DYNAVAX TECHNOLOGIES CORP
Form DEFA14A
November 12, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of

the Securities Exchange Act of 1934

(Amendment No.)

Filed by the Registrant x Filed by a Party other than the Registrant ¨

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DYNAVAX TECHNOLOGIES CORP.

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DYNAVAX

Moderator: Michael Ostrach

November 10, 2009

8:00 am CT

Operator: Thank you for joining us for today s Dynavax Conference Call. As a reminder, today s call is being recorded.

Participating on today s call are; Dr. Dino Dina, President and CEO; Michael Ostrach, Vice President and Chief Business Officer, and Jennifer Lew, Vice President of Finance.

I will now turn the call over to Mr. Michael Ostrach. Please go ahead, sir.

Michael Ostrach: Thank you, Elizabeth. Today, we announced an agreement to acquire Symphony Dynamo, including approximately $20 million in unrestricted cash to support HEPLISAV s registration trials. A copy of our press release can be found on our Web site, at www.dynavax.com.

On today s call, we need to advise that we will be using forward-looking statements that are subject to a number of risks and uncertainties including statements relating to the timing of stockholder approval of this transaction, the nature and timing of planned clinical trials of HEPLISAV and our other product candidates and the development in commercial plans and expectations for HEPLISAV.

Actual results may differ materially due to the risks and uncertainties inherent in our business, including whether this transaction will be approved by stockholders, whether successful clinical development and regulatory approval of HEPLISAV can occur in a timely manner or without significant additional studies or difficulties or delays in development, our ability to obtain additional financing to support commercialization and development of HEPLISAV and our other operations, possible claims against us based on the patent rights of others and other risks detailed in the Risk Factors section in our current SEC reports. Dynavax undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Specifically for today s conference call, I would add that the transaction with Symphony Dynamo will require Dynavax stockholder approval, and Dynavax expects to submit a preliminary proxy statement with the SEC in the near future. Dynavax and its directors and officers may be deemed to be participants in the solicitation of proxies from Dynavax stockholders in connection with the exercise of the option to acquire the Symphony Dynamo equity.

Information about the directors and executive officers of Dynavax and their ownership of Dynavax as stock is set forth in our proxy statement for Dynavax s 2009 annual meeting of stockholders, which can be obtained from the SEC. Investors can obtain more information when the proxy statement relating to stockholder approval of the issuance of shares and other consideration in connection with the exercise of the option becomes available. This proxy statement and any other documents filed by Dynavax with the SEC may be obtained free of charge at the SEC Web site, at www.sec.gov. Investors should read the proxy statement carefully when it becomes available before making any voting decision because it will contain important information.

Finally, and now I would like to turn the call over to our CEO, Dino.

Dr. Dino Dina: Thank you, Michael. Had I known that we had such an introduction, I d have caught a few minutes more of sleep today.

So today s announcement is a significant accomplishment for Dynavax, and it helps us achieve the important corporate objectives. First, we secured approximately $20 million in cash to fund HEPLISAV, which represents the majority of funding required for the remaining registration trials. With the cash funding from this transaction, we can focus on the implementation of our commercial strategy for HEPLISAV, which includes selling directly to concentrated market segments and has a key partnering strategy to expand the reach for the enhanced hepatitis B vaccine.

Second, we regained the rights to our hepatitis C and cancer therapy programs. As we ve mentioned in recent announcements, our hepatitis C therapy has completed successfully a Phase IB trial, and we have now terminated our obligation to spend the remaining $20 million under SDI agreement on hep C, and instead we intent to prioritize partnering to complete the development of this therapy.

Now let s spend a minute reviewing the specific terms of the transaction. Together with Symphony Capital, we ve negotiated new terms for our option to acquire Symphony Dynamo, and the agreement includes the following terms. We will acquire the remaining cash in SDI, which is approximately $20 million, and in return for that, we will issue to Symphony 13 million shares of our stock, which translates to a price of $1.57 per share.

Upon closing of the transaction, Symphony is expected to earn approximately 24% of our total shares outstanding. We will also issue new 5 year warrants to Symphony for 2 million shares of our stock at a ((inaudible)) price of $1.94 per share and cancel the preexisting Symphony warrants.

In addition, we will reacquire the rights to proprietary technology for hepatitis C and the cancer therapy programs. As I mentioned, hep C has shown very good safety in the Phase IB study, and we have seen also notable and reproducible viral load reductions in treating people that have chronic hepatitis C infections. With the trial reaching its completion and no further funding obligations, we have decided to stop spending on this program for the time being. Our key priority now is to seek a partnership to advance the further development of the program. If the partnering activities are successful, Symphony will receive 50% of the first $50 million. That is a maximum of $25 million out of potential upfront payments and development milestones.

Finally, we have agreed to defer the existing $15 million liability for the repurchase of the hepatitis B therapy program due to Symphony in 20 months until December 31, 2012, and convert the obligation, which was previously payable in cash to being payable in stock or cash at our discretion. We will expand our board of directors to include one director designated by Symphony and one independent director acceptable to both Symphony and Dynavax as long as Symphony ownership exceeds more than 10% of the total Dynavax common stock outstanding.

To recap where all of this started and the original agreement in April of 2006, Symphony Dynamo was capitalized with $50 million in cash to fund therapies for hepatitis B, hepatitis C and cancer. The hepatitis B therapy program was repurchased in 2007, and to date, we ve successfully completed a Phase IA and B clinical trials for hepatitis C therapy, which demonstrated safety and reproducible retroviral activity. Under the SDI agreement, we reserved the remaining 20 million to conduct additional studies, which are no longer under planned as the result of the current transaction. Importantly, both Symphony and Dynavax with benefit if we re successful in our partnering efforts, and we ll keep you informed of our progress.

Even more importantly, with this transaction we have secured the majority of funding needed for HEPLISAV s registration trials. In two previous Phase III trials, HEPLISAV has already demonstrated immunogenicity by providing more rapid increased protection against hepatitis B

viral infection. To support licensure, we have planned two registration trials, and the majority of the costs will be funded under the transaction that we announce today. First trial in approximately 600 chronic kidney disease patients has already started enrolling, and the second trial is planned to start at the beginning of 2010. It would be conducted in adults over 40 years of age to demonstrate lot to lot consistency for our manufacturing process.

In addition to our (involvement) in the regulatory process, we have the commercialization strategy for HEPLISAV, which targets servable high margin segments to obtain maximum value for Dynavax and our stockholders. For concentrated market segments such as chronic kidney disease patients, we intend to approach the market directly. Our goal is to sell as much of our HEPLISAV capacity to this segment and to capture the highest possible price for the vaccine we can produce in our Düsseldorf facility.

We also intend to reach broader segments in the U.S. such as chronic liver disease and HIV segments, and for markets outside of the U.S., we are pursuing partnering agreements to broaden the reach of these programs while providing additional cash for our HEPLISAV program. The funding from today s transaction will provide us with an important time window to explore appropriate partnering opportunities for HEPLISAV in broad market segments and internationally.

Just to remind you then of the rest of our pipeline, we are continuing the development of hepatitis B therapy in the Phase IB trial, which requires only a modest investment to reach data in the second half of next year. We also are continuing our activities for the universal flu vaccine program that is still in preclinical development. We re actively exploring funding options, including grants and other forms of support, to move the state of the art approach to for influenza prevention into the clinic next year.

Our remaining programs, which include asthma and interventions in autoimmune disease, are under partnership agreement. We provide a valuable portion of our current revenues and future potential milestones as achieved.

I ll now turn the call over to the operator and take questions.

Operator: Thank you. The question-and-answer session will be conducted electronically. If you would like to ask a question, please do so by pressing the star key following by the digit 1 on your touchtone telephone. If you are using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Again, that is star 1 for questions, and we ll pause for a moment to allow everyone a chance to signal. Once again, ladies and gentlemen, that is star 1 for questions or comments at this time.

And it appears that we have no questions.

Dr. Dino Dina: I think that there is a definite a possibility that, as it happened last time, this is due to people s inability to sign in and ask questions. And so I apologize for those of you that may have questions and have not been able to ask them. We are, of course, available to take those by phone if you want to call the company directly.

But let me complete then our report today by thanking you for your interest and reiterating that the transaction that we just completed with Symphony represents really an important accomplishment, and it helps us meet several corporate objectives.

By securing approximately $20 million in cash for HEPLISAV, we ll be able to fund the majority of future development costs for registration trials that are ongoing and that, with these fundings secured, we can now approach partnering opportunities for HEPLISAV that can be negotiated under much better terms.

Regaining rights to hepatitis C and cancer therapies allow us to focus resources on HEPLISAV on one side and then to start pursuing serious partnering activities to try and continue the development of hepatitis C. We would like to call on our stockholders and invite them to vote their proxy quickly as we anticipate the closing of this transaction in the first quarter of 2010.

We look forward to providing you corporate and pipeline updates as we continue with the implementation of our plans, and again, let me invite you to call us directly with your questions.

Thank you.

Operator: Once again that does conclude today s conference call and we thank you for your participation.

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