



Intralink Spine Inc.

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MANAGEMENT TEAM

Eric Hauck CEO President
Tom Hedman Ph.D. CSO Founder
Elsa Abruzzo CRO
Rick Schackel CPA CFO
Hansen Yuan M.D. Clinical Trials
Champion

INDUSTRY

Medical Device

CURRENT STAKEHOLDERS

Orthopeutics LP
Angel Investors
USC

FUNDING TO DATE

\$1.2 seed funding
\$70K NIH SBIR Phase 1 Grant
\$750K NIH SBIR Phase 2 Grant

FINANCING SOUGHT

\$2.75 Million investment (A round)

USE OF PROCEEDS

Secure Intellectual Property
In Vitro In Vivo Efficacy and
Preclinical work, Formulation,
Biocompatibility,
Regulatory, Clinical trials,
Reimbursement Plan, Administrative,
KFDA, CE Marking, and FDA
Approvals, GMP production facility

BANK

Union State Bank
Chase

LAW FIRM

Merchant & Gould

ACCOUNTING FIRM

Graham, Brown, and Assoc.

COMPANY DESCRIPTION

Intralink-Spine Inc. (ILS) is a company formed to develop, manufacture, and bring to market the NEXT device, a revolutionary nonsurgical technology for **Degenerative Disc Disease (DDD)** and the associated problem of low back pain.

The NEXT device is made by a tissue revitalization reagent that can be injected into the spinal disc to increase stabilization of the joint and decompress the surrounding neural tissues without the high expense and risks associated with spinal surgery. This injected reagent reduces disc bulge under load and significantly strengthens disc tissue, increasing durability and tear resistance for immediate and long-term treatment of DDD and its associated pathologies including **Spinal Stenosis, Herniated Discs, Post-Surgical Syndromes and Back Pain**, affecting over 15 million people each year in the US alone. The NEXT treatment has the potential of replacing spinal fusion surgery by providing superior mechanical outcomes.

This treatment can also address the widely recognized problem of **adjacent segment disease** which is an unfortunate consequence of many of the traditional and emerging surgical procedures currently being performed to treat DDD and other spinal disorders. Our chemically made stabilizing device will address the unmet clinical need for an effective nonsurgical solution which does not simply treat the pain but also addresses the root cause of the pain—mechanical insufficiency—resulting in long term pain relief and positive medical outcomes for our patients.

TARGET MARKETS

Recent studies estimate the point prevalence and lifetime prevalence of lower back pain (LBP) in the adult population to be at 37% and 85%, respectively. Low back pain is the second most common reason for seeing a physician and the third most common reason for surgery. Twenty percent (20%) of LBP sufferers describe their pain as severe or disabling.

Total costs associated with LBP have been estimated at near \$100 billion annually in the US alone. Moreover, the LBP and chronic LBP (CLBP) treatment markets are anticipated to continue to grow approximately 15% per annum. While this treatment has the potential of replacing conventional spine surgeries, the surgical market would be only a small portion of the total market for this nonsurgical alternative as approximately 1 in 20 low back pain sufferers elect to have surgery. Between 4.7% (according to medical records) and 9.4% (according to population surveys) of the US population seeks professional health care annually (1990) for treatment associated with low-back pain.

These numbers point to a prospective patient population in excess of 15 million people per year in the US alone.

COMPETITIVE ADVANTAGE

Current and emerging nonsurgical and minimally invasive treatments for degenerative disc disease (DDD) and back pain are designed to treat pain, but not remedy the cause of the pain. Consequently, many of these treatments are inconsistent and short-lived (e.g. epidural injections), while others achieve pain relief through sacrifice of functional tissue (i.e. discectomies: either surgical, electrothermal, or chemical) or with loss of physiologic motion (i.e. biological fusions, interspinous devices, and dynamic stabilization), often leading to additional problems.

A non-surgical approach to low-back pain treatment would open up substantial new markets of people currently adverse to conventional approaches. It is expected that the generation of new markets would be even greater outside of the US where access to conventional surgical treatment is generally more limited.

Our device immediately stabilizes the spinal disc and decreases disc bulge under load, reducing the patient's pain without the costs and risks associated with surgery.

The procedure can be performed on an outpatient basis and should be completed with just one injection treatment. Another advantage in using our device is that it can be administered to the patient earlier in the onset of DDD, when pain and symptoms of lower back pain first present themselves; in contrast to the more traditional treatment progression where the treatment or surgery is delayed until the patient can no longer manage their daily lives due to increasing pain.

MILESTONES

- Completed and published *in vivo* & *in vitro* efficacy studies (5 published papers)
- Completed formulation and delivery studies
- Established regulatory and clinical paths to markets
- Contacted Notified Body to start CE marking
- Established reimbursement plan
- Established CRO's for First in Man Trials-OUS
- Established Intellectual Property rights; issued patents.
- Successful completion of NIH SBIR phase 1 grant.
- Awarded NIH SBIR Phase 2 grant
- Secured several key management team members including a regulatory expert and clinical trials Champion
- Prepared to commence First in Man trials OUS 4th quarter of 2010

