

Investor Call May 6, 2021

Operator: Good day, everyone and welcome to today's Generex Biotechnology Corporation Investor Conference Call. [Operator Instructions] Please note this call is being recorded. It is now my pleasure to turn the call over to Anthony Crisci, Chief Legal Officer. 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.

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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 everybody for waiting while everybody was trying to register into the call this morning. We were able to catch up and get everybody loaded, so thank you for being patient with the call-in process.

I'd like to thank the board of Generex, the board of NuGenerex Immuno-Oncology, as well as both teams and all of our shareholders for joining the call this morning, as well as our team in both companies.

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So, today, we'd like to talk about the complete COVID vaccine update; as everybody knows, we've been working on that painstakingly over the last year, we've made huge progress and we're really excited about talking about that progress. So, I'd like everybody also, if they get a chance, or they can do at the same time what we have I'm going over the agenda, if you would go to www.newgenerexio.com, you'll be able to see our newly packaged vaccine that now is vialized and powdered, which is very exciting. And we finally have our vials done and we'll get into where we are in our progress.

Also, today, we're going to talk about the launch of our subsidiary, Olaregen, FDA-cleared application areas, 17 of them for hearts, closed wounds, surgery, venus veins and other; the Excellagen product, we have a our federal contract with the VA hospital system and satellites and we're excited that the VA hospital system is now almost fully operational and we are about to launch that product within the VA system as well as have targeted other areas for us to launch and start garnering sales for that product. So, we're very excited about that, we'll get into that.

Also, we're going to talk about the launch of our remote patient monitoring business; we're also, today, going to talk about the build out and completion of our Arizona operations and our business rollout in Arizona with our partner clinics and our partner doctors there, very excited about that. As well as we're going to talk about our public subsidiary, NuGenerex Immuno-Oncology and give a full update on that. We're going to talk today about--we have Gary with us from Altucell; Gary's going to give an update as to where they are, he's got some really great exciting stuff going on there; we'll give a Regentys update as well as any other ancillary updates we can give that may come up.

And then we'll have a full question-and-answer period which we plan on digging in and spending as much time with shareholders to answer all the questions. As everybody knows, the last time we did a call, the question-and-answer format didn't work out too well with technical problems from the provider. So, we plan on hopefully getting a lot of questions today and being able to answer a lot of questions. One of the main reasons why I had this call is because of the number of questions we've been receiving over the last couple of months in regard to all of our initiatives. So, we're very excited about being able to provide a very long question-and-format today.

So, let's talk about the complete vaccine update. And I think it's important that we clarify and quantify what the complete vaccine means: so, for us, the complete vaccine means, on the front end, we give igg antibodies that are neutralizing to the virus; on the back end we give CD4, CD8 T-Cell activation--strong activation--for the long-term memory. As you are all aware of, all the emergency use authorization vaccines now that are on the market, they're all moving to a three-shot booster and then some of these companies have even suggested and/or said definitively that you'll need yearly shots of their vaccine; and that pretty much means, to me, that their long-term memory is in question and that's a problem we feel moving into the future. And we believe that we have a real solution for that with our vaccine because we've always done long-

term memory on all of our vaccines and that's always been one of our focal points.

The front end, which is the IgG neutralizing antibodies, this is a first for us for adding a component that will give that, and we do give a very strong IgG antibody response, that is two-thirds of a complete vaccine.

And the last component is safety. So, for us, we've always had complete safety in everything we've ever done, whether it was breast cancer, prostate cancer avian flu, or any of the other areas that we've been in we've always given that safety, and we've been recognized from the FDA because of that safety as you'll see when our IND package gets approved and the small amount of patience we have to do Phase 1, 2, and 3 unlike all the other players that had to do 30, 40, 50, even 60,000 patients in the Phase 3.

So, for us the complete vaccine is safety, the upfront giving the IgG neutralizing antibodies that neutralize the virus as well as long, long-term memory so you don't need boosters as well as shots every single year. And why is that important? Well, we do know that any of the vaccines today, they all utilize the full-spike protein; and what we do know today from that full-spike protein is that there are 1800 antibodies derived from whether you either get COVID and get over it or you get vaccines that are mRNA or any other gene therapies. Out of those 1800 antibodies, 1791 are non-neutralizing--that's the keyword here, "non-neutralizing"--only nine are neutralizing.

So, for us--and the reason why we have spent so much time and painstakingly done every single kind of test to make sure our vaccine is perfect--which, up to date, it is perfect--that disparity in neutralizing versus non-neutralizing, we see it as not a good thing. Those 1791 non-neutralizing antibodies do nothing to the virus, but they build bad protein and that bad protein over, and over, and over again, through boosters and through shots every year, typically lead to--and potentially could lead to--off-target side effects, months and months, and maybe even a year after vaccination.

We here at NuGenerex Immuno-Oncology, our subsidiary, we do not use the full-spike protein at all; we use the best part of the full-spike protein and those parts are the parts that--the best parts that do not mutate typically, so we also believe, through a lot of the testing we've done, we have a real answer and a solution for all the variants unlike the other players, because that full-spike protein mutates on the fringes and not in the best parts of that spike. And I'll ask rich to highlight some of this from more dumbed-down science discussion when I turn this over to him, but he can go through this with you.

But this is why we believe our vaccine will be a real solution, not only being totally safe, especially for children under 12, pregnant women, as well as the elderly, but we believe that we are going to eliminate the need for constantly getting yearly shots for this very, very debilitating virus.

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So, today, we received--well, yesterday, we received a photograph from our fill-finish team and partners, and I posted that on the website, because it's always great to see, for the first time, your own product that's packaged. It is a prototype product, but that is the way our product will end up looking. It's a powdery product, it comes wafflized, which gives us a huge advantage over all the other players; we're not frozen; we're not refrigerated; we are room temperature, we're wafflized that can be delivered very easily; logistically, it could be sent anywhere in the world, unlike all the other players that are right now in the market.

So, there's definitely a need for us; people had asked me just recently, "Well, you guys are going to be late to the vaccine race." And I said, "How do you figure that? Next year, all 8 billion people, even if they get the vaccine today, they're all going to need another shot next year." So, we're well-positioned to not only help the gene therapy vaccines to give them long-term memory--make them better, once we're ready to commercialize, and we get through the approval process with the FDA--which will take us a lot shorter amount of time than all the work that we've done today.

I mean the amount of work and testing that we have done has been astronomical; we have been able to test; and unlike all the other players, we do not provide Th2, which is another very bad thing; we only provide and skew Th1, which is very, very good; Th2 is very, very bad, all the other players skew that; we provide none of the aisles, our five, six, eight, nine, all the way up to the 20s which are the culprits, typically, for off-target side effect; we provide none of those in all of our testing and ex vivo human trial work that we've done; and we give huge CD4/CD8 T-cell activation on the back end in all of our ex vivo human trials--which is always where we've done quite well in all of our other vaccines.

So, that's the long-term memory and because of that long-term memory, we believe with the front end, that we have a real solution and we have a real winner here that over the next six months to seven months, once we get approval from the FDA, which we believe we will based upon our ex vivo human trials--and in those in vivo human trials, that ought to be the same, we have a real home run here, and we're very excited about that.

I'd like to turn it over to Rich, because Rich Purcell has masterfully run this program. We have not received any government money like everyone else, so we have to be extra careful about how we do things because with government money, you get immunity from criminal prosecution, civil prosecution; but for us that didn't get any government money as of yet, we had to make sure we do all the I's and cross all the T's. And the beautiful thing about our pathway is we can do ex vivo human trials as we've done, all the testing that we've done--and it's numerous--and we have more data than the mRNA vaccines today.

So, if that data fleshes out once we get into our Phase 1--which is a very small Phase 1, and it should be done very quickly--we will know--and it matches up to our ex vivo human trials, we have a grand slam home run here. And

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typically, with all of our trial work, our vaccines get better with time, in people versus the ex vivo human testing. So, if we can have the same track record with this vaccine as we have with all the others, we will be a real answer here for the future of this pandemic as well as all of its variants.

So, Rich, I'd like to turn this over to you to maybe give a complete update; you have your team on the phone as well, you guys have done an incredible job with this vaccine as evident by our newly posted vials of prototype vaccine. So, Rich, please.

Rich Purcell:

Thanks, Joe. Good morning, everybody. I'm Rich Purcell, I'm the Executive Vice President of Research & Development. And the vaccine is moving along, we've done all this work that Joe was alluding to on the ex vivo screening of patients' blood from COVID-recovered patients to identify the areas of the spiked protein and the membrane protein that we've selected from computer algorithms that are promoting immune response; and tested those, predicted what we call epitopes, which are parts of the virus that are recognized by the immune system, and we were able to select five specific peptides that give T-Cell reactions CD4, CD8 reactions; and then also bind antibodies, and we did this blood screening work at CTO Laboratories, great job over there from our partners, they're great immunologists and we've done a lot of T-Cell work, been excellent, and we screened hundreds of patients all together.

And then we've been working with the University of California, San Diego and Dr. Tom Rogers, who is a leading expert in coronavirus and viruses in general, he's been working on HIV for 20 plus years.

And the UCSD work has been focused on the antibody production and they've got a virus neutralization assay with real virus--live virus--that we'll be using in our clinical program to test the advocacy of our vaccine, the production of antibodies to neutralize--kill, essentially--the virus from Washington State--the Wuhan virus--or any of the various from Brazil, UK, New York--there's a lot of different barriers that come up, but all those barriers are available at the UCSD lab and we'll be able to test our Phase 1 data and blood samples from the Phase 1 patients in these assays to determine if we're generating the immune response that we're looking for, both on the antibody side to neutralize the virus and its, as well as on the T-cell side, we'll be screening for activation of the T-helper and T-killer cells that are essential for ridding the virus from our bodies and keeping the immune system active for the long-term immune memory.

So, the ex vivo work was all completed back in the fall, enabled us to select the five peptides that we've gone to GMP production with and we have a group out in California that we've worked with for many years, called Polypeptide, and they have manufactured our GMP peptides, five different GMP epitope-directed peptides that are now then formulated with our formulator also in California, and put into a single solution, and then we've been able to lyophilize the product. We have a full CMC package developed now, all the way through the engineering run you see those pictures of vials there, those are our

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engineering run and the prototype of the vaccine to go into a lyophilized pattern.

We're very, very excited about this work; we didn't expect to be able to do the lyophilization and making a powdered form; we thought we'd have to go to liquid and be frozen for our clinical work; but because of the excellent work by our partners and formulators, we've been able to come up with a process that gives us a lyophilized product that's projected to have a three-year shelf life. We'll keep this refrigerated for now, there's a possibility that we get to room temperature storage at the end of the day; regardless, we do not need any ultracold temperatures, it doesn't need to be frozen, and this gives us a huge commercial advantage in the marketplace especially in foreign countries that don't have the infrastructure to handle cold -80 temperatures that the current vaccines need to be stored at.

The manufacturing run for our clinical supply will be filled on May 18th at the University of Iowa Pharmaceuticals, great specialty fill-finish provider, and they've done a great job for us too; and so, May 18th, we'll be filling our clinical supply. From there, we have to just wait for the stability, stability, and variants tests; it takes six to eight weeks--and this is what Joe has alluded to before with the FDA. We have to have a full CMC package to go to the FDA before we finally move for a Phase 1 IND. Other pharma companies--and I spoke with one of the developers from one of the major pharmaceutical companies, who told me that they were allowed to do a rolling IND and pass information to the FDA all along last year to accelerate the work.

But we didn't get that advantage and we didn't get the advantage of the Operation Warp Speed funding, but we've been able to come up with our vaccine anyway; and we're very excited about where we're at we hope to be able to initiate the clinical trials this summer to then get our data that will tell us whether we have a complete vaccine, and we believe strongly, based upon our work so far, as Joe alluded to before, we vaccinated transgenic animals to show that we produce IgG against the vaccine and that came out positive; and we're currently repeating that experiment to confirm those results and that result will be available in two weeks, just to confirm that we have the complete vaccine with an antibody and a T-cell response in a transgenic animal model.

And that will pave the way for us to move into the clinic to give us these answers; and I think the most exciting part about this is that this peptide-based vaccine--amino acid-based vaccine--doesn't have genetic material in it; it's stable; it's easily manufactured at scale because people have been making peptides for decades, we know how to make large quantity peptides very quickly, we can supplement the current supply of vaccine; especially in international markets, if they don't have access, we can provide access to a new brand of vaccine; and most importantly, from a commercial standpoint, we can be the universal booster. If everybody needs a booster shot with the current vaccines, our vaccine will direct the specific response from the immune system against only those sections of the virus that will neutralize it and give us long-term immune protection; we've eliminated regions of the virus that overlap

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with human sequences, that overlap with old Coronavirus viri like common cold coronavirus sequences, and we've only focused on those regions of the virus that are susceptible to our immune system so that we can direct the immune response specifically.

So, there we go. We're ready to move; we have the ability to manufacture at scale; we have a lyophilization process that is commercial-ready, not just Phase 1 ready like we thought we'd have, we have a full commercial CMC package and we're ready to go to the clinic as soon as we get the FDA go-ahead on our IND.

Thanks, Joe.

Joe Moscato:

Thanks, Rich. I appreciate that. So, I'd like to add to that this is the first time ever that NuGenerex has ever utilized more than one epitope in any of the vaccines that we have done. Let me give you an example of that: NuGenerex has a breast cancer vaccine, we have a prostate cancer vaccine, we even had an avian flu vaccine. So, in each of those vaccines, there's one epitope that we utilized. So, let's say AE37, which is our breast cancer and prostate, that AE37 is an epitope that is utilized that expresses the HER2 protein; that HER2 protein is predominant in liver cancer, kidney cancer, lung cancer, breast cancer, prostate cancer, bladder cancer.

So, we did all that work years, and years, and years ago, but that 180/37 has multiple, multiple applications. Here, we had to totally break down this spike protein, we had to totally pick out the best epitopes that would very precisely utilize that full-spike proteins best parts, which never mutate, which gives us a huge advantage, and it's the first time ever we've used five peptides, linked our Ii-Key to those peptides; and then there's a lot of work that had to go into, "Do they mix together; do they work well together?" So, individual testing of each and then joint testing of each, and then joint testing with the adjuvant from 3M that we partnered with.

So, there's a lot of work that went into the CMC package which took a lot of time; and most of all the other vaccines, because of the height of pandemic, a lot of these processes were not done where we had to do those. So, when we go into the FDA, we're going in with a complete package that we know, based upon our pre-IND, we know based upon the FDA's response to that package--and the very, very clean response to our package which mostly centered around CMC and GMP manufacturing, which is now a very complete robust package.

The only other thing they asked us for was a simple immunogenicity study with transgenic mice. So, it's probably one of the cleanest responses that I've ever seen in a full package pre-IND package; and we've answered all those questions, we submitted all the answers to those questions to the FDA, and we are now cleared to put our IND in. So, once our manufacturing of the complete vaccine for commercial use is done on May 18th, all the rest of the answers which are required to put into the IND package will be complete; and then PPD Worldwide, our other partner, will put that into the remaining parts of the

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package that this information needs to go in, the certified reports all the testing, all the stability, all that will go in and we're pretty confident that we will have a green light to get to a very, very small--it'll take us one month to get that Phase 1 done and we'll have the answers at that point. And if it matches up to our ex vivo human trials, we have a home run here.

So, it's a new day for this team because most of the team wasn't with Dr. Eric von Hofe when he created AE37, which is our HER2 vaccine and, as I said before, fits most solid-based tumor application, so we only made that once and we still keep rolling with that. Here, it was really a very, very big effort by many, many organizations, many, many, many companies as well as this team to get this new way of doing vaccines for us, which is many components, which we never did before, to a point where our testing has been exceptional. I'm very, very proud of the team. Great job, guys.

So, would anyone else like to add anything. Eric, maybe, you'd like to give a little bit since this has been your baby of all these years and maybe you can talk a little bit about your thoughts on how this vaccine work has gone.

Eric von Hofe: Sure. Thanks, Joe. Yeah, definitely, as Joe said, a lot of work's gone into this, into our HER2 focus vaccine, one of the largest Phase 2 studies that's been done now in triple-negative breast cancer. And also, as Joe mentioned, we have experience with the Avian Flu years ago, so we were really ready to go when the COVID pandemic hit.

So, I think it's a perfect indication and a perfect demonstration of where this type of technology fits. As was pointed out, what we're using are the minimal portions of the spiked protein that are critical for getting a neutralizing response, both T-Cell as well as antibodies. And so, the other thing is while we're happy to kind of--coming out the worst part of this, it's not going to be going away, and I think most people agree that there's a reasonable likelihood that this will also not be the last. So, I think that we have something here which very much belongs in not just for COVID, but for all pandemic preparedness. So, it's been gratifying to see this move forward and we've shown, from our clinical studies with AE37, that we get every long-lasting specific immune response against the targets we go after. And I think, again, Coronavirus Sars2 is a perfect example for it.

Joe Moscato: Thanks, Eric. I appreciate that. So, anybody else from the team--on the COVID team like to potentially give their pennies where we are or any insight as to what we've been doing with the vaccine?

Jason Terrell: Yeah, Joe, I would. Hi, everybody. This is Jason Terrell, I'm the Chief Medical Officer. I just wanted to publicly thank and acknowledge Rich Purcell because he has really been the leader and orchestrator of all of our vaccine efforts, and without his experience, and knowledge, and dedication, none of this would have been possible. And also reiterate things that everybody's touched on, that as good as these current vaccines are, they all have major weaknesses, all of which our vaccine addresses and solves. So, the fact that people like to say,

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"We're late to market, we're behind." We're not. It's actually a benefit to us because it's given time to expose these weaknesses and highlight the benefits and advantages that we can provide. So, I'm very proud of all the work that we've done and looking forward to bringing this thing to market.

Thank you, Joe.

Joe Moscato: Thanks, Jason. I'd like to add to that, Jason, you bring up a very good point. For me, a vaccine is not a vaccine that makes you sick; to me, a vaccine doesn't keep you home two, three, or four days after vaccination, especially the second booster; to me, a vaccine is not putting you in the hospital, which thousands and thousands of people worldwide have been put into hospital after the second shot booster of a lot of these vaccines; to me a vaccine is not knowing six months to a year from now, "Will I have that bad protein from those 791 bad guys, those non-neutralizing antibodies?" And that's the keyword here, "non-neutralizing". Will that bad protein create those off-targets, which it has always in the past and will that allow your immune system to attack you? Which is typically cytokine storm, cytokine blitz, and maybe a half dozen much more in these off-target side effects that typically happens later.

So, we offer none of that; we are the safest, we offer none of the things like the [aisles] or the Th2 that typically trigger those off-target side effects later--much later in the vaccination; but here we are, we're getting vaccinated; there has been death, there are extreme hospitalizations from these gene therapies. And again, none of these vaccines, like the mRNAs for the last 30 years, have ever done anything, and never even had positive data in anything that they've done before in the past.

So, it's new research, it seems to be giving certain responses in certain areas of what this pandemic needs right now. Do I believe that this is going to be a long-term solution? No, I don't; especially when you're going to need vaccine year after year as these companies have stated we will need. So, we have a real big opportunity here from a safe, effective, and long-term memory solution based upon our data today. If that holds up through our clinical Phase 1 trial, again, we have a home run here and we're completely different than everyone else. And for sure, I'd put this in my child.

So, it's very exciting and we'll keep everybody updated as we go and make more developments with this vaccine. But our next big initiative is to get the commercial-grade packaged up and get our IND just as soon as PPD puts all the remaining data into that IND, and I'm pretty confident based upon all of our discussions and our correspondence with the FDA, that we have a very, very good shot of getting that approved very quickly and getting that Phase 1 confirmatory study from all of our ex vivo human trials that we've done this last year confirmed; and if we get that confirmed, we have a real home run here. So, I want to thank everybody on the team and also Rich Purcell for handling this program; Jason Terrell, John Hall, and everyone else I want to thank very, very much.

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So, moving on. I'd like to discuss today also, the launch of Olaregen Therapeutix, the subsidiary, with their FDA-approved and cleared product from the FDA, 17 treatment areas. We're now launching in the VA hospital; as we know, the VA hospital system has been shut down since last March for everything other than COVID. So, they're all reopened or in the process of reopening up now. We have now--it's been confirmed, and we got the final docs on our big financing partner, which is going to fully fund the launch of the VA rollout in all 287 major hospitals throughout the VA system and 1100 approximate satellites that the VA system has.

We're very excited about this; and what I'd like to do is turn this over to Terry Thompson. Terry put together the plan with the team from Olaregen, Tony Dolisi, our CEO; Cliff Keeling, who runs our sales operations for Olaregen. It's a very exciting program and now that we're fully funded to not only make enough product to service the whole VA system, but we'll be able to have a sales course they'll be able to educate the docs within the system and we believe the revenue model that Terry has set up with the team is quite good and will bring in significant revenue to Generex once the plan is executed and then fully launched.

So, Terry, if you would, please.

Terry Thompson: Thanks, Joe. I'm pleased to report on the status of revenue-producing assets. I joined the company in 2018 when Joe laid out his strategic plan for the company. I still stand by it as witnessed, we're trying, with the vaccine, the use of our legacy companies and launching those types of products from our legacy companies, but we're also developing and launching revenue-producing products.

So, the two major initiatives I'm going to talk about, we've either financed or have the documents in-house to get the financing to relaunch Excellagen from our Olaregen subsidiary and remote patient monitoring from our NuGenerex Health Family subsidiaries which is a--NuGenHealth is an LLC we set up which is a 50-50 partnership with Worldwide Digitech, a subsidiary of HealthCoast.

So, let me go over--I'm going to go over Olaregen's product strategy first. And as you may recall, we had previously launched Excellagen and in December of 2019, Tony and team had already built it to a \$500,000 in that one month of December of 2019 with no end in sight to the growth of that product. Unfortunately, the COVID pandemic hits and stopped their sales in its tracks and the elective surgeries and these sales calls were shut down completely on the focused sales channel which was the VA where we were starting. They had signed an agreement with [Fab Medical] which has a national contract with the VA; this opened the entire VA system to Olaregen and the Excellagen product. Excellagen is looked at as a best-in-class wound healing product, the FDA has authorized its use in 17 different indications, and they had already completed our tests with the VA and gained acceptance.

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Now, some of the major metropolitan centers may still be closed to us, but many have, in fact, reopened--and are going to have to reopen because people need surgeries that have to be done--we received an exclusive investment document yesterday from an investor that sees the potential of this product. And within an hour of signing the documents, then they will have us the money. So, I feel 100 percent confident that this is happening soon.

So, the use of the funds that we're going to receive for Excellagen will be for four or five different initiatives. First, we've got to convert our existing bulk inventory of Excellagen wounds and forming gel matrix into the final fill finish; and we'll be shipping products to AB Medical from our partners in New England. We've got enough bulk inventory to create approximately 25,000 syringes with 70 percent converted into 0.08 CC syringes and 30 percent into our 3.0 CC syringes for larger wounds. This process is expected to take 60 to 90 days to have the inventory in place to sell. We believe these runs will support our sales forecasts up to approximately \$30 million.

We believe our forecast for this slimmed-down focus on just VA will yield, at the end of Month 12, an annualized run rate of approximately \$10 million, while achieving a positive EBITDA; and Month 6 of this rollout, an EBITDA projected north of 70 percent. Years 2 and 3 is forecasted revenue of 39 million and 92 million respectively, with EBITDA forecasted at 32 million and 65 million.

It's a very profitable business, we believe this is a great way of getting started again. We'll begin our sales initiative with outsourced VA specialized sales group which Tony and team have total expertise in how to coordinate that; and then we'll need to create more bulk inventory, as well as the current inventory, runs out, with timelines of 90 to 120 days to create the bulk inventories and 60 days for each fill finish run.

We have to balance our inventory and sales to ensure that we have shelf life on the product; once we fill-finish, Excellagen has a two-year shelf life. And then once we get a foothold into the VA system, which is now open for business, we will immediately start with managed care and insurance systems. It's an important point because insurance companies spend a lot of money on wound care, hard-to-close wounds, and surgery where our 17 FDA cleared uses allow us to sell our product. If a large insurer pays out \$1 billion, we can save them costs because this best-in-class product is non-sutured; we believe insurers will be able to jump at the chance to save money and make a big plus for us going after this market.

The description I've given is our restart at just the VA; this product could go way beyond the numbers I gave you. Once we're achieving the milestones, the stabilizer company once again will weigh our startup with much more aggressive plans. The VA has over 150 centers and a thousand outpatient centers; we will move more aggressively, it makes sense, so then I get ahead of our cash flow and controls. Managed care is next stop and we're already engaged in discussion with a few as a test; this market is considered low-

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hanging proof given we believe we can save over \$1000 per procedure by converting some current practices to our Excellagen product.

Our physician network and entities are considered a third leg of sales with Medicare reimbursement tests underway by our sales leaders; and we recently announced that Olaregen signed its first Asian distribution agreement with NextGen Medical for exclusive distribution rights in Malaysia. This starts out slow, but they have paid their own way for their equivalent FDA approval and believe they will have such approval at the end of May. We see this as a foothold into the Asian market and NextGen Medical has created their own fill-finish capabilities and stands to open up Malaysia while we retain the license for the product. This partnership could expand as we move forward.

In conclusion, we're excited for this restart and we can't begin to explain the angst we have felt with the impact of the pandemics; we will keep everyone informed as we progress.

Secondly--

Joe Moscato:

I'd just like to add some there, Terry. I think I think it's very important that people realize that our competitor products are all frozen products; we're a refrigerated product, so that gives us a very big advantage. As well as, when you use the competitive product, the insurers have to pay out \$1200 per treatment with that frozen product for suturing; we don't have suturing with our product, our product is self-adhering and it's a non-suture product. That'll save the large insurers up to a half of what they're spending today on the smallest CC syringe. So, if, let's say Aetna, is spending a \$1 billion in hard-to-close wounds, venus veins, moss surgery where we have our approvals, at least 300 to \$500 million is for suturing. So, we know that the managed care insurers and private insurers are going to love this product because they can save money in any area, they're going to do that, and then they're going to order their doctors to only use our product because that's the only product they'll utilize.

So, that's a big--after we launch the VA system, we're going to be hitting the ground hard in that area and we believe acceptance for this product will be unlike any other because we offer at least 50 percent savings on the small syringe and up to 25 percent savings in the 3.0 cc syringe because of the non-suturing. So, it's a great opportunity for us to roll this out now, and we're looking forward to it with the team. Maybe Tony, you'd like to say something; or Cliff, you'd like to say something in regard to what the opportunities are here.

Tony Dolisi:

Sure, Joe. How's everybody doing and thank you for your participation. So, we're very excited about this relaunch. One thing that I could add to that is explaining that as of March 20th of 2020, we did receive the full contract, the BPA contract, along with the IDIQ contract from the VA. Unfortunately, it was the height of the pandemic in March 2020, so we were not able to capitalize on that because of access being shut down for the VA and no elective surgery is being conducted as Joe and Terry have reiterated. However, what the IDIQ

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does--and that stands for the Indefinite Delivery and Indefinite Quantity Contract--that's pretty rare for the VA to give that out; but seeing what the clinical information delivered for Excellagen, the pilot that we did within the VA system, and the results from that pilot were just so impressive that we were also awarded an IDIQ, which allows us access and our representatives have unfettered access to the VA health system; also from a national standpoint, it's approved, so we don't have to have barriers to present to any of the VAs and any of the clinicians within the VA; those that want it on an individual hospital or a federal clinic basis can get it without having stoppage or anything like that.

However, we still need to do the footwork and put the representatives in front of the clinician to educate them on the advantages and the process of how to use Excellagen. So, we're very excited to get the representatives lined up once again and get them in front, face to face, toe to toe with those KOLs within the VA.

So, I thank Joe and Terry and team for finding the funding to bring this to light.

Joe Moscato: Thank you, Tony. I'd like to add that's one of the main reasons why the VA system replaced their existing product--the frozen product, our competitor--with our product. There is no suturing here, so now they save \$1200 per procedure and as being a self-insured entity--which the VA is--we're the perfect product for them. So, we're just very happy to pass along those savings. And again, our profit margins on this product are extremely good and we look forward to Terry and team executing on the VA system and then moving immediately into the managed care space and the self-insured space, which we believe will really catapult our revenue stream exponentially over the next year to three years. So, thank you very much guy. Back to you, Terry.

Terry Thompson: So, the second thing I'd like to talk about is NuGenHealth LLC, our 50/50 partnership with Worldwide Digitech LLC, it's a division of Health Cost, the dashboard and the software a system that they have that's been in the marketplace for several years, and proven and tested, and when seen by the physicians, they really see it as a turnkey operation for remote patient monitoring and/or chronic care management.

So, CMS has promoted RPM especially with the pandemic going on as a reimbursable service and has endorsed it as a value-add to improve patient outcomes. So, we had signed a contract with Paradise Valley Family Medicine several months ago and have been working on the build-out of our lease space within the building for several uses, including NuGenHealth. We funded this kickoff and are coordinating our kickoff with this large primary care practice as we speak; we also have contracts and either signed or in the works to be signed in several other states, and our platform collects data from Bluetooth devices we furnish the patients for free at the physician's direction.

Included in this Bluetooth-enabled glucose monitors, oxygen meters, blood pressure cuffs, thermometers, weight scales, the physician's office will identify a subset of patients population which will benefit from remote patient

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monitoring, and we collect at least 16 days' worth of data on this dashboard and the patients are called at least once a month, and the software the system provides, the practice with the detailed information necessary to bill and collect from CMS as well as the patient data for better care treatment.

The reimbursement varies slightly by state, but all in, it's approximately \$115 PMPM. We do not build or collect from CMS, that is the practice's responsibility; we build a flat fee rate for our software-as-a-system, equipment, our data collection know-how, and patient interface and training. We've got three contracts to implement soon and many more in discussions.

Our forecast is to achieve 3500 to 5000 patients near term, creating next-gen revenues of approximately 3.1 million annualized on that first startup. This is just the beginning. Our partners at Worldwide Digitech include Dr. _____ [00:53:46] and Brian Goldstein; Brian will be heading to Paradise Valley for a kickoff training session as soon as possible. They're ready, we're ready, and we're going to get started.

We're also fortunate to have Sanjay Kumar on our team and is with his lifelong relationships with not only RPM, but other NuGenerex health ventures that will be coming soon. So, I want to turn this over now to Sanjay Kumar and let him speak to you about some of the initiatives that he has underway.

Sanjay Kumar:

Hi. Good morning, everybody. Like Terry said, we are going to be kicking off this RPM initiative very soon, just a matter of days, if not hours. There are about 200 to 300 different companies trying to try to get into this arena already operating, but 95 percent of them have around 1500 patients. Our forecast in this area is between 3500 to 5000 patients in the first six months; so, I can say it with reasonable confidence that we will be in the top 5 percent of the companies in this arena in the next six months, and our goal is to reach over 10,000 in the first year. That is the goal and I think it is very achievable.

The other initiative which we are doing in Arizona is to get into the managed healthcare arena, especially the MSO area. And we are in active negotiation and I'm very confident we will get the contract from--the desired contract, let me emphasize on that--the right and the desired contract from the HMOs and that is a whole different ball game. 1500 lives don't sound much, they sound like a joke; but getting 1500 lives takes a lifelong to have them in your organization. If you look at the MSO market, there are hardly 15 MSOs which have 5,000 and above lines in the whole country, and they have been around for nearly 35 years. And the value of those lives is... if I gave you a number, you will not even believe it. Just to let you know that a thousand lines in managed care arena relates to about \$2.5 million annual EBITDA.

To put it in perspective, your average internist, their billing is between--their total billing--is between 350 to \$500,000. But if they put a thousand lives in a risk contract in managed care, their EBITDA--let me repeat, EBITDA--is \$2.5 million average, and these contracts are only given out in two states: Southern California and below I4 in Florida, and there are at least 300 to 400 doctors

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which have been doing this business for over 30, 35 years. If I go anywhere else and give those kinds of numbers, they think I'm on some kind of drugs or I've lost my mind; they don't believe it, but it is absolutely true, especially in Florida and Southern California. They have given these contracts on a very limited basis in Arizona, and we are very confident that we should be able to procure this contract by the end of this month or beginning of June.

And what Terry said, we have other initiatives which we will be launching that is putting modalities in a few clinics--in at least two clinics in Arizona. It took some time, because of the pandemic to get build-out permits, this, that and everything to finish the build-out. It should be complete in the next seven to ten days, I believe. And we should be well on our way; and I can assure everybody that we will have I will even say 5,000 in the first six months; I'm very confident about that number. And we will be--out of the 200, 300 companies, we'll be in the top five, maybe top ten in the business.

And that's all I have to say. Thank you.

Joe Moscato:

Thank you, Sanjay. I appreciate that. I'd just like to add that Sanjay's incredible experience with starting well over six HMOs, his experience at MSOs and working with the legend, Dr. Patel, his big one was which was WellCare. Sanjay has incredible experience, he knows his business well; the doctor networks love him from his days of creating the largest MSO station modes in the business, and that's the key is the doctor relationships, and that's the only way you get patients. And we have at least 11 other clinics that will be signing up for our RPM business; we signed up one, we announced that today, here in South Florida; we have another big one here in Miami that we'll be signing up very, very shortly, the contracts are out; and then we have about nine other contracts that are out that will give us a substantial doctor partner network for RPM which then we could then move our products and our other services into those clinics.

And as Sanjay stated, build-out is almost complete in Arizona in our first big clinic Paradise, and we will be offering ophthalmology, podiatry, cardiology, bariatric services RPM as well for their patients which have already been identified in two clinics that we have contracts with. Those doctors in those clinics that have partnered with us, we've already identified well over 3500 patients that will immediately start onboarding onto our system; they were pre-qualified, and that that process will all start by Monday of next week.

So, we're very excited about this business and we're glad that now the states are opening up more and more, where it's allowing us to get back to business, get to our profit centers, relaunch a lot of the assets that we've acquired over the years and put those assets to good work with our products, with our services where we believe we'd be back to revenue by next quarter.

So, we're very excited about this. Thank you very much, Sanjay; thank you very much, Terry. Terry, I want to turn it back over to you, buddy.

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Terry Thompson: Well, that's all I had, Joe, unless there's something there anybody else wants to add.

Joe Moscato: Okay. Rich, maybe you'd like to add something about remote patient monitoring since you've been in the business before and maybe give a little insight?

Okay. So, let's now go into an update on our public subsidiary, NuGenerex Immuno-Oncology.

Rich Purcell: This is very exciting to get this going; we've been working on this project for a long time as everybody knows. And Dr. Katz out in Arizona has been great to work with and their whole group; this RPM opportunity together with other remote patient monitoring and chronic care management services is a business that is slowly being adopted by primary care. And 2017 was very slow and the government changed the rules of reimbursement, so it's started to accelerate a bit--but it still hasn't caught out, only about 3 percent of the Medicare patients that were eligible for RPM and CCM were in this system. But the pandemic hit as the acceleration started and everything got shut down.

So, we're perfectly positioned right now, and Sanjay has these wonderful relationships with his physician contacts throughout Florida, Arizona, and California, and other states even, and he's been able to make introductions here with great partner physicians. And that is the key, is to capture patient populations in partnerships with doctors to give them electronic communication capability to do remote monitoring and management outside the offices. The government finally recognizes this; insurance is recognizing this, and you see the pandemic has only accelerated the need for remote monitoring, telemedicine, and we're perfectly positioned to take advantage of this explosive growth that's coming. So, thanks.

Joe Moscato: Thanks, Rich. I appreciate that. So, let's move on to our public subsidiary, NuGenerex Immuno-Oncology to give you an update on that. I have asked Dr. Craig Eagle--Dr. Craig Eagle has been on our board of Generex and NuGenerex now since we've taken control of the company back in 2017. Dr. Eagle has agreed to become our chairman of the board of NuGenerex Immuno-Oncology which is great. Dr. Eagle is a legend in the industry, I don't know too many people that have done the amount of drug development that he has done and who has more drugs approved than him, not only from a science side but running pharmaceutical companies.

So, it's going to be fantastic, pending board approval, that Dr. Eagle will take over the reins of the board of NuGenerex Immuno-Oncology. I'm quite happy with that, his expertise and his experience both from a business and drug development standpoint are bar none, and we are quite proud to have him as our chairman of the board, and I'd like to thank him personally for taking that role, and I'm quite confident that the board of directors, when we have our next board meeting, will unanimously vote him in as new chairman.

In addition--

Jason Terrell: Hey, Joe, one second. Why don't you give them a little bit of background as to Craig Eagle, so they understand what companies he's worked with in the past and why he's such a great fit here.

Joe Moscato: Yeah, we'll be putting up Craig's updated CV onto the NuGenerex Immuno-Oncology website. Craig has just taken a leading role at another pharmaceutical company, he just left Genentech; and we'll have his full new bio up. But Craig, he's a legend in the industry, worked with Pfizer, he was in a leading role at Pfizer. In addition to all the drug development he has done for Pfizer, he was intimately involved in all the partnerships, all the mergers and acquisitions that Pfizer had; as well as he ran Canada, and then he ran England for Pfizer; and then went over to Genentech and was in charge of all their clinical development and drug development there. And now, he's just taking on a new role and he'll be taking on a new role for Generex which we're quite proud of him taking that role on as chairman of the board of NuGenerex Immuno-Oncology.

I'd further also like to tell everybody that our listing is going according to plan to get our public subsidiary stock trading; NGIO is our symbol and we're quite excited about that and we believe shareholders will be very excited about that very soon. If anybody has any questions about NuGenerex Immuno-Oncology and that listing, I recommend them calling Dawson James, and anybody outside of the United States, James does have easy access and they are in other locations where you may be able to get all the information you need on the listing.

Altucell, I'd like to talk about Altucell now. We have Gary, the CEO of Altucell, he's made some tremendous strides in his development and I'm quite excited to have everybody hear all the great new updates that Gary has. Gary, I'd love for you to please tell the shareholders all the great stuff that you guys have put together over there at Altucell.

Gary Harlem: Great. Thanks, Joe. Well, thanks to the Generex team and support of the shareholders to enable us to get to this monumental stage with our technology, so we're really excited right now in the life science space where we're at. We have government approval in Europe that's sanctioned by EMA, that's the European Medical Agency, the Ministry of Health, and the National CNT, National Center for Transplant Society.

So, we feel that we've made tremendous progress with our established technology, our encapsulation technology, which negates the need for using anti-rejection drugs when you're using various types of cells implanted in the body. So, we just did the first in the world human transplant about a month ago, was dosaging-established and a safety study to demonstrate the efficacy behind our encapsulation technology, and it was a very, very powerful steppingstone; we transplanted a female patient of 25 years Type 1 diabetic, 50 kilos, no c-peptide at all, stimulating endogenous insulin to 1.1. We now are being

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supported by five more patients that we have lined up using these cadaver islet cells which are insulin-producing cells in the pancreas.

So, the beauty behind our technology at this stage is, once again, to document and confirm that you do not need anti-rejection drugs when you use our technology. Our Chief Science Officer, the world-renowned, Dr. Riccardo Calafiore has been the most prominent person in the field of about, I'd say close to 35 years of expertise in utilizing this technology, the trade-off of using anti-rejection drugs for a Type 1 diabetic recipient would not be a choice of protocol because there's many secondary complications when you use rejection drugs.

The other exciting thing that we've created is that we have a two-tandem study going on. One is on Laron Syndrome, which is a rare disease; it's enabling us to get orphan-drug status; we were just informed that that'll quantify us for having a voucher. The vouchers have tremendous significant value in the neighborhood of anywhere between 100 million up as far as north of \$300 million, so that's something that is really, really exciting news that we've just been informed of, and we have somebody that has actually helped to write the book on vouchers, Dr. Jonathan Davis; he's the Chief of the Neonatal Advisory Committee for Office of Pediatrics at FDA, so he's very astute to these types of formats and these types of vouchers. So, we're excited about that to create additional value to the Generex team and shareholders.

The other thing that we are excited about is that because we are that much more ahead of the pace in terms of having clinical-grade FDA-approved encapsulation technology, we have procured some companies that are looking to license our encapsulation right now, and so we're excited about that.

So, in essence, we have a three-pronged approach running in tandem right now that we believe is going to be bringing significant value to Generex and the shareholders. And in closing, I would just like to thank the Generex team and all the supporting cast of the personnel who have been extremely helpful and it's very motivating and exciting for us to have this kind of support; and I haven't come across anybody to date, as the CEO of a company that has multiple things going on, to pick up the phone and make himself readily available 24/7; and some of the rest of the team like Rich Purcell, Anthony Crisci, and Tony Dolisi. So, it's just been a real blessing to have this kind of support and I want to, once again, thank them and thank the shareholders for all the support in creating the team effort here.

Obviously, it's a team effort and like any great team, whether it be a sports team, you're only as good as the fans behind the team. So, there's always a big plus and to have that kind of support nexus mechanism behind you. So, once again, thanks again and we'll keep everybody informed as we continue to make these tremendous significant strides.

Joe Moscato:

Thank you very much; I really appreciate the update. It was great also. I'd also just like to say the incredible work that the folks at Altucell doing is leaps and

boundaries ahead of the competition; the competition has major problems with their encapsulation technology or anti-rejection problems, purity problems with their capsules, it is just fantastic that Gary and his team have been able to figure all those problems out. And the beautiful thing is they have five-year data where no one else has data in humans.

So, very, very far out in comparison to the competition and with none of the problems that the competition has. So, we're really excited about Altucell and what that will bring to Generex as well as to NuGenerex because we believe--and maybe, Rich, you could talk to this--that there will be incredible cancer opportunities--cancer treatment opportunities with this groundbreaking technology. So, Rich, maybe you can opine on what our plans would be for the cancer side with this encapsulation technology?

Rich Purcell: Sure. Thanks, Joe. And Gary, what a great job by Gary Harlem and his team to get a clinical trial going in Italy and a clinical trial ready to go in Ecuador with David Rivera, one of the leading diabetes researchers in the world.

This microencapsulation technology for cellular therapy is really a leap from the current technology. As Joe said, the other technologies and competitive technologies are only in pigs right now, not in humans; Gary has five-year human implantation data and now he's got two trials, one's already started and the other one's going. The fact that we have the potential to treat and maybe even cure Type 1 diabetes by implanting cadaver cells--I mean you can harvest cadaver cells, grow them, and put them into these capsules without immunorejecting drugs to produce insulin; and the proof-of-concept clinical trials are ongoing right now.

So, when you think about that you can put cells in these microcapsules and protect them from the human immune system--you can put any cells in there--and cellular therapy for cancer is a brand-new field. A lot of the issues are will the cells stay alive; can you keep the treatment going? And we can ensure that the cells are viable with these capsules, that they don't need anti-rejection drugs that typically suppress the immune system; and you don't want to see something like that in a cancer patient, we want to promote the immune system.

So, for example, we could put cells that produce Ii-Key vaccines into the body and have an antigen presentation of our cancer immunotherapy technology, Ii-Key peptide epitopes.

The other thing that's really interesting is that Dr. Calafiore has gotten a third generation microencapsulate that enables excretion from and secretion from the encapsulated cells of large proteins. And if you think about that, we can put an antibody-producing cell in these capsules, implant it, and those cells will produce antibodies. Well, cancer therapy is all about antibody therapy right now and the ability to continually produce antibodies at the site of the tumor directed at a target specific to that tumor, whether it's a neonatal protein that's caused transformation or a HER2 for breast cancer or prostate cancer--prostate cancer is in a very exciting field here for us and our AE37 molecule. But we

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know that we can target tumors with antibodies, and this opens up a brand-new field of therapy.

So, there's a lot of things that we can do together, and it's really been great working with Gary. So, thank you very much.

Gary Harlem: Thank you, Rich. Well said.

Joe Moscato: So, I'd like to give the next update which is our Regentys subsidiary. Regentys has made some pretty pivotal strides in the development of its product, its cellular matrix for Crohn's and ulcerative colitis. And today, we are in discussions with another finance company that will potentially fund the company for its clinical trials that are coming up now that the product has been protected. We're really excited about this area; as everyone knows, the largest selling drug in the world today is Humira. Humira only works on 50 percent of the patients as a front-line treatment and none of those front-line treatments work for people that have Crohn's and/or ulcerative colitis where the need for surgery is great, and we believe that this product will, at least, take care of a vast majority of that 50 percent. So, we're excited about that, we're excited about the potential of this new funding initiative to get this over the finish line, and get that clinical trial done so we can get approval on that product over the coming days. It's not finished yet, but we're quite confident that this funding partner is in this space, loves the product and, to be quite honest, wants to be part of this really great product potential for the future.

So, very excited about that and now I'd like to open up for questions. I know it's going to be a lot of questions because the last time, our Q&A format didn't work out so well, we had practical problems with our provider. So, we're looking really forward to the Q&A format. This is predominantly why we wanted to do this call because we get so many calls on so many areas of the business and this is always our best way of presenting where we are with all of our varying assets and entities.

So, if you would I'd like to now set this up for the Q&A format.

Operator: [Operator Instructions] And we will take our first question from Michael Robertson.

Michael Robertson: Hi. Are you guys able to hear me?

Joe Moscato: Yes, I hear you. How are you, Michael?

Michael Robertson: I'm well. Thank you. I want to thank the entire team, thank everybody for everything that's going on and what's happening. Very exciting. I appreciate all that. I did just have a question in regarding to the listing of the NuGenerex, what timeframe we might be looking at? And then also, if you guys could provide maybe some contact information regarding... I think it was Dawson James, how we might be able to contact him regarding listing information as well. Thank you.

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Joe Moscato: Yes, in regard to talking about an IPO or talking about anything that's been planned, those plans now are enacted and they're engaged, and where we are under quiet period because we have S-1's filed, the cost of that; but most importantly, now that the investment bank is engaged, then they're now handling the initiative. We can't--there's a little rule called gun-jumping and we can't talk about it as the company.

But yeah, I do highly recommend you get in touch with Dawson James; Dawson James, we're dealing out of Boca Raton, Florida. It's D-A-W-S-O-N; James, J-A-M-E-S. They're our investment bank, they're are our lead on this; there are other larger investment banks that are involved in this transaction, but Dawson James is the lead on this and I would suggest contacting them out of Boca Raton and they can give you whatever up-to-date information that is allowable by rules; of course, we don't want to go over those rules and then hurt the shareholders, and not getting S-1's approved. So, I sincerely suggest you reach out to Dawson James.

So, I wish I could answer a lot of that, but I just can't. I thank you for the question.

Operator: [Operator Instructions] We will move next to Richard Lewis.

Richard Lewis: Yes, my question is whatever happened with the Oral-Lyn and will vaccines ever be administered via rapid spray?

Joe Moscato: That's a really good question. So, Oral-Lyn, Dr. Andy Andersen, on our board, prior to this team taking over Generex in 2017, kind of led the way on where Oral-Lyn went from seven to ten puffs. So, from a utility standpoint back in the day, though it got close to getting FDA approval with its Phase 3 submission, which then the FDA asked for more things from the company; from a utility standpoint, seven to ten puffs and running out of a canister very quickly, that would take it out of the competitive marketplace to subcutaneous injection, was just not something that was doable.

So, Dr. Andersen reformulated Oral-Lyn, got it down to one to two puffs, had that proof-of-concept study done on that product with animals, and it worked perfectly, if not better than spraying seven or ten puffs into the buccal mucosa.

So, our plan is always to have gone back to Oral-Lyn, we want to get back to Ora-Lyn; we can only fund certain things at a time. Since we were--let's call it a one-year delay in our gestation after we acquired all these assets and then had a big drilldown by the FCC which would not allow us to get any of our S-1s approved to bring in the kind of money and a good kind of money from it, from what an S-1 does, we had no choice but to take convertible notes that hurt us, but that was our only choice at the time because we couldn't get these S-1s approved because of the one-year delay with the FCC doing a deep dive on our financials.

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So, we were cleared on that and then we started to get S-1's approved. So, our plan is to go back to that, we will go back to it, we will initiate Dr. Andersen and all his great work that he did with Oral-Lyn to move the product to the next level. But the key for Oral-Lyn is to get back in front of the FDA and find out exactly what they will allow us to do based upon all of the significant data we have from putting insulin to the buccal mucosa. The formulation has changed, so we don't know how they're going to treat that; but, again, insulin is insulin, we just deliver it to the buccal mucosa through a high-gas aerosol formulation and our hope would be that we would have a clearer, easier path once we do get to the FDA and talk about how we how we could proceed with that.

But our only thing right now is we need to fund the things we have in front of us; we need to get to revenueing again; we need to get to the peak where we were where we did the consolidation of some of the businesses we acquired, which is about \$130 million in revenue. If we can get there quickly and then our plan will be to get that Oral-Lyn back up and running because we do believe it's a viable product. And as you heard today with Altucell, we believe that we have a real winner for the Type 1, and Oral-Lyn always belong in the Type 2 diabetic space, so we'll have a one-two punch for diabetics, Type 1, Type 2, one with Oral-L and one with Altucell's phenomenal technology.

So, we're excited about that, but we can only fund a few projects at a time, get to revenue, and then we'll utilize that revenue to get that product going again. I hope that answers your question.

Richard Lewis: Thank you.

Operator: And we will take our next question from Lee Alper.

Lee Alper: Thanks. Joe, you mentioned that mRNA vaccines have failed. Can you give an example of what has failed and why they failed? And then I have a follow-up question.

Joe Moscato: Well, I mean mRNA technology has been out for 30 years; they've done many, many, many different trials in the past. They've never had any trials that were positive--forget about significant positive, let's just call it positive. So, they've got a winner with COVID, though they have multiple problems, one on safety, I believe; efficacy, we know it works for six to nine months, gives protection though you still can get COVID. What we do know from the manufacturers of the mRNAs is that they're not giving long-term protection, otherwise they wouldn't be going to a three-shot booster which they all announced. And for sure, it would be making a statement that you'll probably need a vaccine year after year.

So, for us, that's very bad and the reason why it's bad is, again, 1791 non-neutralizing antibodies, which I would consider them like free radicals cancer cells, floating around in your body that have no way of getting out, they build that protein. So, 1791 times 1791 times 1791, and then next year, another 1791. Well, I mean, eventually, my opinion--and this only my opinion, but I haven't

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been wrong since February on any of this--is that that bad protein, your immune system is going to see that as foreign and it's going to attack it; and if you look up cytokine storm, cytokine blitz, or any of the other off targets that mRNAs have done before in the past, that potentially could be the next big problem. We don't know that yet, but from early indication, after vaccination, people are getting sick, people are getting hospitalized, and there are deaths.

So, the jury's out on mRNAs, they can't do what we can do which is ex vivo human trials and get all of the data necessary on a safety profile as well as a fixed profile. They have to wait, you're probably not going to have that data for at least another year after vaccination with these mRNAs, so the jury's out. But as far as I'm concerned, it's really simple. If you had 1791 neutralizing antibodies versus only nine non-neutralizing antibodies, I'd say, "Why am I even in that business?" because that's a grand slam home run vaccine. It can't hurt you, that's not the case.

So, maybe, Rich, you'd like to add to this point. I hope these mRNAs work and there won't be the long-term effect that has great potential with the 1791 non-neutralizing antibodies--don't forget, it skews all the bad [aisles], but it also skews Th2 and those are all bad things. Though, right now, we need to vaccinate people so the world can open up, and that's my opinion why we're dealing with these mRNAs.

But Rich, maybe you'd like to talk about that or Jason as well, your opinion on mRNAs? I mean, look, I don't want to bash the other vaccines because under emergency use, they've been--the pharmaceutical industry has demonstrated that we can do an unbelievable job for giving the funding and to stop a dangerous pandemic, people come up with vaccines that have protected people here. So, I don't really want to bash them; but at the end of the day, there are steps that were accelerated for emergency use only, that didn't look at the safety profiles of the long term--and a 1 percent, 2 percent serious adverse reaction--and I think it's actually more than that right now in the current epidemiology of the vaccination programs, you've got serious adverse events requiring hospitalization.

So, we don't quite understand completely how the immune system is reacting to these mRNA vaccines. The very rare instances of blood clots do point towards a potential for more serious immune-related side effects, and that's the whole purpose of our vaccine is to target the immune response. And the other point is the uncertainty as to whether you need annual booster shots; and from all indications from the current manufacturers, they're indicating that they will need annual boosters and that's what our technology is originally designed to do.

We are a T-Cell activation vaccine, that's what we do is Ii-Key, we're adding the B-cell epitopes; and if you look at--there's a recent publication from the University of North Carolina that describes the need for a complete vaccine that provides neutralizing targeted antibody responses together with T-cell responses for cell killing to kill any virus that's still in immune cells like

macrophages and neutrophils where the virus resides in long-haul COVID; CD8 cells are required to kill them. So, we are designed to activate CD4 and CD8 cells for not only cell killing immediately, but also long-term immunity through the [CD4] reaction.

So, I think we can augment the current vaccines because of the targeted immune response and the long-term immune response, and not have to do annual boosters; we can replace the annual booster. But at the end of the day, the vaccines have done an amazing job to be able to protect us here in this country and we still are not going to reach anything near herd immunity; we've got a lot of vaccine reluctance out there and we hope to be able to convince some of those people with vaccine reluctance because of our safe technology with using peptide-based epitopes--and the rest of the world needs vaccines too, and we're perfectly positioned for delivering vaccine to the international market.

Jason, maybe you'd like to give your opinion, as well. I mean I know that you've been following this very, very closely.

Jason Terrell: Absolutely. So, to your question, the mRNA as a platform--delivery platform--and approach has been around since probably the early '90s. But this year with COVID, it's the first time we've seen an mRNA vaccine be given to humans after a Phase 1, 2, and 3 on a large scale. So, it was done under accelerated approval, and it was good, and it's been effective. But the truth is the only data--long-term data--we have on humans with mRNA vaccines is what's been demonstrated and recorded thus far in this COVID pandemic and vaccination program. Fortunately, they're relatively safe, it appears, so far, and they have been effective, but like I said earlier, each of them has their own unique weaknesses and each of those weaknesses can be addressed, and the problems can be solved with our platform.

But I'm thankful that they were able to provide this vaccine to the public as quickly as they did, and also grateful that we're able to follow along and improve upon what's already been done.

Lee Alper: Great. That was helpful. Joe, another thing. The Avian Flu, I thought you had a solution for it before, but the problem went away; but I understand it's coming back in Asia. Is anything happening there?

Joe Moscato: Well, I mean right now the big problem in Asia, according to our Chinese partners, is swine flu. We were involved in swine flu, we have a vaccine for swine flu that, if it's anything like our COVID 2002 vaccine that we didn't get into people back in 2002 but did a lot of work on it--we did find out that we that that vaccine is 80 percent matched to the epitopes in this spike protein of COVID. So, in theory, that actually would have protected people, would have still been safe, and would have given long-term memory--if we had that vaccine done back in 2002.

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Swine flu, we worked on, and Eric can opine on this area. He did a lot of work on swine flu; swine flu is acting up in China, all the pig handlers now have been tested and most of them have swine flu, it is starting to creep out. We believe it could be the next potential pandemic problem and China--our partners in China--want to make that the next initiative which is swine flu, and we all contracted with them for them to potentially start the work in that process just as soon as they get their IND approved in China from the Chinese regulators.

So, it's an area that we're watching closely; we now have enacted our infectious disease side where we were focusing mainly on cancer our platform technology; it's an infectious disease and we believe we can respond quickly; we know that China will be able to respond quickly because that's where most of the cases are right now.

But yes, we've been looking at that. And Eric, maybe you can upon on the avian flu piece of it. I didn't know that that was potentially enacting up again, but if it is?

Lee Alper: Sorry, that was my mistake. I meant to say swine flu, not avian flu.

Joe Moscato: Oh, swine. So, swine flu, as I said, it is acting up; there have been reported cases; it can light up very quickly. As we know from SARS CoV 2002, these viruses get better, they get stronger, they get more proficient in protecting itself; they mutate much more like we're seeing now with SARS-CoV-19; and they have one job, and that job is to infect you and kill you. So, it could be a problem and I'd love to hear my team, their opinions on what's going on with swine flu. And Eric, maybe you can start off because you did so much work back in the day with swine flu.

Eric: Yeah, sure. So, just to clarify: the swine flu, the H1N1 and the Avian was H5N1. So, we actually did start looking at the H5N1, the Avian flu, but we looked at a region of the hemoglobin gene--so, this is the H gene which happens to be H5 and Avian H1 in swine, and it turned out that those regions where we identified vaccine peptides were 100 percent conserved between the avian flu and swine flu. So, while we initiated work on H5N1, we actually had vaccine peptides, they were good for both of them, so both H5N1 and H1N1 swine.

So, we're in a good position to move forward with that any time and confront whatever problems may arise with those flus.

Lee Alper: Okay, fine. Joe, one final one: any updates--I may have missed it if you gave it--on the work you're doing with Merck on the cancer vaccine?

Joe Moscato: Yeah, on the breast cancer side. Rich and Eric, you can opine--maybe also, John, you can talk about all your potential discussions on new stuff with Merck. But yes, Rich, why don't you answer the question?

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Rich Purcell: Sure. Well, the COVID pandemic took down a lot of the research centers and things were paused. We are making new clinical supply for that trial as we speak and contracted to make new clinical supplies for that trial. We had a discussion with Merck the other day and they're interested in expanding the potential for using AE37 in combination with their pembrolizumab (Keytruda), and other indications as well. So, our prostate program that we've been talking about, we're focused on advancing AE37 not just in breast cancer, but in prostate cancer and Merck's also interested in doing that.

The AE37 trial for triple-negative breast cancer, we enrolled five patients in that, and the enrollment stopped. And now, we're looking at ways to enhance enrollment--it's been a slow-go for enrollment and NSABP, our partners, the National Surgical Adjuvant Breast and Bowel Project Cooperative is a research centers and academic centers that are conducting this trial for us, lost half the patients to enrollment because pembrolizumab was approved in combination with the [01:43:32] for first line treatment of PD-1-positive patients; it's the same thing that happened with us with the preceptor trial and we're putting this protocol through review to enhance the enrollment so we can bring more patients in and open up new sites to enhance that enrollment, and we'll be doing that over the next couple of months.

Lee Alper: Thank you.

Joe Moscato: I'd like to just answer a question from our email questions. So, Gleiden from Minnesota asks, "What is the difference between your peptide vaccine or protein vaccine versus the other peptide potentials that are on the WHO list?" That's a good question. So, we are completely different than any other peptide or protein program. And the reason is Ii-Key. So, as you see, we have vaccines now in emergency use authorization that are all gene therapies, there are a few that are mRNA, I believe there's one DNA, and then there are, I believe, a couple RNAs that they're working on.

So, those indications are how you deliver the peptides; we deliver our peptides through Ii-Key, so our technologies are Ii-Key whereas one may be mRNA, one may be RNA, one may be a DNA peptide. So, our pathway is Ii-Key, makes peptides much more powerful, anywhere from 100 to 1100 times more powerful--and maybe, Eric, you could talk to how that process works and how much more potent as well as effective Ii-Key peptides are. And that's the big difference, the big difference is the Ii-Key and Eric, if you would, please talk about why Ii-Key is a differentiator between us and regular peptide programs. Eric?

Operator: And at this time, it does not appear Eric is connected.

Joe Moscato: Okay. So, maybe, Rich, you can answer that question.

Rich Purcell: Sure. Ii-Key is part of the invariant chain, so that's the science of this, the invariant chain works with the receptor called the Major Histocompatibility Complex, MHC. The MHC concept presents peptides to T-cells to activate

them; normally, when an antigen-presenting cell gets a protein, or virus, or anything, it chops it up and it presents the peptides associated with that virus on the surface of the MHC molecule. And it doesn't change anything in your body, the MHC complex is constantly presenting our T-cells with foreign invaders, infections, and dead cells, and cancer cells in our body, that's what it does.

What our Ii-Key does is it hijacks that MHC complex externally, it doesn't get processed through the cell; and by hijacking that MHC complex and overloading all of the receptors on these antigen-presenting cells with the Ii-Key attached to our epitopes, it activates the T-cells very specifically against the peptide epitopes that we've targeted against the infectious disease or the tumor antigen.

So, by putting the Ii-Key on an epitope and injecting that into people, it goes through the bloodstream and it hijacks the MHC complexes circulating in the antigen-presenting cells--they're called macrophages and neutrophils--and they then are able to present your target epitope to the T-Cell, so it activates that T-Cell against that specific peptide. The more that immune system sees this invader peptide, the more activated the T-cells become and you have expansion of that T-Cell population that directs the entire complete immune response because it generates B cells, generates CD8 cells, generates CD4 cells all against your target, and that's why we can activate the immune system 250 to 1000 times more than peptides alone because we use that Ii-Key to hijack the immune system directly and regulate it the way we want it to against the target.

Jason Terrell:

And this is Jason. Yeah, if may I add. The one way I've explained it before that seems to be helpful is, with all other peptide vaccines--and I would include in that the mRNA vaccines because they basically provide the blueprint that allows your body to manufacture these peptides; there's other techniques where you can inject the peptide directly into the body, but in the normal setting, that peptide, from wherever it comes has to be internalized into the immune cells. And the peptide--the spiked protein peptide on the Coronavirus, for example, is 1273 amino acids. So, if you picture 1273 amino acids clumped together as a ball, as a single protein, and you were to drop that on the ground, it's going to shatter into many different peptides. It won't always shatter the same way, and you'll get any random combination of peptides generated from that.

Likewise, when that ball is taken into the cell, our cells are going to digest it into small individual peptides, and that's not a very controlled, specific tailored custom process, it's largely random. So, we don't know which peptides are going to be--how that protein is going to be digested or which peptides are going to be created; once they're created by digestion inside the cell, they're then loaded onto MHC molecules that start inside the cell, and then that migrates to the cell surface where it presents it to the rest of the immune system. But again, what peptide is presenting, we don't know, there's no way to predict or control.

Now, if that peptide happens to be super specific and just happens to be perfect for the receptor-binding domain on the spiked protein, then it may cause

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neutron ablation; but if that peptide is also present in the same sequence on another cell in the body, say the heart, liver, or kidney, or anywhere else in the body, then you could potentially get antibodies generated to that, an autoimmune antibody, which is a bad thing, it causes a whole variety of different side effects.

And where Ii-Key is different is that we actually start with the specific 15 amino acids that we pick on that spike protein; we synthesize those, we generate those, it looks exactly the way we want it to look, and we attach Ii-Key to that and inject it, and our Ii-Key peptide is never taken into the cell, there's no option for it to be randomly digested or anything. They go straight to the MHC molecule that's already on the surface of the cell; whatever is there, it kicks it off and it binds with much greater affinity. So, we're able to pick exactly what we want, present it to the immune system and make sure that nothing we don't want presented to the immune system is present. So, that's how we get better efficacy and fewer side effects because it's very customized, very tailored, very specific.

Joe Moscato: That's great, Jason. Thank you. We'll take another question from calls.

Operator: [Operator Instruction] And we'll go next to Dinah Thompson.

Dinah Thompson: Good morning and thank you all for having such a fairly comprehensive presentation and giving us so much information; and thank you for your day-to-day work, one and all. I think this question may have been touched on a little bit by Dr. Eric and Dr. Jason just now with regards to the vaccine for COVID-19, the three mRNAs, as well as yours being so different with the Ii-Key peptides. My question is if one has already taken one of these three mRNAs that are currently available, when your complete vaccine --and I will say when it is approved and comes out--will that be able to reverse any issues and problems resulting from the mRNAs in most people--and I do understand that everyone is very different with immune system, et cetera?

Joe Moscato: As far as reversals--

Jason Terrell: Joe, do you want me to take that?

Joe Moscato: Yes, please, Jason.

Jason Terrell: Our vaccine could certainly be given to somebody who had received an mRNA and, in fact, it would be very beneficial because it would be a fantastic booster. But it would not be able to reverse any effects that had already occurred and that were already present within the body; but what we do know is that any of these off-target effects that were present or existed maybe with the mRNA vaccines would absolutely not be duplicated or replicated with our vaccine because we only give you peptides that we know are on specific spots of the coronavirus proteins, and we only give peptides that we know are not present in any shape, form, or fashion anywhere in the human body.

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So, in theory, the risk of complication from our vaccine is zero. Now, in practice, science is funny, biology is constantly evolving, there's no way we could ever guarantee that. But I can tell you with 100 percent confidence that there is not a safer approach than what we're developing.

Dinah Thompson: Great. So, one can still take the complete vaccine after one of these mRNAs down the road. Thank you very much and congratulations to Dr. Eagle on the position of Board Chairman of NGIO, and please keep continuing to try to help the world.

Joe Moscato: Thank you very much for the call. I'd like to put out a question from Harry, and Harry asks--and this is for you Jason, Rich, and team--"How effective is the GenereX complete vaccine against variants of the virus?" Jason, maybe you can take that.

Rich Purcell: This is Rich. I can also say that we're going to test that and we'll figure that out in our human clinical trials. Right now, we do not know that answer, but we have full confidence because the region of the spike protein that was targeted with our B-cell epitope is 100 percent conserved across all of these variants, and we are able to respond. We also have a number of epitopes that are against other regions of the virus, including the membrane protein. So, we have a multi-targeted response that should overcome any problems with variants, and our specific B-cell antibody-directed epitope is conserved 100 percent from SARS 1 to SARS 2. So, these variants, it's a very important region of the spike protein that doesn't; and we've targeted that specifically for that reason.

Joe Moscato: And that's very important because, again, we use the best parts of the spike protein, the ones that typically--the parts that typically never mutate. So, the chances of all five of our epitopes all not working against one of the variants, in my opinion, is pretty slim. But Jason, maybe you can add to that.

Jason Terrell: Sure. So, when a new variant does arise, it's very rapidly sequenced--genetically sequenced, that's how we know that it is, in fact, a new variant. And with the sequence, the genetic sequence codes for these proteins, one of which is the spike protein--and you can tell which amino acids may be altered or substituted based on the genetic mutation; you can also use techniques such as x-ray crystallography to actually visualize, in three dimensions, the exact conformation of the protein. So, in the variants, we know exactly how they're mutated, and we know if that mutation occurred in the sequence in a region that we target with one of our epitopes; and if it did not, then we could say with relative certainty that we will still be effective against that variant. And if the mutation did occur in a region that was targeted by using our epitopes, then it would be as simple as us manufacturing another peptide, adding that peptide specific to the variant to our formulation, and conferring protection that way.

Joe Moscato: Thanks, Jason. And then another question here from Yon Mayer. This one's a little poor color, but I'll answer this: "Have you sold all the rights to the world including EU, except in the US, Canada, and some other states to China for \$2

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million and you got no licensing fee at all? Who knew who negotiated this stupid deal?" Okay, I'd like to answer that.

So, no, we did not give China exclusive rights to the world; we gave them specific rights to sell our product in certain places in the world. And again, we're dealing with some very large entities in China that are our partners; Big Pharma here in the US has not come knocking to get our vaccine, they all have their own vaccines. And until we get our Phase 1 data that matches our ex vivo human trials and confirms that we are the only complete vaccine--or one of the only complete vaccines; with some of the newer entries maybe that we don't know about could be a complete vaccine. I don't want to say that we're the only one, but as my knowledge, we are the only one based upon the data we have; everything is up for retooling in terms of agreements; if other opportunities come up, we're going to jump at those.

But as of right now, we need help and China is willing to give us the help; China has given us over \$5 million to date to get all this work done; all of this work, once it's done, we have been transferring over to China so they can get their IND in; but they have to wait for us for that IND to go in because we are the sponsor and we need to get our CMC completely done, and all of those last final reports because everything has got to be done the same way--and any of our licensing partners or any of our partners anywhere, if they're manufacturing it in those countries.

So, we're licensing territories for sales; China, in the second contract that we signed with them, well over \$50 million for Ii-Key. Ii-Key is a major component of the vaccine, and we also have a 3M adjuvant partnership; we're using their adjuvant. So, we're very careful about how we handle the IP; we're very careful about how we transfer data; and we're very, very careful about what we give them until, if we're totally paid on the complete two contracts, that will enable them to manufacture themselves. For now, we will ship them the Phase 1, 2, 3 so they can get their approval, that's the complete vaccine. So, they won't be manufacturing anything until they pay us the \$50 million for the Ii-Key. And that's the licensing fee there as well as a few other contracted areas that they need to comply with.

So, again, we can't do it all ourselves with all our other initiatives; China stepped up and they believe in our technology and they've honored, to date, our contracts; we're honoring the requests from them based upon those contracts and what they need to get their IND in, but we're going to be very careful about how we deal with our IP as well as our technology; and again, we filed brand new IP patents as well as this vaccine plans, as well as even our process in our ex vivo human trial work. So, we're not giving any of that up until we're fully paid, and they only get patent rights in China.

So, I hope I answered that question. Again, anytime someone wants to give you \$5 million to do work, we'll take it and that means a solution, the shareholders, they don't have to raise that money through stock and, hopefully, we can get to the level where we will be recognized as a complete vaccine and the real

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solution to the world where we won't have any problems soon. So, that's my hope.

So, we're ready to take more calls; if anybody else is queued in, we'll take that call.

Operator: We will go next to Zacheus Galladian.

Zaccheus Gallidian: Hi, Joe. I have a question. In previous conference calls, you always mentioned going back to NASDAQ market, to date, not. And do you still think you're going to go back to NASDAQ in the near future? That's the question.

Joe Moscato: Well, you got to look at the companies--listen, we had a one-year delay because the FTC drilled down on our financials. We cleared that drilldown; we couldn't get S-1s filed. We had no alternative other than to take convertible notes, which we did take those convertible notes and it hurt us. So, we have 116 million shares out; that's not a lot of shares at all; I can name a company right now that was trading at 29 cents last January and it got as high just recently as \$10, and settled in somewhere between three and five, and they got 700 million shares out. I believe that I am poised to now lift on that deck with that 700 million shares out with hundreds of millions of warrants out.

But we only have about 15 percent of what they have out; I believe if we execute, we get our major asset, which is NuGenerex Immuno-Oncology listed and traded--NGIO traded--that'll give us a huge asset which will definitely boost, hopefully, our stock price in Generex since that will be a major asset and we get a complete vaccine. Look at Novavax, they were trading at \$1 last year, they're trading at close to \$300 a share right now, and they had some serious problems prior to COVID.

So, you never know what is going to happen that's going to move the needle, but we certainly do have enough things to move that needle, and I'm quite confident that needle will rise, and all things will level out where we should be in value. So, we're hugely undervalued in my opinion--massively undervalued--and we just need to keep executing, and now all the different assets that we've acquired over the last couple of years, turn those things back on, get the revenue flowing, stop the dilution, and more importantly, we have a real, real shot here at a major, major product approving on a major, major platform which is Ii-Key. The sky's the limit where we go if we're successful in our Phase 1. So, that's my opinion; I'm certainly not afraid of 116 million shares, that's not a lot of shares at all for a company that has all the things that we have.

Operator: Thank you. We will move next to Tom Smith. Your line is open.

Tom Smith: Hi. Thanks for taking my call; it's been a good call so far, I think. I just had a couple of questions. A first question and a follow-on, if I could please. The first question reverts back to something--kind of ties into a question someone else had earlier regarding the safety of the current vaccines and comparison to our

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vaccine. And obviously, everyone in the public now, the CDC, everyone's saying, "This is the safest vaccine, it's extremely safe, everyone should take it." And you compare and contrast that, and obviously, there's been some questions about that, it's emergency use. And so, there's obviously some issues, and then Rich had mentioned that there are some issues in terms of side effects of 1 percent.

So, I don't know really--it's almost like a question of who to believe, right? There have been some issues, it's been a fast process. I guess just as a question that would help to maybe see where everybody at Genex is or what everybody at Genex is thinking, if I could just ask the scientists there--Craig, and Rich, and Eric, and some of the other guys--have you guys taken the current vaccine, whether it's Moderna, or Pfizer, or J&J? And whether you have or haven't, are you a little bit concerned that you have taken them? And I do have a follow-on after that, if someone could take it.

Joe Moscato: Well, I'll answer first. I have not taken any of the any vaccine and I won't take a vaccine. I'm immunocompromised; a couple years back, I had a major problem--a bone problem--and I just won't take one. And the main reason is it's really simple. Look up Th2, look up 5, 6, 8, 9, 17, 18, 19 that's what these vaccines give you; we don't give any of those things. And I'm not saying that any of those things will create a problem for you because they predominantly don't; but again, we don't know the long-term effects of these vaccines; again, emergency use authorization is just one big, large clinical trial. They're not approved yet; so, for me, I'm going to wait for my vaccine because I know it's completely safe and it will not hurt me whatsoever; and I know based upon all of our data of the last 25 years, we're significantly positive in everything we do, especially on memory.

So, for me, it's worth me waiting and why would I want to take a chance? But that's just my opinion. Maybe Rich, you can give an opinion; Jason, an opinion because this is a good question.

Jason Terrell: Yeah, I can go. I personally have not taken the vaccine, not because I don't believe it's safe, for a few reasons. I was infected with COVID and recovered, and I believe that that also provides long-term immunity; and I also have a unique autoimmune condition which makes me believe that my risk of vaccine may be too high compared to my risk of natural infection. So, it's the peculiarities to me personally.

But I will say that the vaccines out there, I do believe they're safe; I do believe the FDA was perfectly justified in their approval, in allowing their approval, and they're justified in allowing their ongoing use. And although they're safe, they could be safer, and they could be better in many ways. And our vaccine is, in my opinion, much safer and much better in many ways. So, that's for me. Rich, do you want to comment?

Rich Purcell: Sure. I, as opposed to those guys, have gotten vaccinated; I live in a household that needs to be very safe and so I got vaccinated. And every single drug that

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we take, every single vaccine that we take, has a risk/benefit profile and I think that's important to understand. If you look at past vaccines, the FDA can say that this is a safe vaccine because past vaccines, like for smallpox, killed people and past vaccines for polio crippled kids; things happen in vaccines because the individual immune systems respond to those vaccines differently.

So, it's a risk/benefit analysis for each of us, and so I made that decision that it was safer for me to get vaccinated; and I got vaccinated with Moderna, and I'll tell you the Day 2 after I got vaccinated, I was crippled; it as a very strong overreaction of my immune system.

So, I think that the vaccines will be efficacious; long-term safety, we don't know, but that risk/benefit, to me, was better for the vaccine. I don't want to pound the other vaccines, but I do know we have a better vaccine because it's targeted--and it's more important to understand this not just the vaccine itself, but it's the commercial opportunity for our vaccine. The lyophilized vaccine, which is a powder vaccine stored under nitrogen in a vial, is going to be much easier to transport, much easier to administer to get to a big population especially in international markets we have a commercial advantage that can't be touched by the other vaccines. So, we have benefits beyond just efficacy and safety; we will be safer because they're giving the epitopes that we've got, but ours are targeted and overstimulate the immune system just with those targeted regions not the non-specific reasons that they give you the reactions to the current vaccines--that I know I experienced personally, but I'm a healthy person. So, I got through it easily.

Tom Smith: That's a good point, Rich. I mean would it give you pause if you had to take--I don't know which one you got, you said Moderna--and you had to take Moderna every year for the next ten years. If you knew that ahead of time, would that give you pause and make you think that...

Rich Purcell: Well, this is an emergency; this is the point that I keep bringing up, these were all approved under emergency use. And we have a pandemic threat, and I think there's a bit of responsibility on the public's part to take some vaccine initiatives and to make sure that everybody's safe; we have to work together as a country to calm the infection; and the pandemic is only going to be propagated if we don't follow the social distancing, et cetera that's required; masking that's required. When we do those things, we knock the virus down and we're doing it now through vaccination, and it's enabling states to open up and we get back to a full economic health for our country, and we can help the other countries get back to their physical health. As we reduce the population that can be infected, then we can stop this virus.

Now, going forward, do I need to get boosted next year? It depends on the situation at the time for this pandemic; if we cull the pandemic and there's not a lot of virus around, I believe that I'll be safe there. But if you need booster shots, I'm going to be reluctant to take booster shots. That's my opinion, anyway.

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Tom Smith: Okay. I appreciate that. And just the last follow-up for Joe regarding, I guess, the parallel track, for lack of a technical term, the FDA track over in China; you obviously have spoken with your Chinese colleagues, do you feel that they will have a faster track over there to completing--I know over here, we have to wait until May 18th and about another eight weeks--and is it possible that they complete their testing first or are they relying upon us completing and then they going. And if they complete faster, can that actually speed our side up? If you can comment on that Joe, and that was my last question. Thanks.

Joe Moscato: That's a good question. So, they have to wait for us, only because the CMC and the GMT have to be done by us; that process in figuring out what the secret sauce is, what the mixtures are, how much adjuvant, how to mix all five of the Ii-Key peptides together, how you turn that liquid into powder, how do you filter it, those are all the things we're doing. There are tests going on every single day in the CMC space for getting our final commercial on May 18th done. And so, we have to give them all of those things just like we have to give all of those things the FDA and those engineering reports, those testing reports, all have to be certified, all have to be put into that IND package.

So, once we have that package complete, we will transfer that over to them and they'll turn that all into Chinese, just like they did with our pre-IND, but they have to wait for us.

Now, what they did tell me is that they have emergency use authorization window available to them and then what they did tell us is that they have an accelerated pathway approval. So, I don't know what that means under their rules; of course, the different... let's call it, the FDA comparable in each country change yearly, so they're never the same, year by year, by year, by year; but I'm going by what they said, I think that they can probably get it done as just as quick if not quicker because they have one of the partners with the Chinese CDC; but again, they're in control of their own trials, their own submission, but they are dependent on us up until the point of us finishing our IND.

Once that's done, we'll be able to supply it to them where they can enter that IND to their FDA and get that approval; and then it's just up to them how much money they're going to put into getting those trials done. I mean, for us, I think the easiest part of our whole process is our clinical trials because, again, we're not doing massive amounts of people, we're doing under 200 people in Phase 1; a couple hundred people over that on the Phase 2; and then nowhere near with what the other guys have done in the Phase 3. So, that should be our quickest part of the process which is the trials; we have PPD worldwide which is the best, I believe, in the business that handles clinical trials and government relations, so we're with all the right companies to get it done quickly once we get the IND. And my opinion is there's no doubt we're going to get our IND approved based upon all of our great data.

Tom Smith: And I'm sorry, you had said that the IND is mid-July at this point, tentatively.

Joe Moscato: To get the approval, yes. It's our approximation. Now, understand, because we are constantly doing different experiments and there's different processes that we have to do to finish the CMC, things change. I'll give you a couple of examples. Now, I believe we would have been done months ago--and I know we would have been done months ago.

But when we did the immunogenicity study with the mice with the human alleles, the mice, unbeknownst to us, had COVID. So, someone must have sneezed on the mice that COVID; some way, somehow, the mice got COVID. So, when we tested our vaccine and the mice, they got the vaccine, they gave a great immune response and a great IV response. But when we tested the mice that got placebo, they had a neutralizing response and that's not supposed to happen.

So, what happened is the mice got COVID. Now, they weren't symptomatic, there's no way of telling if the mice got them; the second time we did it, we could test those mice now, we took blood from the mice to make sure they don't have COVID, but believe it or not, they got COVID. So, that set us back 60 days.

Or look at our manufacturers. So, we had one of the premier large manufacturers that's doing all the big COVID fill-finish, and we got bumped from one of the Big Pharma and instead of getting fill-finish started in April, they pushed us out to November. So, we had to scramble, we had to find another premier fill finish and get put into the slot. When we were put into that slot for May 18th, but they're doing all the work that leads up to that commercial run of our vaccine; we've already done the three engineering laws, we've already done the packaging on the three engineering runs, we've already done the mixing, we've done all the testing, but now we have one last big thing which is the commercial big run, which will be done in May--started on the 18th.

So, again, there's no way of ever telling, science evolves daily right, and the amount of experiments that we're doing evolves daily and we make things better as we go; and then as problems come up--I mean we didn't know that we could make a lyophilized version of the vaccine, so we had to test all that; we had to see if we can turn that liquid into a powder and will it still be that effective as it was the liquid? So, all those things as we're going, we add, we take away, but mostly, we've been adding and that just makes our IND package 100 times better than where it was each and every month.

So, that's why we keep doing that--because COVID is not going away it's never going to go away. And I believe--again, it may vary from my team, but I listen to the CEOs of these companies and they're saying, "You will need a booster; so next year, you're going to need another shot." So, for me, I don't care if all 8 billion people in the world get vaccinated, next year you're going to need another shot and why wouldn't you want the safest, most complete vaccine which will be us?

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Tom Smith: Okay. Thank you, Joe.

Operator: And we will take our next question from Scott May.

Scott May: Hey, Joe. How are you doing?

Joe Moscato: Hey, Scott. How are you?

Scott May: Good. Hey, thanks to you and the team for all the hard work; particularly, it's been difficult, obviously, for this company to be sitting with no revenues whatsoever. So, to hear the updates today on the Excellagen, and AV, and remote patient monitoring, and CCM, and all that being very close on revenues is good, and it's one of those things that's been going on in the background that we can't see that it's great to hear about. So, thanks to everybody for that.

I wanted to ask you; on the last call, you said that the pre-IND, in its response, had solved some of the issues with the application to BARDA, what can you tell us about the BARDA application and any other funding pursuits you still have going?

Joe Moscato: Well, we were very disappointed in the whole situation with BARDA. We worked with BARDA; I went to Washington a bunch of times, met with people at HHS as I stated. Our application is, I think, will think blow your doors off good; we hired top guys that worked at BARDA, we've hired guys that know the process well, it was one hell of a great application--and that application was told to us by the whole-body task force to put our application in. And they basically told us and one of our consultants, who was a cabinet member of the Trump Administration and ran a big part of government, said he's never heard BARDA ever say, "We want this, we need this, and we want this for our preparedness portfolio, because we have nothing like this, and please put your application in." So, I went, and I spent a billion dollars on putting this application together with all the right people.

And then just as we put our application in, Dr. Rick Bright, Trump demoted down to NIH. Big, huge problem. Our application went in the day before Dr. Bright testified on Capitol Hill and that, I guess, caused the big--my guesstimate--caused a big problem for the past administration in my opinion, and our application went in, it sat there, we didn't hear anything. And we'll go, "How could this be? They said they want this." So, the application was for \$1.3 billion to get the whole thing done--we would have been already done right now if we had not gotten that funding; but then don't forget Operation Warp Speed was created and all the vaccine money went to them, and the guys who are running Operation Warp Speed were wedded to mRNA and they only picked mRNAs, and I believe one DNA, and one RNA, if I remember correctly. They didn't pick any of the alternatives which, according to BARDA--when I was working with them--they were going with many different pathways to give the world the best shot and the best solution long-term, short-term, and midterm with the vaccine.

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But again, BARDA--I mean Operation Warp Speed only picked gene therapies and we were pushed out. Very disappointing.

Scott May: So, are you still pursuing this; is this still an open avenue or are you giving up at this point?

Joe Moscato: We've been--listening, I cannot imagine--I cannot imagine at all--that if our Phase 1 data of a very small study that confirms our ex vivo human trials, that we have a complete vaccine, I would be shocked if every government all around the world would be coming to us to get this vaccine.

Scott May: I understand that, but we won't need it at that point. I mean are their options before that point that you're still pursuing with any other countries that might give us a lift here in the next few months or are we pretty much on our own until we get to testing?

Joe Moscato: Oh, we're not on our own; we have China doing their own and they still owe us \$50 million; we still have Malaysia that's paying for the US trials, Phase 1, Phase 2, Phase 3--Bintai--and they have the money put off to the side, they raised that money, and that money kicks in as soon as we get our IND approval. So, once we get our IND approval, goes to that Phase 1, Phase 2, Phase 3 under our contract will be paid by Bintai in Malaysia.

So, we need to get the IND done, it's in with all of our unbelievable experts in those companies that are facilitating the CMC; once that's done, PPD will get those final reports from the final run, May 18, they will update and plug in the new information, and we will file that IND. And my belief is--there's no doubt in my mind we're going to get approval.

But again, I don't want to say--you can never tell what the FDA is going to do or the 18 members of that panel, but I would be shocked if we don't get our approval. I mean everything is just that--it's just too good not to get approval.
Scott May: Yeah. Can I do a follow-up, focus more on the China angle?
Yesterday's PR, there was a lot of hubbub on the boards and stuff about the word "if"--if Youfang conducts Phase 1, Phase 2, Phase 3 clinical trials--can you give a little color to what that "if" means and why they wouldn't or...?

Joe Moscato: Well, how do I guarantee what another--what three entities, one government entity--decides on doing after they get all my material after they paid me \$5.1 million to do all the work to give them the necessary material to do their own IND, get that approved, and then do the trials? I mean, what happens if one of their vaccines tomorrow, if you have a complete vaccine, it's 100 percent effective and it solves the problem in the world? I don't believe that's going to happen, but how do you say something definitive when it's in someone else's hands? I can't say that. I don't know anybody who pays or gives someone \$5.1 million to the work, you give them the work, and then they just stop; it's an improbability.

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The lawyers are very careful--we have a committee made up of lawyers that whenever a PR release is written, it goes to that committee of those lawyers and they slice and dice it--because listen, there's no secret out there: every single company that got involved with COVID, the regulators look very, very hard at what you say and I would be shocked if not every single company, especially on the OTC, has not gotten those calls to the FTC and been called on the carpet based upon what they're saying about COVID. I just don't want to be one of them. So, our committee of lawyers slices and dices things; if they don't approve it, it doesn't go out, right?

Scott May: So, basically, it's legalese and as, of now, there's no reason to think that China will not proceed with the testing as planned, and your current confidence is high that that is going to happen is all I'm trying to verify.

Joe Moscato: My opinion? Absolutely. No one pays \$5.1 million, tells us, "Do all this work," which we did, and then say, "Thanks a lot, but keep the money."

Scott May: I understand, it was just everybody was freaking out about "if", "if", "if" and I was just giving you a chance to clear that up, "This is happening."

Joe Moscato: Listen, if the contracts are broken or they change their minds and doing something, that would be something material and I have to announce it. Bottom line is we just got about \$2 million--again, people reading into a word like "if"... I mean, again, how do I know what you're going to do? I can sell you my house, but do I know if you're going to move in there or...?

Scott May: You've said enough, sir. I get your point; I'm just letting you know people were wondering why they might not; and if you're saying it's just a legal contract thing and that's good, and we're hoping they proceed and that's just what it--I wanted to give you a chance to say that.

Joe Moscato: I would say they got a lot of time on their hands and nitpicking every single little word; it's kind of ridiculous and they have to understand that lawyers do a lot of this stuff for us because we don't want to get called on the carpet, and I want to be able to state, and if it gets past legal review, then I'm okay with going out and that's the way it's going to be until the world gets back to normal, especially with COVID.

Scott May: Alright. Thanks for your time, Joe.

Joe Moscato: Thank you very much for the question, buddy.

Operator: We will take our next question from Curtis Patterson.

Curtis Patterson: Good afternoon to the Generex team and investors on the call. I'd like to know if someone from the Generex team can confirm the specific number of currently published patents associated with the Ii-Key technology and Generex's planned COVID-19 vaccine. And then I have a follow-on question that is, can you expand on the roughly projected timelines and the number of

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patients involved with the FDA Phases 1, 2, and 3 clinical trials: again, placing the emphasis on roughly projected timelines. I understand that it's not exact, but I'd like to know if you could give some shape and form to investors as to how things will progress if all endpoints were met in each trial.

Joe Moscato: Well, let me start off with this one thing: Generex--and I'm sure many, many people have gone there--and I'm sure my team can correct me if I'm wrong--under Antigen Express, there are all of the patents that the NuGenerex Immuno-Oncology have, they're listed up there, I've gone to the site and seen them all. We have new patents that we filed that--

Curtis Patterson: Which website are you referencing?

Joe Moscato: The us.gov site where patents normally are. I'm not sure if it's uspto; I know it's us.gov and it's a patent side of it. So, again, I don't go to it every single day so I wouldn't know, but they are there, there are many of them, and we just filed a bunch of significant patents that will give us more protection on our Ii-Key as well as our COVID vaccine, as well as our platform, and even how we do ex vivo human testing. So, those patents have not been set up as provisional yet, they're being reviewed now; we're confident they will be granted the provisional on those and that'll give us a brand-new technology and brand-new patent life on our highly regarded Ii-Key technology.

Maybe, Todd, do you know where--I mean I know Generex has at least 100 there on patents on the Generex side and then Antigen's got a bunch. I mean, Rich, you know where the patents are?

Rich Purcell: The patents are listed at uspto.gov. And the most important part of that question is what we've just recently done. We filed a provisional application for our COVID-19 vaccine--our Ii-Key COVID-19 vaccine that includes claims that are directed to the platform. We plan to expand the IP on the platform as a whole and we're continuing to put applications; and based upon the data that we've been able to generate in our clinical programs, a lot of the patents did not include data that we now have showing disease-free survival in a low HER2 population, showing long-term immunity in a prostate cancer population, showing activation of T-cell responses that are directed towards the Th1.

And this is the new mechanistic piece of our IP, that we're going to be able to protect the Ii-Key going forward; we're also able to, with the new lyophilization process in particular, advance the formulation and product patents for new vaccines for Ii-Key, especially with the adjuvant coming, we have new formulation capabilities and an understanding of how to deliver a product in combination with adjuvants; that is going to give us new Ii-Key there.

So, Ii-Key is going to be protected for a much longer time; I can address the clinical trial questions, we're filing the IND by the end of June--the first day of July is the latest that we can possibly do it as far as I'm concerned on my internal timeline, anyway--and we expect to be able to initiate our Phase 1 trial

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with 159 patients targeted based upon the FDA's approval of the protocol; they have it, we submitted that protocol to them.

And it's a very complex and complicated protocol that PPD helped us put together, it evaluates the Phase 2 patients--subjects, if you will; they're not patients, they're not sick--evaluates their immune response very specifically and comprehensively. We're looking at a wide range of T-cell responses and a wide range of antibody responses-- neutralizing antibody responses particularly in that live virus assay at UCSD that's going to look at not only the wild type virus, but also the variants. So, we'll have all that data that is going to give us the information whether we can go directly to Phase 3.

As Joe has pointed out and we've talked about extensively, FDA recognizes the safety of Ii-Key peptide vaccines; the FDA did not require us to do any toxicology work on our coronavirus vaccine. Why? Because we've got data in humans with Ii-Key epitope vaccines that show that it's safe; and so there's a belief with the FDA that our vaccines are safe, and if we show the efficacy in Phase 1, we'll probably be able to jump into an expanded Phase 2/3 right away; we changed that from a Phase 1/2, and waiting for going to a Phase 3 afterwards; we've gone for a Phase 1 because we know we can get that data right out of the Phase 1, that will give us a boost in the market, a boost with potential big pharma partners, a boost with government funding agencies because we're going to have demonstrated the effectiveness of our vaccine in people showing a complete vaccine response.

And that will direct what the future timeline looks like for our Phase 2 and 3 programs. If we have excellent data, we know that it's safe, we'll be able to expand very rapidly--and it'll be an international trial as well. As a matter of fact, this Phase 1 trial is going to have international sites associated with it as well. So, we're confident that we can enroll this Phase 1 trial very rapidly, it's only 160 patients and therefore, get our answers quickly that will guide our future development program and timeline which we hope will be accelerated based upon our data.

Joe Moscato:

I mean, again, our biggest tasks have been the CMC/GMT and dealing with, now for the first time ever, five epitopes, five different peptides, and then linking those peptides. Will they mix together? If they do that, they're great together; a brand-new adjuvant that we think is the best which is from our partner 3M. It's taken us a long time to negotiate a worldwide license with 3M for that adjuvant; they're only in trials--in varying trials--we had to get special permission from the US government, NIH, and HHS to reference their safety profile and data for the FDA packages we put in. And so, it's not only us; I mean we need things from all the different partners, right? And we still don't have all the stuff from 3M, we're waiting on that stuff from them.

So, we're quite confident that we'll have everything together; but sometimes timelines get pushed out; and it's pretty obvious there's only five major manufacturers that can really do these vaccines and they're all being utilized, and someone comes along with an extra \$1 million, or 2 million, or \$10

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million, sometimes, you get bumped. But I believe that we have everything set up, everything's in place to move effectively and efficiently now; and we believe that our last couple pieces, plus the last couple pieces we need from 3M to get the package in would be forthcoming very soon and we can get that package in.

Scott May: Thank you. And going back to the patent, it sounds like relative Ii-Key technology, that no patents have actually been granted for that technology yet?

Joe Moscato: That's absolutely not true. I mean like I told you already on the phone--twice when you called me--there are plenty of Ii-Key patents that are up on the us.gov site and they're all there; we just expanded on them with this new big program for COVID that will now--plus, as Rich said, we have ten-year data on our breast cancer trial the biggest that was ever done in Stage 2b; we have now long-acting data from our prostate trial and all of that stuff is being utilized to make more effective patents.

And that is one of our big initiatives, we've hired probably one of the best in the business to do patents for us; and where our patents used to be four, five, ten pages long, they're now 150 pages long. So, they're much more detailed, they're much more in-depth; and surely, we're setting up a new patent portfolio around the old patent portfolio that'll give us a lot more protection, a lot more value to shareholders; and for sure, a patent portfolio where now we can harness our technology in a big way.

Scott May: Okay. So, my underlying concern is if we don't have ads and we really don't have much to stand on from a competitive standpoint--I'm not saying that that's the only thing that's important.

Rich Purcell: We have a patent until 2031 for AE37 right now and it's going to be expanded with his new patents that we're putting in.

Joe Moscato: We have many patents up; you need to go to Antigen Express on the us.gov site, they're all up there, anyone can see them, and we've had those patents for many, many years.

Scott May: Well, I only asked you questions because I have gone to uspto.gov, I've searched on Antigen Express, I've searched on Olaregen, I've searched on Generex...

Joe Moscato: Maybe you're misspelling the words, I'm not sure, but they're there.

Rich Purcell: Type in "Ii-Key".

Scott May: Okay, I've tried that, but I'll try again.

Joe Moscato: Well, it works. I keep telling you to go to the site.

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Scott May: Well, I'm an investor, so I'm certainly not hoping that they're not there, I just haven't been able to find them. And just as an example, I've seen data from other companies' products--

Joe Moscato: Hold on one second. So, you're asking me a question on where they are; I'm telling you where they are like I told you on the phone, telling you how to get to them. And then you're arguing with us on whether we have it or not, and then you're saying a company doesn't have them. I'm telling you we have them; we have plenty of patents--we've always had plenty of patents; the company's raised well over \$450 million in its lifetime and a company that raises that kind of money needs patents; you're worthless if you don't have patents in this business. Worthless. Big Pharma doesn't come knocking, no one partners with you. So, we have plenty of patents. Please contact me, and I will get you the link to those patents.

Operator: And we will move now to John Fedele.

John Fedele: No more questions.

Joe Moscato: What was that?

John Fedele: I no longer have any questions.

Joe Moscato: Okay. Thank you for being patient; I'm sorry; hopefully, it was answered.

Operator: And we will take our final question today from Emily Lee.

Emily Lee: Hi, Joe.

Joe Moscato: Hi, Emily. How are you doing?

Emily Lee: Good. Thank you so much for taking my call and thank you all for your hard work, it's a great accomplishment that you guys have done for the vaccine to come this far. So, congratulations. I do have a couple of questions. The first question is would you be able to give us some updates on the application you guys put in with Health Canada?

Joe Moscato: You mean in terms of Health Canada. Well, we've had an open dialogue with Health Canada, we've discussed and gone down many different pathways with Health Canada. Health Canada picked a few choices that they wanted to go with--in country. The biggest problem that ended up with Canada was they wanted to fund us, they wanted to partner with us; unfortunately, from what I understand, the reason why we did not get funded or partnered with Canada was they wanted us to provide a matrix on how we expand in Canada and how we put people to work in Canada if they funded us.

And we do not add any of that because we do have offices still in Toronto, we have employees in Toronto, a whole IRPR IT department is up in Canada; and they wanted us to expand all that, they asked us those specific questions; but

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I'll be honest with you, from what I understand, the reason why they went with other folks was that they wanted to keep the money in Canada, fund Canadian companies that would bring on people, create jobs, and that was something that we just couldn't do up there.

So, it's never dead; we know all the folks up there now, we've been very intimate with them all and intimate with Health Canada as well as their regulators and their FDA, and we'll get back to them. Again, my plan would be once I get done with the Phase 1 and that replicates all of our ex vivo human trials that we've done and the data just as good, if not better like always once we're in humans, then I'll go back to them, give them an update to see if we can get something back on track with them.

Emily Lee: I see. Would you be able to give us an update on the MOU that was signed with Binta regarding Australia and New Zealand?

Joe Moscato: Well, again, Bintai, if you read the contract, everything, the next phase whether it's money, whether it's giving them their options and them paying for those options, but it will require an upfront payment, are all contingent on us getting that IND approved. So, once we get that IND approved, their responsibility is to pay for the trials here in the US; and then they're going to do that and we have good Phase 1 data, for sure, I would be exercising that option that they have giving us the money that we request so now they can handle those populations in those countries at which they have potential rights.

Emily Lee: I see. So, the MOU is signed, it's just pending the IND approval; and then once that's approved, it's possible we're going to be able to get money.

Joe Moscato: Yeah, they've already complied with--we went from MOU to contract.

Emily Lee: Oh, so you already have a contract?

Joe Moscato: Oh, yeah. We went from first an MOU, and then we went to a hard agreement, which is something that their type of law requires; then we went to an actual contract which then they paid us \$2 million, which then any other additional monies would be contingent on us getting an IND approval so then they can pay for our Phase 1, 2, and 3.

Emily Lee: Are you talking about the option exercise for Australia and New Zealand. I was wondering.

Joe Moscato: Yeah, I mean if I was them, based upon that option they have, it's only common sense that they're going to pay for phase one, and we'll get the data on the Phase 1 once we get the IND approved. If it emulates all of our ex vivo human trials, I'm sure at that point, they'll be sitting down and negotiating for with us for those territories they have an option on. That's the way I would do it--if I was them, that's the way I would do it, but that's pretty much a standard formula. You want to get milestones before you ignite other options in a contract.

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- Emily Lee: Are there any other potential contracts with other countries? There were a few mentioned last times like Singapore, South Africa. Would you be able to give an update?
- Joe Moscato: Yeah, I can tell you and it was specifically mentioned in the PR we just put out about our China partners; basically, we are in discussions with entities in Ecuador, the government there, as well as Colombia, Peru, and Mexico--those four countries have kind of teamed up and we're in discussions with a big group there--and the government--to facilitate a partnership and for them to help Generex bring this initiative to the forefront. So, we are in discussions; we're nowhere near any kind of announcements, but I think the discussions have gone very well and that's specifically why those countries were called out of any licensing with China or any rights for China to sell in those four countries in South America--and, of course, North America and Mexico.
- Emily Lee: Sorry, I'm a little confused. So, those countries are in negotiation with Generex partners?
- Joe Moscato: No, they're in negotiation with us; we carved those countries out--it's called a carve-out--so, we specifically said that China has no right to sell our vaccine in those four countries. Of course, I have a negotiation.
- Emily Lee: Oh, I see. And then, so it's possible they're interested in our vaccine or they're interested in funding us, or interested in purchasing from us, or what?
- Joe Moscato: I would say it would be a partnership; we're talking more on the partnership level they want to be at the forefront of helping to be a world solution and they feel that Generex has that potential, and we're in discussion. So, at this point, there's discussions; I think the discussion is going quite well, but there's no definitive on anything at this point.
- Emily Lee: Would you be able to give us a rough timeline, like when do you expect something?
- Joe Moscato: Well, I can say the discussions have kind of gone a little slower because there's a new president that's taking power in Ecuador whose kind of leading the charge here within the next week to ten days; so, his administration is not totally in though, we've been talking into the old administration that now, the new administration has taken over. So, it's tough to give a--when you're dealing with so many different people, it is very difficult to give a timeline.
- Emily Lee: Yeah, I know it's hard. I was just... I don't look for a PR, it's just so I have a rough idea.
- Joe Moscato: Yeah, we've been very careful about the PRs that we put out; we haven't been as active there only because we do not want to get under any kind of regulator situation because of COVID and because they've identified COVID companies for investigations. So, we post to the lawyers; the lawyers review it, they

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change things they ask us for proof of this, proof of that. Once they approve it, we put it out; if the lawyer doesn't approve it, we don't put anything out.

Emily Lee: Okay, I understand. Thanks, Joe; thank you so much for answering my questions, I appreciate it.

Joe Moscato: Thank you so much, Emily; it's always nice to hear from you.

Emily Lee: Have a great day. Thank you everybody on the team, I appreciate it.

Operator: And this does conclude our Q&A session for today; I'll turn the call back to our presenters for any further or closing remarks.

Joe Moscato: Well, I'd just like to thank everybody for their participation today, my team and both companies; our board of directors, of course, in both companies; our shareholders and, of course, everybody being patient for getting on the call today; it was a new format, we tried to make it better from last time which we lost to Q&A last time, and I just appreciate everybody be on the call.

And please keep a lookout; we do believe that we have the complete vaccine and a real solution for the world with that vaccine. It's not going to take much more time to find that out; and based upon the data that we do have in all three valuable areas, which is the upfront antibody side, the safety side, as well as the long-term memory side, we believe we are the complete vaccine and we can't wait to get into that Phase 1 to prove that; and once we prove that we have a much, much different company.

But I'm very proud of this team for the work they've done; Rich Purcell, as Jason Terrell had intimated earlier, has done an unbelievable job with not a lot to work with in regards to resources, but managed to put a world-class program together with his team, and I'm quite proud of the work he's done and everybody that's our shareholders should be proud of that as well because, again, we didn't get help from anyone other than China and Bintai out of Malaysia. And it's not cheap to do what we're doing; this is a full program that needs a lot of resources; if we had those resources, we would have been done a long time ago and we would have been a real solution; but now, it's a major, major problem.

So, I look forward to the next call; I thank everybody and for sure, be on the lookout for any updates. And then, of course, next quarter where we'll have our new revenue streams coming in and that's very exciting because, for a company that has all the assets we have, we need to turn everything back on which we're doing, and revenue will change this company pretty quickly.

So, thank you all and look forward to the next call. Anyone else on my team would like to say anything--Rich, Jason, Eric, anyone? Please do.

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- Rich Purcell: Thanks, everybody, very much for the attention today and for your questions; we're really excited about moving everything forward on all levels. Thanks a lot.
- Joe Moscato: Terry, maybe you'd like to say something?
- Terry Thompson: Yeah, we look forward to moving our revenue streams forward on the programs we talked about as fast as we possibly can; and I think that will help the company in terms of being able to have cash, and cash flow, and some EBITDA where we've been struggling with none for quite some time or very little; and I think this is a chance to get it going again and thank Joe for getting the investors involved to get these programs going for us again. So, that's about all I have, Joe.
- Joe Moscato: Alright. Anyone else, please jump in. If not, thank you all. Maybe Jason, you want to say something.
- Jason Terrell: Yeah, I'd just like to say thank you to everybody thanks for being on this call and for your continued support; and as always, we are here; if anybody has any questions, feel free to reach out we're happy to help you to respond.
- Joe Moscato: Sanjay, maybe you'd like to say something, Sanjay.
- Sanjay Kumar: Well, the results will be there in 60 days; that's all I can say. 60 days. Talk is cheap, the results will speak for themselves.
- Joe Moscato: That's great. So, we're all looking forward to Sanjay, to you, and Terry's initiatives going forward. So, thank you all everyone; we're going to end the call now and look forward to potentially next month doing another one; and hopefully we'll have a lot of other great news.

Thank you very much.