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EDITED TRANSCRIPT

MRNA.OQ - Moderna Inc to Discuss Updates on Respiratory Syncytial Virus (RSV) Vaccine Program Call

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OVERVIEW:

Co. discussed updates on respiratory syncytial virus (RSV) vaccine.

REFINITIV

CORPORATE PARTICIPANTS

David W. Meline *Moderna, Inc. - CFO & Principal Accounting Officer*

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

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

Stephen Hoge *Moderna, Inc. - President*

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

CONFERENCE CALL PARTICIPANTS

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

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

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

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

Huidong Wang *Barclays Bank PLC, Research Division - Research Analyst*

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

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

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

Michael Jonathan Yee *Jefferies LLC, Research Division - Equity Analyst*

PRESENTATION

Operator

Good morning and welcome to Moderna's Conference Call. (Operator Instructions). Please be advised this call is being recorded.

At this time, I'd like to turn the call over to Lavina Talukdar, Head of Investor Relations at Moderna. Please proceed.

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

Thank you, operator. Good morning, everyone, and welcome. This morning, we issued a number of announcements that we'd like to discuss on the call with you today. You can access the 2 press releases and statements, as well as the slides that we'll be reviewing by going to the Investors section of our website.

On today's call are Stéphane Bancel, our Chief Executive Officer; Stephen Hoge, our President; Tal Zaks, our Chief Medical Officer; and David Meline, our Chief Financial Officer.

Before we begin, please note that this conference call will include forward-looking statements made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995.

Please see Slide 2 of the accompanying presentation 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 take 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.

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

Thank you, Lavina. Good morning, or good afternoon, everyone. This morning, we issued 2 press releases and also posted the company statement on our website and social media. We thought it would be helpful to organize a short call to summarize briefly each press release and the company statement and make ourselves available for questions.

First, RSV. We announced that we have regained 100% of the commercial rights to develop RSV vaccine in the elderly population from Merck. Merck will focus on the RSV antibody program. We will now have a right to advance RSV vaccine in the elderly. As you recall, until now, we only had the rights for pediatric setting.

On this topic, we are happy to share today that mRNA-1345 or pediatric RSV vaccine is now dosing healthy participants in its Phase 1 study in the U.S. This is Moderna's 11th infectious disease vaccine to enter the clinic.

With these commercial rights for the elderly population, we need to do some work now to decide how to maximize the commercial opportunity for the elderly for RSV, either as a vaccine for RSV only or in combination with other respiratory virus vaccine like COVID-19 or flu. I would like to thank the Merck team for a great collaboration.

Secondly, we announced this morning that Moderna has signed and received a new award from DARPA, which is part of DOD, the Department of Defense, for up to $56 million. This new award aims at developing a factory in a small container, a cube of 6 feet by 6 feet by 6 feet or 1.8 meter for people outside the U.S. And this factory in a container is aiming at fighting future pandemics and outbreaks, where you could literally put that container under a chopper and take it anywhere you want in the world to make mRNA on demand.

This is part of a DARPA NOW, Nucleic Acids On-Demand World-Wide initiative. I would like to thank the DARPA leadership for their trust and the continued support in Moderna since our first DARPA grant in 2013.

Finally, as part of our leadership, in transparent communication during this pandemic, we have shared that we will not enforce our COVID-related patents during the pandemic period. We will provide licenses to our patents for COVID vaccine post the pandemic phase. Like most companies involved in the active response to the pandemic, we are very proud that the mRNA technologies are poised to help in the fight against this pandemic. I would like to thank our Moderna scientists for 10 years of innovation and the Moderna IP team for their work in getting this foundational patent issue.

With that, I will hand it to Stephen to give you more details on these 3 topics. Stephen?

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Stéphane. So first on Slide 4 on the RSV program. As Stéphane mentioned, we regained the rights to the adult RSV program that had previously been with Merck. Merck is going to complete the Phase 1 study of their current candidate, mRNA-1172 and then transfer the program to Moderna. As a reminder, Moderna has advanced 3 different RSV vaccines that are shown on the table on the slide. One of the key differences among these are the different lipid nanoparticle technologies they use. mRNA-1777, the first one, used in industry standard and licensed LNP; mRNA-1172 used in Merck proprietary LNP; and our own candidate, mRNA-1345 use our own proprietary Moderna LNP. It is the same as we use in our COVID vaccine and CMV vaccines. The mRNA construct encoding for the RSV F protein in mRNA-1345, our candidate, is also engineered for enhanced expression.

Now recall that earlier this year, we announced that mRNA-1345 was actively recruiting participants into a Phase 1 trial. And I'm happy to announce today that we've actually initiated dosing in that trial. The Phase 1 trial is an age de-escalation trial as we intend to develop mRNA-1345 in the pediatric setting. We announced this new development candidate just back in January and announced the open IND just this past month. So it's really terrific progress by the team that have already started enrolling.

We're excited now to have the ability to take this candidate into the older adult population, while reducing RSV infection -- where reducing RSV infection is also a significant unmet need. Today's announcement will allow Moderna to evaluate that path forward for mRNA-1345 alone or possibly in combination with other respiratory viruses. It's an important and vulnerable segment of the population that we hope to help.

And now I'll turn it back over to Stéphane to briefly cover DARPA.

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

Thanks, Stephen. So on the DARPA initiative, DARPA is focusing on developing a medical countermeasure manufacturing platform. And we are very excited to announce this new partnership with DARPA to enable small-scale rapid mobile manufacturing of nucleic acid vaccine and also therapeutics. This builds on our relationship with DARPA following our chikungunya antibody therapeutics. So the goal of this mobile manufacturing technology is to be able to either produce on-site remotely vaccines or therapeutics, HLA, chikungunya antibody therapeutics.

The goal is to deliver near-instantaneous protection and treatment to both military personnel and local populations in the case of all drugs. What DARPA envisions is a design of a manufacturing unit capable of producing hundreds of doses of medicine in a matter of days in a small 6-foot by 6-foot by 6-foot or 1.8 meter by 1.8 meter by 1.8 meter container in remote locations around the world. And we are very excited about how this technology will help us take mRNA closer to patients and be able to do more things, especially in case of outbreaks or potentially in the military force.

With this, I'll turn back over to Stephen for IP.

Stephen Hoge - *Moderna, Inc. - President*

Thanks, Stéphane. And so finally, this morning, we also issued a statement regarding our intellectual property related to our vaccine in mRNA-1273 and potentially related to other vaccine development for COVID-19. The statement is here on the slide, and I did want to highlight just a few points.

As many of you know, since our inception, we believe that mRNA has the potential to be a new class of medicine, and we worked tirelessly to try and turn that belief into a reality. With the financial support of our investors, we've created new technologies and advanced discoveries and development candidates through clinical trials over the past 10 years. Many of those discoveries along the way now form our portfolio of significant intellectual property. It's a key asset for Moderna as we become a commercial company and allows us to protect innovation, continue inventing and investing in it in the future.

Our intellectual property is a foundation of our success, and we do believe it is differentiating. But today, we made public on our website a selection of some of the representative patents that pertain to 1273, our vaccine against COVID-19. Now we are pleased that mRNA-based vaccines may play a big part in the potential response to the pandemic. We're quite proud of that progress.

During these extraordinary times, with the continuing pandemic, it is our desire to bring this pandemic to end as quickly as possible. As such, we announced today that we will not enforce our COVID-19 patents against those making vaccines to stop the pandemic. Further, to eliminate any perceived barriers, we'd be willing to extend licenses for the post-pandemic period.

Moderna is really proud of our mRNA technology, we're really proud of our strong intellectual property portfolio, and we are equally proud that it is now poised in our hands and, perhaps, in others' hands to be used to help in this current pandemic.

And with that, I believe we'll turn it over to the operator for any questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Matthew Harrison with Morgan Stanley.

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

I guess 2 things from me. So first, on the Merck decision related to 1172. Can you just maybe give us a little bit more background to your -- you seem to be emphasizing the differences in the LNPs. Was there a tolerability issue or an expression issue with that LNP? Or was this Merck's lack of interest in RSV as a target? Maybe you could just expand on that that would be helpful.

And then second, on the IP, you've made some pretty broad statements. I'm wondering if you're willing to be maybe a bit more specific and just comment on, do you think you have rights that cover other mRNA vaccines as part of your IP estate related to COVID specifically?

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Matt. So yes, let me try and take those 2 in sequence. So first on the Merck 1172 decision and regaining rights. I'd defer you to Merck's own sort of rationale for why RSV as a monotherapy vaccine may not be of interest to them and why they're instead focusing on the antibody program. I think I'll provide my own sort of response to that, and it's consistent with what we said in the past, which is we actually think what will be differentiating about respiratory vaccines in the future will be combinations.

If you look at RSV monotherapy vaccines as a -- as just a competitive point, there are multiple vaccines that are further ahead in pipelines in large pharmaceutical companies. And so for those reasons, from a strategic perspective, obviously, from our viewpoint, would make more sense to come forward with a differentiated vaccine which might be a combination of different viruses. That's actually the approach we're pursuing, as you know, in our pediatric vaccines already.

And so as you know, we've talked about, both at our Vaccines Day and even last month, that our intention is to combine our 1345 RSV vaccine with other respiratory viruses in the pediatric population. And as a strategic point, we'd probably be doing the same thing in the adults going forward.

The -- on the question of intellectual property, so we do think we've made some pretty significant inventions and discoveries in the field of infectious disease vaccines, and we've covered that in the past. And as a further evidence of that, I think we do highlight today a number of issued patents, composition of Moderna-patents in the United States that cover our COVID-19 vaccine, mRNA-1273, and all of which are issued composition Moderna-patents that we think might be relevant for other mRNA vaccines.

Only those companies would know if they were relevant or not because we obviously don't have full transparency of what people are doing. And so under normal circumstances, we likely would be protecting our products. If this were not a pandemic, we would expect to use our intellectual property, which is one of the ways that you protect innovations in this country and globally to protect our product going forward. But these are not normal times. It's the pandemic and I think we feel it is our responsibility to be upfront and transparent of the decision we take and that we're not going to be using those patents and trying to enforce them against others.

Operator

Our next question comes from Ted Tenthoff with Piper Sandler.

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

Great. I applaud the IP decision. That makes a lot of sense. So I'll ask about the new announcement with DARPA. This is a pretty interesting approach. Could you give us -- for example, like I'm envisioning something like an Ebola outbreak or something like that in Africa. But is there the risk by sort of decentralizing the technology that it could be spread outside of your hands? So I just want to kind of think through that a little bit more. Really cool program.

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

Yes, Ted, this is Stéphane. Thanks for the question. I think if you want to really think about the vision that DARPA has, it's kind of an espresso machine for making medicines where basically you will have a self-contained unit where you basically load raw materials in self-contained kind of containers, where you could have the sequence coming remotely through a cellular connection or something like this. And so there's a lot of components that actually through robotic digitalization you can control. We've got the user being able to know -- I mean it's a bit like you're buying an espresso machine, yes, you can take it along on a weekend if you want to, to make another one.

So we think that there is actually a lot of ways for us to still control the process remotely. So we feel comfortable that this is kind of the right thing to do. We're going to be learning a lot. Think about the -- all the kind of investments in technology that needs to be made through that grant in terms of microfluidics and other pieces, which will help us not only for that, but also in terms of just of scientific learning. So we think it's a very exciting project that we hope, in case of a future outbreak, we could actually -- we globally reacting much faster if such a device would exist.

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

Well, that would be a great thing.

Operator

Our next question comes from Salveen Richter with Goldman Sachs.

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

Perfect. This is Andrea on for Salveen. Just wondering if you could speak more on the opportunity for the RSV vaccine in the combination setting. And what are your specific development plans there?

Stephen Hoge - *Moderna, Inc. - President*

Thank you for the question. So as Stéphane said, we've regained these rights, and so we're beginning a strategic process to define better what our specific development plans will be, sorry, so I can't answer the question today. But I can hit the broad strokes of what we've said in the past and what we think will apply to that strategy. If you look at the burdens of disease for respiratory viruses, in particular, things like RSV but also flu and human metapneumovirus are ones we'd point to, those are -- the burden of disease is born in the young and in the elderly, particularly those 65-plus. In that sense, it is a population that are at high-risk of COVID as well, which is another respiratory virus.

And so as you look at what might be necessary in those populations, over time, what happened is you're functionally immune to a virus like RSV for much of your life, your adulthood. But as you age through immunosenescence and other things, you'll start to lose some of that functional protection. And a booster vaccine that allows you to boost up those neutralizing antibody titers and hopefully stave off a severe infection of RSV can be the difference, we hope, between life and death for those who are immunosenescent and maybe become infected.

And as we've talked about in the past, there is an unfortunately large number of deaths in this country every year and globally in that 65-plus population. Now RSV is not the only virus that causes that kind of mortality and morbidity of hospitalizations and deaths. There are other viruses associated with it. One of them is human metapneumovirus. It's a cousin virus of RSV, and has been described by us in the past. And as you know, it's a component of one of our vaccines in the pediatric space.

And then the others that we've talked a lot about recently are influenza, and we announced last month that we're going to be going forward with an influenza program during our R&D Day; and coronavirus, which we're all obviously acutely aware of and we have a vaccine candidate there, as you all know, in Phase 3 with mRNA-1273.

So the specific combination of those respiratory viruses that might make sense as a single respiratory booster for elderly populations, we haven't landed on yet as a company. But we look at those 4 opportunities and we clearly see a huge amount of morbidity and mortality, unmet need and an opportunity to create a truly differentiated product that uses the best of mRNA technology. And those things that we've talked about in the past are the ability to combine antigens into multiple different vaccines. In fact, we already have a respiratory virus vaccine in hMPV and PIV3, which is a combination.

The ability to really complicated antigens and the capital efficiency of it, I mean those 3 points that we've emphasized in the past, are things that we think allow us to perhaps develop a substantially differentiated respiratory vaccine here.

So we'll provide an update on RSV specifically and how we would intend to move forward from a development perspective. But hopefully, that gives you a sense of how we're thinking about it.

Operator

Our next question comes from Michael Yee with Jefferies.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Appreciate the update this morning. I appreciate all the updates on RSV, et cetera, but maybe I could just ask a question on more near-term things as well. Obviously, there were some EUA guideline changes perhaps or an update. And also some people are filing early on a rolling submission to Europe. Maybe you could just comment about the implications of any of that for COVID?

And then secondly, as data starts to come out soon, maybe you could just comment on your confidence that either mRNA vaccines may be differentiated between each other, or more importantly, as a single dose injection, Phase 3 has also started, whether you truly believe your product will be differentiated than some of these others that are coming purely down the pipeline.

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

Thank you for that. This is Tal. Let me take those in sequence. EUA guidance, I don't think there has been a material change as far as I understand it on the FDA's position, there's been an attempt to obviously politicize the back and forth. But if you look at the documents that have been posted to VRBPAC and if you listened to Peter Marks, he's clearly been on record saying, look, this is a guidance. This is what we hope to see, but a little data will go a long way. And that once you cross your interim, we should have a dialogue on the totality of the data.

The proof of that is in the pudding. I mean our protocol is on the web. You can see it. The interim analysis triggers are there. If FDA had mandated a minimum requirement, they would have asked us to change the protocol. So we are keenly aware of the guidance. We're working with the FDA to make sure that when we get our data, we can simultaneously or in very short order thereafter, provide them the totality of safety data as well as efficacy that they would like to see to make the informed decision on an EUA. But I think we're on the right path there, and I don't think there's been any major shift.

Your question on Europe is highly relevant. We intend to start our rolling submission there as well very soon. We've been in dialogue with the Europeans. And our understanding is based on the recent comments that they've made, is that we would expect the same package that's being submitted in the U.S. to be relevant for Europe. Obviously, the relevant part for Europe is when you get the approval, not when you start to file rolling submissions. The clock is determined by the completion of it. So I think we're in a very good stead there and hope to be able to provide additional updates shortly.

In terms of our confidence in the data and our ability to differentiate, look, I think the -- one of the beauties of an mRNA technology is -- let me start there, is that we can boost because the immune system doesn't see the mRNA, it only sees the protein. I think other platforms, the viral ones, the recombinant viruses are obviously limited by both preexisting immunity and then once you dose once, the immunity that you then generate.

So it is possible that within their first dose, they could get to some level of neutralizing antibodies that would be protective for all -- for the sake of all of us, I hope that's the case. But I think if you look at the magnitude of the antibody response, it's pretty clear that every vaccine that is able to prime and boost upon that boost assures a higher level of neutralizing antibody, assures that nobody is left behind. If you look at our data, we're able to mount neutralizing antibodies across all age groups and in everybody.

And I think that higher level and consistency of effect, for me, I'm optimistic that it will bode well into the ability to protect from disease. The proof will be in the pudding. And I think one of the more difficult elements will be for any of us to understand the durability of protection of any of these vaccines because all of the vaccines that will demonstrate efficacy will do so within the first few months of launching. And I think given that it's a pandemic, we'll all do the right thing, which is try to protect the population. And I think it will take months and maybe even longer to understand some of those differentiating factors. All that being said, I do expect in the first crop of efficacy data that you're going to start to see some daylight between different vaccines, over.

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

Okay. Yes. And maybe, Michael, just to add another few words to what Tal just said. I mean as you know and we talked about it in the past, we are focused, including when we pick the dose of a product, on the performance of a product. We said we want to use all the investment in science that we have made, the newly peds manufacturing process to ensure the best product we can to help as many people as we can that are at higher risk.

Tal talked about the elderly. As you know, because a lot of data has been published from Phase I now over mRNA vaccines or adeno products do not have a consistency we've had, I would remind everybody that we have all participants in the young population and in the elderly mounting an immune response. High level of antibody, there's no reduction, as you saw in the elderly versus the young like other platforms.

And if we look at what's happening in the antibody space, recently with Lilly and Regeneron, there's good clinical suggestion that antibodies and neutralizing antibodies are really important for protection. And when you think about those, those are 1 or 2 antibodies and when you vaccinate people, you basically generate a lot of different antibodies through the immune system. And so when you connect all those dots, I continue to believe that we could potentially have one of the best, if not the best, vaccine in the market.

Operator

Our next question comes from Gena Wang with Barclays.

Huidong Wang - *Barclays Bank PLC, Research Division - Research Analyst*

I have 3 quick questions. The first one is regarding COVID-19. Just wanted to get your latest update. I know -- I understand it's changing basically every week. Is the first interim still on track to report sometime in November? And if you did not hit the interim, should we still expecting roughly 8 weeks to see the second interim?

My second question is regarding the 1172 program, the RSV program. So when you take back, will you use Merck with the nanoparticle? Or will you switch to Moderna's lipid nanoparticle? And what is the difference between these 2 lipid nanoparticle?

And last question is regarding the manufacturing. I think you mentioned in the past you're capable of doing lyophilize, since all the other programs is using lyophilize. So the BARDA program, was that for minus 20 storage or would that be lyophilized? And then for the COVID-19, are you planning at some point to produce lyophilized production?

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

So Gena, this is Tal. Thanks for the question. Let me just take the first one. The first interim is on track for sometime in November. We're looking at the epidemiology within our sites. I think our expectation now is that the cases that we're starting to see on trial are tracking the cases in those zip codes. And so I think, by and large, we are on track. So we've been recruiting the right subject into the trial, I think, all of us.

I think the delta between first and second interim, I think it's in the order of 4 to 8 weeks. It's hard -- I think it's probably going to be less than 8 weeks, maybe more than 4. It'll depend on the shape of the pandemic, of course, in the coming weeks. We live in this paradox where the worse is out there, unfortunately, for people, the quicker the readouts for the trial. Let me defer to Stephen on the LNP.

Stephen Hoge - *Moderna, Inc. - President*

Yes. Thank you, Gena, for the questions. So we will focus on 1345, our LNP going forward. From an RSV perspective, we think the advantages of that are obvious, but one is that we've got the most clinical data in our delivery systems. All of our other vaccines are there, including our soon-to-be Phase 3 program in CMV, our current Phase 3 program, 1273 that you just asked about. And as you know, for 1273, we've scaled manufacturing into commercial scales, the ones presented on that in the past.

And so it just makes obvious sense to us from an RSV perspective to stick in that platform. It allows us to do combinations more easily and less complexity. And obviously, it's the most advanced. The 1172 RSV vaccine, it's only been every -- the delivery vehicle, a Merck-proprietary delivery vehicle, is really only ever been done in that one study, in that one Phase 1. So it's just a dramatically different amount of experiencing data between 2. So that will be our focus going forward on our proprietary LNP.

No, go ahead. Do you want to take the other questions?

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

Yes. So Gena, you're right. As we said in the past, the entire vaccine portfolio, but the COVID vaccine is lyo form as we described in the past for 1273, we decided to go liquid, knowing the impact on temperature for 2 reasons. One is to increase the yield and the output we could get out of manufacturing because, of course, every time you add a step in manufacturing processes, you lose yield, no process has a 100% yield. And so as we're already trying to preserve mass to make more vaccine to help more people, adding a lyophilization seems like not a good idea when the goal was to make as many as we could.

And the second piece was the lyo capacity in the world is very constrained. It is expensive capacity. And when you think about the volume for pandemic, there was not a billion dose equivalent of lyo capacity sitting idle and waiting for a pandemic to happen. So it's on this practical side of us to say no, lyo is going to be so hard to find the capacity. So this is why first antibody went liquid.

So now let's talk to the DARPA and the DARPA NOW project. The whole idea here is to be decentralized, close to the point-of-use of the medicine. And so the challenge that you have in traditional commercial product to make a product that could be used on the other side of the world in a year or 2 years where stability is critical is a totally different ballgame.

And so we have not finalized with DARPA all the spec of the project. But again, the -- I think, again, I'll use an espresso machine as kind of humoristic way to describe. The box is going to be, of course, a bit bigger as we describe the size target of DARPA. But I think the whole idea is to have a self-contained unit, a factory in a box where literally when the product comes out, they are used within hours or days.

And if you go back to what we've said around our storage capacity for 1273, we see that 2 to 5 Celsius is a typical fridge temperature. Like you store insulin or other medicines sometime at home for patients, you could store that for at least 7 days and most probably longer if you do not toggle minus 20 in between.

So nothing has been finalized is the punchline. But given the intent of use of that manufacturing device, I think liquid will be a great solution.

Operator

Our next question comes from Cory Kasimov with JPMorgan.

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

This is Matthew on for Cory. So I appreciate all the added color from previous questions, but I'm still trying to reconcile why one of the largest vaccine companies in the world wouldn't intend to focus solely on an antibody approach in RSV. So just to be clear, did the decision have anything to do with the clinical profiles of either mRNA-1777 or 1172? And then separately, can you comment on what you and Merck have seen in RSV in terms of the durability of antibody responses?

Stephen Hoge - *Moderna, Inc. - President*

Thanks, Matt, for the question. So again I can't speak for Merck's own determination here on the RSV program. So you need to -- I'd have to refer your questions to them. I can say that from our side, there's nothing we've seen in 1777 or 1172 or that we hope to see in 1345 that's going to dissuade us from moving forward.

In terms of durability of antibody response, again, I don't think we've published all the data on that yet, but I would point to our CMV data or any place where we have shown durability that has been quite significant, for instance, in the CMV vaccine. And we have no reason to expect it to be dramatically different here. But again, we'll subject to when we have those interim analysis and the studies completed and we'll share those data.

I think -- I do think competitive dynamics are something that would weigh on me if I was making the decision, Matt. So as an example, Merck has a Phase 2 antibody program, and they have a Phase 1 -- this would be a Phase 1 RSV program. And as a mono vaccine in the best tip situations would not be terribly differentiated from the soon-to-be Phase 3 programs from a couple of the other largest vaccines manufacturers.

And so I think it's not an unreasonable strategic determination to just say, look, RSV is a pretty competitive space in the vaccine space and a monotherapy vaccine may not be -- a late entrant monotherapy vaccine may not be as competitive as you might hope. And therefore, focus on the therapeutic sort of path of immune approach that's further along in your pipeline.

Now that's conjecture on my side. I really can't speak for how Merck made their determination. But as we look to make our determination, we're certainly going to consider that competitive dynamic that there are monotherapy RSV vaccines that are soon to be in Phase 3 that are substantially ahead and that if you're going to bring forward an RSV vaccine, it either has to be dramatically better or it has to be in RSV or it has to be good in RSV and also have other benefits. For instance, combination with other viruses to avoid the need for multiple projections.

And so that's how we're thinking about it. That's how I would imagine that Merck might have thought about it. But again, you'd have to ask them directly for anything more.

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

And maybe just to add to Stephen, Matt, we should not forget that in a combination space, we own the rights to flu, we own the rights to COVID. As we've said in the past, vaccine is a strategic modality for Moderna. We want to invest and own assets on the global basis. And so those rights are not open for partnership. So I think the competitive landscape and the combination field, I think, is really important.

Operator

Our next question comes from Geoff Meacham with Bank of America.

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

Just had a couple. On RSV, one of the bigger markets is in newborns and pediatrics, I guess, but more on the treatment side versus vaccines. I know your initial focus is on adults, but just want to get your thoughts on the opportunity in very young patients and what the challenges are from a regulatory perspective.

And then second question, just on your COVID patents, just curious about the path for retrospectively litigating the patent estate after the pandemic subsides. There's obviously going to be a lot more interest in leveraging some components of your technology of the RNA LNP technology, and so obviously, you want to protect that.

Stephen Hoge - *Moderna, Inc. - President*

Geoff -- go ahead, Tal.

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

Yes. Go ahead, Stephen. Well, I was going to take the first question on the regulatory path and pediatrics because we do have a program in RSVP. In fact, we had kept the rights for that all along believing that, that's a high unmet need. And so just like we have a combination already launched for the 2 pediatric respiratory viruses or viruses that have a high unmet need in peds, hMPV and PIV3, we are moving it also with RSV and pediatrics.

Regarding the regulatory path, I think we had disclosed in the past, we've had initial conversations with FDA on how one could combine the development of vaccines for pediatrics against different pathogens that are clinically indistinguishable as is the case of these respiratory pathogens. And so I think there is a path forward that will allow us to develop these for a high unmet need in a way that is ultimately efficient for development. Let me stop there and pass it to Stephen.

Stephen Hoge - *Moderna, Inc. - President*

Yes. The only thing I'd add to that is we actually think RSV in pediatrics, I mean, this is why we declared a development candidate back in the beginning of this year. We actually think it's a significant opportunity. And to some of the prior questions, it's one where the competitive landscape, we think, is more wide open. The programs that others are pursuing are still in the middle stages of development. And they have really been limited to the viral vector approach vaccines for those pediatric populations because of the concern about safety, about recombinant proteins and adjuvants in pediatrics. And so it's a natural place for mRNA, we think, by itself.

And -- but we think it's a place where we really will differentiate as we do combinations in the pediatric space. So there, we're actually quite bullish for that half of the unmet need as you look at it epidemiologically. What's new today is we're also going to be considering combinations in the elderly.

On the COVID patent question, and specifically, I think you said retrospective litigation, so after the pandemic, going out after people. That would be inconsistent with the value statement we're trying to make today. So what we're trying to say today as clearly as we can is we will not enforce these patents for any activity undertaken on the pandemic. And the reason is simple. We do think we've made great inventions. We think the history over the last 10 years of the company, over the last 5 years as we've done vaccines in humans is significant. We've described those inventions to the world. We've shown what's possible and we've been issued composition of Moderna patents that cover key aspects of this. That, under any normal circumstances, you might say is something that would disincentivize others from bringing forward vaccines.

And what we wanted to be clear about today is that we have no interest in that disincentive. We do not want to stop vaccines being brought forward during the pandemic. It's a decision we've taken previously but not disclosed publicly. But as we sort of -- as time passed here, we feel an obligation to now disclose it publicly because there are good well-intentioned questions about IP, the use of IP as vaccines come closer to market, what that would mean where rights are. But it would be -- it will not be our intention retrospectively to kind of come back around and say, no, no, now we're going to enforce for activity that happened in the pandemic. No, that is not what we're saying. We will not enforce productivity to bring forward vaccines during the pandemic, full stop.

Operator

And our next question comes from Hartaj Singh with Oppenheimer & Company.

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

Just a couple of quick questions on mRNA-1273. One is -- and you might have answered this partially earlier, but just want to be sure any recent updates to the FDA guidance, does that shift, I think, the 2 months follow-up safety, et cetera? Does that shift the potential timing for when an Ad Com could happen for EUA? And it seems the agency is going to do it on an individual basis going forward. And then next year, it looks like you should be a company with quite a lot of sales and breakeven. Are you thinking about guidance? And just any -- I know it's very early, but just how you're thinking about how to frame that for investors going forward.

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

Hartaj, it's Tal. Let me take the first question. There is -- I don't think there's a shift in the FDA guidance. I think that the 2 months for us will be crossed November 24. I think the first interim will happen sometime in November. If it happens sooner and the DSMB tells us that we've crossed it, then we'll let the world know and we'll let FDA know and we'll start the prep work. It will take obviously sometime between knowing that we've crossed it and actually running all the analysis and getting ready for that EUA.

So that will probably take, my initial estimate is around 10 to 14 days, likely in between. So along that, if it hadn't happened already, we probably will have crossed the 2 months interim. If it happens all earlier and we're sitting there mid-November and we're a week shy of that date, I still think FDA would like to see the totality of the data, and I'm sure it will be a discussion point for VRBPAC. So again, I think we all understand this as a clear guidance. I think the stars are aligning one way or another for that first interim to happen in November. And I'll pass it over to Stéphane for your second question.

David W. Meline - *Moderna, Inc. - CFO & Principal Accounting Officer*

Yes. This is David Meline. On the guidance question, what I would say is a couple of things. One is that we haven't made a final determination yet as to when we might do that. But I think to the extent that guidance can be helpful to investors to understand how we're viewing the business evolving, we certainly are happy to do that. And we'll have to just see how this evolves.

We'll have the Q3 call coming up at the end of the month. I think right now, there's so much uncertainty, it's unlikely we'd be providing broad guidance there, but we'll give some specific indicators as we did last call of information that we know that we think will be useful to investors. And then as we go to the report out of the full year results, I think the chances increase that there will be visibility looking into 2021.

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

This is Stéphane, just to maybe add a little bit to David's comments. I think everybody realized that this is a very, very unusual time. I've never launched a product during a pandemic for obvious reasons. And as you've seen so far, those are big, big contracts and big orders, where until it is signed, it is not signed. Price has a big impact on value when you multiply it by 10s or 50s or 100 millions of doses. And so to precisely guide, I think, is going to be challenging, as David said. But we're going to do, like we have done so far, and as David said on the call, and also in the 8-K we filed as per the U.S. government partnership, we're going to try to give you as much granularity of what we know so that indeed, analysts and also, of course, investors can have a sense of where we're heading in terms of sales and P&L.

Operator

And our next question comes from Mani Foroohar with SVB Leerink.

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

A quick follow-up. I got cut out for a moment there when Tal was talking about the interim communication plan. So if the interim passes with neither a stop for efficacy or futility, the study continues based on the statistical plan. I presume you would not disclose that because you want to preserve the integrity of the trial. Or would we expect that you would disclose whether or not the interim is passed?

And then a question on relationship with DARPA. Obviously, a fascinating technology could be really relevant, especially for places that lack more robust development, et cetera, lower income countries, that was mentioned earlier. Can you give us a sense of where that technology is in development, still in discovery stage? Or sort of how far along are we to that more mobile manufacturing technology being closer to application?

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

So this is Tal. Thank you for that. Let me take the first question. We, in the interest of transparency, will and we do intend to disclose when the DSMB has reviewed the first 53 cases after the first interim analysis and have rendered an opinion and what that opinion is. There's a high likelihood that we won't cross it. The trial is designed for a reason to go to 151 cases. There is a likelihood that we will cross it. It is up to the efficacy of the vaccine and an element of luck here. But I think that in the current era with all the attention, we have decided to be as transparent as possible short of, as you say, harming the integrity of the trial.

I do not -- and I pray that the fact that people know the result, people will be wise enough to understand that the fact that we crossed it simply means that we did not yet cross it. It will not mean that the trial, that the vaccine is ineffective, it will simply mean that we do not yet know its effectiveness or whether it's effective. So with that in mind, I think our current plan is to disclose the DSMB opinion one way or the other.

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

And it's Stéphane for the DARPA question. So for those of you that have visited Norwood, you have seen the personalized cancer vaccine unit where we make individualized dose for the personalized cancer vaccine program. And that kind of gives you already a sense of where we are in the ability to manufacture in kind of single dose at a time.

And so all of you, again, that have seen it, it's more than 6 feet by 6 feet by 6 feet. So I think the work ahead of us is around kind of how do you make it fit in that space, to [micro fit] this through process improvement, through a lot of other technologies. But we're not starting from 0, we're starting from the ability to do that.

I'll also remind you that we used that capability to do the Phase 1 of 1273 because of the low dose versus a cancer vaccine, which I'll remind you, we dosed at 1 mg, and the fact that we don't make one dose for cancer patients. No, they get a shot every 3 weeks on the same schedule as KEYTRUDA.

When you do the math, you actually realize that that capability, that manufacturing capability is plenty in one run for a Phase 1 for the infectious disease vaccine. And so we are starting from a very interesting base, which I think this is why DARPA was excited to partner with us again is with that capability, they saw that we already made a lot of progress. We had a good line of sight. They still work ahead of us, which is why the plant is up to $56 million. So there's going to be some engineering work. But we have a very interesting starting place to give us, I think, I believe, a high likelihood to make it happen.

Operator

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

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

Well, thank you, everybody, for jumping on the call quickly with us. I hope being available to answer those questions was helpful. I wish everybody to stay healthy and a great day. Speak soon. Bye.

Operator

Ladies and gentlemen, thank you for your participation on today's conference. This does conclude your program, and you may now disconnect.
