December 6, 2018

Zacks Small-Cap Research

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Stellar Biotech (SBOT-NASDAQ)

SBOT: Neovacs' IFN-K Development Accelerating Following Positive Ph2 Results

We forecast revenue in "phase 1" of our model to grow from $212k in 2018 to ~$939k in 2019 and to $4.2M in 2020. And then in "phase 2" to grow to approximately $72M in 2027. Our DCF model, which uses a 12% discount rate and 2% terminal growth rate, values SBOT shares at approximately $7.50.

Current Price (12/06/18)	$1.14
Valuation	**$7.50**

OUTLOOK

While revenue remains immaterial, coming in at $54k in Q4 and $212k for the full year, long-term investment fundamentals remain largely intact in our opinion. Importantly, indications are that clinical trial and overall product development progress continues of those therapeutic candidates that SBOT supplies with their KLH. This includes Neovacs' IFNa-Kinoid (IFN-K) development program.

Earlier this year Neovacs announced positive results from a (multi-country, including U.S.) phase IIb study for the treatment of systemic lupus erythematosus (see our discussion below) and subsequently announced an anticipated orphan drug designation regulatory filing related to the same candidate in S. Korea. Moreover, a separate development program could initiate in China following news in September that Neovacs' partner, Biosense Global, exercised its rights to develop IFN-K for lupus in that country.

SUMMARY DATA

52-Week High	**$7.98**
52-Week Low	**$0.90**
One-Year Return (%)	**-83.53**
Beta	**0.43**
Average Daily Volume (sh)	**114,357**
Shares Outstanding (mil)	**5**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**8**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-19.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 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)
2018	0.0 A	0.1 A	0.1 A	0.1 A	0.2 A
2019	0.1 E	0.1 E	0.3 E	0.5 E	0.9 E
2020					4.2 E
2021					3.8 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2018	-$0.93 A	-$0.90 A	-$0.38 A	-$0.21 A	-$1.76 A
2019	-$0.23 E	-$0.26 E	-$0.27 E	-$0.29 E	-$1.05 E
2020					-$0.91 E
2021					-$0.87 E

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

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WHAT'S NEW….?

Q4 / FY 2018 Financial Results/Update: *Revenue Underwhelming But Investment Fundamentals Intact…*

Stellar (SBOT) reported financial results for their fiscal fourth quarter ending September 30th. While revenue remains immaterial, coming in at $54k in Q4 and $212k for the full year, long-term investment fundamentals remain largely intact in our opinion. Importantly, indications are that clinical trial and overall product development progress continues of those therapeutic candidates that SBOT supplies with their KLH. This includes Neovacs' IFNa-Kinoid (IFN-K) development program.

Earlier this year Neovacs announced positive results from a (multi-country, including U.S.) phase IIb study for the treatment of systemic lupus erythematosus (see our discussion below) and subsequently announced an anticipated orphan drug designation regulatory filing related to the same candidate in S. Korea. Moreover, a separate development program could initiate in China following news in September that Neovacs' partner, Biosense Global, exercised their rights to develop IFN-K for lupus in that country.

And, in addition to supporting commercial clinical trials, Stellar recently secured an agreement with the U.S. National Institutes of Health (NIH) to supply their proprietary KLH for government-sponsored studies. As we explained in our September 20th Note (*NCI Supply Contract: Highlights Growing Interest of KLH for Cancer Immunotherapies*), while it is not yet clear what this contract means in terms of potential financial contribution to SBOT, we think it does add additional validation to SBOT's manufacturing capabilities, the importance of traceability of the source of KLH and the potential utility of KLH in cancer immunotherapies.

Revenue has been negligible and, while we had not expected significant sales at this point, we had anticipated a more obvious steepening of the topline based on assumed more-rapid progression of certain of the company's KLH-supplied clinical trials. Unfortunately, with SBOT's revenue largely tied to progress and stage of their customers' clinical trials, there is not much the company can do other than wait for revenue catalysts to materialize.

Revenue over the last several quarters has largely reflected the lull between the conclusion of earlier-stage trials and commencement of later-stage trials. 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. We have since modified our model to reflect a slower than previously estimated pace of certain of the supported clinical trials and related development programs.

Current customers, including Neovacs and Araclon represent potential opportunities to increase KLH sales with progression of their clinical trials to later stages and, in the case of Neovacs, possibly from initial commercial sales in S. Korea. While Neovacs has not tipped their hand as it relates to next-steps for their multi-country IFN-K lupus program, their press release in July announcing the phase IIb results strongly suggested (i.e. "…very pleased with these results that will enable us to move into phase III within a partnering to be finalized…") that they expect to forge directly ahead with a phase III study. And, as noted above, with Biosense Global presumably developing their own development program, we think that may offer another KLH-supply opportunity for Stellar.

Meanwhile, Amaran/OBI could be moving their metastatic breast cancer candidate into phase III studies. We also think the recent clinical success of certain immunotherapies (including Gilead's Yescarta and Novartis' Kymriah) 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 accelerate. Fiscal 2018 operating expenses were $4.9M, unchanged from that of the prior year. Meanwhile, cash used in operating and PP&E-related investing activities was $4.6M and $383k in 2018, respectively, compared to $4.9M and $302k in 2017. SBOT exited the year with $10.3M in cash and short-term investments on the balance sheet.

Net loss and EPS were $1.1M / $0.21 in Q4 and $5.0M / $1.76 for the full-year 2018, compared to $1.2M / $0.81 and $5.0M / $3.44 in the comparable prior year periods.

Operational Highlights:

Recent highlights on the operational front include

- Sept 2018: Stellar awarded contract to supply KLH for NCI/NIH-sponsored studies
- Neovacs announced positive results from IFN-K phase IIb Lupus study in July
  - July 3rd press release indicates Neovacs plans to move directly to phase III study
  - Sept 2018: Biosense Global exercises option to continue development of IFN-K in Lupus for Chinese market
  - Oct 2018: Neovacs announces that they and S. Korean partner Chong Kun Dang will prepare Orphan Drug Designation (ODD) regulatory filing in that country. ODD, if granted, could allow Neovacs to launch IFN-K for lupus (w/o the need for any additional clinical studies)
- 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. OBI's Sept 2018 investor presentation includes slide describing OBI-822 "Global P3 Trial Design"
- AXON's phase II Alzheimer's study completed enrollment in July 2017
- Araclon commenced phase II Alzheimer's study

Neovacs Announces Ph2 Lupus Results, "Will Enable Us To Move Into Ph3…"
In early July Neovacs announced results of its phase IIb trial investigating safety and efficacy of their IFNa-Kinoid (IFN-K) candidate in the treatment of systemic lupus erythematosus (SLE). The vaccine uses Stellar's KLH as a carrier vehicle. While one of the two co-primary endpoints did not reach statistical significance, the other did (and, in fact, was highly statistically significant). In addition, one of the two secondary efficacy endpoints was statistically significant, while the other showed a positive trend towards significance (although did not reach it). Safety, per Neovacs' press release, was "favorable." Despite the less-than-perfect results, Neovacs appears undeterred and indicated that they expect to move into phase III testing.

As a refresher of Neovacs' Lupus program and SBOT's relationship with the company…
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. The phase IIb study, which had originated in 2015 in Europe, Latin America and Asia, was expanded to the U.S. 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. In December of that year FDA granted Fast-Track status to IFNa-Kinoid in lupus. The Independent Data and Safety Monitoring Board (IDSMB) overseeing the study issued favorable safety-related opinions throughout the duration of the trial.

Stellar's role has been to supply Neovacs with KLH, which is used as a carrier protein for IFNa-Kinoid. In addition to lupus, Neovacs is evaluating IFNa-Kinoid in earlier stage programs in type 1 diabetes as well as for the treatment of dermatomyositis. Stellar and Neovacs recently expanded the supply agreement to ensure sufficient KLH quantities are available to support these 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. The duo are also JV partners in Neostell, which was formed for the purpose of producing and commercializing Neovacs' vaccines (assuming eventually approved).

Phase IIb Study in SLE…
The phase IIb randomized controlled, multi-center study enrolled 185 subjects with moderate-to-severe lupus. Patients were randomized to either IFNa-Kinoid or placebo, administered IM at five prespecified time points; days 1, 7, 28 and month 3 and 6. All subjects also received standard of care including immunosuppressants/steroids.

Per clinicaltrials.gov the following are the primary and secondary endpoints;

Primary endpoints;

- expression of IFN-induced genes (change from baseline) at week-36
- response to IFN-K treatment as measured by BILAG Composite Lupus Assessment (BICLA) at week-36

Secondary endpoints:

- treatment response based on SRI-4 at week-36
- safety (based on number of patients with treatment-related adverse events)

Results (per Neovacs' PR);

Relative to the primary endpoints, Neovacs reported that the change from baseline on the gene-expression measure was highly statistically significant (p<0.0001) but that BICLA was not. The PR did not disclose specifics in terms of response rates of each arm and, in the case of BICLA, the p-value.

In terms of the secondary measures, 54% of IFN-K patients met the SRI-4 endpoint with reduction of steroids to less than or equal to 5mg/day at week 36 compared to 39% in the placebo arm. And while the SRI-4 endpoint did not reach statistical significance (p=0.07), it trended in favor of IFN-K.

Although not disclosed as an endpoint in the clinicaltrials.gov description of the study, Neovacs also reported on Lupus Low Disease Activity State (LLDAS). LLDAS is a relatively 'new', although validated, criteria for evaluating the change in activity of SLE. Based on the LLDS measure, IFN-K patients fared better than those in the placebo arm (53% vs. 30%) and the difference was statistically significant (p=0.002).

Next steps…

Based on the PR, Neovacs plans to forge ahead and expects to be able to move directly to phase III – contingent on first bringing on a partner to help with initiating and conducting a late-stage program in lupus. A phase III program would likely mean more patients than phase II – perhaps twice the enrollment – which should mean incrementally more revenue for SBOT in supplying KLH. The ultimate goal, however, remains to be supplying KLH for a commercialized product – and if IFN-K moves into a phase III lupus program, that would be a significant step closer to reaching that goal.

Although we had hoped these phase IIb results would be somewhat more definitive – specifically, that the data would be overwhelmingly positive and leave no doubt about IFN-K's effectiveness in SLE and its chances for ultimately gaining regulatory approval, that isn't what happened. And while we do not have enough insight at this point to be able to handicap the chances for success of a phase III program, we think there are reasons to be optimistic that the missed primary (and secondary) endpoint(s) in the phase IIb study may not be overly problematic.

Fortunately for Neovacs (and Stellar), but unfortunately for those that suffer from the disease, SLE is a chronic and oftentimes debilitating condition for which no cure exists. Current treatments only address the symptoms and with variable effectiveness. There is a tremendous unmet need for a true SLE therapy, which is the reason why IFN-K in lupus received FDA Fast-Track designation.

Also fortunate for Neovacs is that regulators, including FDA, have indicated receptiveness in considering a variety of primary endpoints for pivotal SLE studies. For example, while FDA's industry guidance for developing medical products for the treatment of SLE recommends certain primary and secondary endpoints, there clearly appears to be some flexibility – that is, as long as the endpoints chosen are clinically meaningful and validated – which was the case for Neovacs' study. For some context/example on this point, primary endpoint of AstraZeneca's phase III pivotal FDA study of its SLE candidate (for reduction of disease activity), anifrolumab, is SRI-4 (@ week 52) – by contrast, FDA recommends BILAG as the preferred endpoint to measure reduction in disease activity.

Meanwhile, European Medicines Agency guidelines for SLE clinical trials recommends using "validated composite indexes s, (i.e., SLE Responder Index [SRI] or BILAG-based Composite Lupus Assessment [BICLA]) , which both include a measure of global disease activity (by SELENA-SLEDAI), specific organ system involvement (BILAG) and overall subject's condition (Physician's Global Assessment)."

As such, we think it is not unreasonable that (for example) SRI-4, separation of which was in favor of IFN-K although not statistically significant in this phase IIb study, could conceivably be used as a primary in phase III – and, with a slightly more robust response, might be successfully met.

Another point relative to reasons to be optimistic is the effectiveness of IFN-K to reduce steroid use as observed in the phase IIb data. Per FDA's guidance, reduction in steroid use "is an important goal in treatment of patients with SLE if it occurs in the context of a treatment that effectively controls disease activity." So, while Neovacs might still need to demonstrate that IFN-K can sufficiently reduce disease activity

(via an 'appropriate' primary endpoint), the ability to reduce steroid use should certainly play in their favor in terms of evidence of clinically meaningful benefit.

And while next-steps relative to the U.S. market have yet to be disclosed, these phase IIb results have culminated in accelerating development activities of IFN-K in other parts of the world. Neovacs announced on September 11th that, in return for an unstipulated fee, their partner Biosense Global has exercised their option to develop and commercialize IFN-K for lupus in China. Meanwhile, Neovacs and their S. Korean partner, Chong Kun Dang (CKD), (per Neovacs' October 11th press release) anticipate preparing a filing supported by these phase IIb results seeking Orphan Drug Designation from regulators in that country. Given that the clinical study formulation presumably utilized Stellars' KLH, we would expect any parallel development programs (such as sponsored by Biosense or CKD or others) to also source KLH from SBOT.

SBOT Scores National Institutes of Health / NCI Supply Agreement

Securing more KLH supply agreements has been one of SBOT's strategic objectives and they recently made additional headway on that goal. In early Stellar announced that they entered an agreement with the U.S. National Institutes of Health (NIH) to supply their proprietary KLH for government-sponsored studies.

While details regarding the potential breadth of the agreement with NIH or specifics about which particularly programs SBOT will support, were not disclosed, the press release does indicate that SBOT's KLH will be used in cancer immunotherapy studies. That includes one or more dendritic cell-based cancer therapy programs sponsored by NIH's National Cancer Institute which will use a vialed formulation of SBOT's KLH.

Dendritic cell vaccines have shown potent cancer fighting ability and have quickly become one of the most promising areas of cancer research. Preparation of dendritic cell vaccines involves extracting (precursor) dendritic cells from the body and then loading them with tumor antigens. They are then put back in the body where they seek out and destroy cancer cells. Studies have indicated that KLH, when combined with the dendritic cells, can enhance immunotherapies' cancer killing efficacy.

While we currently have little insight into the potential significance of this agreement in terms of revenue, we think it is meaningful as providing additional validation of SBOT's manufacturing capabilities (in regards to both quality and capacity) and the importance of traceability of the source of KLH. It also adds additional credence to the potential utility of KLH in these new cancer immunotherapies – related research and development around which has massively accelerated over the last few years.

Our quick query of clinicaltrials.org using search terms 'dendritic, KLH' under a generic 'cancer' indication returned 27 studies – while several are dated, this list likely represents only a fraction of related programs (and also does not include all of the preclinical programs). Our point being that, dendritic cell vaccines represent a potential near-term breakthrough in cancer therapy and Stellar likely represents the only source of reliable capacity and quality KLH

And while this is the latest government agreement that SBOT received, it is not the first. In fact, Stellar has previously received more than $4M of funding from SBIR programs, including at least $3M related to a previous NCI award. That funding was a significant catalyst to building out Stellar's manufacturing and aquaculture capabilities.

"Pipeline" Summary…

- …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. This followed a prior two-year collaboration agreement between the two relative to optimizing Amaran's manufacturing processes for the OBI-822 candidate. The agreement, per Stellar's press release announcing the agreement, 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 specific 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.

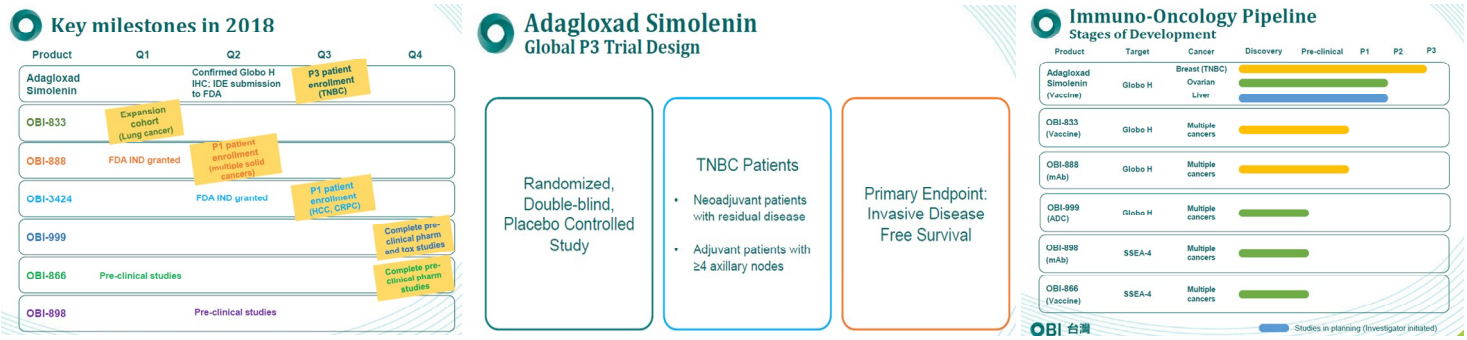
In February 2016 OBI announced that top-line data of the phase 2/3 metastatic breast cancer study did not meet the primary endpoint of progression-free survival. Results were presented in June at ASCO 2016 in Chicago. But, as patients who did show an immune response demonstrated statistically significant 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."

The most recent indication from OBI that this candidate is still being pursued comes from their September 2018 investor presentation, which includes a slide summarizing a phase III trial design as well as one listing "key milestones", one of which suggests OBI-822 phase III enrollment was anticipated to commence in Q3'18. As noted, we have no insight into whether that was the case or as to any other status of this program.

References to OBI-822 in OBI's September 2018 investor presentation



Source OBI Pharma

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 (other than what is depicted in the September 2018 investor presentation, above).

Given the uncertainty as to the status of OBI-822, we continue to refrain from modeling any projected 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 (as discussed earlier) 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.

  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 announced next-steps in lupus, as well as other targets such as diabetes and dermatomyositis. In the meantime, development in China via Biosense and even possible commercialization in S. Korea could commence and potentially provide additional KLH-supply opportunities and related revenue.

  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. **Per Neovac's March 31, 2018, they also expect increasing activity from Neostell.** Neovacs notes that, "Neovacs, together with Stellar Biotechnologies, is progressing the development of Neostell, a state-of-the-art production subsidiary for its Kinoids® vaccines, which is largely supported by a €5 million grant from BPI as part of the "PIAVE" program. The project is expected to start in H2 2018 and be completed in 2023."

- **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 December 2018 Investor Presentation

Key Customer Pipelines

Immunotherapy Program		Indications	Pre-Clinical / Phase 1 / Phase 2 / Phase 3
Amaran Biotech	Adagloxad Simolenin (OBI Pharma)	Metastatic Breast Cancer	Taiwan
Amaran Biotech	Adagloxad Simolenin (OBI Pharma)	Metastatic Breast Cancer	U.S. & Asia
Amaran Biotech	Adagloxad Simolenin (OBI Pharma)	Ovarian Cancer	Taiwan
Neovacs	IFNα-Kinoid Immunotherapy	SLE (Lupus)	U.S., Europe, Latin America, Asia
Neovacs	IFNα-Kinoid Immunotherapy	Dermatomyositis	Europe
Neovacs	IFNα-Kinoid Immunotherapy	Type 1 Diabetes	
Araclon (Grifols)	Beta Amyloid-targeting Immunotherapy	Alzheimer's	
	Multiple programs*	Multiple Myeloma, Opioid Addiction, Others	

* Proprietary research or evaluation programs utilizing Stellar KLH™ in immunotherapy development.
Sources: www.clinicaltrials.gov, company websites and public disclosures.

Stellar BIOTECHNOLOGIES

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 (the lease agreement was extended in February 2018 for another two years) 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, they continue to 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

Updated DCF Values SBOT at $7.50/share

We forecast revenue in "phase 1" of our model to grow from $212k in 2018 to ~$939k in 2019 and to $4.2M in 2020. And then in "phase 2" to grow to approximately $72M in 2027. Our 2027 revenue figure includes KLH sales in support of commercialized immunotherapies as well as some contribution for supply of clinical trials. 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 at approximately $7.50/share.

Stellar Biotechnologies

	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E	2022 E
Total Revenues	$211.8	$61.2	$114.6	$274.4	$488.9	$939.1	$4,176.9	$3,812.0	$7,105.3
YOY Growth	-7.2%	198.6%	78.9%	275.6%	801.2%	343.3%	344.8%	-8.7%	86.4%
Cost of Sales	$445.4	$113.7	$153.7	$274.1	$409.2	$950.7	$2,763.8	$1,819.8	$2,696.3
Gross Income	($233.5)	($52.6)	($39.1)	$0.3	$79.7	($11.6)	$1,413.2	$1,992.1	$4,409.0
Gross Margin	-110.2%	-85.9%	-34.1%	0.1%	16.3%	-1.2%	33.8%	52.3%	62.1%
R&D	$2,087.4	$521.2	$622.8	$712.1	$801.1	$2,657.2	$4,012.4	$4,213.0	$4,756.0
% R&D	985.4%	852.1%	543.5%	259.5%	163.9%	283.0%	96.1%	110.5%	66.9%
SG&A	$2,757.4	$682.5	$748.6	$812.2	$912.4	$3,155.7	$3,850.0	$4,332.7	$5,060.1
% SG&A	1301.6%	1115.7%	653.2%	296.0%	186.6%	336.0%	92.2%	113.7%	71.2%
Operating Income	($5,078.3)	($1,256.3)	($1,410.5)	($1,524.0)	($1,633.8)	($5,824.5)	($6,449.2)	($6,553.6)	($5,407.1)
Operating Margin	-2397.2%	-2053.7%	-1230.8%	-555.4%	-334.2%	-620.2%	-154.4%	-171.9%	-76.1%
Total Other Inc. (Exp.)	$40.1	$37.6	$28.2	$25.9	$20.4	$112.1	$48.5	$62.2	$0.0
Pre-Tax Income	($5,038.2)	($1,218.7)	($1,382.3)	($1,498.1)	($1,613.4)	($5,712.4)	($6,400.7)	($6,491.4)	($5,407.1)
Taxes	$0.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-
Net Income	($5,039.0)	($1,218.7)	($1,382.3)	($1,498.1)	($1,613.4)	($5,712.4)	($6,400.7)	($6,491.4)	($5,407.1)
YOY Growth	0.2%	-13.0%	2.2%	29.5%	42.9%	13.4%	12.0%	1.4%	-16.7%
Net Margin	-2378.7%	-1992.3%	-1206.2%	-545.9%	-330.0%	-608.3%	-153.2%	-170.3%	-76.1%
EPS	($1.76)	($0.23)	($0.26)	($0.27)	($0.29)	($1.05)	($0.91)	($0.87)	($0.69)
YOY Growth	-48.9%	-75.5%	-71.6%	-27.4%	37.5%	12.3%	1.6%	130.7%	227.8%
Diluted Shares O/S	2,869	5,331	5,400	5,500	5,600	5,458	7,000	7,500	7,875

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