

Innovative Leader in Non-Opioid
Pain Therapeutics
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Innovative Non-Opioid Pain Therapeutics

KEY PROGRAMS	PRECLINICAL PHASE 1 PHASE 2 PHASE 3 / PIVOTAL APPROVE	D 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 2024: U.S. launch
ELYXYB® (celecoxib) oral solution (Acute Treatment of Migraine)	Approved for acute treatment of migraine		 1Q 2023: In-licensed U.S. / Canadian rights 2Q 2023: U.S. launch
	Expected to file acute pain indication with FDA in 1Q 2024	■ 2036	 4Q 2023: Canada filing Expected 1Q 2024: Acute pain filing
SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)	Fast Track	■ 2036	 1H 2022: Phase III achieved endpoints 2H 2023: FDA agreed on NDA path
SP-103 Lidocaine Topical System 5.4% (3X) (Chronic Neck Pain)	Fast Track	■ 2031	 2Q 2023: Completed Phase II trial. 4Q 2023 / Q1 2024: File Fast Track for neck pain 3Q 2022: Received Fast Track for low back pain
SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)	Prepare Phase II Trial	2 041	 1H 2022: Completed Phase I trial(s) 2024: Initiate Phase II trials



Innovative Non-Opioid Pain Therapeutics

Platform	Program	Indications	Route	Status	Market Size	Future Partner Opportunity
Non-Opioid Pain Management	ZTlido® 1.8% (Postherpetic Neuralgia-PHN)	Relief of Pain Associate with PHN	Skin Patch	Approved	\$1.9B+ (WW)	Worldwide Rights, except for Japan
	GLOPERBA® (colchicine USP) oral solution (Treatment of Gout)	Treatment to Prevent Gout Flares	Oral Liquid	Approved	\$8.0B+ (WW)	U.S. Rights
	ELYXYB® (celecoxib) oral solution (Acute Treatment of Migraine)	Treatment of acute migraine, with or without aura, in adults	Oral Liquid	Approved	\$1.8B+ (WW)	U.S. and Canada Rights
		Treatment of pediatric migraine	Oral Liquid	Phase 3	\$1.8B+ (WW)	U.S. and Canada Rights
		Treatment of acute pain	Oral Liquid	NDA filing	\$7B+ (WW)	U.S. and Canada Rights
	SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)	Potential Treatment for LRP/Sciatica I	Epidural Injection	pre-NDA	\$18.0B+ (WW)	Worldwide Rights
	SP-103 Lidocaine Topical System 5.4% (3X) (Chronic Neck Pain)	Potential Treatment for Chronic Neck F	Skin Patch	Phase 2/3	\$10.0B+ (WW)	Worldwide Rights, except for Japan
	SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)	Potential Treatment for Fibromyalgia	Oral	Phase 2 ready	\$3.0B+ (WW)	Worldwide Rights



ZTlido

(1.8% lidocaine topical system equivalent to 5% lidocaine for the treatment of Postherpetic Neuralgia-PHN related pain)

Sales Performance Fiscal Year 2023 vs. 2022



- ZTlido gross sales for the fiscal year ended December 31, 2023 were in the range of \$145.0 million to \$150.0 million, compared to \$96.0 million for the fiscal year ended December 31, 2022, representing growth in the range of approximately 51% to 56%.
- ZTlido net sales for the fiscal year ended December 31, 2023 were in the range of \$46.0 million to \$52.0 million, compared to \$38.0 million for the fiscal year ended December 31, 2022, representing growth in the range of approximately 21% to 37%.
- Total product gross sales for the fiscal year ended December 31, 2023 were in the range of \$150.0 million to \$155.0 million, compared to \$96.0 million for the fiscal year ended December 31, 2022, representing growth in the range of approximately 56% to 61%.
- Total product net sales for the fiscal year ended December 31, 2023 were in the range of \$46.5 million to \$52.5 million, compared to \$38.0 million for the fiscal year ended December 31, 2022, representing growth in the range of approximately 22% to 38%.



ZTlido Commercialization Success





ZTlido® 1.8% (FDA approved for relief of PHN pain)

- Lidocaine Patch Market Overview
 - +4.6mm prescriptions in 2022
 - +169mm prescription lidocaine patches sold in the U.S. in 2022¹
- **2** Benefits versus Other Lidocaine Patches
 - Superior adhesion compared to other lidocaine patches head-to-head studies
 - Only lidocaine patch proven in moderate exercise
- 3 How does it compare to Lidoderm (5%)

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

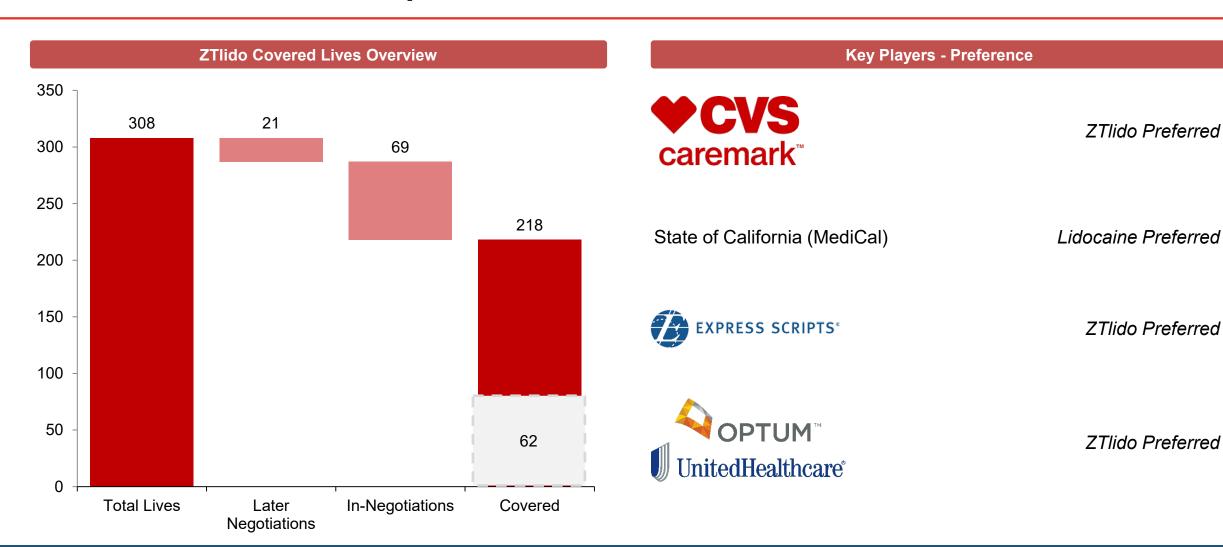


- Only ZTlido delivers a 12-hour adhesion in a non-opioid therapy
- Superior adhesion versus other lidocaine patches in various headto-head studies
- Only lidocaine patch proven in moderate exercise
- Savings & support system makes it easy to receive inexpensive monthly prescription

(1) Symphony Healthcare

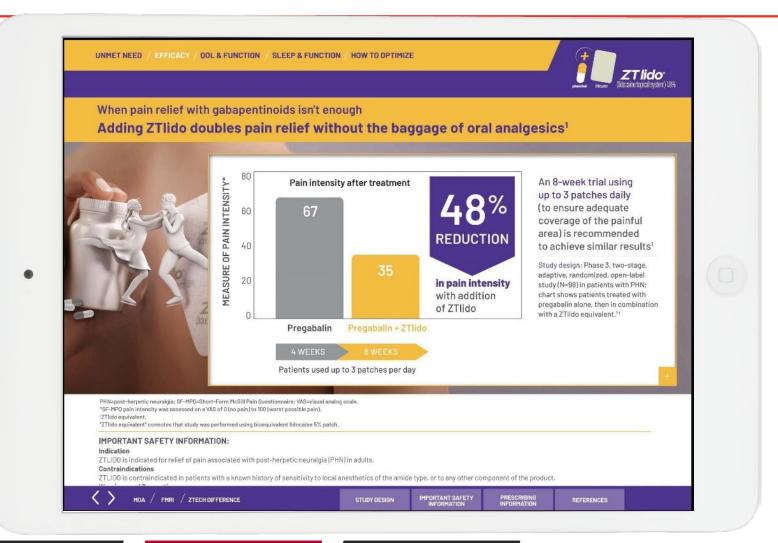


ZTlido Market Access Update



The ZTlido Solution to the Unmet Need with Gabapentinoids





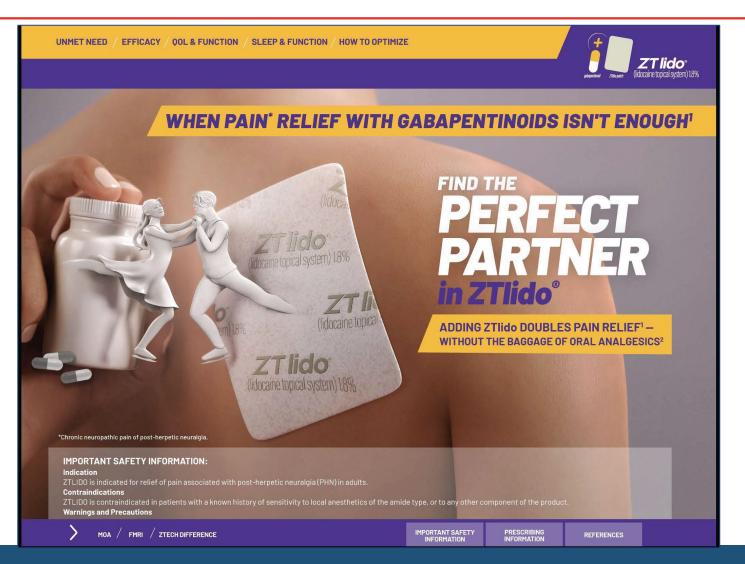


PRODUCT

10

The ZTIido New Campaign as the ideal add-on to Gabapentinoids

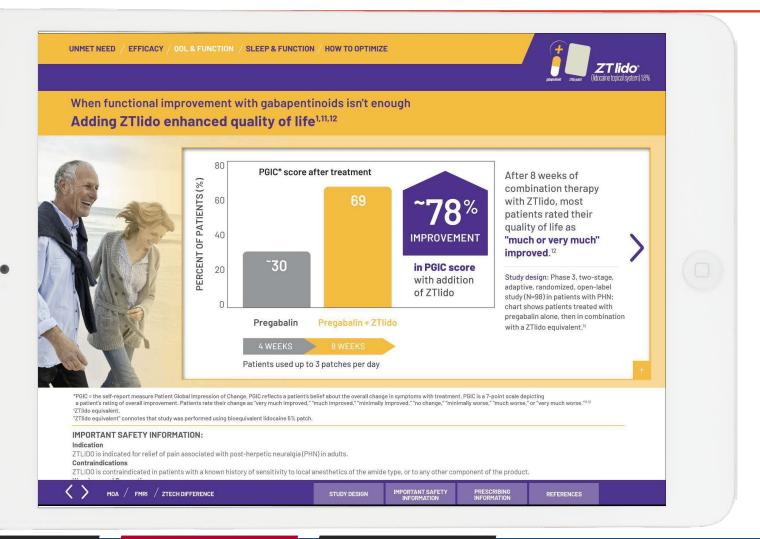




- Designed to allow the brand to achieve its true potential by repositioning from Adhesion to Efficacy)
- ZTlido is uniquely capable of optimizing gabapentinoids – doubling efficacy without the baggage/side effects of other analgesic options (opioids, TCAs, SNRIs, NSAIDs, Acetaminophen).
- This combination efficacy data is "new' as HCPs are unaware of it we can own the data as we believe we the only lidocaine patch being actively promoted.
- Aligns with managed care thinking (step edit ZTlido through gabapentinoids)
- Takes us into a 10X bigger market (gabapentinoids) than the lidocaine patch market

Enhanced Patient Quality of Life







PEOPLE

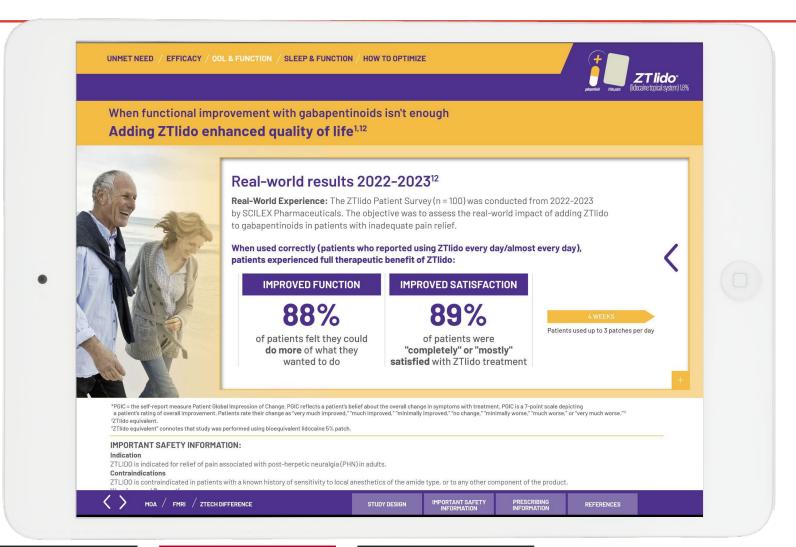


PRODUCT

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Enhanced Patient Quality of Life: Real World Evidence







PEOPLE



PRODUCT

13



Elyxyb (celecoxib) oral solution (Acute Treatment of Migraine)



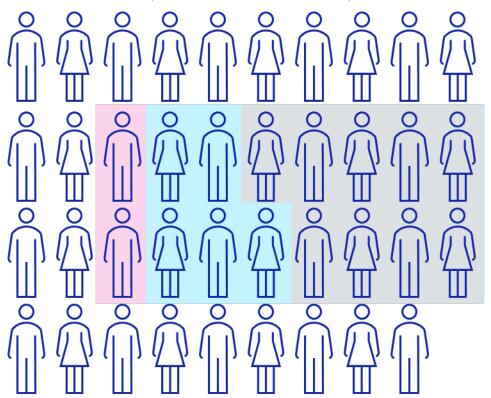
Elyxyb Launched in USA April 2023





Approximately 39M People with Migraine in the US

~39M Prevalence* (Total Patients, 2021)



~43%

~16.8M Patients Diagnosed with Migraine

~36%

~14.0M Patients receiving treatment

~23%

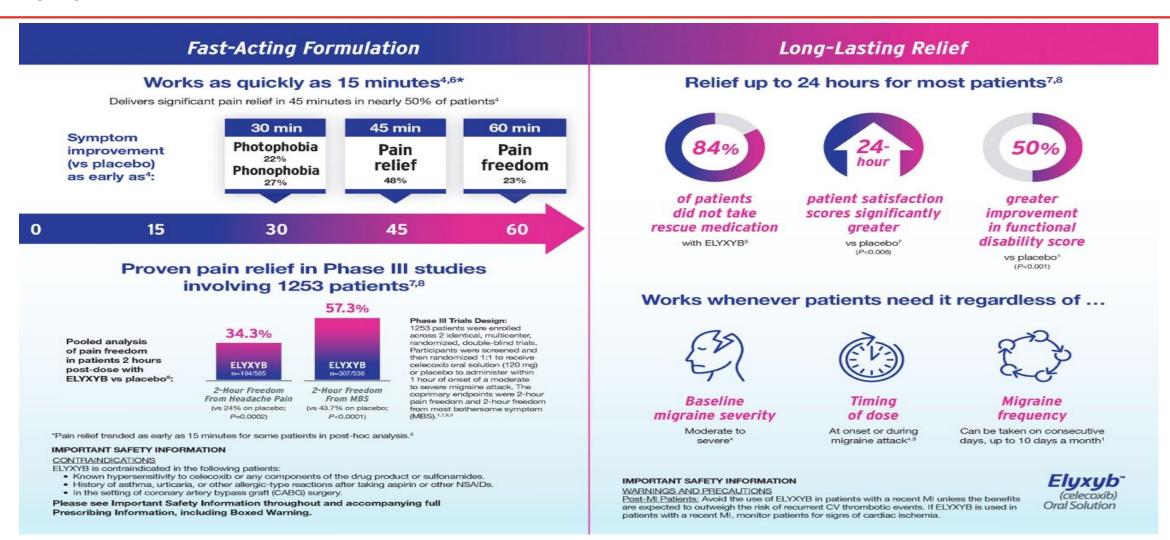
~9.0M Patients treated acutely (Target patient pool)

Some patients may receive both acute as well as preventive treatment

Source: Prevalence by Migraine Research Foundation, 2021; Epidemiology data by DRG



Elyxyb Promotion Materials







Your Go-To COX-2 Solution for Migraine Relief 1.5

Consider ELYXYB for patients who:



Have Contraindications to Triptans

When triptans are contraindicated (uncontrolled hypertension, heart attack, coronary artery disease, peripheral vascular disease)^{11,12}



Experience Breakthrough Migraine

For patients on acute or preventive treatment who are experiencing breakthrough symptoms



Are Dissatisfied With Current Treatment

As many as 40% of people with migraine report dissatisfaction with their current treatment¹³

IMPORTANT SAFETY INFORMATION about ELYXYB™

WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use.
- o ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration, and Perforation

o NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events.

Please see Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.

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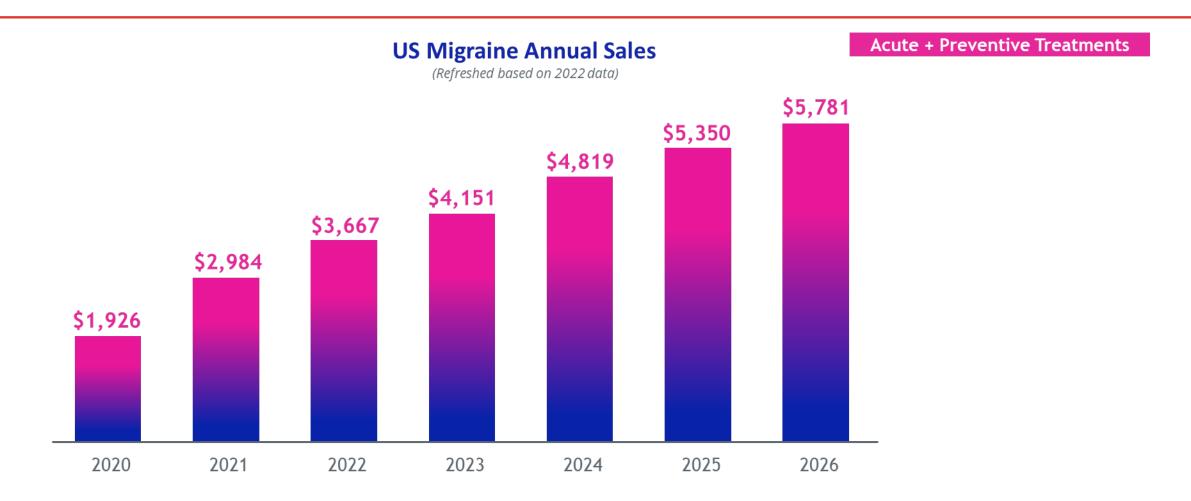
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The US Migraine Market Is Projected To Grow By 195% Between 2021 to 2026

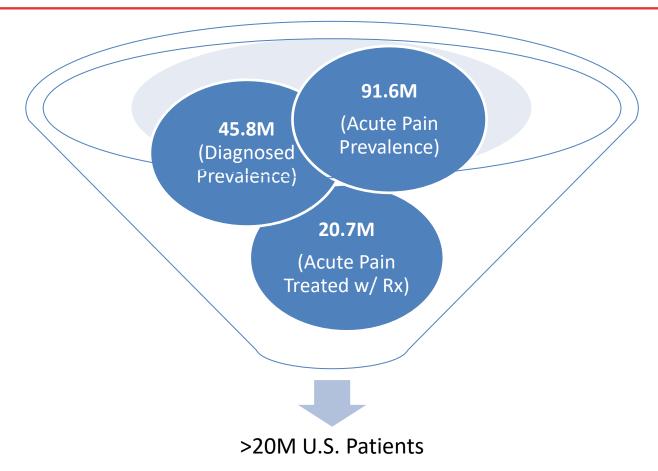




Source: Evaluate; Above data includes both acute and preventative therapies; Data refreshed in January 2022

Elyxyb Acute Pain Opportunity: Market Size





Large market opportunity for Elyxyb in Acute Pain





Key Unmet Needs in Acute Pain:

Fast onset

Need for safer and more effective treatments

Non-Opioid alternatives



Gloperba

(colchicine USP) oral solution (For the prevention of painful gout flares in adults)

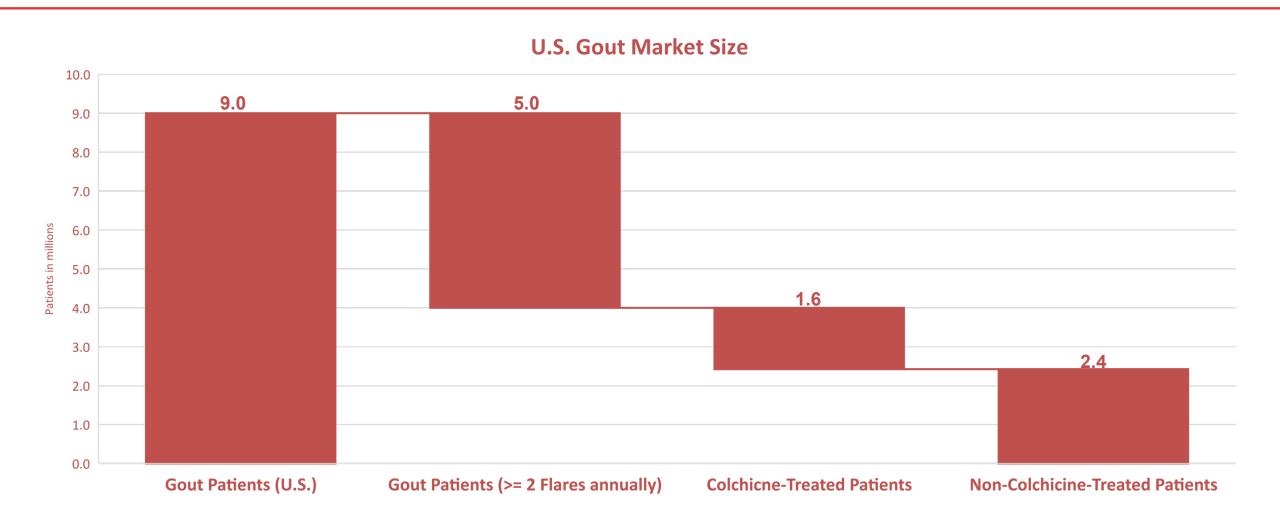


Gloperba Launch in USA Planned in 2024





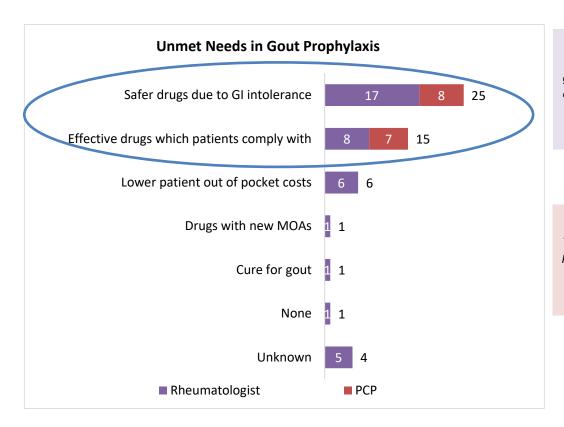




Gout Unmet Needs



Physicians are generally satisfied with the currently available prophylactic gout treatments, particularly colchicine. However, physicians acknowledged that colchicine's ability to cause adverse GI events along with the caution that must be taken when prescribing it to patients with comorbidities warrant new drugs with significantly improved safety profiles.



"A drug that doesn't have any GI adverse events would be good. It should have no side effects. It can't cause toxicity either, considering [tablet] colchicine is already effective."

- Rheumatologist

"There is an unmet need for drugs that can be used in patients who can't tolerate the GI side effects."

- PCP

"Patients don't always adhere to colchicine. We need drugs that patients will take without the GI side effects. Otherwise, it's a very effective drug."

- Rheumatologist

n=39

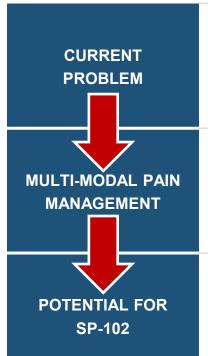


SP-102 (SEMDEXA)

Treatment of Chronic Low Back
Pain/ Sciatica



Focus on Non-narcotic Pain Management Driving Growth



- Prescription opioid abuse is at epidemic proportions in the U.S¹
- Additionally, the CDC states that opioids do not provide clinically meaningful pain relief in patients with low back and chronic pain²
- Multiple medical organizations recommend multi-modal analgesia for chronic pain management, including the American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia (ASRA) & the American Academy of Orthopedic Surgeons.
- SEMDEXA (SP-102) clinical program is intended to demonstrate its utility as a key adjunct treatment for low back pain/lumbar radiculopathy and potential as a new pain management standard

"Consultants, ASA members, and ASRA members strongly agree that epidural steroid injections with or without local anesthetics should be used for radicular pain or radiculopathy." - American Society of Anesthesiology Practice Guidelines for Chronic Pain Management³

^{1.} Center for Disease Control and Prevention. Increases in Drug and Opioid Overdose Deaths 2000-20014. MMWR 2015; 64; 1-5.

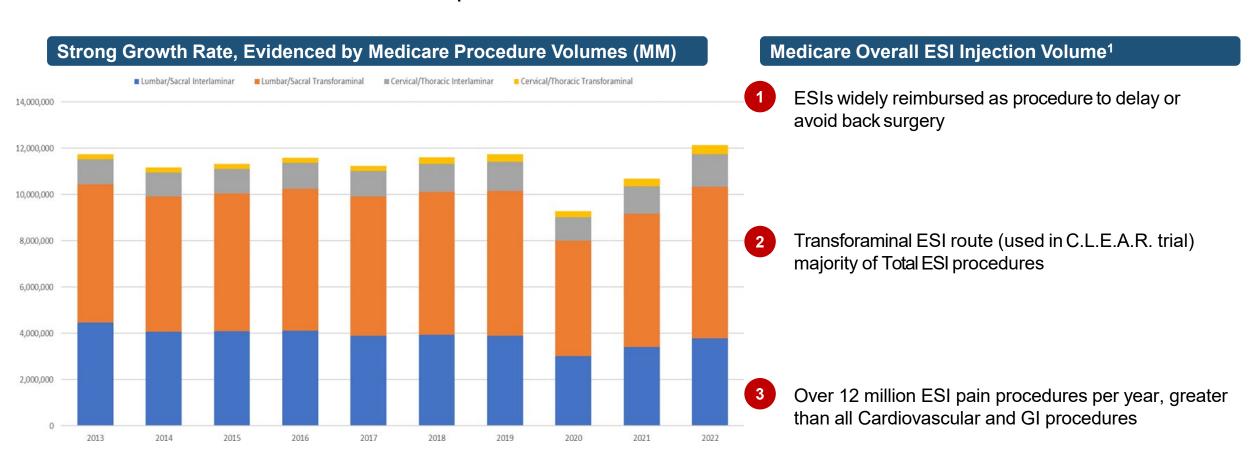
^{2.} Efficacy, Tolerability and Dose Effects of Opioid Analgesics for Low Back Pain. JAMA Internal Medicine. 2016 Jul 1; 176

^{3.} Practice Guidelines for Chronic Pain Management. Anesthesiology. 2010; 112: No 4 Apr 2010.



Epidural Steroid Injections (ESI) for Chronic Back Pain

One of the Most Common Medical Procedures / Top Pain Procedures



^{1.} Syneos Health Consulting/Campbell Alliance market research (Estimated)

On-Track as First Epidural Steroid Injection with a Label to Treat Sciatica

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





Phase III C.L.E.A.R. Trial Achieved Objectives



A total of 401 patients enrolled (202 SP-102 / 199 placebo) across 37 US sites The primary endpoint - change in average daily pain in the affected leg over 4 weeks LS mean (SE) of -0.52 (0.163) compared to placebo, p=0.002. Supported by:

Disability Index, ODI -3.38 (1.388), p=0.015. 23% reduction from baseline (17% clinically meaningful¹)

Global Change, PGIC and CGIC, p<0.001

Worst daily pain in affected leg at Week 4 (p=0.004) and over 4 weeks (p=0.001)

Average daily lower back pain, *p*=0.035

Brief Pain Inventory for pain severity (p=0.003) and pain interference (p=0.049)

Responders at 30%, *p=0.002*

The time to repeat injection (95% CI): 84 (71, 100) days for SP-102 vs. 58 (50, 69) days for placebo, p=0.001 Subjects received repeat injections, open-label SP-102: 134 (66%) SP-102 vs 152 (76%) placebo, p=0.026 Favorable safety profile

No Adverse Events of special interest (paraplegia, hematoma, or infection)

No Serious AEs related to SP-102 or injection procedure

ITT Population

¹Maughan et al, 2010.

SP-102 Regulatory Discussion(s) to Date



- 1 Toxicology program complete
- 2 Pharmacokinetic bridge established to Reference Listed Drug
- 3 Phase II, additional PK / PD / Safety of repeat injection trial completed
- 4 CLEAR Trial completed
- 5 NDA 505(b)(2) application confirmed
- 6 Agreement with FDA on next steps to NDA



SP-103
(5.4%, 3X lidocaine topical system)
for Treatment of Acute Back Pain



Next-Generation, Triple Strength Formulation of ZTlido 1.8%



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

SP-103 Phase 2

Next-Generation, 5.4% Lidocaine Topical System

- √ 3x drug load (108 mg vs 36 mg lidocaine)
- ✓ Triple strength localized dose of lidocaine
- ✓ Expected same superior adhesion and efficient formulation
- ✓ Initiated Phase 2 trial in Q2-2022 with Results Q3-2023. Phase 3 trial in 2024
- ✓ Large market opportunities for neck pain and acute low back pain
- ✓ Fast Track designation granted in low back pain by FDA in August 2022

Neck Pain Market Overview



Neck pain, or cervicalgia, is one of the most common pain presentations in U.S. and the 4th leading cause of disability

52.9M adults suffer from Neck Pain in the U.S.

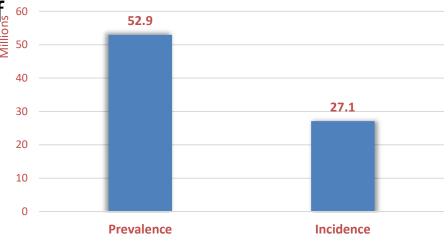
Prevalence of Neck Pain is estimated at >20% of adult population

Neck pain was responsible for job absences among 25.5 million Americans, who missed an average of 11.4 days of work

\$134.5B U.S. low back and neck pain market, which according to a 2020 JAMA (Journal of the American Medical Association)



Neck Pain: U.S. Epidemiology



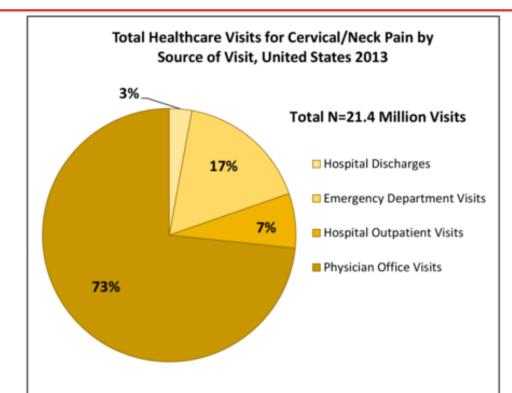
Neck Pain: Unmet Needs



There is no one definitive treatment for neck pain

Majority patients with neck pain are treated nonoperatively, often with alternative treatments, including such treatments as acupuncture, homeopathy, and massage

Nonsteroidal anti-inflammatory drugs (NSAIDs) alleviate pain by reducing inflammation and are the standard of care for pharmacological therapy for Neck Pain



Sources: HCUP National Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), 2013. Agency for Healthcare Research and Quality, Rockville, MD. www.hcup-us.ahrq.gov/nisoverview.jsp; HCUP Nationwide Emergency Department Sample (NEDS). Healthcare Cost and Utilization Project (HCUP). 2013. Agency for Healthcare Research and Quality, Rockville, MD, www.hcupus.ahrq.gov/nedsoverview.jsp; National Ambulatory Medical Care Survey (NAMCS), 2013. www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm_January 14, 2016; National Hospital Ambulatory Medical Care Survey_Outpatient Department (NHAMCS_OP), 2011. www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm May 23, 2016. File: G2C.0.1.1.png



SP-104
Delayed Burst Low Dose
Naltrexone (Fibromyalgia)



Delayed Burst Low Dose Naltrexone (LDN) – Fibromyalgia

- Fibromyalgia is a long-term condition that causes pain all over the body and affects 3% to 6% of the world population (an estimated 10 million people in the U.S., 75-90% women)¹
- Low Dose Naltrexone (LDN) efficacy well documented
 - Routinely used off-label to treat multiple types of chronic pain, including fibromyalgia, complex regional pain and other indications.
 - Demonstrated efficacy in multiple independent investigator-initiated trials.
- Problems with current formulations of Naltrexone:
 - The few treatments approved for Fibromyalgia are marginally effective and have unpleasant side-effects, leading to poor compliance.
 - Adverse events of immediate release formulations including hyperalgesia, dysphoria, nausea, anxiety and insomnia.
 - There are no low-dose non-compounded forms of naltrexone commercially available (< 5 mg/day).
 - Physician hesitancy for off-label prescriptions due to dysphoric effects of naltrexone as well as complications of dose titrating with limited compounding pharmacy supply.
- Phase I SP-104 program of delayed burst release LDN completed
- Phase II clinical trial in Fibromyalgia scheduled in 2024



Management



Management Team



Jaisim Shah
Chief Executive & President

 25+ years of management experience in large Pharma and Biotech. Completed many licensing and M&A transactions



Suresh Khemani Chief Commercial Officer

 25+ years of senior management experience in the industry



Henry Ji, PhD
Executive Chairman

- 25+ years of experience in the biotechnology and life sciences industry
- Founder & CEO & Chair of Sorrento Therapeutics



Suketu Desai Chief Technology Officer

 25+ years in manufacturing / CMC, with expertise in viscous solution products



Dmitri Lissin, MD Chief Medical Officer

 20+ years in clinical development in pain & CNS diseases



Steve LincolnGC and Chief Compliance Officer

 20+ years in industry, with expertise in legal/compliance and international partnering



Stephen MaChief Financial Officer

 15+ years in industry, with expertise in financing, strategic planning, public offering, and M&A transactions

Executive Summary

SCILEX® HOLDING COMPANY

Investment Highlights

- 3 FDA-approved Non-Opioid Acute and Chronic Pain Management Products
 - Worldwide Commercial Rights to Most Product Candidates



- Strong Proprietary Platform with High Barriers to Entry
- Established Reimbursement Access
- Blockbuster Pipeline With Limited Capital Required for Commercialization

Nasdaq (November 11, 2022)



