



## SBIR/STTR SUCCESS



An adult Giant Keyhole Limpet in Stellar's aquaculture facility. They require 5 years to fully mature. The KLH protein can be extracted 3X/year.

# STELLAR BIOTECHNOLOGIES

Nestled beneath the low tide line off the rocky coasts of Southern California and Baha, lives a species of limpet that has provided immense biomedical breakthroughs for forty years. Coined the Giant Keyhole Limpet, this mollusk houses a certain protein that was discovered to work exceptionally well as a vaccine carrier.

### GRANT SUCCESS

\$405,000 from 9/14 – 3/15 in Phase III grant revenue; \$540,222 in follow-on funding from NSF through the Technology Enhancement for Commercial Partnerships program under Phase II and through its California subsidiary for Phase IIB grants

### AGENCIES

NSF

### SNAPSHOT

Grew from 3 employees to 23; Stellar Biotechnologies is meeting an important pharmaceutical need while protecting a potentially threatened marine resource, and generating jobs in Ventura County, California.

### STELLAR BIOTECHNOLOGIES

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Stellar Biotechnologies has harnessed the power of this organism and manufactures an immune-stimulating protein, called Keyhole Limpet Hemocyanin (KLH), which the company continues to use in its patented immunotherapy development. KLH is a safe, potent immune-stimulating molecule, often used as a key ingredient in a new class of drugs known as active immunotherapies or therapeutic vaccines which have been shown to stimulate the body's immune system to target and attack disease.

Immunotherapy is one of the fastest growing biopharma sectors, which has led to an increasing need for KLH. Because KLH can only be obtained from the Giant Keyhole Limpet, Stellar Biotechnologies' contribution has been to eliminate the limitations imposed on the commercial development of promising KLH-based immunotherapies by the supply and regulatory constraints inherent in the reliance on an uncontrolled and potentially threatened wild fishery.

Through Small Business Innovation Research (SBIR) funding through the National Science Foundation (NSF), Stellar Biotechnologies has applied decades of aquaculture experience to this challenge. The company's long-term goal is to ensure a sustainable supply of this vital pharmaceutical ingredient while protecting its natural marine source. The SBIR project titled "Megathura Crenulata Post Larval Culture - Bottleneck for a Valuable Medical Resource," was designed to allow for the full implementation of the commercial scale production of GMP-grade KLH. This was achieved through the application of controlled aquaculture systems for Megathura Crenulata optimized through the SBIR-funded research. The SBIR research also funded the development of a validated KLH-based functional immunogenicity assay.

"In the long path of scientific development, the SBIR program provides an avenue for an early-stage company to focus on innovative technologies that have not yet demonstrated a clear pathway to revenues and therefore would otherwise not attract venture capital or funding from alternative sources," explains Mark A. McPartland, Vice President of Corporate

Development & Communications for Stellar Biotechnologies. “Therefore the SBIR program continues to have a significant, positive impact on scientific innovation through the demonstration of the commercial potential of new innovative technologies that would otherwise not bridge the gap between scientific discovery and commercial validation.”

In a bold move, Stellar went public in 2010 to take advantage of a funding opportunity in an otherwise challenging economic climate for emerging biotechnology companies. The company went public through a reverse merger with a Canadian Capital Pool Corporation (CPC) to access capital and facilitate a smooth transition from a closely held private company to a public entity. Stellar is traded on both the U.S. OTCQB Marketplace (symbol SBOTF) and the Canadian TSX Venture Exchange (symbol KLH). The public company has provided access to capital to meet the critical needs of a growing company as it progressively meets its milestones.

“Looking back, it is clear that the decision to go public was the right decision for Stellar based on the circumstance for industry and economy in 2009-2010,” added McPartland. “As an emerging-stage company, the public entity offers the challenges of corporate maturation as well as the challenge of developing and commercializing core technology, but for Stellar it has also provided access to capital for growth that was otherwise not available.”



**LEFT:** Four adult Giant Keyhole Limpets

**TOP RIGHT:** The rich blue color of KLH protein is the result of its copper-containing properties. This image is from Stellar’s production and testing.

**BOTTOM RIGHT:** KLH protein product in vials

Looking forward, Stellar’s focus is to be the leading provider of commercial-scale KLH for use in immunotherapy. Stellar has developed industry-leading methods to sustainably manufacture KLH. For example, the company now has the world’s only demonstrated aquaculture system with sustainable KLH production capacity. The team is now focused on pursuing commercial opportunities that build on these core-manufacturing strengths. Customers include pharmaceutical companies and academic institutions that use KLH. Stellar is continuing to work with a number of companies who are evaluating the use of its patented Stellar KLH™ for immunotherapy programs. These partnerships will generate long-term revenue potential as well as provide Stellar with an active role in immunotherapy programs targeting cancers, immune disorders, Alzheimer’s, and inflammatory disease.

Even in technology-rich California, Stellar Biotechnologies’ contribution to its local economy is sizable. The company has been instrumental in introducing marine biotechnology as a viable component of the coastal-dependent industry segment of the Ventura County, California economy. With the addition of more than 20 high paying technology jobs in a unique and growing field, Stellar is leaving its mark on the California coast by continuing to grow and innovate in the area of advanced immunotherapy.