UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 21, 2023

SCILEX HOLDING COMPANY
(Exact name of registrant as specified in its charter)

Delaware	**001-39852**	**92-1062542**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

960 San Antonio Road, Palo Alto, California, 94303
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (650) 516-4310

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	SCLX	The Nasdaq Stock Market LLC
Warrants to purchase one share of common stock, each at an exercise price of $11.50 per share	SCLXW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On June 21, 2023, Scilex Holding Company (the "Company") updated its corporate presentation materials that it uses for presentations at conferences and to analysts, current stockholders and others. A copy of the Company's corporate presentation materials that it intends to use at such events and with such parties is attached as Exhibit 99.1 and is incorporated herein by reference.

Neither this Current Report on Form 8-K, nor any exhibit attached hereto, is an offer to sell or the solicitation of an offer to buy any securities of the Company. Such disclosure does not constitute an offer to sell, or the solicitation of an offer to buy nor shall there be any sales of the Company's securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing by the Company, under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Presentation Materials.
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SCILEX HOLDING COMPANY

By: /s/ Jaisim Shah
Name: Jaisim Shah
Title: Chief Executive Officer & President

Date: June 21, 2023

Exhibit 99.1

Innovative Leader in Non-Opioid Pain Therapeutics

(June 2023)

Confidential

Safe Harbor Statements Forward-Looking Statements

Certain statements contained in this corporate presentation (this "Presentation"), along with certain statements that may be made by management of Scilex Holding Company (together with its subsidiaries, "Scilex") orally in presenting this material, are or may be considered "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements can be identified by the fact that they do not relate strictly to historic or current facts. Forward-looking statements are typically identified by words such as "estimate," "expect,""intend," "believe," "plan," "anticipate," "potential," "projected" and other words and terms of similar meaning (including the negative of any of the foregoing) in connection with any discussion of future operating or financial performance or condition, but the absence of these words does not mean that a statement is not forward-looking. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Scilex cautions that these statements are based upon information available as of the date of this Presentation and the current beliefs and expectations of Scilex's management and are subject to significant risks, uncertainties and assumptions. Statements regarding future actions, future performance and/or future results including, without limitation, those relating to the timing for completion, and results of, scheduled or additional clinical trials and the FDA's or other regulatory review and/or approval and commercial launch and sales results (if any) of Scilex's formulations and products and regulatory filings related to the same, financial projections and targets, business strategy and plans and objectives for future operations may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Presentation are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events.

Scilex undertakes no obligation to update publicly or revise any forward-looking statements for any reason after the date of this Presentation or to conform these statements to actual results or to changes in Scilex's expectations, weather as a result of new information, future events, inaccuracies that become apparent after the date hereof or otherwise, except as may be required under applicable securities laws.

For additional information about factors that could cause actual results to differ materially from those described in the forward-looking statements, please refer to Scilex's filings with the Securities and Exchange Commission ("SEC"), including the risk factors obtained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent Quarterly Reports on Form 10-Q filed with the SEC.

Industry and Market Data

Certain data in this Presentation was obtained from various external sources, and neither Scilex nor its affiliates, advisers or representatives has verified such data with independent sources. Accordingly, neither Scilex nor any of its affiliates, advisers or representatives makes any representations as to the accuracy or completeness of that data or undertakes any obligation to update such data after the date of this Presentation. Such data involves risks and uncertainties and is subject to change based on various factors.

Trademarks

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of the products or services of Scilex.

Important Information and Where to Find It

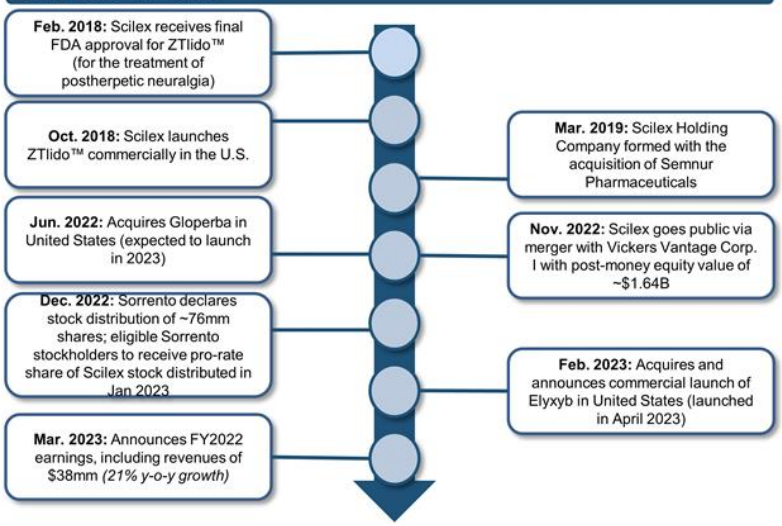
This Presentation does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Investors and securityholders will be able to obtain free copies of the reports that the Company has filed or may subsequently file with the SEC through the website maintained by the SEC at www.sec.gov.

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
  - SP-104 – a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia

Corporate Timeline



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	▪ 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 ▪ **Q4-2023:** 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

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ZTlido

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

ZTlido Sales Performance 2022 - YTD 2023

YTD May 2023

- Gross sales were in the range of $49.2 million to $54.3 million, compared to $32.0 million for year-to-date May 2022, representing growth in the range of 54% to 70%
- Net sales were in the range of $16.0 million to $19.0 million, compared to $11.4 million for year-to-date May 2022, representing growth in the range of 40% to 67%.

Q1-2023

- Gross sales for the first quarter of 2023 were $27.5 million, compared to $18.4 million in the first quarter of 2022, representing growth of 49%.
- Net sales for the first quarter of 2023 were $10.6 million, compared to net sales of $6.8 million in the first quarter of 2022, representing growth of 56%.
- Historically, sales for ZTlido are low during the first quarter of the year due to deductibles with managed healthcare plans.

Full Year 2022

- 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

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[1]

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%)

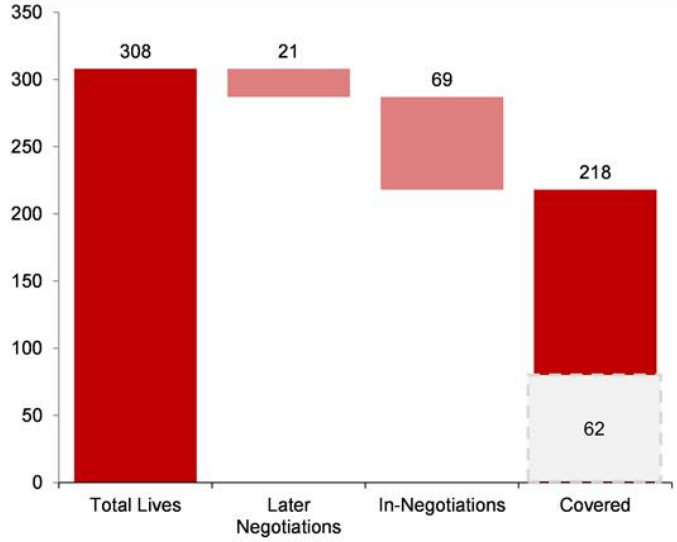
Properties	ZTlido (1.8%)	Lidoderm (5%)
Bioavailability	~45%	~3 ± 2%
Weight	2 grams	14 grams
Thickness	0.8 millimeters	1.6 millimeters
Lidocaine Content	36 milligrams	700 milligrams
Adhesion	Non-aqueous	Water-based

- 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

(1) Symphony Healthcare

ZTlido Market Access Update

ZTlido Covered Lives Overview

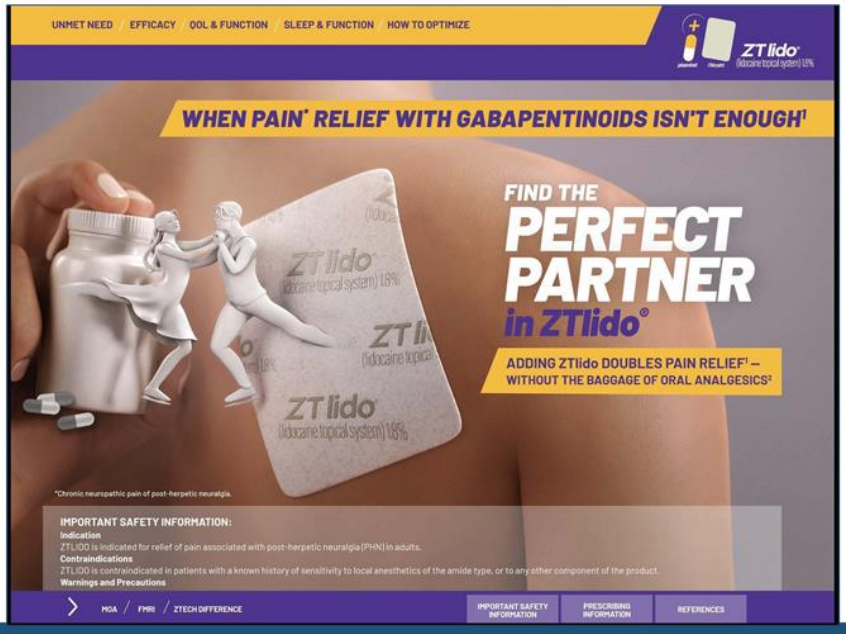


Key Players - Preference

CVS caremark	*ZTlido Preferred*
State of California (MediCal)	*Lidocaine Preferred*
EXPRESS SCRIPTS	*ZTlido Preferred*
OPTUM / UnitedHealthcare	*ZTlido Preferred*

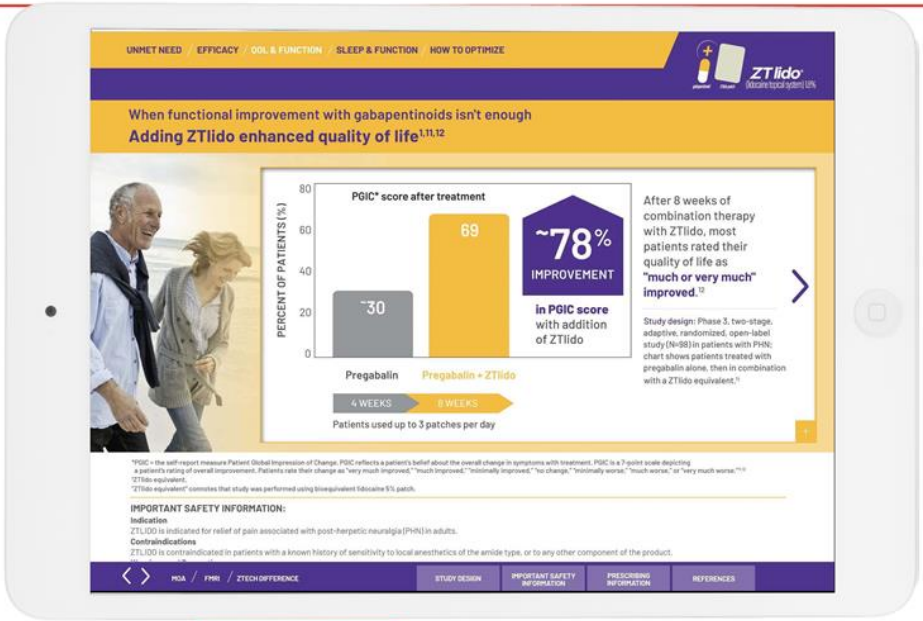
The ZTlido Solution to the Unmet Need with Gabapentinoids

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

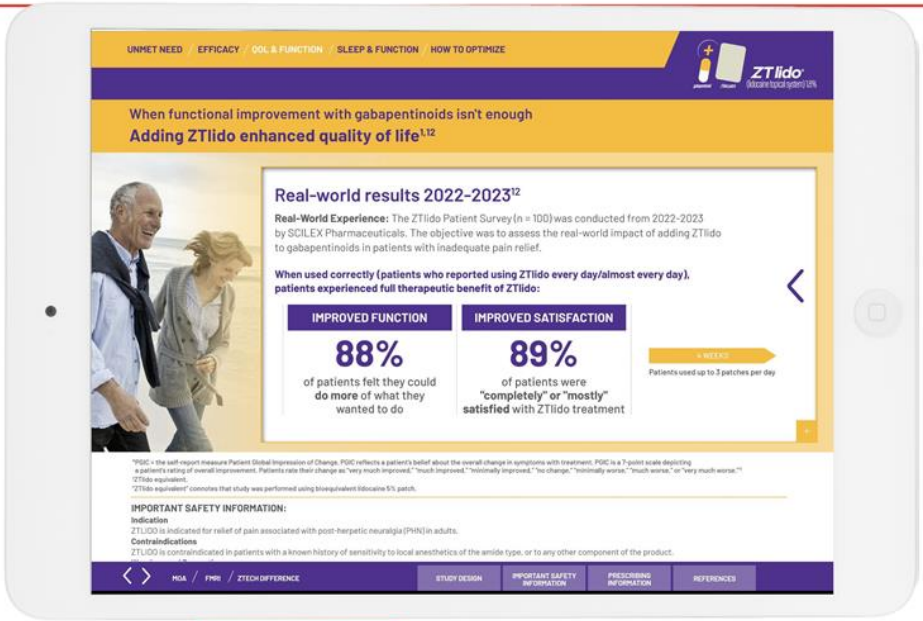


- Designed to allow the brand to achieve its true potential by repositioning from Adhesion to Efficacy)
- ZTlido is uniquely capable of optimizing gabapentinoids – doubling efficacy without the baggage/side effects of other analgesic options (opioids, TCAs, SNRIs, NSAIDs, Acetaminophen).
- This combination efficacy data is “new’ as HCPs are unaware of it – we can own the data as we believe we are 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



Enhanced Patient Quality of Life: Real World Evidence



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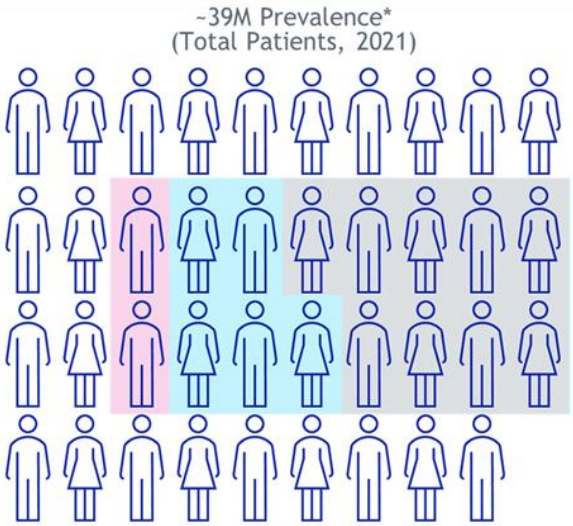
Elyxyb (celecoxib) oral solution (Acute Treatment of Migraine)

Elyxyb Launched in USA April 2023

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

Market Overview and Value Proposition

ELYXYB™ has an opportunity to address unmet need for fast-acting acute migraine therapies as patients cycle through standard therapies

Large and Growing U.S. Market

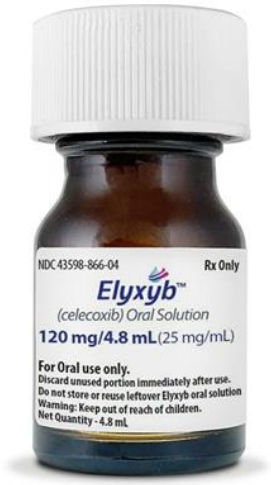
- **39 million** people suffer from migraines in the US, of which 9 million (23%) are on acute Rx therapies[1]
- US oral migraine market is expected to be **$1.8B** in 2022[2]

High Unmet Need in Acute Setting

- **>70% of patients** report inadequate treatment response with acute migraine[3] (primarily Triptans and NSAIDs)
- **OTC NSAIDs** used first-line in acute settings but often associated with GI adverse events and/or slower onset of action
- Acute migraine market **dominated by Triptans** (>70% of prescriptions)[4]
- **CGRPs showing discontinuation at a high rate** (~50% therapy abandonment 90-day post start)[5]

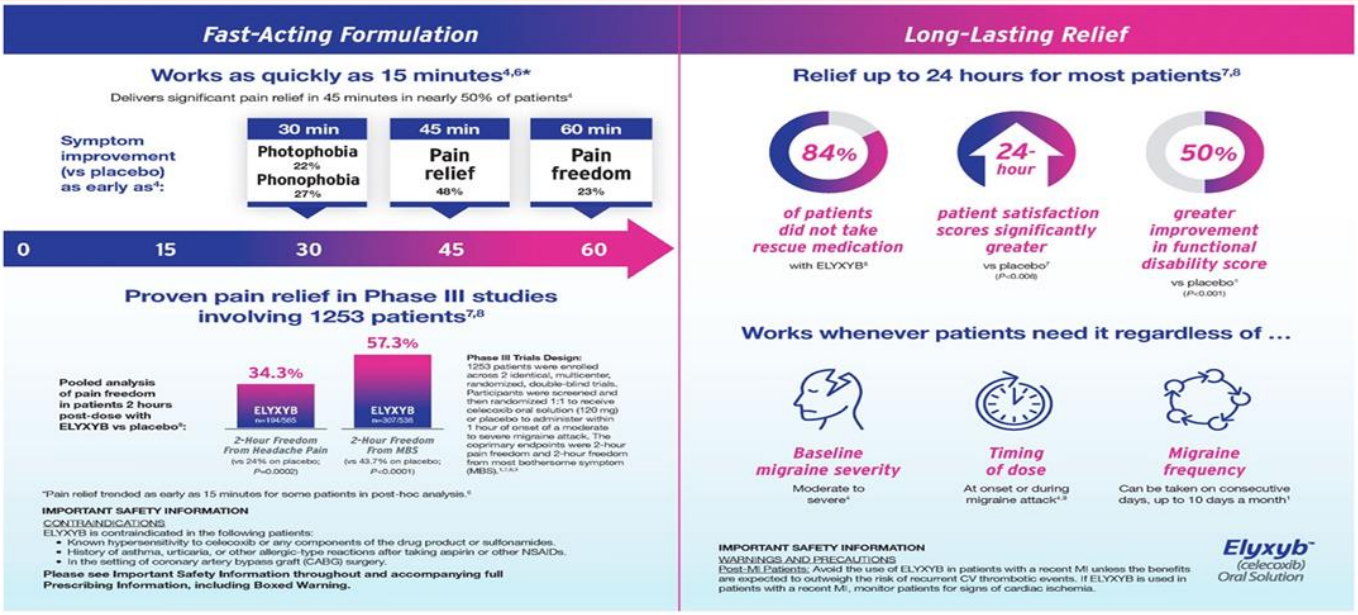
First and Only COX-2 Inhibitor of Its Kind

- **First and only COX-2 inhibitor formulated as a fast-onset oral solution for the acute treatment of migraine**
- Specifically developed to work fast for migraine: Unique delivery system improves bioavailability / absorption
- Fast onset of action: Median TMax of 1 hour
- Efficacious: Proven in 2 large Phase 3 studies of 815 patients
- Safety: No serious adverse events, no drowsiness and favorable GI side effect profile vs traditional NSAIDs
- Convenience: Ready-to-use oral solution – no prep, no steps, just open and drink

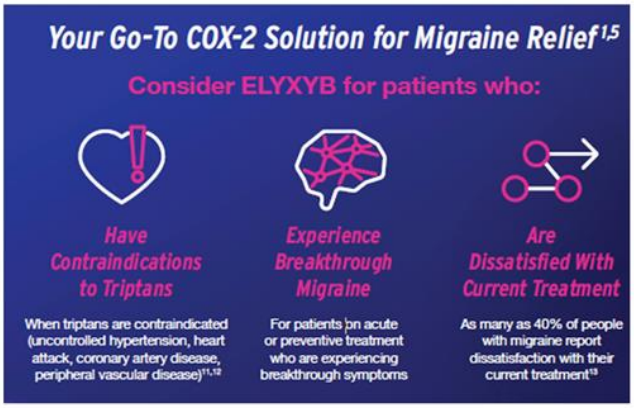


Sources: 1. Migraine Research Foundation, 2021; 2. Evaluate Pharma data February 16, 2023; 3. Lipton RB et al. Headache. 2017; 4. IQVIA NPA Monthly YTD 2022; 5. Symphony Health Patient Claims; 6. Parduzt, NSAIDs in the Acute Treatment of Migraine: A review of Clinical Experiment and Data, 2010;

Elyxyb Promotion Materials



Elyxyb Promotion Materials



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

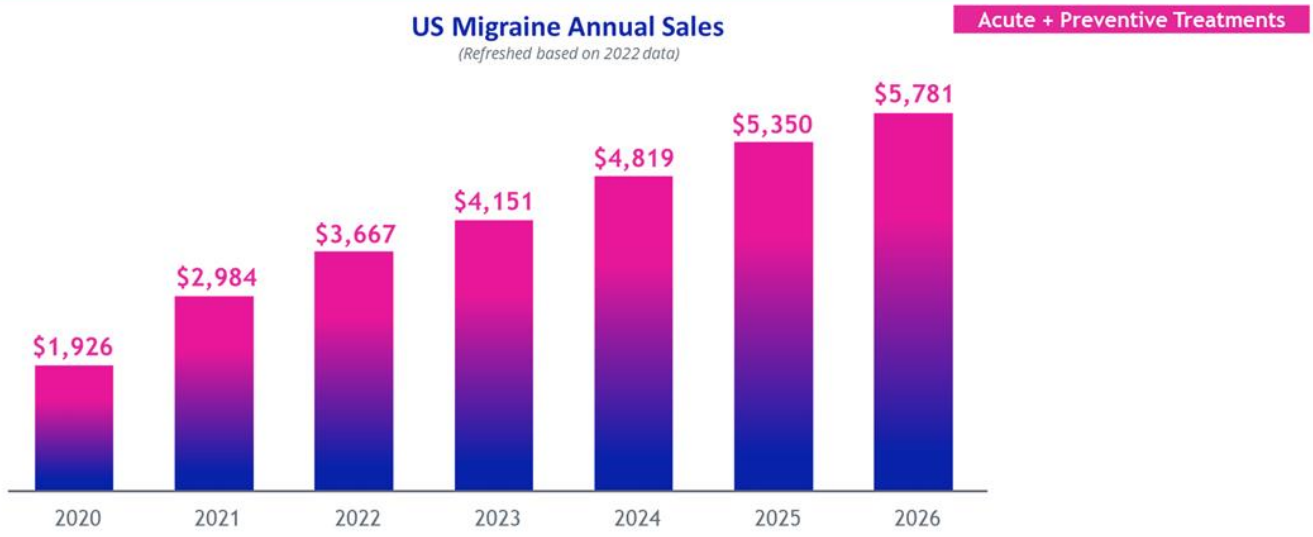
- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history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

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

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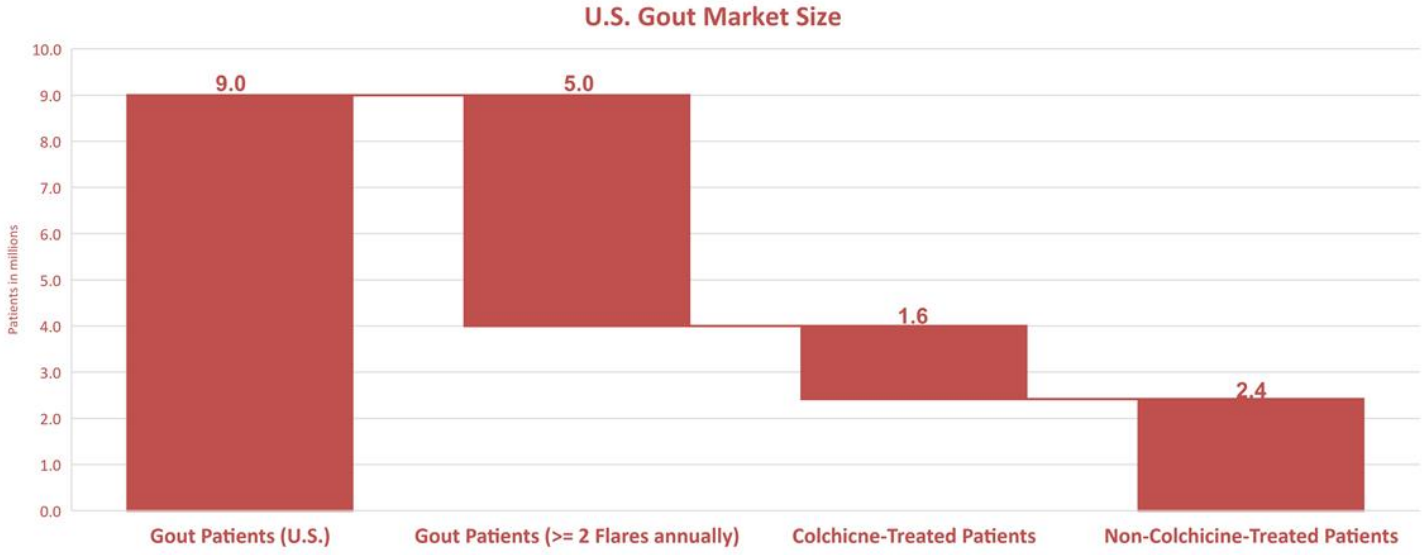
Gloperba

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

Gloperba Launch in USA Planned in Q4 2023

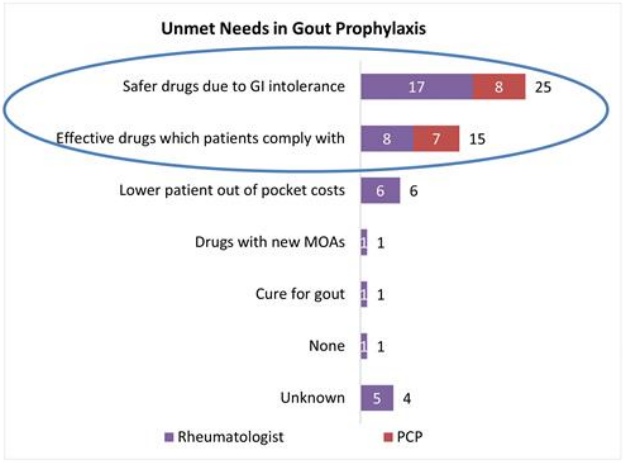
Gout Market Size Overview



Sources: Chen-Xu M, et al. *Arthritis Rheum.* 2019;72(6):991-999; Symphony Healthcare

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

Source: Rheumatologists and PCPs interviewed by Percipient, November – February 2023

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

Focus on Non-narcotic Pain Management Driving Growth

CURRENT PROBLEM	▪ Prescription opioid abuse is at epidemic proportions in the U.S[1] ▪ Additionally, the CDC states that opioids do not provide clinically meaningful pain relief in patients with low back and chronic pain[2]
MULTI-MODAL PAIN MANAGEMENT	▪ 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.
POTENTIAL FOR SP-102	▪ 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 Management[3]

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

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

Medicare Overall ESI Injection Volume[1]

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.

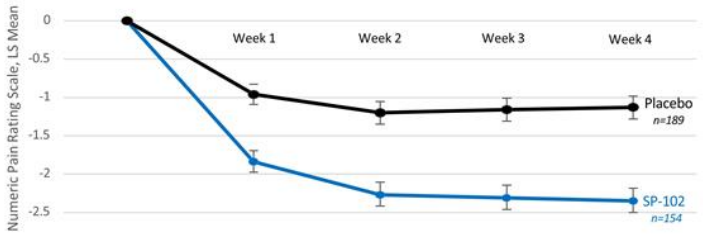
Phase III C.L.E.A.R. Trial Met Primary Endpoint

Phase III Primary Endpoint Overview

- The trial met primary, key secondary and other secondary endpoints with statistical significance over placebo
- Achieved all study objectives, up to 3 months duration of effect with a single injection
- Demonstrated safety profile of SP-102

Phase III SP-102 C.L.E.A.R Trial – Primary Endpoint

Change in Average Daily Pain in Affected Leg



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***

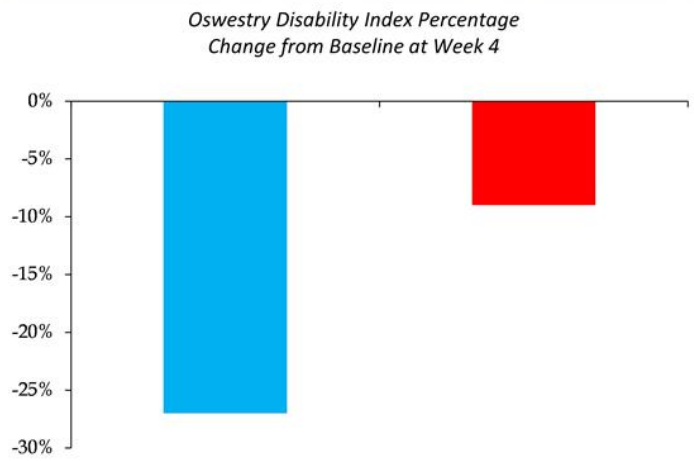
The analysis used a restricted maximum likelihood (REML) based mixed model for repeated measures (MMRM) with fixed effects for treatment (SP-102 or placebo), week, site, Pain Catastrophizing Scale group (<30 or ≥30), baseline averaged daily leg pain score, and treatment-by-week interaction.

C.L.E.A.R. Trial – Key Secondary Endpoint

Phase III Secondary Endpoint Overview

- The Oswestry Disability Index (ODI) - gold standard for measuring degree of disability and estimating quality of life.
- ODI contains 10 topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel.
- The key secondary endpoint of Oswestry Disability Index (ODI), showed a 28% improvement at 4 weeks on SP-102 (SEMDEXA™) compared to baseline (minimal clinically meaningful improvement 8%- 12%).[1]
- The LS Mean (SEM) differences as compared to placebo was -6.28 (1.49), with a p-value <0.001.

Phase III SP-102 C.L.E.A.R Trial – Secondary Endpoint



1. Yoshina et al., 2019 and Ostelo, de Vet. Clinically important outcomes in low back pain. Best Practice & Research Clinical Rheumatology. Volume 19, Issue 4, August 2005, Pages 593-607

C.L.E.A.R. Trial – Effect Duration and Safety

- SP-102 (SEMDEXA™) showed continued reduction of pain beyond one month, and the median time to open-label repeat injection was 99 days (95% CI: 78, 129 days) according to a Kaplan-Meier estimation.
- By contrast, off-label injectable steroids typically provide pain relief for periods ranging from less than a week and up to one month, and then a repeat injection may be required.
- No Adverse Events of special interest (paraplegia, hematoma, or infection)
- No Serious AEs related to drug or injection procedure

Phase III SP-102 C.L.E.A.R. Trial – Conclusions and Summary

- This is the largest prospective, randomized, double-blind, placebo-controlled study testing the effect and safety of a corticosteroid
- SP-102 showed meaningful pain relief with significantly large differences relative to placebo ($p<0.001$) for the primary and almost all secondary pain and QOL endpoints over the 4-week primary analysis period
- SP-102 treatment arm demonstrated significantly longer time to repeat injection (median 99 days) compared to placebo (median 57 days)
- Study also demonstrated SP-102 administration having a safety profile with sparse AEs associated with SP-102 administration
- Data from the C.L.E.A.R. Trial showed that SP-102 (dexamethasone viscous gel) is a safe and effective ESI in the treatment of lumbosacral radiculopathy
- We are submitting a request to the FDA for Type C meeting to clarify expectations for the size of safety database needed for NDA, given no safety concerns identified in the course of clinical development so far, and to agree on acceptance of SP-102 Phase 3 trial data as pivotal evidence of efficacy to support product registration.

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

SP-103 Commercial Opportunity

- Low Back Pain (LBP) most common between the ages of 30 and 50
- Over 30MM people suffer from low back pain[1]
- No product is FDA approved for low back pain
- LBP has a major economic impact in the United States, with total costs related to this condition exceeding $500 billion per year[2]
- Back pain accounts for more than 264 million lost workdays in one year alone[2]
- Physicians use OTC meds like Advil, Tylenol, muscle relaxants, narcotics and antidepressants.

(1) Crow & Willis 2009
(2) IOM: 100 Million Plus in Chronic Pain in U.S. by Emily P. Walker, Washington Correspondent, MedPage Today June 30, 2011

Next-Generation, Triple Strength Formulation of ZTlido 1.8%

ZTlido™
(lidocaine topical system) 1.8%

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

SP-103 Phase 2
Next-Generation, 5.4%
Lidocaine Topical System

- ✓ *3x drug load (108 mg vs 36 mg lidocaine)*
- ✓ *Triple strength localized dose of lidocaine*
- ✓ *Expected same superior adhesion and efficient formulation*
- ✓ *Initiated Phase 2 trial in Q2-2022 with Results Q3-2023. Phase 3 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

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

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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 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

Elizabeth Czerepak
Chief Financial Officer & Chief Business Officer

- 35+ years of finance, business development and operational expertise across pharmaceuticals, biotechnology and venture capital

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

Henry Ji, PhD
Executive Chairman

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

Stephen Ma
Chief Accounting Officer

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

Nasdaq (November 11, 2022)