/none				
	(N=104	1)	(N=130	))	(N=98	)	(N=69	)			
	Subjects, n(%)	Events									
Any TEAE	34 (32.7)	72	41 (31.5)	73	25 (25.5)	46	14 (20.3)	23			
Any TEAE >3% Incidence											
Headache	7 (6.7)	11	11 (8.5)	16	4 (4.1)	4	2 (2.9)	2			
Upper respiratory tract infection	3 (2.9)	3	3 (2.3)	3	0	0	3 (4.3)	3			
Injection site pain	5 (4.8)	5	1 (0.8)	1	0	0	0	0			

Source: SCLX company filings

SP-102 provides a compelling alternative to opioid therapy and off-label ESIs, particularly for patients with radicular pain, as no product has ever secured FDA approval for sciatica to date. Despite limited published evidence for opioids to meaningfully improve chronic lower back pain, over 60% of U.S. opioid prescriptions are used for this purpose and come with serious and potentially life-threatening side effects. SCLX reported that in 2018, 47,000 of 67,000 drug overdose deaths reported were opioid related, in line with reports from the CDC showing that drug overdose deaths rose 29% Y/Y from 2020 to 2021. Upon potential approval, SP-102 will be the first non-opioid novel injectable corticosteroid gel formulation product available in a pre-filled syringe with a label for sciatica and a stronger clinical profile than currently used ESIs with respect to half-life, potential for repeat dosing, and limited emerging safety liabilities, conferring more potent and durable pain reductions. By 2022, Syneos Health Consulting expects more than 12.1M ESIs to be administered across all Medicare and private coverage patients, with lumbar radiculopathy/sciatica procedures comprising approximately 88%. The availability of SP-102 would eliminate concerns surrounding particulate steroids that have been associated with debilitating CNS effects, e.g., stroke, and provide patients with a valuable alternative to opioids with potent analgesia out to 12 weeks. To this end, we believe SCLX will establish a compelling case for the economic benefits of ESIs relative to opioids or surgical interventions and receive a J code for pass-through payment similar to available ESIs.

Strong Case for Outpatient and ASC/Hospital Center Reimbursement with Competitive Pricing Based on Marketed Injectables

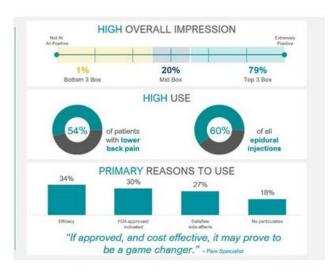
Selected Reimbursed Injectables	Zilretta (triamcinolone acetonide)	Botox (onabotulinum- toxinA)	Gel-One (Hyaluronan)	SynviscOne (Hyalurona)	Monovisc (Hyalurona)	Prialt (ziconotide)
Cost (Strength)	\$566.62(1u/32mg)	\$579 (100u)	\$1,024 (30mg/3ml)	\$1,184.71(8mg/7ml)	\$1,094(22mg/1ml)	\$3,527.35 (100mcg/1ml)
Indication	OA knee pain	Neuromuscular block-various	OA knee pain	OA knee pain	OA knee pain	Severe chronic pain
J Code	J3490	J0585	J7326	J7325	J73227	J2278
Estimated Reimbursement per use(1)	\$500.00	\$571.70 (100units)	\$571.96	\$615.79	\$934.44	\$3,664 (17 mcg/ day for1 month)

Source: SCLX company filings

Existing SCLX infrastructure to support ongoing pre-NDA submission activities and subsequent SP-102 commercialization. Through the clinical development program, Scilex has developed an internal expertise in the formulation and manufacturing of sterile viscous gel and has put a commercial supply chain in place with (1) API secured as the supplier for dexamethasone sodium phosphate; (2) a 20-year supply agreement with a leading commercial provider for the novel excipient component; and (3) a manufacturer in place for production of the drug on a commercial scale and with FDA experience using high-viscosity pre-filled syringes. SCLX is planning scale-up to 120L batches for commercialization, with process validation expected to be completed imminently. Further, the company continues to anticipate a 24-month

shelf-life and upon clearing CMC activities expects to receive priority review at the time of NDA filing. Importantly, if approved, SCLX can leverage key learnings from the ZTlido program and its experience in launching pain management products and achieving coverage with managed healthcare, Medicare, and Medicaid formularies. The product is expected to be used in physician offices and in the ambulatory surgery center/hospital outpatient setting, and SCLX expects to secure competitive pricing and favorable reimbursement as a carve-out (as opposed to a bundle) given the lack of an FDA-approved ESI and the drug's strong, safe product profile. SCLX retains the worldwide rights to SP-102 and has patent protection through 2036 in the U.S. and major markets and has indicated potential life cycle management opportunities outside of lumbar radiculopathy, including potential applications in carpel tunnel, knee and joint injections, arthritis, hip and knee replacements, and acute spinal injury. Taken together, SCLX believes SP-102 may emerge as a blockbuster product with a market potential of \$3B–\$5B in peak annual sales in the U.S. It already has its commercial infrastructure in place via a sales team of 65+ reps promoting ZTlido, which it believes can also reach the target audience for SP-102 and incrementally reduce the likelihood of a flat product launch.

KOL Feedback Suggests a Positive Perception of SP-102 with Expected Use in a Large Share of Sciatica Patients

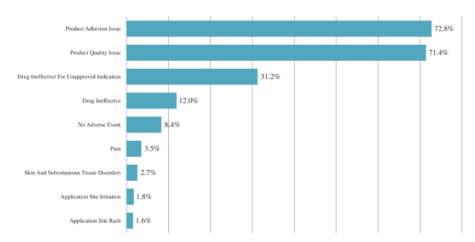


Source: Lumbar Radiculopathy Market Opportunity Quantitative Research; Cognitive Consulting Nov. 2017; Adapted from SCLX company filings

# SP-103 and SP-104: Intriguing and Relatively De-Risked Pipeline Opportunities in Acute and Chronic Pain Indications

SP-103 and SP-104 present additional opportunities for long-term value creation, in our opinion, with SP-103 recently reading out and SP-104 expected to initiate Phase II studies in 2024. SP-103 was designed as a next-generation triple-strength formulation of ZTlido—a 5.4% lidocaine topical system relative to the 1.8% with ZTlido. SCLX designed the clinical candidate for the treatment of acute lower back pain with 3x the drug load of 108 mg lidocaine, versus 36 mg with ZTlido, while retaining the properties of superior adhesion and drug formulation efficiency relative to competitive patches with localized analgesia. Further, the product received Fast Track designation in August 2022, enabling increased access and engagement with the FDA and a potentially expedited path to market, noting recent data reporting of Phase II results in September.

### Product Adhesion Remains the Number One Unmet Need in the Lidocaine Patch Market



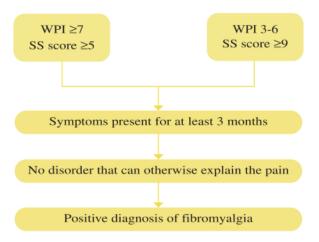
Source: SCLX company filings

SP-103 mid-stage development positions the product as the only approved topical product for acute lower back and neck pain indications. Importantly, the drug load is 3 times that of ZTlido, i.e., 108 mg versus 36 mg, which is also the maximum approved daily dosage of ZTlido, or three topical systems for up to 12 hours during a 24-hour period. While alternative approaches are encumbered by the underlying hydrogel technology that constrains the level of drug that can be loaded into the adhesive of those products, SP-103 is able to deliver potent analgesia with no impact on adhesion. The Phase II study evaluating SP-103 enrolled 75 subjects for a 28-day period with primary endpoints of frequency of AEs and improvement on NPRS and the secondary endpoint of impact to ODI. Subjects will capture daily numeric pain rating scores and topical adhesions assessments in an electronic diary each evening prior to the removal of SP-103. Of the 75 patients enrolled, 38 received treatment with SP-103, and 37 received placebo, with SP-103/placebo applied to the area of the lower back that was most tender in a 12 hours on treatment, 12 hours off treatment regimen. Overall, preliminary analysis determined that SP-103 was safe and well tolerated, with efficacy highlighted by a meaningful reduction in pain over the first week, with a -1.5 point (95% CI: -0.2 to 3.2) reduction observed in a subpopulation of patients with more severe muscle spasms as determined by the Sum of Pain Intensity Differences (SPID-7) analysis. For safety, (1) no serious SAEs or deaths were reported, (2) no TEAEs leading to early withdrawal were noted, and (3) no patients in the SP-103 treatment group had any AEs of special interest, i.e., lidocaine system toxicity, albeit 3 (8.1%) patients in the placebo arm did report some AEs of special interest. Importantly, the increase in lidocaine load in SP-103 vs. ZTlido, i.e., 5.4% vs. 1.8%, did not result in any signs of systemic toxicity and was not found to increase application site reactions over the month of treatment. Overall, low numbers of dermal AEs or site reactions were reported. In addition, the completion of a crossover, placebo-controlled investigatorinitiated trial (IIT) at Johns Hopkins in 76 patients with chronic non-radicular neck pain has supported SP-103 efficacy, with preliminary results demonstrating a reduction in average daily pain over a one-month period. SCLX is currently exploring the patient population and specific indication for subsequent trials and product registration.

Acute low back and neck pain market was estimated to be \$135B in the U.S., as per a 2020 JAMA publication. Neck pain, or cervicalgia, is one of the most common pain presentations in the U.S. and the 4th leading cause of disability. More than 50M adults suffer from neck pain in the U.S., implying prevalence estimated at >20% of the adult population. Neck pain was noted to be responsible for job absences among 25.5M Americans, who missed an average of 11.4 days of work. Low back pain affects ~70% of people in western economies, with a 75% recurrence rate for episodes that may or not be self-limiting. Low back pain is defined as pain, muscle tension, or stiffness below the costal margin and above the inferior gluteal folds, with or without radicular leg pain (sciatica), and is deemed acute when pain persists for less than 12 hours. Current treatments include NSAIDs, which come with adverse GI side effects and limited efficacy relative to more potent analgesics, as well as muscle relaxants, which may reduce pain and improve overall clinical assessment but are also associated with serious AEs, e.g., drowsiness, dizziness, and nausea. Further, epidural steroid injections are used off label but have not been evaluated in controlled clinical settings. (10) Per the Department of Institute for Health Metrics and Evaluation at the University of Washington, Americans spent nearly \$135B in 2016 on treating lower back and neck pain, the highest expenditure among 154 conditions evaluated. In 2018, the CDC reported that 28.0% of men and 31.6% of women aged 18 years old and older had lower back pain in the past three months, which increased linearly with age. While ZTlido is indicated for the relief of pain associated with PHN, SP-103 is positioned for a much larger market opportunity in acute lower back pain and may present a more effective and safer option relative to systemically delivered opioid and non-opioid candidates. Although there are numerous treatments for nonspecific acute lower back pain, most have little evidence

SP-104, a delayed-burst low-dose naltrexone (LDN) formulation, is also a compelling early-stage program in fibromyalgia with a significant TAM. Fibromyalgia is a long-term condition impacting 3%–6% of the world population and an estimated 10M people in the U.S., skewed toward 75%–90% of women. Fibromyalgia is the second most common disorder encountered by rheumatologists, seen in 15% of evaluated patients, and 8% of patients in primary care clinics have fibromyalgia. Management of the condition exerts a significant burden on the healthcare system with \$12B–\$14B in expenditures each year. Fibromyalgia can be associated with opioid or alcohol dependence, marked functional impairment, severe depression and anxiety, obesity and physical deconditioning, and metabolic syndrome, which are currently managed with minimally effective therapeutics, e.g., duloxetine, pregabalin, and milnacipran, that are associated with a 27%–40% reduction of symptoms.

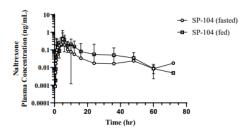
American College of Rheumatology Updated Diagnostic Criteria for Fibromyalgia



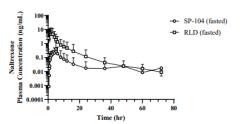
Source: ACR Guidelines Adapted from Buskalia et al.

Currently, there are no low-dose (>5 mg) formulations of naltrexone available, and fibromyalgia is managed with high-dose (50 mg) tablets that are compounded for off-label use. The compounding of naltrexone comes with risks and is inherently inaccurate when done at the individual physician office pharmacy level, as it may introduce impurities because there are no analyses to confirm that the aliquoted product has the target level of drug, and there is no assurance as to content uniformity within a batch. This can result in immediate release of the drug in the stomach, which can result in hyperalgesia, dysphoria, insomnia, and anxiety and, in turn, often leads to poor compliance with therapy. Conversely, SP-104 uses delayed-burst release technology that bypasses the stomach and releases the drug in the upper intestine, with peak drug levels achieved at night during sleep (if taken before bed as indicated), enabling the patient to avoid conscious perception of hyperalgesia and other side effects and maximizing efficacy, as most endorphin/enkephalin release is during sleep. SCLX plans to evaluate the drug in a Phase II study in 1H23 to validate the PK and safety profile observed in Phase I studies relative to immediate-release naltrexone 4.5 mg, including (1) a lower number of SP-104 treated subjects with at least one TEAE (p = 0.0414) and a lower number of subjects with at least one TEAE within 72 hours after administration of SP-104 (n=9; 12 events) versus comparator (n=15; 20 events); and (3) improvement of notable AESIs observed within 72 hours after administration of SP-104; n=6; comparator: n=12).

## Initial PK Analyses from the SP-104-01 Trial



Insignificant food effect, SP-104 may be administered without regard to food.



Exposure to naltrexone and its metabolite  $6\beta$ -naltrexol is lower with SP-104 compared to Reference Listed Drug (50 mg Naltrexone HCI), pharmaceutical bridge established.

Source: SCLX company filings

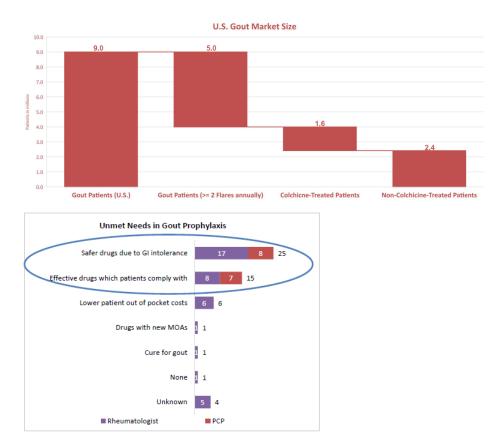


## Recent Gloperba and Elyxyb Acquisitions Enable Incremental Growth Acceleration

Earlier in 2023, SCLX acquired the rights to two additional non-opioid products: Gloperba and Elyxyb. Gloperba (colchicine USP), an oral solution, prophylactic treatment for painful gout flares in adults was approved in 2H22, for which SCLX in-licensed U.S. rights. Elyxyb (celecoxib) is an FDA-approved oral solution for the acute treatment of migraines, for which Scilex in-licensed Canadian and U.S. rights in February 2023.

• Gout is a painful arthritic disorder that can develop in individuals with high levels of uric acid in their blood and often leads to severe episodes of pain. In addition, painful gout flare-ups often occur and are characterized by hot, swollen, and painful peripheral joints. If left untreated, gout can become a chronic condition. Gout affects ~9M patients in the U.S. alone, and while treatment options do exist—i.e., NSAIDS, colchicine, and corticosteroids—there remains a clear unmet need, highlighted by better-tolerated drugs needed to target often occurring GI symptoms and patient compliance. Importantly, Gloperba's oral formulation is expected to provide more adjustable dosing, titration, and dose-reduction options, which may reduce side effects and improve disease management overall.

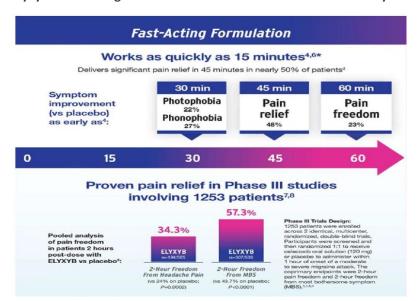
### Gout Remains a Clear Unmet Need in the U.S.



Source: SCLX company filings

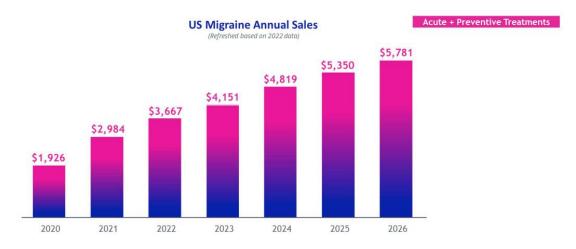
Migraines, a type of headache that is often characterized by moderate to severe throbbing pain from one side of an individual's head, currently affect more than 39M people in the U.S., but with only ~43% diagnosed, only ~36% receiving treatment, and only ~23% of patients actually treated, there is a clear market for helping individuals affected by this disease. Migraines, if left untreated, will typically last between 4 to 72 hours, occurring 1–2 days per month, but some migraines may last 15 or more days. Chronic migraines, those lasting more than 15 days, can lead to major impacts on everyday life, including physical, social, and work life. Elyxyb, a nonsteroidal anti-inflammatory (NSAID) drug has been approved for the treatment, but not prevention, of migraines. Woking in as fast as 15 minutes, Elyxyb is administered as an oral 120 mg solution, reportedly delivering pain relief in 45 minutes in ~50% patients. Market research has highlighted migraine treatment as a quickly expanding area, and therefore, we see SCLX's licensing of Elyxyb as a value generator going forward.

Elyxyb: Fast-Acting Oral Formulation with Demonstrated Efficacy in Phase III Studies



Source: SCLX company filings

Projected U.S. Migraine Market Space, Expected to Grow by 195% between 2021 and 2026



Source: SCLX company filings

# Market Model and Valuation Primarily Focused on Revenue-Generating Commercial Product ZTlido and SP-102 Potential in Sciatica

We base our \$4 price target primarily on SCLX's commercial-stage ZTlido and pre-NDA stage SP-102. Beginning with ZTlido, SCLX initially received approval for the drug in February 2018 and launched the drug 6 months later in a market largely served by Endo Pharmaceuticals' Lidoderm 5% and generic manufacturers such as Mylan. Based on an impressive clinical profile, i.e., demonstrating superior adhesion and bioavailability at a much lower dose of lidocaine relative to Lidoderm and generic patches, SCLX has been able to grow the franchise rapidly since the 2018 launch. The original commercial strategy for the product was based on a target market of 15K–20K physicians spanning neuropathic and chronic back pain specialities, anesthesiologists (32%); interventional pain management specialists (27%); physical medicine and rehab specialists (16%); pain specialists (11%); neurologists (10%); and orthopedic surgeons—with a focus on ~3,000 high-volume pain clinics for the 65-person specialized sales force. Importantly, SCLX has also been able to achieve broad access for ZTlido and is currently covered for >220M lives across major plans, e.g., CVS/Aetna commercial, ESI commercial, Optum Rx, Medicaid, United Healthcare, and Anthem, and recently had a national PBM move 5.5M covered lives from uncovered to covered.

For 2023, total prescription volume for ZTlido is expected to be in the range of ~500K and to grow around 10% in 2024. With an estimated WAC price of \$307.20 (\$10.24/unit in a 30-pack), SCLX is expected to generate net sales of ZTlido of \$43M in 2023 and \$53M in 2024. Importantly, in 2Q21, SCLX received sNDA approval to make efficacy labeling changes based on an incremental study in water stress conditions showcasing the superior adhesion of ZTlido, which we believe will continue to have a positive incremental impact on market share. Looking ahead, at peak, we believe SCLX can generate gross/net revenue of more than \$127M/\$101M by 2030E based on achieving prescription volume of ~724,000.

Multiple opportunities exist for potential upside to top-line revenue, including (1) Y/Y TRx volume growth through capitalizing on incremental distribution channels, e.g., nursing homes, Indian reservations, and growth in total covered lives, and (2) use in the combination setting with gabapentinoids, e.g., Pregabalin. On the latter, lidocaine patch treatment has already demonstrated the ability to reduce pain intensity at a higher magnitude over 4 weeks (without the need for dose titration associated with pregabalin); the ability to reduce the number of acetaminophen tablets required for rescue treatment; and a much stronger safety profile, i.e., 4% discontinuation rate relative to 27% with pregabalin. Lidocaine 5%, pregabalin, and gabapentin are all indicated for PHN, and in a post-hoc pooled analysis conducted by Wieman, et al. from Endo Pharmaceuticals, 9 out of 11 patients who had a partial response to gabapentin monotherapy, i.e., pain >4 on a scale of 0–10, experienced an improvement in pain relief at 2-weeks when adding the 5% lidocaine patch to their treatment regimens. An additional sub-analysis in 35 PHN patients that had an insufficient response to either lidocaine patch or pregabalin monotherapy revealed that upon combining the two for 8 weeks, patients exhibited an average of a 3-point decrease in pain intensity at week 8 with no notable side effects. Ultimately, investigators concluded that combination therapy with the lidocaine 5% patch and a calcium channel alpha2-delta ligand is generally well tolerated, which we believe can unlock a significant incremental market opportunity for SCLX with a much stronger combination partner in ZTlido.

SCLX has framed SP-102 as a key adjunct treatment for lumbar radiculopathy and a potential as a new pain management standard. The product was developed as a novel viscous gel formulation optimized for epidural injection and is positioned to be the first FDA-approved epidural steroid injection product for sciatica in the U.S. despite the fact that over 12M injections are administered on an annual basis and widely reimbursed to delay or avoid back surgery. However, currently, many of these ESIs contain potentially neurotoxic preservatives, particulates, surfactants or solvents, and in 2012, compounded epidural steroids led to >70 deaths due to fungal contamination, prompting the FDA to issue an official required warning on all injectable corticosteroid product labels in 2014. Notably, SP-102 was designed as a preservative-free, surfactant-free, and particulate-free viscous gel formulation of dexamethasone for sciatica with an extended locally targeted effect that provides durable pain relief and functional improvements, e.g., improvement on the Oswestry Disability Index (ODI) following a single injection. The product is also stable at refrigerated temperature and comes in a pre-filled syringe, further reducing the risk of contamination.

Of the >12M ESIs administered annually, a vast majority of injections (~88%) are used for lumbar radiculopathy, establishing a substantial TAM of 10M+ injections that may be captured by SCLX given the lack of an FDA-approved treatment; SCLX expects the product to be used across a variety of specialties, with a focus on anesthesiologists and PMR specialists. Of particular significance will be the reimbursement dynamics for SP-102, as the company will look to rapidly secure pass-through status and a permanent J-code 3–6 months afterwards, enabling premium pricing of average sales price (ASP) +6% and ultimately being reimbursed at a price point of \$350–\$500. In our model, we anticipate the product to be launched in 2026 and to compete for share in a market of 13.1M ESIs. To put the potential market opportunity in context, at a 5% penetration rate and a \$450 price point, we estimate that SCLX can generate ~\$50M in gross sales, which may grow to exceed \$729M by 2030, should the company ultimately be able to capture 20% of the off-label ESI lumbar radiculopathy market. Upon applying market access and reimbursement-related haircuts, including a meaningful gross-to-net discount, we project that SP-102 can achieve \$19.5M in net sales in its first year of launch, potentially growing to \$237M by 2030 at our estimated peak market share of 20%. We currently ascribe a 65% probability of success to SP-102.

Additional revenue streams are also expected from Elyxyb and Gloperba, both acquisitions that we view as being quite prudent for the company's existing commercial footprint. With a launch in 2023 and an expected launch in 2024, respectively, SCLX will be able to heavily leverage its existing commercial sales force and market access teams to drive meaningful revenue with modest incremental SG&A spend. We model relatively low market penetration rates for both of these products. At an anticipated launch price of \$850 for a 6-day supply of Elyxyb, or a \$320/30-day supply and a 6-month treatment duration of Gloperba, we forecast gross sales of ~\$119,000 in 2023 and \$10.5M in 2024, for each respective first year of launch, with the potential to grow to \$42M and \$65M by 2030.

## **Intellectual Property**

**Patent portfolio.** SCLX's patent portfolio contains approximately 16 issued and unexpired U.S. patents, six pending U.S. patent applications, and one pending Patent Cooperation Treaty (PCT) application. The portfolio also includes certain foreign counterparts of these patents and patent applications, including Australia, Brazil, Canada, China, Hong Kong, India, Indonesia, Israel, Japan, Korea, Malaysia, Mexico, New Zealand, Panama, Peru, Philippines, Russian Federation, Singapore, South Africa, Taiwan, Ukraine, and certain countries within the European Patent Convention.

With respect to ZTlido and SP-103, the patents and patent applications cover compositions and methods of treatment. With respect to SP-102, the patents and patent applications include formulations and methods of treatment. The patents are U.S. Pat. Nos. 10,500,284, 10,117,938, and 11,020,485, all of which expire in 2036. With respect to SP-104, the pending Patent Cooperation Treaty application is WO 2022/076470 (and all patents and patent applications that claim priority rights thereto), which covers oral delayed-burst formulations of low-dose naloxone or naltrexone and related methods of treatment. SCLX continues to seek to maximize the scope of patent protection for all programs and has five issued U.S. patents and two pending U.S. patent applications related to lidocaine topical system compositions and methods of treating pain with lidocaine topical system compositions. The patents are U.S. Pat. Nos. 9,283,174, 9,925,264, 9,931,403, 10,765,749, 10,765,640, and 11,278,623, all of which expire in 2031. Related to Gloperba, the licensed patents include U.S. Pat. Nos. 9,907,751, 10,226,423, 10,383,820, and 10,383,821, which relate to liquid colchicine formulations for oral administration and associated methods of use. U.S. Pat. No. 10,226,423 expires in 2037. The remaining patents related to Gloperba expire in 2036.

## **Collaboration Agreements**

Itochu and Oishi product development agreement. SCLX entered into an agreement with Oishi Koseido Cr and Itochu Chemical Frontier Corporation in which the developers agreed to provide exclusive rights to market, sell, and distribute lidocaine tape products, including ZTlido and SP-103. The developers agreed to (1) source and provide the active pharmaceutical ingredient for the products for manufacturing, (2) develop a stable final dosage form of the products suitable for regulatory approvals, (3) conduct product development activities necessary to support the filing of applications for regulatory approvals for the products, and (4) conduct manufacturing scale-up activities and preclinical studies for the products. SCLX will be responsible for conducting all pivotal human clinical trials for the products; completing all regulatory filings, correspondence, and meetings with the FDA or other applicable governmental authorities with respect to the products; and commercially launching the products. In exchange, SCLX agreed to pay a contingent quarterly royalty of 25%–35% to the developers based on the net quarterly profits of the products, and if total net profits for ZTlido and SP-103 are equal to or less than 5% of net sales of ZTlido and SP-103 for a period of four or more consecutive quarters, the developers have the right to terminate the agreement.

**Genzyme supply agreement.** Genzyme agreed to produce and provide sodium hyaluronate, one of the excipients for SP-102, and SCLX agreed to purchase 100% of the clinical and commercial requirements for sodium hyaluronate in specified territories, including the U.S. and all countries of the European Union, exclusively from Genzyme. The Genzyme supply agreement provides for a five-year exclusivity period in favor of SCLX and will remain in effect until 10 years after the effective date unless earlier terminated in accordance with the terms of the agreement, with automatic renewal for additional five-year periods (on an exclusive basis) if the respective requirements for exclusivity are met and for additional two-year periods thereafter unless either party gives notice of termination not less than 18 months prior to the expiration of the then-current term.

**Lifecore master services agreement.** Lifecore is responsible for clinical trial material manufacturing and development services for SP-102, including project management support, development services, clinical trial materials, and stability studies.

**ROMEG license and commercialization agreement.** SCLX entered into a licensing and commercialization agreement with ROMEG Therapeutics for an exclusive, transferable license to use the trademark "Gloperba" for the treatment of gout until July 1, 2027, at which point the license becomes co-exclusive with Granules Pharmaceuticals. In exchange, SCLX agreed to make (1) an up-front payment of \$2.0M; (2) upon achievement of certain net sales milestones, certain milestone payments in the aggregate amount of up to \$13.0M; and (3) certain royalties, at rates that do not exceed 10%, based on annual net sales of the licensed products during the royalty term.

# Management Team and Board of Directors(1)

Jaisim Shah, chief executive officer and president. Jaisim Shah has more than 30 years of experience leading product development, commercializing therapies, and creating companies with documented success in the development and commercialization of pharmaceutical brands. He is a life sciences executive and board director with experience at Bristol-Myers Squibb, Roche, PDL Biopharma, Sorrento, Pfizer/Upjohn, Scilex, and start-ups Elevation and Semnur Pharmaceuticals. Mr. Shah was 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 before joining Scilex, Mr. Shah served as chief business officer of Elevation Pharmaceuticals. 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 as 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, and helped the company improve its profitability potential. At Bristol-Myers Squibb, as vice president of global marketing from 1997 to 2000, Mr. Shah received the "President's Award" for completing one of the most significant collaborations in the company's history. Mr. Shah holds an M.A. in economics from the University of Akron and an M.B.A. from the University of Oklahoma.

Henry Ji, Ph.D., executive chairman of Scilex and co-founder, chairman, CEO, and president of Sorrento Therapeutics, Inc. Henry Ji has more than 25 years of experience in the biotechnology and life sciences industry. Dr. Ji has been chairman of Scilex since March 2019 and served as 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 led the growth of Sorrento through acquisitions 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 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 and Stratagene, co-founded Stratagene Genomics (a subsidiary of Stratagene), and served as its president and CEO and as a member of the board of directors. Dr. Ji received a doctorate from the University of Minnesota and an undergraduate degree from Fudan University.

Dmitri Lissin, M.D., chief medical officer and senior vice president. Dmitri Lissin has served as chief medical officer and senior vice president, clinical development and medical affairs of Scilex/Semnur Pharmaceuticals since 2015. Prior to Semnur, from 2011–2015, Dr. Lissin was vice president of clinical development at Xenoport, responsible for conducting multiple clinical research programs in neurology and dermatology. From 2006–2011, he directed a clinical research team and served as a 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 licensing deals and NDA filings. From 1998–2006, Dr. Lissin managed various clinical R&D programs at Titan Pharmaceuticals, Aerogen, and Synarc. He has 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 the 505(b)(2) drug approval pathway. He received his post-doctoral training at the University of California San Francisco and his medical degree through an exchange program between the Russian National Medical University and Harvard Medical School.

Suketu D. Desai, Ph.D., chief technical officer and senior vice president. Suketu D. Desai, Ph.D., has more than 25 years of experience in the biologics and pharmaceutical Industry. Dr. Desai has served as chief technical officer and senior vice president, chemistry, manufacturing and controls, regulatory CMC, and quality assurance at Scilex Pharmaceuticals since 2015. 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. He 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. From 2007 until its acquisition by Cephalon in 2010, he was with Ception Therapeutics, Inc. as vice president, chemistry, manufacturing and controls, and quality assurance, responsible for biologics drug substance and drug product development and for analytical, manufacturing, quality, regulatory CMC, and technical due diligence for business development. Dr. Desai was previously 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); associate director, pharmaceutical and biologic formulations at AAI Pharma Development Services (2001–2003); director/senior 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. He received his Ph.D. in pharmaceutical sciences from the University of Arizona, Tucson, Arizona, and Master's in Pharmacology and Bachelor's in Pharmacy from the University of Mumbai, Mumbai, India.

Suresh Khemani, chief commercial officer and senior vice president. Suresh Khemani has more than 25 years of global pharmaceutical experience. He has been senior vice president and chief commercial officer of Scilex since March 2019. He manages Scilex's sales, sales operations, marketing, market research, and managed care operations, including its U.S. 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 worked to launch specialty and large market products such as Zelmac/Zelnorm for IBS-D; prepared Dexpramipexole (dex) for ALS and Parkinson's disease and Cubicin, an injectable antibiotic, for market readiness; and developed launch plans for Pulminique, an inhaled cyclosporine, for the U.S. and E.U. and for Abilify, a \$7B product. Prior to Scilex, he held 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.

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.

Steve Lincoln, general counsel and chief compliance officer. Steve Lincoln serves as interim general counsel and as chief compliance officer for Scilex Holding Company and Scilex Pharmaceuticals. He has been involved in the biopharma industry for more than 18 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). He is a graduate of Brown University and the Boston University School of Law.

Dave Lemus, independent director of Scilex, director of Silence Therapeutics, director of Sorrento Therapeutics, Inc., and director of Biohealth Innovation, Inc. Dave Lemus joined Scilex's board of directors in April 2022. Mr. Lemus was previously CEO of Ironshore Pharmaceuticals Inc. and serves on the boards of directors of Silence Therapeutics, Sorrento Therapeutics, Inc., and Biohealth Innovation, Inc. Previously, Mr. Lemus stepped down from Medigene AG's board of directors to serve as the company's chief operating officer and interim CFO. Preceding this position, he served as CEO of Sigma Tau Pharmaceuticals, Inc. Prior to this, he was CFO and executive vice president of MorphoSys AG for more than 13 years, taking the company public in Germany's first biotechnology initial public offering. Mr. Lemus received a M.S. from the Massachusetts Institute of Technology and a B.S. from the University of Maryland. Mr. Lemus is a certified public accountant, licensed in the State of Maryland.

Alexander Wu, director and CEO of Cothera Bioscience, Inc. Yue Alexander Wu is co-founder and CEO of Cothera Bioscience, Inc., a translation medicine and precision therapeutics company. He was previously President, Chief Executive Officer and Chief Strategy Officer of Crown Bioscience International, a leading global drug discovery and development solutions company, which he co-founded in 2006, until 2017. From 2004 to 2006, Dr. Wu was Chief Business Officer of Starvax International Inc. in Beijing, China, a biotechnology company focusing on oncology and infectious diseases. From 2001 to 2004, Dr. Wu was a banker with Burrill & Company where he was head of Asian Activities. Dr. Wu has served as a director of CASI Pharmaceuticals, Inc. (Nasdaq: CASI) since June 2013 and Sorrento Therapeutics, Inc. since August 2016. Dr. Wu received his Ph.D. in Molecular Cell Biology and his MBA from University of California at Berkeley. He earned an M.S. in Biochemistry from University in Shanghai, China.

Jay Chun, director. Jay Chun, M.D., Ph.D., has served as the Chief of Neurosurgery and Director of the Atlantic Health Spine Center at Overlook Medical Center at Atlantic Health System since September 2015. Dr. Chun has served as a member of the Company's Scientific Advisory Board since August 2021 and previously served as a member of Celularity, Inc.'s (Nasdaq: CELU) Scientific Advisory Board from September 2020 to January 2023. Dr. Chun completed his M.D. and Ph.D. at Columbia University College of Physicians and Surgeons. His neurosurgical residency was completed at the University of California at San Francisco, followed by specialization in the discipline of complex and minimally invasive spine surgery at Emory in Atlanta, Georgia. Dr. Chun is board certified and specializes in complex and minimally invasive spine surgery as well as artificial discs. While a member of the Columbia University faculty from June 1995 to June 1997, Dr. Chun

worked in the field of biotechnology. He has received many honors including Medical Research Fellowships from the National Institutes of Health (NIH), working with the late Nobel Laureate Marshall Nirenberg. He received his Ph.D. with Richard Axel, a recipient of the 2004 Nobel Prize. In honor of his stem cell research, he received the NIH Individual National Research Service Award.

**Dorman Followwill, director.** Dorman Followwill was senior partner of transformational health at Frost & Sullivan, a business consulting firm involved in market research and analysis, growth strategy consulting, and corporate training from 2016 to September 2020. He previously held various roles at Frost & Sullivan, including partner on the executive committee managing the P&L of the business in Europe, Israel, and Africa and partner overseeing the healthcare and life sciences business in North America; he initially joined Frost & Sullivan to help found the consulting practice in January 1988. Mr. Followwill has more than 30 years of organizational leadership and management consulting experience. He has performed strategic analyses related to the imperative of growth for clients such as Bayer, Novartis, Merck, GE Healthcare, Siemens, Philips, IBM, and HP, Inc. and has assisted Fidelity in making healthcare investments off its balance sheet. He obtained his B.A. from Stanford University in The Management of Organizations in 1985.



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### **Valuation**

We base our Buy rating and 12-month price target of \$4 per share on a discounted cash flow (DCF) analysis of revenue and cash flow projected through 2030. Our DCF analysis applies a WACC-calculated 12% discount rate and a 2% terminal growth rate, in line with other clinical-stage biotech companies. For 2030, the final projected year of our model, we forecast \$407M in total risk-adjusted revenue.

#### **Risks**

**History of operating losses.** The company has a history of operating losses. Although SCLX has achieved profitability (adjusted EBITDA) in recent quarters, there are no assurances that the company will meet its goals or be able to sustain profitability in future periods.

**Financial results.** The company has raised money via public offerings several times in the past and may need to do so again if it cannot sustain positive cash flow.

**Adoption of assets.** If the adoption of SCLX's various assets fails to materialize, or does so at a slower rate than we estimate, our valuation could be materially affected.

**Unfavorable clinical trial data.** If the products developed by company's spinouts are unable to produce favorable clinical data or are unable to receive regulatory approval, the opportunity for the products could diminish, and our valuation could be adversely affected.

**Regulatory risks.** The company's compounding facilities are regulated on both the state and federal levels and have seen significant regulatory changes in recent years. If new, unfavorable regulations are instituted, this could have a negative effect on SCLX's operations.

**Limited capital.** SCLX is a small company with limited resources, which may force it to scale back on aggressive sales and marketing efforts. SCLX may also need to raise capital to sustain operations, which could further dilute existing shareholders.

**Intense competition.** Many larger companies also focus on SCLX's markets. These companies could develop new, more effective technologies that could decrease SCLX's ability to obtain market share. They could force SCLX and its various spinouts into litigation, which could meaningfully impact FCF and potentially limit commercial opportunities.

**Intellectual property.** The strength, maintenance, and defense of SCLX's patents, trademarks, and other intellectual property are critical in protecting the company from patent infringement. Should certain key patents be found invalid or expire, this could prevent SCLX's products from reaching their peak commercial potential.

**Loss of management and other key employees.** The loss of certain employees and executives could disrupt operations and severely impact the company.



Scilex Holdings, Inc. (SCLX) Income Statement															
S in millions, except EPS	2020A	2021A	2022A	1Q23A	2Q23A	3Q23E	4Q23E	2023E	1Q24E	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E
Revenue	23.6	31.3	38.0	10.6	12.6	9.4	10.5	43.1	11.3	13.5	16.2	16.4	57.4	79.1	121.3
Product revenue	23.6	31.3	38.0	10.6	12.6	9.4	10.5	43.1	11.3	13.5	16.2	16.4	57.4	79.1	121.3
Cost of sales	(2.1)	(3.6)	(10.8)	(3.6)	(4.2)	(3.1)	(3.5)	(14.4)	(3.7)	(4.5)	(5.4)	(5.4)	(19.0)	(19.8)	(17.0)
Gross profit	21.4	27.7	27.2	7.0	8.4	6.3	7.1	28.8	7.6	9.1	10.9	11.0	38.5	59.3	104.3
Intangible Amortization	(3.7)	(3.7)	(3.9)	(1.0)	(1.0)	(1.1)	(1.8)	(4.9)	(2.0)	(2.2)	(2.4)	(2.7)	(9.3)	(13.6)	(13.6)
Research and development	(10.0)	(9.2)	(9.1)	(2.7)	(3.2)	(3.5)	(4.2)	(13.7)	(5.1)	(6.1)	(7.9)	(10.3)	(29.4)	(20.6)	(6.2)
Sales, general and administrative  Operating income (loss)	(43.0)	(50.6)	(64.9)	(28.7)	(27.0)	(25.6)	(25.9)	(107.2)	(26.2)	(26.4)	(26.7)	(28.0)	(107.3)	(118.0)	(135.7)
Change in fair value of derivative liabilities	(35.3)	(0.3)	8.3	(25.5)	(0.1)	(23.9)	(0.1)	(5.5)	(0.1)	(25.6)	(0.1)	(0.1)	(0.4)	(92.8)	(51.1)
Gain on settlement of debt	0.0	(40.5)	28.6	0.0	(3.7)	(3.9)	(4.0)	(11.6)	(4.1)	(4.1)	(4.2)	(4.3)	(16.7)	(15.0)	0.0
Interest income (expenses)	(13.1)	(11.8)	(9.6)	0.0	(0.0)	(0.0)	(3.7)	(3.7)	(3.5)	(3.1)	(2.5)	(1.9)	(11.1)	(1.3)	0.0
Other income (loss)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Loss (gain) on foreign currency exchange	0.0	(0.1)	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income before income taxes	(47.6)	(88.4)	(23.4)	(30.7)	(26.652)	(27.9)	(32.7)	(117.9)	(33.3)	(33.0)	(33.0)	(36.3)	(135.6)	(109.6)	(51.1)
Provision for income taxes	0.1	(0.0)	(0.0)	(0.008)	0.003	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(5.1)
Net income from continuing operations	(47.5)	(88.4)	(23.4)	(30.753)	(26.649)	(27.8)	(32.7)	(117.9)	(33.3)	(33.0)	(33.0)	(36.3)	(135.6)	(109.6)	(56.3)
Deemed Dividend  Net income (loss) to common stockholders	0.0 (47.5)	0.0 (88.4)	0.0 (23.4)	(30.8)	(26.6)	(27.8)	(32.7)	(117.9)	(33.3)	(33.0)	(33.0)	(36.3)	0.0 (135.6)	(109.6)	(56.3)
Basic EPS attributable to common stockholders	(0.36)	-0.67	-0.17	-0.22	-0.19	-0.19	-0.23	-0.83	-0.23	-0.23	-0.23	-0.25	(0.94)	-0.76	-0.39
Diluted EPS attributable to common stockholders	(0.36)	-0.67	-0.17	-0.22	-0.19	-0.19	-0.23	-0.83	-0.23	-0.23	-0.23	-0.25	(0.94)	-0.76	-0.39
Shares, basic (million)	132.89	132.86	134.23	141.66	142.63	142.98	143.34	142.65	143.70	144.06	144.42	144.78	144.24	144.60	144.96
Shares, diluted (million)	132.89	132.86	134.23	141.66	142.63	142.98	143.34	142.65	143.70	144.06	144.42	144.78	144.24	144.60	144.96
													•	•	
Cash Flow Statement \$ in millions	2020A	2021A	2022A	1Q23A	2Q23A	3023E	4Q23E	2023E	1024E	2Q24E	3Q24E	4024E	2024E	2025E	2026E
Net change in cash and cash equivalents	(50.9)	(0.5)	(2.2)	2.9	30.1	16.0	15.2	64.1	22.1	15.5	13.8	13.8	65.2	6.5	105.8
Cash and cash equivalents at beginning of period	55.5	4.8	4.3	2.2	5.1	35.1	51.1	2.2	66.3	88.4	103.9	117.7	66.3	131.5	138.0
Cash and cash equivalents at end of period	4.8	4.3	2.2	5.1	35.1	51.1	66.3	66.3	88.4	103.9	117.7	131.5	131.5	138.0	243.8
CASH FLOWS FROM OPERATING ACTIVITIES															
Consolidated net loss before income taxes	(47.5)	(88.4)	(23.4)	(30.8)	(26.6)	(27.8)	(32.7)	(117.9)	(33.3)	(33.0)	(33.0)	(36.3)	(135.6)	(109.6)	(56.3)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:															
Depreciation and amortization  Amortization of debt issuance costs and debt discount	3.8	3.8	4.0	1.0	1.0	1.1	1.3	4.5	1.4	1.5	1.7	1.8	6.4	6.5	1.4
Scilex Pharma Notes principal increase	10.7	7.9 28.0	3.1 0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payment on the Scilex Pharma Notes attributed to accreted interest related to the debt discount	(10.9)	(12.5)	(21.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(Gain) loss on debt extinguishment, net	0.0	12.5	(28.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Non-cash operating lease cost	0.8	0.4	0.5	0.1	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.1	0.1	0.1
Stock-based compensation	5.4	5.8	5.3	3.7	3.6	3.9	4.3	15.6	4.8	5.3	5.8	6.4	22.2	22.6	23.1
(Gain) loss on derivative liability	(0.8)	0.3	(8.3)	5.3	0.1	0.1	0.1	5.5	0.1	0.1	0.1	0.1	0.5	0.5	0.5
Forfeitures of Private Warrants Other	0.0	0.0	1.7	0.0	3.7	4.1 0.0	4.5	12.4	5.0 0.0	5.5 0.0	6.0 0.0	6.6	23.2	23.6	24.1
Changes in operating assets and liabilities:	0.0	0.0	0.0	0.0	(0.0)	0.0	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Accounts receivables, net	(0.6)	(1.1)	(7.0)	2.0	(8.3)	(9.2)	(10.1)	(25.6)	(9.2)	(10.1)	(11.1)	(12.2)	(42.5)	(43.3)	(44.2)
Inventory	2.4	(1.4)	1.0	(0.9)	(0.8)	(0.9)	(1.0)	(3.7)	(1.1)	(1.2)	(1.3)	(1.5)	(5.2)	(5.3)	(5.4)
Prepaid expenses and other	(1.0)	1.5	(2.6)	0.3	(0.3)	(0.3)	(0.4)	(0.7)	(0.4)	(0.4)	(0.5)	(0.5)	(1.9)	(1.9)	(1.9)
Other long-term assets	2.6	0.0	0.4	1.0	(0.2)	(0.2)	(0.2)	0.4	(0.3)	(0.3)	(0.3)	(0.3)	(1.2)	(1.2)	(1.2)
Accounts payable	(4.1)	(3.8)	2.8	2.0	2.3	2.6	2.8	9.7	3.1	3.4	3.8	4.1	14.4	14.7	15.0
Accrued payroll	1.2	(0.0)	(2.4)	0.4	1.0	1.1	1.3	3.8	1.4	1.5	1.7	1.8	6.4	6.5	6.7
Accrued expenses	(1.1)	0.7	(0.1)	3.5	(2.0)	(2.2)	(2.4)	(3.1)	(2.7)	(3.0)	(3.3)	(3.6)	(12.5)	(12.7)	(13.0)
Accrued rebates and fees	3.1	(0.3)	23.5	4.7	12.2	13.4	14.7	45.0	5.2	5.7	6.3	6.9	24.2	24.7	25.2
Other liabilities Related party payable	(0.6)	(0.1) 18.2	(0.4)	(0.2)	(0.2)	(0.2)	(0.2)	(0.7)	(0.2)	(0.2)	(0.3)	(0.3)	(1.0)	(1.0)	(1.0)
Other long-term liabilities	5.1 0.0	18.2 0.0	30.1 0.2	0.0	1.0 0.0	1.1 0.0	1.3 0.0	3.5 0.0	1.4 0.0	1.5 0.0	1.7 0.0	1.8	6.4 0.0	6.6 0.0	6.7 0.0
Net cash provided by/(used in) operating activities	(31.5)	(28.7)	(21.3)	(7.7)	(13.5)	(13.3)	(16.7)	(51.3)	(24.8)	(23.6)	(22.6)	(25.0)	(96.0)	(69.2)	(20.3)
CASH FLOWS FROM INVESTING ACTIVITIES															
Acquisition consideration paid in cash for Romeg intangible asset acquisition	0.0	0.0	(2.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Purchase of property and equipment	(0.3)	0.0	(0.0)	0.0	(0.0)	(0.0)	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash provided by/(used in) investing activities	(0.3)	0.0	(2.1)	0.0	(0.0)	(0.0)	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CASH FLOWS FROM FINANCING ACTIVITIES															
Proceeds from issuance of shares under Standby Equity Purchase Agreements	0.0	0.0	0.0	1.7	14.5	3.0	3.0	22.2	30.0	30.0	30.0	30.0	120.0	30.0	12.0
Proceeds from issuance of convertible debentures	0.0	0.0	0.0	9.6	14.4	0.0	0.0	24.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from the Business Combination	0.0	0.0	3.4	0.0	0.0	0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0	0.0
Transaction costs paid related to the Business Combination	0.0	0.0	(2.9)	(0.6)	(0.7)	0.0	0.0	(1.4)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Repayment of principal on the Scilex Pharma Notes	(58.9)	(33.4)	(84.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Repayment of principal on Oramed Notes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(12.0)	(17.0)	(17.0)	(17.0)	(63.0)	(38.9)	0.0
Proceeds from sale of common stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Repayment on other loans	0.0	(48.8)	(18.8)	0.0	(2.5)	0.0	0.0	(2.5)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from other loans	11.0	47.8	9.9	0.0	17.5	26.3	28.9	72.8	28.9	26.0	23.4	25.8	104.2	114.6	126.1
December of debt becomes and	0.0	0.0	0.0	0.0	(0.4)	0.0	0.0	(0.4)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payments of debt issuance costs		11	2.1												
Proceeds from stock options exercised	0.1	0.0	0.1	0.0	0.7	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from stock options exercised Proceeds from related party payable	0.1 18.4	0.0 47.9 14.7	0.1 51.9 62.5	0.0 0.0 0.0		0.0 0.0 0.0		0.7 0.0 0.0	0.0 0.0 0.0	0.0 0.0 0.0	0.0 0.0	0.0	0.0	0.0 0.0	0.0
Proceeds from stock options exercised	0.1	47.9	51.9	0.0	0.7 0.0	0.0	0.0	0.0	0.0	0.0	0.0			0.0	

cilex Holdings, Inc. (SCLX) CF analysis																				Mayanl B. Riley +1 (646	Securit	ies	
																				amtani@b		Tern	nin
Fiscal year	20	)20A	20	)21A	202	22A	20	023E	20	)24E	202	25E		2026E	202	27E	2	2028E		2029E	2030E	val	
Fiscal year end date	12/	31/20	12/	31/21	12/3	1/22	12/	31/23	12/3	31/24	12/31	1/25	12	2/31/26	12/3	1/27	12,	/31/28	12	2/31/29	12/31/3	30	
Revenues	\$	23.6	\$	31.3	\$	38.0	\$	43.1	\$	57.43	\$ 7	9.12	\$	121.29 \$	16	55.30	\$	220.07	\$	297.14	\$ 406.	66	
Cost of product sales	\$	(2.1)	\$	(3.6)	\$	(10.8)	\$	(14.4)	\$ (	(18.95)	\$ (1	.9.78)	\$	(16.98) \$	5 (2	23.14)	\$	(30.81)	\$	(41.60)	\$ (56.	93)	
Gross Profit	\$	21.4	\$	27.7	Ś	27.2	Ś	28.8		38.5		59.3		104.3	1	142.2		189.3		255.5	349	9.7	
Intangible Amortization	\$	(3.7)		(3.7)		(3.9)	•	(4.9)															
R&D expense	\$	(10.0)		(9.2)		(9.1)		(13.7)		(29.4)	(	(20.6)		(6.2)		(4.3)		(4.5)		(4.8)	(5	5.0)	
SG&A expense	\$	(43.0)		(50.6)		(64.9)		(107.2)		(107.3)		18.0)		(135.7)	(:	149.3)		(161.2)		(164.4)	(197	· 1	
Total operating expenses	\$	(56.7)		(63.5)		(77.9)		(120.9)		(136.6)		138.6)		(141.9)		153.6)		(165.7)		(169.2)	(202	<del>_</del>	
Operating income (EBIT)	\$	(35.3)	\$	(35.8)	\$	(50.6)	\$	(92.1)		(98.2)	(	(79.2)		(37.6)		(11.4)		23.5		86.4	147	.4	
Taxes		0.1		(0.0)		-		-		-		0.0		(5.1)		(2.5)		1.0		7.3	28	3.1	
After tax operating income		(35.3)		(35.8)		(50.6)		(92.1)		(98.2)	(	(79.2)		(32.4)		(8.9)		22.5		79.1	119	9.3	
(+) depreciation and amortization		14.4		11.7		7.1		4.5		6.4		6.5		1.4		1.6		1.7		1.9	6	5.7	
(-) capital expenditures		0.3		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	(	0.0	
(-) change in working capital		(7.1)		(13.6)		(45.7)		(28.5)		12.7		13.0		13.2		13.5		13.8		14.1	14	1.3	
(+) deferred taxes		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	(	0.0	
(+) other non-cash items		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	(	0.0	
Unlevered free cash flow		(27.7)		(37.7)		(89.2)		(116.2)		(79.0)	(	(59.7)		(17.8)		6.2		38.1		95.0	140	0.3	
Time period (years)								0.17		1.17		2.17		3.17		4.17		5.17		6.17	7.	17	
Discount factor								0.98		0.88		0.78		0.70		0.62		0.56		0.50	0	.44	
PV								(28.5)		(69.2)	(	(46.7)		(12.4)		3.8		21.2		47.3	62	2.3	
EV		612.96																		PV of Teri	ninal Va	lue 6	63
+ Cash and Cash equivalents		34.12																					
Company value		647.09					_	g. 11, 20													Dilut		
- Long-term debt		34.4						,		of conve				18.440 sh				\$8.00				000	
Equity value		\$613						,		of stock	•	ons		31.353 sh				\$4.66				000	
Fully diluted shares outstanding		149.1						,		of warra				27.958 sh				\$8.71				000	
Price/share	\$	4.00								nvested R	SUs			0.000 sh	nares	S		\$0.00	WA	EP		000	
WACC		12.0%		ļ	Possi	ible dil	utior	n (millio	n sha	res)											0.0	000	
Terminal growth rate		2.0%			WACC	. Calaul							D-I	anaa Chaat									
sumptions					WACC	Calcul	atio	ns						ance Sheet al debt						34.36			
te	10/1	1/2023			Risk-fi	ree rate	e			2.0%				ai debt sh and equiv	/aler	nts				34.36			
cal year ending (1-12)		12			Adjust	ted bet	a			1.3				t debt						0.23			
cal year ending (month)		ember			Rm-Rf					7.0%				bt, as a % of	f equ	iity				10.34%			
pjections discounted to (1-12)		12.00			Re					11.0%				sh per share		•				0.23			
pjections discounted to (month)	Dec	ember			Rd					0.0%				sing price, 1		1-23			\$	2.23			
ares outstanding	14	9.055			WACC	calcul	lated	1		11.0%				sing market			-23		Ś	332.39			

\*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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BUY [Buy]	78.19%	41.69%
HOLD [Neutral]	21.81%	24.72%
SELL [Sell]	0.00%	0.00%

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