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MRNA.OQ - Moderna, Inc. - Special Call

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PRESENTATION

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

Good morning, and welcome to the Moderna's conference call where we will discuss the impact of the COVID-19 on business operations and clinical program development. You can access the press release issued last night 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; Lorence Kim, Chief Financial Officer; Juan Andres, Chief Technical Operations and Quality Officer; and Tracey Franklin, Chief Human Resources Officer.

Before we begin, I would like to remind everyone that this conference call will include forward-looking statements. Please see the bottom of the issued press release and 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 turn the call over to Stéphane.

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

Thank you, Lavina. Good morning or good afternoon, everyone. Thank you for joining our call. We wanted to give you a quick update on the disruption to our business due to the SARS CoV-2 pandemic. I hope you and your loved ones are safe and healthy. We have special thoughts for those of you who have family, friends or colleagues who are suffering from COVID-19 disease. This pandemic puts sharply into focus why we do what we do. Helping people in need is at the heart of the biopharmaceutical industry. Even in times of uncertainty, we have to stay focused on our collective mission. I would argue even more so.

As you saw in the press release that we issued last night, I wanted to give you an update on several fronts; our clinical trials, our team and how we are running the business during these changing times and our supply chain. Like every company in our industry, our clinical trials are impacted by the necessity of doctors to focus their time on the public health crisis happening in the hospitals. And the necessity to not put at risk patients or

healthy volunteers by having them go visit hospitals. As you can imagine, this picture is going to be evolving, but we wanted to share with you what we know at this time.

For oncology, Moderna is continuing to treat current patients and enroll new patients. These studies might enroll slower than we had to the pandemic. For rare diseases, Moderna has decided to pause new enrollments and new site initiation to limit the need for children with comorbidity to visit trial sites and also the risk of exposure to their caregivers. For infectious diseases, it is a mixed picture. We anticipate continued enrollment in the Phase I of mRNA-1273 and anticipate being able to enroll in a Phase II. For CMV, Phase II and Zika Phase Is are both fully enrolled. But we don't know how many healthy subjects will come back for each cohort to get additional vaccination. We paused our hMPV/PIV3 Phase Ib study enrollment to protect children from having to visit sites. As you can appreciate, our #1 priority is the safety of patients and the healthy volunteers in our studies. The diversification of our company portfolio gives Moderna resilience.

As of the end of February 2020, Moderna had $1.77 billion in cash and cash equivalents and access to additional grant funding of $183 million, giving Moderna access to up to $1.95 billion in capital. The strength of our balance sheet gives Moderna several years of runway. These numbers are obviously unaudited, but we thought they were important to share with you.

Certain business disruptions related to COVID-19 are likely to lead to lower spending in 2020 while the company is accelerating work on its potential vaccine, mRNA-1273, against COVID-19 and is engaged in discussions for outside funding of such activities. The company will provide an update on 2020 financial guidance on its first quarter 2020 quarterly conference call.

Let's now turn to our team. Being very involved in fighting the pandemic since the first days of January, we anticipated that infections in the U.S. might grow exponentially. In early March, we put a task force in place and we started to implement remote working on March 12 before Massachusetts state asked for a stay-at-home on March 24. Our goals were multiple. First, protect all of our employees and their families; second, reduce the risk to potentially infect the employees in our manufacturing sites and laboratories; and third, obviously, play our part in the Massachusetts community to reduce the spread of infection.

Let me end briefly by touching on our supply chain. Even as we raise to scale up our coronavirus vaccine candidate, we have on hand raw materials for the months to come. We have already placed additional orders in the last weeks and are in regular communication with our suppliers, who are working with us to ensure we can scale up our vaccine supply, if necessary. We are grateful to their support and energy. I could not be prouder of the Moderna team. They are working hard every day in the face of unprecedented challenges to ensure that we deliver on our mission to help patients. More than ever, I am also grateful to the many participants in our clinical trials and to the investigators, CROs and vendors who support them during these difficult times. They are the inspiration that gives us hope and keep us going. We will get through this together.

We will now be happy to take your questions. Operator?

QUESTIONS AND ANSWERS

Operator

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

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

I guess I was hoping, could you maybe just comment on what you think you may need to see broadly to start to resume some of your prophylactic vaccine studies in terms of whether it's infection rate or changes in the social distancing or other things in the U.S.? Maybe you could just help us think about that.

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

Thanks, Matthew. Tal, do you want to take this one?

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

Sure. Matthew, I think it's a question we're all wrestling with. The determination of the ability to enroll subjects is really a very local one. And so depending on the sites where the trials are currently open, as soon as they come back online, we would be able to resume it. I think today, it's premature to say where and when that would happen. We're working very closely with our CRO partners who are obviously monitoring the situation on a global basis, and we would potentially have the opportunity to switch sites, if it seems that that would be better. I think the way this pandemic is moving right now, though, makes it impossible to predict at any given site when they would deem it safe for their local population to get back into business that would be normal enough to come into elective procedures like this.

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

Got it. And then I guess, just one follow-up. I mean how would you think about -- do you need to test people for COVID before you can enroll them? I mean just -- are there any additional requirements that you're going to face as you think about recruiting patients?

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

Yes. So by and large, I don't think so. We expect our immune system to be able to deal with a lot of infections, most of which we're unaware of on an ongoing basis. That being said, I think, in some cases, it may be an interesting confounder. We're collecting serum on an ongoing basis as a routine matter, and so we'll be able to post hoc determine whether we think an intercurrent infection if it had occurred with SARS CoV-2 would be relevant. I don't have any preexisting reason to think that now, with the exception, of course, for the trials that are going to be testing our vaccine against SARS CoV-2.

Operator

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

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

Great. Thank you very much for the update, everybody, and thank you for the hard work for those of us who are waiting for a vaccine. Any update on potential timing from the NIH data from the COVID or the SARS CoV-2 vaccine? And also can you give a sense for where scale could ultimately be and maybe what some of the hurdles are or bottlenecks are for scaling up the vaccine manufacturing?

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

Ted, thanks for the question. So let me start, and then I'll ask Kim to add. So as you know, the Phase I from the NIH is enrolling well in Seattle. This is an NIH consult study. So we're in control of the steady execution, of the data. What they have publicly said is late spring or summer for the data. And so that's the best information we have now. As you can imagine, everybody in the government and at Moderna is very eager to learn about this vaccine candidate and assuming success, move this very quickly towards the next stage of clinical development. And so we are having daily discussions with them and we'll share that information when it's available.

On the question of capacity, as we shared in the past, there are 3 big drivers that Juan's team are working very hard to -- one is to scale up the manufacturing process, which is happening as we speak, i.e., making bigger and bigger lot of material. So basically you get more mass made per unit of time. The second one is to make sure we maximize all the space we have in Norwood. And so we've already placed the order for additional

equipment. And the third one is how do we maximize throughput by moving as much as we can on kind of almost a 24/7 kind of setup to just increase production as much as we can. Juan, I don't know if you want to add anything?

Juan Andres - *Moderna, Inc. - Chief Technical Operations & Quality Officer*

No, just to build on that point, Stéphane. So we have started with the scale-up activities to get to millions of doses. Obviously, we have the uncertainty of the dose to know about the capacity. We are feeding additional suites as well, and we are planning to add additional shifts and personnel to it. And -- so that's basically the situation.

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

Great. And then a real quick question. Beyond Spike protein, are you guys considering other antigens in research for SARS CoV-2 vaccines for maybe a second generation or something that provides extended durability? Or is the focus primarily -- I know on Spike protein now, but are you doing additional research on other targets or antigens?

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

So Ted, as you know, 1273 is encoding for the Spike (S) protein. As you know and as you have seen, the data we presented in our Phase III, we had good success in the rabbit challenge model working with the NIH over the last 18 months, 2 years. So that gives us good confidence. Stephen, I don't know if you want to add anything about what's happening in the lab or it's too early.

Stephen Hoge - *Moderna, Inc. - President*

Just to be clear, the rabbit challenge model was a MERS vaccine. The -- so on 1273, Ted, we are advancing the Spike. From a research perspective, we are looking at other antigens. But at this point, we don't have plans to event any backup candidate to date. We're just focusing on the Spike protein in our clinical program.

Operator

And our next question comes from Salveen Richter from Goldman Sachs.

Andrea R. Tan - *Goldman Sachs Group Inc., Research Division - Research Analyst*

This is Andrea on for Salveen. Maybe as a first question. Can you help us understand how to think about the forthcoming data that's being generated from your Zika and your CMV trials given the potentially variable dosing regimen?

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

Tal, you want to take this one?

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

Sure. So I think what you mean by variable dosing regimens, you are referring to the question on trial continued vaccination in these times. That's how I interpret your question. Did I get that right?

Andrea R. Tan - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Yes.

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

So look, we're looking at the actual data as they evolve. It's a fluid picture right now. I expect right now that we would be able to make the determinations we need to as it relates to immunogenicity and safety and tolerability based on those that are able to come in and complete their vaccination at schedules. We will look at it, we will apply sort of the typical risk-based approach to cases of missing data, just like is normally done to assure ourselves that indeed what we're seeing is what we expect. And we will be reporting that out as these data becomes clear.

Andrea R. Tan - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Got it. And then maybe just with respect to your oncology studies, could you provide additional color on the risk-based framework that you mentioned that's being used to evaluate the initiation of new sites?

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

Yes. I think it is really working very closely with the local institutions and determining how they are looking at their population is one aspect of this framework. The other aspect of the framework and this applies globally to our trials is ensuring that the overall scientific integrity of the trials is being maintained. As you know, there's a lot of sort of centralized infrastructure elements that have to come into play, site monitoring and everything that happens in the back end so that we are confident that the data we see is true and interpretable. And so both of these factors come into play when we look at the ability to do that.

Operator

And our next question comes from Cory Kasimov from JPMorgan.

Cory William Kasimov - *JP Morgan Chase & Co, Research Division - Senior Biotechnology Analyst*

I wanted to follow-up on the previous one on CMV in the Phase II trial and just the plan on handling patients that receive their first dose, but don't get their second. Just I mean dig in a little bit more there. Do you think you would need to reenroll patients? Or is there a window where maybe they can delay that second vaccination? Or is it just a matter of because this is Phase II and not Phase III, you would expect to have enough information to make that go/no-go decision?

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

So Cory, this is Tal. Thanks for your question. I think the answer is yes, and yes. In other words, this is a Phase II, we are collecting the information. And as it stands today, we believe we should have enough information to be able to, at the end of the day, define the necessary immunogenicity, safety and tolerability that we expect to see from this Phase II. But as I said, these are still early days and we are looking at it. We are looking at other approaches like you say that have to do with somewhat extending visit windows and looking at other ways to mitigate the impact of the operational hurdles that sites are facing.

Operator

And our next question comes from Alan Carr from Needham.

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

I wonder if you come back to COVID-19, your work in that one. So how much is -- you mentioned that some work has been done with animal models in MERS, but how much do you have on -- or how much is known around COVID-19 in terms of animal work, in terms of necessary immune response and that sort of thing? And then also you have a 2-injection regimen for this, and I believe all your other vaccine programs have had at least 2, but what are your thoughts on the possibility of a 1? Is that something that might -- 1 shot? Might that ever be feasible with an mRNA vaccine?

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

So let me start back from a few things, Alan, because there's a lot of things in your question, and I'll turn to Tal and Stephen. So if you look at our vaccines, we have vaccines that are 1 injection, like the RSV, vaccines that are 2 injections and vaccines that are 3 injections, like the CMV. So as we've shared on this protocol, we are currently looking at 2 injections, the prime and the boost. We would, of course, be monitoring antibody titers, antibody neutralization after the first injection and after the second injection to get a good sense like we typically do. So we'll make a determination when we'll have the totality of the scientific data. Tal, do you want to add anything?

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

No, I think you covered it Stéphane. I think today, based on what we understand about the immune response to these kinds of globular proteins and the totality of preclinical work, I think we do expect 2-injection regimen, a prime and a boost, to be the most efficacious here. I'll refer to Stephen that you asked about.

Stephen Hoge - *Moderna, Inc. - President*

Yes. On the preclinical work, Alan, we -- so we have been conducting that in parallel. We've been doing that with the Vaccine Research Center at the National Institute of Health. So we are developing data in parallel that is like that, which we've had before. One of the challenges though is setting up the challenge models is happening in -- as I said, in parallel. So we expect that data to be coming in the months ahead and be very informative. So much of that work is happening. It's just happening right now.

Operator

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

Geoffrey Christopher Meacham - *BofA Merrill Lynch, Research Division - Research Analyst*

Just had a few. For 1273, I know you're waiting on the NIH study, but what can you tell us thus far about how you're thinking about the design and the powering of the pivotal? And then on manufacturing, I know you guys have the ability to scale up and quite dramatically, but when you really stress test the theoretical demand numbers for COVID-19, obviously, it could be a bit overwhelming. So I just wanted to get that sort of case from you guys when it comes to priorities in a scale-up world.

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

Thanks, Geoff. So maybe just to remind everybody that the first IND for 1273 is owned and the sponsor is the NIH. But as we've shared before, our plan for moving into Phase II and pivotal is to file our own IND. So I'm going to tell you in a second, give you more update on that to your question.

On the manufacturing front, obviously, we will not be able to make billions of vials per year at this stage. What we are really going to focus on working with the authorities is a high-risk population, as has been documented, and we continue to learn every day about the virus at the epidemiology level. It seems that the young are spared. It seems that really it's the elderly and of people with comorbidity risk.

And so we'll be working very closely with the authorities to decide in a supply-constrained world, even though it'll be millions of vials per month, but it will be still be supply constrained, to work with the authorities that who is in most need for that. And that's how we anticipate to manage the supply and demand environment that we should see at the beginning, assuming the products get to launch. Tal, do you want to give a bit of your thinking on the stage development for 1273?

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

Yes. Thanks, Stéphane. So a couple of points here. The first study that we will do will be a Phase IIa, which will increase the safety database in a stepwise manner and aim to confirm the immunogenicity and eventually expand to populations that are at risk, in this case, specifically the elderly. I think once we have demonstrated as a combination of the Phase I and the Phase IIa neutralizing titers, and there is sufficient comfort that the safety is understood and that these neutralizing titers can be expected to be protective, I think the program will then move rapidly into pivotal trials. I think as you think about what needs to demonstrate here in pivotal trials, it's really 2 things. The first is that safety is there. There is a concern that regulators have raised about potential for enhanced disease.

We're obviously doing in parallel all the preclinical work required to elucidate that or put that concern more at bay, if you will. But it is something we will need to continue to look at as part of the clinical program here, and so that will determine the rate at which we can really expose more and more individuals and eventually individuals at high risk. The second element is proving that the vaccine actually is beneficial in preventing infections and disease. In order to do that, you have to go into a population that is sufficiently naive to having seen the virus and unfortunately, expect an attack rate so that you're able to actually demonstrate a difference from placebo. So we are starting to look very carefully at where those sites could be given the very rapidly evolving epidemiological picture and the anticipation that such a pivotal trial could start in the late summer, early fall time frame.

The final point I'd make is I think it's pretty important that we do this in a placebo-controlled scientifically sound design so that once those trials read out, we actually conclusively know and can demonstrate both the efficacy and overall safety profile of this vaccine. So that's our current thinking. And as Stéphane said, the near-term step is filing our IND and getting started with the Phase IIa as soon as we've cleared the understanding of safety from the Phase I that the NIH is running.

Operator

And our next question comes from Yasmeen Rahimi from ROTH Capital Partners.

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

Thank you for your continued hard work during this critical time, especially on COVID-19. Team, so last Thursday, Dr. Anthony Fauci noted that they're ready to go to really help companies to scale up because one of the really admitting steps is that by the time you approve efficacy and safety, manufacturing is lagging behind. However, he didn't really note at what point they could step in to really give you guys a hand. So can you help us to not only visualize do we expect funding from them to take place post Phase I data? And what else could they do beyond? Are there other alternative ways to really expedite the profit process for you that would be really critical? And then the second question is on CMV. Given that this significant delay on trials, do you think that all commercial prep is now on hold for this time? Or are you guys moving any sort of commercial plans on CMV forward?

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

Thanks, Yasmeen. So let me start on CMV and then go back to manufacturing for 1273. So on CMV, as we say, we are trying to do our best to maximize the data. We'll get out of Phase II, as Tal described. And we anticipate at this stage to be able to make those decisions on the data. Again, this is conditional to where we will end up in a few months. And the team continues to work as hard as we can to keep the program on track and the activities we're having to help with PIII recruitment, which we started is not slowing down. The commercial activity will not slow down. We want to really make sure that we keep extreme focus on CMV.

On the manufacturing of 1273, so as I shared earlier on the call, we are, as we speak, already scaling up manufacturing, using 3 big drivers, the increase of lot size, and Juan and his team, as we speak, are working to scale up the process to larger and larger lot size. So we get more and more mass made for every unit of time versus what we used to use, let's say, a few months ago. And they are doing that across the entire value chain from plasmid mRNA lipid manufacturing and so on and formulation. The second piece is because we had overbuilt Norwood to be ready to do things like launching CMV and other first products before moving to a larger commercial plant, as we've described in the past, we are basically -- we have already placed order for equipment to equip those rooms that are finished but were not used so far to increase capacity there. And also by then, going on to 24/7 shift, which is not what we're doing that Norwood today.

So by hiring new people and going to 24/7, as you can imagine, we'll also increase the output. So we believe those 3 drivers will help us literally month after month to have an increase of output. As I said in my remarks, we are engaged in discussions for outside funding for the 1273 activities, we will share more when we can. But we have very engaged discussions with the right agencies. And you can imagine the U.S. government is very committed to do its best to ensure the protection of American citizens. And everybody is highly aware that if we do not invest in manufacturing capacity now, when the product gets Phase II data, it will be too late. So everybody both inside the company and to our counterpart in the U.S. government is highly aware that every day matters now.

Operator

And that concludes our question-and-answer session for today. I'd like to turn the conference back over to Stéphane Bancel for closing remarks.

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

Thank you, operator. Well, thanks, everybody, for joining us, and thanks for your support and the kind words and emails many of you have sent us over the last weeks. Be assured that the Moderna team is working as fast as we can to move 1273 to pivotal clinical studies and to scale up manufacturing to maximize our output. We know every additional million vials will matter a lot to a lot of people. So thank you so much. We look forward to speak to you soon. Bye-bye.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program, and you may all disconnect.
