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(NASDAQ: SCLX)

Price	\$0.79
52 Week Range	(\$0.73 - \$2.63)
Price Target	\$14.00
Market Cap (mil)	\$150.00
Shares out (mil)	191.79
3-Mo Avg Vol	707,961
Cash per share	\$0.06
Total Debt (mil)	\$104.40
Debt/Equity	(49.0)%

Revenues (millions) \$

Yr	2023A	2024E	2025E
Jun	11A	11A	13E
Sep	13A	16A	19E
Dec	10A	17E	20E
Mar	14A	18E	21E
YEAR	47A	62E	74E

EPS \$

Yr	2023A	2024E	2025E
Jun	(0.18)A	(0.26)A	(0.12)E
Sep	(0.16)A	(0.13)A	(0.10)E
Dec	(0.28)A	(0.10)E	(0.10)E
Mar	(0.20)A	(0.10)E	(0.10)E
YEAR	(0.82)A	(0.50)E	(0.40)E



Scilex Holding Company

Buy

Volatility: 5

Leading the way in non-opioid pain treatment solutions — the Holy Grail of pain treatment

We are initiating coverage on Scilex Holdings, Inc. (SCLX) with a Buy rating and a \$14 price target. SCLX is a revenue-generating company based out of California that is focused on the development and acquisition of non-opioid pain management treatment options for multiple pain conditions. SCLX has three FDA approved non-opioid pain products on the market currently, but the main reason to own SCLX, in our opinion, is for their Phase 3 developmental candidate SEMDEXA, a non-opioid injectable corticosteroid gel formulation for lumbosacral radicular (sciatica) pain. The current treatment for sciatica is an off-label epidural steroid injection, which is injected over 12M times annually in the US. If approved, SEMDEXA could become the standard of care for sciatica, and we believe could become a legitimate blockbuster (\$1B+) product at peak. SCLX's three FDA-approved products are: ZTlido (1.8% lidocaine topical system) for neuropathic pain associated with postherpetic neuralgia (PHN); ELYXYB (celecoxib oral solution) for migraines; and GLOPERBA (colchicine USP) for gout. SCLX's earlier stage pipeline includes SP-103 for chronic neck pain that should be in Phase 3 trials in 4Q24/1Q25, SP-104 for fibromyalgia, and SP-105 to supplement ELYXYB with an acute pain indication. The Centers for Disease Control and Prevention (CDC) details that ~20% of all US adults (over 51M people) experienced chronic pain in 2021, and opioids remain the most common option to manage pain despite their high risk for abuse and addiction. SCLX remains steadfast in providing affected individuals with non-opioid pain alleviating options targeting a broad range of both acute and chronic pain conditions, with plans to continue expanding the pain indications they may target. We are initiating coverage with a Buy rating and a \$14 price target based on SEMDEXA valued at \$12.50/share, and ZTlido, ELYXYB, and GLOPERBA valued at \$1.00/share. We value the remaining assets (SP-103, SP-104, and SP-105) and net cash (less debt, end-'25) at \$0.50/share.

SEMDEXA has a legitimate opportunity to become a blockbuster drug. Sciatica pain has no approved treatment currently, with off-label epidural steroid injections being administered over 12M times annually in the US. SEMDEXA has received Fast Track designation and in the completed Phase 3 C.L.E.A.R. trial SEMDEXA demonstrated a statistically significant ($p < 0.001$) reduction in sciatica pain over 4 weeks with a clean safety profile. If ultimately approved SEMDEXA would be the first corticosteroid approved for epidural injection and could become the standard of care for sciatica. SCLX still needs to complete a Phase 3 safety trial for SEMDEXA that should start 4Q24, with a potential NDA filing in 2026, and if approved followed by launch in 2027. We believe that if ultimately approved SEMDEXA has the opportunity to reach \$1.2B in sales by 2030.

Spin out of Semnur subsidiary to advance sciatica-focused SP-102 (SEMDEXA) candidate. This past August, SCLX announced that its subsidiary, Semnur Pharmaceuticals, Inc., entered into a merger agreement with Denali Capital Acquisition Corp. (DECA, not rated). This transaction is expected to close by 1Q25, which will create a publicly traded biopharma company under the Semnur Pharmaceuticals, Inc. (SMNR, not rated) name, and will take over the remaining clinical development of SEMDEXA, a 10 mg dexamethasone sodium phosphate viscous gel product candidate formulated to target lumbosacral radicular pain or sciatica. See below for more details.

FDA-approved pipeline stands out in the non-opioid treatment space. Avoiding opioids and their associated side effects and addiction potential has long been the Holy Grail of pain management in the US, with many stops & starts that have happened to date. SCLX currently has three FDA-approved products, including their lead ZTlido (1.8% lidocaine topical system) which was approved in October 2018, ELYXYB (celecoxib oral solution) for the acute treatment of migraine with or without aura which was approved in April 2023, and their recently-approved GLOPERBA (colchicine USP), a liquid oral version of the anti-gout medicine colchicine made for the prophylaxis of painful gout flares in adults which was approved earlier in 2024.

Developmental candidates targeting unmet medical needs. Alongside SEMDEXA SCLX's clinical development pipeline are the SP-103, SP-104, and SP-105 candidates. SP-103 is a next-generation 5.4% lidocaine topical system formulated to target

chronic neck pain. This candidate was also granted Fast Track Designation by the FDA for a low back pain indication and is expected to commence Phase 3 development in 4Q24/1Q25. SP-104 is a delayed-release capsule formulation of naltrexone hydrochloride (4.5 mg) developed for the treatment of fibromyalgia, with clinical development currently delayed as SCLX focuses on advancing their other candidates. SP-105 is formulated to supplement ELYXYB and add an acute pain indication to its established acute treatment of migraine indication, with a supplemental New Drug Application (sNDA) in planning to implement this broader indication.

We are initiating coverage with a Buy rating and a \$14 price target. Our price target is based on a sum-of-the-parts analysis. We value SEMDEXA at \$12.50/share, and ZTlido, ELYXYB, and GLOPERBA valued at \$1.00/share. We value the remaining assets (SP-103, SP-104, and SP-105) and net cash (less debt, end-'25) at \$0.50/share for our \$14 price target.

Company Description and Overview

Scilex Holdings (SCLX) is a revenue-generating company focused on developing and acquiring non-opioid pain management treatment options for both acute and chronic pain conditions. Their lead drug product is ZTlido, a 1.8% lidocaine topical system that is an FDA-approved prescription lidocaine topical product targeting neuropathic pain associated with postherpetic neuralgia (PHN), which is lasting pain following shingles. SCLX also possesses two other FDA-approved and marketed drug products, including ELYXYB (celecoxib oral solution) for the acute treatment of migraine with or without aura, as well as GLOPERBA (colchicine USP), a liquid oral version of the anti-gout medicine colchicine made for the prophylaxis of painful gout flares in adults. Alongside their marketed drug products, SCLX's clinical development pipeline also includes SEMDEXA (SP-102) for the treatment of pain associated with sciatica, SP-103 for chronic neck pain, SP-104 for fibromyalgia, and SP-105 to supplement ELYXYB and include an acute pain indication. SCLX's efforts in formulating non-opioid pain treatment options are of great importance as opioids are often utilized to broadly treat pain, despite their heightened risk for potential addiction and drug abuse, specifically in conditions that are chronic and require lifelong treatment. There were over 51M US adults reported who experienced chronic pain in 2021, and with over 6M people reported to have opioid use disorder (OUD) in the US in 2022, SCLX's pipeline further underlines the great need to continue formulating such treatment options for underserved patient populations.

With ZTlido, ELYXYB, and GLOPERBA now FDA-approved, SCLX is working on advancing the clinical development of their remaining product candidates. SP-102 (SEMDEXA) was studied in the Phase 3 C.L.E.A.R. trial and is planned to be studied in a subsequent Phase 3 clinical trial with a possible initiation in 4Q24. SP-103 is also expected to commence Phase 3 development in 2024/2025. SP-104 completed two Phase 1 trials in 1H22 as management focuses on their later stage pipeline.. Lastly, SCLX plans on submitting a supplemental New Drug Application (sNDA) for ELYXYB for acute pain (SP-105) by year-end 2024.

Figure 1: Upcoming Potential Catalysts

Event	Expected Timing
SEMDEXA (SP-102) P3 trial 1st patient 1st visit	4Q24
SP-103 Phase 2/3 registrational trial start	4Q24/1Q25
ELYXYB acute pain sNDA	4Q24/1Q25
SEMDEXA P3 trial topline data	1H26
SEMDEXA NDA filing	2H026

Source: Company reports; AGP estimates

Valuation

Our 12-18 month price target for SCLX is \$14/share based primarily on our expectations for SEMDEXA for sciatica pain. We model that SEMDEXA could get approved for sciatica pain in 2027, with end sales reaching \$1.25B by 2030 as it becomes standard of care for sciatica. We place a 4x multiple on those sales, discounted back 5 years at 15% for our \$12.50/share valuation. We model that ZTLido, ELYXYB and GLOPERBA sales reach \$74M by 2025. We place a 3x multiple on those sales for our \$1.00/share valuation. We value the remaining technology at SCLX (including S0-103 for neck pain, SP-104 for fibromyalgia, and SP-105 for acute migraines) plus net cash (less debt, end-FY25E) at \$0.50/share for our \$14/share price target.

Figure 2: Sum-of-the-Parts Analysis

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Semdexa for sciatica	\$2,520,871	\$12.50
ZTLido, Elyxyb, Gloperba	\$150,000	\$1.00
Tech & Cash (end-'25)	\$229,877	\$0.50
SUM	\$2,750,748	\$14.00
Weighted shares out '25 (000)		200,626

Source: AGP estimates

SCLX's Pipeline

SCLX's pipeline currently includes their three marketed products, ZTlido (1.8% lidocaine topical system), ELYXYB (celecoxib) oral solution, and GLOPERBA (colchicine USP) oral solution. ZTlido was approved for the treatment of postherpetic neuralgia (PHN) related pain, and it was launched in the US in October 2018. ELYXYB was approved for the acute treatment of migraine and launched in the US in April 2023. GLOPERBA was approved for the prevention of gout flares and was launched in the US in June 2024.

Their pipeline also encompasses three product candidates currently under clinical development, including SP-102 (SEMDEXA), SP-103 (lidocaine topical system 5.4%), and SP-104 (low dose naltrexone). SP-102 was studied in a Phase 3 clinical trial as a potential treatment for lumbar radicular/sciatica pain and was granted Fast Track Designation by the FDA to expedite the remainder of its clinical development. SP-103 was recently studied in a Phase 2 trial in low back pain (LBP) patients, an indication for which the FDA granted Fast Track Designation. A Phase 2/3 trial in chronic neck pain patients is also planned to be initiated in 2024.

Figure 3: SCLX's Pipeline



Innovative Non-Opioid Pain Therapeutics

KEY PROGRAMS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	APPROVED	IP	MILESTONES / KEY COMMENTARY
ZTlido® (1.8% lidocaine topical system equivalent to 5% lidocaine)	Approved for the treatment of Postherpetic Neuralgia-PHN related pain					2031	Launched in the U.S. in October 2018
GLOPERBA® (colchicine USP) oral solution (For the prevention of painful gout flares in adults)	Approved for the prevention of painful gout flares in adults					2036	2H 2022: In-licensed U.S. rights June 2024: U.S. launch
ELYXYB® (celecoxib) oral solution (Acute Treatment of Migraine)	Approved for acute treatment of migraine					2036	1Q 2023: In-licensed U.S. / Canadian rights 2Q 2023: U.S. launch 4Q 2023: Canada filing Expected 2H 2024: Acute pain filing
	Expected to file acute pain indication with FDA in 2H 2024						
SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)	Fast Track					2036	1H 2022: Phase III achieved endpoints 2H 2023: FDA agreed on NDA path 2024: Finalizing Phase 3 safety trial to complete NDA package
SP-103 Lidocaine Topical System 5.4% (3X) (Chronic Neck Pain)	Plan to file Fast Track for neck pain in 2H 2024					2031	2Q 2023: Completed Two Positive Phase II trials 2H 2024: File Fast Track for neck pain 3Q 2022: Received Fast Track for low back pain
SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)	Prepare Phase II Trial					2041	1H 2022: Completed Phase I trial(s)

Source: Company presentation

Marketed Products

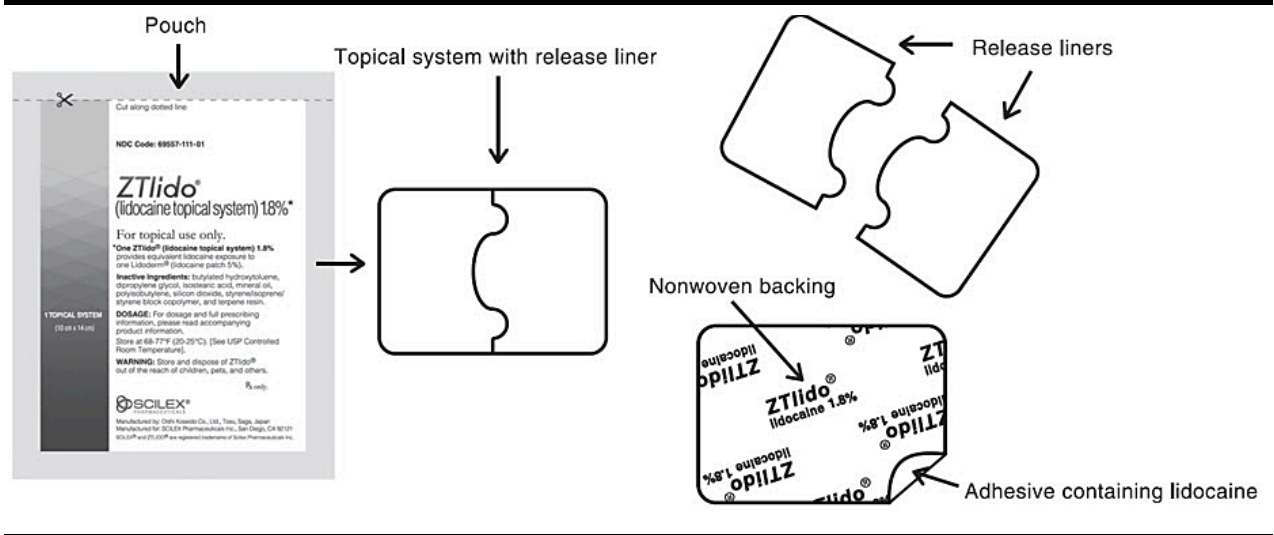
ZTlido - topical lidocaine patch for postherpetic neuralgia (PHN)

ZTlido (1.8% lidocaine topical system) is an FDA-approved prescription lidocaine topical product targeting neuropathic pain associated with postherpetic neuralgia (PHN), which is

lasting pain following shingles. Its composition includes a single-layer, drug-in-adhesive topical delivery system comprised of an adhesive material containing 36 mg lidocaine, applied to a pliable nonwoven cloth backing and covered with a polyethylene terephthalate film release liner. SCLX formulated ZTlido as a 1.8% lidocaine topical system that is equivalent to 5% lidocaine. The composition of ZTlido is also improved from the standard lidocaine patch as it possesses increased stickiness and durability while reducing the amount of lidocaine in the patch that does not get absorbed. SCLX launched ZTlido in the US in October 2018.

More information on ZTlido may be found on its [website](#) and [prescribing information highlights](#).

Figure 4: ZTlido overview



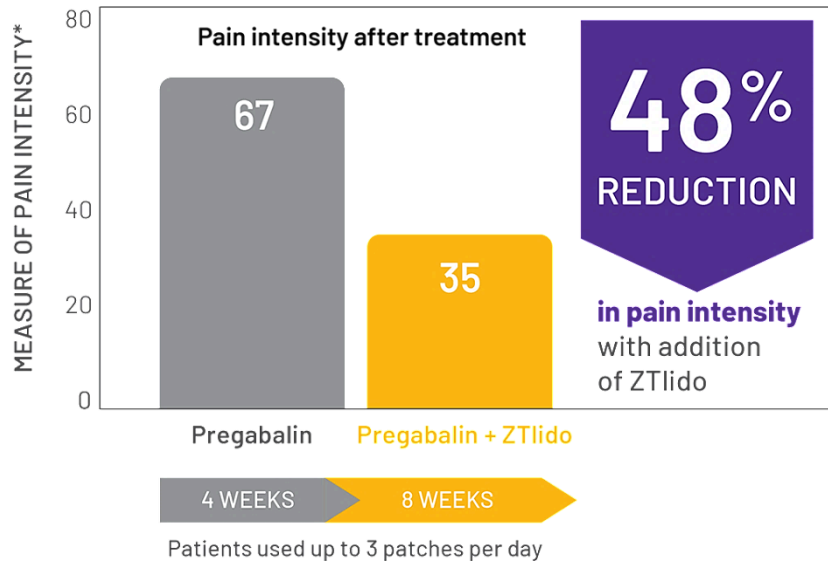
Source: ZTlido prescribing information

ZTlido Clinical Development

ZTlido has been studied in adhesion comparison studies against Endo Pharmaceutical's (NDOI, not rated) Lidoderm (lidocaine patch 5%) and Mylan NV's (MYL, not rated) generic version of Lidoderm. In a study on 44 subjects, ZTlido showed greater adhesion at all time points vs Lidoderm, and ZTlido maintained greater than 90% mean adhesion over the 12-hour administration period, while Lidoderm fell below this benchmark within 3 hours, and Mylan's generic lidocaine patch (separate study, 24 subjects) showed a mean adhesion score of only 80% immediately after application, which progressively worsened over time. Maintaining 90% adhesion (over 12 hours after application) was also a requirement for ZTlido's New Drug Application (NDA) approval.

Moreover, ZTlido has a bioequivalent dose of lidocaine while using a reduced drug load (36 mg for ZTlido vs 700 mg for Lidoderm). Typically, topically administered lidocaine patches need to have a greater lidocaine dose in order for an adequate amount of lidocaine to be absorbed by the patient, as not all of the lidocaine on the patch is absorbed when applied topically. At the end of the 12 hours after application, ZTlido contains 18 mg of residual lidocaine (from 36 mg initially), while Lidoderm leaves 650 mg (from 700 mg initially), which can be harmful to children, pets, and others if not properly disposed of.

Figure 5: Increased pain reduction obtained with ZTlido treatment addition



Source: Company website

A Phase 3, two-stage, adaptive, randomized, open-label clinical trial of ZTlido and pregabalin was also conducted in 98 patients with PHN. Results show that the addition of ZTlido to pregabalin treatment resulted in a 48% reduction in pain intensity, measured using the Short-Form McGill Pain Questionnaire (SF-MPQ), following 8 weeks of treatment (up to 3 patches a day). Additional ZTlido clinical trials are also detailed in Figure 6 below.

Figure 6: ZTlido clinical development overview

Clinical, Cross Discipline Team Leader, and Summary Review
 NDA 207962 ZTlido Patch Complete Response Resubmission

Table 5: Summary of Previous Studies

Study ID / Site	Overview / Design Treatment / Control	1 ^o Objective	Duration / Exposure	Population Total Subject age	Note / Summary
SCI-LIDO-PK-001 NJ	OL, cross-over, BE Cohort 1, Part 1: Lidocaine IV 0.7 mg/kg single bolus dose Cohort 1, Parts 2 and 3 and Cohort 2: ZTlido vs. Lidoderm	Cohort 1: PK Cohort 2: PK with heat, exercise, and normal condition	12 w / 12 h	72 Cohort 1: 58 Cohort 2: 14 18-65 y/o	Main issues: 1- Use of tape 2- Patch was applied after heat & exercise AEs and Safety: Cohort 1: 17 AEs in 12 subjects- mild Cohort 2: 7 AEs in 5 subjects - mild
SCI-LIDO-DERM-001 NJ & FL	R, evaluator-blinded, controlled, within-subject comparison 3 patches for 48 hours ZTlido vs Lidoderm	Cohort 1: Adhesion & Irritation/Sensitization Cohort 2: Irritation/Sensitization	6 w / 48 h x 21 d	248 Cohort 1: 41 Cohort 2: 207 ≥ 18 years	Main issues and DDDP's comment: 1- Lidocaine 1.8% patch was not sensitizing 2- Potential for severe irritation should be added to labeling. AEs and Safety: 24 AEs in 20 subjects: - 3 severe (skin erosion/ reaction) - 12 moderate AEs - 9 mild AEs 4 discontinuations due to AEs No deaths or SAEs ZTlido was more irritating than the lidocaine patch 5%
SCI-LIDO-PHOTO-001 NJ	R, evaluator-blinded, controlled, within-subject comparison ZTlido vs. Lidoderm	Photosensitization/ Photoallergic reaction	6 w / 12 h	60 ≥ 18 years	DDDP's comment: ZTlido was not a photoallergen.
SCI-LIDO-PHOTO-002 NJ	R, evaluator-blinded, controlled, within-subject comparison ZTlido vs. Lidoderm	Phototoxicity	4 d / 12 h	32 ≥ 18 years	DDDP's comment: ZTlido was not phototoxic.

Abbreviations: OL=open label; BE=bioequivalence; PK=pharmacokinetic; w=week; h=hour; AEs=adverse events; SAEs=serious adverse events; d=days; DDDP=Division of Dermatology and Dental Products; NJ=New Jersey; FL=Florida
 Source: Reviewer generated

Source: *ZTlido* NDA summary, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/207962Orig1s000SumR.pdf

Figure 7: Ex-US agreements for ZTlido**ZTlido Partnership Ex-U.S.**

- Established Middle East and NA partnership, filings underway in UAE, Saudi Arabia and North Africa, launched planned for 2025 with minimum purchase commitment from CH Trading for \$105MM for 5 years.
- On July 17, 2024, Scilex Holding Company announces collaboration to leverage ACEA Therapeutics' R&D Expertise and local market connections to support the expansion of ZTlido® program in ex-US and potentially provide additional access to patients in certain key markets in Far East region
 - ACEA Therapeutics ("ACEA") will serve as exclusive territories distributor in Greater China, including mainland China, Taiwan, Hong Kong and Macau, with potential minimum purchase commitment for ZTlido once approved locally in the region.
 - ACEA to immediately start the process to explore potential commercialization of ZTlido®, with the opportunity to distribute with partners across Greater China and further expand the relationship to include other products in Scilex's non-opioid pain portfolio.

Source: Company presentation

ZTlido Partnership Agreements

SCLX currently has a product development agreement with Oishi Koseido Co., Ltd. (private) and Itochu Chemical Frontier Corporation (private). Under the terms of the agreement, Oishi and Itochu are responsible for the development of lidocaine tape products, including ZTlido and SP-103, and SCLX is responsible for marketing, selling, and distributing the products outside of Japan, as well as decision-making control on the marketing and pricing of the products. A commercial supply agreement was also set in place on February 16, 2017, with Oishi and Itochu, which grants them the ability to manufacture, store, handle, and perform quality control testing of the products in their facility in Japan.

In August 2024, SCLX announced that they were entering into a Master Distributor Agreement with CH Trading Group LLC and Devart Middle East Food Supplements to expand the distribution of ZTlido into the countries of Morocco, Tunisia, Libya, Jordan, Iraq, and South Africa for ZTlido. This adds to the current agreement SCLX has with CH Trading Group, who are presently expanding the commercialization of ZTlido in the Middle East and North/South Africa markets, with the opportunity to expand to the broader Islamic world, aiding in increasing the global outreach of ZTlido.

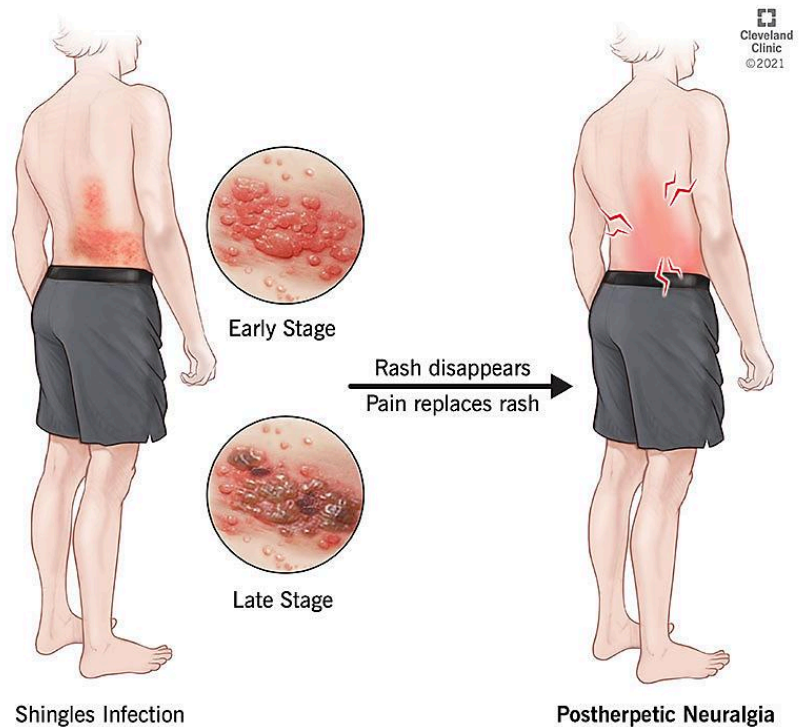
Additionally, SCLX entered into a Memorandum of Understanding (MOU) for collaboration agreement with ACEA, a China-based company focused on the development of innovative treatments for high unmet needs, in order to develop and commercialize ZTlido in mainland China, Taiwan, Hong Kong, and Macau, including a right of first negotiation for SP-103.

Postherpetic neuralgia (PHN) overview

PHN is a type of nerve pain that stems from a shingles infection and causes the sensation of burning pain in a patient's nerves and skin. The Cleveland Clinic details that 1 in 3

people in the US will develop shingles in their lifetime, and 10-18% of people who get shingles will develop PHN, making it the most common complication of shingles.

Figure 8: Shingles to PHN progression



Source: Cleveland Clinic

PHN treatment includes topical lidocaine, gabapentinoids, and antidepressants, with topical lidocaine and gabapentinoids as the preferred treatment for combination therapies for PHN as they pose a low risk for drug-drug interactions. Lidocaine patches are a common treatment option in the PHN patient population considering they are a localized treatment option and work in patients where monotherapy does not address all their symptoms. Topically administered medication also aids in improving patient compliance versus orally administered. The main lidocaine patch competitor is Lidoderm manufactured by Endo Pharmaceuticals and its generic alternative marketed by Mylan NV. SCLX formulated ZTlido with a novel adhesion and delivery technology to provide superior adhesion in comparison to Lidoderm, while also providing efficient delivery of lidocaine. SCLX's ZTlido is lighter and thinner, with a nonwoven backing cloth, and provides better adhesion and an overall better patient experience without causing dermal safety issues or dermal sensitization. Poor adhesion is the main complaint of current topical lidocaine patches. To address this, SCLX formulated ZTlido to use a hot-melt technology, which uses premixing and hot-melt mixing of lidocaine, which was shown to have improved adhesion over Lidoderm and Mylan's generic lidocaine patch at 12 hours after application.

ELYXYB - celecoxib oral solution for migraines

ELYXYB (celecoxib oral solution) is an FDA-approved oral solution for the acute treatment of migraine with or without aura (temporary symptoms such as vision changes and

numbness/pins and needles sensation that warn of an incoming migraine). SCLX launched ELYXYB in the US in April 2023.

More information on ELYXYB may be found on its [website](#) and [prescribing information highlights](#).

Figure 9: ELYXYB overview



Elyxyb Launched in USA in 2023



Newest Addition to our Market Leading Non-Opioid Portfolio

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Source: Company presentation

Migraine overview




Migraines are characterized as a neurological disorder where an affected individual experiences recurring headaches, ranging from moderate to severe intensity. Migraines happen in four phases, with associated symptoms that include nausea, vomiting, fatigue, dizziness, sensitivity to light, and visual problems. The National Headache Foundation details that one in four US households includes someone living with migraine disease, with 9 out of 10 migraine sufferers detailing that they are unable to function normally while experiencing a migraine. The most common treatment for migraines includes over-the-counter (OTC) pain relievers like acetaminophen, ibuprofen, and aspirin as well as triptans which aid in treating migraines by increasing serotonin levels in the brain.

Figure 10: Four phases of a migraine




Migraine

There are four phases of a migraine:




1 - Prodrome occurs up to 24 hours before a headache attack. Symptoms include:

 <p>Mood changes.</p>	 <p>Trouble sleeping.</p>	 <p>Difficulty concentrating.</p>
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2 - Aura happens five to 60 minutes before or during a headache attack. Symptoms include:

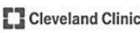
 <p>Muscle weakness.</p>	 <p>Vision changes.</p>	 <p>Ringing in your ears.</p>
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3 - Headache attack lasts between four and 72 hours. Symptoms include:

 <p>Nausea and vomiting.</p>	 <p>Severe, one-sided head pain.</p>	 <p>Sensitivity to sound, lights and odors.</p>
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4 - Postdrome lasts no more than 48 hours. Symptoms include:

 <p>Fatigue.</p>	 <p>Neck stiffness.</p>	 <p>Trouble focusing.</p>
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Source: Cleveland Clinic

Recent FDA-approved migraine treatment options include Pfizer Inc's (PFE, not rated) Zaveprel (zavegepant), which was approved in March 2023, and Abbvie Inc's (ABBV, not rated) QULIPTA (atogepant) approved in April 2023, both of which are calcitonin gene-related peptide (CGRP) receptor antagonists. Both of these treatment options reduce levels of CGRP in the brain, which in turn reduces inflammation, pain, and swelling associated with migraines.

GLOPERBA – oral liquid colchicine for gout

GLOPERBA (colchicine USP) is an FDA-approved liquid oral version of the anti-gout medicine colchicine made for the prophylaxis of painful gout flares in adults. SCLX launched GLOPERBA in the US in June 2024. SCLX acquired rights to GLOPERBA on June 14, 2022, when they entered into a license and commercialization agreement with RxOmeg Therapeutics, LLC (private), which granted them the right to manufacture, promote, market, distribute, and sell pharmaceutical products comprising liquid formulations of colchicine for the prophylactic treatment of gout in adults in the US.

More information on GLOPERBA may be found on its [website](#) and [prescribing information highlights](#).

Figure 11: GLOPERBA overview



Gloperba Launched in USA in June 2024



Expanding our Non-Opioid Pain Management Portfolio

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Source: Company presentation

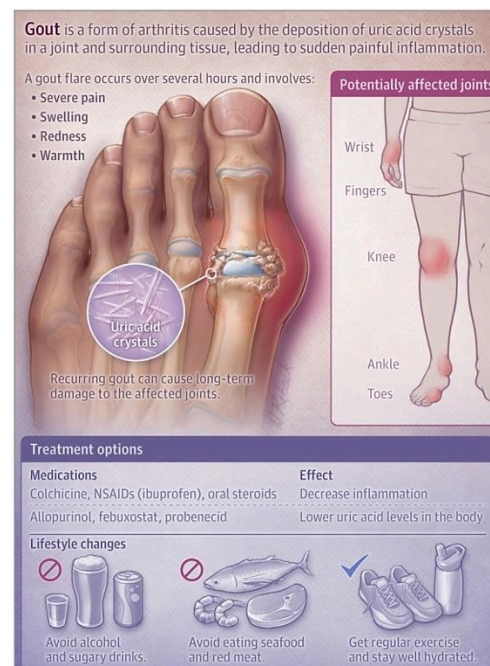
On August 29, 2024, SCLX announced that they received FDA approval for a Supplemental New Drug Application (sNDA) for label updates to GLOPERBA, the only FDA-approved liquid formulation of colchicine for the prophylaxis of acute gout flares. With many gout patients (over 80% of them) having pre-existing chronic kidney disease, as well as suffering from gastrointestinal sensitivity, precision dosing is optimal for their treatment regimen, which is currently not possible with the standard 0.6 mg tablet or capsule. With GLOPERBA's liquid formulation, a lower dose (0.3 mg/day) of colchicine may be utilized in these at-risk patients, making it the first liquid colchicine formulation that allows for

precision dosing. This is especially helpful as precision dosing aids in reducing the likelihood of colchicine toxicity, which leads to impaired renal function and is especially needed to be avoided in this at-risk patient population. The American College of Rheumatology (ACR) guidelines also highlight the need to provide lower doses of colchicine, noting the importance of having this treatment capability in these at-risk patient populations.

Gout overview

Gout is a painful arthritic disorder that affects ~9.2M people in the US (Yip and Berman, 2021). It is caused by the buildup of uric acid crystals in the body and causes inflammation in joints, primarily the big toe, as well as the feet, ankles, knees, and wrists. Chronic gout flares and inflammation in the joints can lead to severe joint damage, also known as chronic gouty arthritis. The uric acid crystals can also form hard lumpy deposits in the skin called tophi. Uric acid is produced when the body digests certain foods and drinks (e.g. red meat, alcohol, and sugar), though high uric acid levels do not always correlate with a gout diagnosis. Outside of diet, risk factors for developing gout include obesity, high blood pressure, chronic kidney disease, genetics, old age, and certain medications (such as diuretics). Affected patients experience flare-ups, which can last several days and encompass pain, redness, warmth, and swelling in one or multiple joints due to the presence of uric acid crystals. Patients can be diagnosed with gout through physical examination and assessment of their medical history, in addition to blood tests which test for uric acid levels, and X-rays that can showcase arthritis in the joint.

Figure 12: Gout overview



Source: Yip and Berman, 2021

There is currently no cure for gout, though treatment with anti-inflammatory drugs (such as colchicine, NSAIDs, and oral steroids) is often utilized to reduce the pain and inflammation

of a flare-up. Lifestyle and dietary changes are also recommended to aid in reducing the patient’s gout severity including reducing intake of alcohol, sugary drinks, and foods that increase uric acid, as well as weight loss and management of high blood pressure.

Another recently FDA-approved treatment option for gout includes Novartis Pharmaceuticals’ (NVS, not rated) ILARIS (canakinumab), which was approved in August 2023. ILARIS is a human anti-IL-1β monoclonal antibody that works by reducing inflammation and was specifically formulated for patients who cannot tolerate NSAIDs or colchicine for gout flares.

Product Candidates Under Development

SEMDEXA (SP-102) viscous steroid gel injection for sciatica

SEMDEXA is a 10 mg dexamethasone sodium phosphate viscous gel product candidate formulated to target lumbosacral radicular pain or sciatica. Specifically, SP-102’s formulation is an injectable viscous gel form of a widely used corticosteroid that addresses the risks associated with off-label epidural steroid injections (ESI). This candidate was granted Fast Track Designation by the FDA, and if approved, could become the only FDA-approved ESI for the treatment of sciatica. SCLX acquired SP-102 from Semnur Pharmaceuticals, Inc. (private) in March 2019.

Figure 13: SP-102 (SEMDEXA) overview

SP-102 (SEMDEXA™) On-Track to be the First Product Approved to Treat Sciatica



- SP-102 is a preservative free, surfactant free and particulate free viscous gel formulation of dexamethasone for sciatica (lumbosacral radicular pain).
- Extended local effect provides durable pain relief and significant improvement in functioning from a single injection with rapid onset.
- Improvement against placebo over 4 weeks and continued effect over 12 weeks with reduced use of rescue therapy.
- Good safety profile for single and repeat injections.
- Common epidural delivery by minimally invasive procedure conducted in outpatient pain clinics.
- Stable at refrigerated temperature in a prefilled syringe.



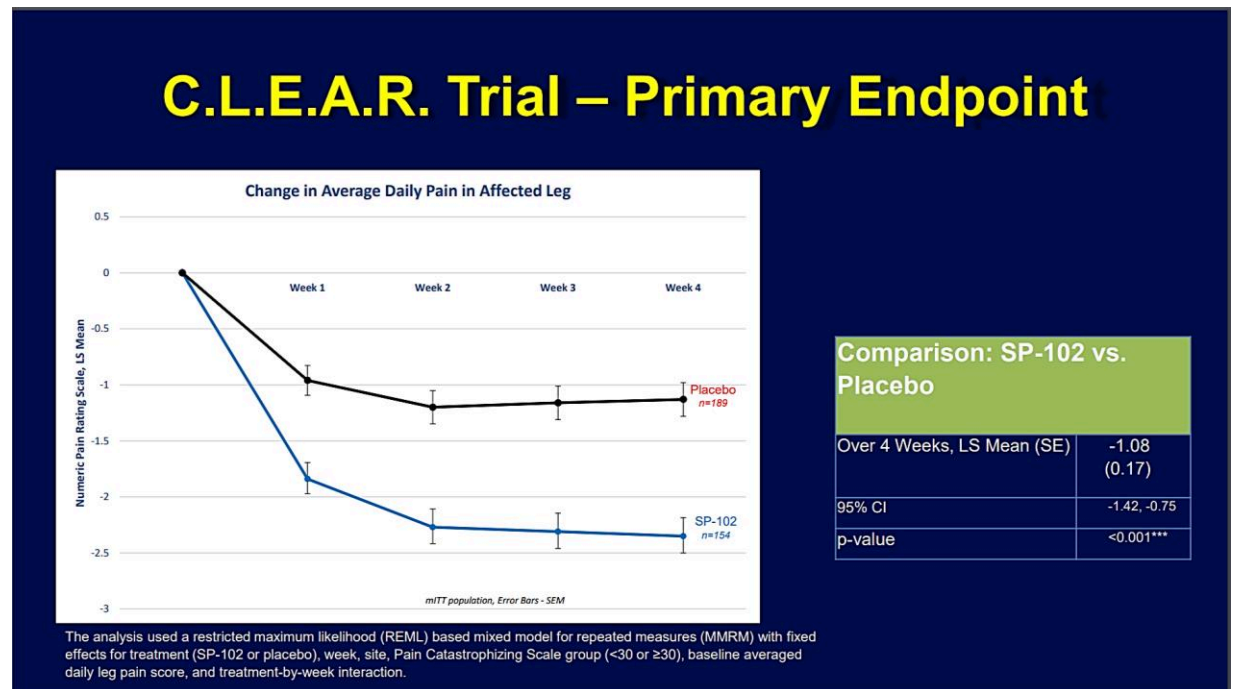
Source: Company presentation

Clinical development of SEMDEXA (SP-102)

SP-102 was studied in C.L.E.A.R. (Corticosteroid Lumbosacral Epidural Analgesia in Radiculopathy), a pivotal Phase 3 double-blind, randomized, placebo-controlled, multicenter clinical trial in sciatica patients following an epidural injection. A total of 401

lumbosacral radicular pain/sciatica patients were enrolled in 40 sites across 25 states in the US.

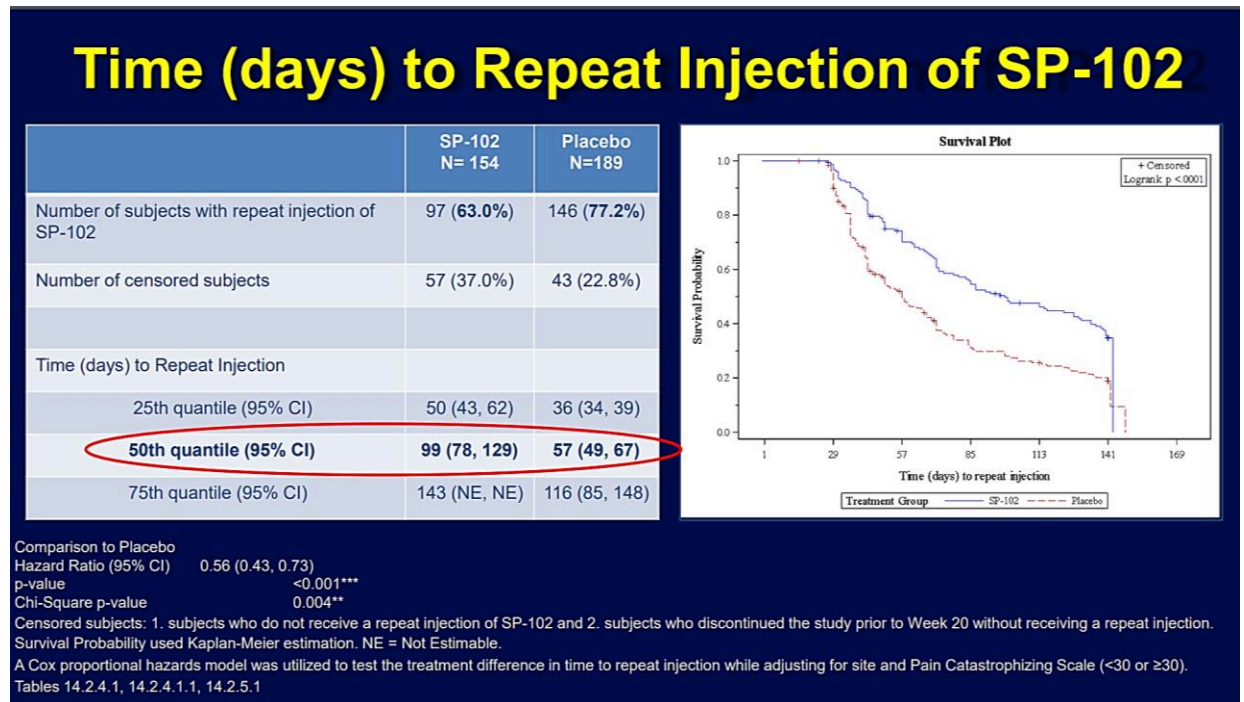
Figure 14: Phase 3 C.L.E.A.R. trial met primary endpoint of leg pain reduction following SP-102 treatment



Source: American Society of Interventional Pain (ASIPP) 2022 conference presentation by Dr. Nebojsa Nick Knezevic, M.D., Ph.D.

The Phase 3 C.L.E.A.R. trial met its primary endpoint of reduction in average daily leg pain following SEMDEXA treatment in comparison to placebo, with an LS Mean (SEM) difference of -1.08 (0.17) ($p < 0.001$). Pain relief was long-term as the median time to open-label repeat injection was 99 days (95% CI: 78, 129) for the SP-102 treated group (n=154) vs 57 days (95% CI: 49, 67) for the placebo group (n=189), using a Kaplan-Meier estimation, detailing sustained pain relief with a single SP-102 injection. Patients who experienced moderate-to-severe radicular pain between 4 and 23 weeks were also allowed to receive additional SP-102 through an open-label extension (OLE).

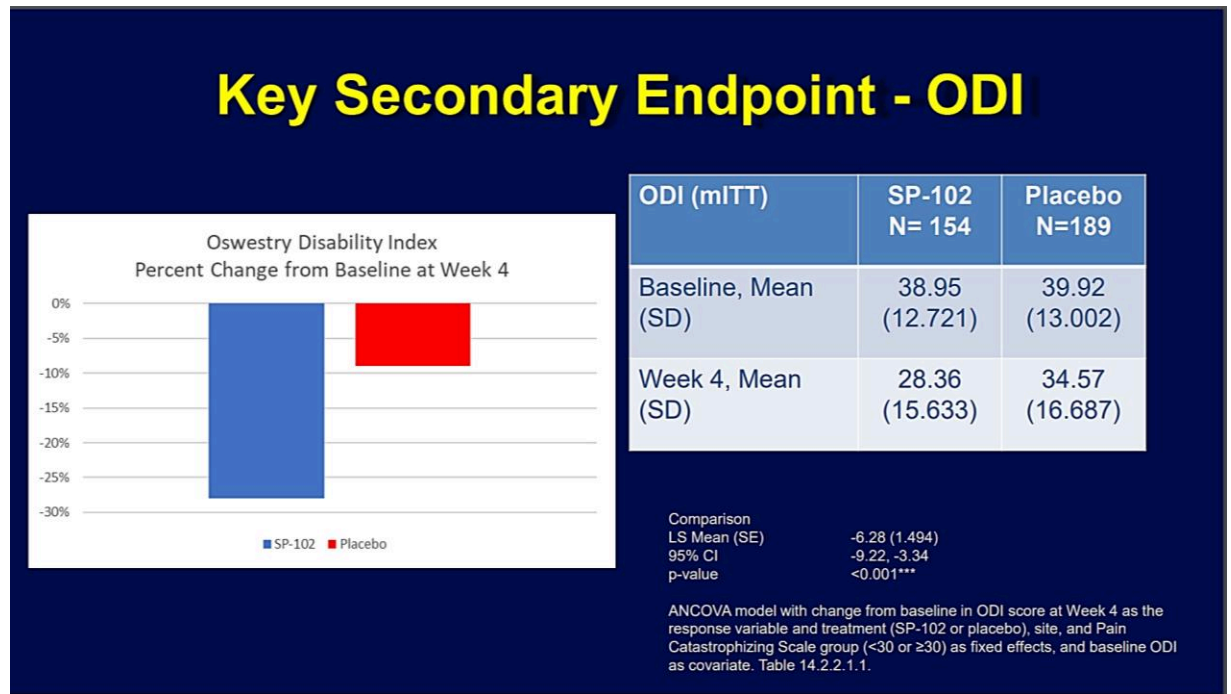
Figure 15: Sustained pain relief with SP-102 analgesic effect lasting up to 99 days after initial injection



Source: American Society of Interventional Pain (ASIPP) 2022 conference presentation by Dr. Nebojsa Nick Knezevic, M.D., Ph.D.

The key secondary endpoint for the trial was the Oswestry Disability Index (ODI), a patient-completed questionnaire used to determine the function in day-to-day living with low back pain. Results here showed an improvement following 4 weeks of SP-102 treatment compared to baseline, with an LS Mean (SEM) difference in comparison to placebo of -3.38 (1.388) [95% CI: - 6.11, -0.65] compared to placebo (p=0.015).

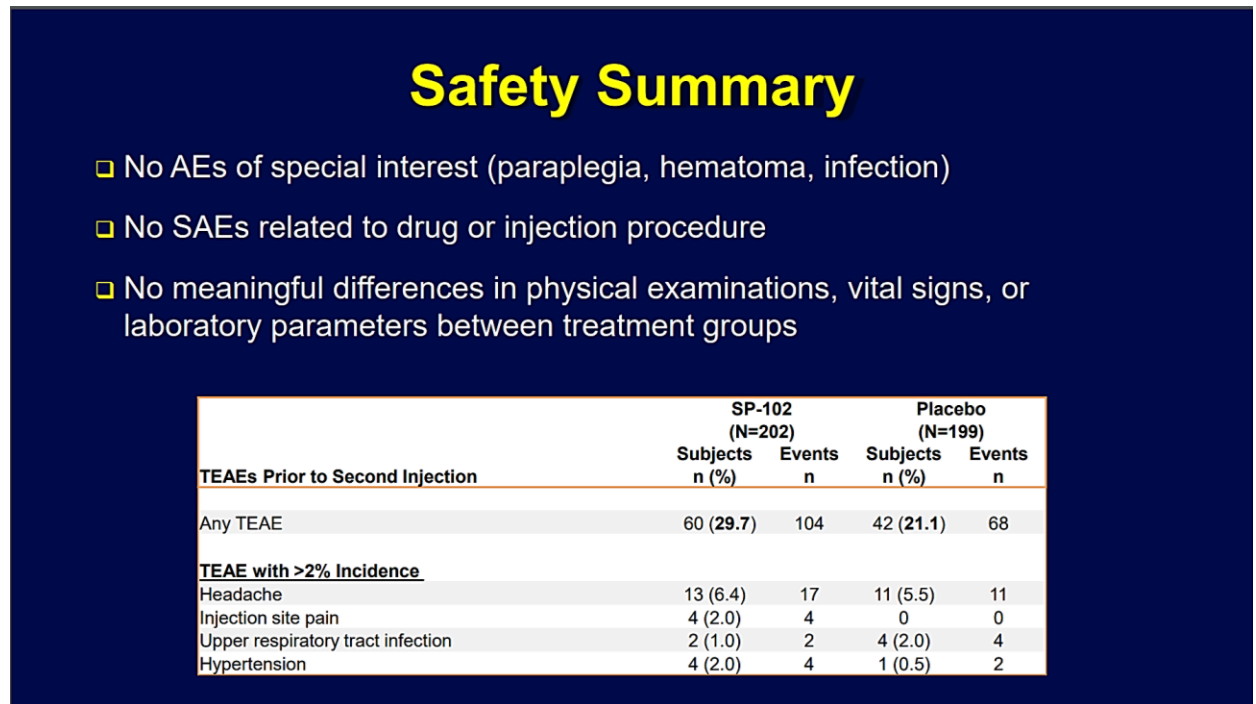
Figure 16: Key secondary endpoint of ODI met with statistical significance in C.L.E.A.R. trial



Source: American Society of Interventional Pain (ASIPP) 2022 conference presentation by Dr. Nebojsa Nick Knezevic, M.D., Ph.D.

SP-102 also displayed an overall positive safety profile with no identified safety risks, nor adverse events of special interest reported. Out of the 354 patients who received at least one injection of SP-102, there were 125 (35.3%) patients that experienced treatment emergent adverse events (TEAEs), with 32 (9.0%) patients that experienced treatment-related adverse events (AEs), 16 (4.5%) patients that experienced medication-related AEs, 23 (6.5%) patients that experienced procedure-related AEs, four (1.1%) patients that experienced serious AEs, and one (0.3%) patient that experienced AEs related to early withdrawal.

Figure 17: Positive safety profile of SP-102 established with no severe AEs reported



Source: American Society of Interventional Pain (ASIPP) 2022 conference presentation by Dr. Nebojsa Nick Knezevic, M.D., Ph.D.

With this trial now complete, SCLX is currently working on finalizing a subsequent Phase 3 safety trial this year to complete its NDA package. This Phase 3 safety trial is planned to be an open-label safety trial in ~650 patients (allowing for a safety database of 1,000+ patients with the inclusion of patients from C.L.E.A.R). Dosing will include up to three SP-102 injections over 24 weeks in patients with sciatica, with all patients planned to be followed for 24 weeks after the last injection. This trial is also planned to be conducted from 4Q24 to 1H26.

Merger of Semnur Pharmaceuticals, Inc. and Denali Capital Acquisition Corp.

In August 2024, SCLX announced that their subsidiary, Semnur Pharmaceuticals, Inc., entered into a merger agreement with Denali Capital Acquisition Corp. (DECA, not rated). This would create a publicly traded biopharma company under the Semnur Pharmaceuticals, Inc. (SMNR) name. This combined company will further the development of SP-102 (SEMDEXA), including its upcoming Phase 3 trial. The closing of this transaction is also expected to occur by 1Q25 and is subject to approval by DECA's shareholders, regulatory approval, and other closing conditions.

Figure 18: Semnur merger with Denali details

Denali SPAC Transaction



- Semnur Pharmaceuticals, Inc., a Wholly Owned Subsidiary of Scilex Holding Company (Nasdaq: SCLX), and Denali Capital Acquisition Corp. (Nasdaq: DECA) Announce Signing of a Merger Agreement for a Proposed Business Combination.
 - On August 30, 2024, Semnur Pharmaceuticals, Inc. ("Semnur"), a wholly owned subsidiary of Scilex Holding Company (Nasdaq: SCLX, "Scilex"), and Denali Capital Acquisition Corp. (Nasdaq: DECA, the "SPAC") announced the signing of an agreement and plan of merger for a proposed business combination (the "Business Combination Agreement"), which provides for a pre-transaction equity value of Semnur of \$2.5 billion.
 - The proposed business combination would create a publicly traded biopharma company and further provide investment into Semnur for the development of a non-opioid product, SP-102 (10 mg injectable dexamethasone sodium phosphate viscous gel), or SEMDEXA™, a Phase 3 novel non-opioid, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, with FDA Fast Track status.
 - Based on the independent market research conducted by Syneos Health Consulting in 2020 and 2021, given the potential substantial utilization of SP-102 (SEMDEXA™), by the 5th year of launch, sales of SEMDEXA™ in sciatica are projected to reach \$1.5 billion to \$2.0 billion annually.
 - Scilex is expected to be the majority holder of the combined company following completion of the proposed business combination, which is expected to close by the first quarter of 2025; the combined company will be led by a management team with proven track record in industry experience.
 - As previously disclosed, the Board of Directors of Scilex approved a resolution to authorize a potential dividend of up to 10% of Scilex's ownership interest in Semnur in connection with certain transactions, including a merger, subject to the registration of Semnur's common stock (or such securities, property or other assets into which or for which such stock may be exchanged or converted in such a transaction) with the Securities and Exchange Commission ("SEC"). No record date has been set for such dividend and the Scilex board of directors may determine not to proceed with such dividend.

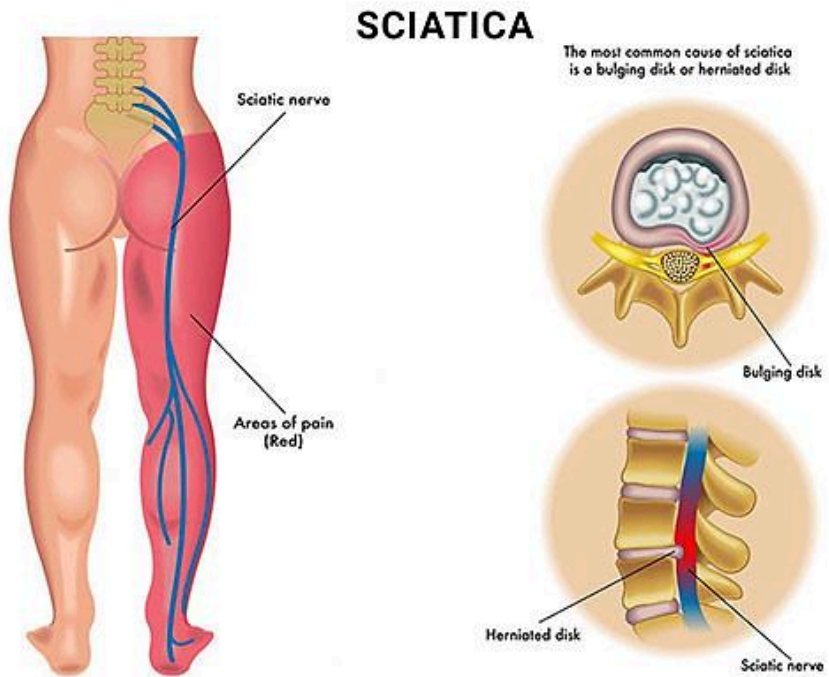
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Source: Company presentation

Sciatica overview

The American Academy of Orthopedic Surgeons details sciatica as chronic leg pain that travels from the lower back down the sciatic nerve in the back of the leg. There are two sciatic nerves in the human body, with each one running through the hip down the leg on both legs. There are also two types of sciatica, such as true sciatica which is any sort of condition that directly affects the sciatic nerve, or sciatica-like conditions, which resemble sciatica but occur due to other reasons related to the sciatica nerve, though both types of sciatica are referred to as solely sciatica as the symptoms are often the same. Symptoms include tingling/pins and needles sensation (paresthesia), numbness, or weakness in the affected leg(s). Sciatica typically stems from a pinched nerve in the back or a herniated disc in the spine, or through conditions such as osteoarthritis or degenerative disk disease, all of which can affect the sciatic nerve. This condition is also common as about 40% of people in the US experience some form of sciatica during their lifetime (Davis et al., January 2024).

Treatment for sciatica is specific to its severity with mild cases usually achieving pain relief through self-treatment that includes ice/heat therapy, stretching, and OTC pain relief like NSAIDs. Steroid injections in the spine, physical therapy, and surgeries like a diskectomy or laminectomy are common treatment options for more severe cases of sciatica.

Figure 19: Sciatica overview

Source: Redefine healthcare, orthopedic pain & spine center

Other treatment options for sciatica-related pain currently in development include Novassay's (private) NVA1309, currently in a preclinical stage, as well as Sollis Therapeutics' (private) STX-015 candidate. Both of these candidates are clonidine-based micro pellets formulated to be injected into the spine which aids in blocking pain signals and reducing inflammation.

SP-103 - 5.4% lidocaine topical system for chronic neck pain.

SP-103 is a next-generation 5.4% lidocaine topical system formulated to target chronic neck pain. SP-103 contains 3x the lidocaine drug load (108 mg) than their marketed ZTlido (36 mg) to provide extra-strength localized pain relief to its targeted chronic neck pain indication. ZTlido is approved for use of up to 3 patches at once, summing up to the same dosage of one SP-103 patch. Fast Track Designation in low back pain (LBP) for this candidate was also granted by the FDA in August 2022.

Chronic neck pain overview

Chronic neck pain is neck pain that lasts longer than 3 months and stems from a multitude of potential causes, including poor posture, injury to the neck, or underlying conditions such as arthritis or spinal stenosis. The Institute Treatments for chronic neck pain are primarily composed of lidocaine and pregabalin-based options.

Figure 20: Chronic neck pain causes



Source: Cleveland Clinic


Clinical Development of SP-103

SP-103 has been researched in two studies, including a Phase 2 clinical trial in acute LBP patients, and an investigator-initiated research study at Johns Hopkins University in 2H23. Both of these trials provided insight into the potential Phase 3 clinical trial design for this candidate. Additional studies were also conducted at the Institute for Biomedical Research and Technologies in Graz, Austria, comparing the drug delivery of SP-103, ZTlido, and control (Pennsaid, 2% diclofenac).

Phase 2 clinical trial of SP-103

SP-103 was studied in a Phase 2, randomized, double-blind, placebo-controlled, parallel-group, multicenter clinical trial in patients with moderate to severe acute LBP. There was a total of 75 patients enrolled across 10 clinical trial sites in the US, with treatment encompassing a 12 hours on/ 12 hours off regimen of either SP-103 or placebo in an area of most tenderness in the lower back. The main results detail that there was a meaningful reduction of pain in the first week following SP-103 treatment, with a reduction of 1.5 (95% CI: -0.2 to 3.2) using the summer pain intensity difference-7 (SPID-7) analysis in patients with higher severity of muscle spasms. SP-103 was also well-tolerated, with no SAEs, TEAEs, or AEs of special interest reported.

Figure 21: SP-103 provides pain relief with 3X extra strength lidocaine compared to ZTlido



Next-Generation, Triple Strength Formulation of ZTlido 1.8%

ZTlido™

(lidocaine topical system) 1.8%

- ✓ Superior adhesion and drug formulation efficiency with only 36mg of lidocaine
- ✓ Safe, convenient, functional pain treatment, label allows for light exercise and under water stress conditions
- ✓ Indicated for relief of pain associated with post-herpetic neuralgia (shingles pain)

SP-103 Phase 2

Next-Generation, 5.4%
Lidocaine Topical System

- ✓ 3x drug load (108 mg vs 36 mg lidocaine)
- ✓ Triple strength localized dose of lidocaine
- ✓ Expected same superior adhesion and efficient formulation
- ✓ Initiated Phase 2 trial in Q2-2022 with Results Q3-2023. Phase 3 Chronic Neck Pain trial in planning
- ✓ Large market opportunities for neck pain and acute low back pain
- ✓ Fast Track designation granted in low back pain by FDA in August 2022

23

Source: Company presentation

John Hopkin’s University IIT of SP-103

An investigator-initiated trial (IIT) was conducted in 2H23 at Johns Hopkins University which studied SP-103 in patients with chronic non-radicular neck pain. The IIT was designed as a randomized, crossover, placebo-controlled trial of SP-103 in 76 patients with chronic non-radicular neck pain. The results show that there was a reduction in average daily pain over a one-month treatment period. SCLX aims to have chronic non-radicular neck pain as the initial indication for SP-103 registration.

Skin-penetration studies of SP-103

A set of studies of SP-103 were conducted at the Institute for Biomedical Research and Technologies in Graz, Austria, which studied the drug delivery from SP-103, ZTlido, and control (Pennsaid, 2% diclofenac) using open flow microperfusion. Results showed that SP-103 resulted in a significantly higher lidocaine concentration in muscle tissue than ZTlido (p=0.008), expected as SP-103 contains 3X the amount of lidocaine as ZTlido. SCLX sees that a higher lidocaine dose concentration may allow for additional pain indications, such as nociceptive musculoskeletal pain, like non-radicular neck and lower back pain, to be targeted.

SCLX continues to analyze these results and may also look into other potential indications of SP-103 outside of chronic non-radicular neck pain, including neuropathic pain and chronic lower back pain. Once the data analysis for these SP-103 studies is completed, SCLX will request an End of Phase 2 (EOP2) meeting with the FDA to discuss its clinical path forward, including Phase 3 development, which is expected to commence in 2024/2025.

SP-104 - delayed-release naltrexone hydrochloride (4.5 mg) for fibromyalgia

SP-104 is a delayed-release capsule formulation of naltrexone hydrochloride (4.5 mg) developed for the treatment of fibromyalgia. Two Phase 1 clinical trials were completed in 2Q22 for this candidate.

Clinical Development of SP-104

Two Phase 1 clinical trials, SP-104-01 and SP-104-02, were completed in 2Q22 for SP-104, both of which were conducted in New Zealand. SP-104-01 is a Phase 1 open-label, three-period, three-treatment, randomized food effect and bridging pharmacokinetic (PK) clinical trial of SP-104 in comparison to Naltrexone HCL tablets (USP 50 mg). This study was also conducted to support the filing of a Section 505(b)(2) NDA. SP-104 and naltrexone HCl tablets were studied under fast and fed conditions in 18 healthy adult patients. Results showed that SP-104 may be administered with or without food. Results also showed that SP-104 was better tolerated than immediate release naltrexone hydrochloride 4.5mg at the same dose in healthy volunteers.

SP-104-02 is a Phase 1 double-blind, randomized, two-period, two-treatment crossover study of SP-104 in comparison to immediate release naltrexone capsules (4.5 mg). This trial was conducted to establish if dosing with delayed release 4.5 mg naltrexone at night mitigates against the drug's adverse events (e.g. hyperalgesia, dysphoria, insomnia, and anxiety) and could lead to better patient compliance. A total of 52 patients were studied, with results showing that there were no serious adverse effects, no AEs leading to discontinuation, and no meaningful differences in physical examinations, vital signs, or laboratory parameters between treatments. Of the 52 patients receiving at least a single injection of SP-104, there were 21 (40%) patients experiencing at least one TEAE, such as nausea and headache, 14 (27%) patients experiencing at least one treatment-related TEAE, 12 (23%) patients experiencing at least one treatment-related TEAE within 72 hours after the first administration of SP-104. Notably, SP-104 administered at night before bed also showed a lower number of patients with at least one AE ($p=0.0414$), with even fewer patients with at least one AE within 72 hours after the first administration of SP-104 when compared to the naltrexone, displaying a better safety profile. When taken at night, SP-104 was also shown to have peak drug levels at night while sleeping, allowing the patient to avoid conscious perception of hyperalgesia (an increased sensitivity to feeling pain and an extreme response to pain) and other side effects. These results overall detail that night-time administration of SP-104 results in a better adverse event profile.

Fibromyalgia overview

The National Fibromyalgia Association (NFA) describes fibromyalgia as a chronic health condition that causes pain flare-ups throughout the body. The primary symptom of fibromyalgia is chronic widespread body pain, with additional symptoms including fatigue, sleep disturbances, sensitivity to touch, light, and sound, as well as cognitive difficulties. Fibromyalgia is often associated with overlapping conditions, such as irritable bowel syndrome (IBS), migraines, and interstitial cystitis (also known as bladder pain syndrome). There is no direct cause for fibromyalgia, though certain risk factors such as older age, gender (females are twice as likely to develop fibromyalgia), and other chronic illnesses may increase one's chances of developing fibromyalgia. With the wide range of symptoms associated with this condition, multiple treatment options are typically used, including OTC pain relief to target the pain associated with fibromyalgia and psychological treatment like antidepressants for mental-health-related symptoms. The Centers for Disease Control and Prevention (CDC) states that fibromyalgia affects about 4M, or 2%, of the US adult population.

Figure 22: Fibromyalgia symptoms



Source: Cleveland Clinic

A current non-opioid treatment option for fibromyalgia close to potential market approval includes Tonix Pharmaceuticals' (TNXP, \$11 price target) Tonmya (TNX-102 SL, cyclobenzaprine chloride sublingual tablets). TNXP formulated Tonmya as a sublingual tablet formulation of cyclobenzaprine hydrochloride (HCL) for the management of fibromyalgia, which displayed statistically significant reductions in fibromyalgia-associated

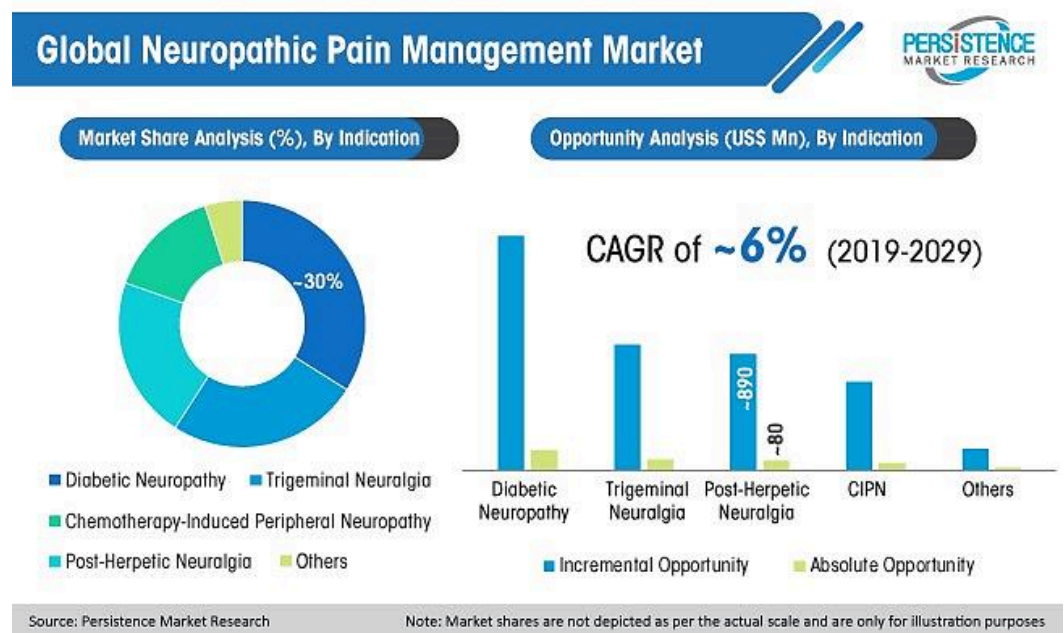
pain in its two positive Phase 3 trials, RESILIENT and RALLY. TNXP is now planning on submitting an NDA for Tonmya in fibromyalgia in 2H24.

ELYXYB (SP-105) for acute migraine pain

ELYXYB (SP-105) was formulated to supplement ELYXYB and add an acute pain indication to its established acute treatment of migraine indication. To do so, the FDA outlined that a supplemental NDA (sNDA) including a Pediatric Study Plan (PSP) that encompasses pediatric studies will be required. SCLX is currently requesting waivers for the PSP as there is a lack of migraine prevalence in pediatric populations. Currently, SCLX is on track to submit the sNDA by year-end 2024 pending PSP agreement with the FDA.

Market Opportunity of Non-Opioid Pain Management

Figure 23: Expected Future Growth in Neuropathy Pain Treatment Space



Source: Persistence Market Research

Formulations of non-opioid treatment options continue to be sought after due to the known risks of long-term opioid use, primarily opioid use disorder (OUD) that affects millions of chronic pain sufferers in the US. The CDC estimated that there were over 6M people in the US aged 12 or older that had OUD in 2022, though the number could be much higher (at least ~3-5x higher) due to unreported cases. With over 51M, or ~20%, of US adults reported who experienced chronic pain in the US in 2021, as noted by the CDC, the need for lifelong non-opioid treatments remains an optimal choice for affected patients. The market for neuropathy pain treatments is valued at approximately \$6B (2019), with an estimated CAGR of 6% from 2019-2029, according to Persistence Market Research.

Select Company Officers

Jaisim Shah, Chief Executive Officer. Jaisim Shah has over 30 years industry success in leading product development & commercializing innovative therapies and creating companies with documented success in development and commercialization of some of today's most recognized pharmaceutical brands. He is a seasoned life science executive and board director with extensive accomplishments at Bristol-Myers Squibb, Roche, PDL Biopharma, Sorrento, Pfizer/Upjohn, Scilex, and start-ups Elevation and Semnur Pharmaceuticals. Mr. Shah has been CEO and President of Semnur Pharmaceuticals (acquired by Scilex Pharmaceuticals) since its inception in 2013. He has served as CEO and President of Scilex Holding and Scilex Pharmaceuticals since March 2019 and also serves on the board of directors of Scilex Holding. Most recently, Mr. Shah served as Chief Business Officer of Elevation Pharmaceuticals where he focused on financing, mergers and acquisitions, and business development. He led the sale of Elevation to Sunovion Pharmaceuticals in 2012. At Facet Biotech and PDL BioPharma, he served from 2000 to 2009 as Chief Business Officer and also held the position of senior vice president of marketing and medical affairs. During this time, he completed numerous licensing/partnering and strategic transactions including with Roche, Bristol-Myers Squibb, Otsuka, and Biogen Idec. Prior to working with Bristol-Myers Squibb, Mr. Shah led international marketing for oncology and virology and was global business leader for corporate alliances at Roche from 1991 to 1997 with Genentech and IDEC, and prepared products for worldwide launch and pre-launch at F. Hoffman-La Roche AG in Switzerland. Mr. Shah holds a M.A. in Economics from the University of Akron and a M.B.A. from University of Oklahoma.

Henry Ji, PhD, Executive Chairperson. Henry Ji brings 25+ years of experience in the biotechnology and life sciences industry. Dr. Ji has been Chairman of Scilex Holding from March 2019 to present and served as the CEO of Scilex Pharmaceuticals from November 2016 to March 2019. Dr. Ji co-founded Sorrento Therapeutics, Inc. and has served as a director since 2006, as its CEO and President since September 2012, and as Chairman of its board of directors since 2017. Dr. Ji also founded Vivasor Inc. and has served as CEO and President, and as Chairman of its board of directors since 2024. During his tenure at Sorrento, he has engineered and led a phenomenal growth of Sorrento through acquisition and mergers including Bioserv, Scilex Pharmaceuticals, Concertis Biotherapeutics, Levena Biopharma, LACEL, TNK Therapeutics, Virttu Biologics, Ark Animal Health and Sofusa Lymphatic Delivery Systems. Dr. Ji has served as Sorrento's Chief Scientific Officer from November 2008 to September 2012 and as its Interim CEO from April 2011 to September 2012. Prior to Sorrento, he held senior executive positions at CombiMatrix, Stratagene, co-founded Stratagene Genomics, a subsidiary of Stratagene, and served as its President & CEO and a member of the board of directors. Henry Ji received a doctorate from the University of Minnesota and an undergraduate degree from Fudan University.

Suketu D. Desai, PhD, Chief Technical Officer, Senior Vice President. Suketu D. Desai, Ph.D. has 25+ years of experience in the Biologics and Pharmaceutical Industry. Suketu is Chief Technical Officer and Senior Vice President, Chemistry, Manufacturing and Controls, Regulatory CMC, and Quality Assurance at Scilex Pharmaceuticals (2015 – present). Prior to Scilex, Suketu 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, Suketu was a CMC consultant in 2013. Suketu was Vice President, Biotechnology Technical Operations for biologics drug substance and drug product, analytical, manufacturing and technical due diligence at Cephalon, Inc. (2010-2012), which was acquired by Teva Pharmaceuticals. During 2007-2010, Suketu was Ception Therapeutics, Inc., Vice President, Chemistry, Manufacturing and Controls and Quality Assurance responsible for biologics drug substance and drug product development, analytical, manufacturing, quality, regulatory CMC, and technical due diligence for business development. Ception was acquired by Cephalon (2010). Suketu

was Principal Scientist, Process Sciences/Technical Operations for late-stage and commercial biologics drug substance and drug product at Centocor, Inc., a Johnson & Johnson subsidiary (2003-2006); Assoc. Director, Pharmaceutical and Biologic Formulations at AAI Pharma Development Services (2001-2003); Director/Sr. Manager at Aronex Pharmaceuticals, Inc. (1996-2001); and Senior Scientist II/I at Novartis Pharmaceuticals, formerly Alcon Labs, Inc., (1992-1996).

Dmitri Lissin, MD, Chief Medical Officer, Senior Vice President. Dmitri Lissin currently serves as Chief Medical Officer and Senior Vice President, Clinical Development and Medical Affairs of Scilex/Semnur Pharmaceuticals (2015 – present). Prior to Semnur, from 2011-2015, Dmitri was Vice President of Clinical Development at Xenoport, responsible for conduct of multiple clinical research programs in neurology and dermatology. From 2006-2011 Dmitri directed a clinical research team and served as member of the Executive Committee at DURECT Corporation, designing and executing clinical trials in chronic nociceptive, neuropathic, and acute post-operative pain, which led to successful licensing deals and NDA filings. From 1998-2006 Dmitri managed various clinical R&D programs at Titan Pharmaceuticals, Aerogen, and Synarc. Dr. Lissin has a broad expertise with proprietary drug-delivery technologies applied to therapeutic products spanning numerous clinical areas including pain and neurological disorders. He received his post-doctoral training at the University of California San Francisco, and his medical degree through an exchange program between Russian National Medical University and Harvard Medical School.

Stephen Ma, Chief Financial Officer, Senior Vice President. Stephen Ma serves as the Chief Financial Officer and Senior Vice President since September 2023. Prior to that, Mr. Ma served as the Company's Chief Accounting Officer and Vice President of Finance. 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. Mr. Ma holds a B.S. in Finance and M.A. in Economics from San Jose State University.

Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early-stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

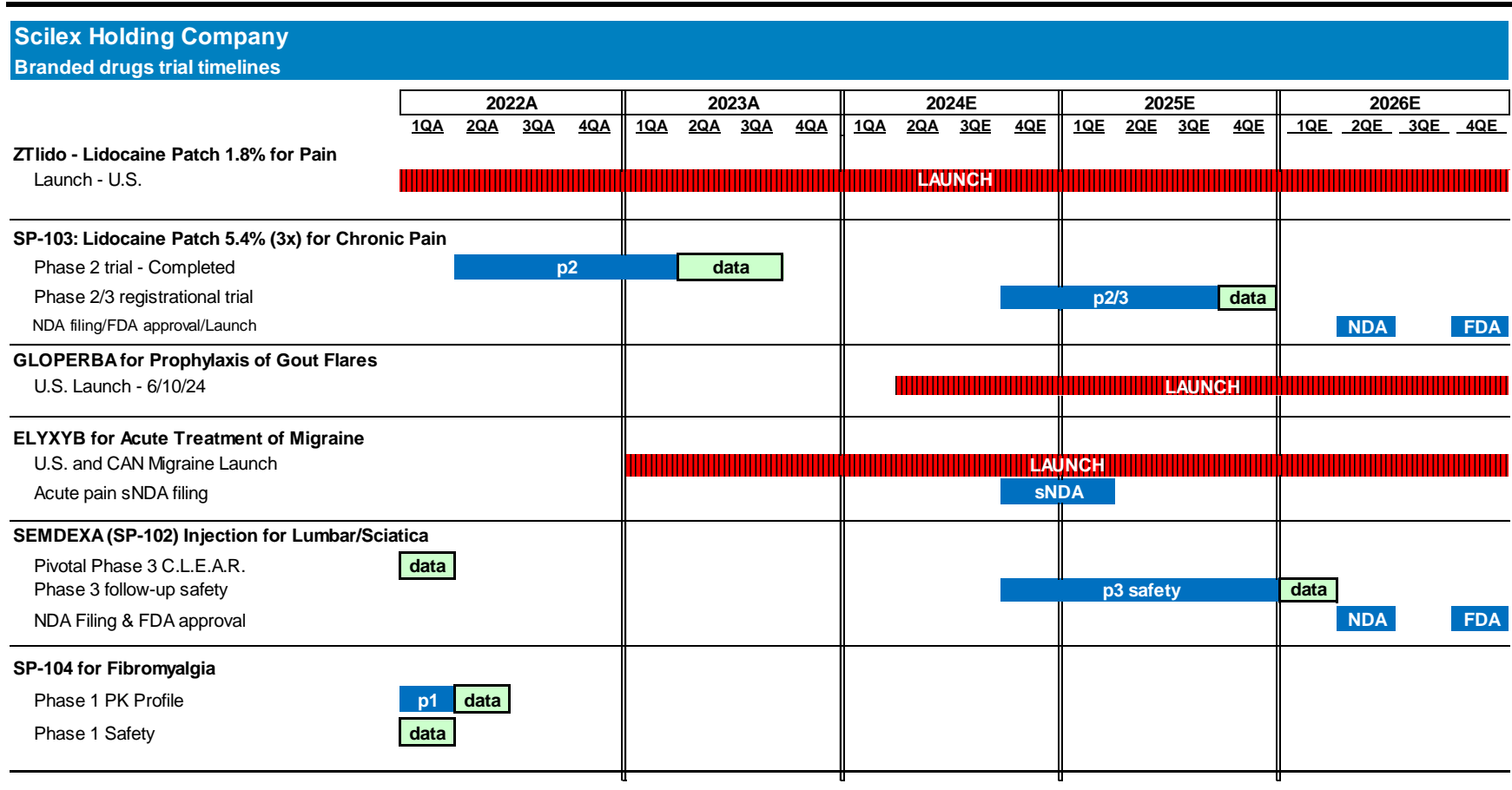
Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

Raising additional capital may cause dilution. If additional funding is required through raises in equity offerings, or similar financial instruments shareholders' ownership interests will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect shareholders' rights.

COVID-19 Impact. If the ongoing economic & social disruption of the response to the COVID-19 virus continues that could materially impact the company's ability to conduct clinical trials or regular business.

Please see the company's SEC filings for a more comprehensive discussion of potential risks.

Figure 25: Potential clinical trial timelines



Source: Company reports; AGP estimates

Figure 26: Quarterly Income Statement

Scilex Holding Company										
Quarterly income statement										
(\$000 except per share)	2023A				2023A Year	2024E				2024E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
Revenues										
ZTLido	\$10,477	\$12,250	\$9,562	\$12,449	\$44,738	\$10,065	\$15,138	\$15,500	\$16,000	\$56,702
Elyxyb	105	332	555	1,013	2,005	819	1,232	1,250	1,750	5,052
Gloperba								1	1	2
Total revenues	\$10,582	\$12,582	\$10,117	\$13,462	\$46,743	\$10,884	\$16,370	\$16,751	\$17,751	\$61,756
Expenses										
COGS	3,591	4,177	3,392	4,521	15,681	3,840	4,390	5,695	6,035	19,961
Gross profits	6,991	8,405	6,725	8,941	31,062	7,044	11,980	11,056	11,716	41,795
R&D	2,736	3,204	4,072	2,734	12,746	3,108	2,004	2,025	1,925	9,062
SG&A	28,701	26,989	40,431	23,520	119,641	29,278	24,598	26,000	27,000	106,876
Intangible amortization	1,027	1,026	1,027	1,026	4,106	1,027	1,001	1,025	1,025	4,078
Total Op exp	32,464	31,219	45,530	27,280	136,493	33,413	27,603	29,050	29,950	120,016
Adj. Inc (loss) from ops	(25,473)	(22,814)	(38,805)	(18,339)	(105,431)	(26,369)	(15,623)	(17,994)	(18,234)	(78,221)
Interest expense	(1)	5	513	551	1,068	531	571	575	575	2,252
Loss on FOREX	20	3	7	88	118	6	5	5	5	21
Inc tax exp/(benefit)		(3)			13					0
Adj. net income	(25,492)	(22,819)	(39,325)	(18,978)	(106,630)	(26,906)	(16,199)	(18,574)	(18,814)	(75,948)
Non-cash & 1x exp										
Loss on derivative liab	5,253	82	(4,245)	(578)	512	457	15,284			457
Change in FV debt + liabs	0	3,748	449	2,992	7,189	3,905	6,099			3,905
Debt extinguish										
Scilex notes prin increase										
Legal settlements				0		(6,891)				(6,891)
NI/(loss) as reported	(30,745)	(26,649)	(35,529)	(21,392)	(114,331)	(24,377)	(37,582)	(18,574)	(18,814)	(78,477)
Adj. EPS	(\$0.18)	(\$0.16)	(\$0.28)	(\$0.20)	(\$0.82)	(\$0.26)	(\$0.13)	(\$0.10)	(\$0.10)	(\$0.50)
EPS as Reported	(\$0.22)	(\$0.19)	(\$0.25)	(\$0.22)	(\$0.88)	(\$0.24)	(\$0.31)			(\$0.51)
weighted avg. shares										
(000)	141,660	142,626	139,808	97,098	130,298	102,407	120,188	192,688	194,688	152,493
Fully diluted shares (000)	189,828	190,794	187,976	145,266	178,466	156,603	194,899	267,399	269,399	227,204

Source: Company reports; AGP estimates

Figure 27: Annual Income Statement

Scilex Holding Company					
Annual income statement					
(\$000 except per share)	2023A	2024E	2025E	2026E	2027E
Revenues					
ZTLido	\$44,738	\$56,702	\$64,500	\$74,175	\$85,301
Elyxyb	\$2,005	\$5,052	\$9,000	\$11,913	\$15,486
Gloperba	\$0	\$2	\$575	\$2,350	\$3,000
Total revenues	\$46,743	\$61,756	\$74,075	\$88,438	\$103,788
Expenses					
R&D	12,746	9,062	12,750	14,500	17,644
SG&A	119,641	106,876	112,750	119,500	131,810
Total Op exp	136,493	120,016	131,250	134,000	156,719
Adj. Inc (loss) from ops	(105,431)	(78,221)	(82,361)	(74,747)	(87,182)
Non-cash & 1x exp					
Interest expense	1,068	2,252	2,350	2,425	2,450
Int income from BS	118	21	0	0	0
Loss on FOREX	13	21	32	40	40
Adj. net income	(106,630)	(75,948)	(79,979)	(72,282)	(84,692)
Goodwill & intang impair	512	457			
Loss to non-control int	7,189	3,905			
Royalty liab int exp	0	(6,891)			
NI/(loss) as reported	(114,331)	(78,477)	(79,979)	(72,282)	(84,692)
Adj EPS	(\$0.82)	(\$0.50)	(\$0.40)	(\$0.35)	(\$0.40)
EPS as reported	(\$0.88)	(\$0.51)			
Weighted avg. shares (000)	130,298	152,493	200,626	207,188	212,938
Fully diluted shares (000)	178,466	227,204	280,626	209,380	215,130
Cash & equivalents	\$3,921	\$2,673	\$8,910	\$14,993	\$15,716

Source: Company reports; AGP estimates

Figure 28: Balance Sheet

Scilex Holding Company							
Balance sheet model							
(values in 000's)	2023A	1Q24A	2Q24A	2024E	2025E	2026E	2027E
Assets							
Cash & equiv.	\$3,921	\$1,818	\$6,888	\$2,673	\$8,910	\$14,993	\$15,716
Accounts receivable	34,597	29,716	38,004				
Inventory	4,214	3,486	3,073				
Prepaid expenses & other	4,049	2,725	2,453				
Total current assets	46,781	37,745	50,418	46,673	56,410	63,743	66,716
PP&E	722	718	714	715			
Right of use asset	2,943	2,763	2,578	3,000			
Intangible assets, net	36,485	35,458	34,456	35,000			
Goodwill	13,481	13,481	13,481	13,481			
Other non-current assets	897	1,075	2,897	3,000			
Total assets	101,309	91,240	104,544	101,869	118,910	129,493	134,716
Liabilities							
Accounts payable	40,954	42,219	41,787	42,000			
Accrued payroll	2,681	3,727	4,073	4,250			
Accrued rebates and fees	89,658	104,088	125,063	125,000			
Accrued expenses	7,408	8,564	7,988	8,000			
Current deferred considera	491	480	469	500			
Current debt payable	108,429	92,923	75,370	75,370	50,000	45,000	40,000
Current op lease	759	731	701	700			
Convertible debentures							
Related party payable							
Total current liabilities	250,380	252,732	255,451	255,820	255,000	260,000	265,000
LT deferred consideration	2,895	2,780	2,667	2,750			
Debt net of issue	17,038	16,323	29,033	29,033	29,033	29,033	29,033
Derivative liabilities	1,518	6,941	30,005	30,000			
Op lease liabs	2,237	2,068	1,893	2,000			
Other non-current liabilities	179	182	187	185			
Total liabilities	274,247	281,026	319,236	319,788	348,283	354,533	360,033
Common stock	16	17	18	20	20	20	20
Additional paid-in capital	407,813	415,341	426,165	439,454	507,978	584,593	669,008
Accumulated other comp i	0	0	1,851	1,851	1,851	1,851	1,851
Accumulated deficit	(490,245)	(514,622)	(552,204)	(568,722)	(648,700)	(720,982)	(805,674)
Treasury stock at cost	(90,522)	(90,522)	(90,522)	(90,522)	(90,522)	(90,522)	(90,522)
Shareholders' equity	(172,938)	(189,786)	(214,692)	(217,919)	(229,373)	(225,040)	(225,317)
Total liab & net worth	101,309	91,240	104,544	101,869	118,910	129,493	134,716

Source: Company reports; AGP estimates

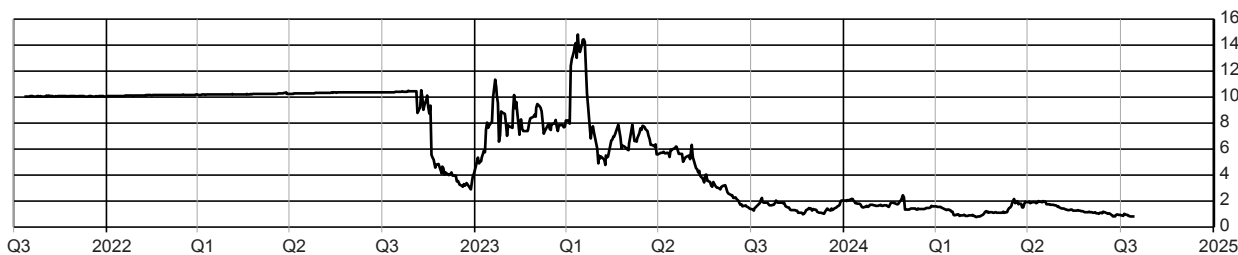
Figure 29: Cash Flow Statement

Scilex Holding Company Statement of cash flows model							
(values in 000's)	<u>2023A</u>	<u>1Q24A</u>	<u>2Q24A</u>	<u>2024E</u>	<u>2025E</u>	<u>2026E</u>	<u>2027E</u>
<u>Operating cash flow</u>							
Net loss	(\$114,331)	(\$24,377)	(\$61,959)	(\$78,477)	(\$79,979)	(\$72,282)	(\$84,692)
Depreciation & amort	4,146	1,031	2,037	4,500	5,000	5,500	6,000
Amort of debt issuance costs	65	31	63	65	65	65	65
Non cash op lease	507	180	365	500	600	750	800
Stock based comp	14,596	3,558	7,171	15,000	16,750	17,000	18,500
Share issue settlement agreement	750	-	-	-	-	-	-
Loss on derivative liab	512	457	15,741	15,741	-	-	-
Warrant issue exp	-	1,375	2,526	2,526	-	-	-
Change in FV of debt	7,189	3,905	10,004	10,004	-	-	-
Other	57	26	53	50	50	50	50
<u>Change in operating assets/liabs</u>							
AR	(13,361)	4,881	(3,407)	-	-	-	-
Inventory	(2,838)	726	1,138	-	-	-	-
Prepaid exp and other	(441)	(39)	474	-	-	-	-
Other LT assets	855	(30)	(30)	-	-	-	-
AP	19,880	1,265	653	-	-	-	-
Accrued payroll	1,327	1,046	1,392	-	-	-	-
Accrued exp	2,310	1,120	470	-	-	-	-
Accrued rebates & fees	58,765	14,430	35,405	-	-	-	-
Other liabs	(711)	(197)	(402)	-	-	-	-
Other LT liabs	16	3	8	-	-	-	-
Cash from operations	(20,707)	9,391	11,702	4,909	(7,514)	6,083	724
<u>Investing cash flow</u>							
Romeg intangible acquisition	(300)	-	(300)	(500)	-	-	-
Purchases of PPE	(30)	(150)	-	-	-	-	-
Cash from investing	(330)	(150)	(300)	(500)	-	-	-
<u>Financing cash flow</u>							
Proceeds issue ATM	35,458	156	156	156	-	-	-
Proceeds issue converts	24,000	-	-	-	-	-	-
Proceeds issue RF	86,354	32,567	65,470	65,470	-	-	-
Proceeds issue FSF deposit	-	-	10,000	10,000	-	-	-
Repayment RF	(69,001)	(33,313)	(65,265)	(65,265)	-	-	-
Repayment Oramed Note	(5,000)	(15,000)	(35,000)	(35,000)	-	-	-
Transact costs bus combo	(1,372)	-	-	-	-	-	-
Repayment convertibles	(15,625)	(4,375)	(4,375)	(4,375)	-	-	-
Debt issuance costs	(380)	-	-	-	-	-	-
Disburse funds to Sorrento	(20,000)	-	-	-	-	-	-
Share repurchase	(10,000)	-	-	-	-	-	-
Transaction costs share repo	(1,987)	-	-	-	-	-	-
Proceeds RDO	-	10,000	25,000	25,000	-	-	-
RDO issuance costs	-	(1,277)	(2,834)	(2,834)	-	-	-
Proceeds warrant & opt excrse	1,135	46	383	383	-	-	-
Share issued	-	-	-	-	13,750	-	-
Cash from financing	23,582	(11,196)	(6,465)	(6,465)	13,750	-	-
FOREX effect	-	-	-	-	-	-	-
Net change in cash	2,545	(1,955)	4,937	(2,056)	6,237	6,083	724
Cash at start	2,184	4,729	4,729	4,729	2,673	8,910	14,993
Cash at end	4,729	2,774	9,666	2,673	8,910	14,993	15,716

Source: Company reports; AGP estimates

Important Research Disclosures

Rating and Price Target History for: Scilex Holding Company (SCLX) as of 10-14-2024



Created by: BlueMatrix

Distribution of Ratings/IB Services

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [BUY]	138	81.66	37	26.81
HOLD [NEUTRAL]	24	14.20	4	16.67
SELL [SELL]	1	0.59	0	0
NOT RATED [NR]	6	3.55	2	33.33
UNDER REVIEW [UR]	0	0.00	0	0

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