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Zacks Small-Cap Research

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Stellar Biotech (SBOT-NASDAQ)

SBOT: Potential Key Milestone Upcoming As Neovacs Confirms Ph2 Lupus Data Expected June 2018

We forecast revenue in "phase 1" of our model to grow from $228k in 2017 to $880kk in 2018 and to $4.6M in 2020. And then in "phase 2" to grow to almost $67M in 2026. Our DCF model, which uses a 12% discount rate and 2% terminal growth rate, values SBOT shares at approximately $5.50.

Current Price (02/14/18)	$0.79
Valuation	**$5.50**

OUTLOOK

Current customers, including Neovacs and Araclon represent potential opportunities to increase KLH sales with progression of their clinical trials to later stages. Both of these companies are expected to have important clinical-program related milestones during 2018, including final data read-out from Neovacs' phase IIb Lupus study which is expected in June. Our modeled step-up in revenue late in fiscal 2018 assumes additional developmental activity from current customers as a result of clinical progression. Meanwhile, Amaran/OBI could be moving their metastatic breast cancer candidate into phase III studies – which we recently got a little bit more information about. We also think the recent clinical success of certain immunotherapies (including two cancer therapies which recently gained FDA approval) is likely to further fuel investment dollars into the space and potentially facilitate additional opportunities for SBOT. The share price and trading volume has languished as of late – and particularly so since SBOT received notice from Nasdaq (late-January 2018) that they were not in compliance with the $1.00 minimum bid-price requirement. The Nasdaq notice is not a reflection of the fundamentals of the company and can have a negative effect on liquidity and trading volume and put resultant downward pressure on share price. We continue to calculate fair value of SBOT at $5.50/share.

SUMMARY DATA

52-Week High	**$2.22**
52-Week Low	**$0.75**
One-Year Return (%)	**-55.26**
Beta	**0.51**
Average Daily Volume (sh)	**72,451**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**2.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 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)
2017	0.1 A	0.1 A	0.0 A	0.0 A	0.2 A
2018	0.0 A	0.1 E	0.2 E	0.6 E	0.9 E
2019					2.9 E
2020					4.6 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2017	-$0.15 A	-$0.11 A	-$0.12 A	-$0.12 A	-$0.49 A
2018	-$0.13 A	-$0.11 E	-$0.12 E	-$0.11 E	-$0.48 E
2019					-$0.60 E
2020					-$0.53 E

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

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WHAT'S NEW…

Q1 2018 Financial Results

Stellar (SBOT) reported financial results for their fiscal 2018 first quarter ending December 31, 2017. Revenue continues at relatively very low levels, reflecting the conclusion of several mid-stage clinical trials that SBOT supported via supply of KLH. But with development progression to (larger) later-stage studies, we continue to expect SBOT's revenue to return to growth. Additionally, an eventual supply agreement for a commercialized product (potentially such as Neovacs' IFNa-Kinoid candidate) would likely significantly steepen the revenue curve.

Q1 revenue was $21k, compared to $142k and $3k in the comparable prior year and quarter periods, respectively. While negligible, we had anticipated as much given that near-term sales are dependent on timing of activity of the company's clinical trial customers. Much of the last several quarters have largely reflected the lull between the conclusion of earlier-stage trials and commencement of later-stage trials. Importantly, it appears most of the clinical programs that SBOT has supported over the recent past continue to successfully progress to later-stage studies. As later-stage studies typically enroll a greater number of patients, SBOT's revenue opportunity increases as well. Successful conclusion of later-stage studies also improves the chances that a drug candidate eventually reaches commercialization and SBOT's opportunity to support the approved product.

Current customers, including Neovacs and Araclon represent potential opportunities to increase KLH sales with progression of their clinical trials to later stages. Both of these companies are expected to have important clinical-program related milestones during 2018, including final data read-out from Neovacs' phase IIb Lupus study which is expected in June. Our modeled step-up in revenue late in fiscal 2018 assumes additional developmental activity from current customers as a result of clinical progression. Meanwhile, Amaran/OBI could be moving their metastatic breast cancer candidate into phase III studies – which we recently got a little bit more information about. We also think the recent clinical success of certain immunotherapies (including two cancer therapies which recently gained FDA approval) is likely to further fuel investment dollars into the space and potentially facilitate additional opportunities for SBOT.

And while revenue has been meager as of late, management has done a good job of controlling expenses and cash burn as they wait for the next phase of customers' clinical programs to commence. Fiscal 2017 operating expenses were $4.9M and a similar run-rate continued through Q1 2018, with OpEx of $1.3M. Meanwhile, cash used in operating activities was $4.7M in 2017 and $1.1M in Q1 2018.

As it relates to cash, SBOT exited Q1 with $5.4M (including ST investments) on the balance sheet, which the company expects to be sufficient to fund operations for at least the next 12 months. In addition to potential debt and equity financings, SBOT will continue to consider licensing opportunities to aid in funding operations. In late-January 2018 the company announced that Deborah Aghib, Ph.D was joined their board of directors. SBOT expects to leverage her extensive experience focused on investments and business and corporate development in the life sciences industry.

Q1 net loss and EPS were $1.4M / ($0.13), compared to $1.5M / ($0.15) in the prior-year comparable period.

Operational Highlights:

Recent highlights on the operational front include

- Enrollment of Neovacs' phase IIb Lupus study completed in July 2017
  - February 2018: IDSMB issues positive final review of phase IIb Lupus study
  - Neovacs shooting for final data results in June 2018
- Neovacs IND approved, allowing for phase IIa dermatomyositis study to expand to U.S.
- Neovacs announced positive results from Type I diabetes POC study, preclinical development continues
- OBI Pharma indicates progress has been made towards pursuit of Ph III studies with OBI-822
- AXON's phase II Alzheimer's study completed enrollment in July 2017
- Araclon commenced phase II Alzheimer's study

➢ …in early March 2017 SBOT announced that they entered an exclusive multi-year agreement with **Amaran Biotechnology** whereby Stellar will supply KLH for Amaran's partners (i.e. OBI's) clinical trials. While this came as little surprise given the prior two-year collaboration agreement between the two

relative to optimizing Amaran's manufacturing processes for the OBI-822 candidate and our expectation that SBOT would remain the KLH supplier to Amaran/OBI, it was nonetheless important as it makes it 'official'. The agreement, per Stellar's press release, commits Amaran to purchase Stellar KLH in amounts necessary to meet its requirements for vaccine production. As we explain below, we continue to eagerly await updates on OBI's clinical programs, the most recent public information surrounding which were announced in January 2017.

As a reminder, 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 II physician-initiated clinical trial in Taiwan for the treatment of ovarian cancer (no recent updates have been announced related to the ovarian cancer program either). OBI-822 utilizes KLH as a carrier protein for the carbohydrate antigen Globo-H, which is often expressed by cancer cells.

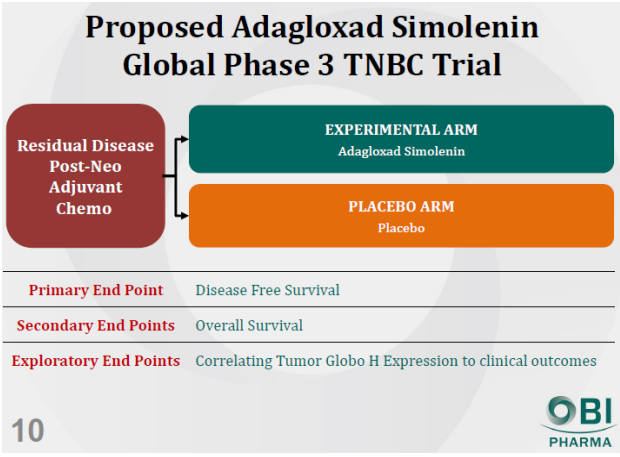
In February 2016 OBI announced that top-line data of the phase 2/3 metastatic breast cancer study did not meet the primary endpoint of progression-free survival. Results were presented in June at ASCO 2016 in Chicago. But, as patients who did show an immune response demonstrated statistically significant 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 III study. But, as we also note below, it is unclear what the actual status is given the less-than-consistent messaging delivered from OBI's press releases since early 2017.

In a January 20, 2017 press release OBI announced that they met with the FDA for its end-of-phase II meeting and "based on the discussion with the FDA, OBI Pharma plans to prepare its phase III protocol". Just days later (January 24) OBI announced that they received approval from the China FDA to conduct a phase III clinical trial of OBI-822 which OBI notes can be used in a future BLA application.

And while Europe was not previously mentioned as a possible location for further development of OBI-822, OBI's website currently states that the "Company held its End of phase 2 (EOP2) Meeting with the US Food and Drug Administration (FDA) in January 2017, and received a written reply from the European Medicines Agency (EMA) regarding questions related to the Company's design of its global phase III clinical trial for Adagloxad simolenin. The Company will amend its global phase III clinical trial accordingly."

We uncovered the latest tid-bit of information from OBI's January investor presentation, developed for their attendance at this year's JP Morgan Healthcare Conference. While contents of the presentation (http://bit.ly/2EDkIC3) do not provide any additional detailed insight into outcomes with OBI's interactions with the various regulatory agencies, they do support the company's previous press releases (regarding positive outcomes of the EOP2 meetings, including CFDA approval to conduct a phase III study) and also clearly indicate that OBI believes (or at least hopes) that there is a viable path to move into phase III studies (in the U.S. and Europe, in addition to China). In addition, the presentation includes a slide of OBI's proposed phase III trial design (below).

OBI Pharma's January 2018 Investor Presentation



But, to say the least, OBI's messaging surrounding OBI-822 continues to be confusing. Additionally, the announcements regarding moving into phase III in China and preparing a phase III protocol for U.S. FDA were somewhat surprising given the missed endpoints in phase 2/3. So, while the status of OBI's clinical programs is still quite ambiguous, if and when there is additional forward progress, it should provide more insight into related potential incremental revenue to Stellar given the recently consummated exclusive multi-year KLH-supply agreement with Amaran (for OBI's studies). And while OBI-822 was also in a phase II study for ovarian cancer, there has also not been any recent updates on that program.

Given the uncertainty as to the status of OBI-822, we have removed estimated contribution to SBOT for supplying KLH to a phase III program – we note, however, that our assumptions are subject to change based on news flow and future potential developmental status updates on this drug candidate.

- **Neovacs** announced in early February 2017 that they will pursue a Type I diabetes program for their IFNa-Kinoid compound. This is in addition to the ongoing Lupus program (phase IIb results anticipated in June 2018) for which SBOT has been supplying KLH. Neovacs made the decision to pursue Type I diabetes following positive results of a mouse model indicating high immunogenicity of IFNa-Kinoid. Similar to Lupus, Type I diabetes is an autoimmune disease characterized by the overexpression of IFNa. In December 2017 Neovacs announced positive initial results from their ongoing Type I diabetes proof-of-concept trial, that they would continue with preclinical development and have a goal to initiate clinical programs in the future for Type I diabetes. Neovacs had previously indicated that they hoped to begin clinical studies sometime in 2018, although it is unclear whether that timeline is still achievable.

  Assuming this program continues to successfully move forward, we would expect SBOT would be supplying KLH for these Type I diabetes studies as well. U.S. prevalence of Type I diabetes is estimated at approximately 2M people, slightly more than the ~1.5M Americans believed to have Lupus. So, while it is much too early to make any assumptions regarding the potential additional demand for KLH that a commercialized Type I diabetes immunotherapy may generate, it is worth recognizing that the patient population and potential future opportunity for SBOT is sizeable.

  And, as a reminder, Neovacs has also made significant recent progress in their Lupus program. In 2011 IFNa-Kinoid completed a phase I/IIa study (n=28) for Lupus. 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 (in 20 countries) and expanded the number of sites from 5 to 15. In July 2017 the study completed enrollment (n=185).

  In November 2016 Neovacs announced that they enrolled the first patient in the U.S. **Importantly, in December 2016 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 facilitate eventual approval in the U.S. market.

  In February 2017 the study's Independent Data and Safety Monitoring Board (IDSMB) issued a favorable safety-related opinion, allowing the study to continue. Subsequent reviews elicited similarly positive opinions (i.e. no safety concerns and no required modifications to the study) from the IDSMB, including one in July 2017 and, most recently, one in mid-February 2018. Per Neovacs' February 13, 2018 press release, they expect final study results in June 2018.

  While we do not think commercialization for Lupus in the U.S. is likely to happen within the next few years, it's possible that a Lupus indication could be a sooner event in 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.

Neovacs continues to expand the potential geographic footprint for their Lupus candidate and in July 2017 signed an exclusive licensing agreement with Centurion Pharma whereby that company will lead development and commercialization of the compound in Turkey.

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 2016 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.

Neovacs is also developing IFNa-Kinoid for **dermatomyositis**, which is considered an orphan disease in both the U.S. and in Europe. The dermatomyositis program commenced in mid-2015. Neovacs presented an update of its ongoing phase 2a study at the World Conference on Myositis in May 2017. The phase 2a study (n=30) is evaluating the immunogenicity, tolerance and biological and clinical efficacy of IFNα Kinoid. In July 2017 FDA approved an IND allowing Neovacs to expand this phase 2a study to the U.S. Results are expected to support design of a pivotal study.

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 has accounted for only a small portion of SBOT's total revenue over the last couple of years but with additional clinical activity as well as potential preparations towards launch, we think this will increase. As such, we are eagerly awaiting read-out of the phase IIb Lupus study as well as updates on the dermatomyositis program, including commencement of the U.S. portion.

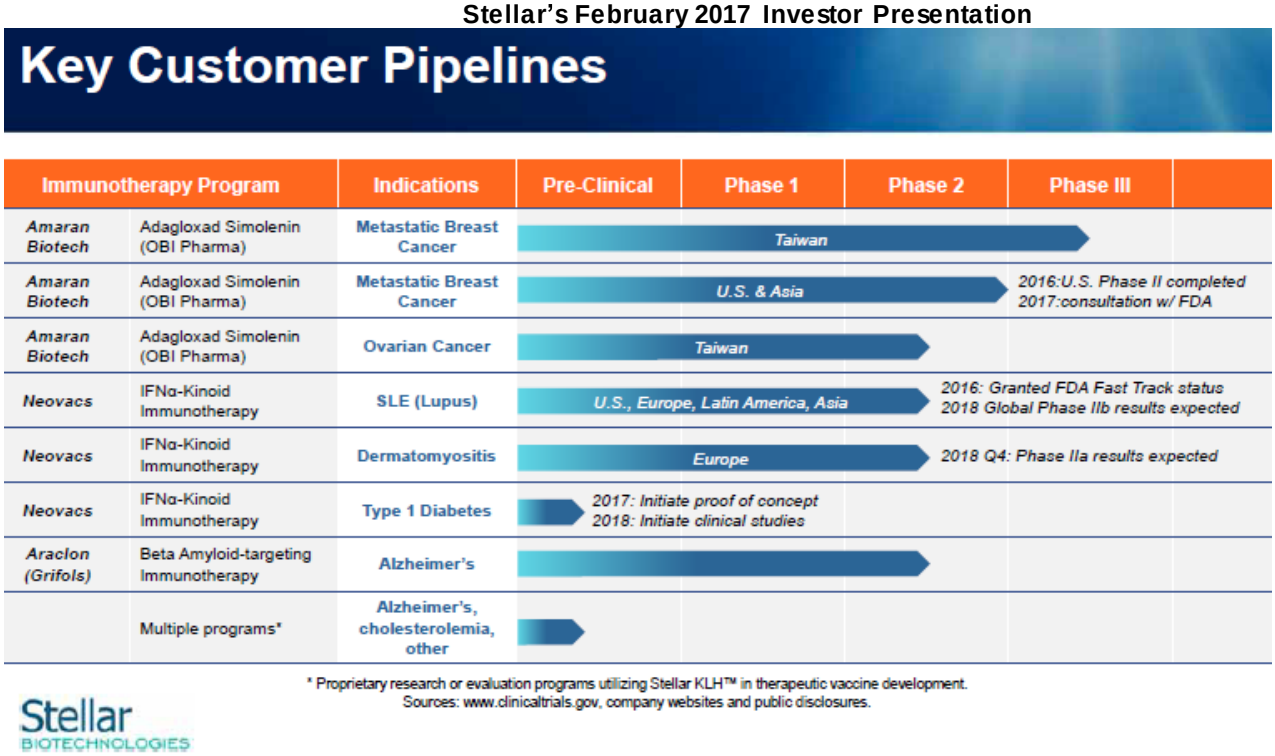
Neostell, the JV formed between Stellar and Neovacs will produce and commercialize Neovacs' vaccines, assuming eventually approved. Neostell will also seek to supply and manufacture KLH-based products for third parties.

- **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). Following authorization from regulators in Spain, in late-June 2017 Grifols announced that a phase II study commenced. The most recent update we were able to find was a September 2017 press release in which Grifols noted that they expected enrollment to begin in October 2017. This phase II study is being conducted at up to 22 sites in Europe and includes 120 patients with mild cognitive impairment (i.e. earliest stages of Alzheimer's). Patients will be randomized 1:1 treatment/control. The study is designed to determine optimal dose for future studies as well as to confirm safety findings of the phase I study. Araclon estimates the study will take about two years to complete.

- **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). 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 and enrollment (n=208) completed in July 2017. ADAMANT 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 is doing so for this phase II study, AXON could represent another source of supply revenue and, potentially, eventually commercialized-product revenue.

Stellar's February 2017 Investor Presentation



Recent Immunotherapy FDA Approvals Could Further Drive Investment

Highly anticipated FDA approvals came in September and October 2017 for two cancer immunotherapies targeting advanced lymphoma. In September FDA approved Novartis' Kymriah (tisagenlecleucel-T), a novel CAR-T cell immunotherapy, for the treatment of children and young adults (ages 3 - 25) with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL). This was followed one month later with FDA approval of Gilead's/Kite's Yescarta (axicabtagene ciloleucel), a chimeric antigen receptor for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy.

The relatively extraordinary efficacy of these drugs as demonstrated in clinical trials has been nothing short of incredible. In fact, a cancer expert and member of the Kymriah FDA advisory panel noted that efficacy of the therapy was the most exciting thing that he had seen in his career. These are truly life-saving therapies (improving 5-year survival to more than 80%, versus 16% - 30% historically), the successful approval and efficacy of which will undoubtedly spur additional investment in the immunotherapy space. These are also expected to be highly profitable products – with per-treatment pricing estimated at between $250k - $500k – which should also help drive investment.

So, as interest and investment in immunotherapies continues to grow, it could provide additional future opportunities for SBOT to supply KLH.

Building Capacity to Meet Expected Increase in Demand…

SBOT continues to forge further ahead with building its production, manufacturing and capacity capabilities in anticipation of increasing demand for its KLH. Management recently noted 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 in late (calendar) 2016 began putting the pieces in place to be able to do so. In December 2016 the company commenced a plan to optimize their protein manufacturing processes in their U.S.-based (California) facility, including evaluating their needs for new equipment – while the current manufacturing system is designed around supporting clinical trials, the optimization plan will be aimed at upgrading this for increased capacity to meet greater demand, such as for a commercialized product.

Most recently their scale-up activities have included the formation of a **Mexican subsidiary** (BioEstelar, S.A. de C.V.) headquartered in Endenada, Baja California, Mexico. BioEstelar's focus will be the (potential, at least as of now) establishment of a second aquaculture facility. As a reminder, In June 2015 Stellar entered an agreement with Ostiones Guerrero S.A. de C.V., a Baja California 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 would increase Stellar's KLH production capacity as well as provide production and KLH-sourcing redundancy to the company's U.S. aquaculture facility.

Stellar's current capacity is approximately 1.5k grams per year. While they continue to expect to build-out KLH capacity to ~20k grams/yr within 5 -7 years, they will do so in a methodical and incremental fashion and with an eye on controlling expenses.

Stellar previously noted that they began quality studies of the KLH produced in Mexico. These studies include confirmation that the Mexico-produced KLH is comparable to that produced in their U.S. facility. Verification of comparability is critical in order to meet FDA quality guidelines. And redundancy – having two separate production facilities – is beneficial not only for the additional capacity but also in significantly reducing risk of production delays or stoppages due to unforeseen events.

Capacity, redundancy and ability to quickly scale production are also potentially very significant competitive advantages in our opinion as they reduce vaccine manufacturers' supply-constraint risk – a risk that can be substantial given that it takes approximately five years for the Giant Keyhole Limpet to fully mature from embryo to a protein-producing adult. As such, we think additional production and redundancy can be a major selling point for SBOT in not only attracting additional supply agreements but also, potentially, even in helping to further validate the practicality of developing and commercializing KLH-based vaccines (i.e. supply risks will not be a concern).

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 and the second (top-down approach), that by (fiscal) year 2021 Stellar begins to generate meaningful revenue from supplying KLH to commercialized immunotherapies.

Through the year 2019 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 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 2021, 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 one-third (33%) of this KLH
- This equates to product sales for Stellar of approximately $67 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 one-third 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 33% supply coming from Stellar may also be low
- Also of interest is that Stellar's current annual capacity of 1.5kg 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 Lymphom	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 Cncrs	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				33%
Total Stellar revenue in 10 years				**$66,928,824.78**
Required KLH Production Capacity (kg)				**1.3**

DCF Values SBOT at $5.50/share

We forecast revenue in "phase 1" of our model to grow from $228k in 2017 to $880k in 2018 and to $4.6M in 2020. And then in "phase 2" to grow to almost $67M in 2026. Our 2026 revenue figure includes KLH sales in support of commercialized immunotherapies as well as some contribution for supply of clinical trials. 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.

The share price and trading volume has languished as of late – and particularly so since SBOT received notice from Nasdaq (late-January 2018) that they were not in compliance with the $1.00 minimum bid-price requirement. The Nasdaq notice is not a reflection of the fundamentals of the company and can have a negative effect on liquidity and trading volume and put resultant downward pressure on share price. SBOT has until July 30, 2018 to regain compliance (i.e. common shares closing bid price must be at least $1.00 per share for at least ten consecutive business days during the 180-day grace period), afterwards which they may apply for an additional 180-day extension (granting of which is based on certain conditions).

Our DCF model, which uses a 12% discount rate and 2% terminal growth rate, values SBOT at approximately $5.50/share.

Stellar Biotechnologies

	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E	2021 E
Total Revenues	$228.3	$20.5	$67.5	$194.0	$597.9	$879.8	$2,850.9	$4,549.7	$3,694.9
YOY Growth	-82.0%	-85.6%	7.1%	844.9%	20658.7%	285.4%	224.0%	59.6%	-18.8%
Cost of Sales	$534.5	$100.9	$145.3	$187.4	$363.9	$797.4	$2,105.0	$2,961.3	$1,782.4
Gross Income	($306.2)	($80.4)	($77.8)	$6.6	$233.9	$82.4	$745.8	$1,588.3	$1,912.5
Gross Margin	-134.1%	-392.3%	-115.2%	3.4%	39.1%	9.4%	26.2%	34.9%	51.8%
R&D	$1,973.4	$631.0	$514.0	$555.0	$702.0	$2,402.0	$3,661.0	$3,844.1	$4,036.3
% R&D	864.4%	3080.2%	761.5%	286.1%	117.4%	273.0%	128.4%	84.5%	109.2%
SG&A	$2,945.0	$678.5	$621.0	$668.0	$729.0	$2,696.5	$4,555.0	$4,873.9	$5,215.0
% SG&A	1290.0%	3311.8%	920.0%	344.3%	121.9%	306.5%	159.8%	107.1%	141.1%
Operating Income	($5,224.5)	($1,389.9)	($1,212.8)	($1,216.4)	($1,197.1)	($5,016.1)	($7,470.2)	($7,129.6)	($7,338.8)
Operating Margin	-2288.6%	-6784.2%	-1796.7%	-627.0%	-200.2%	-570.1%	-262.0%	-156.7%	-198.6%
Total Other Inc. (Exp.)	$194.7	($10.1)	$3.8	$2.2	$1.0	($3.1)	$0.0	$0.0	$0.0
Pre-Tax Income	($5,029.8)	($1,399.9)	($1,209.0)	($1,214.2)	($1,196.1)	($5,019.2)	($7,470.2)	($7,129.6)	($7,338.8)
Taxes	$0.8	$0.8	$0.0	$0.0	$0.0	$0.8	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-
Net Income	($5,030.6)	($1,400.7)	($1,209.0)	($1,214.2)	($1,196.1)	($5,020.0)	($7,470.2)	($7,129.6)	($7,338.8)
YOY Growth	0.1%	-5.7%	9.5%	-0.5%	-2.0%	-0.2%	48.8%	-4.6%	2.9%
Net Margin	-2203.7%	-6837.2%	-1791.0%	-625.9%	-200.1%	-570.6%	-262.0%	-156.7%	-198.6%
EPS	($0.49)	($0.13)	($0.11)	($0.12)	($0.11)	($0.48)	($0.60)	($0.53)	($0.51)
YOY Growth	-13.7%	-9.2%	5.5%	-4.0%	-2.0%	-2.9%	348.8%	359.6%	338.5%
Diluted Shares O/S	10,237	10,520	10,520	10,520	10,520	10,520	12,500	13,500	14,500

Brian Marckx, CFA

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