Zacks Small-Cap Research

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Stellar Biotech (SBOT-NASDAQ)

SBOT: Uplists to NASDAQ, KLH Showing Promise in Alzheimer's Candidate

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	11/24/2015
Current Price (11/25/15)	$7.40
Target Price	**$13.00**

OUTLOOK

KLH is a high molecular weight protein derived from the blood of the scarce Giant Keyhole Limpet. KLH has become the carrier protein of choice in immunotherapies, ramping interest in which has fueled demand for this protein. Stellar's proprietary aquaculture (Giant Keyhole Limpet farms) and production facilities are the only source in the world capable of supplying commercial-scale quantities of the high quality KLH protein. Stellar just signed a collaboration agreement which could increase its production capacity 10-fold. The company has KLH supply and collaboration agreements supporting customer clinical trials. Additional supply agreements and, eventually to supply commercialized immunotherapies, could substantially steepen the revenue curve.

SUMMARY DATA

52-Week High	**$15.50**
52-Week Low	**$5.30**
One-Year Return (%)	**-44.05**
Beta	**1.41**
Average Daily Volume (sh)	**21,008**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$61**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**11**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**40.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2014	0.1 A	0.1 A	0.1 A	0.1 A	0.4 A
2015	0.2 A	0.2 A	0.2 A	0.2 E	0.8 E
2016					1.2 E
2017					1.7 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2014	-$0.75 A	-$0.19 A	$0.45 A	-$0.63 A	-$1.11 A
2015	-$0.17 A	-$0.05 A	$0.06 A	-$0.17 E	-$0.34 E
2016					-$0.76 E
2017					-$0.79 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

AXON's Alzheimer's Vaccine Candidate (Using KLH) Shows Promising Results

Another recent announcement supporting the use of KLH as carriers in immunotherapies came in November 2015 when AXON Neuroscience (private) presented positive phase I data on its Alzheimer's disease active vaccine candidate, AADvac1, at the annual International Trials on Alzheimer's Disease Conference (CTAD) in November. AADvac1, which utilizes KLH as a carrier protein, is being developed to generate specific antibodies against diseased forms of tau protein. The presentation at CTAD showed AADvac1 to be safe, well tolerated and induced a "robust response in the vast majority of the study participants and the average cognition of patients remained stable over 6 months." A phase II study, designed to confirm phase I results in a larger population, is anticipated to begin by current year-end.

Stellar Reverse Splits (1-for-10), Uplists to NASDAQ, Rings Opening Bell

In order to meet the Stellar affected a 1-for-10 stock split to meet certain requirements for trading on NASDAQ and subsequently uplisted. Icing on the cake was management ringing the NASDAQ closing bell on November 5th following the first day of SBOT stock trading on the exchange.



SOURCE: www.nasdaqomx.com

SNAPSHOT

Stellar Biotechnologies, Inc. (SBOT) is engaged in the manufacture and supply of the Keyhole Limpet Hemocyanin (KLH), a high molecular weight protein derived from the hemolymph of the ocean mollusk, the Giant Keyhole Limpet. KLH has been found to be a highly effective carrier protein for (low molecular weight) peptides in immunotherapeutic applications. While KLH has been used for over 40 years in immunological applications, recent ramping interest in immunotherapies, which involves stimulating (or suppressing) the body's own immune system to fight diseases, has fueled demand for the protein and, by default, for the Giant Keyhole Limpet.

The Giant Keyhole Limpet, native only to the waters off of the Southern California and Baja California (Mexico) coasts, is in relatively short supply in the wild. Stellar, founded in 1999 in the Southern California town of Port Hueneme, has been a pioneer in sustainable production of KLH. Funded in part with grants from the National Institutes of Health and National Science Foundation, Stellar has built proprietary aquaculture (i.e. Giant Keyhole Limpet farming) and production facilities which the company believes are the only source in the world capable of supplying commercial-scale quantities of high quality KLH protein.

Unlike Stellar the other KLH suppliers, which is believed to be limited to a small a handful of companies, source the Giant Keyhole Limpet from the wild. This is associated with significant issues, including lack of traceability, inability to guarantee supply and the potential for over-harvesting of an already relatively scarce population. In addition, sourcing from the wild introduces risk of variability of purity and the form of KLH derived from the mollusks, which can be particularly problematic when used as a component in human pharmaceuticals. Unlike other manufacturers Stellar's processes sustain the entire life cycle of the Giant Keyhole Limpet. Studies have shown that not all KLH is of the same quality and Stellar believes that they are the only company that provides Good Manufacturing Practices (GMP) grade product with fully traceable manufacturing methods.

Sold under the "Stellar KLH" brand, the company offers various grades and formulations of KLH protein which are used by life sciences companies in preclinical and clinical applications, particular for drug and assay development. KLH has been used for vaccine conjugation and as a carrier protein in immunotherapies targeting conditions such as cancer, immune disorders, Alzheimer's disease and inflammatory diseases.

Stellar has a wide range of customers including private and publicly held biotechnology and pharmaceutical companies as well as academic and clinical research institutions. This includes recently penned agreements with Amaran Biotechnology related to their lead immunotherapy candidate for breast cancer as well as with Neovacs related to two Kinoid vaccine candidates targeting certain autoimmune disorders. And in late 2014 Stellar entered into an agreement to supply KLH for Araclon Biotech's clinical trials for its beta-amyloid program focused on Alzheimer's disease.

In addition to supply agreements for development programs and, eventually, for commercial products, Stellar is considering and/or currently pursuing other revenue pathways including product co-development agreements, joint ventures and research collaborations. In addition, they have in-licensed proprietary technology for the development of immunotherapies for the treatment of Clostridium difficile (C. diff) infection.

Stellar's facilities, including their land-based aquaculture operations, are located at the Pacific coast providing convenient proximity to the Giant Keyhole Limpet's natural habitat. The current aquaculture facility, which includes 18 production tanks, has capacity to produce 2 kg of KLH per year. Stellar expects, with additional funding and requisite demand, to expand production incrementally over the next few years up to a potential maximum of 20 kg/year. With each gram of GMP-grade KLH valued at approximately $50k, the value of current and future maximum annual production is equal to ~$100M and $1B.

Stellar's advanced aquaculture facilities, industry-leading expertise in KLH production and manufacturing, KLH-related intellectual property and what amounts to a 5 - 10 year headstart as a high-quality KLH supplier acts as barriers to entry. And while Stellar currently supplies only a relatively small amount of KLH, we think tangible competitive differentiation from current suppliers including sustainability of high-volume production and uniformity in quality bode well for accelerated market penetration of Stellar-KLH. In addition, we expect the overall market for KLH to continue to expand as a consequence of the rapidly expanded interest in immunotherapies, a segment which some sources forecast to grow an at annual rate of almost 25% over the next seven years.

BACKGROUND

In order to frame KLH's role and opportunity as therapeutic component and diagnostic agent we think it is helpful to first provide a primer on the immune system and immunotherapies. We then discuss KLH in detail and including its unique characteristics as a carrier protein and provide context of how these can be of benefit to development of novel immunotherapies.

Immune System

The immune system functions to protect the body against disease, or pathogens. A properly functioning immune system can differentiate between healthy and pathogenic tissue and only attack the latter. The immune system can be categorized into two separate sub-components, the innate system and the adaptive system. The innate system, also called the non-specific immune system, acts as an immediate defense to pathogens but is a relatively short-lived response. It also activates the adaptive immune system, also known as the specific immune system. Unlike the innate system, the adaptive system is highly specific to particular pathogens and can provide long-lasting defense.

The major cells of interest of the **innate immune system** include phagocytes and lymphocytes. Phagocytes (derived from the Greek word "phagein", meaning "eat") are a group of immune cells that eat harmful bacteria, viruses and dead or comprised cells. These immune system cells are activated by the presence of antigens - which are substances that the body identifies as foreign. There are different types of phagocytes including mast cells, neutrophils, macrophages and dendritic cells. Mast cells reside in mucosal tissue and while mostly known for their role in allergies, also are involved in fighting pathogens. **Mast cells**, through the release of granules, present characteristic immune response symptoms such as inflammation. Mast cells also recruit neutrophils and macrophages. **Neutrophils** are the most abundant type of white blood cells and are one of the first defenses, eating pathogens until they die. **Macrophages** are found in all tissues. They respond slower than neutrophils but are longer lasting and have more capacity. Macrophages also play a part in alerting the adaptive immune system. **Dendritic** cells are similar to macrophages as they are also eater cells and play an important role in alerting the adaptive immune system. But unlike macrophages, dendritic cells are only found in tissue that is in contact with the external environment such as the skin, nose and lungs, among other areas.

The **adaptive system** is more specialized than the innate system in that specific white blood cells of the adaptive system only bind to specific antigens. This tailored immune response allows for maximum killing efficiency. It also provides for development of immunity to a specific pathogen, which is similar to how vaccines work. Lymphocytes, T cells and B cells, account for about 30% of all white blood cells and are the major cells of the adaptive immune system. Lymphocytes originate in the bone marrow and migrate to parts of the lymphatic system including the lymph nodes.

T cells move from the bone marrow to the thymus. There are two types of T cells; **helper T cells** and **killer T cells**. Helper T cells' role is to activate B cells and killer T cells to eradicate pathogens. Helper T cells must be first activated which occurs when a phagocyte (from the innate system) presents an antigen from a foreign particle which it has eaten to the receptor of a helper T cell. The helper T cell then divides and produces proteins which activate B cells and killer T cells.

B cells and killer T cells have receptors on their surfaces which bind only to specific pathogens. These receptors adapt to pathogenic invasion which accounts for the ability to build immunity. Acquired immunity relies on the ability of these lymphocytes to differentiate between "self" antigens from healthy cells and those of foreign cells. The B and killer T cells search for antigens matching their specific receptors, recognizing infected cells by the presence of traces of the receptor-specific antigen on their surface.

When a killer T cell finds its receptor specific antigen, it kills the foreign cell. When the B cell finds its receptor specific antigen it is activated by the helper T cell, then divides and creates plasma cells and B memory cells. Plasma cells produce B-cell receptor matching antibodies which attract phagocytes which then kill the foreign cells. B memory cells, as their name suggests, remember specific pathogens and help trigger a more rapid immune response the next time it invades the body - which is part of the immunity-building process.

Immunotherapies
Immunotherapies involve the stimulation or suppression (or a combination of both) of the body's own immune system to fight diseases. Currently used immunotherapies are made of one or more natural, recombinant and synthetic components. Cell immunotherapies are those which are composed of living cells.

Active immunotherapies (also known as vaccines) stimulate the immune system by presenting antigens associated with a particular disease which triggers an immune response. Active immunotherapies are believed to have certain significant advantages over traditional drugs such as chemotherapy including less severe side effects and immune "memory". Active immunotherapies can take a wide variety of different forms with an array of ways that they activate a therapeutic benefit. There are three main categories of active immunotherapies; prophylactic, autologous and allogeneic.

- Prophylactic: instead of fighting an active disease, prophylactic immunotherapies prevent a disease by presenting an antigen prior to the disease afflicting a person. Following administration with a prophylactic vaccine the immune system can recognize foreign cells and destroy them. Cervarix (GSK) and Gardasil (MRK), both vaccines against human papilloma virus (HPV), are probably the most recognizable prophylactic immunotherapies.
- Autologous: both autologous and allogenic immunotherapies are given to the patient after the disease is diagnosed. Autologous vaccines are "personalized" in the sense that they contain antigens from each individual patient. While potentially more effective, these are typically more expensive to manufacture and may have less commercial opportunity than allogenic immunotherapies due to their patient-specific nature. Provenge, approved by the FDA in April 2010 for metastatic prostate cancer, was the first autologous cancer vaccine to make it to the U.S. market.
- Allogeneic: most (~70% - 75%) active immunotherapies currently under development are allogeneic (i.e. "non-personalized" or "off-the-shelf"), which are composed of tumor antigens of one or more patients and not specific for a particular person.

Delivery of both autologous and allogeneic vaccines can take several forms including;

- Dendritic cell-based immunotherapy: As explained above, dendritic cells are eater cells located in areas of the body that is in contact with the outside environment. Dendritic cells are taken from the body, pulsed with an antigen, which activates the dendritic cells, and then transfused back into the patient. The dendritic-pulsed cells then eat the antigen-expressing invaders and also initiates the adaptive immune response.
- T-cell adoptive transfer: T cells with affinity to fight specific pathogens or tumors are removed from the body and multiplied in vitro. These are then transferred back into the patient along with administration of certain interleukins, which enhances the T cell cancer fighting activity.
- Autologous immune enhancement: certain immune cells, mostly natural killer cells and T lymphocytes, are removed from the peripheral blood of a patient, multiplied, activated and then transferred back into the patient.
- Genetically engineered T cells: also used primarily with cancer. The goal is to increase immunogenicity of target tumor antigens. To do this the specificity of the T cell receptor is modified. T cells are removed from the body and exposed to a virus that is predisposed to recognize tumor antigens. This creates genetically engineered T cells which are then multiplied and transferred back into the patient.

Passive immunotherapies do not by themselves trigger an immune response but instead directly target the disease by injection of immune compounds (such as antibodies, cytokines, macrophages and B cells) into the disease location. Passive immunotherapies are, essentially, acute treatment where the antibodies kill cells as long as the antibodies remains in the body. Passive immunotherapies have drawbacks compared to active immunotherapies. Those being that they may not specifically target foreign cells and therefore also kill healthy cells and they do not normally licit a "learned" immune response - therefore they do not educate the immune system to fight the disease.

Immunotherapy Market

While forecasts differ in terms of the overall level of expected growth of immunotherapies, it seems there is a consensus that this space is garnering significant interest and will likely be one of the leading areas of drug development.

Healthcare industry research company Decision Resources Group recently published a report which forecasts the global cancer immunotherapy market to grow from $1.1B in 2012 to about $9B in 2022. While this represents a robust CAGR of almost 25%, it pales in comparison to forecasts by Citigroup analysts who expect the cancer immunotherapy market to blossom to up to $35B over the next 10 years. In addition, Citi analyst Andrew Baum believes immunotherapies will be used to treat about 60% of all cancers, citing the potential that these drugs may one day turn cancer into a more manageable chronic disease rather than the typical death sentence of today.

Still, another source, GBI Research, forecasts the cancer vaccines market to grow from approximately $1.7B in 2010 to $6.3B in 2017 (21% CAGR). GBI research notes that this growth will be driven by "the launch of promising Phase III molecules in cervical cancer lung cancer, pancreatic cancer and melanoma."

Carrier Proteins

Molecules that trigger an immune response are termed "immunogenic". While all immunogens are antigens, not all antigens are immunogenetic - that is, not all antigens are capable of soliciting an immune response. Certain attributes must be present for an antigen to be immunogenic; foreign substance, high molecular weight and chemically complex.

While the body may often be able to distinguish "self" from "non-self" substances (i.e. the foreign substance criteria may often be met), certain antigens are of too low molecular weight and/or too low complexity to be immunogenic. Proteins, which are relatively large and complex molecules, are typically highly immunogenic, other molecules such as peptides, lipids, nucleic acids and carbohydrates are generally not due to lack of complexity or weight.

Small molecules and peptides which are used as antigens are called haptens. In order for these haptens to elicit an immune response they must be conjugated with a carrier protein, which is sufficiently large and complex to be immunogenic. Antibodies are then able to be produced against the antigen/hapten. KLH, of high complexity and molecular weight, has been found to be an excellent carrier protein and has been used extensively in clinical drug trials.

KLH

KLH is the most widely used carrier protein. It is a high molecular weight, oxygen-carrying glycoprotein derived from the hemolymph of the ocean mollusk, the Giant Keyhole Limpet (Megathura crenulata). It is a respiratory protein with two copper binding sites used to transport oxygen in the Giant Keyhole Limpet. The copper binding sites give KLH a blue color. The molecular structure of KLH has multiple binding sites and has been found to be a highly effective T cell dependent carrier protein, inducing immune response through antigen presentation. These benefits; large size, multiple binding sites and immune stimulation along with a strong safety profile have generated significant interest in the molecule for development of active immunotherapies.



SOURCE: wunderground.com

The large size and complexity of the KLH protein do not lend easily to synthetically producing the molecule. Instead it is sourced from the Giant Keyhole Limpet, which is native only to the waters off of the Southern California and Baja California (Mexico) coasts, and is in relatively short supply in the wild. While other KLH suppliers obtain KLH by sending divers into the ocean, Stellar has built proprietary aquaculture facilities where they farm the Giant Keyhole Limpet. Wild sourcing can be associated with

significant issues including the potential for over-harvesting of an already relatively scarce population - which could result in government-mandated harvesting restrictions – as well as inability to guarantee supply. In addition, it introduces risk of variability of purity and the form of KLH derived from the mollusks, which can be particularly problematic when used as a component in human pharmaceuticals. By contrast, Stellar's aquaculture and production facilities and their ability to sustain the entire lifecycle of the Giant Keyhole Limpet provides what the company believes is the only source in the world capable of supplying sustainable, commercial-scale quantities of high quality KLH protein.

KLH Biophysical Characteristics

KLH is a very large, high molecular weight, oxygen-carrying metalloprotein from the hemolymph of the marine mollusc *Megathura crenulata*.

The KLH protein is expressed in two subunit isoforms (KLH1 and KLH2) of approximately 360,000 and 400,000 monomeric molecular weight. The KLH monomers are each composed of 7 or 8 functional unit domains; each functional unit contains an oxygen binding site containing two copper atoms.

Both KLH isoforms assemble into native homo-decamers and -didecamers of 4,000,000 to 8,000,000 molecular weight in hemolymph.

KLH's immunogenicity is partly attributed to the presence of unusual carbohydrate moieties, including unique Fuc(alpha1-3)GalNAc, Gal-(beta1-6)Man-, Gal(beta1-4)Fuc-, and Gal(beta1-4)Gal(beta(1-4)Fuc- structural motifs on N-glycans.(1,2,3) Terminal mannose residues are mannose receptor ligands and fucose residues are DC-SIGN ligands, suggesting that endocytosis of KLH via C-lectin receptors for antigen presentation in KLH-based conjugate vaccines. KLH has been reported to stimulate dendritic cell maturation from human monocytes in processes possibly involving the mannose receptor.(4)

Size (and Source) Matters

Due to its exceptional size and unusual glycosylation, KLH has not been reproduced synthetically, and is more efficiently and cost-effectively prepared by purification from the hemolymph of the source animal.

Studies have shown that different forms of KLH have distinctly different structural properties and, importantly, may have different inductive effects on the immune system.(5,6,7,8,9,10,11,12,13)

Further, studies have reported that the culture, handling and processing of KLH can impact isoform structure and immunogenicity.(14,15,16)

Different forms and supply sources of KLH have been associated with differing magnitudes and variability in IgM and IgG responses.(17,18,19)

SOURCE: Stellar Bio, klhsite.org. See citations in Appendix

KLH Being Widely Used in Immunotherapy Development

KLH is being used by private and public research institutions, biotech companies and academic centers for drug development, particularly in immunotherapies. This includes Celldex's phase II EGFRvIII-positive glioblastoma multiforme (GBM) candidate, CDX-110, which earlier this year was granted Breakthrough Therapy Designation by the FDA. This is the first such KLH-based immunotherapy to receive that designation. GBM is the most common and aggressive type of brain cancer and is not effectively treated by traditional chemotherapy.

Another recent announcement supporting the use of KLH as carriers in immunotherapies came in November 2015 when AXON Neuroscience (private) presented positive phase I data on its Alzheimer's disease active vaccine candidate, AADvac1, at the annual International Trials on Alzheimer's Disease Conference (CTAD) in November. AADvac1, which utilizes KLH as a carrier protein, is being developed to generate specific antibodies against diseased forms of tau protein. The presentation at CTAD showed AADvac1 to be safe, well tolerated and induced a "robust response in the vast majority of the study participants and the average cognition of patients remained stable over 6 months." A phase II study, designed to confirm phase I results in a larger population, is anticipated to begin by current year-end.

Below is a sampling of KLH-based immunotherapies and their respective development stages. Note that this includes programs using KLH supplied by Stellar as was as from other sources.

KLH-Based Active Immunotherapy Trials		
Clinical Status	**Indication**	**Company or Institute**
Phase III	Breast Cancer	OBI Pharma (OBI-822)
	Glioblastoma	Celldex (Rintega®)
Phase II	Crohn's Disease	Neovacs (TNF Kinoid)
	Lupus	Neovacs (IFNa Kinoid)
	Alzheimer's	Affiris/GSK (AD02)
	Multiple Myeloma	Abramson Center
	Melanoma	Baylor Research
	Lymphoma	Clinica Navarra
	Melanoma	Dermatologische Klinik
	Ovarian Cancer	Loyola University
	Sarcoma	MabVax
	Ovarian Cancer	MabVax / NCI
	Leukemia	NCI
Phase I	Alzheimer's	Araclon / Grifols
	Alzheimer's	Axon Neurosciences
	N-H Lymphoma	Bayer (Autologous)
	Brain Tumor	Rockefeller
	Glioblastoma	Roswell Park
	Lung Cancer	Sloan-Kettering
	Neuroblastoma	Sloan-Kettering
	Sarcoma, Neuroblast	NCI

SOURCE: Stellar Biotech

Stellar's Aquaculture Facilities

Stellar's facilities, including their land-based aquaculture operations, are located at the Pacific coast providing convenient proximity to the Giant Keyhole Limpet's natural habitat. Initially built in the 1990's for research and production on gastropod mollusks, Stellar's aquaculture facilities have been expanded over the years including a major upgrade completed in 2011 which was funded in part with grants from the National Science Foundation.

The aquaculture operation currently includes 18 production tanks and 400 individual limpet production modules in two temperature-controlled recirculating systems. The closed system which includes seawater intake, recirculation, environmental controls and return of the seawater to the ocean supports the complete lifecycle of the Giant Keyhole Limpet from spawning and larvae development to maturation.

The system can support reproduction and multiple generations of the mollusk. Stellar notes that it takes approximately five years for the Giant Keyhole Limpet to fully mature from embryo to a protein-producing adult. Using a patent-protected non-lethal extraction method, the mollusk can be milked up to three times per year. The benefits of having a self-contained farming system also include being able to gauge production targets must easier than if relying on wild sources, quantities of which can be at risk of fluctuation or harvesting regulations.

Stellar's aquaculture facilities have a current capacity of 2 kg of KLH per year. The company expects, with additional funding and requisite demand, to expand production incrementally over the next few years up to a potential maximum of 20 kg/year. With each gram of GMP-grade KLH valued at approximately $50k, the value of current and future maximum annual production is equal to ~$100M and $1B.

In June 2015 Stellar entered an agreement with Ostiones Guerrero SA de CV, a Baja California (Mexico) based commercial shellfish aquaculture and fishing organization aimed at expanding Stellar's KLH

aquaculture operations. Stellar is leasing undeveloped land from Ostiones and the duo, contingent on findings from a three-year suitability study, will develop marine aquaculture facilities. This will increase Stellar's KLH production capacity and also provide Ostiones with advanced aquaculture know-how and infrastructure. Stellar is responsible for construction costs. Following development the two parties expect to enter into separate usage and supply agreements.

Ostiones Guerrero has permits to farm and harvest approximately 10 square kilometers of ocean including 10 km of coastline and the entire Isle of San Martin. While these areas are home to the Giant Keyhole Limpet, the plan is to build aquaculture facilities similar to those Stellar has in Port Hueneme. The suitability study includes the construction of a facility to pipe in seawater and for a pilot aquaculture facility to demonstrate to customers and regulators that they can meet production quality standards. Stellar expects the construction and data collection to take about three years. And while full-scale production is contingent on results of the study, based on Stellar's expertise in KLH production and aquaculture (CEO Frank Oakes is arguably the world-leading authority) and the fact that they have already done it once, we think it is a reasonable assumption that this suitability study has a good chance of success.

Arial Pic of Stellar's Aquaculture and Production Facilities



SOURCE: Stellar Biotech

Stellar's Land-Based Aquaculture Facilities





Stellar KLH
The company's Stellar KLH is offered in both GMP grade (KLH-20MV) and research grade (KLH20MVR) formulations and in different concentrations which are used for both preclinical and clinical applications in drug discovery as well as for in vitro diagnostics. Stellar KLH is used as vaccine conjugate or carrier protein in immunotherapies being developed conditions such as Alzheimer's disease, cancer, autoimmune disorders, among others. It can also be used as an injectable for immuntoxicology (i.e. measure an individual's response to drugs). In addition, Stellar offers Stellar KLH ELISA assay kits for preclinical research use in the detection of KLH antibodies.

STELLAR KLH™ KEYHOLE LIMPET HEMOCYANIN			
PRODUCT CODE	KLH-20MV	KLH-01NV	KLH-05N
Liquid formulations from sustainable, controlled, aquaculture source.			
Product	Subunit KLH	High Molecular Weight KLH	High Molecular Weight KLH
Grade	GMP Grade	GMP Grade	GMP Grade
Packaging	Type I glass vial	Type I glass vial	Call for details
Protein Content per Vial	15 mg	1 mg	Call for details
Protein Concentration	18-22 mg/mL	0.8-1.2 mg/mL	4.5-5.5 mg/mL
Formulation	Liquid in water for injection	Liquid in DPBS	Liquid in DPBS
Purity by SEC	≥ 90%	≥ 95%	≥ 95%
pH	6.9-7.9	6.8-7.8	6.8-7.6
Endotoxin Level	≤ 5.0 EU/mg		<7.0 EU/mg
Sterile	Yes	Yes	Yes
Pricing & Ordering: KLHinfo@stellarbiotech.com			



SOURCE: Stellar Biotech

The company has generated only limited sales to-date, the volume of which is mostly a determinant of the extent of their products' use in customers' research and development activities. However, with increased awareness of Stellar KLH, additional customer on-boarding and accelerated immunotherapy-related R&D activity we expect revenue momentum to significantly pick up.

Customers / Partnerships / Contracts / Licenses
Stellar has a range of customers including private and publicly held biotechnology and pharmaceutical companies as well as academic and clinical research institutions. This includes recently penned agreements to supply KLH for development of Amaran Biotechnology's lead immunotherapy candidate for breast cancer as well as for Neovacs' three Kinoid vaccine candidates targeting certain autoimmune disorders. And in late 2014 Stellar entered into an agreement to supply KLH for Araclon Biotech's clinical trials for its beta-amyloid program focused on Alzheimer's disease.

In addition to supply agreements for development programs and, eventually, for commercial products, Stellar is considering and/or currently pursuing other revenue pathways including product co-development agreements, joint ventures and research collaborations. In addition, they have in-licensed proprietary technology for the development of immunotherapies for the treatment of Clostridium difficile (C. diff) infection.

- **Amaran Biotechnology:** Amaran Biotechnology was set up in 2010 as a joint investment between the chairman of OBI Pharma and Reuntex Group. Stellar penned a collaborative agreement with Amaran, a Taiwanese biopharma company which owns over 5% of SBOT's outstanding shares and is developing manufacturing capabilities to produce active immunotherapies. OBI Pharma's lead candidate, OBI-822, has been in mid-to-late stage clinical testing in the U.S., S. Korea, India, Hong Kong and Taiwan for the treatment of metastatic breast cancer. It is also in a phase 2 physician-initiated clinical trial in Taiwan for the treatment of ovarian cancer – patient recruitment is expected to be completed by the end of 2015. OBI-822 utilizes KLH as a carrier protein for the carbohydrate antigen Globo-H, which is often expressed by cancer cells. Per clinicaltrials.gov, the ongoing phase II study, being conducted at over 40 international sites with targeted enrollment of 342 patients (actual was 349). The randomized, double-blind study is comparing OBI-822 to placebo in post-treated metastatic breast cancer patients with stable disease or response to treatment. Primary and secondary outcomes are progression free and overall survival, respectively.

Per terms of the agreement, Stellar is responsible for production and delivery of GMP grade KLH for evaluation as a potential carrier protein as well as for method development and process qualification and in return Amaran pays the company for certain expenses and costs. And, if and when Amaran launches a product using Stellar KLH, Stellar might be in an opportune position to enter into a supply agreement. Amaran accounted for approximately 35% of the $372k in total revenue that Stellar generated in FY 2014.

- **Neovacs SA**: Stellar has a supply agreement with Neovacs, a Paris-based biotech company engaged in the development of immunotherapies for autoimmune and inflammatory diseases. Per the terms of the agreement, originally penned in 2008 and recently expanded, Stellar supplies KLH as a carrier molecule for two of Neovacs' Kinoid vaccines under development for the treatment of Lupus and Crohn's disease.

  Neovacs' lead candidate, IFNa-Kinoid, completed a phase I/IIa study (n=28) for lupus in 2011. Results showed IFNa-Kinoid was well tolerated and patients experienced a strong immune response with a significantly higher production of binding antibodies compared to TNF Kinoid in humans. A phase IIb study, which is expected to include approximately 166 patients and began patient enrollment in September 2015, is being conducted in Europe, Latin America and Asia. Neovacs expects results of this study to be available in Q1 2017. In addition a phase IIa study is expected to begin in the U.S. - potentially sometime in 2016. Stellar/Neovacs recently expanded the supply agreement to ensure sufficient KLH quantities are available to support these upcoming studies as well as a potential future commercial launch. In addition, the agreements call for Neovacs to pay Stellar for maintaining a dedicated colony of limpets.

- **Araclon Biotech SL:** In November 2014 Stellar signed an agreement with Spain's Araclon (majority owned by Grifols, SA) to supply KLH for phase II /III clinical trials of that company's Alzheimer's immunotherapy candidate. Araclon's beta-amyloid targeting active immunotherapy against Alzheimer's disease will use Stellar's KLH as a carrier protein. Stellar will also have the potential to supply KLH for an eventual commercial product.

  Clinicaltrials.gov lists one Alzheimer's study which is currently enrolling and sponsored by Grifols (Araclon is not listed as a sponsor of any studies) - although it is unclear whether this is one of the study for which Stellar will supply KLH. The phase 2/3 study will evaluate albumin and immunoglobulin in (n=~350) Alzheimer's patients. Primary outcome is change in cognitive scores (ADAS-Cog and ADCS-ADL). Estimated completion date is December 2016.

- **C. Diff License:** Stellar's first foray into their own product development program was initiated in 2013 when they in-licensed patented technology from the University of Guelph (Ontario, Canada) for the development of immunotherapies for Clostridium difficile (C. diff) infection. The patent protecting the technology expires in 2030 and covers "certain novel cell surface polysaccharides and their chemical structures and vaccine compositions for the treatment, prevention and diagnosis of C. difficile infection." The license grants Stellar the exclusive right to use the technology to develop and commercialize active immunotherapies to treat C. diff. In return Stellar paid a $225k in upfront fees and will pay $20k annually, the latter which is creditable against any future potential royalties on sales. Stellar is also subject to up to $6 million in milestone payments, which are based on achievement of certain financing and development goals.

  Stellar has provided periodic development-status updates. In December 2013 they began initial development of manufacturing methods for a C diff polysacchardide (PS)-KLH conjugate vaccine candidate. During the first half of 2014 Stellar made additional progress towards manufacturing including scale-up and method transfer to a CMO.

  C. diff is a spore-forming bacteria often found in soil and also present in about 3% of the human population. Human transmission of C. diff is via the fecal-to-oral route. The bacteria is particularly robust, surviving for extended periods in and outside of the body, able to withstand many hand cleansers, stomach acid and antibiotics. While gut flora (i.e. “good bacteria”) in the stomach and digestive system controls or kills C. diff, use of broad spectrum antibiotics (for unrelated conditions) can compromise gut flora and result in C. diff related illness. Typical symptoms include diarrhea, fever, weakness and nausea, among others. In severe cases and instances of relapse, C. diff can be fatal, particularly when there is severe inflammation of the colon.

  Incidence of C. diff is on the rise and currently causes about 3M cases of diarrhea and colitis each year in the U.S., causing between 14k and 30k deaths annually. The majority of cases occur in hospitals, with (depending on the source) as much as 30% of hospitalized patients becoming afflicted with the illness.

COMPETITION

We found only three other companies, besides Stellar, that deal in the manufacture and sale of KLH. Along with biosyn Corp., which appears to be the most substantial in terms of volume and pure-play focus, SAFC and Thermo-Fisher are also involved, at least to some extent, with the manufacture and or/sale of KLH and related products. As Stellar notes in their public filings, their KLH is similar to KLH-based products produced by other companies. So Stellar's main potential competitive advantages lie mostly in their ability to produce sustainable high volumes and uniform, high-quality KLH, which is possible through their proprietary aquaculture and non-lethal extraction methods.

biosyn Corporation
Privately-held biosyn, located in Carlsbad, CA, claims to be "the world leader in the manufacture of high quality, clinical/GMP and research grade hemocyanin products." From what we found it appears biosyn has been one of the early pioneer(s) in KLH research and development. The company currently has two commercialized products, IMMUCOTHEL and VACMUNE, which are KLH subunits (immunocyanin) and have been used in clinical trials for a bladder cancer therapy and as carrier proteins in immunotherapy vaccines. IMMUCOTHEL is also sold as a bladder cancer vaccine in the Netherlands, Austria, Argentina and S. Korea. And, similar to Stellar, biosyn also manufactures KLH starting material.

biosyn's product manual indicates that they have developed a non-lethal hemolymph collection procedure. They also allude to aquaculture facility development activities. But the language (which includes, "biosyn is currently developing such techniques") suggests that they do not currently have functioning aquaculture capabilities. This is further supported in another part of their website which notes, "biosyn returns the animals back to its natural habitat…". So it appears that biosyn sources the Giant Keyhole Limpet from the wild by sending divers into the ocean. And we were unable to find anything indicating that biosyn expects to transition to aquaculture farming.

SAFC
Sigma-Aldrich Fine Chemicals (SAFC), part of diagnostics product heavyweight Sigma-Aldrich, manufactures KLH and offers clinical and research grade KLH-related products. In April 2011 Stellar entered into an agreement with SAFC whereby Stellar provides KLH starting material for SAFC's GMP grade KLH for applications in vaccines. However, that contract appears to have rolled off as Stellar has not booked any SAFC-related revenue since 2012 and notes in public filings that the agreement expired in June 2013.

SAFC/Sigma-Aldrich has a product webpage specific to carrier proteins which lists several hemocyanin products. From what we can tell these products are manufactured from SAFC's own KLH starting material. However, we have not been able to find how the KLH is sourced (i.e. ocean harvest or aquaculture) or if non-lethal extraction methods are employed. Stellar, in its public filings, indicates that SAFC sources its own KLH from limpets harvested from the ocean. SAFC's carrier protein product list is below.

Product #	Description	Add to Cart
H7017	Hemocyanin from *Megathura crenulata* (keyhole limpet)	pricing
H8283	Hemocyanin from *Megathura crenulata* (keyhole limpet) PBS solution	pricing
B8556	Hemocyanin from mollusk buffered aqueous solution	pricing
H9035	Hemocyanin from mollusk from *Concholepas sp.*, buffered aqueous glycerol solution	pricing
H5654	Hemocyanin, succinylated from *Megathura crenulata* (keyhole limpet) lyophilized powder	pricing
B7542	Maleimide Activated BSA	pricing
K0383	Maleimide Activated KLH	pricing
T1001	Thyroglobulin from bovine thyroid powder, ≥90% (agarose gel electrophoresis)	pricing
T9145	Thyroglobulin from bovine thyroid (For Gel Filtration Chromatography)	pricing

SOURCE: SAFC/Sigma-Aldrich

Thermo-Fisher Scientific
Thermo-Fisher, a $17B (annual revenue) life sciences company also appears to have some interest in KLH manufacturing, although this is almost certainly an inconsequential piece of the overall company. It appears, based on their website, that the KLH that they offer is research grade only. It is unclear how they source the KLH although their website notes, "KLH is harvested from select population of the mollusk Megathura crenulata (keyhole limpet) that are grown in mariculture, not extracted from wild populations." But it is not clear whether Thermo-Fisher has the mariculture operations or whether they use a third party source. From Thermo Fisher's website below.

A Thermo Fisher Scientific Brand
Features of Imject Mariculture KLH:

• **High-yield conjugation—**each molecule of KLH contains hundreds of primary amines available for coupling haptens via EDC or NHS ester crosslinkers
• **Validated quality—**purified and stabilized mariculture KLH maintains solubility in aqueous solutions, unlike traditional sources of the carrier protein
• **Sustainable source—**KLH is harvested from select populations of the mollusk *Megathura crenulata* (keyhole limpet) that are grown in mariculture, not extracted from wild populations
• **Highly immunogenic—**KLH has a high molecular mass (4.5 x 10^5 to 1.3 x 10^7 Daltons; aggregates of 350 and 390 kDa subunits) and elicits a stronger immune response than BSA or ovalbumin
For Research Use Only. Not for use in diagnostic procedures.

INVESTMENT CONSIDERATIONS

Revenue Dependent on Success of Product Development
Stellar has generated little revenue to-date with less than $400k coming from product sales over the last three full fiscal years. Grant revenue was related to funding from the National Science Foundation of phase II and IIb grants surrounding escalation of the aquaculture systems and development of a KLH-based immunogenicity assay. This grant has since completed. Contract services relates to reimbursement of work under collaboration agreements and fees for maintenance of limpet colonies.

While future grants and services revenue may help fund development activities, success of Stellar will ultimately depend on a significant increase in product sales. Product sales growth has significantly steepened over the last nine months. And while the company does not disclose specific sources or end-users that are generating the increased demand, they note that the recent product sales growth has been spurred by an increase in customer count as well as greater sales through supply agreements and custom manufactured products. Stellar currently has three committed supply agreements which run through October 2017, October 2019 and March 2020, respectively, and are renewable for one-year terms at the customers' request. Supply agreements such as these should provide, at the very least, a base amount of revenue. And continued growth in the customer base, additional development programs and support of larger and later stage trials have the potential to build on the recent product sales growth.

	9 Mths Ending June 30, 2015	August 31, 2014	August 31, 2013	August 31, 2012
Revenues:				
Contract services revenue	$ 150,000	$ 192,000	$ 60,000	$ 60,000
Product sales	$ 408,000	$ 143,553	$ 76,055	$ 131,825
Grant revenue	$ 0	$ 36,579	$ 409,414	$ 94,229
Total Revenue	**$ 558,000**	**$ 372,132**	**$ 545,469**	**$ 286,054**

In the near-term the company's current collaborations represent the most likely catalysts to ramping up revenue. However, eventual regulatory approval (in or outside the U.S.) for any of these programs is not likely to happen for

at least the next several years and, given the historical high failure rates of immunotherapies, it is much more likely than not that any vaccine development program will fail to produce a commercializable product. Additional positive progress in the various clinical programs, including potential interim data announcements, would improve chances of eventual regulatory approvals.

- Neovacs: Neovacs' lead candidate, IFNa-Kinoid, completed a phase I/IIa study (n=28) for lupus in 2011. Results showed IFNa-Kinoid was well tolerated and patients experienced a strong immune response with a significantly higher production of binding antibodies compared to TNF Kinoid in humans. A phase IIb study, which is expected to include approximately 166 patients and began patient enrollment in September 2015, is being conducted in Europe, Latin America and Asia. Neovacs expects results of this study to be available in Q1 2017. In addition a phase IIa study is expected to begin in the U.S. - potentially sometime in 2016. Stellar/Neovacs recently expanded the supply agreement to ensure sufficient KLH quantities are available to support these upcoming studies as well as a potential future commercial launch.

  Approximately 35% of Stellar's total revenue in 2014 came from KLH-supply and limpet colony maintenance for Neovacs' Kinoid vaccine clinical trials. The development progress including commencement of later-stage, larger clinical studies should provide opportunity for increasing KLH-supply sales to Neovacs in the near-term. Eventual commercialization and continuance of the KLH supply agreement would provide the potential for significantly greater revenue upside, although this is obviously dependent on further successful clinical development, including phase II and III trials.

  With approximately 1.5 million - 2.0 million Americans afflicted with Lupus and no currently available targeted therapies for the disease, there is tremendous opportunity for a Lupus vaccine.

- Amaran: Amaran accounted for approximately 35% of the $372k in total revenue that Stellar generated in FY 2014. OBI's lead candidate, OBI-822, has been in mid-to-late stage clinical testing in the U.S., S. Korea, India, Hong Kong and Taiwan for the treatment of metastatic breast cancer. It is also in a phase 2 physician-initiated clinical trial in Taiwan for the treatment of ovarian cancer – patient recruitment is expected to be completed by the end of 2015. OBI-822 utilizes KLH as a carrier protein for the carbohydrate antigen Globo-H, which is often expressed by cancer cells. Per OBI Pharma's August 31, 2015 press release, recruitment of the phase 2/3 metastatic breast cancer study was completed in August 2014 and the company expects to unblind the data by March 2016 and present the trial results at an international oncology conference sometime in 2016. The data should provide some insight into next steps, including potential additional clinical trials.

  Stellar recently announced that they have met all the primary objectives of the collaboration including qualification of GMP-grade Stellar KLH. Next steps will be to optimize manufacturing processes for scale-up of production for support of OBI's planned phase 3 study, as well as for potential follow-on commercial introduction.

  Per terms of the agreement, Stellar is responsible for production and delivery of GMP grade KLH for evaluation as a potential carrier protein as well as for method development and process qualification and in return Amaran pays the company for certain expenses and costs. And, if and when Amaran launches a product using Stellar KLH, Stellar could be in an opportune position to enter into a supply agreement. Breast cancer is one of the most prevalent malignant diseases in the U.S. with approximately 234k new cases diagnosed each year.

- Araclon: Per the November 2014 agreement, Stellar will supply Araclon with KLH to support that company's phase II/III clinical trials for their Alzheimer's candidate. Upon eventual commercialization, Stellar will also have the opportunity to supply KLH for commercial production. Per the only Alzheimer's study (n=350) on clinicaltrials.gov sponsored by Grifols, estimated completion date is December 2016. If this study is successful and another phase III study is not required, this Araclon relationship could possibly represent the most near-term commercial supply opportunity for Stellar. The market for an Alzheimer's therapy is represented by the approximately 5.2 million Americans afflicted by the disease. This includes one in nine people over the age of 65.
- C. diff: While Stellar has provided periodic updates on its C. diff program (initiated in 2013), development is still at an early (preclinical) stage and there remains little visibility on milestone timelines. So while we view the characteristics of the C. diff market as attractive (~3M cases/yr, incidence on the rise, up to 30% of hospitalized patients afflicted), given the early stage of development we do not currently incorporate any contribution from this in our model. This is subject to updating based on substantive development progress.

Rapid Growth of Immunotherapies Bodes Well for Stellar-KLH Demand

Industry analysts forecast immunotherapies to grow by more than 20% over the next 10 years with cancer vaccines expected to represent a market worth as much as $35 billion. This expected rapid growth should bode well for accelerating demand of KLH, the most widely used carrier protein and one that is not conducive to synthetic production. Stellar is among only a handful of KLH suppliers and with the explosive growth in immunotherapy development programs, has the potential to become a major supplier of the carrier protein. Annual production capacity of Stellar's current facilities is approximately 2kg of KLH, equal to about $100 million. In pursuit of their previously stated intention of further expanding their production capacity (to as much as 20kg, or ~$1B annual value), the company just penned an agreement for lease of additional property on the Pacific coast habitat of the Giant Keyhole Limpet. While build-out of this property is contingent on findings from a three-year suitability study, upon completion it could provide significantly greater opportunity for Stellar to exploit the expected accelerated influx of demand for high-grade KLH.

Exploit Expertise & Competitive Advantages

Frank Oakes, CEO of Stellar, has close to four decades of aquaculture experience which, prior to Stellar, included ten years as CEO of The Abalone Farm which under his leadership became the first profitable and largest abalone producer in the U.S. He is the inventor of the patented non-lethal KLH extraction method and has also acted as an aquaculture industry consultant.

Stellar's advanced aquaculture facilities, industry-leading expertise in KLH production and manufacturing, KLH-related intellectual property and what amounts to a 5 - 10 year headstart as a high-quality KLH supplier acts as barriers to entry. While we think that Stellar may currently supply only a relatively small amount of current demand for KLH, we think tangible competitive differentiation from current suppliers including sustainability of high-volume production and uniformity in quality bode well for accelerated market penetration of Stellar-KLH.

We view biosyn as the only meaningful current competition to Stellar for supply of clinical grade KLH. While biosyn was an early leader in KLH-related development, has their products incorporated as a bladder cancer vaccine (in select countries outside of the U.S.) and apparently has been able to generate substantive interest in their product in times of relatively low demand, we believe their reliance on wild-sourcing of limpets does not lend itself well to meeting increasing demand for the carrier protein. Potential drawbacks of wild sourcing, as opposed to aquaculture, include;

- difficulty (or inability) to quickly scale up production to meet higher demand as wild-sourcing does not afford limpet inventory stocking
- inability to guarantee high volumes of KLH at particular time points due to factors such as
    - weather which could make it difficult to dive
    - disease which could reduce limpet populations (as an example abalone populations off the California coast fell by 60% following a 2011 disease-related die-off)
    - overharvesting of limpet colonies
    - future legislation regulating harvest quotas
- less control over the health of the limpet, resultant quality (as well as uniformity of quality) of KLH and less informed traceability of both the limpet and the KLH

For pharmaceutical companies needing to source KLH for drug trials or commercialization of a new therapy, these factors are likely to be of significant interest. Drug companies will want to know their KLH supplier can meet their demand requirements – which can substantially increase with larger trials or increasing demand for a commercialized product. They also have strict quality and traceability mandates which are required to be documented in clinical trial protocols and for GMP manufacturing of finished product. Aquaculture, which provides significantly greater control over production volumes (and more ability to rapidly scale) and quality/traceability, we think is a much better fit to meet the requirements of drug manufacturers than is wild ocean harvesting.

Environmental Regulation

While the Giant Keyhole Limpet is not currently regulated by federal or state agencies there is growing concern that the combination of the relative scarcity of the mollusk and increasing interest in KLH for pharmaceutical applications may result in overharvesting. Several organizations have recently become active in researching the potential issue of overharvesting of the Giant Keyhole Limpet including the Channel Islands National Marine Sanctuary, University of Santa Barbara Marine Science Institute, Reef Check California and Occidental College (L.A., California).

The Channel Islands Marine Sanctuary (CIMS) has had a Giant Keyhole Limpet research program which monitors the population density of the mollusk in the Channel Islands. This organization has raised concerns to the California Department of Fish & Wildlife over the potential adverse effect to Giant Keyhole Limpet populations from interest in KLH from pharmaceutical manufacturers. In a joint meeting in 2006 between CIMS and UC Santa Barbara Marine Science Institute, John Ugoretz of CIMS noted (on the topic of concern of GKL overharvesting) that

“Department of F&G [California Fish & Wildlife] will watch the emerging fishery closely. Although it is not an issue now it has the potential to become an issue if the pharmaceutical product [Biosyn’s bladder cancer vaccine] is approved.”

UC Santa Barbara scientists voiced similar concerns, noting in a 2006 report that, “Very concerned about the emerging fishery that may develop as a result of this demand for this resource. Suggests that it would be better to examine and regulate such a fishery early on rather than wait for fishery to decimate populations.”

Reef Check California is an international organization focused on conservation of the California rocky reefs with a goal of educating people about the current crisis affecting marine life. This includes a monitoring program to investigate the human impacts on California’s nearshore ecosystems. Monitoring includes sending divers into the water to count and sample a variety of species, including a specific focus in invertebrates. The organization publishes Reef Check data manual which details the current state of the California rocky reefs. The manual classifies species, based on a certain rationale for selecting it for observation. Of note is that they have selected the Giant Keyhole Limpet for observation based on it being a species that is “exploited by recreational and commercial fishing”.

Occidental College began a program to study the Giant Keyhole Limpet which was prompted by, “While a popular catch, limited oversight questions whether wild limpet stocks can satisfy a growing commercial demand. Today, scant ecological information and sparse fishery regulations threaten the promising future of this marine invertebrate fishery.”

And while the increased concern over the sustainability of Giant Keyhole Limpet populations in the face of growing interest in KLH for pharmaceutical applications will not necessarily translate into fishery regulation of the mollusk, it presumably does improve the chances of that eventually happening. As an example, California has strictly regulated harvesting of abalone due to a precipitous drop in their populations from overharvesting and disease. Abalone, like the Giant Keyhole Limpet, take five or more years to mature which makes their populations that much more susceptible to the risks of overfishing. So if the California Fish & Wildlife, which is unique to most wildlife regulators in that they have the power to write legislation (i.e. it does not need to pass through the State legislature), deems the Giant Keyhole Limpet at particular risk of overharvesting, precedent indicates that they are willing to do so.

Additional Capital

Cash balance as of the end of the most recent reporting period (6/30/2015) stood at approximately $10 million. Cash used in operating activities has averaged about $1.1 million per quarter over the last two years. The company expects the current cash balance to fund operations for at least the next 12 months. We expect cash burn to increase over the near-term with additional spend on activities related to increasing production in support of new accounts as well as funding the suitability study of the Ostiones facility.

Additional financing to support near-term operations as well as for eventual build-out of the Baja aquaculture facilities (following the 3-year study) is built into our financial forecasts and incorporated into our estimated outstanding share counts (while future financing could come in the form of debt or equity, we use common share issuance as a placeholder).

VALUATION / RECOMMENDATION

Financial Model
There are inherent difficulties in building a financial model for Stellar given the various unknowns – while we think near-term revenue will be mostly driven by the already established relationships, the biggest unknowns relate to what to anticipate in terms of future collaborations and supply agreements in support of additional clinical trials and, eventually, to supply KLH for commercialized products. As such, our modeled revenue incorporates two general assumptions; the first (bottom-up approach) that revenue over the next few years comes mostly from already established relationships (i.e Neovac, Amaran, Araclon, etc) and the second (top-down approach), that by the (fiscal) year 2019 Stellar begins to generate meaningful revenue from supplying KLH to commercialized immunotherapies.

Through the year 2018 over 70% of our modeled revenue relates to contract services and product sales to Stellar's existing customers (most of the remaining ~30% of modeled revenue comes from assumed new service contracts). Our assumptions include that the various supported candidates including IFNa-Kinoid, OBI-822 and Araclon's Alzheimer's candidate successfully complete current clinical trials and progress to later stages. While we assume larger trials require greater quantities of KLH and generate additional services revenue, we also incorporate a revenue haircut to account for the risk of failure - this includes a 50% haircut that a candidate will progress from Ph II to Ph III and a 80% haircut that a Ph III candidate will eventually gain FDA approval. Our chosen haircuts are based on literature about immunotherapy clinical trial and regulatory approval failure rates.

Given that there is no way to know what additional customers may come onboard, our second phase of modeled revenue, which begins to make a meaningful contribution in year 2019, is based on the overall estimated market for KLH in immunotherapy applications. Key assumptions to our top-down model for the second phase include (see our chart below as well);

Annual Market Opportunity Assumptions
- Stellar sells bulk GMP KLH for approximately $50k/gram (equal to $0.05/microgram). Stellar has publicly disclosed this pricing
- Approximately 500 – 700 micrograms (mg) of KLH are used in each vaccine dose – which is based on our due diligence
- Nine doses per patient – which is consistent with cancer vaccine dosing expectations
- 30% - 75% additional KLH required for manufacturing waste, pilot runs, inventory, etc
- Multiply annual U.S. incidence rates of major cancers and other select diseases where KLH is generating interest (including some autoimmune diseases) by cost/per KLH dose. This calculates to a U.S. market worth ~$1.3B
- Assume ex-U.S. market is approximately the same size as U.S. but attainable OUS market is only about 50% as big. Calculates to a WW Mrkt = ~$2.0B
- Assume the market grows at a CAGR of 3% over the next 10 years. This calculates to a total market opportunity of $2.7B in the year 2026

Haircut Assumptions
- Immunotherapies account for 50% of all cancer (and select other disease) treatments in 10 years
- 50% of these immunotherapies use a carrier protein
- 30% of these immunotherapies that use a carrier protein use KLH as that carrier
- Stellar supplies 50% of this KLH
- This equates to product sales for Stellar of approximately $100 million in the year 2026
- We discount this back at 50% per year through fiscal 2019

Additional Comments
- Our calculated total market size is arguably conservative as it is based on only some cancers (albeit all of the most common) and a select number of other diseases. Other diseases with high prevalence rates such as the autoimmune disease, psoriasis, which afflicts as many as 10M Americans, were not included in our estimates as immunotherapies have mostly focused on cancer and only a handful of other diseases. However, we think it is likely that research will broaden to a much greater spectrum of diseases
- Our assumption that 50% of all cancers are treated with immunotherapies is more conservative than the 60% that at least one industry analyst expects

- Our 50% of all immunotherapies using KLH as the carrier protein may also be conservative as KLH is quickly becoming the carrier protein of choice
- Our model assumes 50% of KLH is supplied by Stellar. The only substantive competition today is biosyn but Stellar is the only KLH manufacturer that can rapidly and reliably ramp production. Their additional capacity (from the Ostione's facility) should be online by 2018-2019. As such, our assumed 50% supply coming from Stellar may also be low
- Also of interest is that Stellar's current annual capacity of 2.0kg would be sufficient to supply what we calculate as their total estimated revenue in the year 2026. Stellar's interest in significantly expanding their capacity with the Ostiones facility may indicate that they believe their revenue potential far exceeds our estimates - and given that they are closer to the industry and what to anticipate relative to future KLH demand, this also may imply that our forecasts are conservative

		KLH		
Cancer	Annual U.S. Incidence	mcg/patient	$/mcg	Annual U.S. Mkt Opport.
Breast Cancer	234,000	9,000	$0.05	$105,300,000
Oral	46,000	9,000	$0.05	$20,700,000
Melanoma	74,000	9,000	$0.05	$33,300,000
Kidney	62,000	9,000	$0.05	$27,900,000
Prostate Cancer	233,000	9,000	$0.05	$104,850,000
Uterine/Ovary Cancer	96,000	9,000	$0.05	$43,200,000
Urinary	139,000	9,000	$0.05	$62,550,000
Lung Cancer	224,000	9,000	$0.05	$100,800,000
Colorectal Cancer	137,000	9,000	$0.05	$61,650,000
Other digestive	150,000	9,000	$0.05	$67,500,000
Sarcoma	15,000	9,000	$0.05	$6,750,000
Leukemia	54,000	9,000	$0.05	$24,300,000
Bladder Cancer	74,000	9,000	$0.05	$33,300,000
Multiple Myeloma	24,000	9,000	$0.05	$10,800,000
Lymphoma	81,000			
-Non-Hodgkins Lymphoi	72,000	9,000	$0.05	$32,400,000
Thyroid	65,000	9,000	$0.05	$29,250,000
Brain / Tumors	68,000			
-Glioblastoma Brain Cnc	24,000	9,000	$0.05	$10,800,000
	1,723,000			**$775,350,000**
Other diseases				
Lupus	20,000	9,000	$0.05	$9,000,000
Alzheimer's Disease	500,000	9,000	$0.05	$225,000,000
Clostridium difficile	450,000	9,000	$0.05	$202,500,000
Crohn's Disease	35,000	9,000	$0.05	$15,750,000
Psoriatic Arthritis	23,000	9,000	$0.05	$10,350,000
Rheumatoid Arthritis	230,000	9,000	$0.05	$103,500,000
	1,258,000			**$566,100,000**
Total U.S. Market				$1,341,450,000
Assumed Attainable OUS Market (50% of U.S.)				$670,725,000
Total WW Market Today (pre haircuts)				**$2,012,175,000**
WW Market in 10 years (3% CAGR)				**$2,704,194,941**
Haircut Assumptions:				
Immunotherapies as % of cancer & select other disease therapies				50%
% of immunotherapies that use a carrier protein				50%
% of future immunotherapies that use KLH as carrier protein				30%
% of KLH that is supplied by Stellar				50%
Total Stellar revenue in 10 years				$101,407,310.27
Required KLH Production Capacity (kg)				2.0

DCF Values SBOT at $13/share

We forecast revenue in “phase 1” of our model to grow from about $750k in fiscal 2015 to $2.7M in 2018. And then in “phase 2” to grow to just better than $110M in 2026. Our 2026 revenue figure includes KLH sales in support of commercialized immunotherapies as well as some contribution for supply of clinical trials, in addition to a much relatively smaller revenue stream from service contracts. As detailed above, the bulk of our forecasted growth of longer-term revenue is driven by the expected explosive growth of immunotherapies and cancer vaccines, coupled with the Stellar’s rise as the leading KLH supplier.

Our DCF model, which uses a 12% discount rate and 2% terminal growth rate, values SBOT shares at approximately $13.

Stellar Biotechnologies

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E
Contract Svcs	$192.0	$60.0	$45.0	$45.0	$45.0	$195.0	$230.0	$365.0	$485.0
YOY Growth	*220.0%*	*300.0%*	*-37.5%*	*-25.0%*	*0.0%*	*1.6%*	*17.9%*	*58.7%*	*32.9%*
Product Sales Total	$143.6	$152.7	$142.6	$112.7	$150.0	$558.0	$924.0	$1,373.4	$2,185.0
YOY Growth	*88.7%*	*849.1%*	*236.6%*	*799.3%*	*106.7%*	*288.7%*	*65.6%*	*48.6%*	*59.1%*
Grant Revenue	$36.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	$372.1	$212.7	$187.6	$157.7	$195.0	$753.0	$1,154.0	$1,738.4	$2,670.0
YOY Growth	*-31.8%*	*261.5%*	*64.1%*	*117.5%*	*54.3%*	*102.4%*	*53.2%*	*50.6%*	*53.6%*
Cost of Sales	$760.3	$177.1	$310.0	$285.4	$280.8	$1,053.3	$1,304.5	$1,729.7	$2,233.3
Gross Income	($388.1)	$35.6	($122.4)	($127.7)	($85.8)	($300.3)	($150.5)	$8.7	$436.8
Gross Margin	*-104.3%*	*16.7%*	*-65.2%*	*-80.9%*	*-44.0%*	*-39.9%*	*-13.0%*	*0.5%*	*16.4%*
R&D	$2,458.9	$418.8	$281.6	$129.7	$305.0	$1,135.1	$2,366.0	$2,974.0	$3,358.0
% R&D	*660.8%*	*196.9%*	*150.1%*	*82.2%*	*156.4%*	*150.7%*	*205.0%*	*171.1%*	*125.8%*
SG&A	$2,871.5	$942.2	$785.7	$618.2	$812.0	$3,158.0	$3,621.0	$3,945.0	$4,118.0
% SG&A	*771.6%*	*443.0%*	*418.7%*	*391.9%*	*416.4%*	*419.4%*	*313.8%*	*226.9%*	*154.2%*
Operating Income	($5,718.5)	($1,325.4)	($1,189.6)	($875.6)	($1,202.8)	($4,593.4)	($6,137.5)	($6,910.3)	($7,039.3)
Operating Margin	*-1536.7%*	*-623.3%*	*-634.0%*	*-555.1%*	*-616.8%*	*-610.0%*	*-531.8%*	*-397.5%*	*-263.6%*
Total Other Inc. (Exp.)	($2,693.8)	($8.3)	$772.5	$1,348.6	($180.0)	$1,932.8	($200.0)	$0.0	$0.0
Pre-Tax Income	($8,412.3)	($1,333.7)	($417.2)	$473.0	($1,382.8)	($2,660.7)	($6,337.5)	($6,910.3)	($7,039.3)
Taxes	$27.2	$9.8	$9.0	$9.0	$9.0	$36.8	$40.0	$40.0	$40.0
Tax Rate	-	-	-	-	-	-	-	-	-
Net Income	($8,439.5)	($1,343.5)	($426.2)	$464.0	($1,391.8)	($2,697.5)	($6,377.5)	($6,950.3)	($7,079.3)
YOY Growth	*-41.8%*	*-75.9%*	*-70.3%*	*-86.4%*	*-71.2%*	*-68.0%*	*136.4%*	*9.0%*	*1.9%*
Net Margin	*-2267.9%*	*-631.7%*	*-227.1%*	*294.1%*	*-713.7%*	*-358.2%*	*-552.6%*	*-399.8%*	*-265.1%*
EPS	($1.11)	($0.17)	($0.05)	$0.06	($0.17)	($0.34)	($0.77)	($0.79)	($0.72)
YOY Growth	*-60.4%*	*-77.6%*	*-71.5%*	*-87.0%*	*-72.2%*	*-69.5%*	*127.9%*	*2.2%*	*-8.5%*
Diluted Shares O/S	7,583	7,946	7,955	7,955	7,955	7,953	8,250	8,800	9,800

Brian Marckx, CFA

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LEADERSHIP

Management

Frank Oakes
President, CEO and Chairman
Mr. Oakes has more than 30 years of management experience in aquaculture including a decade as CEO of The Abalone Farm, Inc., during which he led that company through the R&D, capitalization and commercialization phases of development to become the first profitable and largest abalone producer in the U.S.. He is the inventor of the company's patented method for non-lethal extraction of hemolymph from the keyhole limpet. He was the Principal Investigator on the company's Phase I and II SBIR grants from the NIH's Center for Research Resources, NSF grant, and a California Technology Investment Partnership (CalTIP) grant from the Department of Commerce. He has consulted and lectured for the aquaculture industry around the world. Frank received his Bachelor of Science degree from California Polytechnic State University, San Luis Obispo and is a graduate of the Los Angeles Regional Technology Alliance (LARTA) University's management-training program.

Catherine Brisson, Ph.D
Chief Operating Officer
Dr. Brisson has more than 20 years of experience in the biotechnology, pharmaceutical and medical device industries with strong expertise, and broad scientific and operational understanding, in the areas of quality assurance, quality control, regulatory affairs, manufacturing, and product development. She has extensive background in process development and in the preparation and review of regulatory submissions and subsequent maintenance; as well as a strong working knowledge of global regulatory requirements. Previously, Dr. Brisson held key senior management positions with startup biotechnology companies, as well as Sicor Pharmaceuticals (Teva Parenteral Products). Dr. Brisson holds a B.S. degree in Chemistry from North Carolina State University and a Ph.D. in Organic Chemistry from the University of North Carolina.

Kathi Niffenegger
Chief Financial Officer and Corporate Secretary
Ms. Niffenegger has more than 30 years of experience in accounting and finance in a range of industries. She currently holds the positions of Chief Financial Officer and Corporate Secretary, having previously served as Stellar′s outside CPA since the Company′s founding in 1999 and Controller since 2012. Ms. Niffenegger was previously technical partner in the audit division of Glenn Burdette CPAs, obtained CFO experience at Martin Aviation, and began her CPA career at Peat, Marwick, Mitchell & Co. (now KPMG LLP). She held leadership roles for audits of manufacturing, aquaculture, pharmaceutical, and governmental grant clients, and developed specific expertise in cost accounting systems and internal controls. Ms. Niffenegger holds a B.S. degree in Business Administration from California State University, Long Beach.

Mark McPartland
V.P. of Corporate Development and Communications
Mr. McPartland has more than 16 years of experience in business development, capital markets advisory, corporate communications and C-suite consulting. Prior to joining Stellar, he served as Senior Vice President at MZ Group, a subsidiary of @titude Global, the world′s largest independent global investor relations (“IR”) consulting firm, which served as Stellar′s IR agency. Mr. McPartland′s background includes guiding the development and execution of corporate strategy for private and public companies at all stages of commercial evolution, including early- and mid-stage biopharmaceutical entities. His previous positions include Vice President and Partner at Alliance Advisors, LLC and Regional Vice President of Hayden Communications, Inc. Mr. McPartland holds a B.S. in Business Administration and Marketing from Coastal Carolina University.

Scientific Advisory Board

Andrew Saxon, MD
Dr. Saxon received his medical degree from Harvard Medical School. He is board certified in Internal Medicine, Allergy and Clinical Immunology and Diagnostic/Laboratory Immunology. He has published over 180 peer reviewed research publications primarily dealing the control and assessment of the human immune response. Dr. Saxon and colleagues at UCLA were the first to recognize AIDS in 1980, brought this new disease to the attention of the CDC in 1981, and published the first research publication describing this disease in the New England Journal of Medicine that same year. Dr. Saxon and his collaborators have made seminal discoveries on the mechanisms that control human antibody responses and particularly allergic antibodies (IgE) as well as pioneered research into the role of environmental factors in the modulation of the human immune response. As part of his work, Dr. Saxon has had extensive experience with the KLH in its various molecular forms. Dr. Saxon is also the Editor-in-Chief of Clinical Immunology, the official journal of the Clinical Immunology Society.

Daniel Adelman, MD
Dr. Adelman serves as Adjunct Professor of Medicine at UC-San Francisco. He has also been working in the biotechnology industry. He is currently Senior VP, Development and Chief Medical Officer at Alvine Pharmaceuticals. Prior to that, Dr. Adelman was Senior VP, Development and Chief Medical Officer at Sunesis Pharmaceuticals. He served in various roles at Pharmacyclics, including VP, Clinical Operations and Biometrics and was a Clinical Scientist at Genentech. Dr. Adelman has been involved in all stages of pharmaceutical drug development and shared responsibility for the early development of Xolair and Avastin. Dr. Adelman holds a BA in Biology from the University of California and an M.D. degree from the UC-Davis. After completing his residency in Internal Medicine at Cedars-Sinai Medical Center in Los Angeles, he did post-doctoral fellowship training in Clinical Immunology and Allergy at UCLA.

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Daniel Morse, Ph.D
Dr. Morse is the Wilcox Professor Emeritus of Molecular Genetics and Biochemistry, and Director of Marine Biotechnology, at the University of California, Santa Barbara (UCSB). He is a renowned expert in the structure and function of the KLH molecule. Previously, he was the Silas Arnold Houghton Associate Professor of Microbiology and Molecular Genetics at Harvard Medical School. Dr. Morse′s honors include NIH Career Development Award, American Cancer Society Faculty Research Award, Scientific American Top 50 Technology Innovator, International Molluscan Research Society Lifetime Research Award, American Association for the Advancement of Science Fellow, Materials Research Society Fellow, and Smithsonian Institution Regents Fellow. He was named the 7th Kelly Lecturer at University of Cambridge and 3M Lecturer at University of British Columbia, and served as Director of UCSB-MIT-Caltech Institute for Collaborative Biotechnologies and distinguished visiting professor at universities in France, UK, Japan and Singapore. Dr. Morse holds a B.A. degree in Biochemistry from Harvard, and Ph.D. in Molecular Biology from Albert Einstein College of Medicine.

Gregory Baxter, Ph.D
Dr. Gregory Baxter, a member of Stellar's Board of Directors since August 2012, is a Senior Scientist in the Department of Clinical Drug Development for CCS Associates, Inc. He also serves as Adjunct Associate Professor at Cornell University in the College of Chemical Engineering and on the Founders Board of Stanford University's StartX Med Program. Dr. Baxter's background spans both science and business arenas including Program Director for the National Science Foundation (NSF) Division of Industrial Innovation and Partnerships; Founder and CSO of Hurel Corporation; Founder and CEO of Aegen Biosciences; and Research Scientists for Molecular Devices Corporation. Dr. Baxter received his Ph.D. in Biochemistry/Molecular Biology from the University of California, Santa Barbara.

Charles Olson, D.Sc
Dr. Charles Olson is a biotechnology industry professional with broad scientific and operational experience, and specialization in manufacturing operations and process development. Dr. Olson currently serves as Vice President of CMC and Technical Operations for NGM Biopharmaceuticals and Vice President of Protein Sciences for Anthera Pharmacetuicals. His background includes the positions of Senior VP of Product Development and Operations for Nexbio Inc.; VP of Hayward Operations for Cell Genesys; Senior Director of Manufacturing, Facilities and Process Development for Biomarin Pharmaceuticals; and Director of Manufacturing Sciences for Onyx Pharmaceuticals. Dr. Olson received his D.Sc. in Biochemistry from Hawthorne University.

APPENDIX

Citations for KLH Description Inset

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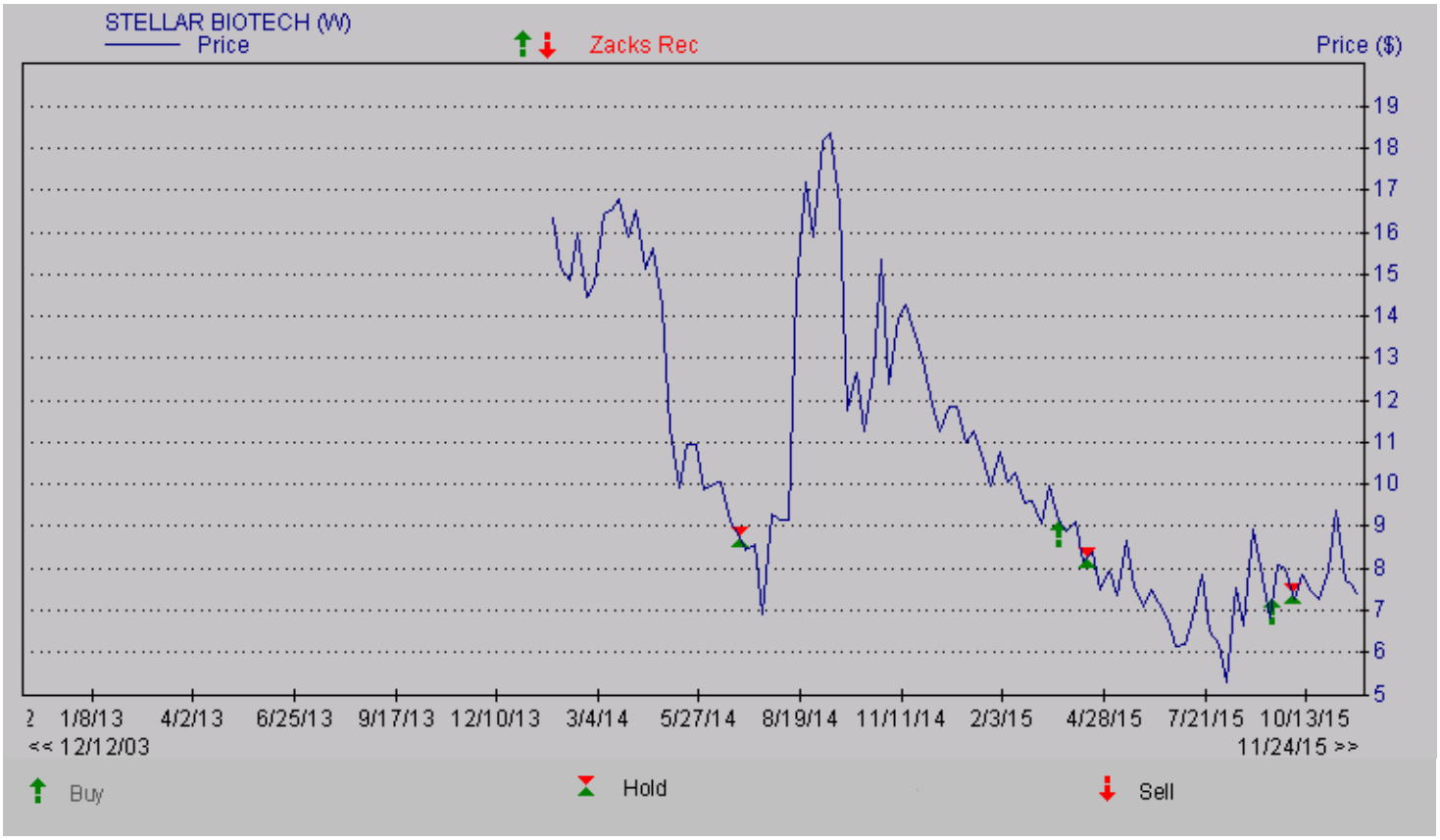

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