Bone-Rad Therapeutics, Inc.

a revolutionary treatment paradigm for tumors in bone

Executive Summary

Spine-Rad™ Brachytherapy Bone Cement

Contact: Joyce H. Keyak, Ph.D.
jhkeyak@uci.edu

Harry B. Skinner, M.D., Ph.D.
949-939-5132
hskinner@hskinner.net

Business Focus

Bone-Rad Therapeutics, Inc. is a Delaware corporation whose objective is to develop and market **Spine-Rad™ Brachytherapy Bone Cement** as an innovative, improved, and cost-effective treatment paradigm for the management of cancer tumors in the spine which affect over 230,000 patients per year in the U.S. and a similar number in the E.U.

Four patents covering this technology have been issued and exclusively licensed to Bone-Rad Therapeutics. An additional patent is pending.

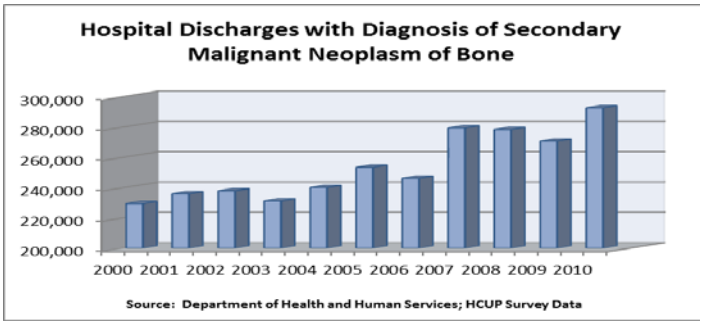
Developed at The University of California Irvine, Spine-Rad™ Cement delivers internally-targeted radiation therapy directly to the tumor as it simultaneously treats existing or impending vertebral fractures, restoring strength to the bone. Administered in a single procedure, Spine-Rad™ Cement will eliminate the 10-20 hospital visits typically needed for external beam radiation therapy (EBRT) as well as the significant side effects of EBRT.

Physicians and hospitals will benefit from a simplified treatment paradigm which reduces the burden on the healthcare system.Payers will benefit from a reduction in treatment cost, and patients will experience improved quality of life (QOL) due to the elimination of the multiple hospital visits and side effects associated with EBRT.

Market Opportunity

Over 400,000 cancer patients will develop metastases to the bone annually and are associated with approximately 350,000 deaths per year. 70% of these cases will involve metastatic tumors of the vertebrae, and over 230,000 patients per year will develop symptomatic tumors of the vertebrae.

The incidence of bone metastases is increasing due to an increasing elderly population, as well as improved cancer treatments allowing patients to live longer with the disease.



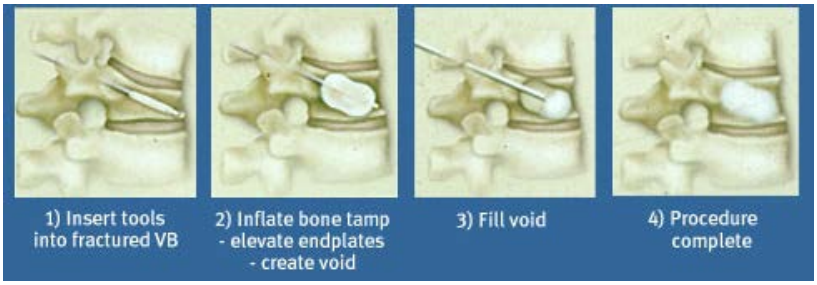
The Department of Health and Human Services (Agency for Healthcare Research and Quality) annual survey shows hospital discharges for patients with bone metastases increasing at 2.5% annually.

Current Treatment for Vertebral Tumors

Spinal tumors can cause severe pain and can lead to serious complications due to spinal cord compression and vertebral fracture. Treatment of these tumors must typically address two issues: (1) restore the structural integrity of the bone, and (2) minimize the potential for tumor progression.

Conventional treatment is a two phase process. First, a minimally invasive surgical procedure (kyphoplasty or vertebroplasty) is performed to restore strength to the bone.

Phase 1: Conventional treatment starts with a kyphoplasty or vertebroplasty procedure to restore bone strength. Bone cement has a long history of use in kyphoplasty and vertebroplasty to repair bones with defects created by cancerous tumors.



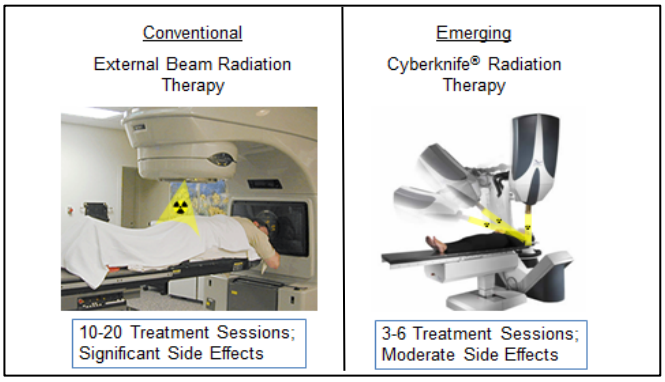
Standard Kyphoplasty Procedure

Restoring integrity of the bone will reduce the pain associated with vertebral fracture and tumor presence, but will not provide maximal pain relief or affect the progression of the tumor, so patients must return for further treatment.

The second phase of treatment is radiation therapy from an external source to destroy tumor cells in the bone. External beam radiation therapy (EBRT) is the standard of care for this phase of treatment.

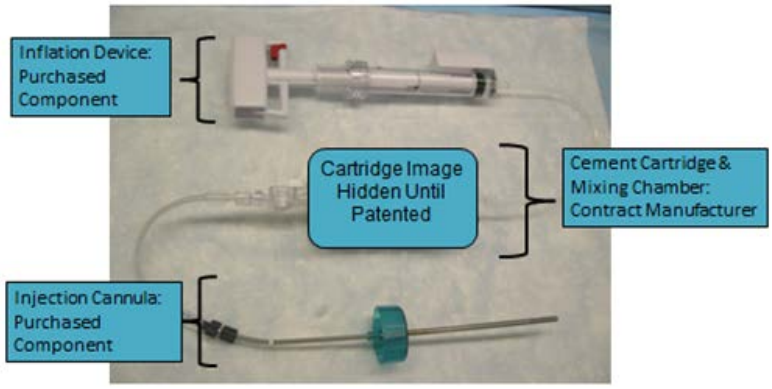
External beam radiation therapy exposes the spinal cord, nerve roots, bowel, and skin to radiation causing a variety of side effects including nausea, vomiting, diarrhea and skin reactions.

Phase 2: Patients are required to undergo 10-20 External Beam Radiation Therapy sessions to kill the tumor. Newer technologies such as the Cyberknife utilize methods to reduce exposure to nearby healthy tissues and to minimize treatment sessions. However, these systems are not widespread due to high equipment and operating costs, resulting in hospital billing that is much greater than traditional EBRT.



Spine-Rad Brachytherapy Bone Cement

Spine-Rad™ Cement is the formulation of commercially available, medical-grade bone cement that has been mixed with an insoluble form of the radioisotope Phosphorus-32 (P-32). The Spine-Rad Cement powder is loaded into the Cement Cartridge and Mixing Chamber and sent out for sterilization.



Spine-Rad™ Mixing and Delivery System Functional Prototype

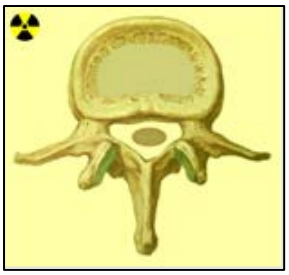
The Spine-Rad Mixing and Delivery System is a simple device utilizing standard components (inflation device and injection cannula) and a Cement Cartridge and Mixing Chamber modified to facilitate the handling of bone cement containing a radionuclide.

Spine-Rad™ Brachytherapy Bone Cement simplifies the conventional two phase treatment approach into one simple procedure that simultaneously strengthens the vertebrae and delivers a therapeutic radiation dose to the tumor site.

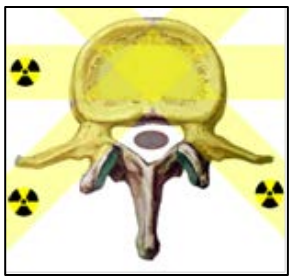
Spine-Rad™ Cement is delivered in a standard kyphoplasty procedure and will not require physicians to be trained to perform a new surgical procedure. These procedures are performed by over 14,000 physicians in the U.S. which will make treatment with Spine-Rad™ Cement widely available and not dependent on expensive external radiation equipment.

The characteristics of the P-32 radionuclide emissions are optimal for precise delivery of radiation to the tumor.

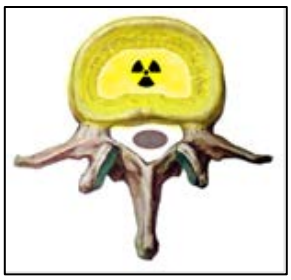
P-32 has a half-life of 14.3 days and the radiation travels approximately 4-5mm through bone. Cement placement allows precise targeting of the tumor without exposing adjacent structures, and due to the optimal half-life, a therapeutic dose is delivered over a 10-week period after which very little radiation remains.



EBRT
Broad exposure, 10-20 sessions, significant side effects due to irradiation of adjacent structures and intestinal tract.



Cyberknife
Better targeting, 3-6 sessions with moderate side effects, more costly, and limited availability.



Spine-Rad™
Precise radiation delivery, single procedure, no external beam side effects, lower cost, better QOL.

Regulatory, Reimbursement & Clinical

Bone cements and brachytherapy devices are Class II devices. Brachytherapy Bone Cement is a new type of device to the FDA and they have requested that Spine-Rad™ Cement follow a PMA regulatory pathway.

Spine-Rad™ Cement is a Class IIB product in the E.U. and will require a small safety study to be included in the CE Mark Submission. The regulatory timeline as a Class III device in the U.S. is as follows:

Year 1	Year 2	Year 3	Year 4	Year 5
Preclinical, biocompatibility, animal study, quality sytstems	Complete small pilot safety study, set up pivotal trial	CE Mark & EU Launch, Implement Pivotal Study	Complete pivotal study, PMA prep and submission	FDA review and approval.

Existing brachytherapy CPT codes apply and can be used for coding and billing for the brachytherapy components of this procedure, including treatment and management as well as the radiation source material. Kyphoplasty CPT codes can be used for the kyphoplasty components of the procedure.

Financial

Bone-Rad has utilized a $760,000 DOD grant to complete research and to develop functional prototypes and manufacturing processes for Spine-Rad™ Cement and for the Mixing and Delivery System.

Bone-Rad will require $2MM to conduct pre-clinical activities and complete an IDE submission. An additional $3MM will be required to obtain CE Mark. The total capital required to get Spine-Rad through FDA approval will be $23-25MM depending on the number of patients required in the pivotal trial.

(000's)	Year 5	Year 6	Year 7	Year 8	Year 9
Procedures	1.1	3.3	6.6	11.2	17.6
Sales	$6,693	$23,165	$47,604	$81,825	$131,151
Gross Margin	$5,260	$19,503	$41,604	$72,944	$117,301
GM%	79%	84%	87%	89%	89%
Op. Expenses	$5,605	$9,611	$17,081	$26,421	$39,838
Pre-tax Income	$ (345)	$ 9,892	$ 24,523	$ 46,523	$ 77,463

Revenues begin OUS in Year 3 after funding. U.S. sales begin in year 6 after funding. Spine-Rad will reach $100MM in U.S. revenues (7% market penetration, $8000 ASP, 90% GM) by the end of the 4th year of sales. Years 3-5 cumulative OUS revenues are $10MM at 75% GM offsetting expenses prior to U.S. launch.

Management

Harry B. Skinner, M.D., Ph.D., Founder, orthopaedic surgeon and materials scientist; Kyphon, Norian

Joyce H. Keyak, Ph.D., Founder, biomedical engineer U.C. Irvine, co-inventor of Spine-Rad™ Cement

Steven J. Naber, Chairman of the Board, 20 Years finance and operations; Eyeonics, Intralase, SenoRx, Biopsys

Gary Mistlin, BOD, 20 years as general manager, finance and operations, BioForm, PercuSurge, Mentor Corp.

John Wimer, COO, 20 years quality systems and operations; Calcitec, Parallax, Norian

Sean Tutton M.D., Chief of Vascular and I.R.at Medical College Wisconsin, Lead investigator Benvenue Medical

Janice Hogan J.D., Partner at Hogan Lovells and regulatory adivsor with a focus on Medical Devices