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

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Stellar Biotech (SBOT-NASDAQ)

SBOT: Neovacs Announces Ph2 Lupus Results, Says It "Will Enable Us To Move Into Ph3…"

We forecast revenue in "phase 1" of our model to grow from $228k in 2017 to ~$700k 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 $7.50.

Current Price (07/09/18)	$1.86
Valuation	**$7.50**

OUTLOOK

Neovacs announced results of its phase IIb trial investigating safety and efficacy of their IFNa-Kinoid candidate in the treatment of 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 was "favorable." Despite the less-than-perfect results, Neovacs appears undeterred and indicated that they expect to move into phase III testing. Although we had hoped 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.

SUMMARY DATA

52-Week High	**$10.08**
52-Week Low	**$1.65**
One-Year Return (%)	**-78.05**
Beta	**0.22**
Average Daily Volume (sh)	**1,366,223**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**8**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-10.5**
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	**High,**
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 A	0.1 E	0.5 E	0.7 E
2019					2.9 E
2020					4.6 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2017	-$1.03 A	-$0.76 A	-$0.84 A	-$0.81 A	-$3.44 A
2018	-$0.93 A	-$0.90 A	-$0.45 E	-$0.24 E	-$1.93 E
2019					-$1.36 E
2020					-$1.10 E

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

WHAT'S NEW…

Neovacs Announces Ph2 Lupus Results, "Will Enable Us To Move Into Ph3…"
Last week 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). Neostell will also seek to supply and manufacture KLH-based products for third parties. Per Neovac's March 31, 2018 PR, they expect increasing activity from Neostell, noting 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."

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.

VALUATION

Recent equity-based financings beef-up cash balance, increase share count
In mid-May SBOT (via Wainwright) raised ~$4.7M net ($5.5M gross) via the (public) sale of 2.08M common shares @ $2.65/share. The deal included 100% warrant coverage (5yrs, $2.65 strike).

Later that same month, 1.12M warrants were exercised @$2.65, resulting in gross proceeds to SBOT of ~$3M. In return for exercising, the warrant-holders received an equal number of warrants with the same terms (i.e. 5yrs, $2.65 strike) plus 2.24M warrants exercisable for 7 months @ $2.65.

The capital raises substantially beefed-up SBOT's cash balance, but also significantly increased the outstanding share count. Cash balance (inc ST investments) was $3.8M at the end of fiscal Q2 (March 31st). Following these capital raises and with quarterly cash-burn recently averaging ~$1.3M, we ballpark current cash balance at approximately $9.5M – which represents almost 2 years' worth of operating capital at the recent burn rate. Meanwhile, the outstanding common share count increased from 1.5M as of May 7th (i.e. filing date of the Q2 10-Q) to 5.1M as of June 1st (per prospectus filed June 18th).

DCF Values SBOT at $7.50/share
(See our Q2 '18 update on May 10th for additional details regarding our valuation methodology). We forecast revenue in "phase 1" of our model to grow from $228k in 2017 to ~$700k 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. 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 $7.5/share (adjusted from prior target of $25/share due to greater than anticipated increase in share count).

Stellar Biotechnologies

	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E	2021 E
Total Revenues	$228.3	$20.5	$64.1	$136.3	$475.2	$696.0	$2,850.9	$4,549.7	$3,694.9
YOY Growth	-82.0%	-85.6%	1.6%	563.6%	16400.0%	204.9%	309.6%	59.6%	-18.8%
Cost of Sales	$534.5	$100.9	$140.0	$152.8	$303.8	$697.5	$2,105.0	$2,961.3	$1,782.4
Gross Income	($306.2)	($80.4)	($76.0)	($16.5)	$171.4	($1.5)	$745.8	$1,588.3	$1,912.5
Gross Margin	-134.1%	-392.3%	-118.6%	-12.1%	36.1%	-0.2%	26.2%	34.9%	51.8%
R&D	$1,973.4	$631.0	$493.9	$539.0	$682.0	$2,345.9	$3,661.0	$3,844.1	$4,036.3
% R&D	864.4%	3080.2%	771.1%	395.6%	143.5%	337.1%	128.4%	84.5%	109.2%
SG&A	$2,945.0	$678.5	$774.0	$668.0	$729.0	$2,849.5	$4,555.0	$4,873.9	$5,215.0
% SG&A	1290.0%	3311.8%	1208.4%	490.3%	153.4%	409.4%	159.8%	107.1%	141.1%
Operating Income	($5,224.5)	($1,389.9)	($1,343.9)	($1,223.5)	($1,239.6)	($5,196.9)	($7,470.2)	($7,129.6)	($7,338.8)
Operating Margin	-2288.6%	-6784.2%	-2098.1%	-898.0%	-260.9%	-746.7%	-262.0%	-156.7%	-198.6%
Total Other Inc. (Exp.)	$194.7	($10.1)	($8.7)	$4.6	$3.2	($10.9)	$0.0	$0.0	$0.0
Pre-Tax Income	($5,029.8)	($1,399.9)	($1,352.5)	($1,218.9)	($1,236.4)	($5,207.8)	($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)	($1,352.5)	($1,218.9)	($1,236.4)	($5,208.6)	($7,470.2)	($7,129.6)	($7,338.8)
YOY Growth	0.1%	-5.7%	22.5%	-0.1%	1.3%	3.5%	43.4%	-4.6%	2.9%
Net Margin	-2203.7%	-6837.2%	-2111.6%	-894.6%	-260.2%	-748.4%	-262.0%	-156.7%	-198.6%
EPS	($3.44)	($0.93)	($0.90)	($0.45)	($0.24)	($1.93)	($1.36)	($1.10)	($1.05)
YOY Growth	-13.7%	-9.2%	18.1%	-46.3%	-70.3%	-44.0%	45.7%	21.9%	131.9%
Diluted Shares O/S	1,462	1,503	1,503	2,696	5,120	2,705	5,500	6,500	7,000

Brian Marckx, CFA

HISTORICAL STOCK PRICE

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