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Monthly Biotech Focus – September 2014



Anavex Life Sciences (AVXL)

Probability of success, as emphasized in last month's biotech focus, is an important element in analyzing biotech equities, whose returns are less correlated to the overall sector than they are to the success of their products. This is particularly true of biotech firms in the medicinal rather than energy field, for whom the results of clinical trials and FDA approval requests are paramount. However, when analyzing a biotech firm, one must also examine the market for which the firm's product is intended: a product with a small market will reach a limit of returns no matter how high its probability of success. One significant market is the Alzheimer's market, which represents an increasing proportion of the U.S. population. The number of people with the disease is expected to be triple its current value (5 million) by 2050. Furthermore, none of the currently approved drugs on the market that treat Alzheimer's have the capability of curing the disease, only of reducing its symptoms. The market for treating this disease therefore has enormous medicinal and investment potential.

From the standpoint of sales, projected revenues of the top drugs currently treating the symptoms of Alzheimer's in 2013 are expected to range around \$12.5 billion. The range of one of these drug types, donepezil, has been projected to be between \$2.5 billion and \$4 billion. The market is therefore ripe for Anavex Life Sciences Corporation (AVXL), this month's biotech focus, whose current product lineup focuses on treating the cause of the disease while having the potential to cause large reductions in symptoms when combined with the already-approved drug donepezil.

Anavex is a biotechnology company whose Alzheimer's products (the company's most significant market; it also participates in cancer research) focus on triggering a specific protein receptor (sigma-1), which naturally reduces the number of malformed proteins in the brain that increase in number as people age and which may contribute to Alzheimer's disease. The company's main product, Anavex 2-73, has already passed Phase 1 testing in which, as the press release reports, it demonstrated "reversal of memory loss (anti-amnesiac properties) and neuroprotection in several models of Alzheimer's disease." As the firm has clearly stated, the testing heretofore completed can only be concluded to "*potentially* modify" the disease, which, if successful, would be an enormous step above the current mainstream practice of merely treating the symptoms of its currently irreversible progress.

There are a number of indicators that we will briefly discuss with regard to, once again, the probability of product success:

- 1) As stated above, the drug Anavex 2-73 has already passed Phase 1 and thus is ready for Phase 2 testing, in which it must provide results better than those of drugs currently on the market. It has, however, received a clean data profile from Phase 1.
- 2) Even more promising, the combination of Anavex 2-73 with the currently available donepezil has been demonstrated to produce a reversal in memory loss nearly 80% greater than that seen in patients who receive only one drug or the other. This combination of the two drugs (Anavex Plus) is on its way to Phase 2 testing along with Anavex 2-73 in 2014. The fact that donepezil has already been cleared and has garnered revenues of \$4 billion globally is a significant indicator both of Anavex Plus' probability of success at the next clinical phase (since half of the combination of drugs is already approved) and of the size of the market in need of merely the symptom-treating portion of the drug combination.
- 3) Finally, the company has acquired \$10 million in available funding, which is expected to be sufficient for the completion of the Phase 2 trial.

Given the current general lack of understanding of Alzheimer's disease and the difficulty in treating its underlying causes up to this point, there is, of course, reason to be cautious with any company delving into the cure of this particular disease. For this reason, the synergy resulting from combining Anavex 2-70 with donepezil cannot be understated. It indicates that there exists a market for Anavex Plus (should it clear trial testing) regardless of whether Anavex 2-70 in itself proves sufficient to modify Alzheimer's disease. The possibility of being able to reverse the Alzheimer's process is therefore the promise of an additional market should the Phase 2 trials of that drug be successful, not a prerequisite for the firm's success, since an approved Anavex Plus should continue to thrive in the current market treating the symptoms of Alzheimer's. For these reasons, Anavex Life Sciences Corporation (AVXL) satisfies the criteria both for probability of success and for a significant target market.

Anavex Life Sciences (AVXL) Relevant Statistics

Market Capitalization¹	9.18 M
Property and Equipment²	2,000
Cash and Cash Equivalents	8.18 M
Total Assets	9.31 M
Total Liabilities	1.91 M

The market cap of the firm reveals that it is quite small (about 1% of the average firm size in the NASDAQ Biotechnology Index). However, the firm has the aforementioned

¹ As of 9/16/2014.

² All other data as of 6/30/2014.

\$10 million in available funding, \$8.18 million of which, as seen on their balance sheet, is in cash and cash equivalents. It has only \$1,000 worth of long-term liabilities—thus, most of its current liabilities derive from the cost of its current Phase 2 trials for Anavex Plus and Anavex 2-70. The fact that Phase 2a is already ongoing (2014) suggests that the company should well be able to sustain itself until it is determined whether Anavex Plus exhibits in trial the same significant advantage over donepezil use in isolation that it exhibited in preclinical tests.