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**Recent Events: Dynavax's novel hepatitis B vaccine, HEPLISAV™, is in the final stages of development, with two Phase 3 registration trials in process; a universal flu vaccine entered clinical trials in 2010, with just-released preclinical data confirming its potential efficacy and dose-sparing benefits; \$41 million was raised in a recent financing, bringing cash at June 30, 2010 to approximately \$57.4 million.**

### KEY CONSIDERATIONS

- Dynavax's HEPLISAV hepatitis B vaccine holds the potential to become the standard of care in a projected \$1 billion worldwide market, owing to its enhanced immunity and superior convenience compared to the current market leader.
- HEPLISAV has been shown to be safe and efficacious in 10 trials and more than 2500 subjects. In head-to-head trials with the market leader, it provided enhanced immunity in less time and with fewer doses -- two vs. three doses in one vs. six months.
- Dynavax's second potential blockbuster candidate is a universal flu vaccine that currently entered Phase I development. It's designed to offer protection against divergent flu strains as well as increase the efficacy and potentially reduce the dose of standard and pandemic flu vaccines. Novartis supplies a key component of Dynavax's universal flu vaccine and has an option to participate in development and commercialization.
- The company is developing therapies for hepatitis B and hepatitis C infections. Both are being offered for partnership based on Phase 1b data.
- Pharma partners have provided funding for programs in other areas and leveraged Dynavax's expertise in infectious disease. AstraZeneca has funded a program in asthma / COPD since 2006. The GlaxoSmithKline program expects to have a product candidate ready for human trials this year.
- Average net cash usage for Q1 and Q2 of 2010 was \$12 million/quarter.

### Dynavax Technologies Corporation (Nasdaq: DVAX)

Recent Price:	\$1.85 - \$2.01
Shares O/S:	86.6M
Approx. MktCap:	\$160M
Cash 6/30/10:	\$57.4M
Fiscal Year Ends:	Dec. 31

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### HEPATITIS B VACCINE

The company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to elicit enhanced protection more rapidly and with fewer doses than current licensed vaccines. Two Phase 3 trials are ongoing. One is a Phase 3 trial in chronic kidney disease patients, the other is a Phase 3 lot-to-lot consistency and safety trial in adults over 40 years of age. Immunizations of more than 2,400 patients in the lot-to-lot consistency and safety study is complete. The study will finish in May 2011. This timeline allows Dynavax to plan the submission of its application for licensure, or BLA, before the end of 2011. HEPLISAV's safety profile has been shown to be equivalent to that of the market leader, Engerix-B from GlaxoSmithKline. Patient enrollment and immunization in the chronic kidney disease study is ongoing.

HEPLISAV has demonstrated superior immunogenicity in multiple Phase 1 and Phase 2 trials in the general adult population and in chronic kidney disease patients, and in two Phase 3 trials in adults that tested HEPLISAV head-to-head with Engerix-B. Data from a Phase 3 trial comparing two doses of HEPLISAV on a 0,1 month schedule with three doses of Engerix-B on a 0,1,6 month schedule demonstrated the enhanced immunogenicity provided by HEPLISAV. In subjects over age 40 who are typically more difficult-to-immunize, two doses of HEPLISAV protected 97 percent of subjects vs. three doses of Engerix-B which protected 75 percent of subjects.

Compliance with the recommended

dosing regimen of the current category leader is understandably problematic and low. Few vaccinated individuals complete the six month regimen, and as a result, many do not acquire the immunity needed to fight the infection. With close to 100 percent immunity in two vs. three doses over one vs. six months, HEPLISAV is expected to significantly increase compliance and immunogenicity of those who are vaccinated, driving it to category leadership.

### HEPATITIS B VACCINE MARKET

The adult hepatitis B vaccine market, projected to exceed \$1 billion worldwide, is large and growing. Vaccine usage is driven by CDC recommendations for vaccination, and the key market segments include approximately 750,000 patients with chronic kidney disease in the US and key European markets, large and growing populations of HIV-infected patients, or those with chronic liver disease, populations with high risk behavior, and travelers to endemic areas. Most governments have mandates to vaccinate healthcare workers and first responders, such as police and fire personnel. Between 0.5 and 1.2 million people with chronic hepatitis B infection die annually, mostly from infections that result in liver cancer.

A key segment for HEPLISAV is the chronic kidney disease market. Chronic kidney disease almost inevitably leads to end-stage renal disease, or ESRD. These subjects respond poorly to current vaccines, and require 8 to 12 dose equivalents (vs. 3 doses for the general population). Even with this aggressive vaccination regimen, approximately 35 percent of these immunocompromised ESRD patients do not respond to vaccination and 20 percent require boosters. Vaccination for these patients occurs regularly at dialysis centers, making it a renewable and easily serviceable market.

Dynavax plans to sell HEPLISAV directly into concentrated markets (such as kidney dialysis centers) as well as use multiple

distribution channels such as specialist sales alliances and distributors, and to gain market penetration with a premium-priced, high margin product, manufactured at its own licensed facility in Dusseldorf Germany.

### UNIVERSAL FLU VACCINE

The company's novel universal flu vaccine entered a Phase 1 trial in late June. Proof-of-concept is expected by 2011, and rapid development is possible. The candidate vaccine is designed to offer protection against divergent strains of influenza as well as increase the efficacy and potentially reduce the dose of seasonal and pandemic flu vaccines.

Dynavax's approach is based on combining two highly conserved antigens which offer protection against divergent strains with a proprietary second-generation Toll-like Receptor 9 (TLR9) agonist which works to enhance efficacy and enable dose-sparing of flu vaccines. Dose sparing could extend the quantity of seasonal and pandemic flu vaccines and help avoid shortages.

The company's research and development program has been partially funded by grants from the National Institutes of Health. Dynavax has established a worldwide supply and option agreement with Novartis Vaccines and Diagnostics, Inc. for the universal flu vaccine program. Once proof-of-concept data is in hand, Novartis has a right of first refusal to become Dynavax's commercialization partner. If not, the supply agreement remains in place.

### HEPATITIS C THERAPY

Dynavax believes its hepatitis C therapy candidate, called SD-101, may represent a potentially attractive opportunity. Dynavax's studies appear to differentiate the compound from standard-of-care and emerging treatments for chronic hepatitis C virus infection. The therapy utilizes a novel second-generation Toll-like Receptor 9 (TLR9) agonist that appears to be well tolerated and may offer a more effective option in the \$3 billion therapeutic market for patients chronically infected with the hepatitis C virus. Phase 1b data was presented at the 45th Annual Meeting of the European Association for the Study of the Liver in Vienna in April 2010.

### HEPATITIS B THERAPY

Dynavax's hepatitis B therapy, called DV-601, is currently in Phase 1b clinical development, with data due before the end of this year. This novel treatment approach, which for the first time combines both the surface and core hepatitis B virus antigens, may offer a more effective therapeutic option for the more than 350 million

patients worldwide chronically infected with hepatitis B. The infection can lead to cirrhosis of the liver and liver cancer. The more than \$1 billion spent on current therapies delivers only modest benefit.

### AUTOIMMUNE-INFLAMMATORY/GSK

Dynavax and GlaxoSmithKline entered into a worldwide strategic alliance in 2008 to discover, develop, and commercialize novel TLR inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. Each indication has the potential to generate future development and commercialization milestones totaling approximately \$200 million. GSK can exercise an exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances, after which GSK would carry out further development and commercialization of these products. In turn, Dynavax would receive tiered, up to double-digit royalties on sales and has retained an option to co-develop and co-promote one product. In February 2010, Dynavax selected a candidate for clinical development in its collaboration with GlaxoSmithKline, and clinical development is planned to begin by year-end 2010.

More than 20 million individuals in the U.S. and Europe have autoimmune diseases such as lupus, psoriasis, and rheumatoid arthritis. Key biologic drugs used to treat these conditions generate

over \$15 billion in worldwide sales each year. The TLR inhibitors developed in this alliance have demonstrated a highly targeted effect on key immune cells and pathways that play a role in multiple autoimmune and inflammatory diseases. In contrast, currently marketed and pipeline products are broadly immunosuppressive with variable efficacy and substantial toxicity.

### ASTHMA THERAPY/ASTRAZENECA

Together with AstraZeneca, Dynavax has developed a novel, first-in-class candidate drug for asthma, called AZD1419. This therapy uses a second-generation Toll-like Receptor 9 agonist and represents a new strategy for the treatment of allergic respiratory diseases. It is designed to modify the course of a respiratory disease by changing the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms.

Analysts estimate that therapies for asthma and chronic obstructive pulmonary disease, or COPD, currently represent a \$15 billion category. The biggest sellers are corticosteroids and bronchodilators, which treat the symptoms of these respiratory diseases. AZD1419 is intended to be a disease modifying therapy that has demonstrated the potential to inhibit and induce durable changes to the allergic response that causes the symptoms.

## SUMMARY POINTS

- **Dynavax is in the final stages of clinical testing of its lead vaccine candidate, HEPLISAV. It has been shown in multiple clinical trials to provide enhanced protection against hepatitis B infection with fewer doses and in a shorter period of time than GSK's Engerix-B, the current category leader. The company expects to submit a BLA before the end of 2011.**
- **Multiple news events will mark progress towards this goal, including completing all immunizations, safety assessments by an independent safety monitoring committee, completion of a smaller trial in chronic kidney disease patients, and potential commercialization partnerships/distribution agreements. Each of these events typically represents value inflection points.**
- **In Dynavax's pipeline, the universal flu vaccine candidate recently moved into a Phase 1 study. A program in partnership with GlaxoSmith Kline is being readied for human testing, the entry into which will generate a significant cash milestone for Dynavax.**
- **Dynavax is one of the few remaining independent developers of vaccines for important commercial markets. The vaccine industry is undergoing robust growth and several mega deals of recent vintage (Pfizer/Wyeth and J&J/Crucell) evidence large pharma interest in the category.**
- **Dynavax's cash position will take it well into 2011. Partnerships are being sought to fund non-core assets and to provide potential incremental clinical support.**

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