1 Stock Ready to Rocket on the Back of a "Sure Thing" Phase 3 Trial

Biotech Gems

Investors Alley

Dynavax Technologies: An Updated View After FDA Decision and Why Major Upside Lies Ahead

It has not been the best of times for small biotech company **Dynavax Technologies (NASDAQ:DVAX)**. The stock has been hammered since the FDA pushed back the PDUFA date (the deadline for when the FDA will approve a new drug) for its Hepatitis-B vaccine HEPLISAV-B by three months to give it more time to analyze a huge set of trial data. Although this should be a temporary setback, the stock nonetheless has fallen by one-third since this delay was announced. Before we review implications for Dynavax and whether this is an opportune time to take a longer view on the investment case for the stock, let us review the company's business and various assets.

Company Overview:

Dynavax Technologies Corporation is a small clinical-stage biopharmaceutical company with multiple product candidates in development for the prevention of infectious disease, the treatment of autoimmune and inflammatory diseases, and the treatment of cancer. The company currently has a market capitalization of just over $450 million and a stock price just south of $11.00 a share. Dynavax is developing what it hopes will be innovative immunotherapies based on Toll-Like Receptor ('TLR') biology and its ability to modulate the immune system.

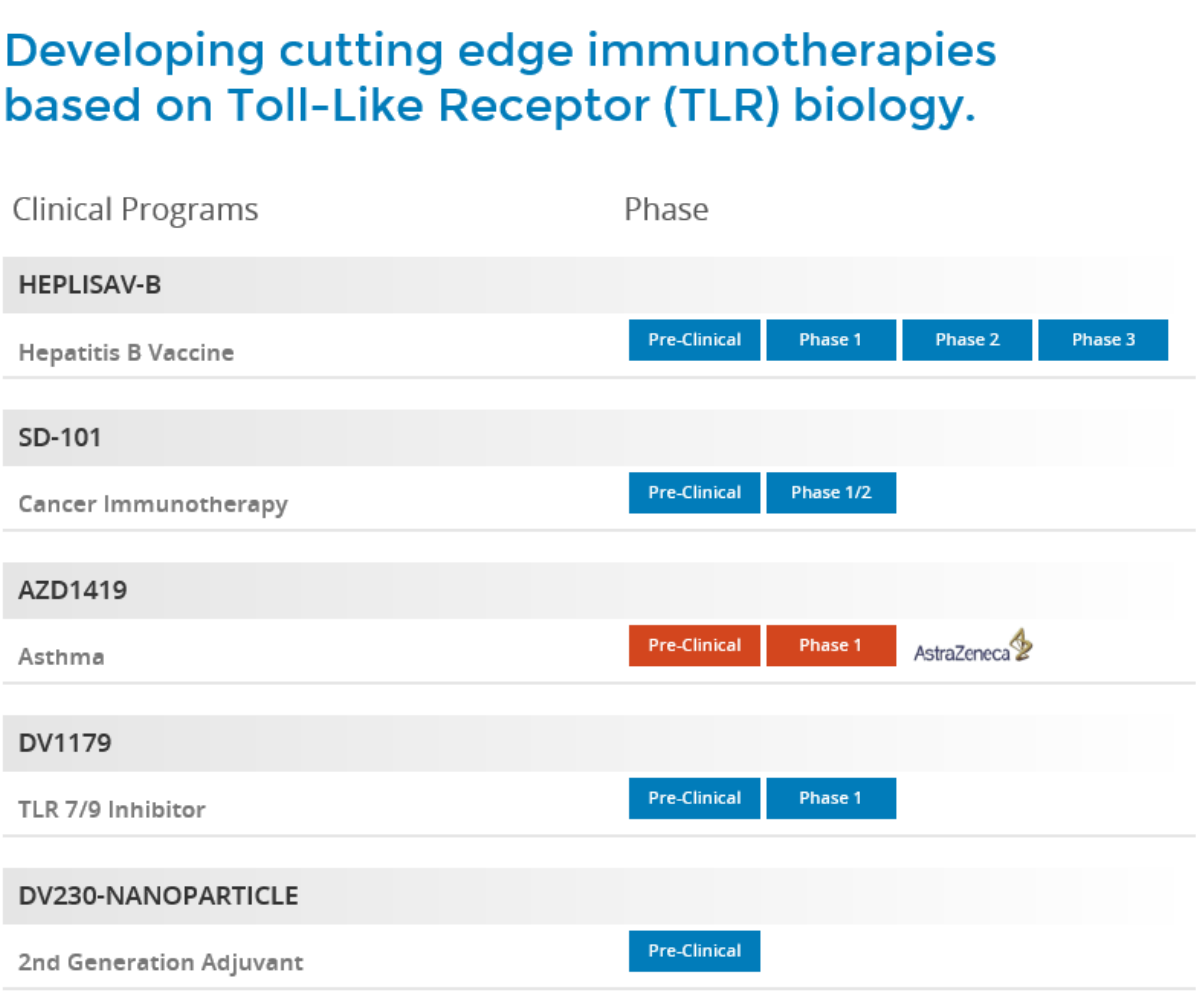
TLR signaling plays an important role in a variety of immune-mediated diseases including asthma and certain autoimmune and inflammatory diseases. Through modulation of TLR signaling Dynavax developing product candidates that can inhibit stimulation of TLRs that lead to autoimmune and inflammatory diseases.

Before we get to HEPLISAV-B, it is important to remember the company has other significant assets.

Pipeline:

Dynavax has two other intriguing compounds other than HEPLISAV-B in mid-stage development, SD-101 and AZD149. SD-101 is a proprietary TLR9 agonist designed to elicit a potent and focused immune response to cancer. SD-101 activates two of the principal TLR9 signaling pathways. One pathway leads to rapid Interferon-α production that, in turn, stimulates a number of critical activities including activating natural killer T-cells, blocking immune suppression, and promoting Th1 and CD8+ T cell homing into the tumor. The second pathway leads to efficient generation and activation of tumor-specific cytotoxic CD8+ T cells. By stimulating the natural immune response, SD-101 has the potential to be broadly effective in multiple tumor types.

SD-101 has completed two Phase 1 trials in 60 subjects. These trials provided safety data and dose optimization for biological activity. Dynavax is currently conducting a Phase 1/2 study (known as LYM-01) to assess the safety and preliminary efficacy of Intratumoral SD-101 in adults with untreated low-grade B-cell lymphoma in combination with low-dose radiation. At least one investment analyst has stated SD-101 has more possible potential than HEPLISAV-B.



Dynavax sees AZD1419 as a possible treatment for asthma, under their worldwide collaboration with **AstraZeneca (NYSE: AZN)**. AZD1419 is another proprietary TLR9 agonist and represents a new strategy for the treatment of allergic respiratory diseases. Obviously, this compound has a huge target market. According to the World Health Organization, asthma affects 300 million people worldwide. In addition, COPD, a term used to describe chronic lung disease that limits airflow in the lungs, affects 210 million people worldwide.

Analysts estimate the current worldwide market opportunity for asthma and COPD therapies to be over $15 billion annually. Just a small piece of that market would be significant to state the obvious.

Dynavax has completed a Phase 1 study in healthy subjects that demonstrated an acceptable safety and tolerability profile and proof of mechanism observed through induction of interferon-regulated genes stimulated by AZD1419. AstraZeneca is in the process of conducting a Phase II trial on AZD1419.

HEPLISAV – B Updated View:

Hepatitis B can be a chronic disease that may lead to cirrhosis of the liver, hepatocellular carcinoma, and death. Over 750,000 people die of hepatitis B each year. About 300,000 of these are due to liver

cancer. There is no current cure for hepatitis B, and disease prevention through effective vaccines is critical to reducing the spread of the disease.

The company's hepatitis B vaccine completed Phase III trials late in 2015 and successfully hit its co-primary endpoints in a study involving over 8,000 subjects. Specifically, Heplisav demonstrated clear superiority in seroprotection vs. Engerix-B in the general population and especially in diabetics, with a similar safety profile. Engerix-B is the current primary vaccine for hepatitis B and is manufactured and distributed by drug giant **GlaxoSmithKline (NYSE: GSK).** In the last completed quarter, Engerix-B delivered $194 million in revenues. HEPISAV-B delivered superior protection to Engerix-B (95.4% versus 81.3% in recently concluded Phase III trial and 90% versus 65.1% for the diabetic population in the trial).

It is critical to note that Engerix-B has requires an administration of three separate doses over a six-month calendar. HEPLISAV – B was effective in two doses over a one-month period. The compliance rate for the current three dose regimen is just over 50%. A one-month regimen should obviously bump that compliance rate up significantly perhaps into the low to mid 80s. Combined with greater protection rates, HEPLISAV-B could be 50% to 100% more effective in making the hepatitis B population effectively vaccinated.

Outlook:

The company has turned over 14,000 individual trial sets (10,000 for HEPLISAV-B, 4,000 for Engerix-B) which it believes shows conclusively that safety levels between the two vaccines are similar. As I stated in a recent post of mine, Cowen & Co. concluded that the FDA moved its date back as it is struggling to "manage" its workload given the amount of data that needs to be sorted through and analyzed. This seems logical and I fully expect HEPLISAV-B win approval at its PDUFA date in mid-December.

Obviously, the delay does not help the company's cash flow situation. Over 2015, Dynavax burned cash at an approximate rate of $25 million a quarter. The company did end 2015 with just over $195 million in cash on the balance sheet so that appears manageable.

Dynavax will probably need additional funding when HEPLISAV-B is approved in order to roll out sales. It could go about this several ways. It could wait for FDA approval and do a dilutive secondary offering hopefully in a better environment. It could do a debt only deal like the one **Relypsa (NASDAQ: RLYP)** just successfully did to raise $150 million in funding to continue to roll out its new hyperkalemia drug Veltassa. Dynavax might also be tempted to do a distribution deal with a larger player with an established salesforce. This would involve a large upfront payment, milestone payouts, and, of course, a percentage of overall sales as royalties. This would solve a host of problems and seems like it always could be a possibility.

Finally, a large buyer could make Dynavax an offer to purchase the entire company outright. Subtracting cash, the company is currently valued at approximately $400 million. So what is a company that has a promising mid-stage oncology as well as asthma compound along with a vaccine that is clearly superior to the current standard, which is running at an $800 million annual sales rate worth?

In the current bearish environment around the biotech sector right now, that is hard to ascertain. However, it seems obvious that the value is much, much higher than the the market is currently putting on Dynavax. If I were Glaxo, I would happily pay over $1 billion just to pick a much superior hepatitis B vaccine franchise and have that market's revenues continuing to roll into their coffers, especially since they already have all the logistics and sales force in place.

Recommendation: Buy DVAX up to $20.00 a share.

Position: Long DVAX

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