Scilex Holding Company (SCLX)
Rating: Buy

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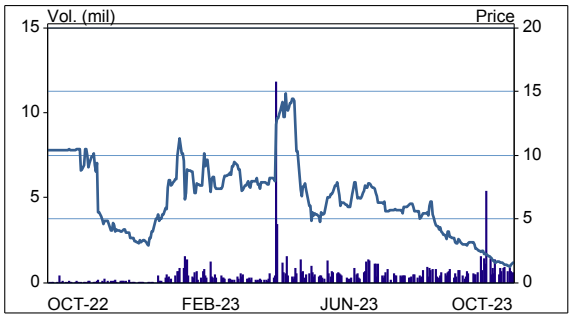
Pulverizing Pain Without Opioid-Based Drugs; Initiating at Buy and $12 PT

Stock Data	10/06/2023
Price	$1.57
Exchange	NASDAQ
Price Target	$12.00
52-Week High	$16.90
52-Week Low	$1.21
Enterprise Value (M)	$238
Market Cap (M)	$234
Shares Outstanding (M)	153.5
3 Month Avg Volume	678,976
Short Interest (M)	2.75
Balance Sheet Metrics	
Cash (M)	$34.1
Total Debt (M)	$37.7
Total Cash/Share	$0.22
Book Value/Share	$0.07

EPS ($) Diluted			
Full Year - Dec	2022A	2023E	2024E
1Q	--	(0.22)A	(0.14)
2Q	--	(0.19)A	(0.11)
3Q	--	(0.16)	(0.07)
4Q	--	(0.16)	(0.04)
FY	(0.17)	(0.72)	(0.35)

Revenue ($M)			
Full Year - Dec	2022A	2023E	2024E
1Q	--	10.6A	18.8
2Q	--	12.6A	25.0
3Q	--	13.9	32.3
4Q	--	16.3	40.5
FY	38.0	53.4	116.6



A rapidly emerging powerhouse in pain relief—without opioids. We are initiating coverage of Scilex Holding Company, a commercial-stage specialty pharmaceuticals enterprise with a diversified portfolio of marketed products as well as mid- to late-stage clinical assets that all constitute risk-mitigated prescription therapeutics. Scilex's marketed portfolio comprises the following products: (1) ZTlido (medicated lidocaine plaster), a novel, proprietary topical lidocaine patch product for neuropathic pain, particularly post-herpetic neuralgia (PHN); (2) Elyxyb (celecoxib oral solution)—a liquid formulation of a cyclooxygenase-2 (COX-2) inhibitor originally marketed by Pfizer under the trade name Celebrex—to treat migraines; and (3) Gloperba (oral colchicine solution) for gout prophylaxis. Scilex also has three intriguing advanced clinical-stage assets: (1) SEMDEXA (SP-102; dexamethasone gel for injection), which has already yielded positive Phase 3 pivotal data in sciatica or lumbar radicular pain; (2) SP-103 (medicated lidocaine plaster triple-strength), a higher-concentration version of the same formulation of lidocaine used in ZTlido for acute lower back pain (LBP), now in Phase 2 testing; and (3) SP-104 (delayed burst low-dose naltrexone) for treatment of fibromyalgia, which may enter Phase 3 assessment this year. Our rating is Buy with a 12-month price target of $12.

Addressing pain with novel formulations of existing agents. In our view, Scilex is seeking to provide comprehensive pain management solutions in areas of high unmet need with novel formulations of existing drugs that do not constitute opioids. The opioid addiction crisis has become one of the severest medical problems in America over the past two decades, affecting an estimated 13M adults (5% of the total U.S. adult population) and contributing to 564K deaths in the U.S. alone from 1999 to 2020. Physicians are thus attempting to identify alternatives to opioid medications for pain management, which has proven challenging because of the well-established potency of these drugs. Scilex has successfully advanced multiple non-opioid pain relief agents for use in specialty indications that are difficult to manage and cannot be addressed using over-the-counter (OTC) analgesic drugs (e.g., acetaminophen, aspirin, ibuprofen). In our view, the fact that Scilex's portfolio consists of well-known active pharmaceutical ingredients (APIs) with well-established mechanisms and lengthy track records of safe, non-addictive human use mitigates risk and facilitates market uptake due to the extensive familiarity that specialist prescribers already have with these compounds.

Forward-integrated, diversified corporation demonstrating commercial execution. Scilex has an established sales and marketing organization in the U.S. spanning over 70 specialty sales representatives. The company achieved $38M in top-line revenue last year, which we project to rise to $53.4M in 2023 and $116.6M in 2024. In our view, Scilex's valuation could eventually approach that of Pacira BioSciences (PCRX; Buy; Livnat), which trades at a $1.4B valuation and $1.8B enterprise value with a portfolio consisting of two franchises—namely, EXPAREL (bupivacaine liposome injection) for post-surgical pain and ZILRETTA (triamcinolone acetonide extended-release injectable) for knee osteoarthritis pain.

Targeting large, well-established markets with potentially best-in-class therapeutics. Scilex's marketed products are aimed at massive markets—ZTlido is positioned in the neuropathic pain arena, which represents a roughly $1.9B+ annual opportunity worldwide in PHN alone, while Elyxyb targets the migraine indication that comprises 39M patients in the U.S. alone and Gloperba is being positioned in the gout segment, spanning 8M U.S. patients. We believe that ZTlido peak sales could exceed $260M annually in the U.S. by 2030, while we expect Elyxyb peak annual U.S. sales to reach $270M by 2031. Gloperba could generate peak annual U.S. sales totaling almost $830M in 2035. Among the development-stage products, we expect SP-102 to reach peak annual U.S. sales of $1.7B in 2035, while the triple-strength lidocaine product candidate (SP-103) could achieve peak annual sales of $276M in 2030. While fibromyalgia constitutes a rapidly growing market that is estimated to afflict 4M U.S. adults—about 2% of the overall population—we do not currently ascribe value to Scilex's SP-104 product candidate as we are awaiting definitive clinical proof-of-concept data.

Initial SP-102 Phase 2 data appear favorable. Last month, Scilex reported the completion of its SP-103 Phase 2, randomized, double-blind, placebo-controlled, parallel group, multi-center study to evaluate the safety and efficacy in subjects with acute LBP. Objectives of the trial were to assess safety and tolerability of SP-103 and to provide treatment effect estimates in patient population that can be used to power future studies. The trial enrolled 75 subjects, 38 received SP-103, and 37 received placebo. Topical systems were applied to the area of most tenderness in the lower back in 12-hours ON/12-hours OFF regimen. Preliminary analysis demonstrated a favorable safety profile, with no serious adverse events (SAEs) or deaths observed and no treatment emergent adverse events (TEAEs) leading to early withdrawal. None of the subjects in the active group and 3 (8.1%) subjects in placebo group had adverse events (AEs) of special interest (signs of lidocaine systemic toxicity). Incidence of dermal AEs or application site reactions was low overall. SP-103 was generally seen to be safe and well-tolerated. The trial data also indicated that an increase in lidocaine load in topical system by three-fold (3x) vs. approved ZTLido—i.e., 5.4% vs. 1.8%—did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment. A meaningful reduction in pain was observed over the first week, using a sum of pain intensity differences (SPID-7) analysis, -1.5 (95% CI: -0.2 to 3.2) was seen in a sub-population of patients with greater muscle spasm severity. Overall, the trial achieved its objectives according to Scilex and further data is slated to be released in the coming months. We expect the clinical development path for SP-102 to be clarified in 1H24.

Valuation and risks. We assess Scilex using a discounted cash flow (DCF)-based valuation methodology. This applies an 80% probability of approval to SEMDEXA (SP-102), while we assume 100% probability of approval for ZTlido, Elyxyb, Gloperba and SP-103. In our view, the SP-103 candidate should readily achieve market entry because it is simply a triple-strength version of the existing ZTlido product. We utilize a 10% discount rate and 1.5% terminal growth rate. In our view, these assumptions are reasonable given the well-established, mature and broad nature of Scilex's target markets and the risk-mitigated, well-characterized nature of its portfolio of marketed products and development-stage candidates. Our assumptions correspond to a total firm value of $3.35B, which yields a price objective of $12 per share assuming roughly 274M fully-diluted shares outstanding as of end-3Q24. Risks include, but are not limited to: (1) inability to achieve meaningful market traction with ZTlido, Elyxyb or Gloperba due to greater-than-anticipated competitive pressures or setbacks in obtaining reimbursement and formulary access; (2) failure to obtain regulatory approval in the U.S. for SEMDEXA or SP-103; (3) financial market risks; (4) broader macroeconomic risks related to the U.S. government shutdown negotiations and ongoing geopolitical fallout related to the Ukraine war; and (5) possible near- to medium-term dilution risk.

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I. Company Overview

Company Highlights

Snapshot

- Sector: Healthcare
- Classification: Specialty Pharma
- Founded in 2020
- Headquarters: Palo Alto, CA
- Employees: 90

Financial Highlights

- Vickers Vantage Corp. (a Special Purpose Acquisition Company, or SPAC) acquired Scilex Holding Co. for $1.5 billion in stock through a reverse takeover (deSPACing completed November 17, 2022)
- Shares trade on NASDAQ (ticker: SCLX)
- Cash position: $34.1 million as of end-2Q23, with roughly $15.6 million remaining to be drawn on a convertible debt facility and $18.3 million remaining to be drawn on a collateralized loan

Major shareholders:

- Vanguard Group (1.9%)

Focus

- Scilex is a commercial-stage firm focused on acquiring, developing and commercializing non-opioids for pain management
- The company's flagship asset, ZTlido, is deployed for treatment of pain due to post-herpetic neuralgia (PHN) and possibly other forms of neuropathic pain as well
- In addition, the company recently in-licensed commercial rights to Elyxyb (migraine) and Gloperba (gout prophylaxis)
- In the next 12-18 months, we expect the principal stock catalysts to be sales of commercial drugs as well as results generated with clinical-stage assets in proof-of-concept or pivotal studies

ZTlido

- ZTlido is an FDA-approved skin patch that delivers efficacy for over 12 hours (45% bioavailability vs. 3% to 11% observed in competitor products, despite heavy drug loading)
- In addition, combining ZTlido with pregabalin could reduce pain intensity, suggesting potential combination therapy in many pain indications
- ZTlido was launched in October 2018 and is being promoted by a sales force of roughly 70 people

Elyxyb

- Elyxyb is a first-of-its-kind oral solution of celecoxib for migraine treatment (FDA approved in 2020)
- 33% of Elyxyb-treated patients (with or without aura) achieved pain relief at 2 hours, with 55% of those treated sustaining benefits through 24 hours
- Elyxyb was re-launched in 2Q23

Gloperba

- Gloperba is a novel colchicine oral solution designed to prevent gout flares and facilitate dose adjustment in comorbid patients (previously impossible to achieve with existing colchicine formulations)
- This product is scheduled for launch in late 2023

Pipeline Programs

- SP-102 (SEMDEXA) produced positive Phase 3 data when evaluated in sciatica patients (launch in 2024)
- SP-103 (three times the dosage strength of ZTlido) is being evaluated in a Phase 2 study for treatment of low back pain, with potential launch in 2025
- SP-104 (low-dose naltrexone hydrochloride delayed-release capsules) is being evaluated for the treatment of fibromyalgia (Phase 2-ready)

Company Pipeline

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 ▪ **2023:** 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
SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)				Fast Track / Pre-NDA		▪ 2036	▪ **1H 2022:** Phase III achieved endpoints ▪ **1H 2023**: FDA discussion on Pre-NDA
SP-103 Lidocaine Topical System 5.4% (3X) (Acute Back Pain)				Fast Track		▪ 2031	▪ **2Q 2022:** Initiated Phase II trial
SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)			Prepare Phase II Trial			▪ 2041	▪ **1H 2022:** Completed Phase I trial(s) ▪ **2023:** Initiate Phase II trials

Our assumptions: ZTlido (PHN) POA 100% (FDA approved February 2018); Elyxyb (migraine) POA 100% (FDA approved May 2020); Gloperba (gout) POA 100% (FDA approved February 2019); SP-102 (Sciatica) POA 80% (positive Phase 3 data reported); SP-103 and SP-104 are not modeled in our financial forecasts.

Source: Scilex Holding Company.

Catalyst Calendar

Agent	Indication	Potential Events	Timing	Impact on Stock
Gloperba	**Gout prophylaxis**	**U.S. launch**	**Late 2023**	**High**
SP-102	**Sciatica**	Pre-NDA meeting	Late 2023	Low
		SP-102 U.S. launch	**2024**	**High**
SP-103	Low back pain	Final Phase 2 data	Late 2023	Medium
SP-104	Fibromyalgia	Phase 2 initiation	Late 2023	Low

Our assumptions: ZTlido (PHN) POA 100%; Elyxyb (migraine) POA 100%; Gloperba (gout) POA 100%; SP-102 (Sciatica) POA 80%; SP-102 and SP-103 are not modeled in our financial forecasts.

Source: H.C Wainwright & Co. estimates; Scilex Holding Company.

Our Assumptions

Base Case Scenario		
Gloperba	Gout prophylaxis	Gloperba launched in the U.S. in late 2023
SP-102	Sciatica	SP-102 launched in the U.S. In 2024
Upside Scenario		
SP-103	Low back pain	SP-103 demonstrates proof-of-concept (POC) clinical efficacy in Phase 2 study; potential U.S. launch in 2027
SP-104	Fibromyalgia	SP-104 demonstrates POC clinical efficacy in Phase 2 study; potential U.S. launch in 2026
Downside Scenario		
ZTlido	Post-herpetic neuralgia (PHN)	Slower-than-anticipated expansion of sales due to market access issues or competitive pressures
Elyxyb	Migraine	Failure to achieve market traction due to saturation of target indication with newer, more disruptive drugs
Gloperba	Gout prophylaxis	Slower-than-anticipated sales of Gloperba due to perceived lack of differentiation vs. older colchicine formulations
SP-102	Sciatica	FDA may require the company to conduct a second confirmatory Phase 3 study prior to granting approval
Growth Drivers of Stock		
Near-Term Drivers	Market penetration of ZTlido, Elyxyb and Gloperba; FDA approval of SP-102; clinical success with SP-103 and SP-104	
Long-Term Drivers	Portfolio expansion into additional indications; Global partnerships with established companies; commercial launch of additional candidates	

Note: Our assumptions: ZTlido (PHN) POA 100%; Elyxyb (migraine) POA 100%; Gloperba (gout) POA 100%; SP-102 (Sciatica) POA 80%; SP-102 and SP-103 are not modeled in our financial forecasts.

Source: H.C Wainwright & Co. estimates; Scilex Holding Company.

Proven Leadership With Track Records of Success

Jaisim Shah
President & Chief Executive Officer

- Seasoned industry leader with 30 years of experience in drug development and commercialization
- Previously, Mr. Shah served as CEO of Semnur Pharma (acquired by Scilex)
- Mr. Shah holds an M.A. in economics from the University of Akron and a M.B.A. from the University of Oklahoma

Stephen Ma
Chief Financial Officer

- Previously served as Scilex's Chief Accounting Officer starting in November 2022 and as Vice President of Finance from January to November 2022
- Previously served as Director of Finance and Operations for Anwita Biosciences, a privately-held clinical-stage company
- Mr. Ma holds a B.S. degree in finance and an M.A. in economics from San Jose State University

Dmitri Lissin, M.D.
Chief Medical Officer

- Dr. Lissin serves as Chief Medical Officer and SVP Clinical of Scilex/Semnur Pharma (2015 – present)
- He received his post-doctoral training from the University of California at San Francisco, and his medical degree through an exchange program between Russian National Medical University and Harvard Medical School

Suresh Khemani
Chief Commercial Officer

- Mr. Khemani has been Senior Vice President and Chief Commercial Officer of Scilex since March 2019
- His therapeutic expertise include pain, neurology, oncology, immunology, and cardiovascular disease
- Mr. Khemani holds a bachelor's degree in pharmacy from Bombay University

Henry Ji, Ph.D.
Executive Chairman

- Dr. Ji has over 25 years of experience in the biotech and life sciences sectors
- Previously, he served as the CEO of Scilex (2016 to 2019) and continues to serve as CEO and President of the entity from which Scilex was spun out
- Dr. Ji received a doctoral degree from the University of Minnesota

Suketu D. Desai, Ph.D.
Chief Technical Officer, SVP

- Dr. Desai has over 25 years of experience in pharmaceuticals, including positions at Allergan (acquired by AbbVie), Cephalon (acquired by Teva) and Ception Therapeutics
- He received a Ph.D. in Pharmaceutical Sciences (University of Arizona), along with a master's degree in pharmacology and bachelor's degree in pharmacy from the University of Mumbai

We believe that Scilex's management team and board of directors collectively possesses an extensive and successful track record in drug discovery, clinical development, marketing and generation of sustained revenue growth across multiple therapeutic areas and products. In our view, the team has the pertinent scientific and financial expertise to advance the company's commercial products and clinical programs.

Source: Scilex Holding Company.

II. Investment Thesis

1. A Vertically Integrated, Non-Opioid Pain Management Powerhouse

Agent	Indication	API	Route	Stage	Future Market Opportunity	Comments
ZTlido	PHN	Lidocaine (1.8%)	Skin patch	Commercialized	$1.9B+ (WW)	Non-aqueous technology that delivers more active agent than competitor products; potential to commercialize globally (except in Japan); opportunity to capture significant market when combined with gabapentinoids
Elyxyb	Migraine	Celecoxib	Oral liquid	Commercialized	$1.8B+ (WW)	39 million U.S. migraine patients; re-launched in 1H23; first oral celecoxib solution with fast onset and low GI side effects
Gloperba	Gout	Colchicine	Oral liquid	Commercialized	$8B+ (WW)	8 million U.S. gout patients; First and only liquid colchicine formulation; possible dose adjustment in comorbid patients
SP-102	Sciatica	Dexamethasone	Epidural injection	Pre-NDA	$18B+ (WW)	Over 10 million ESI procedures annually in the U.S.; Phase 3 data showed pain reduction with durability lasting for over three months; pre-NDA meeting anticipated in the coming weeks
SP-103	Acute low back pain	Lidocaine (5.4%)	Skin patch	Phase 2	$10B+ (WW)	Delivery of 3x lidocaine load vs. ZTlido; Phase 2 started in 2022; Fast Track designation granted by the FDA
SP-104	Fibromyalgia	Naltrexone	Oral	Phase 2-ready	$3B (WW)	Low-dose naltrexone showed efficacy in multiple independent investigator-initiated trials; Phase 2 study slated to start in 2023

Scilex is an emerging commercial-stage company developing non-opioid solutions to address unmet medical needs in multiple pain disorders. The company's value proposition is based on its ability to identify below-the-radar firms with novel reformulations of well-known, off-patent products with substantial market potential. Scilex holds exclusive rights to three commercial products (with two of these already launched in the U.S. and other markets).

The near-term narrative for Scilex is likely to be dictated by continued market adoption of ZTlido in PHN and potential off-label use (e.g., neuropathic pain), with supporting contributions from market penetration of Elyxyb and Gloperba. In addition, while we acknowledge the spillover effects of various financial and equities markets turbulence, we think such headwinds are already priced into Scilex's share price. Thus, we believe that the current Scilex share price constitutes an attractive entry point for investors.

Source: Scilex Holding Company.

With Multiple Partnership Agreements in Place, Scilex Is Positioning Itself as a Formidable Competitor in the Burgeoning Non-Opioids Pain Market

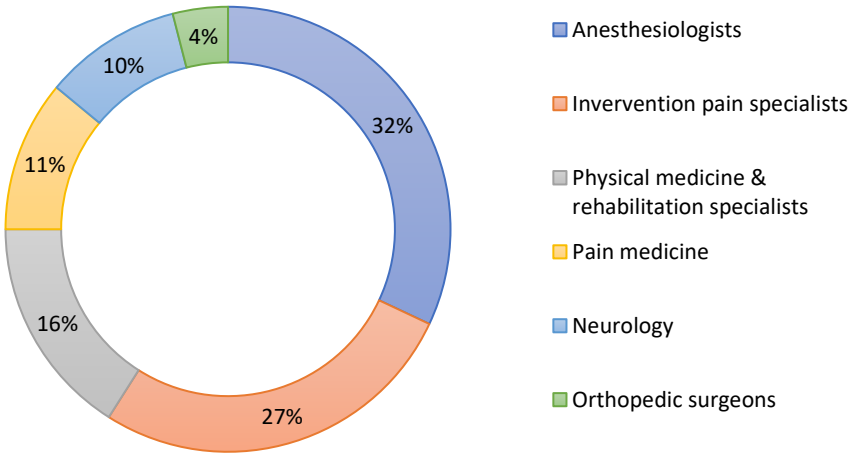
Agent	Indication	Originator/Developer	Comments
ZTlido	PHN	Oishi Koseido Co., Ltd. (Oishi) and Itochu Chemical Frontier Corporation (Itochu)	Scilex holds exclusive worldwide rights, except Japan; quarterly royalty between 25% and 35% to the original developers
Elyxyb	Migraine	Dr. Reddy's Laboratories; BioDelivery Sciences International, Inc. (BDSI) and Collegium Pharmaceutical	Royalty (estimated at 12% flat rate) on net sales for all indications and additional amounts if certain sales milestones are achieved
Gloperba	Gout	RxOmeg Therapeutics LLC (Romeg Therapeutics)	Up-front payment of $2 million, certain sales-based milestone payments in the aggregate amount of up to $13 million and royalties on net sales at a rate not exceeding 10%
SP-102	Sciatica	Semnur	Sodium hyaluronate used as an excipient in SP-102 is obtained from Genzyme (Sanofi); sales-based milestone payments totaling up to $240 million payable to Semnur legacy shareholders; Mahendra Shah is entitled to a low single-digit royalty (we assume 2%) on net sales
SP-103	Acute low back pain	Oishi Koseido Co., Ltd. (Oishi) and Itochu Chemical Frontier Corporation (Itochu)	Scilex holds exclusive WW rights, except Japan; quarterly royalty between 25% and 35% to the original developers
SP-104	Fibromyalgia	Aardvark Therapeutics	$3 million owed to Aardvark at FDA approval; $20 million upon attainment of certain net sales thresholds; single-digit royalty on net sales

We believe Scilex is carving its niche in the non-opioid pain management drug class, moving into a pain market space that is shifting away from opioids due to the well-documented risks of addiction, abuse and diversion. From our vantage point, Scilex's disciplined execution to acquire underrated assets with high market potential bodes well for the company's long-term intent to become a powerhouse in pain management.

Source: Scilex Holding Company.

Driving Revenue Growth With a Disciplined Sales Force Executing on Synergies

Target Physicians Treating Neuropathic and Chronic Pain (~15K to 20K U.S. Physicians)



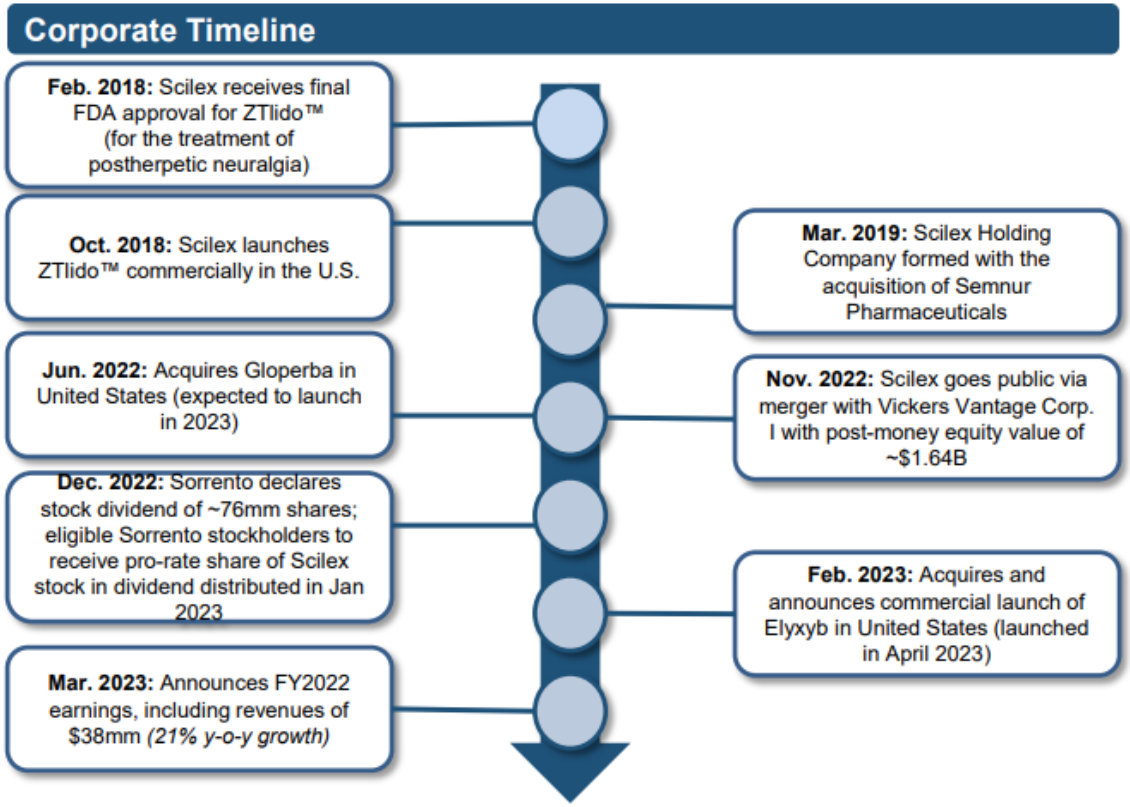
Scilex invests heavily in sales & marketing to accelerate revenue growth. Per management, the current sales force is comprised of ~70 pain specialists targeting over 10,000 primary care physicians, pain specialists, neurologists and palliative care physicians who treat the majority of pain indications. Given the synergies between pain indications targeted by the company's products, we expect considerable efficiency across Scilex's commercial infrastructure and momentum that should enable even more new products to be launched in future with minimal additional investment.

In our view, Scilex's workforce constitutes a critical component to successful deployment of products in global markets. While we acknowledge headwinds from established and smaller competitors, the uniqueness of the products, substantial unmet needs and lengthy intellectual property (IP) lifespans should bode well for the long-term commercial outlook, in our view. We consider Scilex's commercial operations to be well-positioned because of the diversity already apparent in the company's marketed product portfolio.

From our perspective, Scilex's commercial footprint in the U.S. has been strengthened significantly by acquiring three commercial products—including ZTlido, currently the primary revenue driver. With the impetus from a galvanized sales force that is further bolstered by direct-to-patient marketing strategies and the general industry shift towards non-opioid drugs, we expect steady improvement in sales performance over the course of 2023 and beyond. The recent launch of Elyxyb and the upcoming market introduction of Gloperba should act as accelerants, in our view.

Source: Scilex Holding Company.

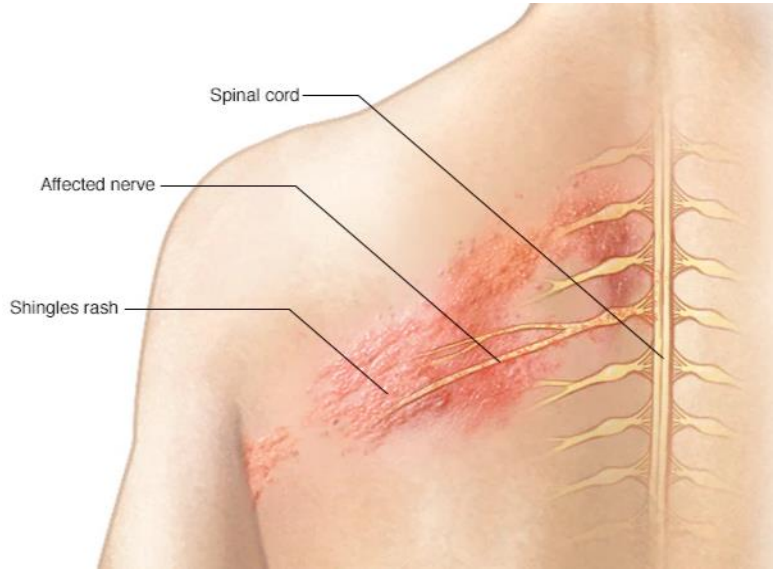
Disciplined Execution on Multiple Fronts Positions Scilex to Create Transformational Impact on Patients' Lives

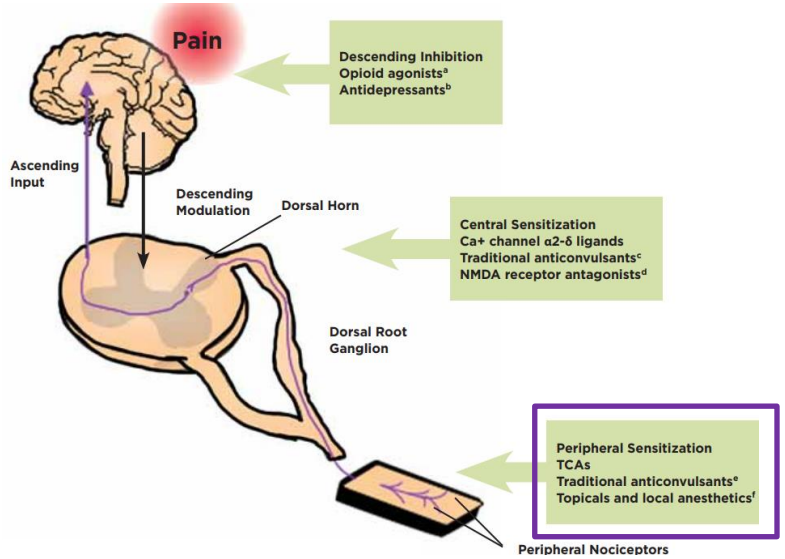


By harnessing the power of non-opioids, Scilex attempts to break new ground in managing and treating pain indications. Notably, the team's industry acumen and proactive approach to business development could steadily grow the pipeline in the coming years by acquiring strategic assets with well-understood biology and the ability to address areas of unmet need, in our view. Importantly, Scilex's risk-mitigated product offerings, differentiated drug development approach and attractive valuation at current levels may make it an attractive future acquisition target.

Source: Scilex Holding Company.

2. ZTlido: A Next-Generation Anhydrous Lidocaine Patch for PHN Treatment and More



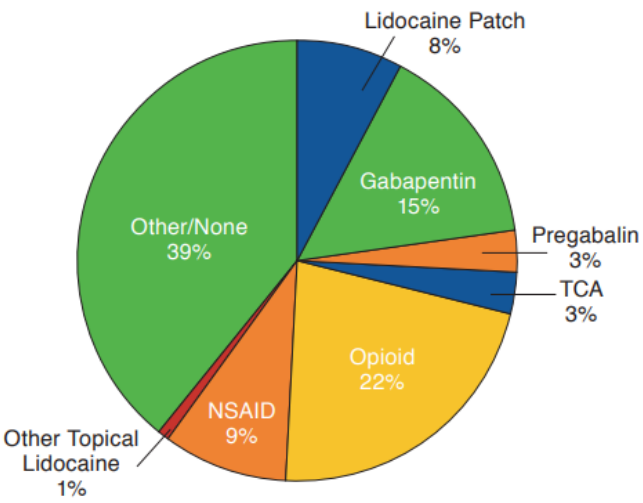


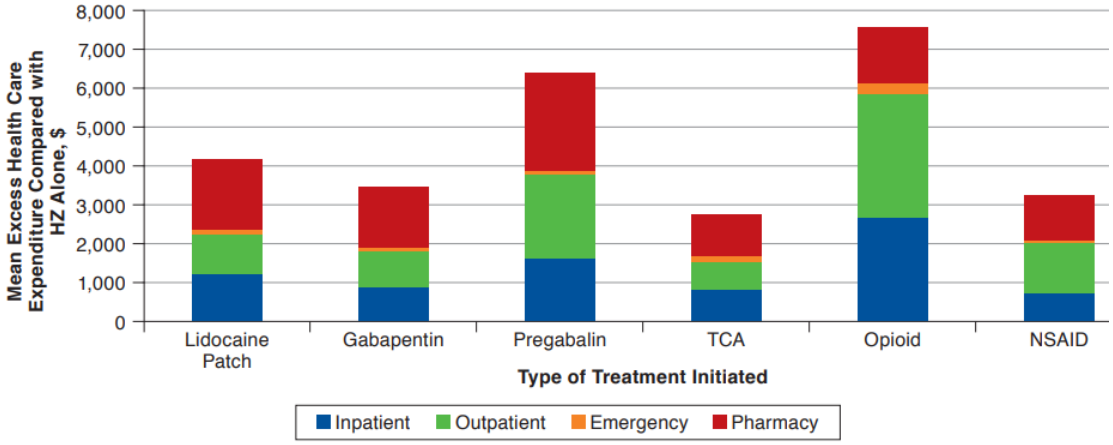
Post-herpetic neuralgia (PHN) is a chronic neuropathic pain syndrome occurring in the areas of the herpes zoster (HZ) rash (~9 to 14% of HZ patients develop PHN). The central and peripheral nervous system components (nerve fibers and skin) are affected, with symptoms (localized neuropathic pain of burning, shooting or stabbing nature, exaggeration of pain response and painful sensation for non-painful stimuli) lasting for years, causing several physical and disabilities.

In the front-line (1L) setting, oral tricyclic antidepressant (TCA) drugs, the gabapentinoid agent pregabalin, and the lidocaine 5% patch are routinely preferred. However, advanced presentations necessitate either combination regimens or treatment with opioids. Unfortunately, there is no cure for PHN, though palliative options reduce pain duration and severity. Accordingly, new agents are urgently needed to manage disease symptoms. The preference among medical practitioners is clearly for non-opioid solutions, but these are often not potent enough.

Source: Mayo Clinic; Gharibo & Kim, Pain Medicine News (2011).

Multiple Agents are Deployed to Treat, Though Caveats Remain





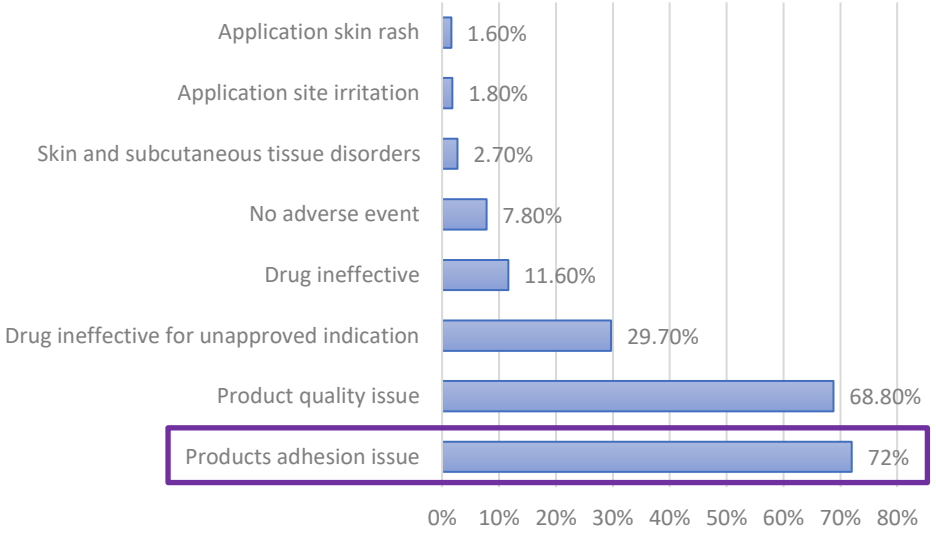
A study analyzing medical and pharmacy claims from 2010 to 2014 (n=232M, with the majority of patients aged <65 years) suggested that over 8% of PHN treatment involves lidocaine patches (see figure on the left). In terms of expenditure, patients on opioids had higher expenses ($7,601; p<0.05) vs. pregabalin ($6,428; p<0.05), lidocaine patches ($4,213; p<0.05), gabapentin ($3,478; p<0.05), NSAIDs ($3,304; p<0.05), and TCAs ($2,797; p<0.05). Scilex management indicated that the current lidocaine patch market size is about 15% to 18% of the PHN market (for context, ~147 million lidocaine patches were sold in the U.S. in 2021).

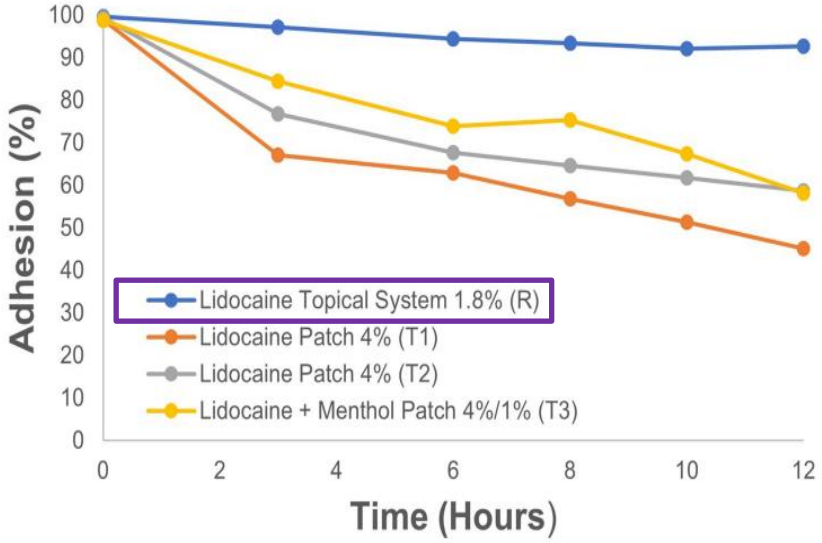
In the 1L setting, topical lidocaine patches (sodium channel blocker) are increasingly preferred for their local effects, minimal systemic exposure and fewer drug-drug interactions. However, the key sticking point continues to be low adhesion, requiring high drug loading. For example, the bioavailability of Lidoderm (700mg lidocaine) – the original branded product market leader in the lidocaine patch segment – is about 3% (high drug loading could inadvertently result in a sub-optimal benefit-risk profile). This underscores the need for novel reformulations with superior bioavailability and improved adhesion properties. Such requirements provide favorable positioning for ZTlido—an FDA-approved lidocaine topical agent (36mg drug load; 45% bioavailability) delivered in a patch that does not absorb water.

Source: Gudin et al., Journal of Managed Care and Specialty Pharmacy (2019).

ZTlido Addresses the Achilles' Heel of Traditional Lidocaine Patches—Poor Adhesion

% of Respondents Reporting Lidocaine Patch Concerns (n=3,861)





Superior adhesion is a key metric that determines topical lidocaine efficacy and potential market adoption. Among several concerns cited in the FDA Adverse Event Reporting System (FAERS), over 68% of users reported product adhesion issues. Given the fact that competing products are overloaded with APIs (~700mg lidocaine per patch) to compensate for poor bioavailability (~3%), their thickness must be increased, which inadvertently compromises the product's pliability, resulting in poor adhesion.

Scilex's ZTlido employs an anhydrous, single-layer, drug-in-adhesive topical delivery system that is lighter, thinner and patient-friendly (flexible to the body's contours). When tested in an open-label study involving healthy volunteers, ZTlido demonstrated superior adhesion for over 12 hours vs. three active comparators (lidocaine-containing over-the-counter or OTC products), suggesting differentiation. Notably, mean adhesion was >90% during various activities (see figure on the right), indicating no significant loss in product performance.

Source: Fudin et al., Journal of Pain Research (2022); Vought et al., Journal of Pain Research (2021); Scilex Holding Company.

ZTlido's Superior Adhesion and Greater Bioavailability Outperform Competitor's Products, Which Could Translate Into Greater Market Adoption, in Our View

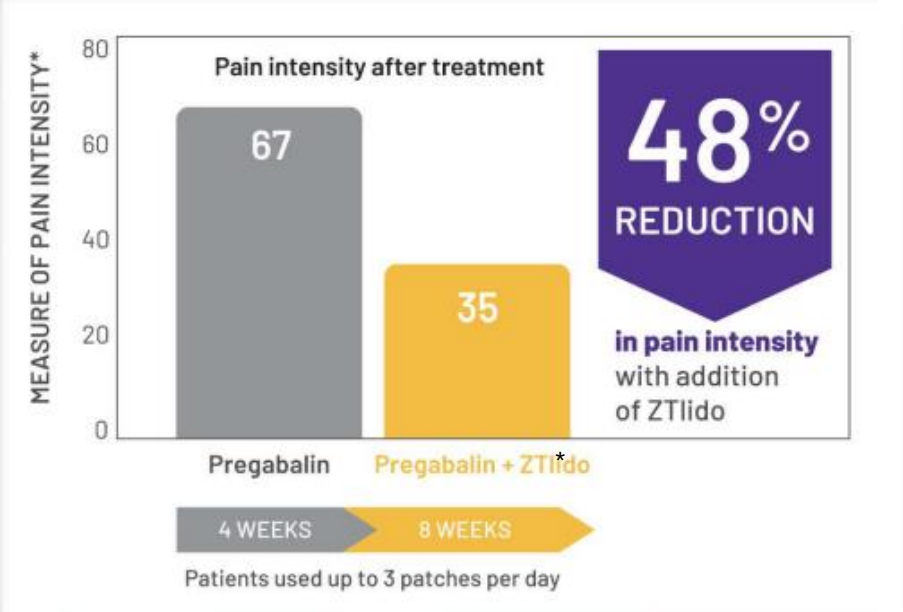
Attribute	ZTlido (Scilex)	Lidoderm (Endo)	Lidocaine Patch (Teva)	Lidocaine Patch (Viatris)
Technology	Single-layer DIA non-aqueous multi-polymer matrix	Single-layer aqueous base (hydrogel)	Unique adhesion technology	Single-layer DIA non-aqueous multi-polymer matrix
Adhesion (after 12h)	>90% adhesion	<65% adhesion	Not studied	<30% adhesion
Label advantage	Can be used after heat exposure, during exercise and showering	Label states that getting the patch wet should be avoided as it may not stick	Label states that getting the patch wet should be avoided as it may not stick	Label states that getting the patch wet should be avoided as it may not stick
Drug load	36mg/patch; 1.8% strength	700mg/patch; 5% strength	700mg/patch; 5% strength	140mg/patch; 5% strength
Bioavailability	~48% (in-house studies)	3±2%	3±2%	11±4%
Residual drug after use	16 to 17mg	665mg	665mg	115mg (at least)
Perforated release liner for ease of removal	Yes	No	No	No

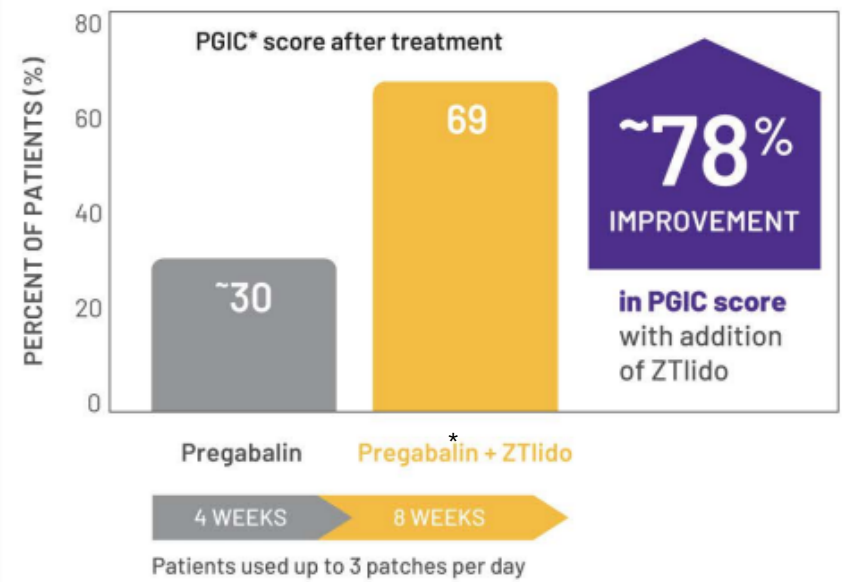
While lidocaine patches have unique advantages (superior compliance, low systemic exposure and fewer drug-drug interactions, to name a few), the bottleneck continues to be the patch's poor adhesion. In addition, the use of hydrogel technology limits bioavailability, necessitating the need for a higher drug loading in traditional 5% lidocaine patches.

In contrast, ZTlido's thin patch design showed superior adhesion performance (>90% adhesion at 12 hours after application) that fits the body's natural contours (even during exercise and showering). Notably, the proprietary non-aqueous technology facilitates less drug loading (36mg vs. 700mg in Lidoderm), superior bioavailability and less residual drug. In addition, per the label, users may apply ZTlido to a treatment site after moderate heat exposure, highlighting its value in heat therapy. The smaller amounts of lidocaine required also reduces the cost of goods.

Source: H.C. Wainwright & Co. equity research; company reports.

Combining Traditional Lidocaine Patches (5% Strength) With Pregabalin Resulted in Significant Reduction in Pain Intensity, Suggesting Opportunities for ZTlido Indication Expansion





Studies show that pregabalin as a monotherapy does not elicit adequate pain relief. However, adding a competitor's lidocaine patch (5%) to the treatment region decreased pain intensity by 48%. We believe such findings could encourage physicians to use ZTlido in off-label settings.

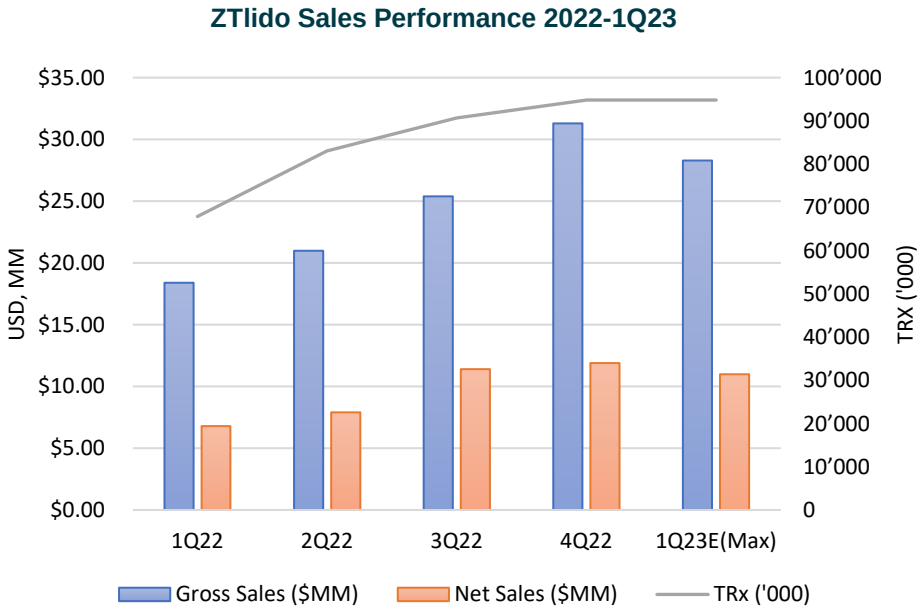
In the same study, a 78% improvement in self-reported Patient Global Impression of Change (PGIC) was observed, suggesting improved QoL.[1] Such attributes could be reciprocated with ZTlido, in our view.

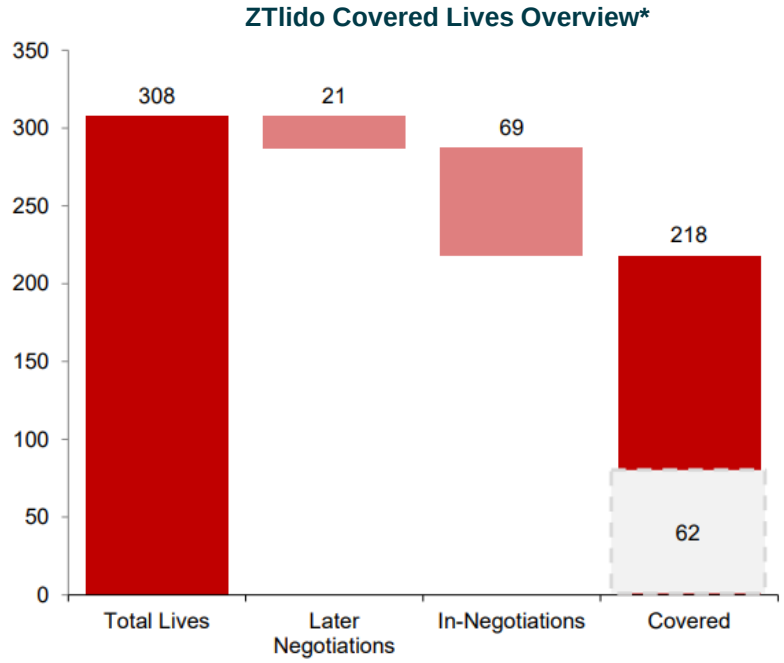
The efficacy of traditional lidocaine patches (5% strength) in combination studies involving gabapentinoids could spur ZTlido off-label use (potential indications: neuropathic pain, diabetic pain and neuropathy back pain). Notably, adding ZTlido could subdue the adverse side effect profile of gabapentinoids as the dosage will be significantly reduced, in our view.

*Note: * ZTlido denotes ZTlido equivalent, which is a traditional lidocaine (5%) patch; [1]Study design: Phase 3, two-stage adaptive, randomized, open-label study (N=98) in patients with PHN; chart shows patients treated with pregabalin alone, then in combination with a ZTlido equivalent.*

Source: Scilex Holding Company.

ZTlido Continues to Gain Traction in the U.S Market, as Evidenced by Steady Increases in Sales, TRx Volume and Payor Coverage



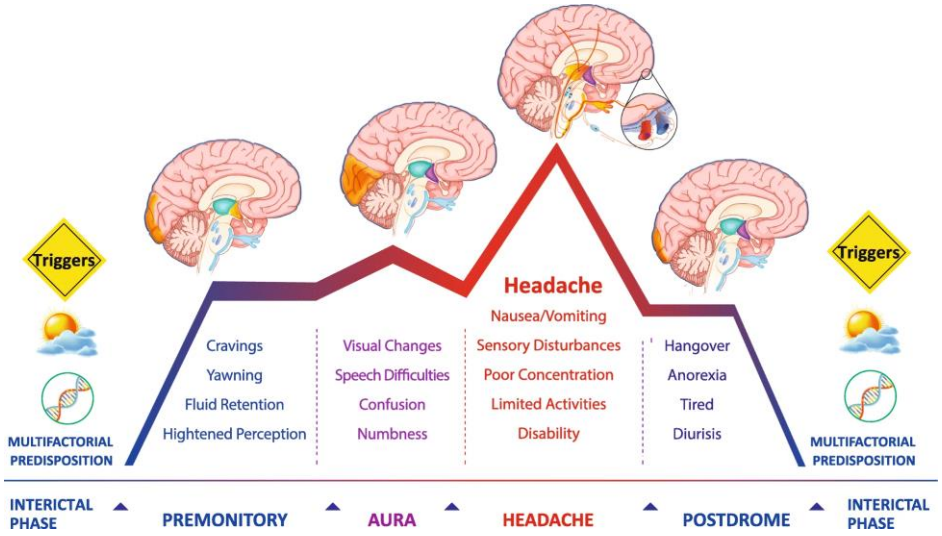


Note: CVS, MediCal, Express Scripts, Optum and United Healthcare all prefer ZTlido.

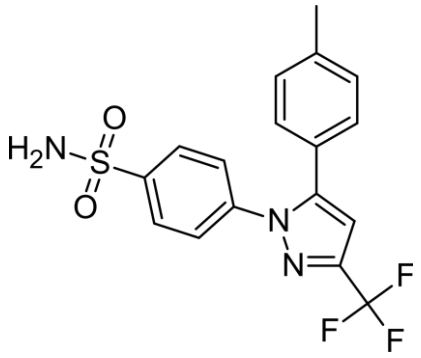
Source: Scilex Holding Company.

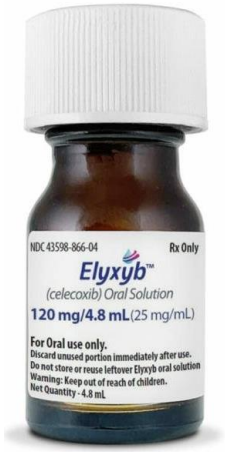
3. Elyxyb: A First-of-its-Kind Celecoxib Liquid Formulation With a Fast Onset of Action for Effective Migraine Treatment

The Cyclical Nature of Migraine Attack



Elyxyb Indicated for Migraine (With or Without Aura)





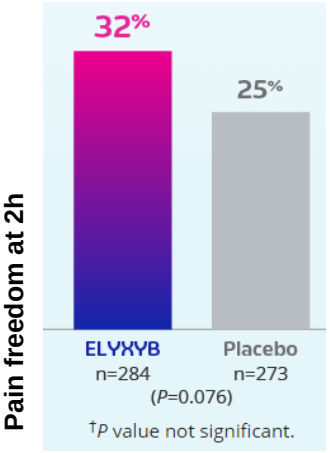
Migraine is the second-most common neurological disorder characterized by unilateral throbbing headache, photophobia, nausea and vomiting. In particular, one-third of migraine patients experience aura (a series of sensory and language disturbances) and over three-quarters of patients experience a premonitory phase before the onset of headache. Given migraine's complex etiology affecting brain pathways, multi-pronged approaches are required to meaningfully improve patient response rates and the overall patient experience.

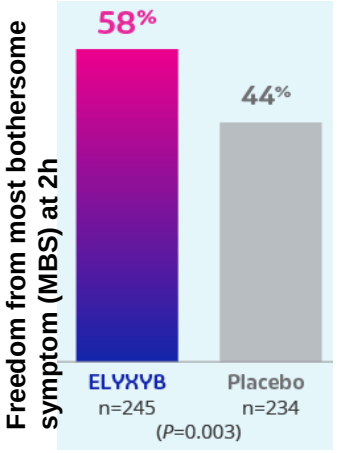
Celecoxib is an oral, selective cyclooxygenase-2 (COX-2) inhibitor indicated for treating migraine, among others. Notwithstanding its favorable GI profile (fewer gastric erosion/ulcer vs. other NSAIDs), celecoxib is less preferred due to its slow onset (C_{max}: 3 hours; partly due to low solubility). Scilex's Elyxyb is a novel, oral liquid formulation of celecoxib with improved solubility characteristics and faster onset (C_{max}: ~1 hour in moderate-to-severe migraine patients), with sustained pain relief lasting up to 24 hours after drug administration. Such attributes are unheard of in other celecoxib formulations, in our view.

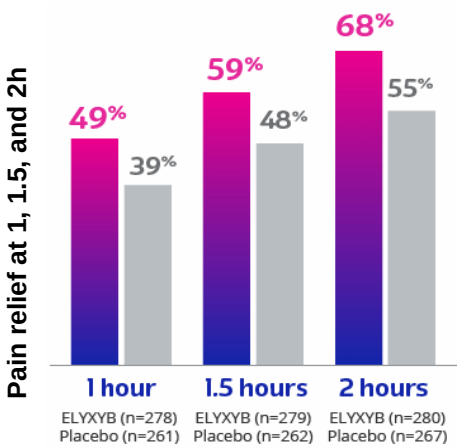
Source: Andreou & Edvinsson, The Journal of Headache and Pain (2019); Scilex Holding Company.

When Tested in Two Phase 3 Studies, Oral Elyxyb Solution Delivered Clinically Meaningfully Migraine Relief Within One Hour, Suggesting Fast Onset and Differentiation

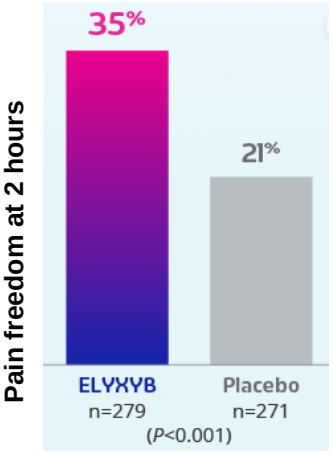
Study 1

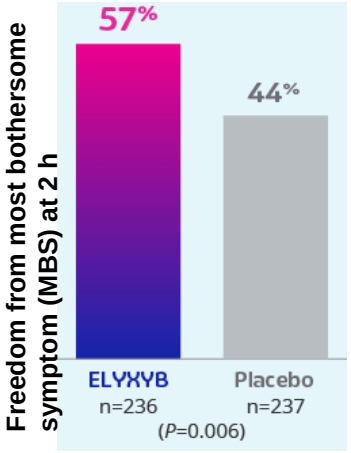


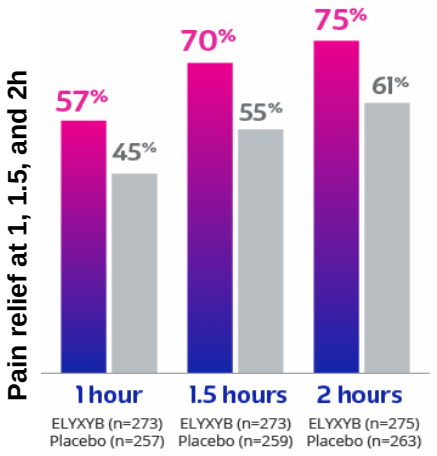




Study 2



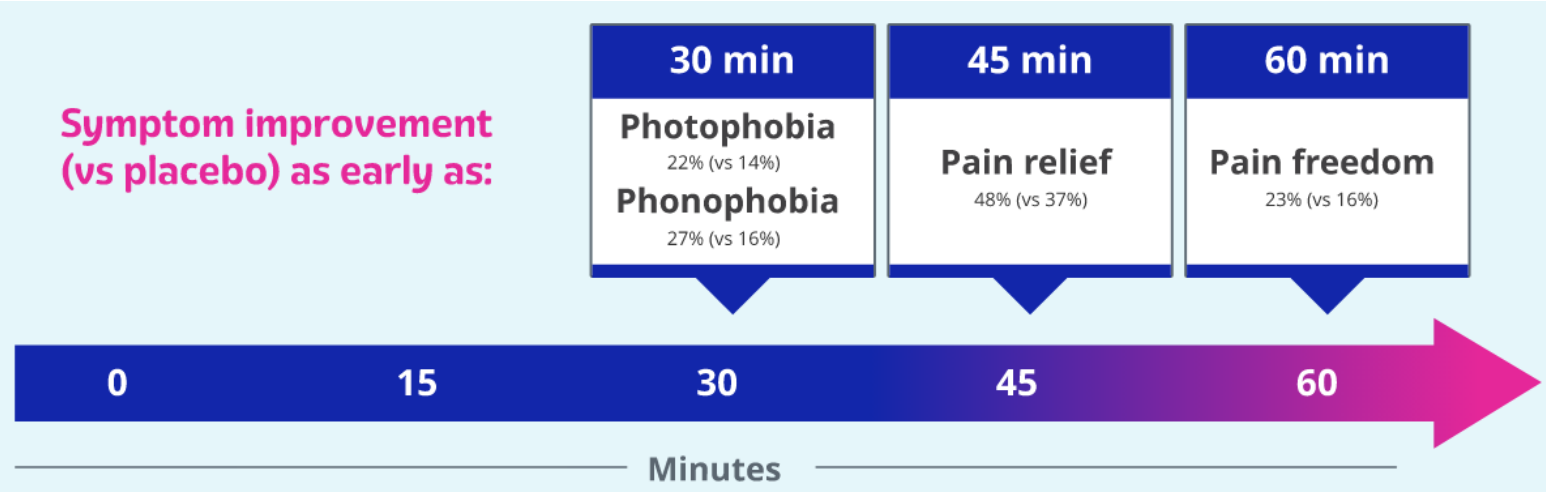




Source: Scilex Holding Company.

In Addition, Elyxyb Demonstrated Improvements in Secondary Endpoints, Suggesting Transformative Benefits and Improved QoL

Photophobia freedom	Phonophobia freedom	Nausea freedom
Study 1 **57%** vs 41% on placebo[8]	Study 1 **58%** vs 46% on placebo[8]	Study 1 **67%** vs 59% on placebo[8,10]
Study 2 **58%** vs 44% on placebo[9]	Study 2 **61%** vs 55% on placebo[9]	Study 2 **68%** vs 62% on placebo[9]



Source: Scilex Holding Company.

Migraine Treatment Landscape is Extremely Crowded, Though There is No One Magic Bullet, in Our View

Acute treatment

First-line medication
- NSAIDs (acetylsalicylic acid, ibuprofen or diclofenac potassium)

Second-line medication
- Triptans
- When triptans provide insufficient pain relief, combine with fast-acting NSAIDs

Third-line medication
- Ditans
- Gepants

Adjunct medications for nausea and/or vomiting
- Prokinetic antiemetics (domperidone or metoclopramide)

Preventative treatment

- Recommended for patients adversely affected on ≥2 days per month despite optimized acute therapy

First-line medication
- Beta blockers (propranolol, metoprolol, atenolol, bisoprolol)
- Topiramate
- Candesartan

Second-line medication
- Flunarizine
- Amitriptyline
- Sodium valproate[a]

Third-line medication
- CGRP monoclonal antibodies[b]

Managing migraine in special populations

Older people
- Secondary headache, comorbidities and adverse events are all more likely
- Poor evidence base for all drugs in this age group

Children and adolescents
- Be aware that presentation can differ from migraine in adults
- Parents and schools have important roles in the management of young children
- Bed rest alone can be sufficient
- Use ibuprofen for acute treatment and propranolol, amitriptyline or topiramate for prevention

Women who are pregnant or breastfeeding
- Use paracetamol for acute treatment
- Avoid preventive treatment if possible

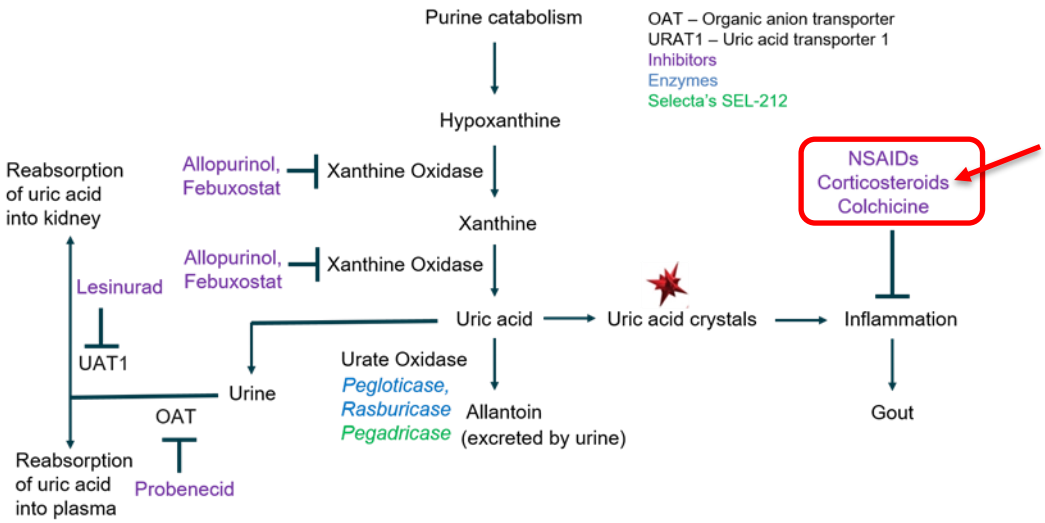
Women with menstrual migraine
- Perimenstrual preventive therapy with long-acting NSAID or triptan

As seen above, the acute migraine market is vast, with multiple competing drugs. For context, there are over 39 million migraine patients in the U.S., of which roughly 60% were diagnosed (23 million individuals).

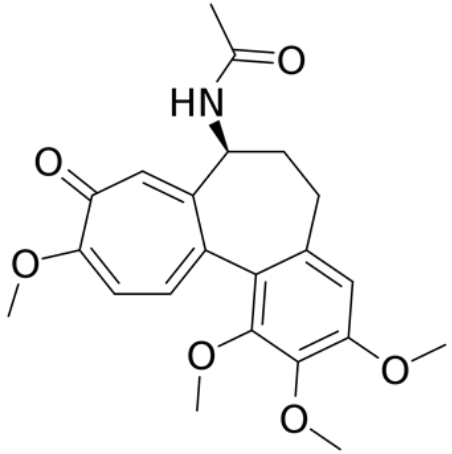
Despite the fact that migraine represents a highly competitive treatment landscape, we believe the migraine market could support multiple agents provided that clinical differentiation is evident. Elyxyb's novel formulation (oral solution), fast onset of action and durability lasting for up to 24 hours could lead to rapid market uptake, in our view.

Source: Eigenbrodt et al., Nature Reviews Neurology (2021).

4. Shifting the Narrative of Gout Flares Prophylaxis With a Novel Colchicine Liquid Formulation



Colchicine: A Well-Established Anti-Gout Drug



Abnormal purine catabolism is believed to trigger the formation of urate crystals—the causative agent for swelling and painful inflammation that could also trigger renal insufficiency. Accordingly, agents that reduce inflammation and pain are urgently needed.

Gout is a common form of inflammatory arthritis characterized by sudden, painful attacks in one or more joints. Gout is widely believed to occur due to abnormal purine catabolism (see above figure), resulting in the accumulation of uric acid crystals (hyperuricemia). Given gout flares are excruciatingly painful, prophylactic strategies are considered highly beneficial to patients. An estimated 8.7 million U.S. patients are affected by gout, of which over 100,000 patients are considered treatment-refractory.

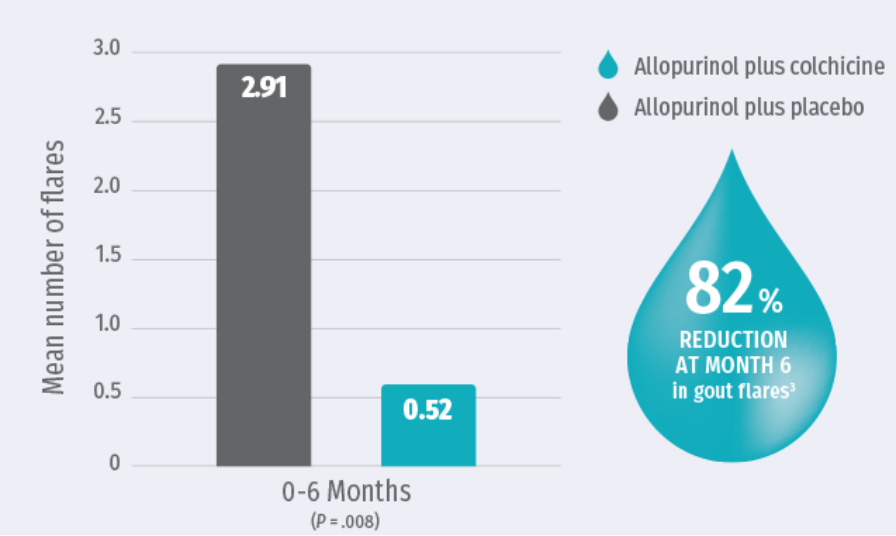
Colchicine blocks neutrophil-mediated inflammatory responses induced by monosodium urate crystals in synovial fluid. However, concerns including GI side effects, a narrow therapeutic index and cumbersome dosage adjustment blocked its broad market adoption.

In the 1L setting, oral colchicine (tablet/capsule) prevents gout glares, notwithstanding its caveats (e.g., GI side effects and dose adjustments). Prior attempts to develop an oral liquid dose were unsuccessful due to the photodegradation of colchicine. Scilex's Gloperba (oral colchicine solution initially developed by ROMEG Therapeutics) is designed to address the shortcomings of colchicine and is stable for at least three months in refrigerated, ambient and accelerated temperatures, highlighting differentiation.

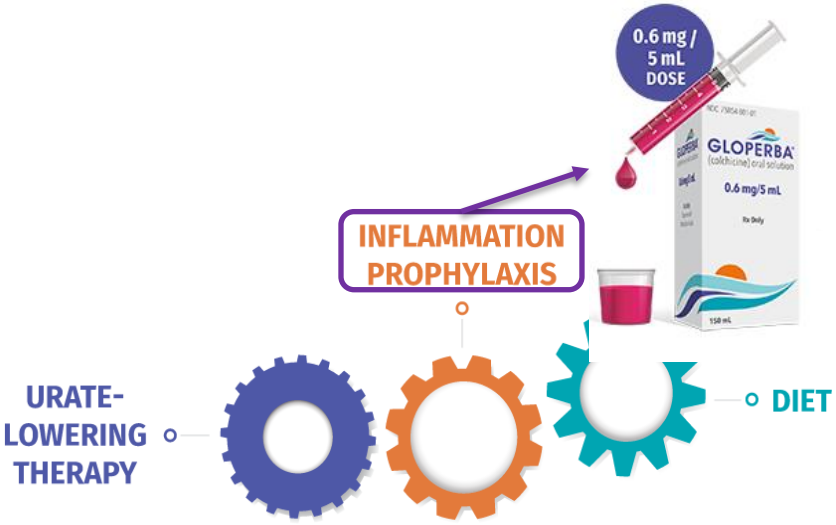
Source: Company reports.

Gloperba Offers Individualized Colchicine Dosing for Gout Prophylaxis Without the Gastrointestinal (GI) Side Effects Observed in Solid Colchicine Formulations

Gloperba Efficacy



Gout Treatment

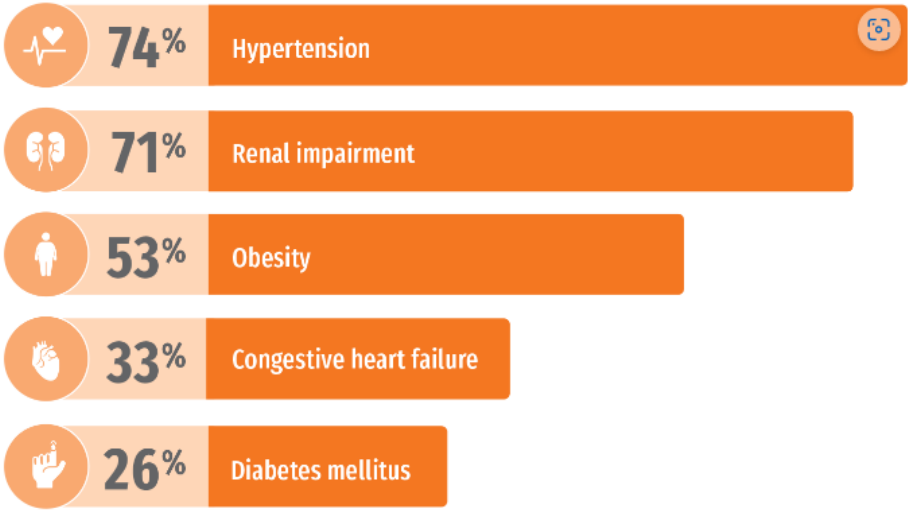


Multiple clinical studies suggested that prophylaxis during the initiation of urate-lowering therapy (ULT) can significantly reduce the incidence and severity of gout flares. As seen above, combining colchicine with allopurinol (a xanthine oxidase inhibitor first approved by the FDA in 1966 to decrease urate levels) resulted in an 82% reduction in gout flares at month 6 (vs. 0.52 flares observed in ULT alone), suggesting its therapeutic utility.

A key sticking point in oral colchicine treatment is the patient's difficulty swallowing pills. In contrast, Gloperba is an oral liquid colchicine solution that allows adjustable dosing, titration and dosing reduction in comorbid populations with renal or hepatic impairments. Such attributes should improve Gloperba compliance and market adoption, in our view.

Source: Scilex Holding Company.

Gloperba Offers Individualized Colchicine Doses for Gout Patients Who Often Exhibit One or More Comorbid Symptoms



Colchicine mg to GLOPERBA mL Conversion Table

Colchicine (mg)	GLOPERBA (mL)
0.1 mg	0.83 mL
0.2 mg	1.67 mL
0.3 mg	2.5 mL
0.4 mg	3.33 mL
0.5 mg	4.17 mL
0.6 mg	5.0 mL
0.7 mg	5.83 mL
0.8 mg	6.67 mL
0.9 mg	7.5 mL
1.0 mg	8.33 mL
1.1 mg	9.17 mL
1.2 mg	10.0 mL

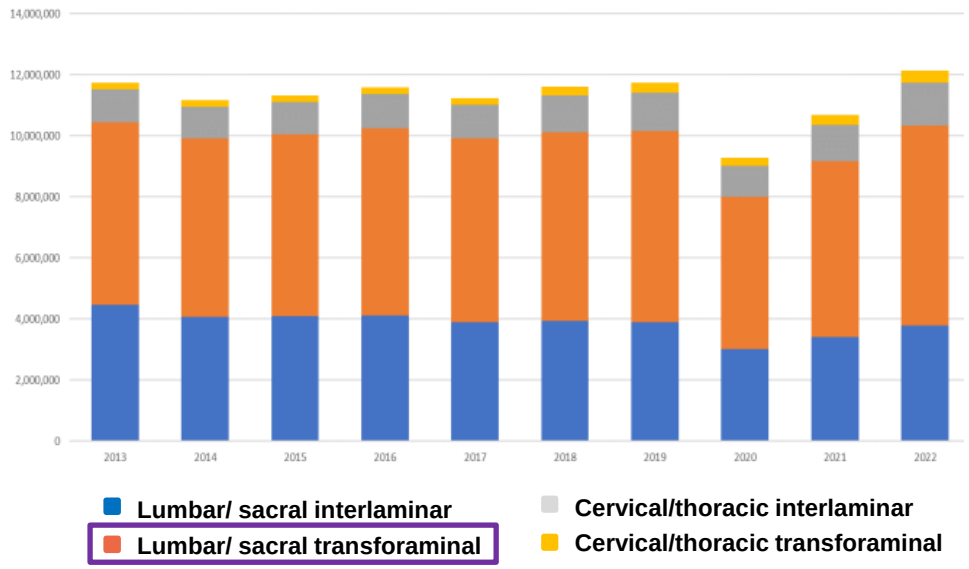
Observational studies revealed correlations between gout triggered by serum urate and other diseases (metabolic syndrome, cardiovascular dysfunction and renal insufficiency), although causal relationships remain unclear. In addition, estimates suggest that over 90% of gout patients have one or more comorbidities. This poses significant challenges to physicians who often want to adjust doses to suit patient needs.

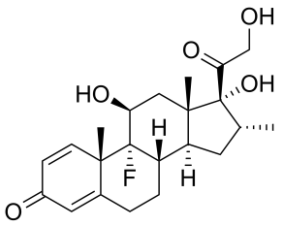
Gloperba is indicated for gout prophylaxis, with a recommended dose of 0.6mg (5mL) once-daily (QD) or twice-daily (BID), with a maximum dose of 1.2mg daily. In addition, Gloperba's unique oral liquid formulation allows simple and precise titration (see above chart), which could be particularly helpful in aged gout patients who exhibit comorbid symptoms. In our view, the ability to deliver colchicine in an oral solution should drive penetration in gout prophylaxis, although not in acute treatment settings.

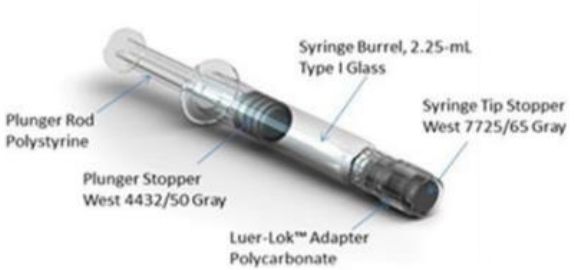
Source: Scilex Holding Company.

5. Forging a New Standard-of-Care in Sciatica With SP-102

ESI Injection Volume (Medicare)





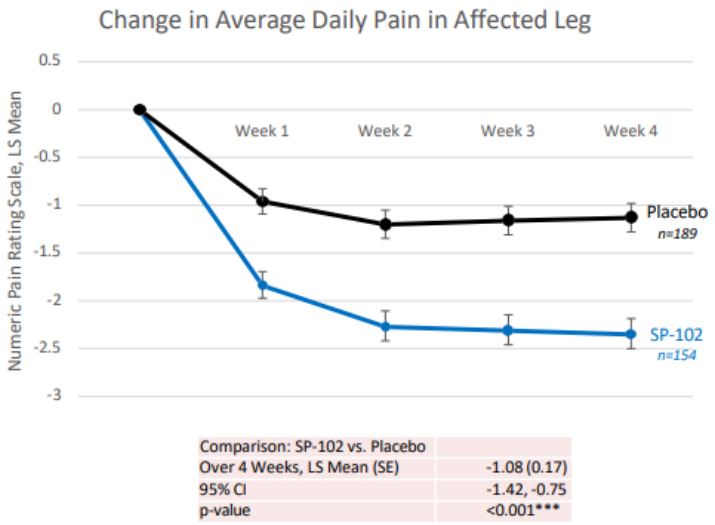


Sciatica (Lumbosacral radicular pain) represents a group of symptoms associated with pain, tingling and numbness in the legs, mainly caused by sciatic nerve injury. Estimated lifetime incidence of sciatica ranges from 10% to 40% in the U.S. (prevalence: ~4.8 million cases). While there is no FDA-approved treatment, epidural steroid injections (ESIs) are commonly used in off-label settings. A key finding from the analysis of 25 placebo-controlled clinical studies suggested that ESIs are efficacious, albeit the effects are small and short-term (days/weeks). In addition, all off-label ESIs carry a warning stating paralysis and/or death. Despite these shortcomings, about 11 million ESIs are delivered annually.

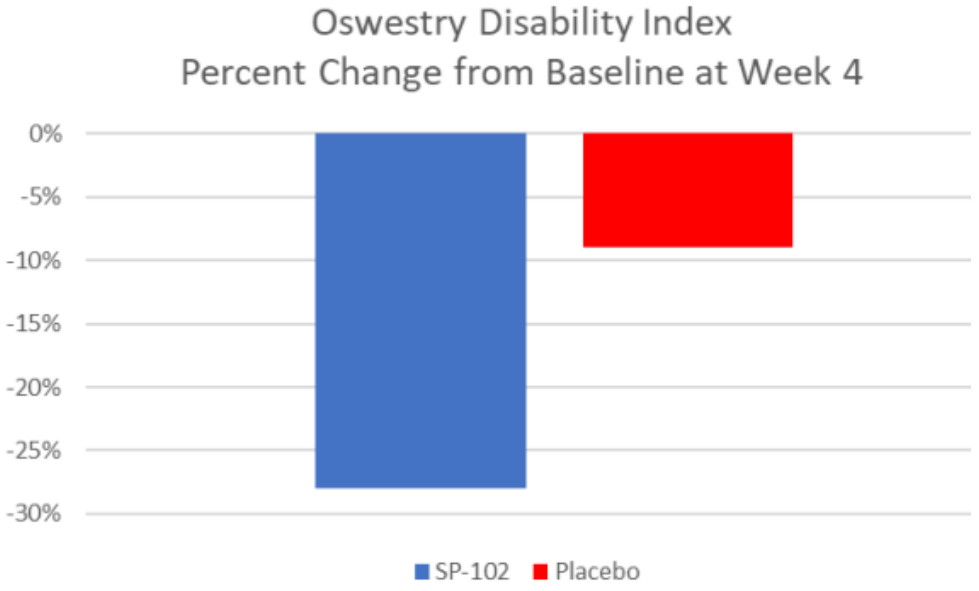
SP-102 (SEMDEXA™)—a novel, viscous gel formulation of widely used dexamethasone—is designed to produce durable pain relief for sciatica in a single injection. Furthermore, since the formulation does not contain any preservatives, surfactants and particulates, SP-102 elicits a benign safety profile (clinical data), suggesting opportunities for rapid market adoption, in our view. Importantly, SP-102 could prevent the need for opioids that are routinely used in advanced sciatica patients despite their questionable clinical impact and well-documented safety risks, in our view.

Source: Scilex Holding Company.

In a Phase 3 Study, SP-102 Demonstrated Clinically Meaningful and Statistically Significant Improvements in Pain Reduction, Suggesting Benefits in Sciatica Patients



Comparison: SP-102 vs. Placebo	
Over 4 Weeks, LS Mean (SE)	-1.08 (0.17)
95% CI	-1.42, -0.75
p-value	<0.001***



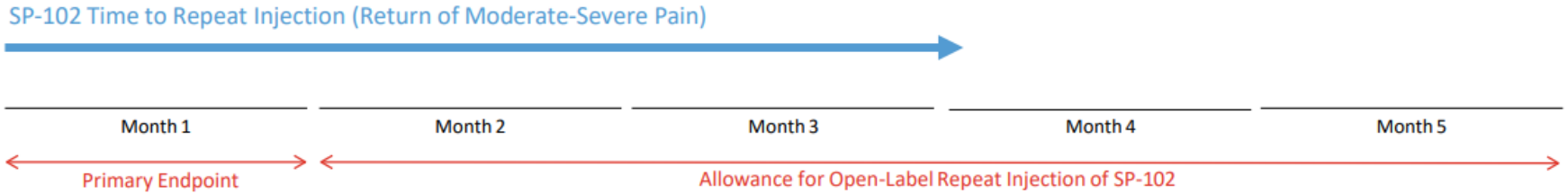
The analysis used a restricted maximum likelihood (REML) based mixed model for repeated measures (MMRM) with fixed effects for treatment (SP-102 or placebo), week, site, Pain Catastrophizing Scale group (<30 or ≥30), baseline averaged daily leg pain score, and treatment-by-week interaction.

On the heels of positive POC findings, a randomized, double-blind, placebo-controlled Phase 3 study was initiated to evaluate the efficacy-risk profile of SP-102 (n=401 total; 40 U.S. sites). Results suggested that a single transforaminal injection of SP-102 resulted in rapid onset of pain relief (primary endpoint), with a -1.08-point improvement against placebo over the first 4 weeks ($p<0.001$). Importantly, the effects were durable, unlike standard-of-care (SOC); the median time to repeat injection was 99 days (95% CI: 78, 129 days).

In addition, SP-102 treatment resulted in a 28% improvement in the Oswestry Disability Index (a measure of the degree of disability and QoL improvement; secondary endpoint) vs. placebo (6%; $p<0.001$). No adverse events of special interest were noted; safety findings were comparable between treatment groups. We believe SP-102 has the characteristics to become the first FDA-approved ESI and could capture the lion's share of the market, given no FDA-approved treatment.

Source: Scilex Holding Company.

SP-102 Represents the High-Water Mark of ESI Durability, With Significant Life Cycle Management Opportunities in Other Indications



SP-102 Life Cycle Management Opportunities	
Carpel tunnel	Hip and knee replacements
Trigger point injections	Complex Regional Pain Syndrome (CRPS)
Injections for knee, shoulders, wrists, articles and joints	Lumbar spinal stenosis
Cervical radiculopathy	Acute spinal injury
Knee arthritis	Discogenic pain

Scilex is slated to have a Type D meeting with the FDA in the coming months so as to secure alignment with the agency regarding SP-102's clinical meaningfulness, safety and clarity on acceptance of the Phase 3 CLEAR study as evidence of efficacy to support registration.

In general, many sciatica patients require four to six ESI procedures, given the limited efficacy profile of off-label agents. From a reimbursement standpoint, payors typically cover only three to four procedures, after which patients will be required to switch to oral therapies or pay out-of-pocket for future ESI procedures. For context, the durability of off-label ESIs ranges from a few days to weeks.

As seen above, results from the Phase 3 CLEAR study suggested that a single SP-102 shot delivered efficacy that lasted for about three months (median durability: ~99 days). We consider the results a high-water mark of ESI durability, which could differentiate SP-102 from competing, oft-risky unapproved agents. Given its once-every-three-months dosing schedule, we believe SP-102 could satisfy payor limits of 3-4 injections per year. SP-102 could also become the first agency-approved ESI, with utility in multiple indications (see table at left), in our view.

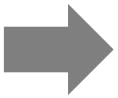
Source: Scilex Holding Company.

6. Multiple Additional Shots on Goal

SP-103—a Triple Strength Version of ZTlido—Could Transform Investors' Thinking About a Traditional Lidocaine Patch and Might Become a Blockbuster Product

Attribute	Details
Study Type	Randomized, double-blind, placebo-controlled, parallel group, multicenter Phase 2 study to evaluate the safety and efficacy of SP-103 in subjects with moderate to severe acute lower back pain (LBP)
Study Size	80 LBP patients at 10 sites across the U.S.
Primary Objective	Adverse events and numeric pain rating
Secondary Objectives	Oswestry Disability Index (Day 7 and 28)
Therapy	Once-daily application of topical SP-103 (5.4%) for 28 days
Future Indications	In addition to LBP, SP-103 could be deployed in strains, sprains and other types of mechanical pain, in our view

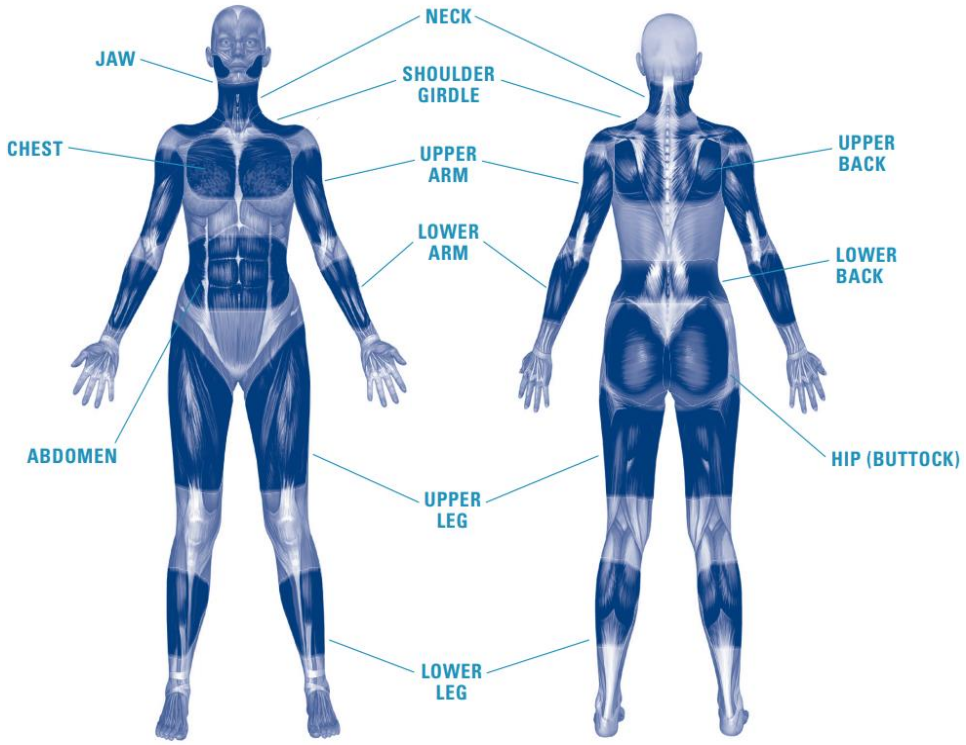
Acute low back pain (LBP) is caused by sudden muscle/ligament injury that supports the back, wherein the pain could last for six to 12 weeks. An estimated 65M U.S. adults suffer from acute LBP. In the 1L setting, patients are often treated with lidocaine patches and/or NSAIDs (either as monotherapy or combined with muscle relaxants, such as cyclobenzaprine), though there is no FDA-approved treatment option. Advanced patients receive opioids, notwithstanding the lack of evidence of benefit and potentially life-threatening side effects. In addition, LBP presents a significant social and economic burden, accounting for 19% of all workers' compensation claims in the U.S., suggesting the need for novel agents.



SP-103—a next-generation patch—delivers three times the drug load of ZTlido (108mg vs. 36mg) in a single topical system. As far as we know, no other topical patches – either approved or in development – deliver this payload level, suggesting differentiation. A Phase 2 study has completed enrollment, with data slated for release in 2H23. We expect the Phase 2 data to show clear evidence of benefit, as SP-103 is built on learnings from FDA-approved ZTlido. However, we acknowledge the often higher-than-expected placebo response in pain indications. Importantly, even a 1% market penetration rate could position SP-103 as a blockbuster (although we only assume peak annual sales for both ZTlido and SP-103 totaling about $570 million).

Source: Scilex Holding Company.

Fibromyalgia Represents a Major Unmet Medical Need



Fibromyalgia affects at least 2% of the adult population in Western countries. Importantly, patients exhibit limited efficacy when treated with SOC, i.e., responders demonstrate a 27% to 40% reduction of symptoms (far below the commonly accepted threshold of 50%).

Fibromyalgia (FM), a musculoskeletal pain disorder, is characterized by fatigue, sleep, memory and mood issues. While its exact cause is unknown, scientists believe an abnormal level of nerve stimulation in the brain and spinal cord accompanied by increased chemicals that mediate pain signaling could trigger the disease progression.

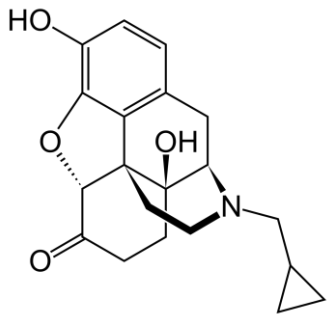
Per CDC, FM affects over 4 million in the U.S., with the majority being women patients. Unfortunately, diagnosing FM is a challenge, given no clinical or laboratory tests. In 2016, The American College of Rheumatology (ACR) provided working definitions for FM diagnosis: a widespread pain index (WPI) score ≥7 and symptom severity scale score (SSS) ≥7; WPI score between 3 and 6 and the SS score ≥ 9; generalized pain in at least of 4 of 5 pre-specified regions (left upper, right upper, axial, left lower and right lower regions) with symptoms lasting for at least three months that could not be correlated with other diseases.

The FDA had originally approved three drugs for fibromyalgia—namely, duloxetine (Cymbalta; Eli Lilly & Co.), pregabalin (Lyrica; Pfizer) and milnacipran (Savella; AbbVie, formerly Cypress Bioscience). However, patient compliance has been poor due to sub-optimal efficacy-risk profiles for all these drugs. In addition, the evidence of opioid use for managing FM symptoms remains uncertain, though it is commonly prescribed for advanced patients. Accordingly, non-opioid agents that exhibit improved efficacy-risk profiles vs. older-line agents are urgently needed.

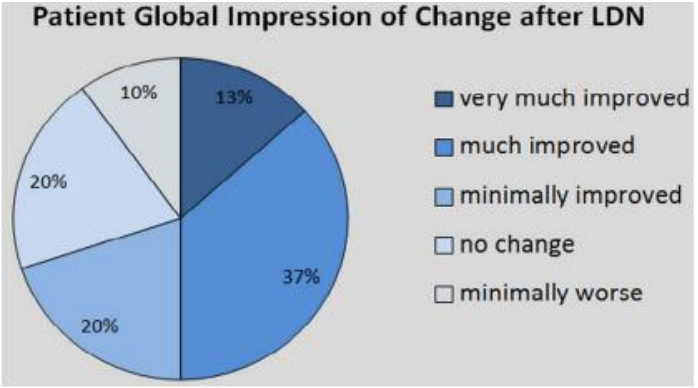
Source: ACR Guidelines; Scilex Holding Company.

SP-104 Could Leverage the Mechanistic Underpinnings of Low-Dose Naltrexone, While Simultaneously Addressing the Caveats of Previously Attempted Agents

Naltrexone



Naltrexone, a competitive antagonist of the opioid receptors, is approved for alcohol and opioid addiction disorders.



In a double-blind, crossover, counterbalanced study (n=30), about 50% of the participants treated with LDN (4.5mg) exhibited a significant pain reduction of pain, suggesting efficacy.

Naltrexone—an FDA-approved drug for the treatment of opioid and alcohol addictions—is a competitive antagonist of the endogenous opioid receptors μ, κ and δ receptors in the CNS that also has an effect on toll-like receptor 4 or TLR4). While a typical dosage ranges between 50 to 100mg, studies suggested that low-dose naltrexone (LDN; 4.5mg; less than 1/10th of the typical dosage required for opioid addiction) exhibited analgesia and anti-inflammatory actions that could be exploited for reducing fibromyalgia symptoms.[1] However, concerns related to pharmacy compounding and GI complications associated with immediate-release drugs precluded further clinical advancement.

Scilex believes that delayed-release, low-dose naltrexone (<1/10th of standard dose) could be patient-friendly (less GI side effects) and eliminate issues related to pharmacy compounding, offering potential benefits to fibromyalgia patients. While such attributes are appealing, our conviction on the prospects of SP-104 is limited at this juncture, given inherent challenges associated with fibromyalgia drug development (e.g., Aptinyx's NYX-2925 failed to achieve statistically significant separation from placebo, despite evidence of drug activity in a prior biomarker study). In our view, positive preliminary POC data might partially de-risk the asset and increase investor confidence.

Source: [1]Younger et al., Clinical Rheumatology (2014).

7. An Extensive and Multi-Faceted Intellectual Property Estate

Scilex's Selected IP Portfolio

Agent	Patent Number	Title	Expiration
ZTlido	US9283174B2	Non-aqueous patch	2031
Gloperba	US9907751B2	Composition and method of use of colchicine oral liquid	2036
Gloperba	US10226423B1	Colchicine drug-to-drug interactions	2037
Elyxyb	US20220202776A1	Methods of treating pain	Pending
SP-102 (Semdexa)	US10744144B2	Pharmaceutical formulation	2034

Scilex possesses a robust patent portfolio (including 16 issued and unexpired U.S. patents and 6 U.S. pending applications) covering compositions, formulations and methods of treatment in both U.S. and ex-U.S. markets. We believe such an IP portfolio provides a lengthy commercial window of opportunity (anticipated expiration between 2031 and 2037, without any extensions).

Note: Only granted U.S. patents are listed.

Source: USPTO.gov.; Scilex Holding Company.

III. Financials

ZTlido Market Model

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
ZTilido™ (topical lidocaine)													
Low concentration (1.8%)	*252'681*	*379'022*	*606'434*	*909'652*	*1'091'582*	*1'200'740*	*1'284'792*	*1'323'336*	*1'124'835*	*731'143*	*402'129*	*180'958*	*135'718*
Mid concentration (3.6%)	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
High concentration (5.4%)	*0*	*0*	*60'000*	*72'000*	*208'800*	*354'960*	*425'952*	*468'547*	*445'120*	*289'328*	*188'063*	*84'628*	*63'471*
Revenue per script (1.8%)	$169.71	$173.95	$178.30	$182.76	$186.42	$190.14	$193.95	$197.83	$201.78	$205.82	$209.93	$214.13	$218.42
Revenue per script (3.6%)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Revenue per script (5.4%)	$0.00	$0.00	$530.00	$543.25	$554.12	$565.20	$576.50	$588.03	$599.79	$611.79	$624.02	$636.50	$649.23
Total annual sales ($MM)	**43**	**66**	**140**	**205**	**319**	**429**	**495**	**537**	**494**	**327**	**202**	**93**	**71**

Source: Company reports and H.C. Wainwright & Co. estimates.

Elyxyb Market Model

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
U.S. Population	338'290'699	340'726'392	343'179'622	345'650'515	348'139'199	350'645'801	353'170'451	355'713'278	358'274'414	360'853'989	363'452'138	366'068'994	368'704'690
% growth	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*
Patients experiencing migraines	38'903'430	39'183'535	39'465'657	39'749'809	40'036'008	40'324'267	40'614'602	40'907'027	41'201'558	41'498'209	41'796'996	42'097'934	42'401'039
% prevalence migraines	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*
Patients prescribed triptans	15'547'832	15'659'777	15'772'527	15'886'089	16'000'469	16'115'672	16'231'705	16'348'574	16'466'283	16'584'840	16'704'251	16'824'522	16'945'658
% patients prescribed triptans	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*	*40%*
Patients on Elyxyb for migraines	933	4'698	7'886	12'709	17'601	25'785	30'840	37'602	44'459	26'536	20'045	13'460	10'167
% penetration	*0.01%*	*0.03%*	*0.05%*	*0.08%*	*0.11%*	*0.16%*	*0.19%*	*0.23%*	*0.27%*	*0.16%*	*0.12%*	*0.08%*	*0.06%*
Annualized price of Elyxyb per patient	4'800	4'944	5'092	5'245	5'402	5'565	5'731	5'903	6'080	6'263	6'451	6'644	6'844
% price growth	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*
Elyxyb sales ($ MM)	**4**	**23**	**40**	**67**	**95**	**143**	**177**	**222**	**270**	**166**	**129**	**89**	**70**

Source: Company reports and H.C. Wainwright & Co. estimates.

Gloperba Market Model

U.S. market	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Chronic gout patients (prevalence)	8'610'752	8'715'182	8'820'395	8'926'449	9'033'352	9'141'110	9'249'731	9'359'274	9'469'749	9'581'163	9'693'523	9'806'895	9'921'287
Patients requiring prophylactic therapy (68%)	5'855'312	5'926'324	5'997'868	6'069'986	6'142'680	6'215'955	6'289'817	6'364'306	6'439'429	6'515'191	6'591'596	6'668'689	6'746'475
Gloperba (liquid colchicine) penetration (%)	0.03%	0.12%	0.26%	0.54%	0.83%	0.97%	1.12%	1.24%	1.45%	1.67%	1.78%	2.12%	2.19%
Number of patients treated	1'622	7'112	15'594	32'778	50'984	60'295	70'446	78'917	93'372	108'804	117'330	141'376	147'748
Estimated annual cost ($)	$4'300	$4'386	$4'474	$4'563	$4'654	$4'748	$4'842	$4'939	$5'038	$5'139	$5'242	$5'347	$5'453
Gloperba sales ($MM)	**$7.0**	**$31.2**	**$69.8**	**$149.6**	**$237.3**	**$286.3**	**$341.1**	**$389.8**	**$470.4**	**$559.1**	**$615.0**	**$755.9**	**$805.7**
Chronic gout patients (incidence)	104'430	105'213	106'055	106'903	107'758	108'620	109'544	110'475	111'414	112'361	113'372	114'392	115'422
Newly-diagnosed refractory gout patients (10%)	10'443	10'521	10'605	10'690	10'776	10'862	10'954	11'047	11'141	11'236	11'337	11'439	11'542
Gloperba (liquid colchicine) penetration (%)	0.3%	1.2%	1.9%	2.4%	2.9%	3.6%	4.2%	4.8%	5.3%	5.9%	6.7%	7.5%	9.2%
Number of newly-diagnosed patients treated	31	126	202	257	312	391	460	530	590	663	760	858	1'062
Accumulated newly-diagnosed patients given Gloperba	31	126	202	458	771	1'162	1'622	2'152	2'742	3'405	3'484	3'645	3'978
Estimated annual cost ($)	$4'300	$4'386	$4'474	$4'563	$4'654	$4'748	$4'842	$4'939	$5'038	$5'139	$5'242	$5'347	$5'453
Gloperba sales ($MM)	**$0.1**	**$0.6**	**$0.9**	**$2.1**	**$3.6**	**$5.5**	**$7.9**	**$10.6**	**$13.8**	**$17.5**	**$18.3**	**$19.5**	**$21.7**
Gloperba sales for treatment of gout ($MM)	**$7**	**$32**	**$71**	**$152**	**$241**	**$292**	**$349**	**$400**	**$484**	**$577**	**$633**	**$775**	**$827**

Source: Company reports and H.C. Wainwright & Co. estimates.

SEMDEXA (SP-102) Market Model

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036
U.S. Population	338'290'699	340'726'392	343'179'622	345'650'515	348'139'199	350'645'801	353'170'451	355'713'278	358'274'414	360'853'989	363'452'138	366'068'994	368'704'690	371'359'364
% growth	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*	*0.72%*
Patients suffering from acute lower back pain	202'974'419	204'435'835	205'907'773	207'390'309	208'883'519	210'387'481	211'902'271	213'427'967	214'964'648	216'512'394	218'071'283	219'641'396	221'222'814	222'815'618
% prevalence of acute lower back pain	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*
Patients undergoing epidural steroid injection (ESI) procedures	10'987'135	11'066'242	11'145'919	11'226'170	11'306'998	11'388'408	11'470'405	11'552'992	11'636'173	11'719'954	11'804'338	11'889'329	11'974'932	12'061'152
% back pain patients undergoing ESI procedures	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*
Patients on SP-102 (dexamethasone injection)	-	3'320	27'865	89'809	248'754	478'313	757'047	1'028'216	1'361'432	1'769'713	2'219'215	2'663'210	3'149'407	2'544'903
% penetration	*0.0%*	*0.03%*	*0.3%*	*0.8%*	*2.2%*	*4.2%*	*6.6%*	*8.9%*	*11.7%*	*15.1%*	*18.8%*	*22.4%*	*26.3%*	*21.1%*
Annualized price of SP-102 per patient		400	412	424	437	450	464	478	492	507	522	538	554	570
% price growth		*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*
SP-102 sales ($ MM)	**-**	**1**	**11**	**38**	**109**	**215**	**351**	**491**	**670**	**897**	**1'158**	**1'432**	**1'744**	**1'451**
Royalty rate payable to Mahendra Shah		**2%**	**2%**	**2%**	**2%**	**2%**	**2%**	**2%**	**2%**	**2%**	**2%**	**2%**	**2%**	**2%**
Milestone payments to Semnur stockholders	**0**	**0**	**0**	**0**	**20**	**20**	**50**	**150**	**0**	**0**	**0**	**0**	**0**	**0**
Net revenue to Scilex from SP-102 sales ($ MM)	**-**	**1**	**11**	**37**	**87**	**191**	**294**	**331**	**656**	**879**	**1'135**	**1'403**	**1'709**	**1'422**
Risk-adjusted revenue to Scilex from SP-102 sales ($ MM)	**-**	**1**	**9**	**30**	**69**	**153**	**235**	**265**	**525**	**703**	**908**	**1'122**	**1'367**	**1'138**

Source: Company reports and H.C. Wainwright & Co. estimates.

Valuation

Scilex Holding Company ($MM except amount per share)	Product	Launch Year	Generic Entry	Peak Sales ($M)	Royalty Rate	Probability To Launch	NPV	Amount Per Share
Neuropathic pain	**ZTlido®**	2018	2039	$537	25% - 35%	100%		
Migraine	**Elyxyb™**	2023	2035	$270		100%		
Chronic gout	**Gloperba®**	2023	2037	$827	8% - 10%	100%		
Acute lower back pain	**SEMDEXA™**	2024	2036	$1'744	2%	80%		
							$3'421	$12.40
Enterprise value							$3'421	$12.40
Debt at end-3Q23							$122	$0.40
Cash at end-3Q23							$51	$0.20
Market value of the firm							$3'350	$12.00

- Using a 10% discount rate and 1.5% terminal growth rate, our discounted cash flow (DCF)-based analysis has resulted in an estimated enterprise value of approximately $3.4 billion. We believe our discount rate assumption is reasonable, considering the substantial size and well-established nature of the target markets in neuropathic pain, migraine, gout and lower back pain as well as the well-known nature of the active pharmaceutical ingredients (APIs) used in each of Scilex's marketed products and its most advanced clinical-stage asset, SEMDEXA. Similarly, we believe that our 1.5% terminal growth rate is reflective of the status of the company's intellectual property (IP) estate plus the indication expansion possibilities with its existing portfolio and may even be considered conservative given the omission from our valuation assessment of any contribution from ex-U.S. sales of any of Scilex's products as well as any other pipeline candidates, notably SP-103 and SP-104.
- We have assumed that Scilex would continue to self-commercialize ZTlido, Elyxyb and Gloperba with its existing proprietary sales force and deploy this infrastructure in order to launch SEMDEXA as well in the U.S. In our view, the company should only need to make incremental additions to its current sales and marketing organization to be sufficiently staffed to support the commercialization of all four products in the U.S.
- The company has several debt instruments outstanding, one of which is associated with issuance of multiple tranches of warrants depending upon the timing of repayment. Assuming roughly 274 million fully-diluted shares outstanding as of end-3Q24 (which assumes issuance of all warrants based on no early debt repayment), this leads to a 12-month price objective of $12 per share.
- Although we have forecasted some generic erosion starting in 2035 or 2036 for all forecasted product sales, we note that there are multiple layers to Scilex's patent estate and the company's proprietary knowledge involves sophisticated formulation expertise that may prove difficult for generic drug makers to replicate. Accordingly, our projections with respect to the timing of generic erosion may prove conservative as well.

Source: Company reports and H.C. Wainwright & Co. estimates.

Discounted Cash Flow Analysis

Fiscal Year Ending	31/12/2023	31/12/2024	31/12/2025	31/12/2026	31/12/2027	31/12/2028	31/12/2029	31/12/2030	31/12/2031	31/12/2032	31/12/2033	31/12/2034	31/12/2035	31/12/2036
Revenue ($MM)	**$53**	**$117**	**$249**	**$430**	**$689**	**$971**	**$1'200**	**$1'358**	**$1'693**	**$1'696**	**$1'794**	**$1'992**	**$2'244**	**$1'724**
EBIT	**($97)**	**($67)**	**$150**	**$260**	**$416**	**$587**	**$725**	**$821**	**$1'023**	**$1'025**	**$1'084**	**$1'203**	**$1'356**	**$1'042**
Less: Taxes	$0	$0	$0	$0	$0	($175)	($216)	($245)	($305)	($306)	($323)	($359)	($405)	($311)
Debt-Free Earnings	**($97)**	**($67)**	**$150**	**$260**	**$416**	**$412**	**$509**	**$576**	**$718**	**$719**	**$760**	**$844**	**$951**	**$731**
Less: Capital Expenditures	($2)	($3)	($7)	($13)	($21)	($29)	($36)	($41)	($51)	($51)	($54)	($60)	($67)	($52)
Less: Working Capital Requirements	($0)	($2)	($4)	($5)	($8)	($8)	($7)	($5)	($10)	($0)	($3)	($6)	($8)	$16
Add: Depreciation and Amortization	$1	$2	$5	$9	$14	$19	$24	$27	$34	$34	$36	$40	$45	$34
Total Net Investment	**($1)**	**($3)**	**($6)**	**($10)**	**($15)**	**($18)**	**($19)**	**($18)**	**($27)**	**($17)**	**($21)**	**($26)**	**($30)**	**($2)**
Net Debt-Free Cash Flows:	**($98)**	**($70)**	**$144**	**$250**	**$402**	**$393**	**$490**	**$557**	**$691**	**$702**	**$740**	**$819**	**$921**	**$729**
Discount Period	0.23	1.23	2.23	3.23	4.23	5.23	6.23	7.23	8.23	9.24	10.24	11.24	12.24	13.24
Discount Factor 10.0%	0.98	0.89	0.81	0.74	0.67	0.61	0.55	0.50	0.46	0.41	0.38	0.34	0.31	0.28
PV of Net Debt-Free Cash Flows:	**($96)**	**($62)**	**$116**	**$184**	**$268**	**$239**	**$270**	**$280**	**$315**	**$291**	**$279**	**$281**	**$287**	**$206**

DCF Assumptions	
Discount Rate	10%
Tax Rate	30%

Growth Rate

Discount Rate	-2.5%	-0.5%	1.5%	3.5%	5.5%
6%	5'011	5'202	5'563	6'502	14'954
8%	4'037	4'123	4'262	4'523	5'204
10%	3'316	3'358	3'421	3'522	3'713
12%	2'760	2'783	2'814	2'860	2'934
14%	2'322	2'335	2'351	2'374	2'408

Perpetuity Growth Assumptions	
2041 Cash Flow (1.5% Growth Rate)	$146.4
Growth Rate	0.02
Terminal Value	**$1'723**
Discount Period	18.24
Discount Factor @ 10.0%	0.18
PV of Terminal Value	**$303**

Distribution of Value	
Period Cash Flow	91.1%
Terminal Cash Flow	8.9%
Total	100.0%

Source: Company reports and H.C. Wainwright & Co. estimates.

Financial Review and Outlook

Revenue

We project $53.4 million in top-line revenue for 2023, rising to $116.6 million in 2024 as Scilex establishes Elyxyb and Gloperba alongside its existing established franchise, ZTlido. In addition, we believe SEMDEXA (SP-102) could be introduced into the U.S. market in late 2024, becoming a modest revenue contributor in that year. This assumption is contingent upon the FDA's willingness to accept a single Phase 3 trial.

Operating expenses

We forecast total R&D spending of $12.7 million in 2023, rising to $18 million in 2024. This reflects the expenses associated with pursuit of regulatory approval for SEMDEXA, along with ongoing spending associated with the advancement of earlier-stage pipeline programs, including conduction of Phase 2 development for SP-103 and SP-104. Our assumptions also include SG&A spending of $114.7 million in 2023, rising to $128 million in 2024. In our view, total annual expenses associated with the company's proprietary in-house specialty sales force should approximate roughly $30 million, even assuming some degree of headcount expansion in this group.

Share Count

Scilex Holding Company closed 2Q23 with approximately 153 million shares of common stock outstanding. The company also has roughly 31.4 million options and about 11 million warrants to purchase common stock outstanding, plus an additional 13 million warrants issuable to a debt holder. The options have a weighted average exercise price of $4.66 per share, while the outstanding warrants are all exercisable at $11.50 per share and the issuable warrants have an exercise price of $0.01 per share.

Balance Sheet

As of June 30, 2023, Scilex had roughly $34.1 million in cash and equivalents on its balance sheet and was eligible to draw an additional $15.6 million in proceeds from its convertible debenture facility as well as other proceeds from a separate loan facility. We expect these resources to be sufficient to fund operations at least into early 2024.

Gross Margin

In our view, Scilex's marketed products and clinical-stage candidates ought to enjoy typical gross margins associated with small molecule ethical pharmaceuticals, which generally are >90%. We have forecast gross margins in the >90% range.

Taxes

Scilex Holding Company is headquartered in Palo Alto, CA. We therefore project an effective tax rate of 29.84%, which corresponds to the 21% statutory federal corporate income tax rate in the U.S. along with the 8.84% corporate income tax rate applicable in California. We have assumed that the company could begin generating taxable income in the 2027 timeframe, with accumulated net operating loss carry-forwards offsetting taxable income until then.

EPS

We project a net loss of $0.72 per share in 2023 and a net loss of $0.35 per share in 2024. In our view, Scilex may not turn cash flow-positive until 2025 depending upon the pace of sales growth for its marketed products and timely launch of SEMDEXA.

Cash Flow

We expect Scilex to remain cash flow-negative for the foreseeable future, as it continues the commercialization of its marketed product portfolio and advances development of its mid- and late-stage clinical candidates. The company may only begin to generate positive cash flow from operations in 2025, depending upon market uptake of ZTlido, Elyxyb and Gloperba as well as timely approval and launch of SEMDEXA. Progress with other agents may drive upside to our forecasts.

Investment Risks

Financial outlook risk

Scilex has never been profitable and may require additional capital in the future to drive the development of its pipeline and finance the acquisition of other products and pipeline candidates. Thus, the company's stock could experience above-average risk and volatility.

Commercial risk

Scilex may not achieve commercial success due to market size, penetration rate or competition. Further, we cannot have absolute certainty that other therapies in development might not be preferred by clinicians, to the detriment of the company's drugs. Sales may lead Scilex to profitability but may differ materially from our projections. Scilex may need to seize market share from substantially more significant, more established firms, which might prove challenging.

Regulatory unpredictability

The regulatory process involves the submission of large amounts of clinical and preclinical data, and there is no guarantee that such data sets, even if furnished, would be sufficient for FDA approval. Applications for approval in the EU may require additional studies, including increased numbers of European patients.

Reimbursement risk

The U.S. drug pricing environment is subject to constant change and is currently the basis of controversy. We do not expect the debate over drug pricing to subside near-term in the U.S. In other countries, reimbursement is subject to tighter controls due to budgetary concerns and single-payer healthcare systems. Accordingly, achieving reasonable pricing may not be possible ex-U.S.

Competitive landscape risk

Scilex is primarily developing novel non-opioid drugs for pain management. Although we find the preclinical and clinical data encouraging, this cannot be considered a guarantee of future clinical or commercial success in the context of the preclinical nature of the data and the current competitive landscape. The company's key competitors include both small and established commercial entities, including firms like Amgen, AbbVie, Axsome, Eli Lilly & Co., Pfizer, Teva, Viatris and others.

Intellectual property risk

Scilex's IP estate includes include 16 approved U.S. patents (6 pending U.S. applications) that are slated to expire between 2031 and 2037. Scilex relies on patents and trade secrets to protect its products from competition, which is rife. In extreme cases, this may lead to lawsuits in the pursuit of protection of IP. There can be no guarantee that Scilex, if a party to such litigation, would prevail against potential opponents.

Historical Income Statement and Financial Projections

FY end December 31
$ in thousands, except per share data

	2022A	2023E 1QA	2023E 2QA	2023E 3QE	2023E 4QE	2023E	2024E 1QE	2024E 2QE	2024E 3QE	2024E 4QE	2024E
Revenue											
Product revenue	38'034	10'582	12'582	13'948	16'252	53'364	18'785	24'964	32'332	40'537	116'618
Service revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-	-
Total revenue	38'034	10'582	12'582	13'948	16'252	53'364	18'785	24'964	32'332	40'537	116'618
Expenses											
Cost of product and service revenue	10'797	3'591	4'177	4'882	5'851	18'501	6'011	7'739	9'376	10'945	34'071
Research & development	9'054	2'736	3'204	3'300	3'500	12'740	3'800	4'200	4'700	5'300	18'000
Selling, general and administrative	64'895	28'701	26'989	29'000	30'000	114'690	32'000	32'000	32'000	32'000	128'000
Intangible amortization	3'922	1'027	1'026	1'000	1'000	4'053	800	800	800	800	3'200
Total expenses	88'668	36'055	35'396	38'182	40'351	149'984	42'611	44'739	46'876	49'045	183'271
Gain (loss) from operations	(50'634)	(25'473)	(22'814)	(24'234)	(24'099)	(96'620)	(23'826)	(19'775)	(14'544)	(8'508)	(66'653)
Other income/expense											
Interest income/expense	(9'604)	1	(5)	(1'700)	(2'292)	(3'996)	(1'950)	(1'490)	(1'050)	(480)	(4'970)
Gain (loss) on derivative liability	8'310	(5'253)	(82)	-	-	(5'335)	-	-	-	-	-
Gain (loss) on debt extinguishment	28'634	-	-	-	-	-	-	-	-	-	-
Scilex Notes principal / debenture fair value change	-	-	(3'748)	-	-	(3'748)	-	-	-	-	-
Loss (gain) on foreign currency exchange	(66)	(20)	(3)	-	-	(23)	-	-	-	-	-
Total investment income and other	27'274	(5'272)	(3'838)	(1'700)	(2'292)	(13'102)	(1'950)	(1'490)	(1'050)	(480)	(4'970)
Loss before provision for income taxes	(23'360)	(30'745)	(26'652)	(25'934)	(26'391)	(109'722)	(25'776)	(21'265)	(15'594)	(8'988)	(71'623)
Deferred income tax benefit	(4)	(8)	-	-	-	(8)	-	-	-	-	-
Net loss/income	(23'364)	(30'753)	(26'652)	(25'934)	(26'391)	(109'730)	(25'776)	(21'265)	(15'594)	(8'988)	(71'623)
Net loss per share (basic)	(0.17)	(0.22)	(0.19)	(0.16)	(0.16)	(0.72)	(0.14)	(0.11)	(0.07)	(0.04)	(0.35)
Net loss per share (diluted)	(0.17)	(0.22)	(0.19)	(0.16)	(0.16)	(0.72)	(0.14)	(0.11)	(0.07)	(0.04)	(0.35)
Weighted average number of shares outstanding (basic)	134'226	141'660	142'626	158'725	168'775	152'946	183'850	198'950	209'050	219'150	202'750
Weighted average number of shares outstanding (diluted)	134'226	141'660	142'626	158'725	168'775	152'946	183'850	198'950	209'050	219'150	202'750

Source: Company reports and H.C. Wainwright & Co. estimates.

Historical Balance Sheet and Financial Projections

FY end December 31
$ in thousands, except per share data

		2023E					2024E				
	12/31/22A	3/31A	6/30A	9/30	12/31	12/31/23E	3/31	6/30	9/30	12/31	12/31/24E
Assets											
Current assets:											
Cash and cash equivalents	2'184	5'069	34'122	51'428	30'573	30'573	94'097	78'432	162'438	159'050	159'050
Accounts receivable	21'236	19'244	27'568	27'568	27'568	27'568	27'568	27'568	27'568	27'568	27'568
Inventories	1'378	2'275	3'110	3'110	3'110	3'110	3'110	3'110	3'110	3'110	3'110
Other assets and prepaid expenses	4'810	4'516	4'447	4'447	4'447	4'447	4'447	4'447	4'447	4'447	4'447
Total current assets	29'608	31'104	69'247	86'553	65'698	65'698	129'222	113'557	197'563	194'175	194'175
Property and equipment	772	762	760	(276)	(1'312)	(1'312)	(1'912)	(2'512)	(3'112)	(3'712)	(3'712)
Intangible assets	40'591	39'564	38'538	38'538	38'538	38'538	38'538	38'538	38'538	38'538	38'538
Operating lease right-of-use asset	1'131	987	3'294	3'294	3'294	3'294	3'294	3'294	3'294	3'294	3'294
Goodwill	13'481	13'481	13'481	13'481	13'481	13'481	13'481	13'481	13'481	13'481	13'481
Other assets	944	153	1'144	1'144	1'144	1'144	1'144	1'144	1'144	1'144	1'144
Total Assets	86'527	86'051	126'464	142'734	120'843	120'843	183'767	167'502	250'908	246'920	246'920
Liabilities and shareholder equity											
Current liabilities											
Accounts payable	8'450	9'817	11'412	11'412	11'412	11'412	11'412	11'412	11'412	11'412	11'412
Accrued expenses	3'136	6'679	4'949	4'949	4'949	4'949	4'949	4'949	4'949	4'949	4'949
Accrued payroll and rebates	32'247	37'342	50'531	50'531	50'531	50'531	50'531	50'531	50'531	50'531	50'531
Current portion of deferred consideration	264	391	516	516	516	516	516	516	516	516	516
Current portion of long-term debt	-	9'600	35'399	35'399	35'399	35'399	35'399	35'399	35'399	35'399	35'399
Other current liabilities	745	773	776	776	776	776	776	776	776	776	776
Total current liabilities	44'842	64'602	103'583	103'583	103'583	103'583	103'583	103'583	103'583	103'583	103'583
Operating lease liabilities	665	6'484	2'594	2'594	2'594	2'594	2'594	2'594	2'594	2'594	2'594
Other long-term liabilities	163	168	169	169	169	169	169	169	169	169	169
Long-term portion of deferred consideration	3'387	3'260	3'135	3'135	3'135	3'135	3'135	3'135	3'135	3'135	3'135
Derivative liabilities	1'231	461	6'566	6'566	6'566	6'566	6'566	6'566	6'566	6'566	6'566
Total Liabilities	50'288	74'975	116'047	116'047	116'047	116'047	116'047	116'047	116'047	116'047	116'047
Shareholder's equity											
Common and preferred stock	17	18	18	38	38	38	68	68	88	89	89
Additional paid-in capital	412'136	417'725	443'715	480'895	480'895	480'895	564'565	564'565	658'545	658'545	658'545
Accumulated income (deficit)	(375'914)	(406'667)	(433'316)	(454'246)	(476'137)	(476'137)	(496'913)	(513'178)	(523'772)	(527'760)	(527'760)
Total shareholder's equity	36'239	11'076	10'417	26'687	4'796	4'796	67'720	51'455	134'861	130'873	130'873
Total liability and shareholder's equity	86'527	86'051	126'464	142'734	120'843	120'843	183'767	167'502	250'908	246'920	246'920

Source: Company reports and H.C. Wainwright & Co. estimates.

Cash Flow Statement and Financial Projections

FY end December 31
$ in thousands, except per share data

	2022A	2023E 1QA	2023E 2QA	2023E 3QE	2023E 4QE	2023E	2024E 1QE	2024E 2QE	2024E 3QE	2024E 4QE	2024E
Cash flows from operating activities											
Net loss	(23'364)	(30'753)	(26'652)	(25'934)	(26'391)	(109'730)	(25'776)	(21'265)	(15'594)	(8'988)	(71'623)
Adjustments for:											
Stock-based compensation	5'280	3'720	3'587	4'000	4'500	15'807	5'000	5'000	5'000	5'000	20'000
Depreciation & amortization	3'961	1'037	1'036	1'036	1'036	4'145	600	600	600	600	2'400
Accreted interest related to debt discount	(21'190)	-	1	-	-	1	-	-	-	-	-
Amortization of debt issuance costs and debt discount	3'142	-	-	-	-	-	-	-	-	-	-
(Gain) loss on debt extinguishment, net	(28'634)	-	-	-	-	-	-	-	-	-	-
(Gain) loss on derivative liability	(8'310)	5'253	82	-	-	5'335	-	-	-	-	-
Change in fair value of convertible debentures	-	-	3'748	-	-	3'748	-	-	-	-	-
Forfeitures of private warrants	1'697	-	-	-	-	-	-	-	-	-	-
Other non-cash expense	492	144	(5)	-	-	139	-	-	-	-	-
Change in operating assets & liabilities											
Accounts receivable	(6'968)	1'992	(8'324)	-	-	(6'332)	-	-	-	-	-
Inventory	1'184	(897)	(835)	-	-	(1'732)	-	-	-	-	-
Prepaid expenses and other current assets	(2'629)	294	(303)	-	-	(9)	-	-	-	-	-
Other non-current assets	350	997	(193)	-	-	804	-	-	-	-	-
Accounts payable	2'806	2'001	2'333	-	-	4'334	-	-	-	-	-
Accrued payroll, rebates and fees	21'152	5'095	13'189	-	-	18'284	-	-	-	-	-
Accrued expenses	(123)	3'543	(2'018)	-	-	1'525	-	-	-	-	-
Other liabilities	(392)	(175)	(163)	-	-	(338)	-	-	-	-	-
Related party payable	30'125	-	1'043	-	-	1'043	-	-	-	-	-
Other long-term liabilities	163	5	1	-	-	6	-	-	-	-	-
Total change in operating assets & liabilities	45'668	12'855	4'730	-	-	17'585	-	-	-	-	-
Cash flows from operating activities	**(21'258)**	**(7'744)**	**(13'473)**	**(20'898)**	**(20'855)**	**(62'970)**	**(20'176)**	**(15'665)**	**(9'994)**	**(3'388)**	**(49'223)**
Cash flows from investing activities											
Investment in PPE	(7)	-	(8)	-	-	(8)	-	-	-	-	-
Intangible asset acquisition consideration	(2'060)	-	-	-	-	-	-	-	-	-	-
Cash flows from investing activities	**(2'067)**	**-**	**(8)**	**-**	**-**	**(8)**	**-**	**-**	**-**	**-**	**-**
Cash flows from financing activities											
Proceeds from business combination	3'375	-	-	-	-	-	-	-	-	-	-
Transaction costs paid related to business combination	(2'949)	(634)	(738)	-	-	(1'372)	-	-	-	-	-
Proceeds from loans	9'857	9'600	7'938	-	-	17'538	-	-	-	-	-
Proceeds from convertible debentures	-	-	24'000	-	-	24'000	-	-	-	-	-
Exercise of stock options	96	-	-	-	-	-	-	-	-	-	-
Payment of debt issuance costs	-	-	(380)	-	-	(380)	-	-	-	-	-
Repayment of principal on notes	(84'808)	-	-	-	-	-	-	-	-	-	-
Repayment on other loans	(18'800)	-	(2'528)	-	-	(2'528)	-	-	-	-	-
Proceeds from related party payable	51'900	-	-	-	-	-	-	-	-	-	-
Proceeds from related party note payable	62'500	-	-	-	-	-	-	-	-	-	-
Proceeds from issuance of common stock and warrants	-	1'663	15'246	37'200	-	54'109	83'700	-	94'000	-	177'700
Cash flows from financing activities	**21'171**	**10'629**	**43'538**	**37'200**	**-**	**91'367**	**83'700**	**-**	**94'000**	**-**	**177'700**
Net increase/ decrease in cash and cash equivalents	**(2'154)**	**2'885**	**30'057**	**16'302**	**(20'855)**	**28'389**	**63'524**	**(15'665)**	**84'006**	**(3'388)**	**128'477**
Cash and cash equivalents, beginning of period	4'338	2'184	5'069	35'126	51'428	2'184	30'573	94'097	78'432	162'438	30'573
Cash and cash equivalents, end of period	2'184	5'069	35'126	51'428	30'573	30'573	94'097	78'432	162'438	159'050	159'050

Source: Company reports and H.C. Wainwright & Co. estimates.

Public Companies Mentioned in this Report

AbbVie (ABBV; not rated)
Amgen (AMGN; not rated)
Aptinyx (APTX; not rated)
Axsome Therapeutics (AXSM; Buy)
BeyondSpring (BYSI; not rated)
Collegium Pharmaceuticals (COLL; Neutral; Livnat)
CVS Health Corporation (CVS; not rated)
Dr. Reddy's Laboratories Ltd. (RDY; not rated)
Eli Lilly & Co. (LLY; not rated)
Endo International plc (OTC: ENDPQ; not rated)
Pacira BioSciences (PCRX; Buy; Livnat)
Pfizer (PFE; not rated)
Teva Pharmaceutical Industries Ltd. (TEVA; not rated)
Viatris Inc. (VTRS; not rated)

Important Disclaimers

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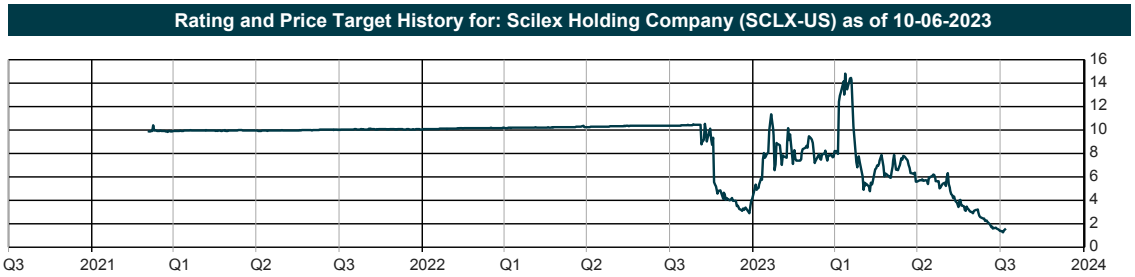
H.C. WAINWRIGHT & CO, LLC RATING SYSTEM: H.C. Wainwright employs a three tier rating system for evaluating both the potential return and risk associated with owning common equity shares of rated firms. The expected return of any given equity is measured on a RELATIVE basis of other companies in the same sector. The price objective is calculated to estimate the potential movements in price that a given equity could reach provided certain targets are met over a defined time horizon. Price objectives are subject to external factors including industry events and market volatility.

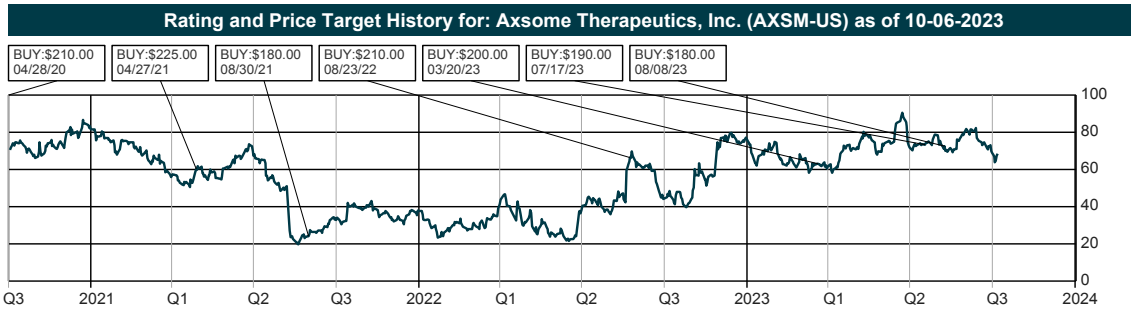
RETURN ASSESSMENT

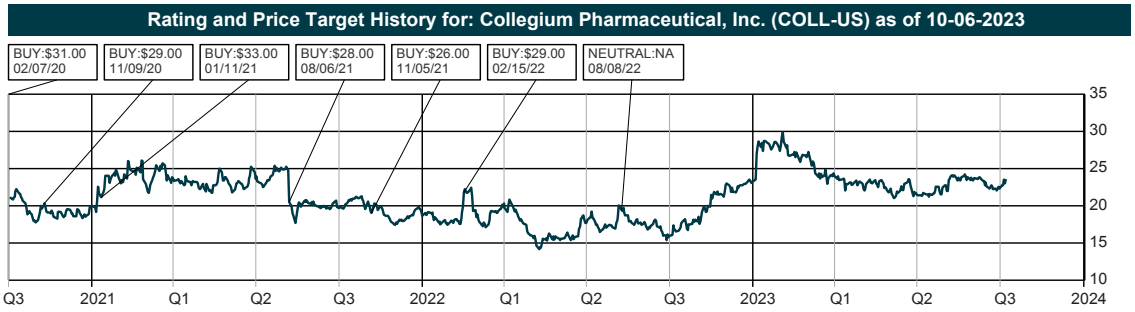
Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

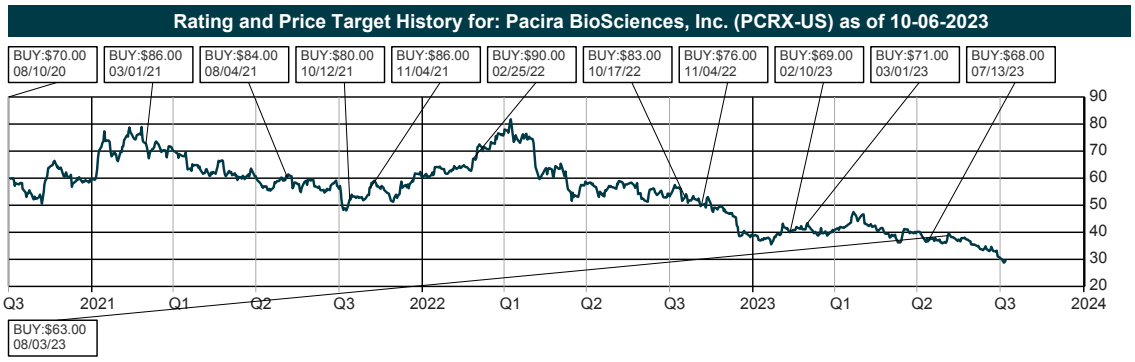
Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

Market Underperform (Sell): The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.








Rating and Price Target History for: Pacira BioSciences, Inc. (PCRX-US) as of 10-06-2023
BUY:$70.00 08/10/20
BUY:$86.00 03/01/21
BUY:$84.00 08/04/21
BUY:$80.00 10/12/21
BUY:$86.00 11/04/21
BUY:$90.00 02/25/22
BUY:$83.00 10/17/22
BUY:$76.00 11/04/22
BUY:$69.00 02/10/23
BUY:$71.00 03/01/23
BUY:$68.00 07/13/23
BUY:$63.00 08/03/23
90
80
70
60
50
40
30
20
Q3 2021 Q1 Q2 Q3 2022 Q1 Q2 Q3 2023 Q1 Q2 Q3 2024

Related Companies Mentioned in this Report as of Oct/06/2023					
Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap
Axsome Therapeutics, Inc.	AXSM	Buy	$180.00	$68.60	$3237
Collegium Pharmaceutical, Inc.	COLL	Neutral	$NA	$23.60	$820
Pacira BioSciences, Inc.	PCRX	Buy	$63.00	$29.80	$1383

Investment Banking Services include, but are not limited to, acting as a manager/co-manager in the underwriting or placement of securities, acting as financial advisor, and/or providing corporate finance or capital markets-related services to a company or one of its affiliates or subsidiaries within the past 12 months.

Distribution of Ratings Table as of October 6, 2023				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	561	89.05%	144	25.67%
Neutral	61	9.68%	11	18.03%
Sell	0	0.00%	0	0.00%
Under Review	8	1.27%	3	37.50%

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