Operator: Good day, everyone and welcome to today's Generex Biotechnology Corporation Investor Conference Call. [Operator Instructions] Please note this call may be recorded. And it is now my pleasure to turn the call over to Anthony Crisci. Please, go ahead.

Anthony Crisci: Hello, everyone. Forward-looking statements included in this presentation are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements relate to future events, or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activities, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements.

In some cases, you can identify forward-looking statements by the use of words such as “may”, “could”, “expect”, “intend”, “plan”, “seek”, “anticipate”, “believe”, “estimate”, “predict”, “potential” or “continue”, or the negative of these terms, or other comparable terminology.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors that are, in some cases, beyond our control, and that could materially affect actual results, levels of activity, performance, or achievements. A more detailed description of these and other risks and uncertainties may be found in our annual report on Form 10-K and other public filings with the Securities and Exchange Commission.

If any of these results or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from what we projected. And any forward-looking statements you read in this presentation reflect our current views with respect to future events and are subject to these and other risks, uncertainties, and assumptions relating to our obligations, operations, results of operations, growth strategy, and liquidity.

We assume no obligation to publicly update or revise these forward-looking statements for any reason, whether as a result of new information, future events, or otherwise.

Now, I’d like to turn over the call to Joe Moscato, President and Chief Executive Officer of Generex Biotechnology Corporation.

Joe Moscato: Good morning, everyone. I’d like to thank our Board of Directors of Generex and NuGenerex, both companies' management teams, and employees, and our shareholders for making this call today; I’d also like to thank all the other interested parties who are attending what you'd like

to find out more about our COVID complete vaccine initiative and how things are going with this potential world-saving initiative.

Today's agenda, NuGenerex Immuno-Oncology listing update; I'll cover the complete vaccine update, our universal vaccine booster plan, our new neutralizing antibody therapeutic plans; update on our Chinese partnership, update on our partnership with Bintai Kinden out of Malaysia; Altucell update and acquisition plans; and update on all of our other subsidiaries and plants.

Before we get into the program, everyone must realize both Generex and NuGenerex are in a quiet period. Generex has three S1s filed with the Securities and Exchange Commission; two of them are effective, one is pending; and NuGenerex has three that are pending which are not effective yet and we are in the process of listing its shares on the NASDAQ Stock Exchange. So, we cannot talk about numbers, projections, or any financial statements, or forward-looking statements that could be deemed gun-jumping or violating any of other securities rules from the regulatory bodies such as the SEC or FINRA. So, I just ask everybody that I can't answer a lot of questions as it pertains to those areas.

But it's important today that we talk about our vaccine program; it has come a long way and we have done a lot of work, and that work has identified the complete vaccine that we're going to give our results to-date from our science team today. What is a complete vaccine? Well, for us, the complete vaccine is three major components: the first component is it's safe; the second component is it's effective and it protects people; and the third is it gives long, long-term memory. Now, long-term memory is something that we've been involved with for over 25 years with all our other vaccine work, that includes our breast cancer--we just had our ten-year data come out six, seven months ago and that ten-year data was quite good as well as significantly positive, and that just proves out that after ten years, we don't need to keep inoculating people with vaccine year after year, which is still the jury out on all the vaccines that have emergency use right now.

So, our hope is that we have a complete vaccine; our results are showing that we're on track for, that they're exceptional in all the areas of testing--which we'll get into today--and our hope is you'll understand where we are with the vaccine and what the potential could mean as a real solution for being the complete vaccine.

So, I'd like to turn this over to Rich Purcell. He's our team leader on the vaccine program and him and his team will go through the three big areas which is the update on where we are with all of our testing; the universal vaccine booster plan we have; as well as a new program which

is neutralizing antibody therapeutic which was borne out of the work we've been doing on the vaccine front.

So, Rich, if you would. And everybody we will be asking questions at the end, so we can answer all of your questions. So, Rich, please take it.

Richard Purcell: Thanks, Joe. Thank you very much, everybody, for joining here this morning. First, I'd like to thank our team: Jason Terrell, our Chief Medical Expert and Chief Scientific Officer; and John Hall, our Senior Director of Clinical Operations. And all of us have been working pretty diligently to move this vaccine ahead; we started this about ten months ago and through a conservative effort through our partners, and I'd like to thank them too. We've been able to make significant progress in actually developing a vaccine; as a small biotech company that hasn't received all the monies that big pharma has received, we've still been able to do this.

So, first, I'd like to thank EpiVax, our partner in computational vaccinology; they've done the algorithms to identify the epitopes that will be most likely to achieve a vaccination for us. Working with CTL, Cellular Technology Laboratories in Ohio, we've done all our T-cell work--spectacular work by them; the University of California in San Diego and Tom Rogers are on our Scientific Advisory Board who's led the antibody work and doing virus neutralization in his BSL Speed Laboratory; Covance, which is doing our preclinical animal immunogenicity study. We don't require toxicology, I think it's important to note that the FDA has said that we do not need to do animal toxicology for our Ii-Key vaccines because with the proven safety previously in our avian influenza vaccine as well as our cancer vaccine, so we don't have to do any toxicology work.

But we do have to prove that the vaccine will elicit the immune responses both T-Cell and antibody responses we seek to provide protection and long-term immunity. So, we're doing this transgenic animal study that I'll talk about later on, and Covance is doing that right now. And I'd like to thank 3M and IDRI, Infectious Disease Research Institute out in Seattle, that has been working with 3M on their adjuvant and has done a mixing study for us to show that our Ii-Key peptides could be mixed with the adjuvant from our clinical program.

So, let's start here with how this program has progressed over the last ten months or so. We've partnered with EpiVax, we licensed their technology; and then selected, out of the thousands of epitopes that are in the membrane proteins of the coronavirus, we've selected 33 that are high probability of being immunogenic and recognized by the human immune system. And we tested those 33; we manufactured 33 Ii-key peptides, and we tested those at CTL and T-Cell assays, and what are

called ELISpot assays. We tested for gamma interferon which measures the Th1, the good T-cell response, CD4 helper cells; measured granzyme B which indicates the presence of CD8 killer cells. We want that activity because we want to kill any virally infected cells and CD8 cells do that; and we tested for IL-5 which indicates the trend towards Th2 which is the negative CD4 response that we do not want to see; that would indicate a potential for cytokine stems and antibody-dependent enhancement disease.

So, those T-Cell response assays came back, and we tested 46 blood samples from patients who had COVID and we tested 30 samples from patients who did not have COVID because they were collected in 2017 and 2018, and therefore we were able to determine whether our Ii-Key vaccines were specifically-generated immune reactions against COVID rather than against normal human blood samples that may have been exposed to previous coronavirus infections.

I just got a note that I'm muffled. I'll try to speak clearly. Thank you. Please tell me if I continue to be muffled; I'll try to speak more clearly.

So, the results of the T-cell assays indicated that we have positive reactions with CD4 Th1 response with gamma interferon; we have positive CD8 response with the killer cells; and we have no indication at all of the Th2 response from IL-5. We're very excited about those results, they were very encouraging.

We also, at the request of FDA, did a cytokine bead array to analyze other cytokines. We measured IL-6 and IL-8, as well as the CXCL9/MIG. And IL-6 is a pro-inflammatory cytokine that has both good and bad effects; good early because they're responsible for the reaction to acute infection and that pro-inflammatory response early is positive to knock out the infection. Late IL-6 can cause tissue damage. IL-8 is an inflammatory cytokine chemoattractant that attracts neutrophils; IL-8 is an indicator of potentially damaging cytokine response. And then the MIG response is an accurate measure of the Th1 t-helper response and it confirms the results of the gamma interferon because it's reduced by gamma interferon, and it's a better measure of Th1 response.

In the cytokine bead array, we've also measured all this against all of our Ii-Key peptides and determined that the IL-6 response is there--which is great for us, it indicates that the CD4 cells are recognizing the peptides and therefore can generate a pro-inflammatory response that's beneficial. IL-8 was elevated in all these samples especially in the early samples from patients who were only three weeks out from having COVID disease as compared to samples that were three and four months out, you

saw the reduction in the IL-8 response, but still high levels of IL-8; we did not induce further levels of IL-8.

So, again, we've demonstrated the IL-6 potential, the MIG potential--the monocyte induced by gamma is MIG, that's the name of that cytokine--and we showed very good correlation between our gamma interferon results and the MIG results confirming that we are skewing towards Th1, which is very positive for the FDA.

And lastly, we did an evaluation of the HLA. Now, HLA is really important for our Ii-Key vaccines; we are human-specific vaccines, we're activating the immune system that is human-specific to the human leukocyte antigen, HLA. That's also the MHC complex, it's the one thing about immunology. The wording they use sometimes gets confusing, but "HLA" and "MHC" are the same thing, and they are specific for epitopes based upon human, mouse, monkey, et cete-ra. It makes it difficult for us to evaluate Ii-Key vaccines in animal models, but there is--there's one and I'll talk about that in a second called the DR4 mice, that is a transgenic mouse that we can do these measurements.

But for humans, we have to make sure that the epitopes that we've selected will cover the population. When you get a transplant, you have to have a transplant match: that's what they do, they match the HLA, and therefore we have to match our epitopes to the human population of HLA alleles. And in our evaluation of HLA, we've identified that the coverage of our vaccine is greater than 95 percent across populations, so we're very comfortable now that we have epitopes of the recognizable human immune system, it will be across the population regardless of ethnicity, and we'll have good coverage of our vaccine.

The other thing we did beyond the immune analysis of the T-cell populations is the antibody binding, and that work has been done at UCSD; we were able to screen serum samples from convalescent patients again, and showed that in an ELISA assay, the Ii-Key epitope peptides did bind to antibodies from the serum--which is very surprising to us because mostly, the antibodies will bind to 3D structures, not linear epitopes like we have. But we did have binding. We took the next step and tried to purify those antibodies from serum samples, pooled serum samples, but, unfortunately, we're unable to purify enough antibodies to do the neutralization assays that we wanted there; I don't believe that the affinity of the linear epitopes was sufficient enough for purification.

So, that was the only one experiment that didn't come out; but, by and large, we do know that they bond, and we do know that they activated T-cells, so we have something to go forward with, and we selected five of the of these Ii-Key epitopes that will bind antibodies and elicit the T-Cell responses we are looking for. And of those five epitopes, we made a

laboratory batch that is currently in an immunogenicity study. And we've also gone to GMP production--we've gone to GMP production at risk, it's a little later than what we would have done if we had the government funding that allowed all the other companies to go and manufacture complete GMP.

Lots of risk, but we had to wait till we had the science first and we've been letting the science drive our decisions all along; and by doing that, we've got a lot of information about the immunological regulation of our vaccine prior to even going to humans because we've been working with ex vivo human samples. We know we have human data, and therefore, our science has been able to direct us and now we've gotten to the point where we've selected these five Ii-Key epitopes and gone to GMP production; two of them are almost completed on the first round of GMP, the engineering run, and the others are currently in the engineering run for GMP.

At the same time, I mentioned before this immunogenicity study. We have transgenic mice with a piece of the human immune system in it called DR4; it's a human allele that could recognize the human-specific epitopes of the Ii-Key vaccine. We vaccinated those animals with and without adjuvant from 3M IDRI at different doses, and we have now sacrificed those animals this week--a little delayed because of the weather and the snowstorm storm delayed it for a couple of days, but it's been done. The spleens were collected and shipped to CTL for the T-Cell analysis and the serum was delivered--they were shipped yesterday and delivered today, the serum analysis for the neutralizing antibody studies that will be done next week. And within ten days or so, we'll have an answer whether we have this complete vaccine.

We know from our historical science that the Ii-Key should activate the T-cell response that's necessary for long-term immunity; the experimental piece of this is will we generate the neutralizing antibody response that we're looking for from the complete vaccine? And we'll have that answer within a few days. And at that point, we'll know whether we have the overall complete vaccine or whether we'll be pushed towards a universal booster for long-term memory--and either way, we're going to go after this booster program. It's been very clear to us that long-term memory and long-term immunity which is required for--if you don't want to have booster shots like with the flu vaccine every year, you have to have long-term memory, and the Ii-Key is designed to produce the long-term immunological memory through the CD or Th1 response, and that's where we're skewing right now. So, we're pretty excited about that.

At the end of the day, however, given that there's a lot of vaccines out there already, we really feel that this is a giant opportunity for us to

evaluate the Ii-Key vaccine as a universal booster on top of the ability to be vaccinated. Why is that important? We're safe, we've got a peptide vaccine--peptide-based vaccine that the FDA has recognized as safe, the fact that they don't ask for toxicology work, and we can respond very quickly to potential variants. We've already made a couple of those variants and we'll be moving forward and testing those variant peptides in our T-cell assays as well. But it's important to note that we can respond quickly, and we can target the immune response specifically to whatever targets we're looking for, whether it's a variant or the source coronavirus that we have now. So, that's continuing and we're looking forward to those results in a few days.

Joe mentioned previously, we've initiated discussions with a major academic institution that has identified monoclonal antibodies; they currently have ten monoclonals that they've identified, three of which are in advanced stages of analysis where they've determined the bonding sites and they've done neutralization studies not only with the Coronavirus, but also with the variants, and we've shown that these antibodies have potential for therapeutic efficacy against both the proto bars and the variants, and those discussions with that academic research institute have just started now and we'll be moving forward there to see what kind of licensing opportunity there would be. Our Chinese partners are certainly interested in this and we're interested in it as well here for the United States and the rest of the world.

Lastly, we're working with our CRO, PPD, and they've finalized the protocol; we've been working diligently to get to a final protocol, I think we've got that now and the IND is in preparation; the folks are working in coordination with our GMP manufacture, our finish partner here, a major corporation doing full finish for us, and all of the T-cell results and antibody results are being incorporated right now into that IND.

And we're looking forward to moving ahead here; we've got a lot of programs here, a lot of opportunities here. And that's it for us, Joe. I'll give more updates as we get more data.

Joe Moscato: And I'd like to add a couple of things to what Rich has presented. We don't use the full-spike protein; what we use is the best parts of that full-spike protein and those epitopes that are only going to provide neutralizing antibodies. So, all the other players out there use the full-spike, but we do know one thing: that in that full-spike protein especially after you get over COVID--or any of the vaccines that use the full-spike--that delivers 1800 antibodies; out of those 1800, we do know 1791 non-neutralizing.

Well, by the very word "non-neutralizing", it means they do nothing, kind of like free radicals that just go out throughout the body and they

build up protein. That is a very, very, very bad thing in my opinion; that's when off-targets and potential allergic reaction off-target side effect all come into play, that cytokine storm, because that protein has got to go somewhere; and that protein stays in the body and typically-- eventually--with that buildup of protein, the immune system can go after that protein and attack your own body. That's how you get these cytokine storms or these big off-targets. And if you look at all the new data that's coming out--or articles that are coming out now on the vaccines--or even on people that have had COVID--those off-targets are already starting to rear its ugly head, you're seeing thousands of people that are getting off-target side effects, they're getting allergic reaction as well as people are dying.

So, we won't have any of that with our vaccine if we're successful; and we have this one last study, if this one last study of immunogenicity with the human-mice physiology works as well as all of our other tests, we'll have a complete vaccine that will offer safety, protection, and long-term memory where we don't have to keep getting shots year after year building up that bad protein from full-spike protein vaccines.

So, we're really excited about being completely different than them in regard to being able to offer those three big key components without giving any off-target side effects and/or allergic reactions; but more importantly, being the safest vaccine out there--if our results keep coming in the way it has been coming. So, it's very, very exciting and the beautiful thing about vaccines is not only can it be utilized to give that first full dose shot to somebody and protection, but we can make the other vaccines better in our booster program. And I don't know anybody who wouldn't take our vaccine because we've always been safe on all the vaccine work, we've ever done, and if we continue to get the results that we've been getting today into the future, there'll be no reason for anyone not to take our vaccine or our booster as added protection.

And we all need added protection because I believe some of the other vaccine makers have already said they're going into three boosters now; so that means that they're worried about their long-term memory. Some have said that you will need yearly shots. Well, in our opinion, that is a very bad thing. Our hope is that we'll be able to cover all three of the key components which is important to have a complete vaccine, one that will offer total safety, no off-target side effects, which will give protection, and at the end of the day, give long, long term memory which will eliminate the need to getting these vaccines over and over again.

So, I thought that was very important to add and I’m very excited about the next ten days; we have the one last big test, once that's complete, and if it's anything like all of our other testing, we'll move right into filing our IND, and we'll get the rest of the work done.

Now, I'd like to add also that our vaccine will be, at the very best, a room-temperature vaccine, so we won't have the shipping problems that everybody else has, or the logistical problems that everyone else has with these other vaccines that have to be frozen at -4 degrees or -80 degrees, delivered frozen. Ours will be completely mixed together; a lot of these vaccines have bedside administration where you have to add the adjuvant to it, ours won't. And we're really excited about this program and within the next ten days, that will really tell the story and we get the last set of results, and they're good, we have a complete vaccine where not a lot of other people can say that.

And the beautiful thing about our program is all of our initial testing has been ex vivo human trials; and in those ex vivo human trials, we will know more than the vaccines that are have already been in people, that they're waiting on getting the types of results that we've been getting ex vivo. So, that's one of our advantages and something that we've taken our time with all the testing to really understand every single piece of each component and what those components represent in a complete vaccine.

So, thank you, Rich. Jason, maybe you have anything you'd like to add, or Eric, maybe you'd like to add something as well while we're on the topic of the science and what we've done so far? Maybe, Jason, you can start off; and then Eric, you can finish up?

Jason Terrell: Yeah, sure, Joe. I don't really have much to add. I think you and Rich both did an excellent job of explaining the program and all the advantages, benefits in the future. But certainly, if there are any questions out there, I'd be happy to take them.

Joe Moscato: Eric, do you have anything?

Eric von Hofe: And maybe just to emphasize something Joe said, and that is that the vaccine we're developing is the minimal unit required to generate a specific long-lasting immune response. So, it's really exactly what once for this type of a vaccine; so, it's those portions of the spike membrane protein that generate a long-term protective response, and that's really kind of the power of the technology that we're applying to SARS-CoV-2. And again, happy to take questions later.

Joe Moscato: Thanks, Eric, I really appreciate that. Thank you, Jason.

So, I'd like to move on. Let's talk a little bit about our Chinese partnership; we've signed three contracts, as everybody knows, with our Chinese partners; we've been advanced $100,000 dollars that we had announced--a guaranteed payment of $100,000 in the addition to the 5 million licensing we were charging our partners in China; they've also advanced us a $1 million dollars on development costs, which we

received; so, we've received $1.1 million from China to date; we're still waiting for the 5 million.

There was a new entity that was set up in China that Generex will own a percentage of; we will be signing that contract soon. The entity has just been completely set up and approved by the Chinese government which was important, and it took a little longer than they had expected for that new entity to be formed. It's a Chinese pharmaceutical company that we'll have a percentage of ownership in, where our signs will sit and the license will sit with the Chinese partners.

And we found out that it's very difficult to get money out of China; it has to go through an approval process, get an allotment for a year of what they can wire out of the country; and then even after they get the allotments they're looking for, they have to then get approval to wire significant money out of the country. So, we've been assured that within the coming days, we'll get our $5 million dollar payment, and we can get to work in China.

We're very excited about that work; they've already hired up to 25 people according to them as they've told us; they also have ten members of the Chinese CDC that their scientists will be working on our programs. PPD China--our partner PPD worldwide, their Chinese office--is already working with the new entity and our partners to design the clinical trials in China. They just got their estimates to do Phase 1, Phase 2, Phase 3; and after next week, once we get our final readout on the complete vaccine, we will ship them Phase 1 and 2 materials so they can start their trials immediately.

They believe that they can do their trials a lot quicker than we can; the CDC of China is one of our partners--they're our technical partner there--so, they're going to be spearheading a lot of that effort with their scientists to get this through the clinic as quickly as possible. So, that's very exciting for us; we'll also have access to the data they'll do in FDA-associated guidelines, so we'll be able to utilize some of that data as well as they get moving.

And they're also highly interested in the monoclonal antibody therapy that we're in the process of licensing right now with partners; as well as we have two other contracts that we're working on in regard to our wound care product, Excellagen, they're licensing that from us; as well as they'll be licensing our Altucell product in addition to our Regentys products.

So, there are a bunch more contracts we'll be signing with the Chinese partners, we're excited about that, we're working on those contracts. But the big thing was the entity that needed to be established and set up, and

then necessary personnel to be hired as well as the facilities there in China which they've done now. So, really looking forward to this partnership; they're going to put a lot of money into our technology and not only on the infectious disease side, because they want to get moving on swine flu influenza as well as all of our cancer applications and do those trials in China immediately. So, really exciting, this partnership; we're thankful we have it and we look forward to working with our partners there.

In addition, our partnership in Malaysia with Bintai Kind of kinder is going well; we've been feeding them our results every step of the way; we just sent them a catalog of bills that we've acquired from all our varying partners to get to this point, which we're expecting payment as they are paying for all these costs for our work here in the United States. So, we're excited about that and we're hoping that once we come out with these results next week--ten days--which is the final, and get that IND approved, then we can get back to licensing Australia and New Zealand, which they have first right of refusal on that which we've already worked out the terms and we're hoping to sign that on these last set of results.

In addition, Altucell, Gary, the CEO of that company, is on, and he's had some really great developments. And I'd like Gary, if you would, why don't you give a quick update on all of your great accomplishments and successes. Gary Harlem?

Gary Harlem: Hi. Thanks, Joe. And thank you all for being on this call. And thanks to the Generex team as well for being very supportive of our endeavors and our mission.

We're really excited, we've had some groundbreaking news: we'll be the first in the world now to be able to go into human trials with our technology; we've had proof of concept and studies from our encapsulation--advances in encapsulation technology of five years with basically no toxicity and totally safe in humans.

So, this is something that's resonating right now around the globe and we're really excited about the study because we believe that this is potentially the holy grail for Type 1 diabetes. As I mentioned, we have all the government approvals in place, the trial is ready to begin shortly, barring COVID hotspots, at the one of the leading institutions over in Milan, Italy; and so, we're really excited about that, and we believe that this is going to be a gamechanger in the world. And we feel that in this space--in this stem cell space, this is just the beginning of major groundbreaking activity that's going to take place, not only for diabetes, but immune diseases and all types of inflammatory diseases. So, it's a basically endless type of structure here that we have, in fact.

Again, we've already demonstrated long-term safety with our encapsulation--Altu encapsulation technology. And just to give a shoutout to our world-class science team, we're in really good shape right now and this is something we've been waiting for quite a few years to climb up to this level; we've got both pre-clinical and clinical data now to support the efficacy studies and get government approval to do that.

We also have another study simultaneously going on for what's called Laron's syndrome, which is the stimulation of growth hormones and IGF-1 insulin growth factor. We will be the first in the world to also demonstrate that we can stimulate growth hormones and IGF-1, which is basically the catalyst and precursor to a lot of diseases, ailments, and conditions.

So, we're really excited and we've got a really strong support cast behind this, and that's the update of where we're at right now.

Joe Moscato: Thank you very much, Gary. I appreciate that. So, I'd move on to our Q&A format. I know that everybody's got questions and that's really important here. So, I'd like to move on to the Q&A format, and we have everybody on from all of our different divisions as well as our science team for the vaccine as well as all the other science work that can answer questions.

So, I'd like to turn it over to calls now. Thank you all.

Operator: [Operator Instructions] Our first question comes from Richard Plumen. Please, go ahead.

Richard Plumen: Good morning. This is Richard. I just want to thank you all. I'm a shareholder and I appreciate everything you've done. You guys stay well and keep up the good well.

Joe Moscato: Thank you, Richard.

Operator: [Operator Instructions] And our next question comes from Dustin Frederickson. Dustin Frederickson: I just want to start by saying thank you, Joe Moscato, and the rest of the GNBT team subsidiaries. I've been a long-time investor since 2009; love the company, love what you guys are doing, love the direction, all the growth, and what's going on with the vaccine.

My question, I guess, just with all that going on, obviously excited about that, excited about NuGenerex. Are shareholders of GNBT going to be able to buy NuGenerex shares before they go on the open market?

Joe Moscato: That's a good question. Our investment bank, Dawson James, will be making all of those decisions now. The beautiful thing about where we are, we've completed our last component for listing NuGenerex Immuno-Oncology, which is a public company now, listing that on the NASDAQ stock exchange. As everyone knows, our application is in; the last piece they were waiting for was out by evaluation work, which is complete, that was turned over to the NASDAQ, given to them with our new cap table after we re-architected our capital structure. And we're just waiting for them to hopefully give us a pre-approval so we can go to market; and that would be up to the Dawson James on how they're going to handle all that.

Dustin Frederickson: Great, great, great. Just would you let us know that potentially and how would that look like if you were going to let the stockholders of GNBT know that they're able to purchase that beforehand?

Joe Moscato: Yeah, if that's what the plans will be, then I'm sure we would, once that's available too on the rules, make any further announcements on anything an offering, we would definitely do that.

Operator: And our next question comes from James Williams. Your line is open.

James Williams: Yes, sir. I just wanted to just to thank Mr. Moscato and everyone that has contributed here today for talking about all the initiatives. But my main question is in regard to Generex Oral-lyn, it's kind of like that ugly stepchild that's kind of never mentioned. And I just wanted to see if we can receive some type of updates, since it is the drug platform that is the furthest along; it has been in Phase 3 trials for about a decade now, and I just want to see, since it could possibly be the most lucrative drug in which Generex does own that's in Phase 3, can we receive some type of updates as to where that stands currently right now; and what do you expect to do with that in the next six months to the next year?

Joe Moscato: Well, what we've done is, a few years back, we reformulated Oral-lyn, we made it a much better formulation, much more effective in regard to from use perspective, much less puffs than it was before it was seven to ten puffs, now it's down to one to two puffs. So, our plan is to always get back to Oral-lyn when the second contract from China kicks in on the $50 million licensing fee for IIP; our plan was to take some of that $50 million and put it back into that program, get to the FDA and rekindle that program.

So, the Chinese contracts that we signed equals about $65 million in upfront payments licensing fees; the first one is the $5 million for COVID; and then the second one is the $50 million for the Ii-Key platform. That's all-free cash when we get that, and we do plan on

putting some of those funds back into that program because we believe it's still a viable pathway and a potential product for us in the future.

James Williams: Okay. Thank you.

Joe Moscato: And our next question comes from James Molds. Please go ahead.

James Molds: Hello, everyone. Quick question. Once we get kind of IND approval, can someone walk us through what the timeline would be in terms of additional trials before--the additional human trials and what that would look like yeah?

Joe Moscato: I'll have Rich and team answer. But I can say that we're very fortunate because of all the work we've done over the last 25 years in the vaccine space. So, because of our safety record in past applicational areas, the FDA's agreed that we don't have to do these big, huge, 20, 30, 40, 50, 60,000 patient studies for our vaccine. We'll do 10,000 or maybe less, which based upon all the institutions that we have relationships with, that we've even okayed, we believe we'll be able to get those trials done very, very quickly--a lot quicker than most others.

And if you take a look at all these vaccines have been approved on very small samplings of their large-patient population trials. So, for us, to do 8 to 10,000 patients will be very, very quick; but I'll have Rich answer that since he's mapped out the whole program. So, Rich, if you will?

Richard Purcell: Sure. When we get our IND approved by the FDA, we'll be initiating a Phase 1, Phase 2 stepwise trial that we enroll cohorts. First, we want to determine the adjuvant dose that we're going to incorporate within the final vaccine--these are still Phase 1, Phase 2, everybody's got to remember; Phase 3 is when we'll have our final commercial product which it will be a [lyophilized biofuel], and that will be the final formulation for Phase 3.

But Phase 1 and Phase 2 will be able to move through--there are about 900-and-something patients in the Phase 1 and Phase 2 plan starting out with the healthy adults, moving onto elderly populations, pediatric populations that we're hoping to get to much faster than the other vaccines because of our safety profile and the backing of our scientific advisory board which are specialists in pediatric vaccines and pediatric medicines. We've got some backing from there to go into the pediatric populations and pregnant women populations who have not really been served with the current vaccines debate.

So, we'll do the stepwise enrollments of cohorts to get through and that'll take a couple of months; we have Phase 1 units that that'll be enrolling the Phase 1 program will go very quickly; Phase 2, we'll move on when

we determine the dose that we're going to use. And then, at the end of the day depending on what the FDA requires for Phase 3 studies, now that there's a lot of vaccines out there, there are biomarkers of efficacy that may be available to us and the FDA is evaluating those biomarkers of efficacy immune responses that will signal that we have an effective immune response and we won't have to wait for people to get COVID like these current vaccines have had to do for their emergency use authorizations--everybody's got to remember none of these vaccines are approved yet, they're only approved under emergency use, they're not approved as full commercial products at this point.

So, we're still moving forward here to be able to get done this year and have commercial supply at the end of the year without a doubt.

Joe Moscato: And our next question comes from Frank Duda. Please, go ahead.

Frank Duda: Hello, Joe. I wanted to know how effective the vaccine is going to be against COVID, against these different variants that are coming in--the UK variant, the Brazilian variant, and the South African variant? Or is this vaccine going to have to be customized to each variant?

Joe Moscato: That's a good question. Rich, go ahead, please.

Richard Purcell: Let me talk about that. We've been looking at these variants very closely and there are a couple of things to understand with the variants, and one of the reasons is that the current vaccines should cover the variants as well. We just generate an immune response to neutralize that virus and there are multiple regions of the spike in the membrane protein that we're targeting; if one of those variants is an escape, the other Ii-Key epitopes will cover--and just like the whole spike protein is giving--the whole spike protein--to generate these 1800 antibodies that have been identified, many of them will neutralize. So, one escape variant should not change things too much.

Now, long-term immunity, that can change. We can target specific epitopes to the variant; right now, we don't believe we have to because we have multiple sites that we're targeting, but if there are specific breakthrough variants, we can make--rapidly--new variant peptides--we've already made some on the laboratory scale--to evaluate the immunogenicity and the neutralizing antibody responses to those new Ii-Key peptides specifically generated to the variant, which gives us more of a target for the universal booster shot that we've been talking about. If there's a variant that pops up, we can rapidly make a new Ii-key to attack that specific variant of the booster. And the specificity of the Ii-Key immune regulation is what makes us special, is that we can target specific regions without causing all these non-target, off-target immune

responses that lead to the complications of COVID, and that's what we're excited about.

We hope that the vaccine itself has enough coverage by targeting multiple sites and multiple epitopes to generate the neutralizing immune response and a long-term memory response; but if there is a breakthrough, we can rapidly respond easily with new Ii-Key epitopes.

James Mold: So, for many of these variants--and this is a follow-up question--there will be a commonality with them sharing particular epitopes that your vaccine already deals with, and that's basically what I wanted to know, and that's a very good thing.

Joe Moscato: The beautiful thing about our vaccine compared to everyone else's, is that our vaccine is only neutralizing, it's only binding; we only skew Th1--all the others skew Th2, they have non-neutralizing antibodies in it, which is bad. So, for us, we use the best parts of the spike protein; the membrane, we're using epitopes; the envelope, we're using epitopes; and the core, we're using epitopes. So, we're using only the neutralizing antibodies from that spike; so, that sets us completely different than anybody else, and that's where our safety threshold comes in because those are the only things you want: Th1 skewing only neutralizing, because the very word "neutralizing" means exactly what it says, it neutralizes the virus.

Non-neutralizers, which are predominantly the spike proteins, 1791 of those, are things that you don't want whether you get COVID or whether you take one of the other vaccines. So, that's what makes us special, makes us different, and gives us the safety profile-- and the long-term memory piece that's needed to be a complete vaccine.

Eric von Hofe: Also, Joe, this is Eric. Just if I could jump in to underscore the caller's point that there is kind of an inherent backup in our system. So, just to make the point in our cancer trial, we have one peptide that's sufficient to cover the base of the whole population, we don't need to do HLA typing, that's how we've chosen this peptide. For the COVID vaccine, we're going to have five peptides, so the caller is correct, there is backup in there and we've looked at the current mutations out there as variants and they do not affect what we currently have getting ready for the clinic.

Operator: [Operator Instructions]

Joe Moscato: Let's just give it another minute, and then we'll end the call, guys.

Operator: [Operator Instructions]

Joe Moscato: Okay. So, I guess that's it with the questions. I just want to thank everybody for attending the call, and I'd just like to add that over the next seven to ten days on our last test we will have, we will alert everybody to that final result which will give us what we believe is a complete vaccine, which is safe, effective, and with long-term memory. And immediately thereafter, our IND will be filed, and we'll get into clinic for this complete vaccine.

So, we're very excited about the future, we thank everybody for the call. Be on the lookout in the next week to ten days for our results. If it's good, we'll be able to make claims that not a lot of other companies can at this point.

So, pretty exciting stuff and thank you all for today. Thank you, team, and have a great day, everybody. Thank you.