
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 8-K

Current Report

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): July 20, 2011

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware
(State or other jurisdiction
of incorporation)

33-0728374
(IRS Employer
Identification No.)

**2929 Seventh Street, Suite 100
Berkeley, CA 94710-2753**
(Address of principal executive offices, including zip code)

(510) 848-5100
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events

On July 20, 2011 at 9:00 a.m. Eastern Daylight Time, Dynavax Technologies Corporation (“Dynavax”) hosted a conference call and live webcast to discuss its HEPLISAV™ Phase 3 top-line data along with its financial results for the second quarter ended June 30, 2011. A copy of the conference call transcript is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibit

Exhibit No.	Description
99.1	Conference Call Transcript dated July 20, 2011.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DYNAVAX TECHNOLOGIES CORPORATION

Date: July 22, 2011

By: /s/ Michael S. Ostrach

Michael S. Ostrach

Vice President

EXHIBIT INDEX

Exhibit No.	Description
99.1	Conference Call Transcript dated July 20, 2011.

DYNAVAX TECHNOLOGIES CORPORATION**Moderator: (Shari Annes)****July 20, 2011****9:00 a.m. ET**

Operator: Good day, ladies and gentlemen and welcome to the Dynavax Top Line Phase 3 Data and second quarter financial results call.

I would now like to turn the call over to (ShariAnnes) of Dynavax (inaudible) investor relations team. Please go ahead.

(Shari Annes): Good morning. I'm (Shari Annes) of the Dynavax Investor Relations Team and I'd like to thank you for joining this call.

Today we reported positive top line results from our Phase 3 trial comparing Heplisav, Dynavax's investigational hepatitis B virus vaccine to a currently marketed HBV vaccine Engerix-B.

Earlier this morning, we also reported our financial results for the 2011 second quarter. Copies of both releases may be found on our Web site.

Participating with me on the call are Doctor Dino Dina, our CEO, Doctor Tyler Martin, president and Chief Medical Officer and Michael Ostrach our Vice President and Chief Business Officer.

Before discussing today's topics, we need to advise that we will use forward looking statements that are subject to a number of risks and uncertainties including statements regarding our tax position, our expectation of confirmation by the FDA of our analysis of lot to lot consistency and our other clinical programs.

Actual results may differ materially due to the risks and uncertainties inherent in our business including the FDA's assessment of the data from the study and any request it may make to conduct additional studies.

Whether successful clinical development and regulatory approval of Heplisav and our process for manufacture can occur in a timely manner or without significant additional studies or difficulties or delays in development, whether our studies can support registration for commercialization of Heplisav, the results of clinical trials and the impact of those results on the initiation and completion of subsequent trials and issues arising in the regulatory process, our ability to obtain additional financing to support the development and commercialization 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 report.

Dynavax undertakes no obligation to revise or update information herein to reflect events or circumstances in the future even if new information becomes available.

I'd now like to turn the call over to Dino Dina, our CEO to walk you through the topline results of our Phase 3 trial. As we will make an oral presentation of the full results of the study at ICAAC on September 18 in Chicago, we will be discussing the results of our primary end point analyses and leave most of the secondary end point analyses to ICAAC and other medical meeting posters and presentations.

At the conclusion of Dino's comments, Doctor Tyler Martin, President and CMO will also provide perspective on the data and then we'll open the call to Q and A in which Tyler and Michael Ostrach will participate.

Dino?

Dino Dina:

Thank you, Shari. And good morning to all of you and thank you for joining this call.

Before I jump into the Phase 3 data and provide my perspective on that, I'd like to comment about our second quarter financials and specifically our cash position of \$61.7 million.

Earlier in the year we committed to maintaining a cash balance of more than one year of cash and we've clearly accomplished that in the second quarter. We intend to use and continue to use a variety of mechanisms available to us to maintain such a strong cash position and therefore, enabling to maintain flexibility to evaluate any potential opportunities and of course, continue to develop Heplisav and bring it to completion.

Getting then to the results of the study, let me remind you that the – in this study we evaluated it to those regiment of Heplisav given that zero and one month compared to three doses of Engerix given at zero, one and six months in 2,449 healthy adults and the age was 40 to 70 years.

The results we are reporting today for this study are clearly consistent with that obtained before you know, our prior studies. Data showed that Heplisav is as safe as Engerix-B, superior to Engerix-B in terms of rapid onset, seroprotection and superior peak protection. What's new and remarkable is that duration of immunity is also vastly improved over Engerix.

With respect to the consistency analysis of the three consecutively manufactured lots of Heplisav we've concluded that the study showed consistency based on the complete immunogenicity data demonstrated by the three vaccine lots over the six months following second immunization.

By the way, we have provided a clear view of the data in a graph that is at the bottom of our press release as this may not be present in data reported through various agencies. Anybody who wants to see that can go to our Website and see clearly there and I think is quite definitive on scientific grounds that the three lots behave in a very similar way throughout the duration of the study by two measures, GMC and SPR which are different measures but consistent again, throughout the study.

We met the pre-specified consistency criteria four out of the five time points. It all – these time points each lot was superior to Engerix as well. Where we missed one lot was going to be slightly higher than the pre-specified 150 percent upper limit as compared to the GMCs of the other two vaccine lots.

This was due to a higher than expected standard deviation and not to an inconsistency in how the lot was manufactured or behaved.

So, these are the data in FDA and we expect to have confirmation of our analysis in the near future.

We're confident that our assessment of (inaudible) data is accurate and indicates that our manufacturing process can reliably produce vaccines with a profile that is significantly better to that of Engerix-B.

You know, at the end of the day, and I think that this is the most important aspect and while we're confident that we're going to succeed on scientific grounds in our conclusion that we have achieved consistency and I think Tyler can comment both about the precedents and how this is viewed in terms of how other vaccines have been licensed, if we, by any – for any reason had to do a confirmatory study not only we're prepared to do it but we could complete it in time to incorporate this in a filing that would contain data from both CKD and the HBV 16 and stay on the timeline that we have always outlined for that specific strategy.

So, this, in our view announce that works with – to an inconvenience but our level of confidence that we're going to come out with a confirmation of consistency is high.

Tyler, be useful perhaps if we could comment a little bit more at this point on the safety and how it compares to what we've seen before and the distribution we've seen in – among the two vaccines.

Tyler Martin:

Thank you, Dino. Good morning, everyone.

This protocol included careful, active surveillance for new onset autoimmune disease that was – that would result in a more robust safety evaluation than in our previous trials and we want to make the point that our previous trials did not show evidence for an increased rate of autoimmune disease.

At each visit, subjects were administered a questionnaire to identify signs and symptoms of autoimmune disease. Anyone who developed signs or symptoms of autoimmune disease by that questionnaire was referred for specialist evaluation.

Those specialist evaluations were then sent forward to a committee that we call the Safety Evaluation and Adjudication Committee which consisted of three independent experts at the Mayo Clinic who would assess each of these potential autoimmune adverse events. We also had a data safety monitoring board which is an objective, independent group of experts who could look in an un-blinded fashion at the potential accumulation of events by treatment group.

So, with all that background, and again, it's a very careful, active surveillance plan, I'd like to discuss the results.

There were seven potential autoimmune adverse events reported by investigators to the Safety Endpoint – Safety Evaluation and Adjudication Committee. The Committee determined that five of those events were, in fact, autoimmune adverse events. Further investigation showed that two of them existed prior to study entry so there were a total of three autoimmune adverse events that occurred while on study.

This study included a four to one randomization, therefore, the probability of being assigned to Heplisav was 80 percent for any individual subject. All three of the subjects were in the Heplisav arm. Given the four to one randomization and three events occurring, the probability of all events occurring in the Heplisav arm was 51.2 percent. So, this finding is not unexpected based on the four to one randomization.

I would specifically mention that none of these three cases were serious adverse events. In fact, they were two cases of hypothyroidism that occurred in females and one case of vitiligo that occurred in a male. So, minor adverse events that are expected in the population studied.

We conducted an analysis and forwarded our analysis to both the SEAC and the DSMB looking at the literature and what would be the expected event rate in a population of healthy adults age 40 to 70 for hypothyroidism. Amongst a population of 2,449 subjects we would have expected there to be about 8 cases. So, the fact that there were only three is evidence of the excellent screening that was done at baseline and therefore only three cases occurred on study.

I would also specifically like to mention that there were no cases of ANCA associated vasculitis and no cases of Wegener's Granulomatosis in this trial.

Dino?

Dino Dina: So, you know, I think that we believe that this provides us with a very strong starting point for continuing on our path to filing for approval and I'd like to open it at this point for questions and then revisit some of the issues based on our questions and answers before we close.

Operator: Thank you. Ladies and gentlemen if you have a question or comment please press star then one on your touchtone phone. If your questions have been answered and you wish to remove yourself from the queue you can do so by pressing the pound key. Again, if you have a question, please press star then one on your touchtone phone.

Our first question is from Thomas Wei of Jefferies and Company. Your line is open.

Thomas Wei: Hi. Thanks. I wanted to ask a little bit more about the autoimmune adverse events that occurred in this study. If you – first of all for the hypothyroidism cases was I hearing correctly that those were found because the patients were symptomatic or was that a sub clinical cases hypothyroidism that was really just detected through laboratory measurements.

Tyler Martin: So these – Thomas, these were clinical diagnoses that occurred during the 12 months that subjects were followed up for this study. And again to emphasize the point that one would expect in a population this age of there to be eight events that would occur spontaneously in a population of this age over a 12 month follow-up period.

Thomas Wei: And...

Dino Dina: Also worth noting, Tom, that in the PHAST study the rate of occurrence of this particular disease was approximately 0.1 percent. And that's exactly what we've seen in these studies. So, there's really nothing out of the norm in the result.

Thomas Wei: And what has happened subsequently to those patients who – these three patients who did develop these autoimmune events. What is the treatment and the outcome like for those particular side effects?

Tyler Martin: So, the treatment for hypothyroidism is to be put on thyroid hormone which is – the brand name is Levothyroxine and it's a very common drug that women over the age of 40 are commonly on. In fact, my mother was prescribed Levothyroxine just this last week. So, it's a very common event that occurs in older women.

The subject with Vitiligo, there is no treatment for Vitiligo and I will just make a comment that the SEAC struggled with this particular case because the diagnosis occurred because the subject received a sunburn and as a result of the sunburn they identified that the person had hypo pigmented patches in their skin. The sunburn occurred while the subject was on study but of course, the onset of when the actual Vitiligo occurred is unknown. So, to be conservative, the committee considered it to be a new onset autoimmune adverse event because, in fact, the diagnosis was made on study but the actual onset in that case was difficult – well, in fact, impossible to assess.

Thomas Wei: And can you share with us with the other, I guess, the other four autoimmune adverse events that were submitted to the committee. What were those? And in particular to the two that were deemed not to be autoimmune adverse events?

Tyler Martin: So, the two that were deemed not autoimmune adverse events, I must say I would have to go back and review their information because we focused on those that the expert committee determined to be autoimmune adverse events for our analysis.

The two that we excluded from the analysis were two other cases of hypothyroidism but in the screening samples for those subjects they were found to be hypothyroid at screening and therefore they were excluded as not being new onset cases.

Thomas Wei: I'm sorry. One last question and I'll jump back in the queue. The two that were deemed not to be, were they on the Heplisav arm?

Tyler Martin: Yes. They were.

Thomas Wei: So, it would have been – so excluding the two hypothyroid – I'm sorry – just to be clear – the two that were deemed not to be autoimmune adverse events were in the Heplisav arm.

Tyler Martin: The two that were determined not to be – the two that were not new onset events, that is they were hypothyroidism that was pre-existing before they came into the study were in the Heplisav arm.

Thomas Wei: And then the two others, that's basically what I was asking. The two other cases, were those in the Heplisav arm? Or in the – in the control arm.

Tyler Martin: They were also in the Heplisav arm.

Thomas Wei: OK. Thank you.

Operator: Thank you and this question is from Phil Nadeau of Cowen. Your line is open.

Phil Nadeau: Good morning. Thanks for taking my questions. First on the autoimmune reactions, I believe in the data that you've presented previously for the Phase 3 population as a whole, there was a mis-balance in autoimmune reactions that actually favored Heplisav. If the – if I remember the incidents correctly it was a 0.2 percent autoimmune event rate for Heplisav in the Phase 3 dataset as a whole and 0.4 percent for Engerix.

So, when I put this morning's data into the context of all the other Phase 3 data it seems like the autoimmune events are now perfectly balanced about 0.2 percent for Heplisav and 0.2 percent for Engerix. Is my analysis there correct? Is that what you guys also see when you integrate the autoimmune events now from the – all of the Phase 3 studies that you've done?

Tyler Martin: Yes, Phil, that is correct. To be specific, the analysis for Heplisav is now 0.22 percent and for Engerix is 0.28 percent.

Dino Dina: And that's based on 4,500 people for Heplisav and roughly 1,500 for Engerix.

Phil Nadeau: OK. That's great. That's very helpful. Then, on the manufacturing consistency data, just one clarification, looking at the graph that's in the press release on your Website it actually looks like two of the bars went above the upper 50 percent...

Tyler Martin: Yes. So...

Phil Nadeau: Is that a misprint? What's the discrepancy between the one that you're talking about and the press release in the conference call and what seems to be the difference?

Tyler Martin: Yes, so Phil, there's actually not a discrepancy. The bars that are shown on the slide represent ratios of the GMC from Lot A to Lot B so the two bars that are out of the bounds are Lot – the ratio of Lot 10 to Lot 8 and the ratio of Lot 10 to Lot 9. So the point that Dino made in his commentary is that it was, in fact, the higher immunogenicity of Lot 10 versus eight and nine that resulted in those two bars at that one time point being out of the pre-specified range.

Phil Nadeau: OK.

Dino Dina: So, in fact, if you look at the red bar, which reflects eight versus nine, its entirely within the bounds all the way through the study. So, the big issue we're dealing with is that lot 10 was slightly more immunogenic than the other lots and that the increased standard deviation, which is obvious from the bars on the graph caused it to fall outside the limits.

But as you can see the GMCs per set, which are the symbols in the middle standard deviation bars are very consistent throughout this study and very similar.

Phil Nadeau: OK. In your prepared remarks, you briefly mentioned that Tyler would provide us some precedent with how the FDAs dealt with situations like this in the past. Tyler, do you have any examples where this has happened and what the FDAs done about it?

Tyler Martin: So I would just say that from a historical perspective this is an area that is often subject to negotiation. So, one specific example I can give you that's fairly recent is the Prevnar-13 approval which is a Pfizer pneumococcal vaccine. For Prevnar-13, in their consistency studies, three of the 13 serotypes missed the pre-specified criteria and that product was approved based on what I assumed was negotiation. You can specifically find that by looking at the FDA reviewers comments beginning on the clinical review, page 252.

Another example would be the recent approval of Menveo, which is the Novartis meningococcal disease. For that product there was a higher standard deviation than most products have and, therefore, the pre-specified consistency criteria were point five and two. And you can see by the figure that we've provide with you, that had we pre-specified those criteria, point five and two, all of our end points would have been within that boundary.

So this is often an area that, for vaccine approvals, is based on negotiation when you look at the data that's available.

Dino Dina: You know, I think it's important to consider that while some of self-appointed experts out there may define this as a failed study that consistency lot compares to, are not in the same category as efficacy and safety which are definitive prerequisite requirements for approval. And while, in fact, we have to show consistency for approval, the whole notion that this would be considered a failed study simply because one of the points was slightly higher than the others is down right silly.

Phil Nadeau: OK.

- Tyler Martin: I – I – can I just make one other comment on this point. It's really important one that, you know made before and that is each of the HEPLISAV lots at each of these time points were superior to the Engerix lots.
- So in fact, what we actually have in this scenario is at week eight, one of them was more superior than the others. So, you know, we have consistency of superiority versus the comparative product throughout the study and consistency amongst our own products over the other time points that we mentioned in our – in the – in the figure.
- Phil Nadeau: OK. And you mentioned that you submitted this data to the FDA, essentially get their signoff on it. Do you have a sense of when they'll get back to you and what type of communication that will be?
- Do you need a – might be a negotiation here or is it possible to look at the data and say that seems fine to us and clearly communicate that to you.
- Dino Dina: I don't think everything is ever that simple with any of the regulatory agencies. But I think we have reasons to believe that we'll get an answer soon as we'll be able to comment on that when it's formalized and particularly in the form of a letter or a fax that would reflect their views.
- Phil Nadeau: OK. And in the worse case, if you had to do a new consistency trial, it sounds like you could do a 12-week study. Do you have a sense of the size of that trial and the cost? Is it a relatively small study?
- Tyler Martin: There's a range and that would depend if we were requested to do another study it would depend on how we would negotiate that new study. So for instance, if we were to use younger patients which would have a smaller standard deviation, we could have a smaller sample size. If we redefine the consistency criteria to be between the point five and point two range, we can use a smaller sample size. So, there's a variety of variables that we would have to negotiate out, but it could be very straightforward.

And again, if you look at the data we have, Phil, that we provided in this figure, you can see simply redefining the endpoint to 12-weeks would meet those criteria with the same

Dino Dina: So as I mentioned earlier this is definitely not on the critical path to approval and at worst, if we were to redo it, it'd be essentially a modest cost and an inconvenience, but we could still fit it in our basic plan for filing in the first half of next year.

Phil Nadeau: OK. And just one last question, what do think happened to that lot with the eight-week time point? You mentioned it doesn't seem to be a manufacturing issue or discrepancy. Is it just simply a fluke that in some number of patients they had better antibody titers at week eight than you would have expected?

Dino Dina: I think it was really strictly related to the a higher standard deviation– a miscalculation on our part to what the standard deviation would be in this population. Based on looking at previous studies. I think it's obvious if you look at the data that the error bars on the first point are much wider than those on the later points and that was unexpected and that's the nature of the problem.

Phil Nadeau: OK. That makes a lot of sense. Thanks for taking my questions.

Operator: Thank you. And next question is from Katherine Xu of William Blair. Your line is – your line is open.

Katherine Xu: Great. Thank you. Good morning. So any other, from your studies have you seen any hypothyroidism from indirect Engerix-B arm ever?

Tyler Martin: Yes, in our previous integrated autoimmune event slide, Katherine, that you've seen, we're publically shown on many occasions, there was – there has been one case in the Engerix arm from previous studies.

Dino Dina: So it was one in a thousand in that study and it's two in two thousand in this study.

Katherine Xu: Great. The SPR for this study is ninety percent, I mean it's kind of lower. I mean, it's good, but it's lower than what we saw before. I'm just curious, is people dropping out or, why that's the case and also why did it climb to 92 percent at one year?

Dino Dina: Well it's still really consistent, Katherine with what we've seen before. And I can tell, from my perspective, that that's one of the things that happen when you get older. This population was 40 to 70, instead of 40 to 55, and so, what you see is the impact of having an older population affecting the outcome by approximately five percent, it was 95 percent, as I recall.

In the PHAST study climbing to 98 and it's 90 percent climbing to 95 in this study so – the important point, though, that I'd like to remind you is that not only the same thing happens to Engerix but it happens more to Engerix instead of 80 percent, 82 percent, it's 70 percent and it climbs to, what is it, 72 percent versus 75 percent.

And once more, let me go back to the point that I made earlier, you know 11 months out, HEPLISAV is still than 90 percent and Engerix is close to 50 percent six-months after the last immunizations. So one of the critical issues that is still unresolved in Hepatitis B immunization in adults is the duration of immunity and I think we can make a huge difference from that point of view.

Katherine Xu: All right. I just want to – since the FDA is known to go by the book, so I just want to assess your level of comfort, you know, if you go in and do the negotiations, data looks compelling but if the eighth week is the primary endpoint, you know, of course, you didn't specify a wider interval, I mean, what are your sense basically on your level of comfort and confidence on that negotiation?

Dino Dina: You know, what we found consistently and that is really how we got off clinical hold in the past is that FDA responds very well to scientific arguments. That is their mantra and I can tell you that we found that if you approach them on rational grounds, they respond in kind. And given the precedent and given, as you pointed out, how solid that data are, I think we're very comfortable that they will agree with our analysis. Needless to say, we need to see their response before we can be sure. But I think our level of comfort is high.

- Katherine Xu: OK. So, again, when do you think you will hear and can you give us an interval?
- Dino Dina: There are not PDUFA timelines that mandate responses on these kind of, you know, direct interaction. We have every reason to believe it will be in the near future.
- Katherine Xu: So on the filing strategy, I mean, are you pretty much thinking that you're going to do the filing together of Protocol 16 & 17 together next year, same quarter next year or ...
- Dino Dina: No that decision has not been made and, you know, once we have settled this issue, I think we'll be in a position to start talking to FDA about a pre-BLA meeting which we hope will happen this fall and it's in that meeting that we will identify a strategy and get their concurrence on that strategy. So the option still exists for filing with 16 alone, we simply can't say at this point. And, you know, we've always said that that was going to be a negotiated outcome and we'd either file with 16 alone by the end of the year or with both in the 2nd quarter of next year and that's unchanged.
- Tyler Martin: And I would just reinforce, Dino's point to say that the team is working towards and executing on the support that's required to be able to file 16 alone by the end of the year, should that pathway be clarified.
- Katherine Xu: Thank you.
- Operator: Thank you. And the next question is from Duane Nash of Wedbush Securities. Your line is open.
- Duane Nash: Good morning, so we've briefly addressed this already, but on the lot to lot consistency topic, can you discuss the likelihood that the company would institute any changes in the manufacturing process? And of related note, the two precedents that Dr. Martin discussed of prior third-party trials which had issues but were proved anyway. Do we know if there were any manufacturing changes there or if the FDA accepted the data purely based on scientific arguments?

Dino Dina: You know, we – we're not planning any manufacturing changes. In fact, we are manufacturing commercial lots starting this week, so I don't believe that that's going to be an issue.

Duane Nash: And the two precedents that Dr. Martin discussed? Do we know if they made any manufacturing changes?

Dino Dina: We have no visible to those issues.

Duane Nash: OK. Great. Well thank you very much.

Operator: Thank you. The next question is from Tom Brakel of Federated Investors. Your line is open.

Tom Brakel: Yeah, hi Dino and congratulations with the data.

Dino Dina: Thank you.

Tom Brakel: I guess could be said. I was just wondering, do you have a sense that supports the favorable cost-benefit analysis regarding vaccination and diabetes patients?

Dino Dina: You know, we have commented on that based on past results. We will present data on various hyporesponsive populations in the next meetings. But I think it'd be reasonable to expect that HEPLISAV is better than Engerix you know of those target populations and let me leave it at that.

Tom Brakel: All right, good. All right, thanks a lot.

Operator: Thank you again. If you have a question, please press "star then one" on your touchtone phone.
Our next question is from Alan Leong of Biotech Stock. Your line is open.

- Alan Leong: Oh, thanks for taking my question. Any plans for an extension study on this seroprotection rate to recognize, you have one on chronic kidney disease, but any for our normal patients or other groups?
- Dino Dina: You know, what's typically done as part of completing the range of studies that you do with vaccines, you go for approval for a specific population, typically an age group. And then there are small studies, investigators – initiated studies or small studies that are done in specific populations and in our case I think it would be reasonable for us to do such studies in HIV infected individuals and perhaps in chronic liver disease individuals. We will have data on diabetics so I expect that there'll be some rounding up, but those are most likely are going to happen either during the approval process, of course approval.
- Alan Leong: And just a confirmatory question, if you have the – if you file on consistency alone, are there any other small trials that have to be completed between now and hypothesized submission in December?
- Dino Dina: None other than those that we have outlined previously. We have an ongoing study in CKD on boosting patients with – that have previously been immunized and then we have the longevity study, but that will not be required for filing.
- Alan Leong: Thank you.
- Operator: Thank you. Ladies and gentlemen, this ends the Q&A portion of today's conference. I'd like to turn the call over to Dr. Dino Dina for any closing remarks.
- Dino Dina: Thank you. So I'd like to sort of close by reminding you that we've set for ourselves this year for key objectives. One was to maintain a strong cash position, that's critical, both in terms of supporting our programs, and also continuing our negotiations with potential partners for the commercialization of the vaccine, especially outside of the U.S.

The completion of the Phase III studies and the submission of our BLA and MAA for HEPLISAV, identifying partners for the commercial launch of HEPLISAV and then continuing our earlier program and in particular the clinical of development of universal flu and the TLR nine and seven inhibitors that is part of our collaboration with GSK.

I think we've shown both diligence and success on all of these points. So we are moving forward in a very meaningful consistent and I think timely way.

With the Phase III results we reported today, I think we are definitely one step closer to completing the program and a lot closer to filing. And I think this is a very strong foundation of data that shows not only superiority, but most importantly, and let's not forget that, the impeccable safety of the vaccine.

This really provides us, then, a much stronger basis for continuing our discussions on commercial partnering. I've commented before on the fact that we have a number of initiatives ongoing. Those discussions have been quite active for many months and some new ones have gained momentum recently. The intention in these discussions to anticipate the questions that you're not going to be able to ask is, of course, between our desire to retain profitability and our potential partners' desire to increase theirs. And these are never particular easy discussions but I think that we're on solid grounds and that we will find a very strong partner to commercialize outside of the U.S.

We remain committed to selling the vaccine in the U.S. ourselves, keeping, of course, the option open of a potential alliance with GSK or Merck and those discussions are also underway, although that's all I can say about them at this point in time.

In addition, we've been successful in maintaining a very strong cash position that addresses both the issue of finishing the programs and maintaining a competitive attitude we respect of the negotiations that I just mentioned.

Before closing, I'd like to remind you that we have two partner programs. One is with Astra-Zeneca and the other one is with GSK. We continue to make progress on both of them in the case of GSK autoimmune disease program. We did the Phase I study that has been completed now and we have received the expected \$6 million milestone from them and we're making progress with AZ on the potential start of a clinical program, although we are not yet 100 percent there.

Finally, we did two studies with flu. Those have provided results are completely in line with the preclinical data we have obtained and have shown that the biology and the (pharmaco) dynamic immune response generated by the vaccine are appropriate for continuing the program and moving to a proof of concept study.

Thank you for your attention and your time and we will update you soon again on our progress.

Operator:

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program. You may now disconnect and have a wonderful day.

END