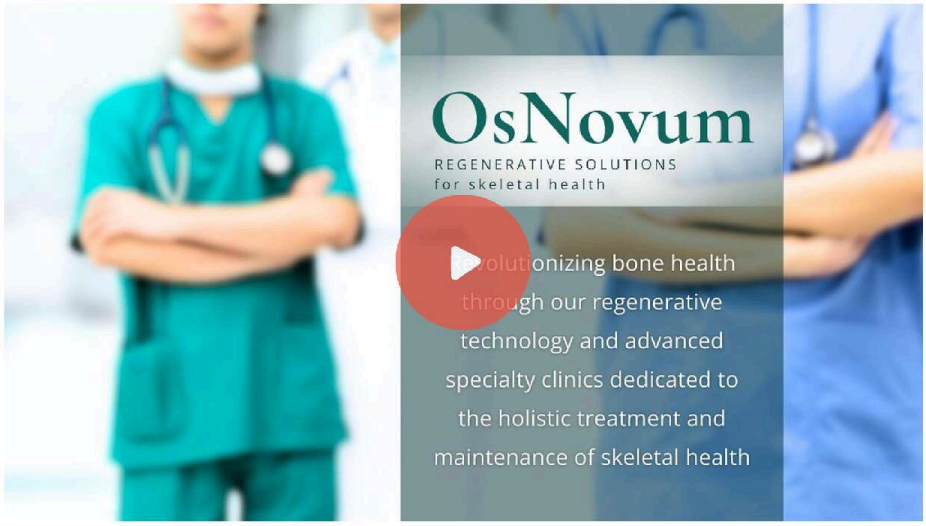
INVEST IN **OSNOVUM**

Revolutionizing skeletal health through the science of bone regeneration



osnovum.com Henderson, NV

Technology | Female Founder | Healthcare | B2C | Biotech

Highlights

1. OsNovum founders own the patent to this technology
2. Already FDA-cleared for maxillofacial use, streamlining the track to clearance in the skeleton
3. Disruptive new technology for the $25B osteoporosis treatment industry
4. Parent company, SteinerBio, world leader in bone regeneration provides building and staff
5. Clear exit (not guaranteed) through acquisition in 3 years following scaling and market penetration
6. Specialty clinics launch using our tech, guided by leading scientists, staffed by premier clinicians
7. Profits generation from our regenerative technology, but accelerated through the OsNovum clinics

Our Team

Gregory Steiner CEO SteinerBio and OsNovum

Discovered and patented the molecule that stimulates bone growth

I have devoted my career to bone regeneration. There is nothing that is more exciting to study and nothing more satisfying to watch someone regain their health!

Roslynn L Steiner President SteinerBio and OsNovum

Guided and executed plans for the growth of SteinerBio into a world leading

Guided and executed plans for the growth of SteinerBio into a world leading maxillofacial bone graft company

Daniel Vargas VP Marketing

Developed, planned, and executed the strategy for making SteinerBio a world leading biotechnology company

The Story of OsNovum

SteinerBio began the research to introduce its technology for the treatment of failing bones due to osteoporosis in 2016. While the regenerative material was cleared for use in the jaws, a separate FDA clearance was needed to use the material in the skeleton. The study has been ongoing continuously since 2016.

However, anyone who has lived long enough or is a student of economic history knows that the United States experiences a financial crisis every 10 years. You can mark it on your calendar. The last financial crisis was in 2008-2009, so we knew a financial crisis was on its way and because the economy had been booming, we figured the bust was likely to be even bigger. We began watching the economy closely in 2018 but the stock market was still booming and the economy was still growing with no end in sight.

In 2019, we knew a financial crisis had to be near, so SteinerBio restructured and prepared for the hit. All unnecessary costs were stopped. Research and development staff and projects were halted, except for OsNovum. Debts were paid off. We were lean. We decided that the one area we wanted to move forward at full speed was FDA clearance for treating osteoporotic bones. However, that move was very expensive and did not fit into our financial survival posture. At that point, we decided to break off this R & D program from SteinerBio and officially form OsNovum.

OsNovum would raise investment dollars to keep the program running full speed throughout any foreseeable financial crisis. We knew a financial crisis was coming but we had no idea it would be as big as Covid. When Covid hit, we flipped the switch into survival mode at SteinerBio and rolled out OsNovum for investment. After, reaching our first milestone of raising $60,000 from private funds, we finally went live on the public crowdfunding portal Wefunder.

Through Wefunder, we raised enough money to begin the 510(k) application required by the FDA, using FDA-cleared SteinerBio technology as the predicate technology on which to base OsNovum clearance. The FDA's skeletal division has never approved a device that actually stimulates bone growth, so they were in uncharted territory and no one seemed to be able to make a decision. Our original path was to submit the device exactly how our dental bone grafts were classified and regulated because it is the identical material. Yet, the skeletal division says that because our material does not exist in their database (skeletal database) we will first need to go through a submission process that classifies the device. We accomplished this and waiting patiently for their response. To our amazement, even though the material was approved as a bone graft in the maxillofacial division, the skeletal division does not recognize the existence of our products at the FDA because it is a different division.

The FDA finally responded to our Q Submission, which is a list of questions proposed by a company asking for decisions on key issues that need to be answered before a submission to the FDA. The questions were previously raised during our 510(k) submission. However, the FDA officers in charge are not equipped to make final decisions that control the path of the submission, so a formal Q Submission needs to be sent to the FDA for final clarification. The ultimate decision was that because our device is a Class III and since the Skeletal Device division does not recognize maxillofacial devices as part of their division, a 510(k) submission has been ruled out. Since a PMA submission is highly impractical in our position, that leaves us one exception — De Novo requests.

De Novo submissions are for products that are unique, have no submission history, and are classified as moderate risk. We fit the requirement very nicely.

Shortly after receiving our Q submission response from the FDA, we received a call from a former FDA principal involved with our original submissions who informed us they have left the FDA, are now working as a consultant, and want to assist in our submission. We have contracted with this person's consulting firm to pursue our De Novo application. To have this person on our side is monumental.

We raised the funds to complete the required tests and sent a 510(k) application to execute that process to the end. The result was not what we wanted, but we did stay on budget and completed what we budgeted for. At this point, we will need to raise additional funds to pay consulting fees and application fees. Both of these items will cost approximately $50,000. The FDA fee for submission of a De Novo device is approximately $30,000 alone. The consulting fees are for putting together a submission outlining how our device is moderate risk requesting clearance to submit a De Novo application. If approved, we will not require human clinical trails, but possibly more laboratory testing. The FDA never gives something without demanding something in return.

We are now going back to Wefunder for a second round of financing. Startup companies fail when they run out of money. When we set up this company, it was designed to never allow that to happen. We have no employee salaries. We have no rent or utilities or ongoing costs. This allows us to have a zero cash burn rate and never be in a position of running out of money. Money is only spent on budgeted projects. The company was designed in this manner because we are committed to bring OsNovum to market no matter what path that takes, and our path has just gotten a lot clearer.

As always, no matter how much is raised, OsNovum is moving forward at full speed.

Downloads

OsNovum Pitch Deck 2024.pdf