

OsNovum

**A REGENERATIVE SOLUTION**  
FOR POORLY MINERALIZED BONES

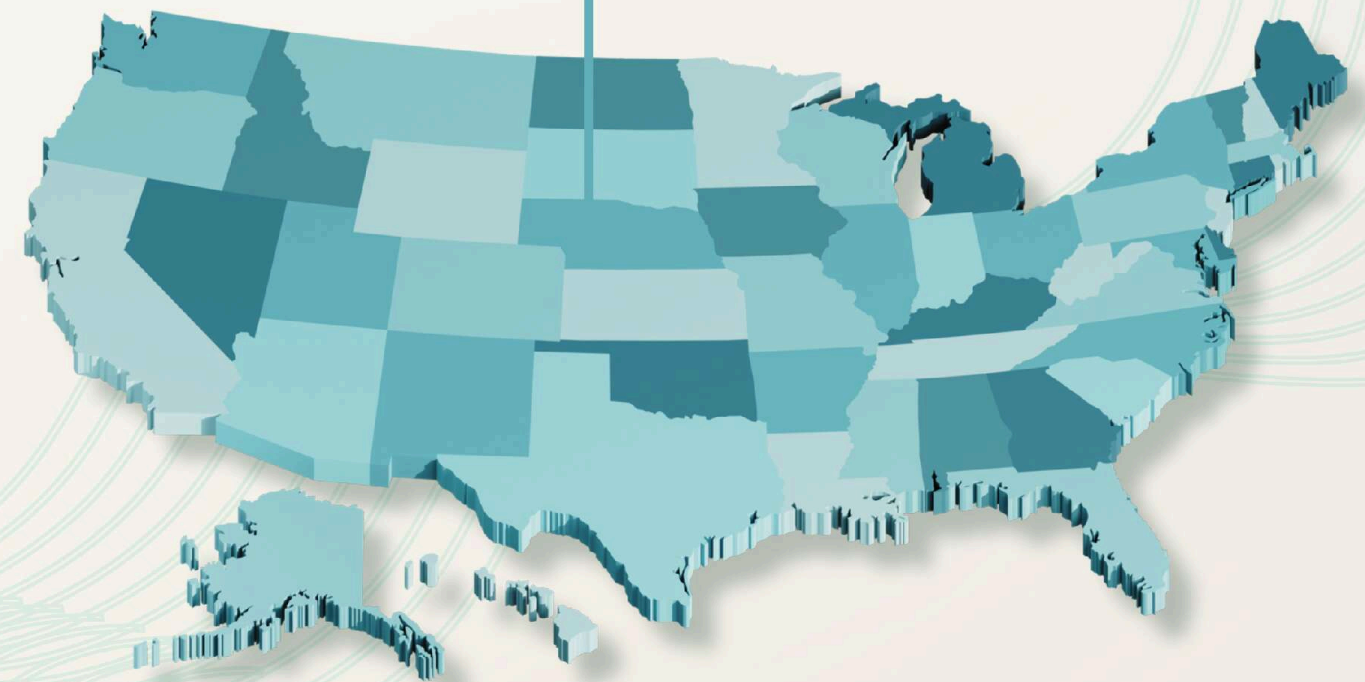
[www.osnovum.com](http://www.osnovum.com)

# OSTEOPOROSIS: THE SILENT EPIDEMIC

A growing epidemic threatens mobility and independence.

- 200M+ people worldwide have osteoporosis
- 8.9 million fractures annually
- 1 in 3 women over 50 will suffer a fracture

\$57B spent annually  
on fractures in the  
United States alone.



The problem isn't just big—it's growing.  
Patients need better solutions.

# CURRENT TREATMENTS AREN'T GOOD ENOUGH

Despite billions spent, most treatments leave patients with fractures, pain, and frustration.

## Existing Treatments

- Bisphosphonates: GI issues, jawbone necrosis, atypical fractures.
- Low adherence rates: ~50% stop treatment within a year.
- Limited efficacy: Most drugs slow loss, but don't rebuild bone.

## What Patients Need

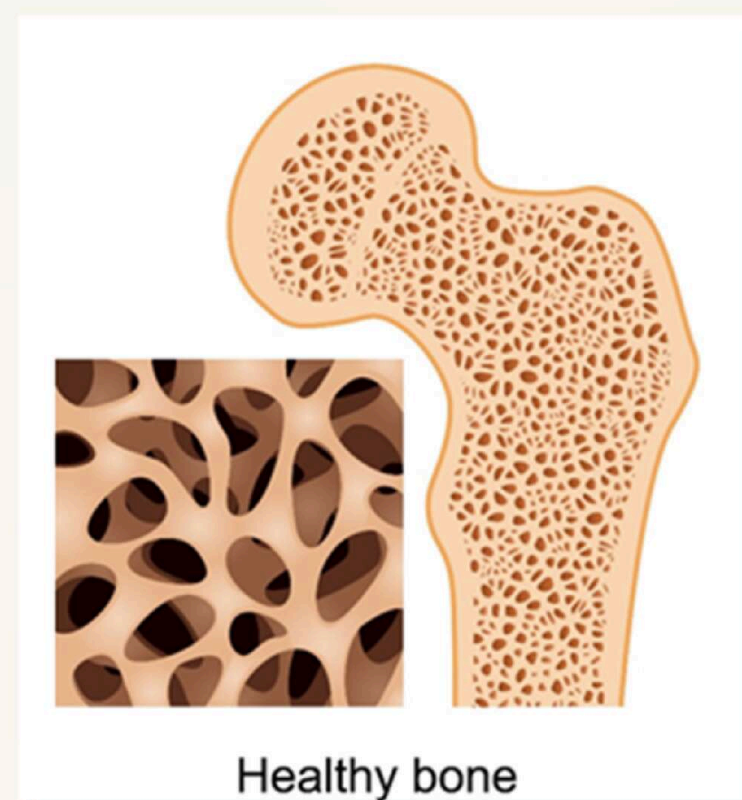
- A treatment that regenerates bone, not just preserves it.
- Safe, effective, with fewer side effects.
- High adherence and patient demand for innovation.

Osteoporosis patients deserve more than temporary solutions.  
It's time for real innovation.

# THE OSNOVUM SOLUTION

Our patented molecule activates the patient's own bone growing process.

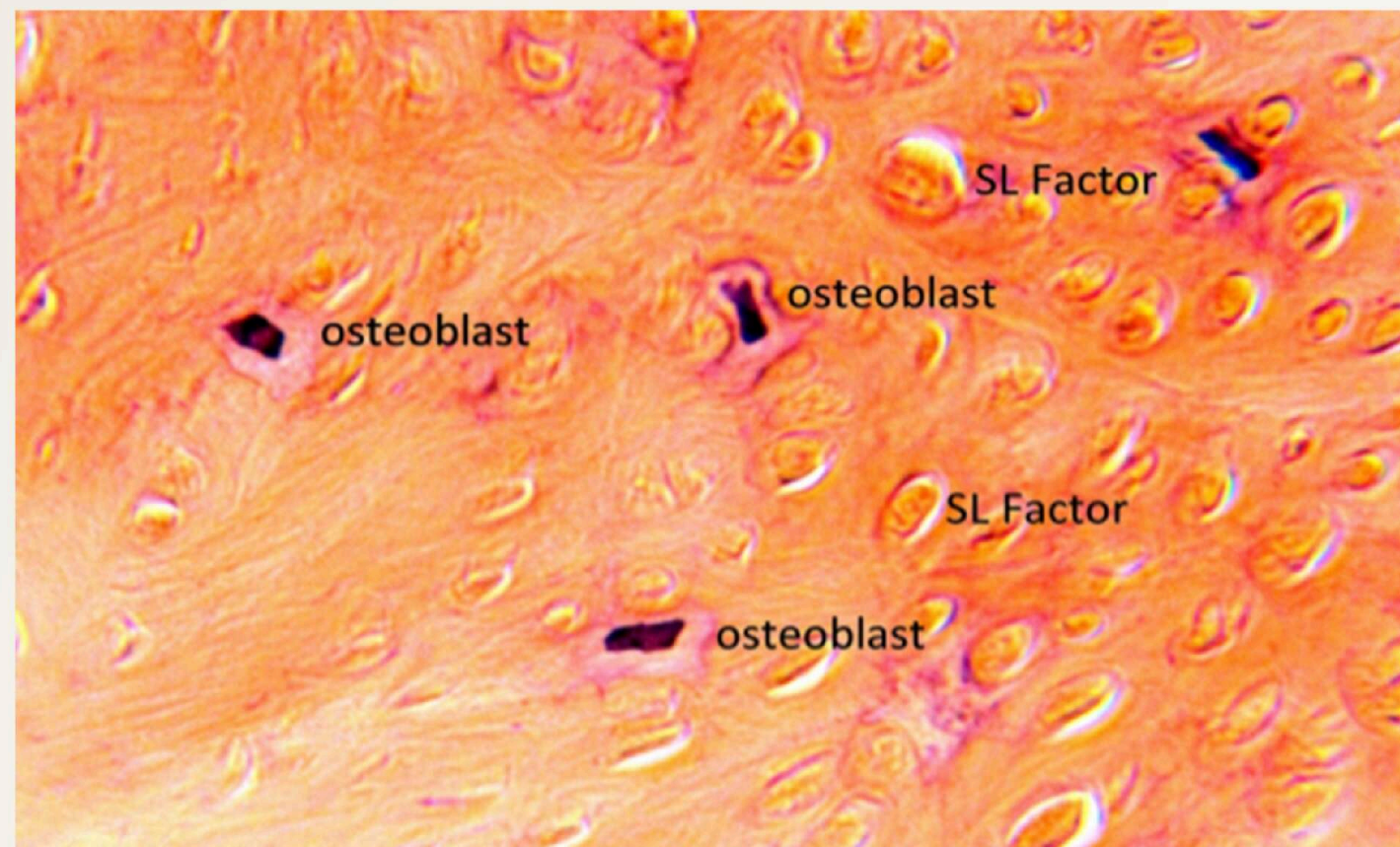
- 1 Our regenerative material is applied locally into an area of low bone density at risk of fracture
- 2 The patient's osteoblasts proliferate and absorb our compound before migrating into surrounding tissue
- 3 Since they are bone-growing cells, the osteoblasts increase mineral density and vitality of local and surrounding bone



**Without our compound,  
no other material can truly  
stimulate bone growth.**

# REGENERATIVE TECHNOLOGY

The proliferation of millions of osteoblasts is initiated upon absorbing our patented organic molecule (**SL Factor**) and the rapid growth of healthy, vital bone occurs.



Osteoblasts migrating into OsNovum



After six weeks, OsNovum is forming healthy vital bone

Increasing bone density enables the ability to prevent fractures.

# THE CONTEXT

## WORLDWIDE

Global Incidence

More than **200 million people** struggle with osteoporosis across the globe.

## UNITED STATES

Nationwide Incidence

**54 million Americans** are at risk of an osteoporotic or osteopenic bone fracture

## U.S. HEALTHCARE

The Price of Osteoporosis

Osteoporosis is predicted to account for **\$25.3 billion** in annual costs related to fractures

The staggering, incalculable cost of medication and loss of productivity further underscores the demand for our technology.

Data

1. International Osteoporosis Foundation
2. Bone Health and Osteoporosis Foundation

# PROVEN TECHNOLOGY

Our technology has already been FDA-cleared to regenerate poorly mineralized maxillofacial bone for over a decade thanks to decades of vigorous R&D offered by our founders through **SteinerBio**.



Our performance as a seasoned market disruptor with an unrivaled innovation allows for a strong competitive edge.

It's time to take this material to the skeleton.

# CURRENT TRACTION

Upon receiving our Q submission response from the FDA on device classification and requirements, we augmented our OsNovum team with a veteran FDA principal who now works as a consultant.

We have contracted with their consulting firm and we now have a regulatory expert assisting in our De Novo application.

To have this person on our side is monumental.



# THE MODEL

Introducing new technology into the healthcare industry will take more than just time and effort.

OsNovum will contract with leading scientists from various fields to formulate the diagnostics and treatment protocols to be utilized by the OsNovum clinics.



OsNovum Clinics exclusively focused on treatment that preserves skeletal health

# THE STATUS QUO

Because osteoporosis is poorly understood, treatment is often unsuccessful, producing undesirable and sometimes permanent side effects.

Systemic drugs are virtually the only available option for patients seeking who are at risk of or are recovering from an osteoporotic bone fracture.

**Our material** is target-specific, intended to be applied directly to a lesion and treated locally without the worrisome systemic effects.

**Our clinics** will utilize the input of clinical experts to generate the protocols needed to maintain skeletal health for a lifetime.

# GO-TO-MARKET

Upon receiving FDA clearance, our GTM strategy focuses on:

## **Audience Outreach**

Osteoporosis patients, healthcare providers, orthopedic specialists, pharmaceutical companies, medical device manufacturers, and research institutions

## **Market Entry**

Phase 1: Initial launch in major U.S. cities with high prevalence of osteoporosis

Phase 2: Expansion to key international markets in Europe and Asia

## **Marketing**

Digital Marketing, Public Relations, Educational Content

## **Distribution Channels**

Direct and Online Sales: Partnering with healthcare institutions and clinics for direct integration of our device  
Distributor Partnerships: Collaborating with medical device distributors to reach a broader audience

## **Strategic Partnerships**

Healthcare Institutions, Pharmaceutical Companies, Research Collaborations

## **Sales Team:**

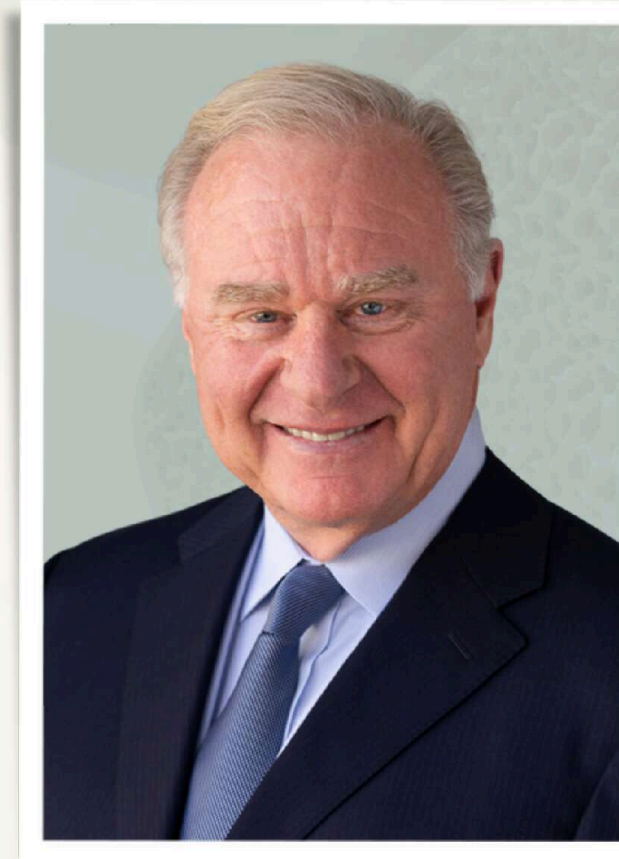
Dedicated Sales Force and Training Program

# OUR TEAM

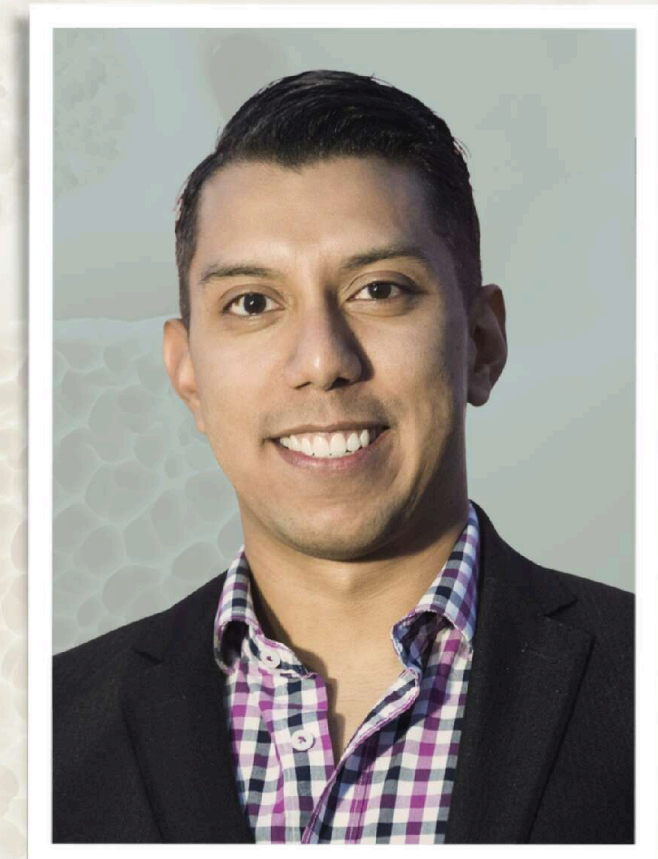
We not only have a seasoned, well-rounded team, but we have recently contracted with a former FDA assistant director and current biotech regulatory consultant to assist with our De Novo application.



**ROSLYNN STEINER**  
PRESIDENT AND CEO



**DR. GREG STEINER**  
CHIEF SCIENCE OFFICER



**DANIEL VARGAS**  
VP, MARKETING

The world needs **OsNovum**.  
Let's make it happen.

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**Thank You**

# INVESTMENT OPPORTUNITY



**We are seeking \$130,000 in this funding round.**

The FDA is requiring a De Novo device classification request.

The fee for this submission is approximately \$30,000.

\$20,000 in consulting fees are needed to assemble the submission that outlines how our device is of moderate risk for De Novo clearance.

If approved, we will not require any human clinical trials, but there may possibly be more laboratory testing.