



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



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## Executive Summary

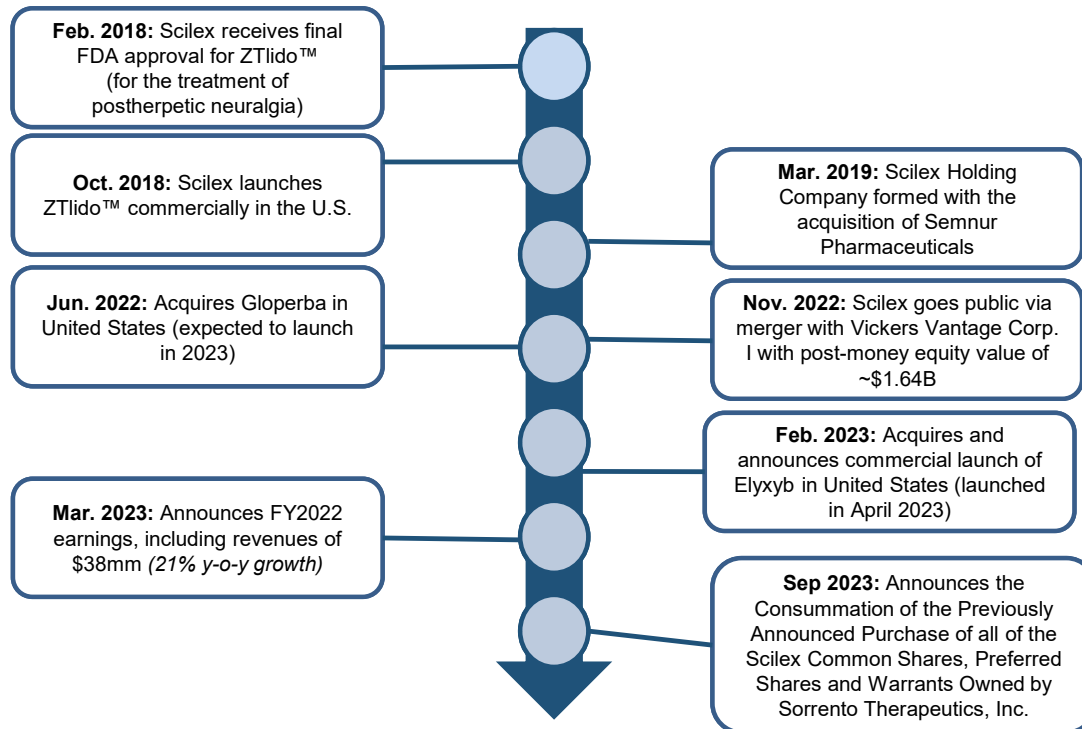
# Company Background



### Company Overview

- Scilex Holding Company (“Scilex”) is an innovative revenue-generating pharmaceutical firm focused on developing and commercializing non-opioid acute and chronic pain management products
- Scilex targets indications with unmet needs and large market opportunities in acute and chronic pain, including shingles, migraine, gout, sciatica and fibromyalgia
- Lead commercial product, ZTlido 1.8%, is a prescription lidocaine topical product for the relief of neuropathic pain associated with postherpetic neuralgia PHN (shingles pain). FDA-approved product Elyxyb (acute migraine) launched in April 2023
- Additional planned 2023 launch for FDA-approved product Gloperba (gout)
- Scilex has multiple products in its pipeline, including a Phase 3 candidate, a Phase 2 candidate and a Phase 1 candidate that is expected to enter Phase 2 in 2023:
  - SP-102 (SEMDEXA™) – a Phase 3, novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat sciatica
  - SP-103 (5.4%) – a Phase 2, next-generation triple strength formulation of ZTlido for the treatment of low back pain. Trial completed in Q3-2023
  - SP-104 – a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia

### Corporate Timeline





## *Executive Summary*

# Investment Highlights



1

***3 FDA-approved Non-Opioid Acute and Chronic Pain Management Products***

2

***Worldwide Commercial Rights to Most Product Candidates***

3

***Strong Proprietary Platform with High Barriers to Entry***

4

***Established Reimbursement Access***

5

***Blockbuster Pipeline With Limited Capital Required for Commercialization***





## Executive Summary

# Innovative Non-Opioid Pain Therapeutics



KEY PROGRAMS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	APPROVED	IP	MILESTONES / KEY COMMENTARY
ZTlido® (1.8% lidocaine topical system equivalent to 5% lidocaine)	Approved for the treatment of Postherpetic Neuralgia-PHN related pain					2031	<ul style="list-style-type: none"> <li>Launched in the U.S. in October 2018</li> </ul>
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	<ul style="list-style-type: none"> <li><b>2H 2022:</b> In-licensed U.S. rights</li> <li><b>2024:</b> U.S. launch</li> </ul>
ELYXYB™ (celecoxib) oral solution (Acute Treatment of Migraine)	Approved for acute treatment of migraine					2036	<ul style="list-style-type: none"> <li><b>1Q 2023:</b> In-licensed U.S. / Canadian rights</li> <li><b>2Q 2023:</b> U.S. launch</li> </ul>
SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)	Fast Track / Pre-NDA					2036	<ul style="list-style-type: none"> <li><b>1H 2022:</b> Phase III achieved endpoints</li> <li><b>2H 2023:</b> FDA discussion on Pre-NDA</li> </ul>
SP-103 Lidocaine Topical System 5.4% (3X) (Chronic Neck Pain)	Fast Track					2031	<ul style="list-style-type: none"> <li><b>2Q 2023:</b> Completed Phase II trial</li> </ul>
SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)	Prepare Phase II Trial					2041	<ul style="list-style-type: none"> <li><b>1H 2022:</b> Completed Phase I trial(s)</li> <li><b>2024:</b> Initiate Phase II trials</li> </ul>





## **ZTlido**

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



# Sales Performance 2022 - YTD 2023



## YTD Q3-2023

- ZTlido gross sales were in the range of \$100.0 million to \$102.0 million, compared to \$64.8 million for year-to-date September 2022, representing growth in the range of 54% to 57%.
- ZTlido net sales were in the range of \$32.0 million to \$33.0 million, compared to \$26.1 million for year-to-date September 2022, representing growth in the range of 23% to 26%.
- Total product gross sales year-to-date September 2023 were in the range of \$103.0 million to \$105.0 million, compared to \$64.8 million for year-to-date September 2022, representing growth in the range of 59% to 62%.
- Total product net sales year-to-date September 2023 were in the range of \$32.4 million to \$33.4 million, compared to \$26.1 million for year-to-date September 2022, representing growth in the range of 24% to 28%.

## Full Year 2022

- ZTlido Gross sales for full year 2022 were **\$96.0 million**, compared to net sales of \$63.9 million in 2021, representing a growth of 50%.
- ZTlido Net sales for full year 2022 were **\$38.0 million**, compared to net sales of \$31.3 million in 2021, representing a growth of 21%.



## ZTlido Commercialization Success

**Aiming to Improve the World of Non-Opioid Management**





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

## 1 Lidocaine Patch Market Overview

- +4.6mm prescriptions in 2022
- +169mm prescription lidocaine patches sold in the U.S. in 2022<sup>1</sup>

## 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	ZTlido (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

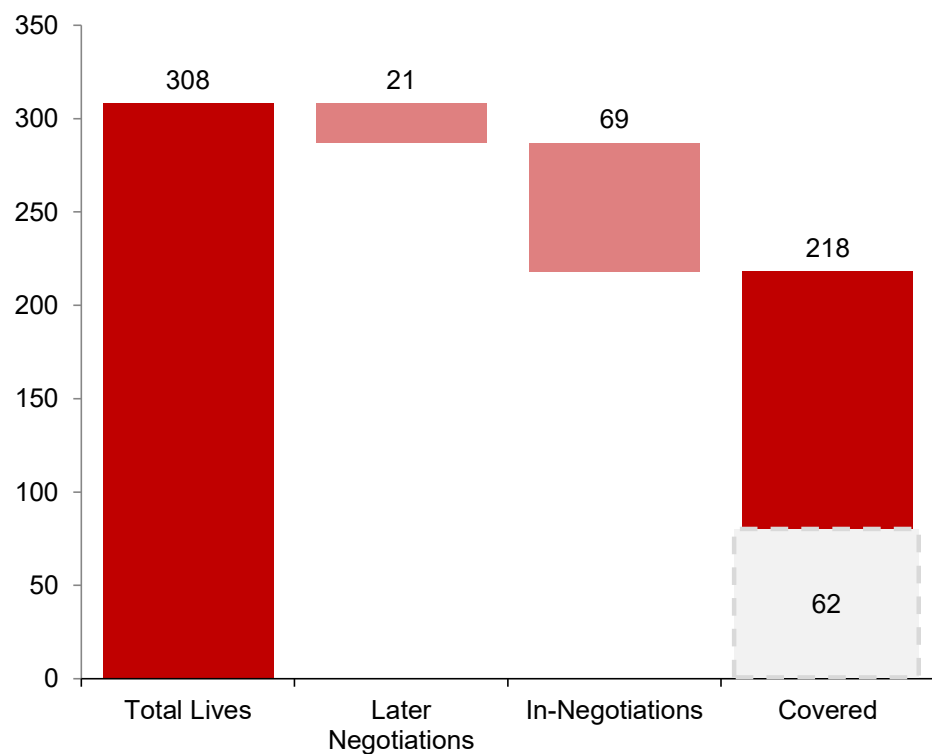


- Only ZTlido delivers a 12-hour adhesion in a non-opioid therapy
- Superior adhesion versus other lidocaine patches in various head-to-head studies
- Only lidocaine patch proven in moderate exercise
- Savings & support system makes it easy to receive inexpensive monthly prescription



# ZTlido Market Access Update

ZTlido Covered Lives Overview



Key Players - Preference



*ZTlido Preferred*

State of California (MediCal)

*Lidocaine Preferred*



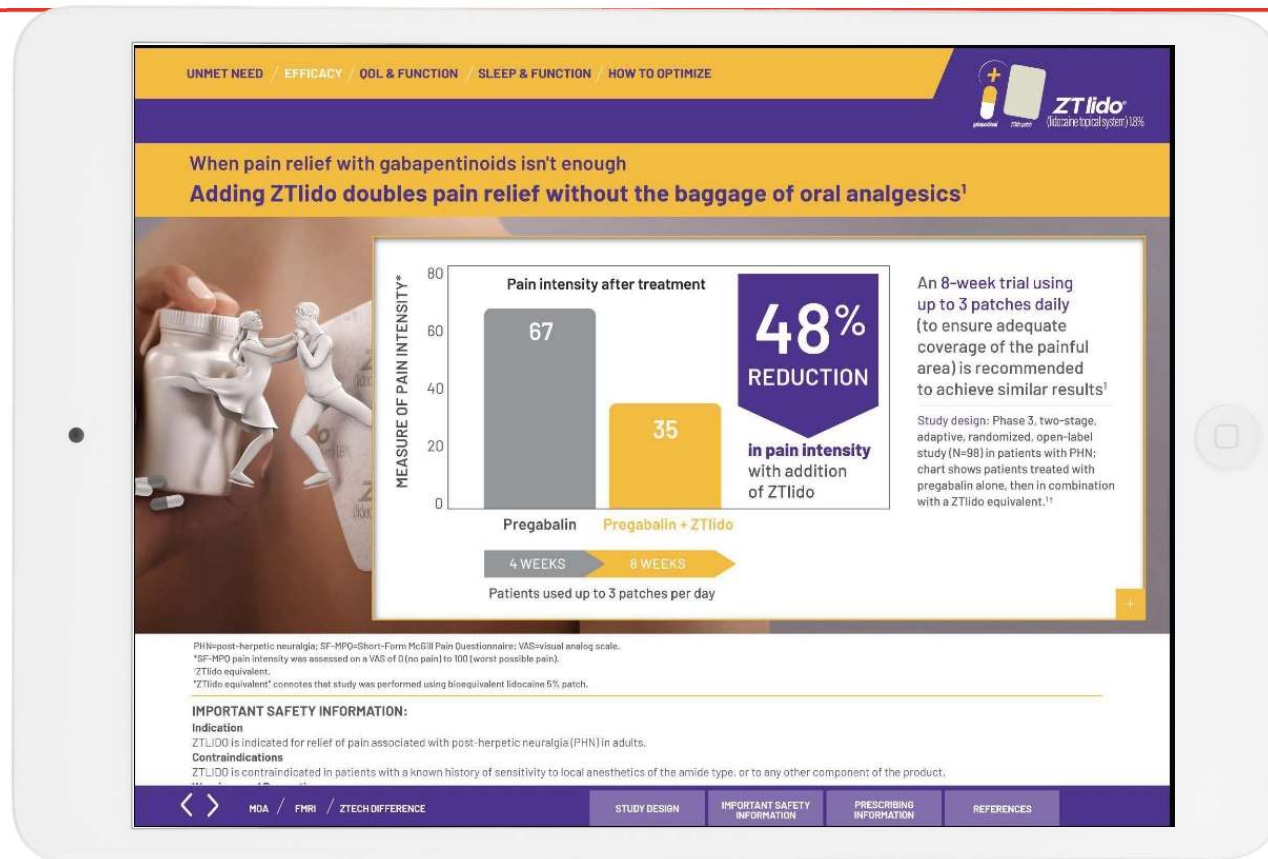
*ZTlido Preferred*



*ZTlido Preferred*



# The ZTlido Solution to the Unmet Need with Gabapentinoids





## The ZTlido New Campaign as the ideal add-on to Gabapentinoids



UNMET NEED / EFFICACY / QOL & FUNCTION / SLEEP & FUNCTION / HOW TO OPTIMIZE

**WHEN PAIN\* RELIEF WITH GABAPENTINOIDS ISN'T ENOUGH\***

**FIND THE PERFECT PARTNER in ZTlido®**

**ADDING ZTlido DOUBLES PAIN RELIEF\* – WITHOUT THE BAGGAGE OF ORAL ANALGESICS\***

\*Chronic neuropathic pain of post-herpetic neuralgia.

**IMPORTANT SAFETY INFORMATION:**  
**Indication**  
ZTLIDO is indicated for relief of pain associated with post-herpetic neuralgia (PHN) in adults.  
**Contraindications**  
ZTLIDO is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.  
**Warnings and Precautions**

MOA / FMRI / ZTECH DIFFERENCE

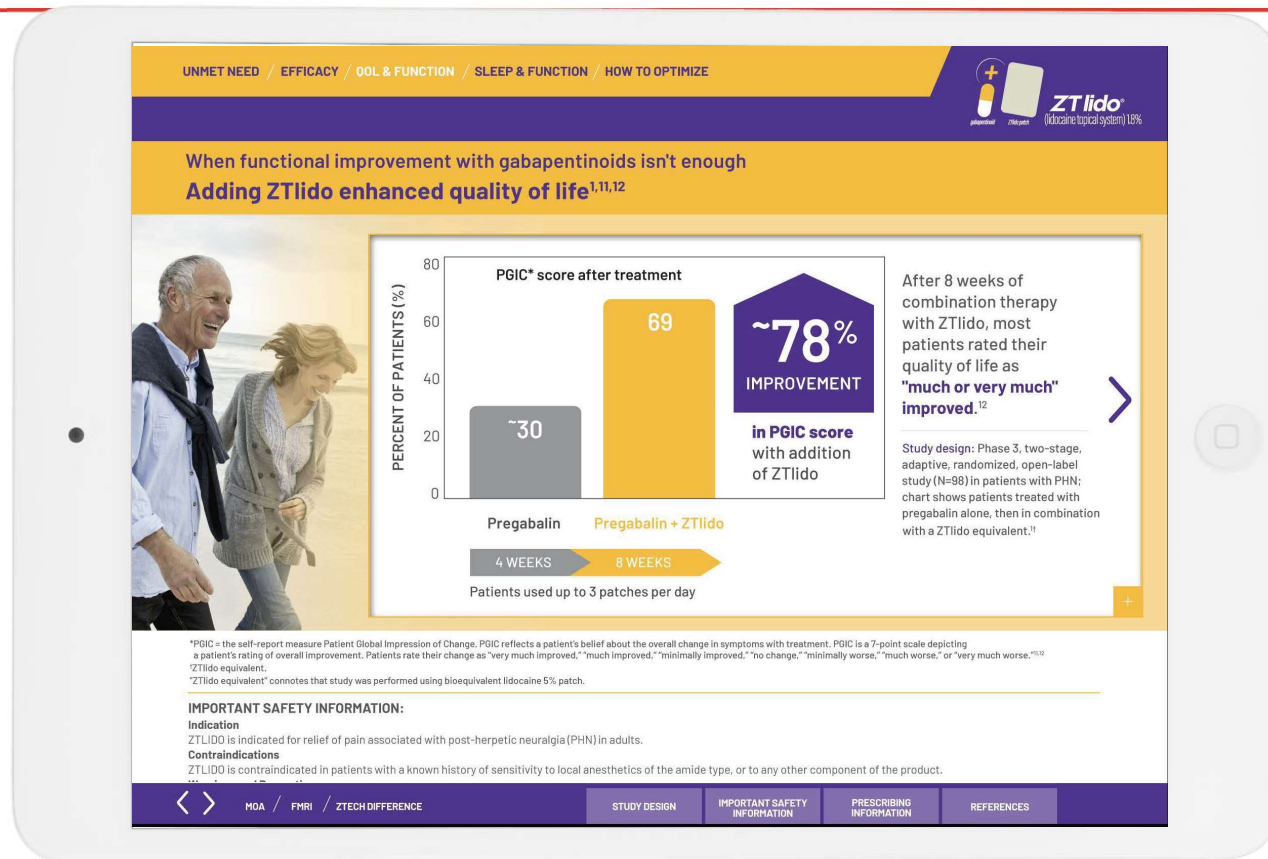
IMPORTANT SAFETY INFORMATION | PRESCRIBING INFORMATION | REFERENCES

- ⊗ 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

Confidential, not for distribution

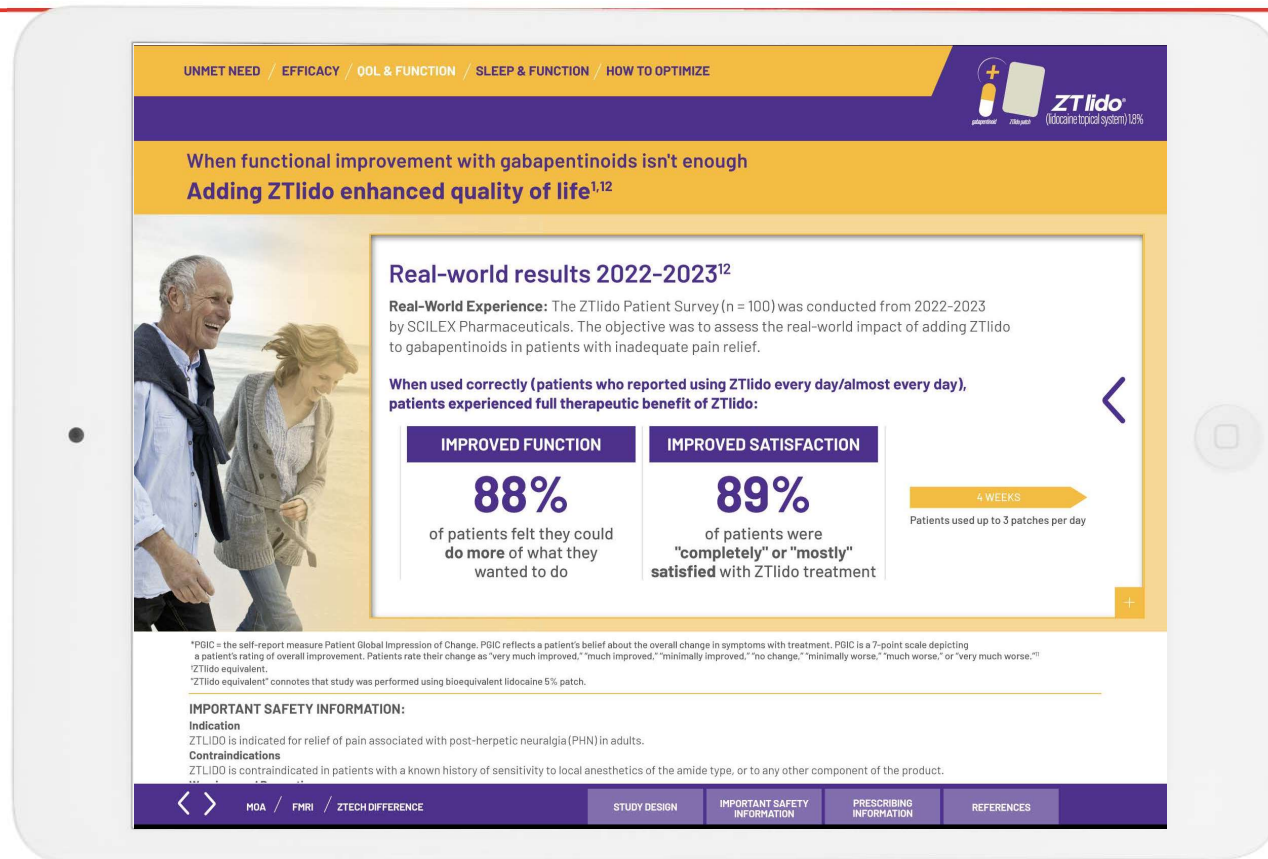


# Enhanced Patient Quality of Life





# Enhanced Patient Quality of Life: Real World Evidence







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



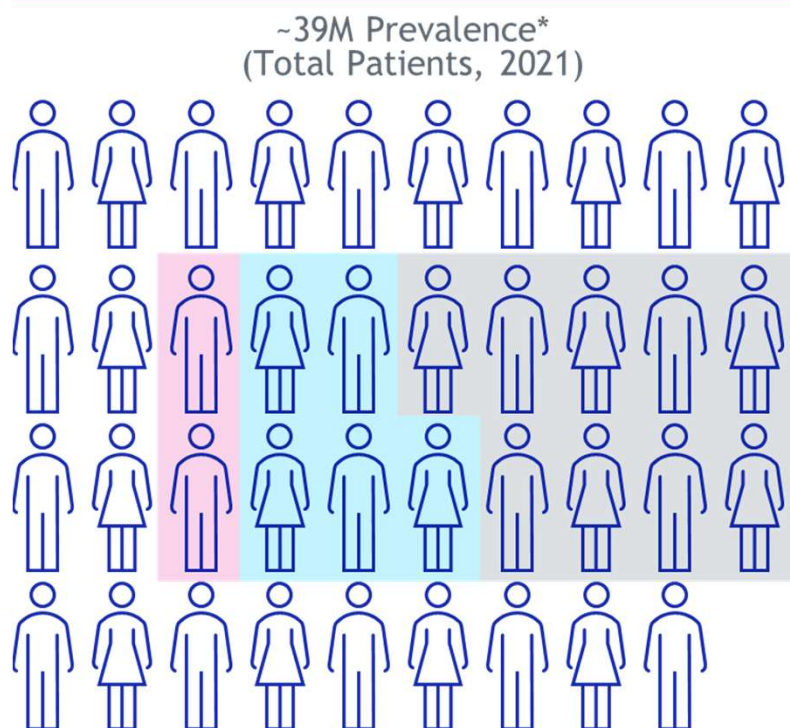
## Elyxyb Launched in USA April 2023

Newest Addition to our **Market Leading Non-Opioid Portfolio**





# Approximately 39M People with Migraine in the US



**~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

## Fast-Acting Formulation

**Works as quickly as 15 minutes<sup>4,6\*</sup>**

Delivers significant pain relief in 45 minutes in nearly 50% of patients<sup>4</sup>

Symptom improvement (vs placebo) as early as<sup>4</sup>:



**Proven pain relief in Phase III studies involving 1253 patients<sup>7,8</sup>**

Pooled analysis of pain freedom in patients 2 hours post-dose with ELYXYB vs placebo<sup>9</sup>:



**Phase III Trials Design:**  
1253 patients were enrolled across 2 identical, multicenter, randomized, double-blind trials. Participants were screened and then randomized 1:1 to receive celecoxib oral solution (120 mg) or placebo to administer within 1 hour of onset of a moderate to severe migraine attack. The coprimary endpoints were 2-hour pain freedom and 2-hour freedom from most bothersome symptom (MBS).<sup>1,7,8,9</sup>

\*Pain relief trended as early as 15 minutes for some patients in post-hoc analysis.<sup>6</sup>

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

ELYXYB is contraindicated in the following patients:

- Known hypersensitivity to celecoxib or any components of the drug product or sulfonamides.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.

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

## Long-Lasting Relief

**Relief up to 24 hours for most patients<sup>7,8</sup>**



**Works whenever patients need it regardless of ...**



### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

**Post-MI Patients:** Avoid the use of ELYXYB in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

**Elyxyb™**  
(celecoxib)  
Oral Solution



# Elyxyb Promotion Materials

## Your Go-To COX-2 Solution for Migraine Relief<sup>1,5</sup>

Consider ELYXYB for patients who:



**Have  
Contraindications  
to Triptans**

When triptans are contraindicated (uncontrolled hypertension, heart attack, coronary artery disease, peripheral vascular disease)<sup>11,12</sup>



**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 treatment<sup>13</sup>

### 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.
- ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

##### Gastrointestinal Bleeding, Ulceration, and Perforation

- 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.

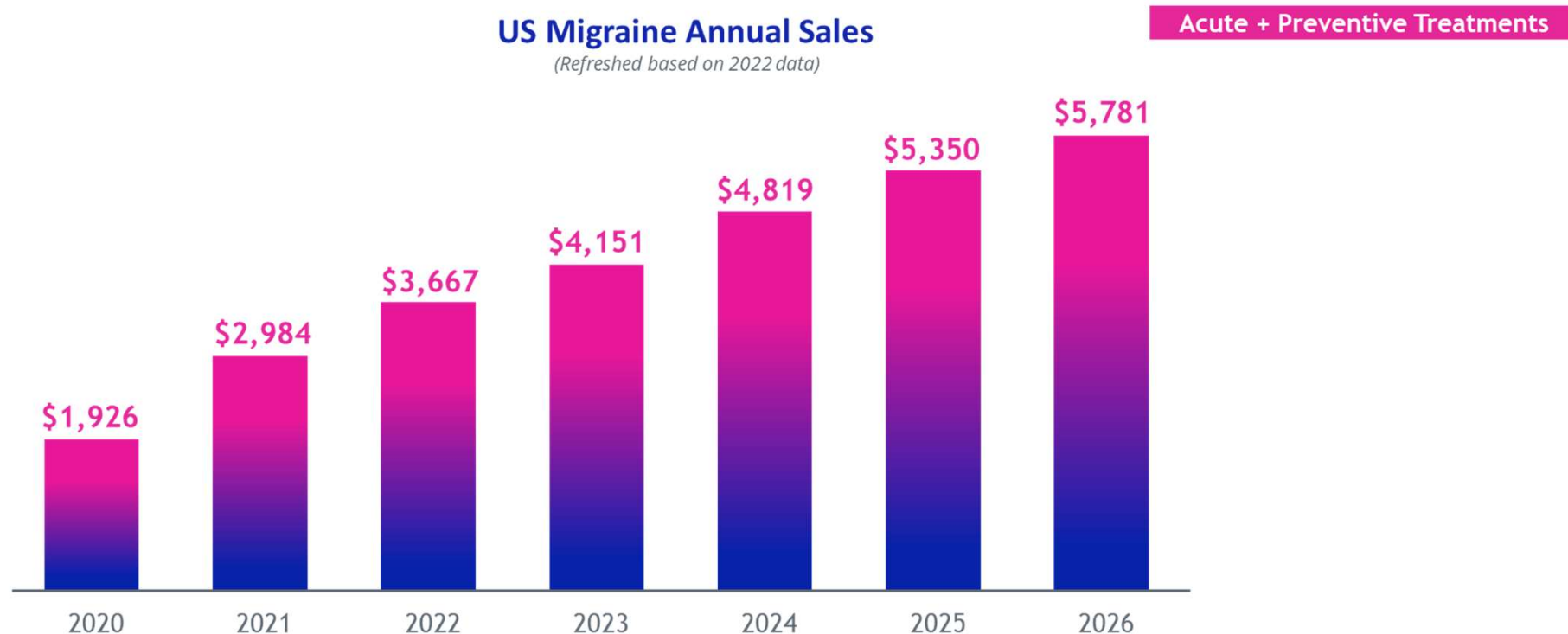
Please see Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.

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ELY-00054 04/2023

**Elyxyb™**  
(celecoxib)  
Oral Solution



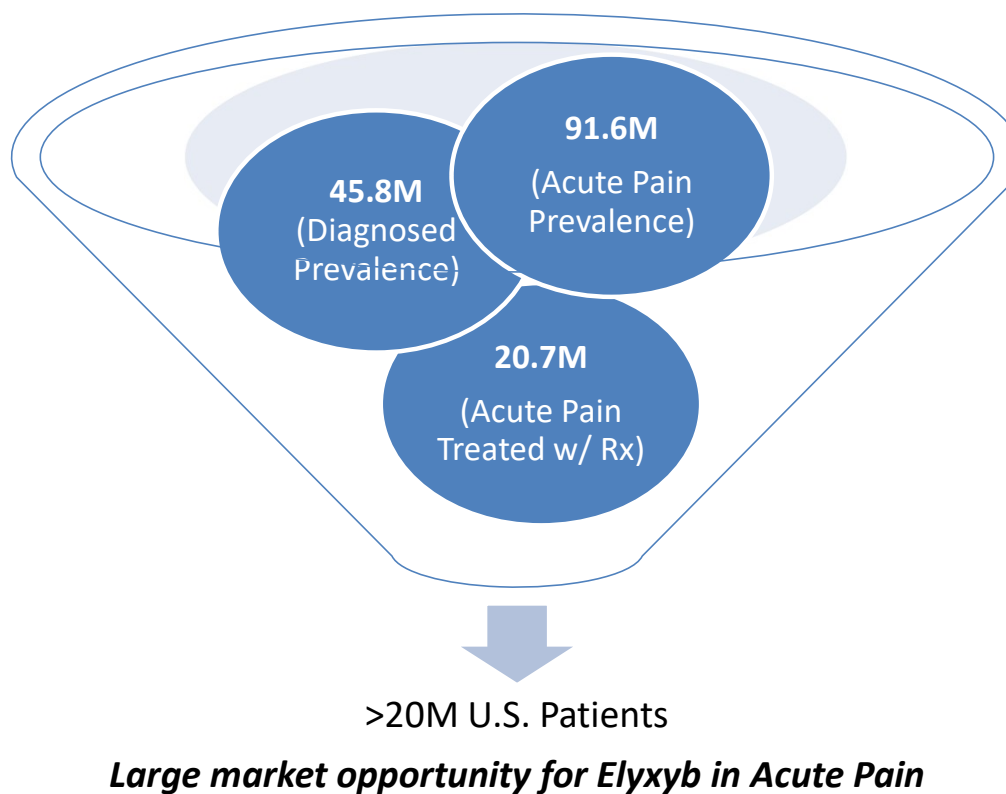
## The US Migraine Market Is Projected To Grow By 195% Between 2021 to 2026



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



## Elyxyb Acute Pain Opportunity: Market Size





## Elyxyb Acute Pain Opportunity: Unmet Needs

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### Key Unmet Needs in Acute Pain:

- Fast onset

- Need for safer and more effective treatments

- Non-Opioid alternatives





## **Gloperba**

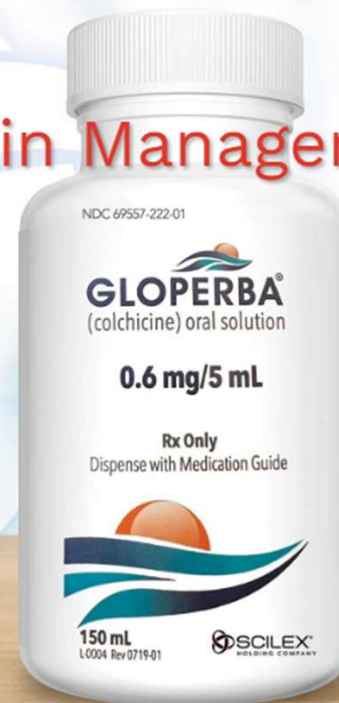
**(colchicine USP) oral solution (For the prevention of painful gout flares in adults)**



## Gloperba Launch in USA Planned in 2024

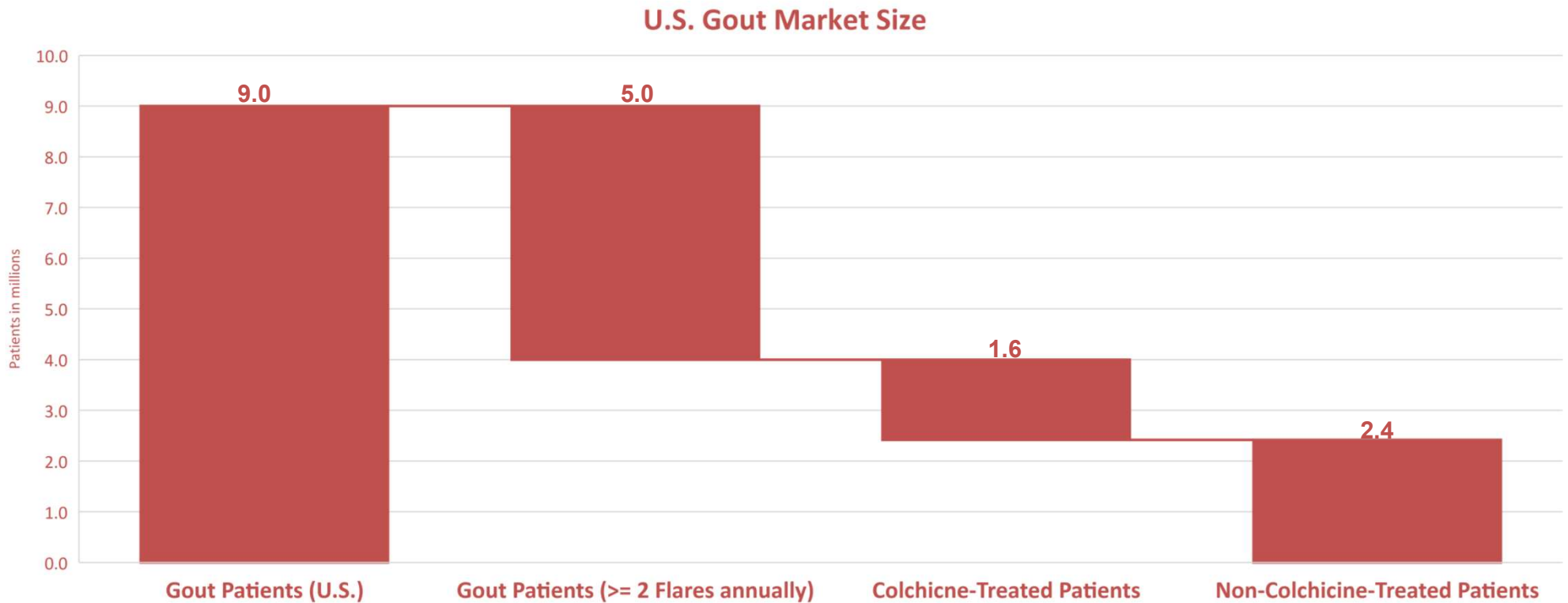


**Expanding our Non-Opioid Pain Management Portfolio**





# Gout Market Size Overview

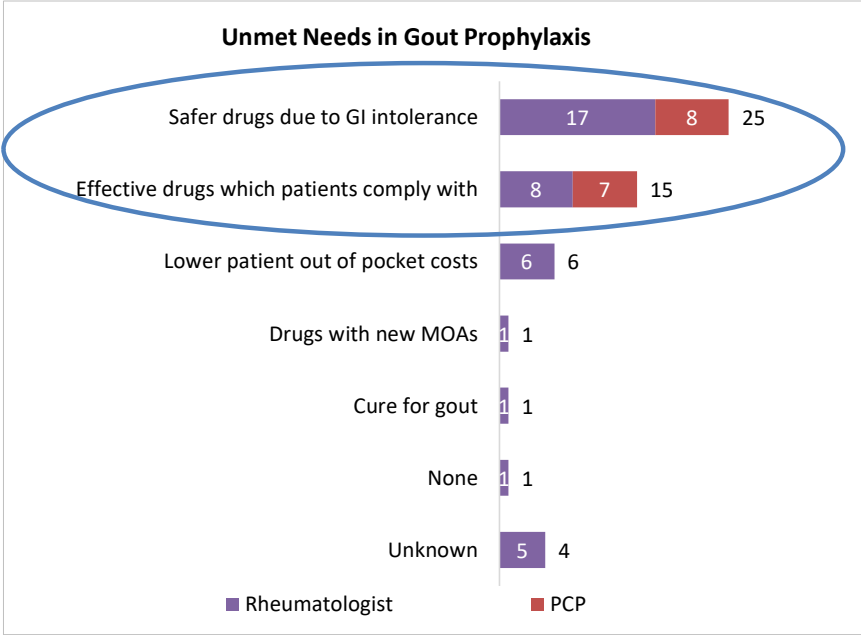




# Gout Unmet Needs



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

*“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

*“There is an unmet need for drugs that can be used in patients who can’t tolerate the GI side effects.”*

- PCP

n=39

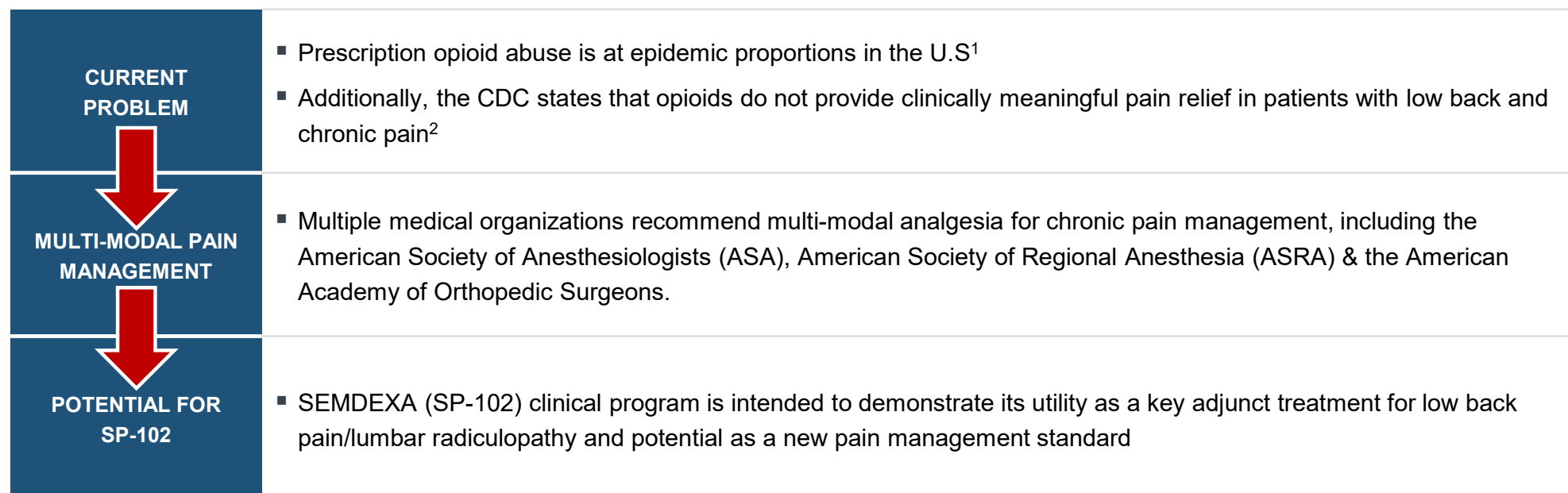




**SP-102 (SEMDEXA)**  
**Treatment of Chronic Low Back**  
**Pain/ Sciatica**



## Focus on Non-narcotic Pain Management Driving Growth



**“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 Management<sup>3</sup>**

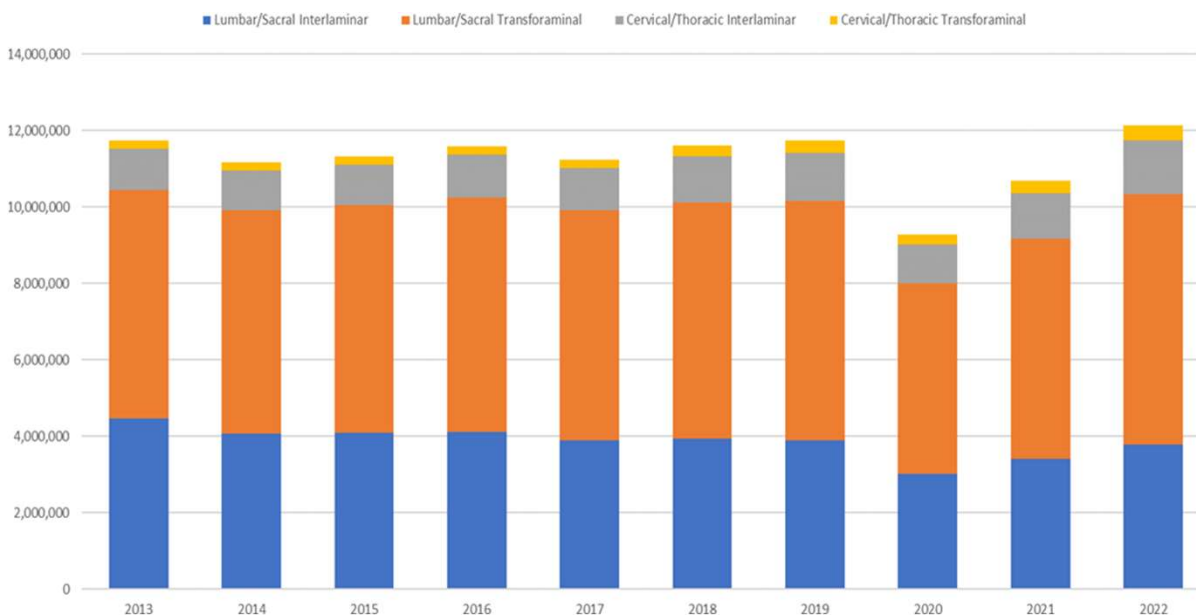
1. Center for Disease Control and Prevention. Increases in Drug and Opioid Overdose Deaths 2000-2014. MMWR 2015; 64; 1-5.  
 2. Efficacy, Tolerability and Dose Effects of Opioid Analgesics for Low Back Pain. JAMA Internal Medicine. 2016 Jul 1; 176  
 3. Practice Guidelines for Chronic Pain Management. *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

## Strong Growth Rate, Evidenced by Medicare Procedure Volumes (MM)



## Medicare Overall ESI Injection Volume<sup>1</sup>

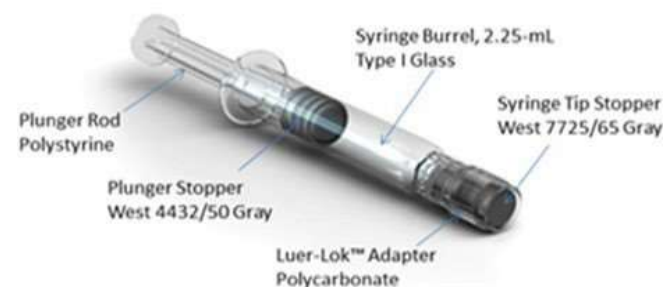
- 1 ESIs widely reimbursed as procedure to delay or avoid back surgery
- 2 Transforaminal ESI route (used in C.L.E.A.R. trial) majority of Total ESI procedures
- 3 Over 12 million ESI pain procedures per year, greater than all Cardiovascular and GI procedures

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.
- ❖ Good safety profile for single and repeat injections.
- ❖ Common epidural delivery by minimally invasive procedure conducted in outpatient pain clinics.
- ❖ Stable at refrigerated temperature in a prefilled syringe.





## 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 meaningful<sup>1</sup>)

- 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



## SP-102 Regulatory Discussion(s) to Date

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- 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 Pending FDA meeting minutes 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%

### **ZTlido**<sup>TM</sup> (lidocaine topical system) 1.8%

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

### **SP-103 Phase 2**

*Next-Generation, 5.4%  
Lidocaine Topical System*

- ✓ 3x drug load (108 mg vs 36 mg lidocaine)
- ✓ Triple strength localized dose of lidocaine
- ✓ Expected same superior adhesion and efficient formulation
- ✓ Initiated Phase 2 trial in Q2-2022 with Results Q3-2023. Phase 3 trial in Q1-2024
- ✓ For the treatment of acute low back pain – a substantially larger market opportunity than PHN
- ✓ Fast Track designation granted 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.**

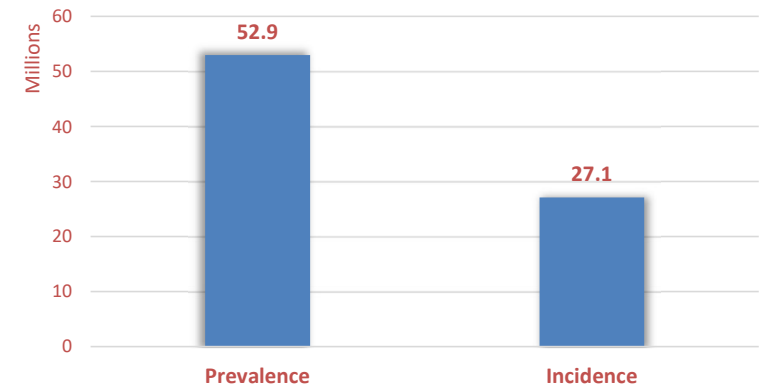
Prevalence of Neck Pain is estimated at >20% of adult population

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**



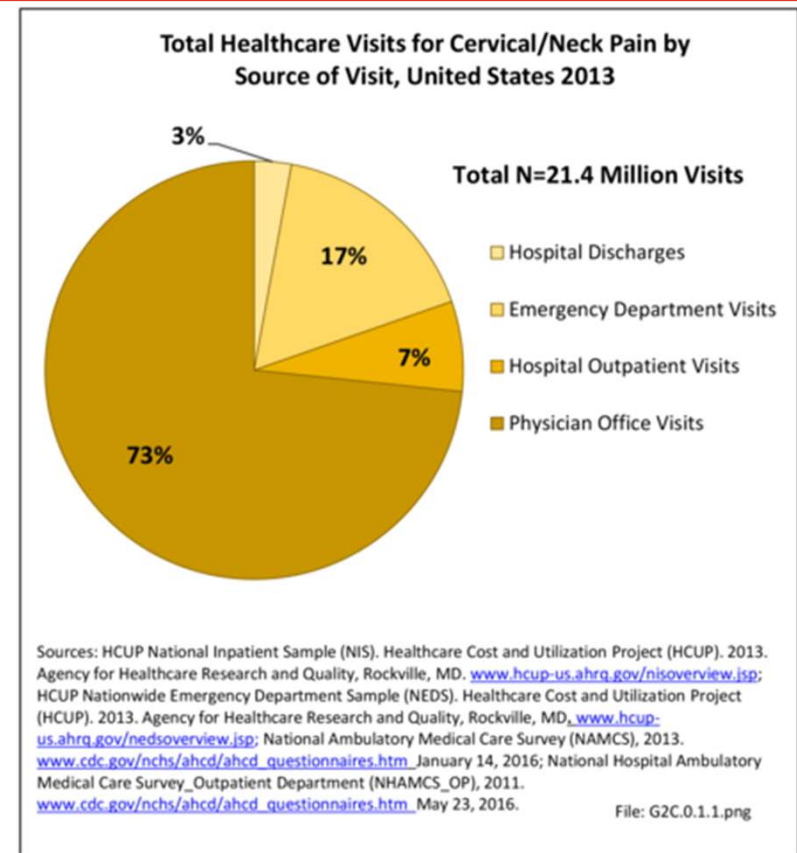


# Neck Pain: Unmet Needs

There is no one definitive treatment for neck pain

Majority patients with neck pain are treated non-operatively, 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**





## Phase II Trial Summary

- Phase II, randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate the safety and efficacy of SP-103 in subjects with moderate to severe acute lower back pain.
  - Subjects are expected to apply investigational product for 12 hours per study day. Study days 1 through 28 to record the time of investigational product applications and removals in an electronic diary
  - Subjects will capture daily numeric pain rating scores and topical adhesions assessments in the electronic diary each evening prior to the removal of investigational product
  - On day 28, subjects will return to the study site to complete the end of study visit
  - Estimated enrollment of 80 subjects
  - Primary outcome measures: Adverse Events [Time Frame: 28 days] and Numeric Pain Rating Scale (0-10, 0 is no pain, 10 is worst pain imaginable) [Time Frame: 7 days]
  - Secondary outcome measures: Oswestry Disability Index (0-100, 0 is with no disability, 100 is the maximum disability) [Time Frame: Day 7 and 28]
  - [ClinicalTrials.gov link: Safety and Efficacy of SP-103 in Subjects With Moderate to Severe Acute Lower Back Pain - Full Text View - ClinicalTrials.gov](#)
- Trial initiated in 2022 and it is fully enrolled and results expected to be in Q3-2023





**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)<sup>1</sup>
- ⊗ 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 2023

1. Arthritis Rheumatol. 2015 Feb;67(2):568-75., PLoS One. 2015;10(9):e0138024. Epub 2015 Sep 17.





## **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



**Henry Ji, PhD**

Executive Chairman

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



**Dmitri Lissin, MD**

Chief Medical Officer

- 20+ years in clinical development in pain & CNS diseases



**Steve Lincoln**

GC and Chief Compliance Officer

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



**Suresh Khemani**

Chief Commercial Officer

- 25+ years of senior management experience in the industry



**Suketu Desai**

Chief Technology Officer

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



**Stephen Ma**

Chief Financial Officer

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



## Nasdaq (November 11, 2022)

