

SECURING FDA APPROVAL AND COMMERCIALIZING A “NANOMEDICAL DEVICE”

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INTRODUCTION

Angstrom Medica is a privately-held, early-stage, biomaterials company engaged in the development and commercialization of its proprietary calcium phosphate nanotechnology - NanOss™ - for orthopedic applications. We are developing nanostructured formulations for creating: i) structural, weight bearing implants and ii) injectable, endothermic, weight bearing cements. Angstrom Medica has also received the first clearance from the United States Food and Drug Administration (FDA) for a “nanomedical device.”[1] The process of commercializing nanotechnology in a regulated industry, such as medical devices, which involves balancing multiple factors to minimize time to market and capital input and to maximize value will be discussed.

CLINICAL NEED

Current orthopedic devices are primarily constructed of metal or plastics (polymers) and do not biologically integrate with natural bone. As a result, displacement, non-uniform healing, foreign body reactions, bone atrophy or re-injury can occur at the injury/surgical site. Alternatively, human bone materials (e.g. autograft and allograft) are also used for surgical repair but with significant morbidity concerns and significant supply, contamination and integrity issues associated with them, respectively.

TECHNOLOGY AND PRODUCTS

NanOss™ is an innovative calcium phosphate biomaterial that is highly osteoconductive, structural and resorbable with applications in the sports medicine, trauma, spine and general orthopaedics markets. It is an engineered synthetic bone and is the first material that duplicates the microstructure, composition and performance of human bone. Utilizing nanotechnology, calcium and phosphate are manipulated at the molecular level and assembled to produce materials with unique structural and functional properties not seen before in other calcium phosphate based materials.

Structural NanOss™ A 100% dense, highly consistent, crystalline hydroxyapatite (HA), biphasic calcium phosphate (BCP) or tricalcium phosphate (TCP) that has the strength of stainless steel. Based on Angstrom’s unique ability to combine strength with controlled resorption, NanOss™ implants will provide the gold-standard benefits of autograft with the strength found in metal or composite devices. Initial applications for the material include suture anchors, ACL interference screws and spinal cages.

Injectable NanOss™ An endothermic, rapidly setting, calcium phosphate composite cement providing a

structural, osteoconductive material for vertebroplasty, trauma and general orthopaedic applications.

We anticipate that our calcium phosphate nanotechnology will also provide the ideal foundational matrix for growing bone via stem cell and tissue engineering and for joint resurfacing. In all cases, the superior properties of the Angstrom’s nanotechnology platform are expected to allow it to deliver mechanical strength and provide for controlled resorption, while offering a platform for future development of new composite structures for the delivery of drugs or genetically engineered materials.

REGULATORY STRATEGY

Angstrom Medica anticipates that using the nanotechnology platform to transform conventional biomaterials into new variations permits the Company to leverage similarities to existing commercial materials when applying for FDA clearance. Angstrom Medica’s starting materials are composed of HA, BCP and TCP - materials recognized by the FDA as acceptable for use in humans. While Angstrom Medica offers a “different” orthopedic biomaterial with superior strength and biocompatibility suitable for load-bearing applications, it is chemically the “same” as conventional HA, BCP and TCP. Depending on the indicated use for the devices using these materials, the FDA has previously permitted FDA 510(k) clearance.

ECONOMIC POTENTIAL

The worldwide market opportunity for orthopedics devices is currently estimated at >\$25 billion dollars in annual sales. Fueled by an aging population, expanded use of implants and premium pricing on new technologies, the market has experienced several years of an average annual growth rate of 16%. We believe that immediate opportunities for Angstrom Medica’s products exist in the spinal fusion and bone fixation segments, representing greater than \$1 billion worth of business.

REFERENCES

1. President’s Council of Advisors on Science and Technology, [The National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel](#), United States Government Printing Office, p. 16, May 2005.

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