

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): December 13, 2021

VICKERS VANTAGE CORP. I  
(Exact Name of Registrant as Specified in Charter)

Cayman Islands  
(State or Other Jurisdiction  
of Incorporation)

001-39852  
(Commission File Number)

N/A  
(IRS Employer  
Identification No.)

1 Harbourfront Avenue, #16-06, Keppel Bay Tower, Singapore 098632, Singapore  
(Address of Principal Executive Offices) (Zip Code)

(646) 974-8301  
(Registrant's Telephone Number, Including Area Code)

Not Applicable  
(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 (see General Instruction A.2. below):

- 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
Units, each consisting of one ordinary share and one-half of one redeemable warrant	VCKAU	The Nasdaq Stock Market LLC
Ordinary Shares, par value \$0.0001 per share	VCKA	The Nasdaq Stock Market LLC
Redeemable warrants, exercisable for ordinary shares at an exercise price of \$11.50 per share	VCKAW	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 December 13, 2021, Scilex Holding Company (“Scilex”), a majority-owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE), posted a presentation on its website regarding its business, which included information regarding the execution of a letter of intent between Scilex and the Registrant for a proposed business combination between the parties. A copy of the presentation is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 7.01 and Exhibit 99.1 furnished as part of Item 9.01 of this Current Report on Form 8-K is being furnished and shall not be deemed “filed” for the 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 it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

99.1	<a href="#">Investor Presentation</a>
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

**SIGNATURE**

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.

Dated: February 18, 2022

VICKERS VANTAGE CORP. I

By: /s/ Jeffrey Chi

Name: Jeffrey Chi

Title: Chief Executive Officer

# Scilex Holding Company

*Innovative Leader in Non-Opioid Pain  
Therapeutics*

December 2021

# Scilex Holding Company

## 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. They use words such as "estimate," "expect," "intend," "believe," "plan," "anticipate," "potential," "projected" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or condition. Scilex cautions that these statements are based upon 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, plans and objectives for future operations, and statements regarding the proposed business combination (the "Proposed Business Combination") between Scilex and Vickers Vantage Corp. I (the "SPAC") 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

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## **Scilex Holding Company**

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.

### **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 references the Proposed Business Combination between Scilex and the SPAC. 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. In connection with the transaction described herein, contingent upon execution of the proposed merger agreement for the business combination (the "Merger Agreement"), the SPAC would file relevant materials with the SEC, including a registration statement on Form S-4, which will include a proxy statement/prospectus.

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## Scilex Holding Company

**Investors and security holders of the SPAC are urged to read these materials (including any amendments or supplements thereto) and any other relevant documents in connection with the transaction that the SPAC files with the SEC when, and if, they become available because they will contain important information about the SPAC, Scilex and the proposed transaction.** The preliminary proxy statement/prospectus, the definitive proxy statement/prospectus and other relevant materials in connection with the transaction (when and if they become available), and any other documents filed by the SPAC with the SEC, may be obtained free of charge at the SEC's website ([www.sec.gov](http://www.sec.gov)). The documents filed by the SPAC with the SEC also may be obtained free of charge upon written request to: Vickers Vantage Corp. I, 85 Broad Street, 16th Floor, New York, NY 10004.

### **Participants in the Solicitation**

If the parties execute the proposed Merger Agreement, the SPAC and its directors and executive officers may be deemed participants in the solicitation of proxies from SPAC's shareholders with respect to the Proposed Business Combination. Information about the SPAC's directors and executive officers and a description of their interests in the SPAC will be included in the proxy statement/prospectus for the Proposed Business Combination and would be available at the SEC's website ([www.sec.gov](http://www.sec.gov)). Additional information regarding the interests of such participants will be contained in the proxy statement/prospectus for the Proposed Business Combination when available.

## Scilex Holding Company

Scilex and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of the SPAC in connection with the Proposed Business Combination. Information about Scilex's directors and executive officers and information regarding their interests in the Proposed Business Combination will be included in the proxy statement/prospectus for the Proposed Business Combination when available.

### **Non-Solicitation**

This Presentation is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the potential transaction and shall not constitute an offer to sell or a solicitation of an offer to buy the securities of the SPAC, Scilex or the combined company, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended.

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# Scilex Holding Company

## Agenda

- 1) Scilex Holding Corporate Overview
  - 2) ZTlido® 1.8% Update
  - 3) SP-102 (SEMDEXA) for Lumbar Radicular Pain / Sciatica
  - 4) SP-103 (3X ZTlido) for Low Back Pain
  - 5) DBR Low Dose Naltrexone (LDN) for Fibromyalgia
  - 6) Company Summary
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Scilex Holding Company

## Corporate Overview

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## Scilex Holding Company

# Scilex Business Combination with Vickers Vantage Corp I



### Vickers Vantage Corp. I

#### **IPO Overview:**

**Gross Proceeds:** \$138.0 Million

**IPO Date:** January 6, 2021

**Sponsor:** Vickers Venture Partners

### About Vickers Venture Partners

- ⊗ Founded in 2005
- ⊗ Deep technology focused global VC
- ⊗ \$432 Million invested to-date across six funds<sup>(1)</sup>
- ⊗ Gross Value across six funds circa \$1 Billion<sup>(1)</sup>
- ⊗ Global footprint with international transaction and diligence experience
- ⊗ 21 investment professionals across sectors and geographies, almost all with advanced degrees in their respective specialties

### Vickers Strengths

- ⊗ Strong deal structuring, investing and M&A experience within the fin-tech space
- ⊗ Significant private and public investment experience
- ⊗ History of working within highly regulated industries requiring vast and rigorous due diligence efforts
- ⊗ Necessary experience in working with international governments and government regulators

### Scilex LOI

Scilex Holding Company (Scilex), a subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE), and Vickers Vantage Corp I (Nasdaq: VCKA) signed a letter of intent for a proposed business combination, which provides for a pre-transaction equity value of Scilex of approximately \$1.5 billion, subject to adjustment, with expected gross proceeds of up to \$140 million

Note: (1) As of 30 June 2021.


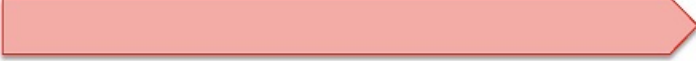


# Scilex Holding Company

## Scilex Executive Management Team

<i>Name</i>	<i>Position(s)</i>	<i>Experience</i>
Jaisim Shah	<i>CEO &amp; President</i>	<ul style="list-style-type: none"><li>▪ 25+ years of management experience in large Pharma and Biotech</li><li>▪ Lead commercialization of multiple blockbusters Rituxan®, Abilify®, Pegasys®, BuSpar®, Tequin</li><li>▪ CEO, Semnur Pharma; CBO, Elevation; CBO, PDL BioPharma; VP, Bristol-Myers; Director, Roche</li></ul>
Suresh Khemani	<i>SVP, Commercial</i>	<ul style="list-style-type: none"><li>▪ 25+ years of senior management experience in the industry</li><li>▪ Senior management positions at BMS, Chiron, PDL BioPharma, Knopp Bioscience</li><li>▪ Multiple blockbuster product launch experiences in US and overseas</li></ul>
Dmitri Lissin, MD	<i>SVP, Chief Medical Officer</i>	<ul style="list-style-type: none"><li>▪ 20+ years in clinical development in pain &amp; CNS diseases</li><li>▪ VP Clinical, Xenoport; VP Clinical, Durect</li></ul>
Steve Lincoln	<i>Interim Chief Legal and Compliance Officer</i>	<ul style="list-style-type: none"><li>▪ 20+ years in industry, with expertise in legal/compliance and international partnering</li><li>▪ Sciclone Pharma, Kosan Bio, SuperGen, PDL BioPharma</li></ul>
Najam Asghar	<i>Interim Chief Financial Officer</i>	<ul style="list-style-type: none"><li>▪ 17+ years functions of Finance, Accounting and Tax, instrumental in several acquisitions</li><li>▪ CFO, NuVasive, Inc., PricewaterhouseCoopers</li></ul>
Henry Ji, PhD	<i>Executive Chairman</i>	<ul style="list-style-type: none"><li>▪ 25+ years of experience in the biotechnology and life sciences industry</li><li>▪ Founder &amp; CEO, Chair Sorrento Therapeutics &amp; Scilex Holding</li></ul>

## Scilex Holding Company

# Best-in-Class Non-Opioid Pain Therapeutics

Platform	Program	IND	Phase 1	Phase 2	Phase3 Pivotal	NDA	Approved	Upcoming Milestones
 Non-Opioid Pain Management	ZTlido® 1.8% (Postherpetic Neuralgia-PHN)						Launched US October 2018	
	SP-102 (SEMDEXA) (Lumbar Radicular / Sciatica Pain)						Pivotal Phase 3 trial enrollment completed & topline results in December 2021	
	SP-103 Lidocaine Topical System 5.4% (3X) (Low Back Pain)						Initiating Phase 2 in January 2022	
	SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)						Initiating Phase 1 in Q4-2021	

## Scilex Holding Company

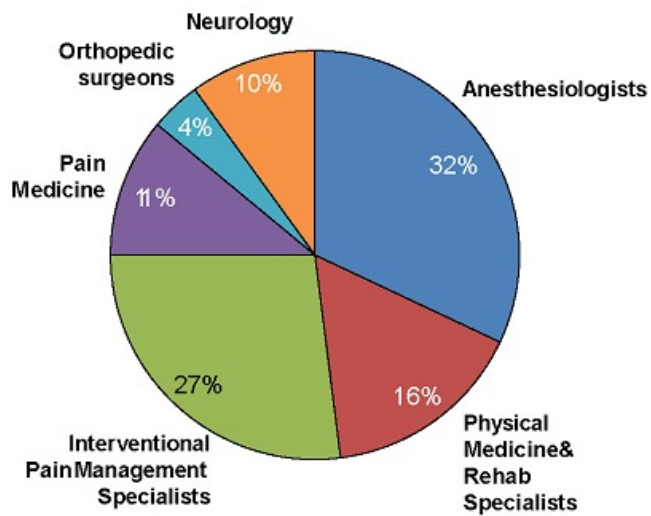
# 2021 Scilex Business Update

- ⊗ In April 2021, Scilex received a supplemental new drug application (sNDA) approval from the FDA for ZTlido to expand the label for use in water stress conditions
  - ⊗ In 2020, ZTlido had US net sales ~\$27MM, which represents a ~35% growth rate YoY 2019
    - Scilex is currently projecting strong sales growth in 2021 ZTlido in the US.
    - Discussions ongoing for registering/partnering ex-US rights to ZTlido and other pipeline programs
  - ⊗ SP-102 (SEMDEXA) pivotal Phase 3 trial completed enrollment in July 2021, with highly significant positive topline results released in December 2021. Fast Track status granted by FDA
  - ⊗ Executed a LOI/term sheet for business combination with a SPAC (Vickers Vantage Corp. I) for a pre-transaction equity value of approximately \$1.5 billion, subject to adjustment, and expected total proceeds of \$140 million
  - ⊗ SP-103 (3x formulation of ZTlido) Phase 2 trial acute back pain on track to commence in January 2022
  - ⊗ SP-104 (Delayed Burst Low Dose Naltrexone) Phase 1 clinical trials began in Q4-2021
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# Scilex Holding Company

15,000-20,000 Target Physicians Consist of a Mix of Health Care Specialists, Focus in High Volume Clinics

## Physicians treating neuropathic and chronic back pain



### Significant concentration in high volume clinics

- ~3,000 pain clinics (<1,000 interventional)
- Sales team in 2021 of 65+

Source: Campbell Alliance Market Research; Clinical Guidelines: Lumbar Disk Herniation with Radiculopathy. NA Spine Society, 2012. <http://www.guideline.gov/content.aspx?id=46414>. Primary Research.

## Scilex Holding Company

### Scilex Holding Company Headquarters



- 960 San Antonio Road,  
Palo Alto CA 94303
- Satellite Office: 4955  
Directors Place, San Diego,  
CA 92121



Scilex Holding Company

**Scilex Pharmaceuticals**

**ZTlido 1.8% for Post-Herpetic Neuralgia (PHN)**

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# Scilex Holding Company

**Marketed Product: ZTlido® 1.8% (FDA approved for relief of pain associated with PHN)**

## Lidocaine Patch Market Overview

>3.5 million prescriptions per year

More than 129 million prescription lidocaine patches were sold in the US in 2020 according to IMS

## Benefits vs. other lidocaine pain patches

Superior adhesion vs. other lidocaine patches in various head-to-head studies

Only lidocaine patch proven in moderate exercise

Properties	ZTlido® 1.8%	Lidoderm® 5%
Bioavailability	~45%	~3±2%
Weight	2 g	14 g
Thickness	0.8 mm	1.7 mm
Lidocaine content	36 mg	700 mg
Adhesive	Non-aqueous	Water-based

**ZTlido™**  
(lidocaine topical system) 1.8%

US FDA APPROVAL – FEBRUARY 2018

COMMERCIAL LAUNCH – OCTOBER 2018

When conventional lidocaine patches don't stick, **do they work?**

ZTlido®  
(lidocaine topical system) 1.8%  
PROVEN 12-HOUR ADHESION



Did you know? HALF of patients surveyed report that other lidocaine patches detach ≥3 times in 12 hours.\*

**Only ZTlido® delivers 12-HOUR adhesion in a non-opioid therapy**  
(zee-tee-lie-doh)

\*According to a 2018 survey of patients with postherpetic neuralgia (PHN). Reference: S. Ferris, P. Cozzani. Online from: May 1, 2018, 2018. Pain Patients & Nurses Study. Our Report. June 6, 2018. Supported by funding from Scilex. Please consult doctor.

Indication:  
ZTlido is indicated for relief of pain associated with postherpetic neuralgia (PHN).  
Report all Safety Information

Application site reactions can occur during or immediately after treatment with ZTlido. They may include development of blisters, itching, burning sensation, hyperaesthesia, dermatitis, discoloration, edema, erythema, exfoliation, fissures, pruritus, urticaria, vesicles, rashes, or to the loss or disruption of scales. These

# Lidocaine Patches are as Efficacious as Gabapentinoids

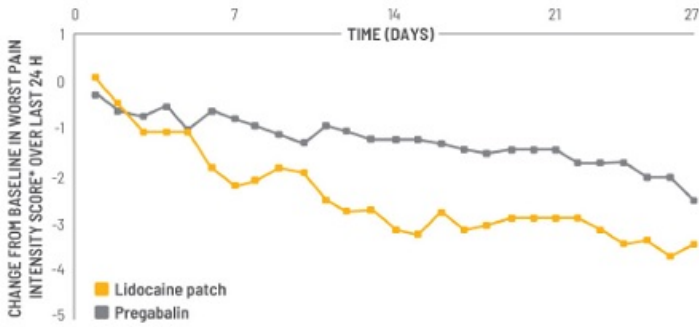
Pain control **continues to improve** over 4 weeks<sup>1</sup>

Lidocaine patches are as efficacious as gabapentinoids<sup>1</sup>

Lidocaine patch

vs Pregabalin

Change from baseline in patients' recalled worst pain intensity in the last 24 h



<sup>1</sup>11-point numeric rating scale (NRS) of 0 (no pain) to 10 (worst pain imaginable). Change computed as post-treatment score

Results of a subanalysis of a 4-week comparison study:

Superior benefit/risk ratio vs pregabalin at 4 weeks<sup>1</sup>

- **Benefit:** Pregabalin decrease in pain intensity over 4 weeks was less pronounced, despite titration to effect (vs no titration for lidocaine patch)
- **Benefit:** Lidocaine patch treatment reduced the average number of acetaminophen tablets taken as rescue medication by half; no change was observed with pregabalin
- **Risk:** Lidocaine patches were significantly better tolerated than pregabalin. Discontinuations due to drug-related adverse events were 4% with lidocaine patch vs 27% with pregabalin

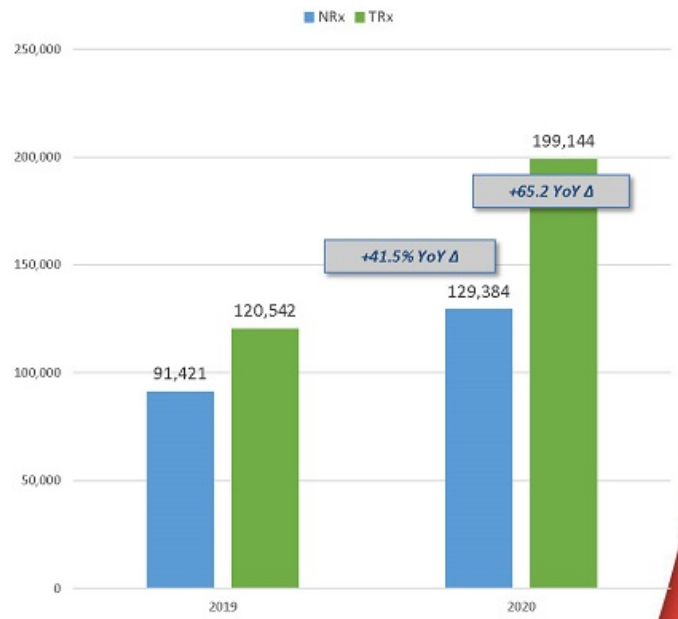
# Scilex Holding Company

## ZTlido strong prescription growth continued at faster pace than market through 2020, despite COVID-19 pandemic impact

Lidocaine Market Annual TRx & NRx



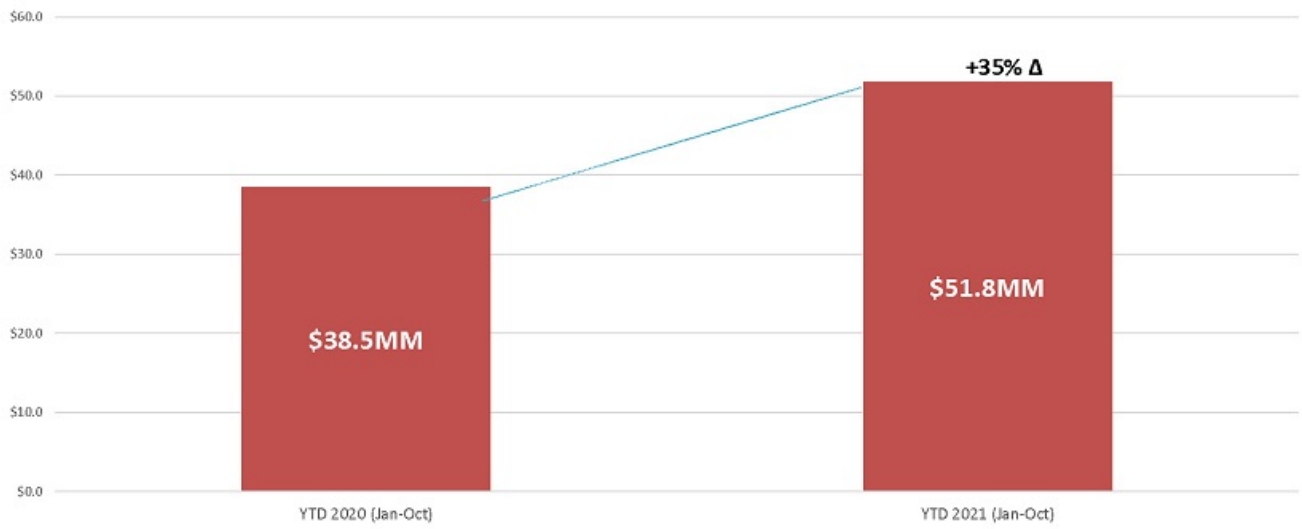
ZTlido Annual TRx & NRx



# Scilex Holding Company

## ZTlido YTD Sales Performance Comparison

ZTlido Gross Sales YTD '21 vs '20 (Jan-Oct)

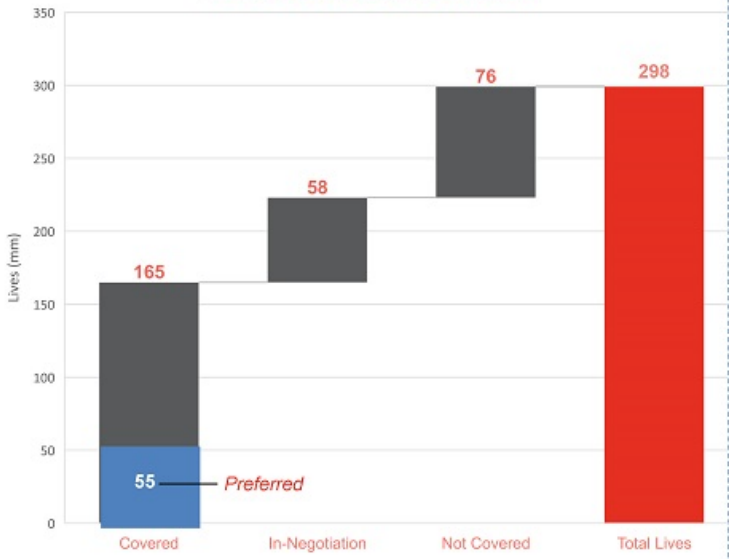


# Scilex Holding Company

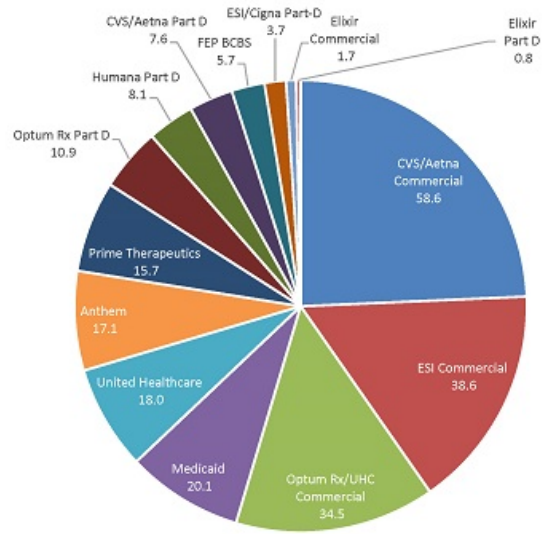
ZTlido Reimbursement Market Access Update: Preferred Lido patch on Medi-Cal from Jan 1. Negotiating with CVS

## ZTlido Market Access continuing to improve

ZTlido Covered Lives Overview



ZTlido MHC Notable Contracts: Signed & In-Negotiations



Sources: MMIT, Scilex Analysis, lives in Millions

## Scilex Holding Company

# ZTlido Global Intellectual Property

### Family 1 – Expiring in 2031

- U.S. 9,283,174 – Non-aqueous patch comprising lidocaine – Orange Book listed
- U.S. 9,925,264 – Methods of treating pain using patch – Orange Book listed
- U.S. 9,931,403 – Non-aqueous patch comprising lidocaine – Orange Book listed
- U.S. 10,765,749 – Non-aqueous patch comprising lidocaine – Orange Book listed
- 1 pending U.S. application
- Ex-U.S. applications in: **AT, BE, BR, CA, CH, DE, EP, ES, FR, GB, IT, JP, MX, NL, TW, HK** (granted patent in **bold**)

### Family 2 – Expiring in 2031

- U.S. 10,765,640 – Non-aqueous patch comprising lidocaine (stretch support) – Orange Book listed
- 1 pending U.S. application
- Ex-U.S. applications in: **AT, BE, BG, BR, CA, CH, CZ, DE, EE, EP, ES, FI, FR, GB, GR, HK, HR, IE, IT, JP, LT, LU, MC, MK, MX, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR, ZA** (granted patent in **bold**)

### Family 3 – Expiring in 2036

- Ex-U.S. applications in: **AU, BR, CA, CN, ID, IL, IN, JP, KR, MX, MY, NZ, PA, PE, PH, RU, SG, UA, ZA** (granted patent in **bold**)

## ZTlido Summary

- ⊗ ZTlido sales continues to show impressive growth 2 years after launch (growth of 35% in 2020, projected strong growth in 2021)
  - ⊗ Effective September 1, 2021, ZTlido® (lidocaine topical system) 1.8% has been added to multiple formularies, including two national PBMs (United Health and Optum Rx), a national health plan and two regional health plans – thereby expanding coverage by up to additional 33 million lives. ZTlido now on >55% of MHC formularies (>165 MM US lives covered)
  - ⊗ Expecting additional lives covered in 2022 on commercial, Medicare part D and Medicaid formularies to >200MM covered lives
  - ⊗ Scilex has WW rights to ZTlido (ex-Japan) and patch technology for other APIs, patent protected through 2031 in the US.
  - ⊗ Regulatory discussions ongoing in multiple ex-US markets
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Scilex Holding Company

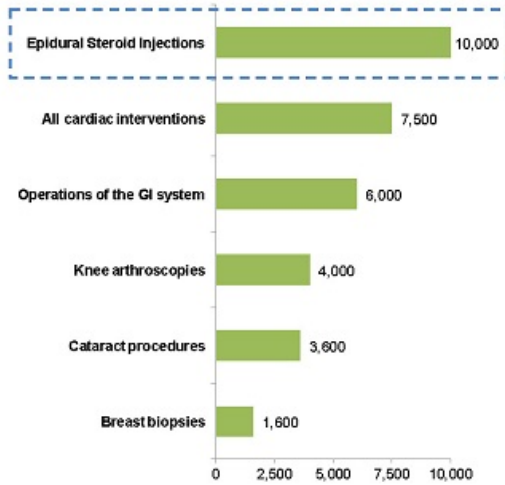
SP-102 (SEMDEXA) for Lumbar Radicular Sciatica Pain

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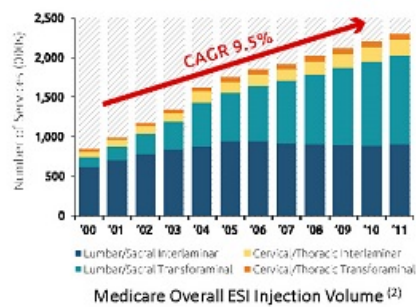
## Scilex Holding Company

# Epidural Steroid Injections One of the Most Common Medical Procedures and Top Pain Procedure in the U.S.

Common Surgical Procedures (thousands) <sup>(1)</sup>



Strong Growth Rate, Evidenced by Medicare Procedure Volumes



- ESIs widely reimbursed as procedure to delay or avoid back surgery
- Transforaminal ESI route (used in C.L.E.A.R. trial) majority of procedures

(1) CDC, HCUP, Scilex data on file

(2) <http://updates.pain-to-plc's.org/2012/01/epidural-steroid-injections.html>, Accessed ABIPP Conference 2012, Manchikanti, Medicare Slides.

## Scilex Holding Company

# Focus on Non-narcotic Pain Management Driving ESI Growth

### Current Problem

Prescription opioid abuse is at epidemic proportions in the U.S.<sup>1</sup> Additionally, research shows that opioids do not provide clinically meaningful pain relief in patients with low back and radicular pain<sup>2</sup>

### Multi-Modal Pain Management

Multiple Medical Organizations Recommend Multi-modal Analgesia for chronic pain management, including the American Society of Anesthesiologists, American Society of Regional Anesthesia & the American Academy of Orthopedic Surgeons.

### Potential for SP-102

The SP-102 clinical program is intended to demonstrate its utility as a key adjunct treatment for 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<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.

# Scilex Holding Company

## Important Environmental Factors Fungal Meningitis Outbreak with ESI (2013-14)

### MEDPAGE TODAY®

Pain Management > Back Pain

#### FDA Panel Wants Safer Epidural Steroid Shots

— Majority votes to end epidural injections with "particulate" steroids.

by Shannon Firth, Contributing Writer, MedPage Today  
November 25, 2014

SILVER SPRING, Md. -- An FDA advisory committee urged the agency to modify labels of certain formulations of corticosteroids in an attempt to make epidural injections safer following a 2-day meeting that ended Tuesday.

#### The New York Times

#### *After Doctors Cut Their Opioids, Patients Turn to a Risky Treatment for Back Pain*

What few doctors or patients know is that Pfizer, faced with hundreds of complaints about injuries and complications related to the shots, asked the Food and Drug Administration to ban that type of treatment five years ago. The company cited the risk of blindness, stroke, paralysis and death — a request that neither the agency nor Pfizer made public.

# Scilex Holding Company

## CDC Data: Drug Overdose Deaths Top 100K for First Time

The 12-month tally of estimated deaths overlaps with COVID-19 and marks another grim milestone in the country's fight against the opioid epidemic.

By [Steven Ross Johnson, U.S. News](#)

Nov. 17, 2021, at 10:00 a.m.

CDC: Drug Overdose Deaths Top 100K for First Time



Opioid-related deaths rose by 35% over comparative 12-month periods, from an estimated 56,064 as of April 2020 to 75,673 in the period ending in April 2021. (GETTY STOCK IMAGES)

The number of drug overdose deaths in the U.S. reached a grim milestone by exceeding 100,000 for the first time over a 12-month period, according to new federal estimates, with cases involving the use of opioids driving the increase.

Provisional data released Wednesday by the [Centers for Disease Control and Prevention](#) shows drug overdose deaths rose by nearly 29% over a 12-month period ending in April 2021, to an estimated 100,306.

Opioids – encompassing drugs including heroin and the highly potent fentanyl – remain the leading cause of drug overdose death, accounting for more than 75% of deaths during the time frame. Opioid-related deaths rose by 35% over comparative 12-month periods, from an estimated 56,064 as of April 2020 to 75,673 in the period ending in April 2021.

Overdose deaths from synthetic opioids – primarily fentanyl – as well as from psychostimulants such as methamphetamine also increased over the 12-month period, according to the CDC, as did deaths from natural and semisynthetic opioids such as prescription pain medication and from cocaine.

## SP-102: On-Track to be the First Novel Epidural Steroid Formulation with an FDA-approved Label to Treat Sciatica

Potent non-particulate steroid (injectable dexamethasone sodium phosphate viscous gel)

Pre-filled syringe for epidural use

Gel formulation for extended local release and substantial magnitude of pain relief

Well-tolerated. Key viscous excipient, long history of use including safety

Fast acting onset of effect with less spread and safer repeat injections

No preservatives, no surfactants, no particulates. Non-opioid and non-addictive

Projected 24 month shelf life



Scilex Holding Company

# SEMDEXA – Product Development & Regulatory

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# Scilex Holding Company

## Preclinical Supporting Studies

### *Hydrodynamic Animal Study*

- ⊗ Addition of viscosity agent results in a dose dependent prolongation of the residency time of the product within the epidural space
- ⊗ Commercial injectable steroid products (i.e., Kenalog, Depo-Medrol and Decadron) have an epidural residency half-life of ~15 minutes and have large spread away from effected site
- ⊗ SP-102 has an epidural residency half-life of >110 minutes
- ⊗ SP-102 is more localized to the injection site than commercial products, spread limited to 1 vertebrae vs 6-7 for others

### *SP-102 Toxicology Program*

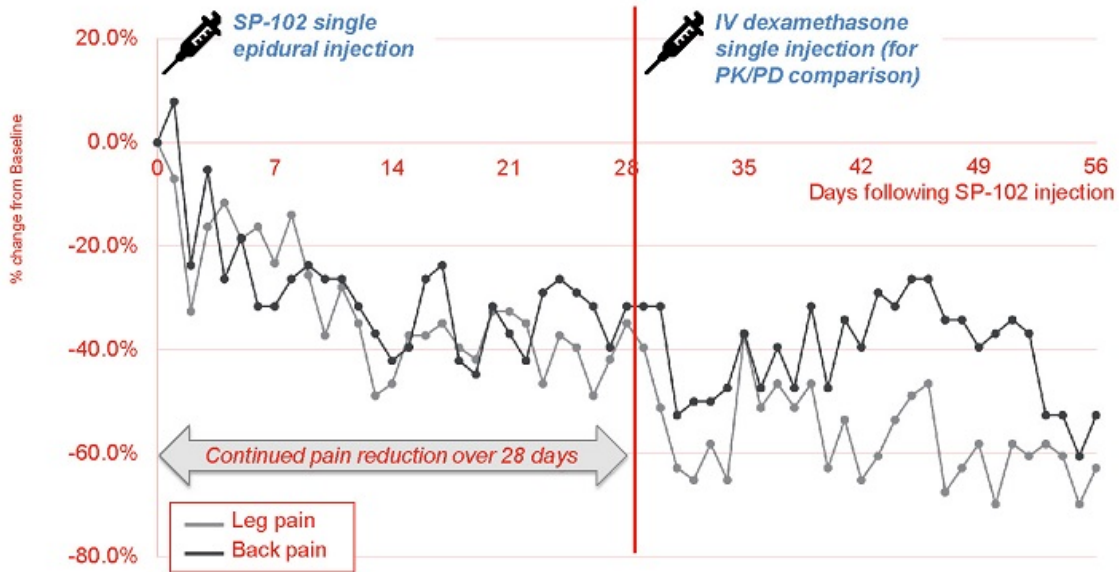
- ⊗ All tox studies completed concurrence with FDA pre-IND meeting
  - No toxicology red flags in either species (dog & pig) after both single and repeat dosing
- ⊗ No drug-related toxicity with SP-102, local (spinal area) or systemic (including brain), macroscopic or histopathology after both single & repeat (once-a-week for 4W regimen)
- ⊗ Histopathology clean with SP-102 in both routine and special stains, NOAEL is highest dose tested 10 mg/animal single dose & repeat dose
  - Placebo arm clean - non toxic, both routes in both species
  - PK data, plasma & CSF, shows clearance in 24h
- ⊗ Additional vascular tox study completed
  - Direct injection of SP-102 into vertebral artery of pigs
  - No SP-102 toxicity: vessel occlusion or macroscopic brain injury as reported with
  - Clean histopathology: no brain or vascular injury with SP-102



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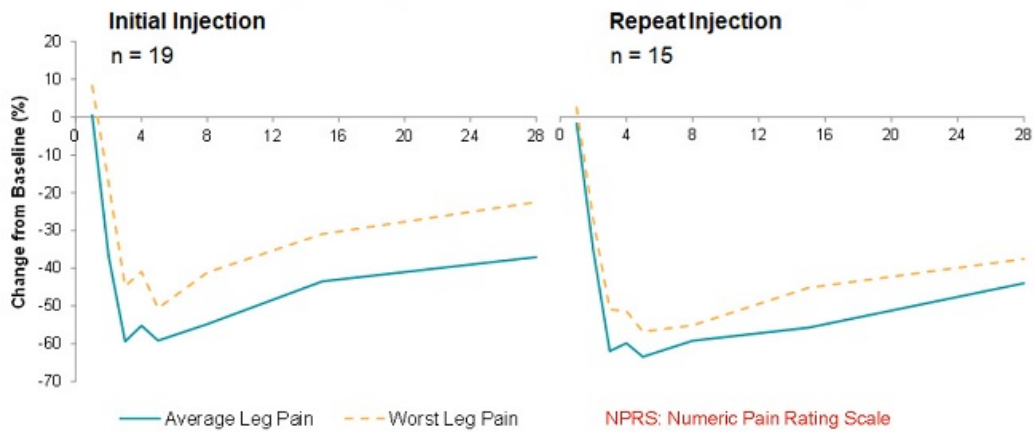
## Phase 1/2 Trial in Patients with Radicular Pain: SP-102 Led to a Continuous Reduction in Leg Pain and Back Pain

Phase 1/2 Open-Label Crossover Study in Patients with Radicular Pain (PK/PD Bridging)  
Mean change from baseline in pain scores (N=12)



# SP-102 Phase 2 – Repeat Dose Trial

Mean Percentage Change in Sciatica-Related Leg Pain as Measured by NPRS



- Clinical Response (over 50% pain reduction) with Average Leg Pain
- Greater effect with second treatment, demonstrating added benefit
- Cortisol Suppression Time is not extended by repeat dose
- No interference with clinical decision of repeat dose administration

The logo for Scilex Holding Company features a stylized, circular arrangement of lines radiating from a central point, resembling a fan or a molecular structure. The lines are thin and dark, set against a red background that has a subtle gradient and a slight shadow effect on the right side.

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# SP-102 Pivotal Phase 3 C.L.E.A.R. Trial Topline Results

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## SP-102 C.L.E.A.R. Phase 3 Trial Objectives

### ⊗ Primary objective:

- Evaluate the analgesic effect on average leg pain (as measured by the Numeric Pain Rating Scale in the affected leg) following a single transforaminal (TF) injection of SP-102 compared to an intramuscular injection of placebo over 4 weeks.

### ⊗ Secondary objectives:

- Evaluate degree of disability over time as measured by the Oswestry Disability Index (ODI).
  - Characterize the change of the subject's radiculopathy symptoms and overall condition using PainDETECT, Brief Pain Inventory–Short Form (BPI-SF), Clinical Global Impression of Change (CGIC), and Patient Global Impression of Change (PGIC).
  - Evaluate the safety of single and repeat SP-102 TF injections.
-

# Scilex Holding Company Phase 3 SP-102 C.L.E.A.R. Trial Design

(Corticosteroid Lumbar Epidural Analgesia for Radiculopathy)

## Inclusion

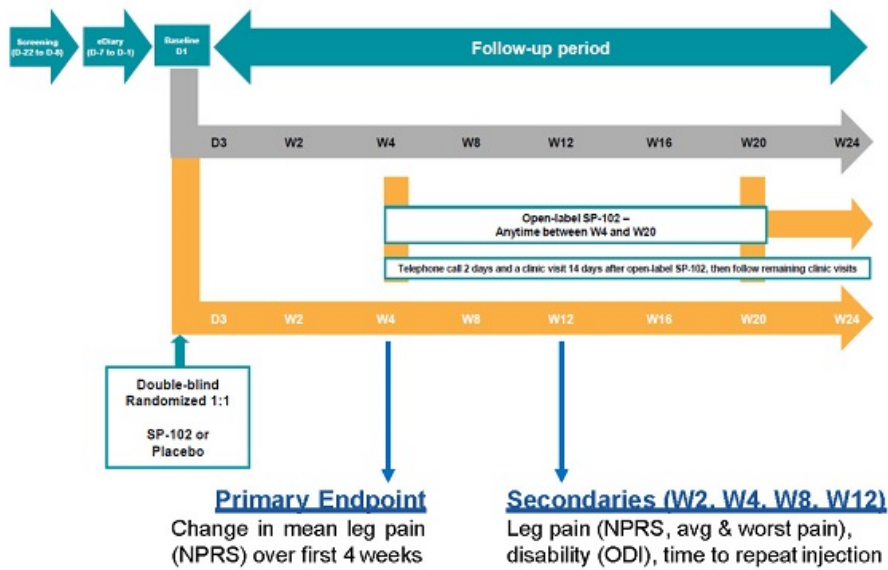
Radicular leg pain episode (4-9 NPRS)

MRI confirmed

No prior ESI (epidural steroid injection)

No opioids or NSAIDs

Stable, >4 avg NPRS pain in 21d screening



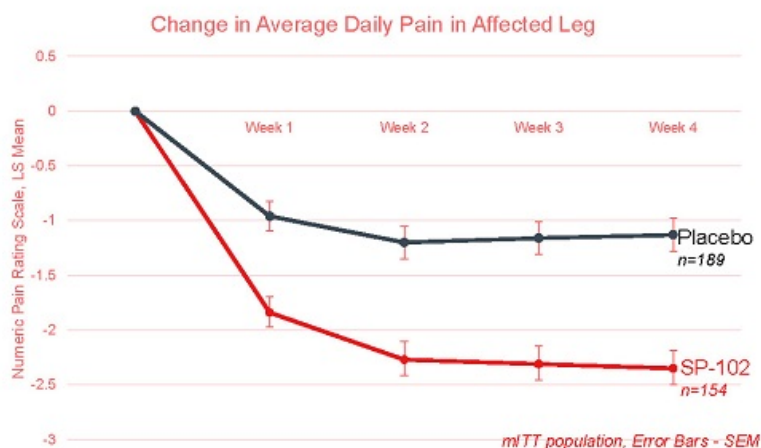
## Phase 3 SP-102 C.L.E.A.R. Trial – Sample Size

### ⊗ Statistical Analysis Plan

- The sample size provides 90% power to detect a 1-point difference in change from Baseline in the mean NPRS average daily leg pain score in the affected leg over 4 weeks between the 2 treatment groups.
  - The sample size was calculated with a Student's t-test at the 2 sided 0.05 significance level assuming a standard deviation (SD) of 2.8.
  - In order to account for an expected 15% dropout rate, approximately 400 subjects overall will be enrolled in approximately 45 study sites in the US. If the dropout rate is higher than 15% then additional subjects will be enrolled to achieve a total of 332 completed subjects.
- ⊗ The trial enrolled 401 subjects, yields 343 completers.
-

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## Phase 3 SP-102 C.L.E.A.R. Trial – Primary Endpoint



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.

Sensitivity analysis using pattern mixture model (PMM) of Mean Change from Baseline to Week 4 showed the same results.

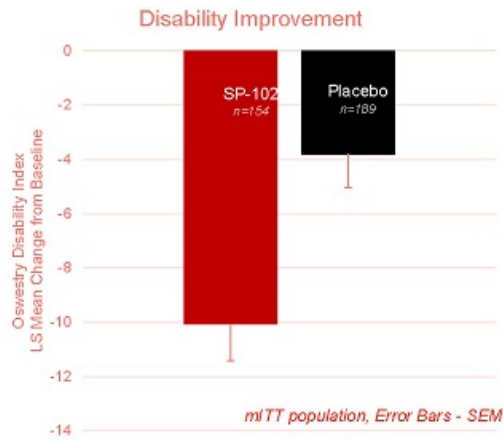
## Oswestry Disability Index

- ⊗ The gold standard for measuring degree of disability and estimating quality of life in a person with low back pain.
  - ⊗ 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.
  - ⊗ Each question scored 0-5, where 5 indicating most severe disability.
  - ⊗ All scores are summed, multiplied by 2 to obtain the Index (range 0 to 100). Zero is equated with no disability and 100 is the maximum disability possible.
  - ⊗ The ODI obtained at Screening, Baseline, W4, W12, and W24.
-



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## C.L.E.A.R. Trial – Key Secondary Endpoints



Comparison: SP-102 vs. Placebo	
At Week 4, LS Mean (SE)	-6.28 (1.494)
95% CI	-9.22, -3.34
p-value	<0.001***

ANCOVA model with treatment, site, and Pain Catastrophizing Scale group (<30 or ≥30) as fixed effects, and baseline ODI as covariate.

### Days to Open-Label Repeat Injection

	SP-102 (N=154)	Placebo (N=189)
Number of subjects with repeat injection of SP-102 (%)	70 (46%)	126 (67%)
Time (days) to Repeat Injection		
25 <sup>th</sup> quantile (95% CI)	50 (43, 62)	36 (34, 39)
50 <sup>th</sup> quantile (95% CI)	NE (78, NE)	57 (49, 67)
75 <sup>th</sup> quantile (95% CI)	NE (NE, NE)	NE (85, NE)
Comparison to Placebo		
Hazard Ratio (95% CI)	0.49 (0.36, 0.65)	
p-value	<0.001***	

Quartiles estimated using Kaplan-Meier estimation. A Cox proportional hazards model adjusting for site and Pain Catastrophizing Scale (<30 or ≥30).

NE – Not estimable.

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# C.L.E.A.R. Trial – Adverse Events

	SP-102/SP-102		PBO/SP-102		SP-102/none		PBO/none	
	(N=104)		(N=130)		(N=98)		(N=69)	
	Subjects, n(%)	Events	Subjects, n(%)	Events	Subjects, n(%)	Events	Subjects, n(%)	Events
Any TEAE	34 (32.7)	72	41 (31.5)	73	25 (25.5)	46	14 (20.3)	23
Any TEAE >3% Incidence								
Headache	7 (6.7)	11	11 (8.5)	16	4 (4.1)	4	2 (2.9)	2
Upper respiratory tract infection	3 (2.9)	3	3 (2.3)	3	0	0	3 (4.3)	3
Injection site pain	5 (4.8)	5	1 (0.8)	1	0	0	0	0

- ⊗ No Adverse Events of special interest (paraplegia, hematoma, infection)
- ⊗ No Serious AEs related to drug or injection procedure

## Phase 3 SP-102 C.L.E.A.R. Trial - Conclusions

- ⊗ The trial met primary and key secondary endpoints with statistical significance
  - ⊗ Demonstrated clear safety profile of SP-102
  - ⊗ Achieved all study objectives
  
  - ⊗ Next steps in 2022
    - Apply for Breakthrough Therapy Designation with FDA
    - Request pre-NDA meeting with the FDA
    - Advisory Board meeting following complete data analysis in March 2022
    - Prepare for publication of results in prestigious journals (NEJM, JAMA, etc), presentations at ASRA, ASIPP, SIS, AAPM physician annual conferences
-

# Scilex Holding Company

## The SP-102 Manufacturing On-Track for NDA Submission to FDA in 2023

### Commercial supply chain in place

- API: Dexamethasone sodium phosphate supplier in place
- Novel excipient: Supply from leading commercial provider, 20-year supply agreement for specific type for use
- Drug product: Commercial manufacturer in place, FDA experienced with biocompatible excipient, sterile injectables, and high viscosity pre-filled syringe filling

### CMC Activities to Submission

- Current 20L scale – planning scale-up to 120L in 2021 (acceptable scale for commercial)
- Process validation / registration / commercial batches at 120L – 2022
- Current stability indicates pre-filled injectable syringe with 2 year shelf life
- Gross margin projected to be well in the range

Scilex has developed significant know-how and expertise in formulation and manufacturing of sterile viscous gel

## Scilex Holding Company

# SP-102 (SEMDEXA) Global Intellectual Property

- ⊗ Patent family expiring in 2036
    - U.S. 10,117,938 - methods of treating inflammation and/or pain
    - U.S. 10,500,284 – composition of matter and syringe
    - U.S. 11,020,485 – composition of matter
    - 1 pending U.S. application
  - ⊗ Ex-U.S. applications in **AT, AU, BE, BR, CA, CH, CN, DE, EP, ES, FR, GB, HK, IN, IL, IT, JP, KR, MX, NL, NZ, TW** (granted patent in **bold**)
-

## Scilex Holding Company

### Summary SP-102 (SEMDEXA)

- ⊗ No FDA approved products to treat Sciatica/chronic back pain. All currently used off-label products have FDA warnings not to use
  - ⊗ Scilex will meet with FDA to discuss NDA filing for SEMDEXA in 2022
  - ⊗ Breakthrough Designation filing with Phase 3 results in 2022
  - ⊗ Priority Review filing at time of NDA filing in 2022/23
  - ⊗ Scilex has experience with launch of pain management products and obtaining approval on Managed Health Care/ Medicare/Medicaid formularies
  - ⊗ Scilex has WW rights to SEMDEXA, patent protected through 2036 in US and major markets
-

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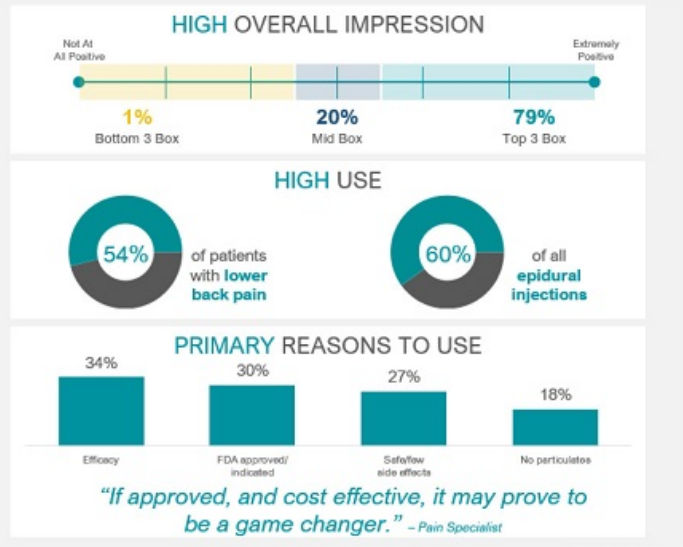
# SEMDEXA – Commercial Strategy & Outlook

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# SEMDEXA Overall Physician Impression

PERCEPTIONS OF SP-102

SP-102 is perceived positively and is planned to be used for majority of patients



Source: "Lumbar Radiculopathy Market Opportunity" Quantitative Research (Nov'17); Cognitive Consulting



## Scilex Holding Company

# SEMDEXA – Broad Potential for Life Cycle Management

Physicians indicated there is potential opportunity for spontaneous use of SEMDEXA outside of lumbar radiculopathy which could represent an additional upside of ~50-200%\* over LR

### Additional Uses

- Carpel Tunnel
- Trigger Point Injections
- Injections for Knee, Shoulders, Wrists, Ankles, Joints
- Cervical Radiculopathy
- Knee Arthritis
- Hip and Knee Replacements
- Complex Regional Pain Syndromes (CRPS)
- Lumbar Spinal Stenosis
- Acute Spinal Injury
- Discogenic Pain

\*Assumes similar degree of utilization for additional indications

Source: Syneos Consulting (Campbell Alliance) Market Research

## Scilex Holding Company

# SP-102 Reimbursement Scenario

- ⊗ SP-102 is expected to be used in the Office setting as well as in Ambulatory Surgical Centers and Hospital Outpatient clinics
  - ⊗ Scilex expects SP-102 to secure favorable pricing and reimbursement due to its strong product profile, meeting important unmet medical needs in pain management and lack of other approved products
    - As the only ESI that is preservative and particulate free and FDA approved option for lumbar radiculopathy, SP-102 will have a strong case for reimbursement by payers
  - ⊗ Reimbursement consultants believe SP-102 will receive a carve out reimbursement due to its clinical profile and as the only FDA approved ESI with a unique formulation that is effective and safe
  - ⊗ Scilex has engaged reimbursement experts and healthcare experts to ensure strong reimbursement at launch
-

## Scilex Holding Company

# High Barriers to Competition

### Intellectual Property

- SP-102 Method of Use: US Patent issued (2036 expiry)
- SP-102 Formulation: US Patent approved (2036 expiry); ex-US major markets issued and pending

### Proprietary Excipient

- Exclusive supply agreement for novel ~~biologic~~ excipient in SP-102 (for epidural injection)

### Novel Gel Formulation, Potentially Improves Localized Effects

- Viscous gel formulation for extended local duration of drug, at the site of injection

### Complex Manufacturing Process & Know-How for Pre-Filled Viscous Gel

- Manufacturing involves specialized equipment, extensive trade secrets and processes

### Full Nonclinical Safety & Clinical Package Likely Required by FDA for any Alternate Formulation

## Scilex Holding Company

### Summary – SP-102 (SEMDEXA)

- ⊗ Market with high unmet need & no FDA approved products to treat sciatica pain
  - ⊗ Scilex will meet with FDA to discuss NDA for SEMDEXA in 2022 and pursue Breakthrough Designation and Priority Review applications
  - ⊗ SEMDEXA is a potential blockbuster product with market potential of \$3-5 billion in peak annual sales in the US
  - ⊗ Target audience for SEMDEXA reached using sales team (65+) currently promoting ZTlido
  - ⊗ Scilex has global rights to SEMDEXA, patent protected through 2036 in US and major markets
-

Scilex Holding Company

SP-103 for Low Back Pain & Delayed Release  
LDN for Fibromyalgia

## SP-103 is a 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**

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**
- ✓ **Expect to initiate Phase 2 trial by January 2022**
- ✓ For the treatment of acute low back pain – a **substantially larger opportunity than PHN**

## Scilex Holding Company

### **SP-104 Delayed Burst Low Dose Naltrexone (LDN) – Fibromyalgia**

Fibromyalgia is a long-term condition that causes pain all over the body and affects ~2% of general population (5-8 million patients, 80-90% women)

#### **Low Dose Naltrexone (LDN) efficacy well documented**

- Routinely used off-label to treat multiple types of chronic pain –fibromyalgia, complex regional pain, and other indications. Demonstrated efficacy in multiple independent investigator-initiated trials

#### **Problems with current formulations of Naltrexone**

- There are no low-dose non-compounded forms of naltrexone commercially available (< 5 mg/day)
  - Poor compliance due to immediate release undesirable effects including hyperalgesia, dysphoria, nausea, anxiety, and insomnia with current formulations
  - Physician hesitancy for off-label prescriptions due to dysphoric effects of naltrexone as well as complications of dose titrating with limited compounding pharmacy supply
  - The few treatments approved for Fibromyalgia are marginally effective with unpleasant side-effects
  - Phase 1 SP-104 program of delayed burst release LDN underway
  - Phase 2 trial in Fibromyalgia scheduled for 2022
-

Scilex Holding Company

## Summary

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# Scilex Holding Company

## Acute/Chronic Pain Major Global Healthcare Problem

- Pain is reported in about 90% of the global population
- 94% report pain in their back or lower back
- 69% of people endure long-lasting pain which negatively impacts quality of life


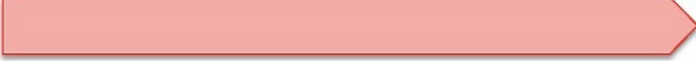
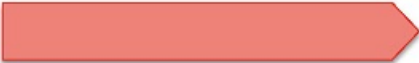


### Percentage of people who experience body pain



Source: Global Pain Index Summary Report.

## Scilex Holding Company





# Best-in-Class Non-Opioid Pain Therapeutics

Platform	Program	IND	Phase 1	Phase 2	Phase3 Pivotal	NDA	Approved	Upcoming Milestones	
 Non-Opioid Pain Management	ZTlido® 1.8% (Postherpetic Neuralgia-PHN)						Launched US October 2018		
	SP-102 (SEMDEXA) (Lumbar Radicular / Sciatica Pain)						Pivotal Phase 3 trial enrollment completed & topline results in December 2021		
	SP-103 Lidocaine Topical System 5.4% (3X) (Low Back Pain)						Initiating Phase 2 in January 2022		
	SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)						Initiating Phase 1 in Q4-2021		

# Scilex Holding Company

## Epidural Steroid Injections (ESIs) Market are a Huge Opportunity for a Potential Blockbuster Like SP-102

*Pursuing a proven strategy for novel locally-delivered products for pain indications*

Osteoarthritis intra-articular injection products	Post-operative acute pain local anesthetic products	Chronic low back pain epidural steroid gel injection
<p><b><u>4M+ procedures / year</u></b></p> <p> HYLAN G-F 20 &gt;\$500M peak sales</p> <p> triamcinolone acetonide extended release injectable suspension 32 mg <b>Purchased by Pacira for &gt;\$930M</b></p>	<p><b><u>8M+ procedures / year</u></b></p> <p> (bupivacaine liposome injectable suspension) \$430M sales in 2020 Pacira: \$2.6B market cap</p> <p> <b>Projected &gt;\$700M peak sales</b> Heron: \$1B market cap</p>	<p><b><u>12M+ procedures / year</u></b></p> <p><b>Scilex SP-102 gel in pivotal Phase 3 (completed enrollment 2021 with positive results )</b></p> <p><b>Projected &gt;\$1.5B peak sales</b></p>

## Scilex Holding Summary



Commercial non-opioid pain management company with 3 clinical stage programs in large markets with very high unmet need

Launched rapidly growing ZTlido (lidocaine topical system 1.8%) in 2018 with in-house commercial and sales team

Semnur Pharma merged with Scilex in 2019 and lead program SP-102 for sciatica back pain, has blockbuster potential, Fast Track Designation; Phase 3 trial completed enrollment and positive results

Former investors and partners include leading global venture capital firms and Itochu a global conglomerate. Currently Scilex is a subsidiary of Sorrento Therapeutics, Inc.

### Non-Opioid Pain Analgesics

ZTlido™  
(lidocaine topical system) 1.8%

SP-102 SP-103 SP-104

sorrento  
THERAPEUTICS

ITOCHU

VIVO  
CAPITAL

Canaan

FRAZIER  
HEALTHCARE PARTNERS