UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): September 22, 2016

SORRENTO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

9380 Judicial Drive
San Diego, CA 92121
(Address of principal executive offices)

Registrant’s telephone number, including area code: (858) 210-3700

(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 communication 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))
Item 7.01  Regulation FD Disclosure.

On September 22, 2016, Scintilla Pharmaceuticals, Inc. ("Scintilla"), a subsidiary of Sorrento Therapeutics, Inc. ("Sorrento"), commenced an equity financing process (the “Proposed Financing”). A presentation regarding Scintilla has been posted under the “Investors” section of Sorrento’s website at www.sorrentotherapeutics.com and is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information contained in, or incorporated into, this Item 7.01, including Exhibit 99.1 hereto, 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 (the “Securities Act”), or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

This Current Report on Form 8-K, including Exhibit 99.1 hereto, is neither an offer to sell any securities, nor a solicitation of an offer to buy any securities, 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 any such state or jurisdiction. Any sales of securities in the Proposed Financing will be made solely to “accredited investors,” as defined under Regulation D under the Securities Act (“Regulation D”), pursuant to the exemptions from registration provided by Rule 506(c) of Regulation D.

Safe Harbor for Forward-Looking Statements

Any statements contained in this Current Report on Form 8-K, including Exhibit 99.1 hereto, other than statements of historical fact, including statements about management’s beliefs and expectations regarding the Proposed Financing and Scintilla’s prospects and future results, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and should be evaluated accordingly. These statements are made on the basis of management’s views and assumptions regarding future events and business performance. Words such as “estimate,” “believe,” “anticipate,” “expect,” “intend,” “target,” “should,” “may,” “will” and similar expressions and their negative forms are intended to identify forward-looking statements.

Forward-looking statements involve risks and uncertainties that may cause actual results to differ materially from any future results, performance or achievements expressed or implied by such statements. These risks and uncertainties include, without limitation, Scintilla’s ability to complete its proposed acquisition of Semnur Pharmaceuticals, Inc. and to integrate Semnur Pharmaceuticals, Inc.; developments regarding Scintilla’s research and development efforts and clinical trials; regulatory reviews and approvals; and Scintilla’s ability to hire and retain key employees.

These and other risks and uncertainties are discussed in more detail in Sorrento’s filings with the Securities and Exchange Commission (the “SEC”), including Sorrento’s most recent Annual Report on Form 10-K, most recent Quarterly Reports on Form 10-Q and recent Current Reports on Form 8-K. Many of these risks are beyond management’s ability to control or predict. Should one or more of these risks or uncertainties materialize, or should the assumptions prove incorrect, actual results may vary in material aspects from those currently anticipated. Investors are cautioned not to place undue reliance on such forward-looking statements as they speak only as of the date the statement is made. All forward-looking statements attributable to Sorrento or Scintilla or persons acting on behalf of either Sorrento or Scintilla are expressly qualified in their entirety by the cautionary statements and risk factors contained or referenced in this Current Report on Form 8-K and Sorrento’s filings with the SEC. Except as required under the federal securities laws or the rules and regulations.
of the SEC, neither Sorrento nor Scintilla undertakes any obligation to update or review any forward-looking statement or information, whether as a result of new information, future events or otherwise, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

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: September 22, 2016

SORRENTO THERAPEUTICS, INC.

By: /s/ Henry Ji, Ph.D.
Name: Henry Ji, Ph.D.
Title: President and Chief Executive Officer
Disclaimer

The Company’s financial statements, reports, presentations, and other information contained in this presentation or in other materials of the Company along with certain statements that may be made by management of the Company orally in presenting this material may contain "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements can be identified by the use of words such as "believe," "expect," "anticipate," "estimate," "project," "intend," "potential," "future," "future performance," "future financial performance," "future results," "future actions," "future events," "future financial results," "future plans," "future investments," "future developments," "future events," "future performance," and similar expressions. These forward-looking statements are based upon the current beliefs and expectations of the Company’s management and are subject to significant risks and uncertainties.

Scintilla Pharmaceuticals Inc is a subsidiary of Sorrento Therapeutics Inc, a publicly traded company on the Nasdaq Stock Market. Certain statements contained in this presentation or in other documents of the Company along with certain statements that may be made by management of the Company orally in presenting this material may contain "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements can be identified by the use of words such as "believe," "expect," "anticipate," "estimate," "project," "intend," "potential," "future," "future performance," "future financial performance," "future results," "future actions," "future events," "future financial results," "future plans," "future investments," "future developments," "future events," "future performance," and similar expressions. These forward-looking statements are based upon the current beliefs and expectations of the Company’s management and are subject to significant risks and uncertainties.

All other trademarks and trade names are the property of their respective owners. Scintilla™, Sorrento™, G-MAB™, CAR-TNK™, TNK-Therapeutics™, and the Scintilla logo are trademarks owned by Sorrento Therapeutics Inc. All other trademarks and trade names are the property of their respective owners.

Nasdaq: SRNE
**Vision**

To significantly advance treatments and outcomes for pain patients with innovative, non-opioid pain management solutions.

**Mission**

To develop and commercialize a new generation of pain medications targeting moderate to severe pain with improved efficacy and reduced risk of opioid side-effects and abuse potential, meeting significant unmet patient and healthcare system needs.
Scintilla Overview

Scintilla Pharmaceuticals is a majority-owned subsidiary of Sorrento Therapeutics. Announced proposed acquisition of Semnur Pharmaceuticals in August 2016.

Portfolio of Two Investigational Product Candidates Spanning Interventional Pain Spectrum

**SP-102**: First non-opioid epidural steroid injectable potentially for the treatment of intractable cancer pain.

- Cancer Pain IND target early 2017
- Phase 1/2 clinical trials confirmed activity consistent with animal models
- Phase 1/2 trial in chronic back pain completed dosing
- IND filing target in Q1 2017
- Projected to begin Pivotal Phase 3 clinical trials in 2017


- Cancer Pain IND target in Q1 2017
- Phase 1/2 trial in chronic back pain completed dosing
- Phase 1/2 trial in cancer pain completed dosing
- Phase 1/2 trial in Lumbosacral Radiculopathy Pain
- IND filing target in Q1 2017
- Projected to begin Pivotal Phase 3 clinical trials in 2017

Orphan Drug Designation

- Semnur Pharmaceuticals
- Scintilla Pharmaceuticals

Sorrento Therapeutics
Innovative Non-opioid Pain Management Portfolio
Large Established yet Underserved Target Markets
Worldwide Commercial Rights to All Product Candidates
Strong Proprietary Platform with High Barriers to Entry
Two Products with Blockbuster Potential Poised to Replace Current Standard of Care
Innovative, Non-opioid Pain Management Portfolio
The Right Team to Deliver Long-Term Value
The Pain Market is Expanding and Underserved

- Chronic pain affects 116 million or almost one in three Americans (1)
- Costs the United States approximately $560 to $635 billion annually (2)
- Nearly 30 million patients suffer from lower back pain in the U.S. (3)
- Greater than 80% of cancer patients have uncontrolled pain during course or disease (4)
- Growing government, physician and patient backlash against opioid-based products
- Not suitable for long term use
  - Depression
  - Myriad of serious side effects (Respiratory, GI)
  - High rate of addiction
  - Backlash against opioid-based products
  - Growing government, physician, and patient backlash

- Pain likely a major reason for hospitalization
- Pain likely a major reason for hospitalization
- Chronic pain affects 16 million, or almost one-in-three Americans (1)

Scintilla Focuses on a Broad Segment of the Pain Market

Scintilla Focuses on Acute, Chronic, and Chronic Non-Malignant Pain

- Acute Pain
- Chronic Pain
- Chronic Non-Malignant Pain
- Malignant Pain

- Pain: 1.8 to $635 billion annually
- Cost of United States approximately $560 billion

- Myriad of serious side effects (Respiratory, GI)
- High rate of addiction
- Backlash against opioid-based products
- Growing government, physician and patient backlash

- Not suitable for long term use
  - Depression
  - Myriad of serious side effects (Respiratory, GI)
  - High rate of addiction

Scintilla Focus on a Broad Segment of the Pain Market

The Pain Market is Expanding and Underserved
**Strong Pipeline with Breakthrough Potential**

**Positioning**

**Market Opportunity**

**Development Milestones**

**SP-102** Potentially the first approved preservative and surfactant free steroid indicated for epidural administration to treat lumbar radiculopathy

- **Positioning**
  - Progressive disease
  - Often leading to expensive back surgery
  - Current therapies provide limited pain relief and have potential for serious side effects

- **Market Opportunity**
  - No currently approved injectable product for epidural administration
  - Estimated ~10 million epidural steroid administrations per year in US alone
  - Potentially significant reduction in opioid use

- **Development Milestones**
  - Phase 1 / 2 trial in chronic back pain completed dosing
  - IND filing target in Q1 2017
  - Projected to begin Pivotal Phase 3 clinical trials in 2017

**RTX** Novel non-opioid potential for treatment of intractable cancer pain

- **Positioning**
  - Possible single injection efficacy with longer term benefit
  - Pain reduction
  - Increase quality of life, particularly mobility
  - Can be used in addition to opiate medications

- **Market Opportunity**
  - More than 80% of cancer patients experience uncontrolled cancer-related pain during course of disease
  - Chemotherapy induced neuropathic pain seen in up to ¾ of patients with a cost of management of $2.3 billion
  - Potential to replace current costly invasive treatments (nerve stimulation, intrathecal opioids, radiotherapy)
  - Phase 1 / 2 clinical trials confirmed activity consistent with animal models

- **Development Milestones**
  - IND filing target early 2017
  - Scheduled to begin Phase 2 clinical trials in 2017
  - Filing for Breakthrough designation if granted would allow for rapid approval

**Lema et al 2011**

**NEJM July 3 2014**

**Editorial: Epidural Glucocorticoid Injections in Patients with Lumbar Spinal Stenosis; Gunnar B J Andersson M D Ph D**
Significant Near Term Clinical Milestone Targets for Scintilla Programs

Multiple clinical milestones for all programs expected in the next 12 months

Mid to late stage trials commencing for SP-102 & RTX programs

In addition, potential corporate development milestones may also be achieved with potential collaborations or licensing in ex-US territory in 2017

<table>
<thead>
<tr>
<th>Program</th>
<th>Period</th>
<th>Phase 1 / 2</th>
<th>Phase 2</th>
<th>Phase 3</th>
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</table>
SP-102: Innovative Non-opioid Injectable for Chronic Pain
SP-102 Chronic Pain Opportunity

**Profile**
- Novel SP-102
- Response to physicians seeing an FDA-approved particulate and preservative-free product as novel, which could potentially avoid growing liability risk
- Very Positive

**Program Development**
- Shortened
- Established 505(b)(2) program
- Positive FDA PIND Meeting in 2014
- Scheduled to begin Phase 3 clinical trials in early 2017
- Very strong investigator interest

**Risk**
- No long-term systemic toxicology or dose finding studies required
- Preclinical and Phase 1/2 clinical data support higher probability of success
- Scheduled to begin Phase 3 clinical trials in early 2017; very strong investigator interest

**Market**
- Large number of interventional back pain treatment procedures in U.S. (~10M)
- Large, growing unsatisfied market
- Familiarity and rapid acceptance of prescribing physicians with SP-102 treatment

**Low Technical Risk**
- No interventional prescription pain product approved or in late stage for epidural use in U.S.

**Unmet Clinical Need**
- Large number of interventional back pain treatment procedures in U.S. (~10M)
Primary endpoint at 4 weeks. Secondary at 12 weeks.

- Potential for reducing size of safety database for SP-102 is dependent on tox study and Phase 3 clinical trial results.
- FDA expressed interest in supporting a long-acting injectable steroid with a good safety profile.
- FDA focus on local tox, did not express concerns on systemic tox with API and excipient.
- FDA expressed interest in supporting an ESI product with good safety profile.
Fungal Meningitis Outbreak (2012-14)

Newsweek
04 24 2016
THE KILLER PHARMACY
INSIDE
AMERICAN MASS MURDER
CASE
Meningitis outbreak caused by compounding pharmacy produced steroids for epidural injections contaminated with Aspergillus fumigatus
Infected more than 800 people across 20 states, >60 of whom died
By Kurt Eichenwald / April 16 2015
http://www.newsweek.com/2015/04/24/inside-one-murder-murderous-corporate-crimes-us-history-322665.html#VTLgIv4aBsI
Epidural Steroid Injections (ESIs) Are One of the Most Common Medical Procedures in the U.S.

- **Common Surgical Procedures in Millions (1)**
  - 10,000 All cardiac interventions
  - 7,500 Operations of the GI system
  - 6,000 Knee arthroscopies
  - 4,000 Cataract procedures
  - 3,600 Breast biopsies
  - 2,500 Esophageal procedures
  - 2,000 Carotid procedures
  - 1,600 Breast biopsies
  - 1,200 Arthrocentesis
  - 1,000 ESI (2)

**Key Points**

- Epidural steroid injections are one option to relieve pain associated with Lumbar Radiculopathy.
- The Medicare market for this treatment option is expanding rapidly, with a CAGR of 9.5%.
- Lumbar/Sacral Transformational ESIs have increased 665% per 100,000 Medicare beneficiaries.

**Medicare Overall ESI Injection Volume (2)**

- **Operations of the GI system**
- **All cardiac interventions**
- **Epidural Steroid Injections**

**Common Surgical Procedures in Millions (1)**

- **Breast biopsies**
- **Carotid procedures**
- **Knee arthroscopies**
- **All cardiac interventions**
- **Epidural Steroid Injections**

Accessed: ASIPP Conference 2012 Manchikanti Medicare Slides
Lumbar Radiculopathy is a subtype of Low Back Pain characterized by debilitating pain usually requiring medical intervention. This condition is typically caused by a herniated or bulging disc, which puts pressure on the spinal nerve root. Imaging scans are required to determine the specific cause of the pain. Some physicians may administer an Epidural Steroid Injection (ESI) without an imaging scan.

### Epidemiology

#### Lumbar Radiculopathy
- Common condition with an estimated U.S. prevalence of 13.4%.

#### Spinal Stenosis
- 27% of about 30 million (NIH).
- Patients with Low Back Pain:
  - 11.5 million Americans (ASIPP).
- Chronic Pain:

#### Pain

#### Degenerative Disc Disease

#### Lumbosacral Radicular Pain Market Trends

If SP-102 were able to capture even a small share of this large market, the revenue potential would be significant. 40%

### Source

A Focus on Non-narcotic Pain Management Will Drive the Growth of Epidural Steroid Injections

Prescription opioid abuse is at epidemic proportions in the U.S.1

Additionally, research shows that opioids do not provide clinically meaningful pain relief in patients with low back pain.2

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.

The American Society of Anesthesiology Practice Guidelines for Chronic Pain Management3

The American Society of Regional Anesthesia & the American Academy of Orthopedic Surgeons

Multi-modal analgesia is the use of two or more analgesic agents or techniques to improve pain management while minimizing risk of adverse events.

The American Society of Anesthesiology recommends multi-modal analgesia for chronic pain management including multiple medical organizations.

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 in patients with back pain.4

Centers for Disease Control and Prevention, Increases in Drug and Opioid Overdose Deaths, 2001–2014. MMWR 2015; 64; 1.


Chronic Back Pain: Steroid Injections

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulation</th>
<th>Potential Issues</th>
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</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>Decadron</td>
<td>• Neurontoxiccy of benzyl alcohol &amp; EDTA</td>
</tr>
<tr>
<td>Soluspan</td>
<td>Betamethasone sodium phosphate</td>
<td>• Neurotoxicity of benzalkonium chloride &amp; EDTA</td>
</tr>
<tr>
<td>Kenalog</td>
<td>Triamcinolone acetonide</td>
<td>• Neurotoxicity of benzyl alcohol &amp; EDTA</td>
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<tr>
<td>Depomedrol</td>
<td>Methyldipropionate acetate</td>
<td>• Neurotoxicity of benzyl alcohol &amp; EDTA</td>
</tr>
</tbody>
</table>

All current ESI products have preservatives and surfactants.

Administration of corticosteroids have not been established
for death, have been reported with epidural injection.

Some resulting in serious neurologic events, some resulting in death, have been reported with epidural injection.

The safety and effectiveness of epidural administration
of corticosteroids have not been established and
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of corticosteroids have not been established and

All marketed products have bolded label warnings:

“serious neurologic events, some resulting in death, have been reported with epidural injection.

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## Differentiated Product Profile & Positioning

### Dexamethasone

- **Depo-Medrol**
- **Kenalog**
- **SP-102** (Potential)

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Depo-Medrol</th>
<th>Kenalog</th>
<th>SP-102 (Potential)</th>
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<tbody>
<tr>
<td>FDA-approved for lumbar epidural pain</td>
<td>✔️</td>
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<tr>
<td>Important Treatment Attributes</td>
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<tr>
<td>Novel formulation with prolonged residency time at injection site</td>
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<tr>
<td>Lower risk of neurologic AEs</td>
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<tr>
<td>Safer repeat injections</td>
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<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Reduction in disability in LR</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Duration of efficacy</td>
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<tr>
<td>Fastest onset of effect in LR with less spread</td>
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<tr>
<td>Clinical data demonstrating safety and efficacy</td>
<td>✔️</td>
<td>✔️</td>
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</tr>
</tbody>
</table>

### Clinical Data

- **FDA-approved for lumbar epidural pain**
- **Important Treatment Attributes**
- **Novel formulation with prolonged residency time at injection site**
- **Lower risk of neurologic AEs**
- **Safer repeat injections**
- **Reduction in disability in LR**
- **Duration of efficacy**
- **Fastest onset of effect in LR with less spread**
- **Clinical data demonstrating safety and efficacy**

---

**Asterisk**

- Prefilled Syringe
- No Particulates
- No Preservatives
- No Surfactants

**Notable Clinical Outcomes**

- Reduction in disability in LR
- Duration of efficacy

**Key Points**

- Fastest onset of effect in LR with less spread
- Clinical data demonstrating safety and efficacy

**Potential Benefits**

- Safer repeat injections
- Lower risk of neurologic AEs
- Novel formulation with prolonged residency time at injection site

**Product Attributes**

- **Dexamethasone**
- **Depo-Medrol**
- **Kenalog**
Clinical Utility of Product Concept is Consistent with Pain Specialists Needs

Physicians reacted favorably to the SP-102 product profile giving the steroid an average score of 6.2 on a favorability scale of 1-7. Overall, the majority of specialists scored the profile favorably, with an average score of 6.3.

Cost was cited often as the only negative aspect of the profile. An 8-week duration of effect would increase favorability in some physicians but decrease favorability in others due to less revenue caused by lower volume of injections.

"It's novel and disruptive. The non-particle and non-preserve aspects are exciting."

Anesthesiologists, PMR specialists, and other specialists generally scored the profile favorably, with an average score of 6.1. However, orthopedic specialists scored the profile less favorably, with an average score of 6.

Steroid A's stated duration of effect was 1-7 weeks, with seven physicians scoring it with a 7, four with a 6, and four with a 5. On a favorability scale of 1-7, seven physicians scored it with a 7, four with a 6, and four with a 5. Anesthesiologists, PMR specialists, and other specialists generally scored the profile favorably, with an average score of 6.3. However, orthopedic specialists scored the profile less favorably, with an average score of 6.
Lifecycle Management Summary

Opportunities

Physicians indicated there is potential opportunity for spontaneous use of SP102 in the U.S. outside of lumbar radiculopathy which could represent an additional upside of ~50-200%.

**LR Procedure Volume**

- Total Procedure Volume: 5.5 M
- Non-LR Procedure Volume: 8.3 – 16.5 M
- LR Procedure Volume: 5.5 M
- Non-LR Procedure Upside: -50-200%
- LR Injection Procedure Forecast: 6.5 M

**Additional Uses**

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

*Assumes similar degree of utilization for additional indications.
Identical program in >100 Beagle dogs and Mini-Pigs (each program costs approximately $2m)

Multi-dose epidural control (saline)
- 10 mg in 1 mL
- SD Epidural High dose:
- 2 mg in 0.4 mL
- SD Epidural Med dose:
- 1 mg in 0.4 mL
- SD Epidural Low dose:
- SD Epidural Placebo 0.4 mL
- SD Epidural Placebo 1 mL
- SD Epidural Placebo 1 mL

Multi-dose epidural med dose (once a week for 4 weeks)

Multi-dose epidural high dose (once a week for 4 weeks)

Multiple arm GLP study using 2 routes:
- SD Intrathecal control (saline)
- SD Intrathecal low dose
- SD Intrathecal Med Dose
- SD Intrathecal high dose

SP-102 Toxicology Program Design Plan
Preclinical Study Results

Hydrodynamic Study Results

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, Medrol) have an epidural residency half-life of ~15 minutes and have large spread away from the affected site.

Has an epidural residency half-life of >110 minutes and is more localized to the injection site than commercial products. Spread limited to one vertebrae in the first hour for greater local effect vs. 6-7 hours with commercial products.

Additional Vascular toxicity study mentioned by FDA also completed successfully.

Placebo arm clean – non toxic, both routes in both species.

- Histo-pathology: no brain or vascular injury
- No toxicity: vessel occlusion or macroscopic brain injury as reported with Depo-Medrol, clean
- Direct injection into vertebral artery of pigs

Additional Vascular toxicity study mentioned by FDA also completed successfully.

NOAEL is highest dose tested 10 mg / animal single dose & 2 mg / repeat dose.

Placebo arm clean – non toxic, both routes in both species.

Additional Vascular toxicity study mentioned by FDA also completed successfully.

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NOAEL is highest dose tested 10 mg / animal single dose & 2 mg / repeat dose.

Placebo arm clean – non toxic, both routes in both species.
Corporate Clinical Strategy is based on a two stage approach:

- Stage 1: IND to pivotal Phase 3 decision
  - Phase 1 / 2 trial in chronic back pain completed dosing
  - Open-label long-term safety study
  - Pediatric study (plan to request deferral to conduct post-marketing study)
  - Adequate and well-controlled efficacy trial #2

- Stage 2: Commercial scale up decision through NDA
  - Phase 2 open label safety study
  - Open-label long-term safety study
  - Adequate and well-controlled Phase 3 efficacy trial #1 (USA)
  - Phase 1 / 2 trial in chronic back pain completed dosing
  - Pediatric study (plan to request deferral to conduct post-marketing study)

Corporate Clinical Strategy is based on a two stage approach...
Clinical Development: Ongoing Phase 1 / 2

An Open-label Single-arm Two-period Fixed Sequential dose Study to Characterize the Pharmacokinetics Pharmacodynamics and Safety Administered by Epidural Injection Compared with Dexamethasone Sodium Phosphate Injection USP 10 mg Dexamethasone Administered by IV Injection in Subjects with Lumbar Radiculopathy

- Number of patients: 12 subjects dosed
- Epidural Injection Procedure
  - Avoid dilution (no contrast, no local anesthetic)
  - CT-guidance
  - Contain drug in epidural space (interlaminar approach)

Interim Analysis completed
- Enrollment completion September 2016
- Projected Enrollment completion September 2016
- LPLV October 2016
- CSR delivered January 2017

Injection in Subjects with Lumbar Radiculopathy
- Injection, USP 10 mg Dexamethasone administered by IV Injection Compared with Dexamethasone Sodium Phosphate Pharmacodynamics, and Safety Administered by Epidural Injection to Characterize the Pharmacokinetics.
- An Open-label, Single-arm, Two-period, Fixed Sequential-dose
Corticosteroid Lumbar Epidural Analgesia for Radiculopathy (C.L.E.A.R)  

Evaluate the analgesic effect on leg pain following a single transforaminal epidural injection compared to a single sham injection of placebo saline (0.9% sodium chloride, 2 mL) in subjects with unilateral lumbosacral radiculopathy.

- Leg pain (VAS ≥ 9) present for at least 2 months and not more than 9 months, intensity being equal or worse than any concurrent lower back pain
- Clinical symptoms consistent with the MRI diagnosis of nerve root compression
- Functional status consistent with the MRI diagnosis of nerve root compression
- Clinical symptoms consistent with the MRI diagnosis of nerve root compression
- Selection criteria
  - Lumbar radicular pain
  - Indication

- Indication
  - Lumbosacral radicular pain

- Evaluation:
  - Evaluate the safety and tolerability of multiple epidural injections
  - Characterize duration of analgesic effect
  - Oswestry Disability Index (ODI)

- Evaluation:
  - Evaluate pain at 4 weeks and degree of disability as measured by the Oswestry Disability Index
  - Evaluate opioid consumption as compared to placebo

- Evaluation:
  - Subjects with unilateral lumbosacral radiculopathy
  - Compared to a single sham injection of placebo saline (0.9% sodium chloride, 2 mL) in subjects with unilateral lumbosacral radiculopathy

- Evaluation:
  - Evaluate the analgesic effect on leg pain following a single transforaminal epidural injection

Controversial: Lumbar Epidural Analgesia for Radiculopathy (C.L.E.A.R.)
High Barriers to Entry Protect SP-102

Intellectual Property

- Trademarking
- FDA requirement for approval of local tox, PK, efficacy/safety studies for new route
- Patents claiming proprietary formulation, method-of-use possible in Orange Book
- Long-term supply and exclusivity agreement with key excipient pharma provider completed
- Use of specific excipient in formulation (not in label) will require determination and repeat local tox studies, required for increase in residency time for target indications
- Patents claiming proprietary method of use possible in Orange Book

Generics

Barriers to Competition

- U.S. Provisional Application No. 62/106,045 ("Pharmaceutical Formulation") filed January 21, 2015
- December 4, 2014
- Published
- U.S. Application No. 14/757,223 (January 23, 2015) and No. 61/776,617 (March 11, 2013)
-Filed January 23, 2014 (with priority to U.S. Provisional Application No. 61/755,723 (January 23, 2013), Published)
- Filed IP filing claiming novel formulations (viscosity, dissolution profile, stability, residency time) and method
RTX: First-in-class Therapeutic for Intractable Pain
### Product Overview: RTX

**Ultra potent TRPV1 agonist selectively targeting afferent neurons in chronic pain states**

- Highly specific: affects only TRPV1 expressing nerves (A and C fibers)
- 18 Billion Scoville units
- 18 Billion Scolville units
- Jalapeno 2.5 Billion
- Dorsal horn > 12,000 times capsaicin
- Dorsal horn = < 12,000 times capsaicin

**Pharmacological sequence of effects in vivo**

- TRPV1 receptor activation → depolarization → apoptosis

**Mechanism of Action**

- Potentially permanent clinically meaningful analgesia regardless of type of pain (nociceptive visceral and neuropathic)
- Improvement in QoL and function
- Concomitant reduction in opiate use
- Alteration of heat sensation in the targeted area
- No effect on normal acute pain perception / sensation or muscle function
- Patient need not discontinue current analgesic medications prior to injection

**Dosage**

- One injection
- Targated single injection for treatment of intractable pain

**Safety**

- No effect on normal acute pain perception / sensation or muscle function
- Dorsal horn = > 12,000 times capsaicin

**Efficacy**

- Concomitant reduction in opiate use
- Nociceptive, visceral (and neuropathic)
- Potentially permanent clinically meaningful analgesia regardless of type of pain

**Patient need not discontinue current analgesic medications prior to injection**

**Concomitant reduction in opiate use**

- Improvement in QoL and function

**Targeted single injection for treatment of intractable pain**

- No effect on normal acute pain perception / sensation or muscle function
RTX Cancer Pain Epidemiology Overview

Intractable cancer pain is a subset of cancer pain usually requiring significant medical intervention.

WHO estimates 10% – 20% of cancer pain patients cannot be adequately managed even with optimal opioid therapy.

80% of cancer patients experience moderate to severe pain during the course of their disease progression.

80% of cancer patients experience moderate to severe pain during the course of their disease progression.

3 M Moderate

10 M Cancer Pain

18 M Cancer Prevalence

Estimated Patients 2019

3.1 Million (3)

18 Million Americans (1)

53% or about 10 Million (3)

53% or about 10 Million (3)

33% or about 3.1 Million (3)

- Cancer Pain

- Moderate-Severe Cancer Pain

- Patients with Pain

RTX is positioned to replace costly interventional pain management procedures.

- Intervention

- Intractable cancer pain is a subset of cancer pain usually requiring significant medical intervention.

RTX Cancer Pain Epidemiology Overview
Cancer Pain is the Expected Regulatory Path for First Approval

RTX Breaks Neurogenic Inflammation Cycle: Cancer Pain Cycle

- Chronic Regional Pain
- Phantom Limb
- Post Herpetic Trigeminal
- Focal Neuropathies
- Cancer Pain

Organ Failure
- Congestive Heart Failure
- Cardiac Application

Heart is innervated by TRPVR1 expressing afferent nerves and essential for cardiogenic sympathoexcitatory reflexes during myocardial ischemia.

Source: (Zahner MR et al 2003; Wang HJ et al 2014)
RTX POC: Canine Bone Cancer Pain

Preclinical Findings

- Permanent Reduction in Pain Measured at Week 14
- No side effects as seen with opiates or high dose NSAIDS such as sedation, constipation or nausea
- Could sense normal pain signals (0 VAS)
- No loss of muscle function
- Fully alert post-treatment
- Return of "normal" personalities reported by owners
- Source: Brown et al, Anesthesiology 2005; 103:1052

**Observational Pain Score**

VAS (0 to 100 mm)

- n=18
- n=8
- n=5
- n=4

**p=0.0001** for all time points

Number of weeks:

- 0
- 2
- 4
- 6
- 10
- 14
- 20
- 30
- 40
- 50
- 60
First In-Human Study Confirms Activity

Study Overview

Results From First-In-Human Studies

Reduced Opiate Usage

- 3 non- or poorly-ambulatory patients able to become ambulatory
- MTD not reached with 1 mL RTX over 2 min via infusion pump
- No unexpected toxicities
- Improved pain and increased activity with reduced opioids

First-in-Human dose

Pain in refractory cancer not controlled by standard treatment

Severe refractory pain

Refractory Pain

Reduced Opiate Usage

No unexpected toxicities

MTD not reached with 1 mL RTX over 2 min via infusion pump

3 non- or poorly-ambulatory patients able to become ambulatory

ClinicalTrials.gov NCT00804154 (IND64323). Study conducted at the NIH (Neurological Division).
Epidural injection into or near the dorsal root ganglion (DRG) for unilateral or diffuse pain.

Intrathecal injection into the cerebrospinal fluid space (CSF) targeting both DRGs and dorsal horn neurons.

Note: Green = Substance P as marker of Afferent nerves.

Untreated Intrathecal Epidural

Switch to Epidural
### Human Program Status

#### Clinical, Preclinical, Regulatory
- Cancer Pain
  - IND planned early 2017
  - Mini Pig study at UCLA ongoing
  - Pre-IND meeting with Cardio Division, Q1 2017
- Cardiovascular
  - 2nd Hypertension Model at Nebraska ongoing
- Epidural MED study 2017

#### Tox
- Mutagenicity studies completed
- Lumbar GLP completed, pathology and reports ongoing

#### CMC
- GMF API completed (3 registration batches)
- Commercial supply chain established, investigational drug product available
### Current Treatment Cost

#### Estimated Cost of Patient Controlled Morphine Treatment

<table>
<thead>
<tr>
<th>Year</th>
<th>Today</th>
<th>Year 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Today</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

#### Year 2000

- **Pump Rental, medication refill charges, and supplies (Per Day):**
  - **6 Month treatment:**
    - $5.2750
    - $5.6945
    - $5.228
  - **Per Month:**
    - $5.158
  - **Today:**
    - $5.00

#### Year

- **Total Cost of Uncontrolled Pain (6 month window with one admission):**
  - **Admission Cost of Uncontrolled Pain:**
    - Fever
    - Pneumonia
    - Dehydration
    - Uncontrolled Pain
    - Sepsis
  - **5%**
  - **6%**
  - **8%**
  - **11%**
  - **15%**

- **Source:** MSA Internal Research of the following:
Market Research

Initial Price Point

Our evaluation suggests that the market will support a potential price range of $15,000 - $30,000.

Based on Key Study Findings

- A majority of payers consulted have suggested that a range of $10,000 - $30,000 is within a coverage "comfort zone" considering the cost of IT drug therapy, surgical, and neurolytic procedural options.
- Current coverage of comparator therapies (IT drug infusions) at a cost ($60 - $100K in first year) is predictably higher than this range for the targeted population.
- Payers are not expected to limit coverage or access for effective pain management in the terminal population.
- Payers have given a favorable impression of the early clinical profile and results with RTX in this targeted population.
- Payers have supported palliative care and quality of life improvements in this population.
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(1) Study approved by Scintilla and prepared by Alliance Life Sciences

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Inadequate treatment for cancer patients with intractable pain

- Innovative non-opioid analgesic that works by selectively killing the neurons responsible for cancer pain while leaving other neurons intact
- Superior efficacy and safety (TBD) profile with potential competitive cost advantage over opioids

With long-term use, opioids gradually lose their effectiveness and patients need progressively higher doses to get pain relief at the cost of a host of debilitating side effects, including impaired consciousness, nausea, vomiting, and constipation. In addition, for patients who do not get relief from morphine, there are not a lot of options.

Inadequate treatment for cancer patients with intractable pain.
Significant Near Term Clinical Milestones for Scintilla Programs

Multiple clinical milestones for all programs expected in the next 12 months

Mid to late stage trials commencing for SP-102 & RTX programs

In addition, potential corporate development milestones may also be achieved with potential collaborations or licensing in ex-US territory related to SP-102 and RTX in 2017

Programs for 2016-2018:

<table>
<thead>
<tr>
<th>Program</th>
<th>Period</th>
<th>Phase 1/2 Start</th>
<th>Phase 3 Start</th>
<th>Phase 3 Results</th>
<th>Phase 1/2 Complete</th>
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<tr>
<td>2016</td>
<td>2H</td>
<td>IND and Phase 1/2</td>
<td>Phase 3</td>
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<td>SP-102</td>
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<td>2018</td>
<td>2H</td>
<td>RTX</td>
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</table>

2017 - Mid to late stage trials commencing for SP-102 & RTX programs

- Multiple clinical milestones for all programs expected in the next 12 months
Financing and Use of Proceeds

$100 M Private Placement of Common Stock

- Fund clinical trials and NDA submissions
- Pipeline additions
- Key hires across departments
- Commercial launch prep
- General corporate purposes
- Payment to shareholders related to Semnur acquisition

~$100 M Private Placement of Common Stock
Investment Highlights

- Innovative Non-opioid Pain Management Portfolio
- Large, Established, Yet Underserved Target Markets
- Innovative, Non-opioid Pain Management Portfolio
- Worldwide Commercial Rights to All Product Candidates
- Strong Proprietary Platform with High Barriers to Entry
- Established Reimbursement Access
- Two Products with Blockbuster Potential Posed to Replace Current Standard of Care