Zacks Small-Cap Research

December 19, 2016

Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Stellar Biotechnologies (SBOT-NASDAQ)

SBOT: 2016 A Solid Year From Both Financial and Operational Perspective

We forecast revenue in "phase 1" of our model to grow from about $1.2M in fiscal 2016 to $3.3M in 2018. And then in "phase 2" to grow to almost $92M in 2026. Our DCF model, which uses a 12% discount rate and 2% terminal growth rate, values SBOT shares at approximately $8.50.

Current Price (12/19/16)	$2.02
Valuation	**$8.50**

OUTLOOK

Looking at the full year, fiscal 2016 was a solid year – from both a financial as well as operational perspective. KLH product sales grew 120% from the prior year to $1.2M, which follows 293% growth to $564k in 2015. For 2016, the major revenue contributors included OBI Pharma which accounted for 41% of product sales, Eurogentec 25% and Neovacs 10%. With additional activity expected from these customers, including Neovacs' recently initiated phase 2b U.S. study for its IFNa-Kinoid Lupus candidate as well as the potential for additional customer onboarding, we expect 2017 will be another record revenue year for SBOT. We note that Neovacs' Lupus candidate, which now has fast-track status in both the U.S. and S. Korea, could soon materialize as the first KLH-based commercial product that SBOT supports.

SUMMARY DATA

52-Week High	**$7.75**
52-Week Low	**$1.79**
One-Year Return (%)	**-71.51**
Beta	**0.54**
Average Daily Volume (sh)	**57,641**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**8**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**49.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2016	0.5 A	0.3 A	0.2 A	0.3 A	1.3 A
2017	0.3 E	0.4 E	0.6 E	0.6 E	2.0 E
2018					3.3 E
2019					4.1 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2016	-$0.19 A	-$0.10 A	-$0.14 A	-$0.13 A	-$0.57 A
2017	-$0.18 E	-$0.14 E	-$0.13 E	-$0.13 E	-$0.58 E
2018					-$0.59 E
2019					-$0.58 E

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

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW…

Q4 2016 Financial Results

Stellar reported financial results for their fiscal fourth quarter 2016 ending September 30. While revenue was moderately lower than our estimate, it was up fairly significantly on both a yoy and sequential basis. And despite the "miss" to our topline number, this was more than offset by strong gross margin and lower than modeled operating expenses. The net result was EPS of ($0.13), a penny better than what we were expecting.

Q4 revenue was $276k (vs. $375k estimate), all of which relates to product sales. As a reminder, as a result of the conclusion of services related to a two-year contract, SBOT has not booked any contract services-related revenue since fiscal Q1 2016.

Gross margin was a relatively very healthy 26% in Q4, driven by product margin of 57% - which looks to be an all-time high. We continue to look for both greater stabilization and growth of gross margin with higher KLH production volumes as SBOT supports larger clinical trials and brings on additional contracts and supply agreements.

Operating expenses were $1.4M, up about 29% and 17% from the year-earlier and quarter-earlier periods, respectively, but about 6% lower than what we were anticipating. Stellar recently brought on additional professional personnel in anticipation of increased demand for KLH and eventual production scale-up. While this will have the effect of incrementally pushing up OpEx, this should be at least partially offset by expected near-term revenue growth and expanding gross margins.

Q4 net loss and EPS were $1.3M and ($0.13) vs. our $1.5M and ($0.14) estimates. Cash balance (inc liquid investments), which was bolstered by the $6M (net) equity raise in July, was $11.4M at fiscal year-end. Cash used in operating activities was $1.2M and $4.5M in Q4 and the full year, respectively. Another $107k and $470k was used for capital purchases and contribution to the Neostell JV in Q4 and the full year, respectively. Management is currently guiding for total expenditures to be approximately $6M in fiscal 2017 and expects the cash balance to fund operations for at least the next 12 months.

Looking at the full year, fiscal 2016 was a solid year – from both a financial as well as operational perspective. KLH product sales grew 120% from the prior year to $1.2M, which follows 293% growth to $564k in 2015. For 2016, the major revenue contributors included OBI Pharma which accounted for 41% of product sales, Eurogentec 25% and Neovacs 10%. With additional activity expected from these customers, including Neovacs' recently initiated phase 2b U.S. study for its IFNa-Kinoid Lupus candidate as well as the potential for additional customer onboarding, we expect 2017 will be another record revenue year for SBOT. We note that Neovacs' Lupus candidate, which now has fast-track status in both the U.S. and S. Korea, could soon materialize as the first KLH-based commercial product that SBOT supports.

On the operational side, SBOT made additional significant progress in 2016 towards scaling operations in anticipation for increased demand for its KLH as well as to manufacture and sell KLH-based vaccines. Management noted on the Q4 call that their goal is to have the capacity and operational infrastructure in place to be able to support multiple commercial launches of KLH-based therapies and have been putting the pieces in place to be able to do so within an approximate two-year timeframe (i.e. length of time required to prepare based on lifecycle of limpets).

Part of the infrastructure upgrades relate to their existing manufacturing and production facilities in California – the first phase was completed and the second phase, per management's comments, will begin in the coming months. This includes additional equipment and other activities and assets aimed at increasing production capacity of KLH. The other part of the infrastructure upgrades relates to their Baja California (Mexico) location. Management noted that they have made additional progress related to this facility.

The recent equity raise as well as the appointment of a V.P. of Chemistry, Manufacturing and Controls as well as adding an Executive VP of Corporate Development are also aimed at fortifying and accelerating plans towards increasing capacity and readying for support of commercial product launches, including that through Neostell.

Neostell Will Supply KLH For Neovacs' Lupus Candidate (if and when approved), Just Granted FDA Fast-Track…
As a reminder, SBOT and Neovacs have had an ongoing relationship through a supply agreement whereby Stellar has supplied KLH for Neovacs' Kinoid vaccine candidates targeting certain autoimmune disorders.

Per the terms of the supply 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 had originally expected to include approximately 166 patients and began patient enrollment in September 2015, has been ongoing in Europe, Latin America and Asia. In April 2016 Neovacs received IND approval from FDA to extend the study to the U.S. which also prompted an increase in total enrollment to 178 patients (in 21 countries) and expanded the number of sites from 5 to 15.

On November 7, 2016 Neovacs announced that they enrolled the first patient in the U.S. and also noted that they are seeing strong interest from a large number of U.S. clinical sites. **Importantly, earlier this month (12/7) Neovacs announced that FDA granted Fast-Track status to this IFNa-Kinoid Lupus candidate.** Fast-Track is granted to candidates that address serious diseases which are not well controlled with existing therapies. Fast-Track, which aims to facilitate faster time to approval, allows for seamless cooperation with FDA as well as priority review. As such, this could speed eventual approval in the U.S. market. Neovacs is still aiming to have full results in summer 2017.

It's possible that a lupus indication could be even a sooner event in to S. Korea. In mid-April 2016 Neovacs announced S. Korean health authorities approved an IND for their phase IIb lupus study. Importantly S. Korea is the only OECD country in which lupus is considered an orphan disease. As such Neovacs expects to file for orphan designation, granting of which could mean Neovacs may be able to launch IFNa-Kinoid commercially in S. Korea without the need to conduct a phase III study. Neovacs has already started preparing for a potential commercial launch by partnering with Chong Kun Dan Pharmaceuticals, a S. Korean pharmaceutical (immunotherapies) company.

And there are other signs of Neovacs' confidence in their Lupus candidate as the company has made other recent preparations to scale up production. This includes the November announcements that they acquired interferon alpha manufacturing technology (from Amegabiotech) and signed a production partnership (with 3P Biopharmaceuticals) for the manufacture of interferon alpha. These agreements put in place an important piece for Neovacs to be able to manufacture IFNa-Kinoid in commercial scale.

Stellar/Neovacs also 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. Neovacs accounted for 10% of SBOT's total 2016 revenue but with additional clinical activity in 2017 as well as potential preparations towards launch, we think this will increase in the coming year.

And while this and SBOT's other supply agreements are important for several reasons, including validation of the quality and sustainability of supply of SBOT's KLH as well as providing some early revenue and offering potential to supply KLH for an eventual approved therapy, this new JV offers the additional upside of participating in KLH-based vaccine sales and manufacturing. The JV will not only produce and commercialize Neovacs' vaccines (assuming eventually approved), it will also seek to supply and manufacture KLH-based products for third parties.

Details of Neostell S.A.S. include;

- located in Paris, France
- SBOT holds 30% equity interest and will initially contribute €120,000 (~$134k), 50% of which has already been paid with the remainder payable upon "occurrence of certain defined future events" (which is interpreted to mean, 'positive results of Neovacs' IFNa-Kinoid phase II lupus study')
- additional future funding will be on a pro rata basis (i.e. SBOT 30%, Neovacs 70%)
- "If the joint venture does not achieve certain milestones by December 2017, the joint venture will be dissolved, unless (i) the parties mutually agree to pursue the joint venture arrangement, or (ii) either party

decides to purchase the equity interests of the other party. Each of the parties is entitled, upon the occurrence of certain defined events, to acquire the interest of the other party" (copied from Q3 10-Q)

- "In connection with the formation of the joint venture and the performance of its goals and projects, the parties and the joint venture agreed to enter into (a) an exclusive supply agreement within a limited field of use for the Company to supply KLH to the joint venture, (b) a supply agreement designating the joint venture as the exclusive manufacturer and supplier of the other party's vaccines, and (c) services agreements for the provision of various knowledge and expertise by each of the parties to the joint venture. The other party will also license certain of its intellectual property to the joint venture
- "The joint venture has an initial ten-year term, renewable for successive five-year terms. If either party provides notice at least six months prior to the expiration date of an applicable term that it does not wish to continue the joint venture transaction, the other party will have a right to acquire all of such terminating party's equity interests in the joint venture"
- Per Neovacs' Jan 21st press release announcing the collaboration, Neostell is expected to hire between 50 and 100 employees

We view this JV as another endorsement for the quality and sustainability of the source of KLH that SBOT provides. It also provides the opportunity for SBOT to participate in the full product cycle from supply, manufacturing and sales – which broadens the scope and breathe of SBOT operations and revenue opportunities. And finally, we think this JV is another step in progress towards exploiting the expected rapid growth of immunotherapies, superiority of KLH as a carrier protein and SBOT's position as the only company in the world capable of supplying commercial-scale quantities of the high quality KLH protein.

Noteworthy Customers / Supply Contracts…

- **Amaran / OBI Pharma:** OBI's lead candidate, OBI-822 (Adagloxad Simolenin), had 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 was also in a phase 2 physician-initiated clinical trial in Taiwan for the treatment of ovarian cancer (no recent updates have been announced related to the ovarian cancer program). OBI-822 utilizes KLH as a carrier protein for the carbohydrate antigen Globo-H, which is often expressed by cancer cells.

  In February 2016 OBI announced that top-line data of the phase 2/3 metastatic breast cancer study did not meet the primary endpoint of progression-free survival. Results were presented in June at ASCO 2016 in Chicago. But, as patients who did show an immune response demonstrated statistically significant progression-free survival versus placebo, coupled with the secondary endpoint of overall survival trending towards statistical significance and no safety issues reported, **OBI noted in their February 2016 press release that they expected to forge ahead with a phase 3 study** in (Taiwan)**.** While the next step towards that goal would be for OBI to meet with regulators regarding design of a phase 3 study, OBI has yet to publicly announce whether a meeting has been scheduled.

  Another potential confounding factor towards moving into later stage trials relates to an investigation into allegations that certain OBI executives illegally sold shares of OBI Pharma prior to the public release of the phase 2/3 results missing the primary endpoint. While the investigation and related outcomes has no bearing or influence on the clinical data or interpretation thereof, it is almost certainly a distraction and could affect the company's ability or cost of raising additional capital.

  What the missed endpoint in phase 2/3 means for Stellar is currently an unknown. While any supply of KLH to OBI for their clinical trials was never going to be an overly significant source of revenue for the company, supplying for a commercialized product could be. And while that is still a possibility, the likelihood became less so with the phase 2/3 study missing the primary endpoint. If and when OBI meets with regulators relative to moving to a phase 3 study, the viability of a pathway forward may become more clear. We note, however, that even in the event OBI does not move directly to phase 3 with their metastatic breast cancer program, that SBOT could still be providing KLH to OBI for earlier stage studies in breast and other cancers.

  Stellar recently announced that they have met all the primary objectives of the collaboration with OBI including qualification of GMP-grade Stellar KLH. The formal collaboration agreement, whereby SBOT was 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 paid the company for certain expenses and costs, expired on December 31, 2015. However, the expiration has no effect on the duos' working relationship. If all goes well, SBOT could eventually be supplying KLH for an OBI commercialized product. Next steps will be to optimize manufacturing processes for scale-up of

production in the event that OBI moves into phase 3 for metastatic breast cancer. OBI Pharma accounted for approximately 41% of SBOT's total revenue in 2016.

- **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 had originally expected to include approximately 166 patients and began patient enrollment in September 2015, has been ongoing in Europe, Latin America and Asia. In April 2016 Neovacs received IND approval from FDA to extend the study to the U.S. which also prompted an increase in total enrollment to 178 patients (in 21 countries) and expanded the number of sites from 5 to 15. On November 7, 2016 Neovacs announced that they enrolled the first patient in the U.S. and also noted that they are seeing strong interest from a large number of U.S. clinical sites. Importantly, earlier this month (12/7) Neovacs announced that FDA granted Fast-Track status to this IFNa-Kinoid Lupus candidate. Fast-Track is granted to candidates that address serious diseases which are not well controlled with existing therapies. Fast-Track, which aims to facilitate faster time to approval, allows for seamless cooperation with FDA as well as priority review. As such, this could speed eventual approval in the U.S. market. Neovacs is still aiming to have full results in summer 2017.

  It's possible that a lupus indication could be even a sooner event in to S. Korea. In mid-April 2016 Neovacs announced S. Korean health authorities approved an IND for their phase IIb lupus study. Importantly S. Korea is the only OECD country in which lupus is considered an orphan disease. As such Neovacs expects to file for orphan designation, granting of which could mean Neovacs may be able to launch IFNa-Kinoid commercially in S. Korea without the need to conduct a phase III study. Neovacs has already started preparing for a potential commercial launch by partnering with Chong Kun Dan Pharmaceuticals, a S. Korean pharmaceutical (immunotherapies) company.

  And there are other signs of Neovacs' confidence in their Lupus candidate as the company has made other recent preparations to scale up production. This includes the November announcements that they acquired interferon alpha manufacturing technology (from Amegabiotech) and signed a production partnership (with 3P Biopharmaceuticals) for the manufacture of interferon alpha. These agreements put in place an important piece for Neovacs to be able to manufacture IFNa-Kinoid in commercial scale.

  Stellar/Neovacs also 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. Neovacs accounted for 10% of SBOT's total 2016 revenue but with additional clinical activity in 2017 as well as potential preparations towards launch, we think this will increase in the coming year.

  And while this and SBOT's other supply agreements are important for several reasons, including validation of the quality and sustainability of supply of SBOT's KLH as well as providing some early revenue and offering potential to supply KLH for an eventual approved therapy, this new JV offers the additional upside of participating in KLH-based vaccine sales and manufacturing. The JV will not only produce and commercialize Neovacs' vaccines (assuming eventually approved), it will also seek to supply and manufacture KLH-based products for third parties.

- **Araclon:** Per a November 2014 agreement, Stellar will supply Araclon with KLH to support their 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. In August 2016 Araclon (and partner Grifols) announced positive results from a Phase 1 (n=24) safety study of their ABvac40 (short C-terminla peptide conjugated to KLH with alum) Alzheimer's candidate which showed no difference in adverse effects between patients treated with ABvac40 (n=18) and those given placebo (n=6). A Phase II study is planned.

- **AXON Neuroscience:** As a reminder, in November 2015 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." Results were published in December 2016 in Lancet Neurology.

  And while AXON's announcement did not specify where they source their KLH, it appears that it may be from Stellar (we asked on the Q4 2015 conf call but due to confidentiality agreement mgmt. could not confirm) given that revenue from AXON contributed ~$120k in fiscal 2015. A phase II study (titled

ADAMANT), designed to confirm phase I results in a larger population, commenced in June 2016. ADAMANT, per clinicaltrials.gov is a 24-month, randomized, placebo-controlled, parallel group, double-blinded, multi-center study to assess the safety and efficacy of AADvac1 in patients with mild Alzheimer's disease. The primary objective is to confirm the positive Phase I results. While we cannot confirm that SBOT has supplied KLH to AXON in the past (although it appears that was the case) or may do so in this Phase 2 study, AXON could represent another source of supply revenue and, potentially, eventually commercialized-product revenue.

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.

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[1]		
Status	**Indication**	**Company or Institute**
Phase III	Breast Cancer	OBI Pharma (Adagloxad Simolenin)
Phase II	Lupus	Neovacs (IFNa Kinoid)
	Crohn's Disease	Neovacs (TNF Kinoid)
	Ovarian Cancer	OBI Pharma (OBI-822)
	Alzheimer's	Araclon/Grifols
	Alzheimer's	Axon Neurosciences
	Multiple Myeloma	Abramson Center
	Melanoma	Baylor Research
	Lymphoma	Clinica Navarra
	Ovarian Cancer	Loyola University
	Sarcoma	MabVax
	Ovarian Cancer	Gyn Oncology Group/NCI
	Neuroblastoma	Memorial Sloan-Kettering
	Glioblastoma	Roswell Park/NCI
	Lymphoma	Simmons/NCI
	Sarcoma, Neuroblastoma	NCI
Phase I	Multiple System Atrophy	AFFiRis
	Hypercholesterolemia	AFFiRis
	Brain Tumor	Rockefeller
	Lung Cancer	Memorial Sloan-Kettering
	Multiple Myeloma	Roswell Park
	Myeloid leukemia	Charite University
	Neuroblastoma	Moffitt/Johns Hopkins
	Multiple Myeloma	Fred Hutchinson/NCI
	Ovarian Cancer	MSKCC/Genentech

[1]SOURCE: www.clinicaltrials.gov, Stellar websites, public disclosures, Stellar presentation

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 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 / OBI Pharma:** OBI's lead candidate, OBI-822 (Adagloxad Simolenin), had 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 was also in a phase 2 physician-initiated clinical trial in Taiwan for the treatment of ovarian cancer (no recent updates have been announced related to the ovarian cancer program). OBI-822 utilizes KLH as a carrier protein for the carbohydrate antigen Globo-H, which is often expressed by cancer cells.

  In February 2016 OBI announced that top-line data of the phase 2/3 metastatic breast cancer study did not meet the primary endpoint of progression-free survival. Results were presented in June at ASCO 2016 in Chicago. But, as patients who did show an immune response demonstrated statistically significant progression-free survival versus placebo, coupled with the secondary endpoint of overall survival trending towards statistical significance and no safety issues reported, **OBI noted in their February 2016 press release that they expected to forge ahead with a Phase 3 study** in Taiwan**.** While the next step towards that goal would be for OBI to meet with regulators regarding design of a Phase 3 study, OBI has yet to publicly announce whether a meeting has been scheduled.

A confounding factor towards moving into later stage trials could be an investigation into allegations that certain OBI executives illegally sold shares of OBI Pharma prior to the public release of the phase 2/3 results missing the primary endpoint. While the investigation and related outcomes has no bearing or influence on the clinical data or interpretation thereof, it is almost certainly a distraction and could affect the company's ability to or cost of raising additional capital.

What the missed endpoint in phase 2/3 means for Stellar is currently an unknown. While any supply of KLH to OBI for their clinical trials was never going to be an overly significant source of revenue for the company, supplying for a commercialized product could be. And while that is still a possibility, the likelihood became less so with the Phase 2/3 study missing the primary endpoint. If and when OBI meets with regulators relative to moving to a Phase 3 study, the viability of a pathway forward may become more clear. We note, however, that even in the event OBI does not move directly to Phase 3 with their metastatic breast cancer program, that SBOT could still be providing KLH to OBI for earlier stage studies in breast and other cancers.

Stellar recently announced that they have met all the primary objectives of the collaboration with OBI including qualification of GMP-grade Stellar KLH. The formal collaboration agreement, whereby SBOT was 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 paid the company for certain expenses and costs, expired on December 31, 2015. However, the expiration has no effect on the duos' working relationship. If all goes well, SBOT could eventually be supplying KLH for an OBI commercialized product. Next steps will be to optimize manufacturing processes for scale-up of production in the event that OBI moves into phase 3 for metastatic breast cancer. OBI Pharma accounted for approximately 41% of SBOT's total revenue in 2016.

- **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 had originally expected to include approximately 166 patients and began patient enrollment in September 2015, has been ongoing in Europe, Latin America and Asia. In April 2016 Neovacs received IND approval from FDA to extend the study to the U.S. which also prompted an increase in total enrollment to 178 patients (in 21 countries) and expanded the number of sites from 5 to 15. On November 7, 2016 Neovacs announced that they enrolled the first patient in the U.S. and also noted that they are seeing strong interest from a large number of U.S. clinical sites. Importantly, earlier this month (12/7) Neovacs announced that FDA granted Fast-Track status to this IFNa-Kinoid Lupus candidate. Fast-Track is granted to candidates that address serious diseases which are not well controlled with existing therapies. Fast-Track, which aims to facilitate faster time to approval, allows for seamless cooperation with FDA as well as priority review. As such, this could speed eventual approval in the U.S. market. Neovacs is still aiming to have full results in summer 2017.

  It's possible that a lupus indication could be even a sooner event in to S. Korea. In mid-April 2016 Neovacs announced S. Korean health authorities approved an IND for their phase IIb lupus study. Importantly S. Korea is the only OECD country in which lupus is considered an orphan disease. As such Neovacs expects to file for orphan designation, granting of which could mean Neovacs may be able to launch IFNa-Kinoid commercially in S. Korea without the need to conduct a phase III study. Neovacs has already started preparing for a potential commercial launch by partnering with Chong Kun Dan Pharmaceuticals, a S. Korean pharmaceutical (immunotherapies) company.

  And there are other signs of Neovacs' confidence in their Lupus candidate as the company has made other recent preparations to scale up production. This includes the November announcements that they acquired interferon alpha manufacturing technology (from Amegabiotech) and signed a production partnership (with 3P Biopharmaceuticals) for the manufacture of interferon alpha. These agreements put in place an important piece for Neovacs to be able to manufacture IFNa-Kinoid in commercial scale.

  Stellar/Neovacs also 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. Neovacs accounted for 10% of SBOT's total 2016 revenue but with additional clinical activity in 2017 as well as potential preparations towards launch, we think this will increase in the coming year.

  And while this and SBOT's other supply agreements are important for several reasons, including validation of the quality and sustainability of supply of SBOT's KLH as well as providing some early revenue and offering potential to supply KLH for an eventual approved therapy, this new JV offers the additional upside of participating in KLH-based vaccine sales and manufacturing. The JV will not only produce and commercialize

Neovacs' vaccines (assuming eventually approved), it will also seek to supply and manufacture KLH-based products for third parties.

- **Araclon:** Per a November 2014 agreement, Stellar will supply Araclon with KLH to support their 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. In August 2016 Araclon (and partner Grifols) announced positive results from a Phase 1 (n=24) safety study of their ABvac40 (short C-terminla peptide conjugated to KLH with alum) Alzheimer's candidate which showed no difference in adverse effects between patients treated with ABvac40 (n=18) and those given placebo (n=6). A Phase II study is planned.

- **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.

VALUATION

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 Neovacs, Amaran, Araclon, etc) and the second (top-down approach), that by (fiscal) year 2020 Stellar begins to generate meaningful revenue from supplying KLH to commercialized immunotherapies.

Through the year 2018 over 90% of our modeled revenue relates to contract services and product sales to Stellar's existing customers (most of the remaining ~10% 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 60% 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 as well as more recent outcomes.

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 2020, 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 45% 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 40% of this KLH
- This equates to product sales for Stellar of approximately $81 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 40% 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) could be online in the coming years. As such, our assumed 40% 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 Lymphoı	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				40%
Total Stellar revenue in 10 years				**$81,125,848.22**
Required KLH Production Capacity (kg)				**1.6**

DCF Values SBOT at $8.50/share

We forecast revenue in “phase 1” of our model to grow from about $1.2M in fiscal 2016 to $3.3M in 2018. And then in “phase 2” to grow to almost $92M 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 $8.50.

Stellar Biotechnologies

	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Total Revenues	$1,271.7	$307.8	$423.8	$578.8	$638.8	$1,949.0	$3,352.5	$4,094.3
YOY Growth	*67.6%*	*-37.0%*	*29.9%*	*219.6%*	*131.4%*	*53.3%*	*72.0%*	*22.1%*
Cost of Sales	$1,128.0	$290.0	$363.2	$458.6	$492.0	$1,603.9	$2,461.5	$2,805.1
Gross Income	$143.7	$17.7	$60.6	$120.1	$146.7	$345.1	$891.0	$1,289.2
Gross Margin	*11.3%*	*5.8%*	*14.3%*	*20.8%*	*23.0%*	*17.7%*	*26.6%*	*31.5%*
R&D	$1,729.5	$670.0	$685.0	$690.0	$700.0	$2,745.0	$3,358.0	$3,540.0
% R&D	*136.0%*	*217.7%*	*161.7%*	*119.2%*	*109.6%*	*140.8%*	*100.2%*	*86.5%*
SG&A	$3,322.7	$1,130.0	$830.0	$810.0	$835.0	$3,605.0	$4,118.0	$4,310.0
% SG&A	*261.3%*	*367.2%*	*195.9%*	*140.0%*	*130.7%*	*185.0%*	*122.8%*	*105.3%*
Operating Income	($4,908.5)	($1,782.3)	($1,454.5)	($1,379.9)	($1,388.3)	($6,004.9)	($6,585.0)	($6,560.8)
Operating Margin	*-386.0%*	*-579.1%*	*-343.2%*	*-238.4%*	*-217.3%*	*-308.1%*	*-196.4%*	*-160.2%*
Total Other Inc. (Exp.)	($110.5)	$7.0	$5.0	$4.0	$4.0	$20.0	$0.0	$0.0
Pre-Tax Income	($5,019.0)	($1,775.3)	($1,449.5)	($1,375.9)	($1,384.3)	($5,984.9)	($6,585.0)	($6,560.8)
Taxes	$7.2					$0.0	$40.0	$40.0
Tax Rate	-	-	-	-	-	-	-	
Net Income	($5,026.2)	($1,775.3)	($1,449.5)	($1,375.9)	($1,384.3)	($5,984.9)	($6,625.0)	($6,600.8)
YOY Growth	*76.8%*	*8.9%*	*68.3%*	*14.4%*	*3.9%*	*19.1%*	*10.7%*	
Net Margin	*-395.2%*	*-576.9%*	*-342.1%*	*-237.7%*	*-216.7%*	*-307.1%*	*-197.6%*	
EPS	($0.57)	($0.18)	($0.14)	($0.13)	($0.13)	($0.58)	($0.59)	($0.58)
YOY Growth	*59.4%*	*-10.0%*	*40.1%*	*-7.1%*	*-2.6%*	*1.6%*	*2.3%*	
Diluted Shares O/S	8,826	10,136	10,150	10,400	10,700	10,347	11,200	11,400

Brian Marckx, CFA

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2016, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brian Marckx, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.