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# EDITED TRANSCRIPT

MRNA.OQ - Moderna, Inc. - Award from U.S. Government Agency  
BARDA to Accelerate Development of mRNA Vaccine (mRNA-1273)  
Against Novel Coronavirus

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APRIL 17, 2020 / 12:00PM, MRNA.OQ - Moderna, Inc. - Award from U.S. Government Agency BARDA to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus

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## PRESENTATION

### Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Moderna's conference call. (Operator Instructions)

I would now like to hand the conference over to your speaker today, Ms. Lavina Talukdar. Please go ahead, ma'am.

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**Lavina Talukdar** - Moderna, Inc. - Head of IR

Thank you, operator. Good morning, and welcome to Moderna's conference call. Today, we will discuss the award from the Biomedical Advanced Research and Development Authority, or BARDA, to accelerate the development of mRNA-1273, our vaccine against the novel coronavirus. You can access the press release issued yesterday evening by going to the Investors section of our website.

Today on this call, we have Stéphane Bancel, Chief Executive Officer; Stephen Hoge, President; Tal Zaks, Chief Medical Officer; Juan Andres, Chief Technical Operations and Quality Officer; and Lorence Kim, Chief Financial Officer.

Before we begin, please note that this conference call will include forward-looking statements. Please see our SEC filings for important risk factors that could cause our actual performance and results to differ materially from those expressed or implied in these forward-looking statements. We undertake no obligation to update or revise the information provided on this call as a result of new information or future results or developments.

With that, I will now turn the call over to Stéphane.

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**Stéphane Bancel** - Moderna, Inc. - CEO & Director

Thanks, Lavina. Good morning or good afternoon, everyone. Thank you for joining us.

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So I propose that I'm going to quickly summarize a few key points of last night's press release, and then we'll take your questions. So I'd like to cover 2 themes: one is, of course, BARDA and the BARDA grant; and two is a quick clinical plan update.

So on the BARDA front, let me start by thanking the BARDA leadership, the administration, U.S. Congress and U.S. Senate. As many of you has followed in the last few weeks, the government has moved very quickly to enable several bills that were partially funding BARDA for HHS. And as you know, we have been working in the past with BARDA for Zika grant, which was, of course, very helpful to know the leadership of BARDA and for them, especially to get to know more than our team, the capabilities we have, the platform, our site. And so we are very thankful and humbled by their support.

As you saw in the press release, the grant that is up to \$483 million is going to be a big accelerator to the development of mRNA-1273. The grant covers basically 2 chapter. One is the development of mRNA-1273 up to FDA licensure that includes the multiple studies that will be run and, of course, the material that will be prepared by Juan's team to run those studies and all their cost and preparation of the BLA readiness, filing and so on.

The second component of the award is very critical for our ability to supply as many doses as we can, as fast as we can in parallel to the clinical plan without waiting for the derisking for the typical Phase I, Phase II, Phase III. BARDA is awarding some considerable capital, so that we can work on the manufacturing process scale-up, so that we can increase our scale in production as fast as we can, so that we can maximize the output. So we're very thankful for their willingness to fund the development plan. Because of the magnitude of it, talented team will be able to really partner and interrogate as much as we can different subpopulation and really scale quickly the size of those studies to potentially speed and the velocity that we'll not have achieved alone. And the ability to invest at risk is also of course, extremely enabling. And we are thankful for the government to be willing to take such risk, so that we can maximize the potential success of this product.

As part of this, we also announced that we will be adding up to 150 new team member to Moderna to make all that work happen between now and the end of the year. As you can imagine, mostly in clinical development, clinical teams, clinical operation teams, regulatory teams, also teams in research for assay development and so on, process development, process scale-up and so on.

On the clinical plan update, what we communicated in the original Phase I, which, as you recall, was 3 healthy adult cohort, young healthy adult, 18 to 55 years old, we are noting that it's fully enrolled at 25, 100 and now 250 microgram. And so we're announcing that we are expanding to 6 additional cohorts, 3 cohorts in an older population, 51- to 70-year-old; and yet another 3 cohorts in an older population, 71-year-old and above. As you can appreciate, we are eager with the NIH who is running the study to learn as much as we can from the safety standpoint and the emergency standpoint in different populations given the different population that are most vulnerable to the virus. Our plan is still to start the Phase II study in the U.S. in the Q2 time frame.

So with that, I would like to thank our teams who are really working around the clock and now have been working 7 days a week for 3 months because we know every day matters in this fight against this virus. I would like to thank our partners. Dr. Tony Fauci's team at NIAID has been really wonderful to work with both in preclinical work and in the clinical teams. And of course, the BARDA teams who are very happy to have this new partnership with them.

And so with this, we'll be happy to take any questions that you have. Thank you.

## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) And our first question comes from Matt Harrison with Morgan Stanley.



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**Matthew Kelsey Harrison** - Morgan Stanley, Research Division - Executive Director

I guess 2 things. One, could you just sort of outline where the expansion is going to take place? And is this a physical expansion? Or is this just more steel tanks, et cetera, at Norwood to be able to scale up? And then the second thing is what -- maybe you could just comment a little bit on what has allowed you to expand into older individuals and to enroll these additional cohorts in the Phase I study.

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

Thank you. I'll take the first one. So our plans are both. So we are going to be expanding in Norwood, the capacity as we scale up. And also we are going to be expanding also with a partner CMO that we will announce shortly both in the U.S. and outside of the U.S.

**Tal Zaks** - Moderna, Inc. - Chief Medical Officer

Matt, this is Tal. Let me take your question on the expansion into adults. I think really, there's 2 factors here: one is the totality of data that we've had on our platform, both preclinical and clinical; and I think the other one is having enrolled fully the adults and being able to look at the safety there is the primary and gating here. I would defer sort of the granular questions to the team at NIH, and I give them a lot of credits for pushing the envelope here on behalf of all of us.

**Operator**

And our next question comes from Ted Tenthoff with Piper Sandler.

**Edward Andrew Tenthoff** - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Thanks for the update, continued progress and all the hard work you guys are doing. I'm just trying to get a sense. This is really fantastic to see the government moving so quickly behind you to support your efforts. I want to kind of come back to something we talked about a little bit at the Vaccine Day, which is sort of how this could emerge as either stockpile or commercial opportunity. And my question kind of has to deal with both either overseas government as well as the U.S. government in terms of stockpiling sort of in the first wave. So maybe you can kind of just give some early thoughts on how that could evolve.

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

Ted, so this is Stéphane. That's a great question. So as you have observed in the past for different outbreaks, different governments around the world have decided what clinical studies were happening to basically preorder stockpile product. So that in case of success, they are as much product as they can ready to be distributed in their geography. This grant does not include stockpiling. As I said in my remarks, this is really funding clinical developments, studies and the material and the process scale-up. So as we potentially enter into discussions of stockpiling with governments at the right time, we will give updates. But this grant does not include stockpiling.

**Operator**

And we have a question from Salveen Richter with Goldman Sachs.

**Salveen Jaswal Richter** - Goldman Sachs Group Inc., Research Division - VP

So with regard to the COVID trial, could you just talk about the dose level and cohort sizes of the 6 additional cohorts here? And if you're not going to higher doses, why not? And what you hope to learn in the older population?



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**Tal Zaks** - Moderna, Inc. - Chief Medical Officer

Yes, this is Tal. Thank you, Salveen. So similar sizes and same dose levels such that we're testing the 25, 100 and 250. Why not go higher? I think it's based on the totality of data that we've seen so far from our clinical trials. If you sort of connect the dots and perhaps the most informative one was CMV, you can see a very nice dose response curve at about 180 to 300 there, it seemed to plateau. And recall that CMV actually has 6 different mRNAs in one. So realistically, the amount is -- because they're all more or less equal weight, the amount there is about 30 micrograms, really, if you look at the sort of that mid-level 180.

And then if you go back to the history of our simpler vaccines, the ones that are non-American nature, prefusion proteins, whether it's RSV, H7, H10, we seem to be hitting the stride sometimes as early as 25 microgram up to 100 in the case of H7. And we think it has plateaued with a very nice response. And I think finally, just this week, you saw the Zika data. It looks like it was so long ago now. We're already at 10 microgram. We see that we've got immunogenicity. So I don't think based on the totality of our expectation that going higher than 250 is likely to be warranted. Now we'll be looking at the data. And as this has been enrolling on a stepwise fashion, as soon as we get a sense for the immunogenicity, we may choose to go and expand the bracket either up or frankly down. We may have overshot with an initial dose of 25 microgram. But I think based on the totality of the data, we expect this is where we'll land.

Your question about the elderly is salient. We have some experience there in our RSV already that was the first trial that we did with Merck. There was already an elderly cohort there. It's not a prime boost. It's really a boost scenario but still had elderly. And I don't think our sense was that as far as that antigen and this technology, there was a difference in the immunogenicity we were able to elicit in the elderly.

**Salveen Jaswal Richter** - Goldman Sachs Group Inc., Research Division - VP

And Tal, if I could just follow up, do you still expect safety data in the spring and then efficacy data in the summer? And can you just help us understand what you're really looking for here for this to be a positive result?

**Tal Zaks** - Moderna, Inc. - Chief Medical Officer

Yes. I think what we're looking for this to be positive are 2 things. The first is to demonstrate the ability to induce neutralizing titers significantly so consistently so and to understand the relationship between the dose and the ability to do so.

The second element is going to be to try and understand what level of those neutralizing titers is relevant for the expectation of protection. And that will rely not just on this trial but on all the correlative work that's happening in parallel work streams whether it's looking at convalescent serum or various animal models to sort of connect the dots, if you've got neutralizing antibodies, and this is their quality, and this is our quantity, what is the expectation in terms of protection. That effort is obviously going to be more challenging. It's just started a couple of months ago, and so we're in the early days of that. But it's a combination of these 2 data points that I think are going to be informative in the first instance for the potential benefit of this vaccine.

Now in the second instance, just looking at neutralizing titers to the degree that we get a sense that those levels are significant, they're consistent and that they happen in the majority of the population and we understand the relationship between the dose and the ability to elicit them, that in and of itself should allow us to start trials with clinical end points in the late summer.

**Operator**

Our next question comes from Cory Kasimov with JPMorgan.



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**Matthew Thomas Holt** - JP Morgan Chase & Co, Research Division - Analyst

This is Matthew on for Cory. So just a follow-up to Salveen's question. For the patient's dose so far in the Phase I study, just wondering if you've seen any data to suggest the reduction of neutralizing titers in patients.

**Tal Zaks** - Moderna, Inc. - Chief Medical Officer

Matthew, it's Tal. That's the question we ask every day. It's early days. And as soon as we have a cogent body of information where we're able to share it, I'm sure we will as (inaudible).

**Matthew Thomas Holt** - JP Morgan Chase & Co, Research Division - Analyst

Okay. Great. And then just curious of the award total. What portion is earmarked for development versus manufacturing?

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

This we have not disclosed, Matthew. This is confidential information between the government and Moderna.

**Operator**

And our next question comes from Geoff Meacham with Bank of America.

**Alec Warren Stranahan** - BofA Merrill Lynch, Research Division - Associate

This is Alec on for Geoff. First question from me. Could you maybe detail how much of the manufacturing scale-up do you expect to be covered by the BARDA grant? Will this funding get you through the completed build-out, meaning you'll be able to then produce millions of commercial doses? And how quickly do you think this will happen?

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

So let me take this one. So what we are doing is scaling up the process in addition to producing in parallel for the clinic. The scale-up that we are going to be completing, the first stage, we have already done, which is beyond what we did for Phase I. So we are going to that one, and that one is in the pocket. The next one is what we're going to be doing in the next few months with this grant. And that will define the scale, which we will replicate in a number of different places as we install the capacity. So that would go very, very quickly as soon as we do that, as we have the targeted scale. And just as a reminder, our process is self-free, so it is not traditional biotech. We don't need huge bioreactors in order to go and build. So once we define the target final process, which we are confident to achieve, we will be able to replicate in a number of different notes.

**Loren H. Kim** - Moderna, Inc. - CFO & Treasurer

I would jump in that the BARDA grant is not funding the replication of those notes, the build-out of additional capital equipment.

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

That is correct. It is meant to fund the scale-up.



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**Alec Warren Stranahan** - BofA Merrill Lynch, Research Division - Associate

Okay. Got it. And maybe 1 last from me. Could you detail the 2-year base period of performance? And how much of the \$483 million is included in the first 2 years? And sort of what the gating would be to get the full option exercise for the 5.5 years?

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

So again, Alec, it's Stéphane. We don't disclose details like that. I mean as you can imagine, this is a typical grant, which is based on success. So as you can appreciate, if the vaccine probably was to fail in Phase II, the cost that is earmarked for a Phase III, of course, will not be paid. And of course, we'll not want to use taxpayer money if we don't need to. So you just gate it on success. Those are just the typical gates you will see in this type of work, nothing more.

**Operator**

We have a question from Yasmeen Rahimi with ROTH Capital.

**Yasmeen Rahimi** - Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Co-Head of Biotechnology Research

Congrats on the amazing update that you provided us with, and thank you for your continued hard work against the fight for COVID. Two questions for you. First question is, can you share with us what is maybe the rate-limiting step when we think about taking manufacturing to millions of doses? And then as we go -- and then the second part of the question is, are there any components or elements of the manufacturing that you could outsource, even though you guys are amazing, doing everything on your own, just to expedite production?

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

Thank you, Yasmeen. So in -- scaling up is all about integrating the different pieces. So there is not 1 single rate-limiting thing that is bringing up the scale, bringing the equipment, bringing the process, and we are doing all of that in parallel, including the raw material. So we're working very, very close with our partners, suppliers and contractors to be able to do that. So I want to thank them as well for being so close to us.

And then as I mentioned before, yes, we are thinking to expand beyond Norwood. We are starting, and we have the fantastic capability there that allows us to go much faster as we replicate. But we are going to be working with other partners both at the manufacturing end as well as with (inaudible).

**Operator**

And we have a question from Hartaj Singh with Oppenheimer.

**Hartaj Singh** - Oppenheimer & Co. Inc., Research Division - Research Analyst

And I also echo the thoughts on all the great work. Just a couple of quick questions. One is on -- again, on COVID-19. In the press release, the BARDA Director, Rick Bright, is quoted as saying that we could shave off a few months of development of COVID-19 vaccine. Stéphane and Tal, is that -- with this scale-up, are you still thinking it's 12 to 18 months, assuming proper clinical development pathway and this crisis doesn't get worse? Or do you think that you could actually shave months off of that 12- to 18-month time frame that people have been thinking? And I just had a quick follow-up on other vaccines.



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**Tal Zaks** - Moderna, Inc. - Chief Medical Officer

Thank you, Hartaj. Let me take that. This is Tal. Look, every day matters here, and we're looking at months, weeks, days, in some cases, hours, as my colleague, Juan, likes to remind me. The reality here is that the pace of development will depend on our ability over time to expose subjects who are at risk of getting infection and our ability to do that in places where we can demonstrate versus a placebo that, indeed, there is a clinical benefit. That's at least as far as the clinical end points go here. The ability -- as I was mentioning earlier to Salveen, I think the ability to demonstrate potential benefit based on antibody levels, we should be able to see that this summer, but that will be very early, and in terms of development and safety database at that point is going to be limiting.

This is a long-winded way of saying that I think it will take the totality of the understanding both safety and efficacy and dialogue with the agency to align on what is the minimal data package that should enable us in the context of a benefit risk where the potential benefit is so huge given the unmet need out there, what would be the right amount of data to enable broader use and how do we in a stepwise fashion enable that broader access to the people who need it the most. I think I'm really happy that we have good collaborations with the U.S. government. Now BARDA has shown up with their experience. They've been set up to exactly think about these kinds of problems.

Obviously, having different arms within the same department HHS, it's going to have to be a conversation with BARDA, with the CDC, with the FDA in terms of looking at the data as it emerges. My -- our responsibility is to demonstrate the clinical benefits, derisk the safety database as we go along as fast and as diligently as humanly possible, and that's what my team and I are going to be focused on.

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**Hartaj Singh** - Oppenheimer & Co. Inc., Research Division - Research Analyst

Great. That really helps, Tal. With this support from BARDA, does this give any insights into a potential, for example, emergency use? I know that that's been a pathway that the FDA has rarely taken but might be appropriate in this case. Does this contract give any additional insight into emergency use based on, let's just say, Phase I data neutralizing antibodies or not really?

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**Tal Zaks** - Moderna, Inc. - Chief Medical Officer

So Hartaj, it's a fair question. This is not what the contract deals with. The concept of how one would deploy this is going to depend on 2 things: the scale-up, which is not part of this contract as -- I'm sorry, not the scale-up, but the actual supply agreement, as Stéphane had alluded to. And then the discussion on emergency use is going to be an evolving one that will take those aforementioned parties together with us as the data matures to make that determination. It's on a case-by-case basis, depending upon the data and the need that is going to exist at that particular moment. So it's very hard to predict today.

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**Hartaj Singh** - Oppenheimer & Co. Inc., Research Division - Research Analyst

Yes. No, I think that's fair. Last question is just on the other vaccines with TMV and stuff. With this scale-up going and a tremendous amount of support and focus from Juan's team, just any thoughts on the other vaccine programs? I assume that barring any unforeseen circumstances the manufacturing and everything there is going along as needed.

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**Tal Zaks** - Moderna, Inc. - Chief Medical Officer

From a clinical development, absolutely, yes, I will let Stéphane answer the rest of it.

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**Stéphane Bancel** - Moderna, Inc. - CEO & Director

Yes, it's a good question. On the rest of the pipeline, the supply keeps moving. As you know, we tend to be making things ahead. Recall we made another Phase II of CMV. We're ahead of starting the Phase II. We've already mentioned that we've been already working on the Phase III material

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for the CMV. And so thankfully, given the scale of Norwood, we can accommodate the rest of the pipeline as well. We'll have to think and as a team we mentioned is we have not communicated yet how we plan to expand beyond Norwood. And when we'll be ready for that, we'll, of course, communicate. But we are all highly aware that if a vaccine gives good safety and efficacy data over time, every additional dose is going to be extremely important. And so the team is extremely focused on how do we maximize Norwood first because that's we -- the best way we can have short-term impact, including the process scale-up that BARDA is funding, but also how potentially do we extend beyond Norwood. But we have nothing to communicate about that at this stage.

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### Operator

And we have a question from Alan Carr with Needham & Company.

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### Alan Carr - Needham & Company, LLC, Research Division - Senior Analyst

So to what extent does this BARDA contract and maybe the -- your COVID vaccine developments overall help Moderna in the long-term with respect to other development programs? Is it just around manufacturing capacity? Or you're learning certain efficiencies from this effort? How do you think this is going to impact Moderna in the long term, this experience with COVID-19 and the funding from BARDA?

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### Stéphane Bancel - Moderna, Inc. - CEO & Director

Yes. So let me take that one. It's going to impact the company in a tremendous positive manner. The analogy we have within Moderna is that if we're going to grow in 6 months what would have taken us 4 years to grow. So it's going to be a bit painful and hard, and that's why we need to add resources. But if you think across the company from a regulatory standpoint, getting ready to fight our first BLA, all the learnings that would be well supplied to a Zika, to a CMV, to all the other products, same thing on CMC. As you all know, getting into a Phase I is 1 thing, but getting the organization, the analytical method and all the documentation and data to be able to file a BLA is another thing. So I think the infrastructure buildup in terms of capabilities around teams, IT systems and as you know, digital is a very big focus for the company, so that we can scale this platform across many, many products. So it's a massive acceleration.

We have been talking about commercial. We also -- we should be able in the near future to give some updates there. So we have in commercial. And the other piece, too, is around government relationship. Being able to help governments that have thousands of their citizens dying, hundreds of millions of them getting sick, the impact on the economy, we think that being there to help, which is really the mindset we have and the attitude that we have, we want to be very helpful in all those discussions and be part of the solution as diagnostics company are, as companies working on treatment and as other vaccine companies are. This is a big puzzle. We all need to work together. And so all this learning across the company, all these capabilities we're going to build is going to be just tremendous for us as we roll out those products.

We showed the Zika data on Tuesday that are encouraging in a clinic. This is now our seventh clinical data set in the vaccine front. We presented and introduced in February a new vaccine that is the pediatric EBV, as we said on Tuesday at our Vaccine Day. Stephen's team is working hard to work on the next generation of new vaccines that we wish to move into development at a later date. And then you have all the other modalities, including the VIV systemic sampling. So the acceleration this is providing to the company, while it is complicated and what the teams have to do kind of extraordinary work because of time compression, it is massively enabling. And if again, everything goes to plan, and there are many ifs that could derail us as we've talked about, but if we are able to file a BLA, let's say, in 2021 and be commercial 12, 18 months from now, as you know, this is very different from the plan before corona. And so in the long term, this is going to be tremendously enabling for the company.

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### Operator

And we have a question from Mani Foroohar with SVB Leerink.



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**Mani Foroohar** - SVB Leerink LLC, Research Division - MD of Genetic Medicines & Senior Research Analyst

It's a follow-up on a few of the questions around manufacturing and supply. Obviously, operating at the population, perhaps even one could argue, species, global scale that would be necessary to address this, should you develop a successful vaccine that's clinically effective requires a lot of scale. Can you give us a little sense of the trajectory of your cost of goods for a potential vaccine? Does this relationship or investment reduce that? And beyond that, is another \$500 million, does that cut your cost in half? Is another \$1 billion required? Like what is the scale required to truly supply the global coronavirus vaccine end market to the extent that it evolves to be as large as it essentially could be?

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

Yes. So thank you for the question. Let me take a stab at it, and Tal, if you want to add anything. So the scale-up product process, as you can appreciate, is not an important impact on the cost of good per dose because as we scale the plasmid process, as we scale the mRNA process, as we scale the lipid process, per unit of time in the same room to just crank many more doses. So all your fixed costs, all your labor costs, your depreciation costs, you just fix. As we've seen the same suite for the same amount of time, you can make, let's say, 10x more product. You can do the math easily because only your material then goes up just because of the quantity you have to make. So the impact across this product line and the rest of the portfolio because of the platform is just a massive acceleration of cost of good reduction.

On the scaleout, which is adding manufacturing nodes, as we said earlier on this call, we are working on it. We will come back when we will have more firm plans. But we're going to really work out to shoot for as big as we can.

**Operator**

I'm showing no further questions at this time. I'd like to turn the call back to Stéphane Bancel for any closing remarks.

**Stéphane Bancel** - Moderna, Inc. - CEO & Director

Well, thank you very much, everybody, for joining us. Thank you for your support and your thoughts. Stay safe, everybody, and have a nice weekend. Thank you.

**Operator**

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect. Everyone, have a great day.

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