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Q1 2020 Earnings Call

Company Participants

- Juan Andres, Chief Technical Operations and Quality Officer
- Lavina Talukdar, Head of Investor Relations
- Lorence Kim, Chief Financial Officer
- Stephane Bancel, Chief Executive Officer
- Stephen Hoge, President
- Tal Zaks, Chief Medical Officer

Other Participants

- Alan Carr, Analyst
- Alec Stranahan, Analyst
- Cory W. Kasimov, Analyst
- Gobind Singh, Analyst
- Hartaj, Analyst
- Hartaj Singh, Analyst
- Matthew Harrison, Analyst
- Salveen Ritzer, Analyst
- Ted Tenthoff, Analyst
- Yasmeen Rahimi, Analyst

Presentation

Operator

Good morning, and welcome to Moderna's First Quarter 2020 Conference Call. At this time, all participants are in a listen-only mode. If you are part of the press or media, please disconnect at this time. Following the formal remarks, we will open the call up for your questions. Please be advised that the call is being recorded.

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

Lavina Talukdar {BIO 19691239 <GO>}

Thank you, operator. Good morning, everyone. Welcome to Moderna's conference call to discuss our first quarter 2020 business updates and financial results. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors Section of our website. Speaking on today's call are Stephane Bancel, our

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CEO; Tal Zaks, our CMO; Stephen Hoge, our President; and Lorence Kim, our CFO. Before we begin, please note that this conference call will include forward-looking statements. 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 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 Stephane.

Stephane Bancel {BIO 15174250 <GO>}

Thank you, Lavina and good morning or good afternoon everyone. Thank you for joining the call. I hope you and your families are in good health. As you know, we believe mRNA has a potential to be a new class of medicines with the opportunity to address many unmet medical needs, with medicines with higher probability of technical success, with greater speed of research and clinical development that is traditional medicines and with greater manufacturing capital efficiency and lower cost of goods been injectable recombinants. Given the amount of working with the new technology, we have been laser-focused on managing risk, technology risk, biology risk, execution risk and financing risk.

As many of you know, 2019 was an important inflection year for Moderna, we reported clinically validating data from key programs in two of our modalities, prophylactic vaccines and systemic secreted and sensor-based therapeutics. Data that we believe fundamentally change the risk profile of each of these two modalities that we now call modalities. As a result, our strategy is to double down in these two core modalities with many important new development candidates. We have already announced five new development candidates in these core modalities since January 13, at the JPMorgan Conference, three new development candidates in infectious disease prophylactic vaccines and two in the Systemic Secreted & Cell Surface Therapeutics modality.

While we focus on doubling down in core modalities, we are still very interested in understanding the potential of our mRNA technology in our current exploratory, modalities, cancer vaccines, intratumoral immuno-oncology, localized regenerative therapeutics and systemic intracellular therapeutics. So when we think about the company, we basically have two distinct area of focus. This is a significant point in our strategy, we have core modalities, we want to scale and invest, and exploratory modalities that's causing to be a big driver for the company's future as we await clinical data to decide the path forward.

So stepping back, I would like to share with you the progress of the company toward a new class of medicines. This is a strategic plan that we shared with you in February 2020. In the early days of the company, our goal was to enter the clinic safely, we spent years investing and developing mRNA science, formulation delivery and manufacturing technologies.

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The company pivoted out of that growth phase when we entered the clinic, we were H10 influenza vaccine in December 2015. In the clinic, our next goal was to learn how well our technology was working or not, we explored our technology across six different modalities, we tested 16 different molecules in the clinic in a short four-year period. In 2019, we generated important data in two of the six modalities and identified our first two core modalities infectious disease prophylactic vaccines and Systemic Secreted & Cell Surface Therapeutics.

Early in the year, we entered a new phase of the company's development. Our goal for this next phase in our history is to file multiple BLAs, while continuing our clinical programs in the full exploratory modalities, and continue to invest aggressively in earlier research to invent new modalities, such as our ongoing collaboration with Vertex. When we first presented this plan in early February this year, we had imagined that the next phase of growth of the company will have taken us three to four years. Our vaccine against SARS-CoV-2 virus, mRNA-1273 is a major acceleration of our company's development.

Today, we're very happy to announce that we received yesterday clearance from the FDA to proceed with Phase 2. It is just nine days from filing our R&D on Monday, April 27, the FDA gave us a green light. We intend to start the clinical trial as soon safely possible. We were saying out this morning that we're finalizing the Phase 3 protocol and our aim is to stop dosing to the Phase 3 in early summer 2020. This means that we have a potential for BLA approval for mRNA-1273 in 2021. That is an acceleration of several years, that is the plan, we had just months ago.

Moderna should be a commercial company -- sorry, Moderna should be a commercial status company in 2021, that is two to three years ahead of our previous plans, plans we outlined just months ago. This is a unique opportunity, so we're working actively to get the company ready. To deliver on this acceleration of the company's plan, we are expanding our leadership team in areas where our expertise will be instrumental to allow us to successfully file several BLAs and be ready commercially. Today, we're announcing three new addition to the leadership roles of Moderna.

First, Patrick Bergstedt. Patrick, joins Moderna as Senior Vice President, Commercial Vaccines. Patrick will report to me. Patrick joins from Merck & Company, where he most recently was Head of Global Marketing and Commercial operation for the entire vaccine business at Merck. Patrick, will start on June 1st. Patrick's global initiatives will focus on revenue growth and access expansion. The 20 plus year with the run in the biopharma industry, Patrick has held various leadership position within the infectious disease and global health at Merck, in the U.S., in Europe, but also in Asia.

Second, Jacqueline Miller, Dr. Jacqueline Miller, Jackie will be joining Moderna on May 11th from GSK as Senior Vice President, Infectious Disease Development. Jackie joins company from GSK, where had a variety of leadership roles since 2005. Most recently Jackie was the Vice President and Head, Clinical R&D and Epidemiology, where she built and lead the clinical and epidemiology research team at the first GSK research and development center in the U.S. And third Dr. Charbel Haber, Charbel joined Moderna on April 21st, as Senior Vice President, Regulatory Affairs.

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Charbel joins us from Biogen, where he served as, Vice President, Global Safety and Regulatory Science, since 2017. In this role, he built and led the Global Regulatory Strategy Department, the Clinical Trial Application Group and the medical writing groups. Prior to Biogen Dr. Haber was Head of Global Regulatory Affairs for Immunology and Neurology at EMD Serono. I am very excited to welcome Patrick, Jackie and Charbel and look forward to their contribution at Moderna, as we embark on the commercial stage phase of our company.

It is a bittersweet moment to announce today the departure from the company of Dr. Lorence Kim, our Chief Financial Officer. Lorence joined the company in 2014, when the company was private. As some of you remember, it was a preclinical stage company with zero development candidates. Lorence took a chance on Stephen Hoge and I and decided to leave a great job at Goldman Sachs to join us.

The company is now public with 23 development candidates and preparing it's first Phase 3. Lorence will manage the best for smooth transition, he will do Moderna second quarter conference call in August with us before leaving the company. I am very thankful for all his contribution over years and from a constructive discussion, he and I had about entering a smooth transition. There is never a good time for leadership transitions, but the company is very well capitalized. We've around $2.4 billion of capital to invest to create value and we need to focus on the next phase of readiness for the company to be commercial. We have retained the Russell Reynolds for the search for Moderna next CFO. We will focus on the CFO. We are a public company and commercial and global operation experience given this is where Moderna is heading.

Before I hand over to Tal for clinical updates, I will just take a few minutes to frame the opportunity in our vaccine modality. We believe mRNA has a potential to be a new class of vaccines, where each of the four drivers are value applied. We are very excited about the potential of our vaccines to drive this value. First, as we discussed, a very large opportunity, the ability to do first-in-class vaccines that do not have product on the market today to protect as many people as we can.

Second, a relatively high probability of technical success. As we discussed our vaccine there, Dr. Andrew Lo from MIT has shown that from the start of the Phase 2 is was Phase 1 to approval vaccines at 42% probability of approval. This is the highest probability amongst all categories of medicine in clinical trial. We think this is a very important value driver for this franchise.

Third we think an important driver is speed. Speed in the labs, given we have a platform, we can send you many candidates in parallel in preclinical setting. Once we pick a development candidate to take into the clinic, we can do it very quickly as we have shown recently, with the SARS-CoV-2 vaccine. Going from design of a vaccine on January 13 to injecting the first human on March 16, as we still have 63 days.

Finally, we believe the capital efficiency of our platform offers significant advantages over traditional vaccines, because of manufacturing process to make mRNA molecule is a cell-free manufacturing process. It can drive much lower capex as recombinant protein

manufacturing. The second dimension is a capex leverage across value chain. For example, when we decide to grow at the SARS-CoV-2, we did not have to buy any new machine. Our team was able to leverage existing capex in a matter of days.

With that overview, let me now turn over to Tal. Tal?

Tal Zaks {BIO 19987702 <GO>}

Thank you, Stephane and good morning, everyone. I'll start with a quick reminder on the data generated to date with our vaccines. In over 1,500 healthy volunteers and seven positive Phase 1 data sets to date, we have observed the safety profile that's consistent with the safety of adjuvanted vaccines and we've time and again demonstrated the ability to elicit an immune response in the form of neutralizing antibodies.

I'll start with a high level progress on mRNA-1273, our vaccines against SARS-CoV-2 and we'll give more detail shortly. As you heard from Stephane earlier, we have the FDA clearance to move into our Phase 2 study and we plan to start it shortly. This study will run in parallel with the NIH run Phase 1 study, which has completed enrollment of the first three dose cohorts. Our CMV Phase 2 dose confirmation study is fully enrolled and we still expect data readout to come in the third quarter of this year, despite having had some COVID-19-related disruptions.

At our Vaccines Day on April 14th, we announced positive interim analysis of our Phase 1 study for our Zika vaccine. At the two lower doses of 10 microgram and 30 microgram, we achieved seroconversion rates of 94% and a 100%, respectively. The two higher dose cohorts of a 100 microgram and 250 microgram are now fully enrolled. As a reminder, we paused our hMPV/PIV3 Phase 1b study enrollment as a cautionary measure to protect children and their caregivers due to COVID-19 disruptions. Our RSV program with Merck continues.

So this has been covered in detail, but just to quickly base everybody in the same place. Our SARS-CoV-2 vaccine, mRNA-1273, which was a subject of much work in discussion in the first quarter of this year, demonstrates the kind of speed that we believe the platform can provide from first selection of a sequence by our scientists and our collaborators at NIAID on January 13 to the production of a clinical batch on February 7, 25 days later. That had been released by February 24th and by March 4th was associated with an open IND that the NIH had filed. The strong collaboration between us and NIAID led to this -- the trial opening within 63 days and we've spoken about this before.

On April 17th, we were awarded a contract from the U.S. government agency BARDA to accelerate the development. And on April 27th, we announced an IND was submitted to the U.S. FDA for the Phase 2 study. Last Friday we announced a collaboration with Lonza to manufacture mRNA-1273 at scale with the goal of producing up to 1 billion doses a year. Of course, today, we announced the FDA clearance to start the Phase 2 part. In parallel, we have been working on the Phase 3 protocol and we are finalizing that with a name to start the study in the summer of 2020.

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The design of the Phase 1 study is on Slide 17. The study started as a 45 subject trial with three dose cohorts, 25, 100 and 250 microgram with each participant receiving two vaccinations a month apart. These three dose cohorts have now been fully enrolled and the safety and immunogenicity data from them will be shared when available. The NIH is expanding the trial to include two additional age cohorts of 56 to 70 year-old cohort and a 71 and above age cohort. Each of these age cohorts will include three dose levels also at 25, 100 and 250 microgram at the same vaccination schedule.

In terms of the late phase development for mRNA-1273, as mentioned before, the Phase 2 study is expected to start shortly. The study will evaluate the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given one month apart. Volunteers will receive either placebo 50 or 250 micrograms at both vaccinations. This study will enroll 600 healthy participants and two cohorts of adults ages 18 to 55 and 55 year-old and above. The study is meant to both increase our safety database as well as confirm the immunogenicity seen in the phase that we expect to see in the Phase 1. We are finalizing, as I said, the Phase 3 protocol and the study is expected to begin this summer.

Now, last week Moderna and Lonza announced its strategic collaboration with the goal to enable manufacturing of up to 1 billion doses a year and this is assuming a dose of 50 micrograms. Technology transfer is expected to begin this June and we anticipate the first batches of mRNA-1273 to be manufactured at Lonza U.S. sites in July of this year. I would be remiss not to mention BARDA's willingness, the BARDA award is allowing for us to move as quickly as we are -- would scale up both internally and with Lonza.

Moving on to CMV. Slide 20 reviews our late stage development plans for CMV. As previously announced, the Phase 2 dose confirmation study is fully enrolled and we remain on track for data readout in the third quarter of 2020. Importantly, greater than 70% of participants have now received their second vaccine dose. A protocol amendment was submitted to expand the time frame for the remaining participants to receive their second dose as well.

As a reminder, we plan to select the dose for the Phase 3 after the first interim analysis, which is the data post to second vaccination. We continue to prepare for the Phase 3, which is intended to start in 2021 in the U.S. and Europe. During the first quarter of '20, we also received constructive feedback from a Type C CMC meeting that we've had with the FDA.

Moving on to mRNA-1893, our Zika vaccine program. Let me recap on Slide 24, the data that we recently presented at our Vaccines Day, where we reported an interim analysis of the ongoing Phase 1 trial. This study has demonstrated fairly benign safety profile consistent with what we've seen before for other vaccines and up to two lower doses of 10 and 30 micrograms after a two dose vaccination regimen boost the seroconversion rates were 94% and a 100%, respectively. These data are encouraging and we are preparing to move forward with this program into our Phase 2 trial. The exploratory modalities are a critical part of our strategy and we continue to make up a significant part of what we do in the clinic.

And on Slide 26, you see a -- if you scan the page, you'll see many readouts in catalog from each of the programs both from our core modalities as well as the exploratory ones.

With that, let me now turn the call over to Lorence.

Lorence Kim {BIO 18670491 <GO>}

Thank you, Tal. Let me first cover an update on the Vertex agreement. In July 2016 we entered into a strategic collaboration and license agreement with Vertex aimed at discovery and development of central mRNA medicines for the treatment of cystic fibrosis or CF, by enabling cells in the lungs of people to see as to potentially produce functional CFTR proteins. In July of 2019, the initial research term was extended by six months and based upon promising preclinical data generated in March of 2020, we were pleased that Vertex elected to extend this collaboration for further 18 months.

I'd now like to turn to financial results. In today's press release, we've reported our first quarter 2020 financial results. Note that these results are unaudited. We raised approximately $550 million in net proceeds from the February public equity offering, which resulted in us ending Q1, 2020 with cash, cash equivalents and investments of $1.72 billion. This compares to $1.26 billion at the end of 2019. Net cash used in operating activities was a $106 million for the first quarter of 2020 compared to $144 million in 2019. And just as a reminder that latter number includes in-licensing payment $22 billion, which will not recur.

Cash used for purchases of property and equipment was $6 million for the first quarter of 2020 compared to $8 million in 2019. Revenue for the first quarter of 2020 was $8 million compared to $16 million in 2019. This decrease of $8 million in revenue was mainly, due to cumulative catch-up adjustments resulting from changes in our estimated costs for our future performance obligations, coupled with the timing of amortization of deferred revenue due to the satisfaction of our performance obligations.

R&D expenses for the first quarter of 2020 were $115 million compared to $130 million in 2019. The decrease of $15 million in R&D was mainly driven by a decrease in lab supplies and materials and clinical trial and manufacturing costs, partially offset by personnel-related costs. G&A expenses for the first quarter 2020 were $24 million compared to $27 million in Q1 2019. This decrease of $3 million was primarily attributable to decreases as a legal and other consulting and outside services spend. And net loss for Q1 of 2020 was $124 million compared to $133 million in Q1 2019.

I'll turn now to what we expect for the remainder of 2020. If you look at our cash flow line as you can see our cash used in operating activities and purchases of property and equipment by quarter are laid out here. In Q1 of 2020, we used $112 million of cash on these two items, which is in line with our expectations. If you go back to Q1 2019, we used a $152 million of cash on these two items, and remember again that number included that licensing payments.

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Overall, you can see the decline in our quarter-over-quarter, cash used for these are through Q4 2019 was a slight uptick in Q1 2020. And so consistent with our initial 2020 guidance which we issued back in November, we expect our 2020 net cash used in operating activities and purchases of property and equipment to be approximately $500 million.

While we have seen parts of our spend slowdown as a result of the impact of COVID-19 such as certain clinical trial expenses and laboratory supplies, we are also investing in preparedness for the late-stage development and potential BLA filing for our COVID vaccine. That results in bringing our cash flow guidance back to its original levels. Recognize that much of our COVID vaccine spend is covered by the BARDA award. Note that the award is not cash upfront, but rather reimbursement as expenses are incurred. We do expect to incur significant expenses this year in relation to that BARDA award, but we expect in general of matching of expenses and reimbursements.

Let's drill down. Next on our balance sheet strength and the composition of the $2.4 billion of cash and available funding we have to invest and create value. We ended Q1, 2020 with cash, cash equivalents and investments of $1.72 billion. On April 16 of 2020, we entered into an agreement with BARDA to accelerate development of our mRNA vaccine candidate against the novel coronavirus for funding of up to $483 million, of which $430 million has been committed. Additionally, we are fortunate to have established strategic alliances with private and government sponsored organizations including the Bill & Melinda Gates Foundation, DARPA and another BARDA award comprising additional available funding of a $180 million. Together this creates multiple years of cash runway considering cash guidance that we've shared today and a strong ability to invest for the long run in many aspects of the business.

The next slide shows our pipeline and the programs through the various phases of development with a snapshot here. But before I turn it back to Stephane, let me just reiterate an important point from my announced departure this morning, which is that I expect to seamlessly transition my responsibilities through August, but I'll make a brief remark now.

First of all, I'm so grateful to have been invited to be a part of this company, what an opportunity to contribute to Moderna's mission of turning mRNA into a new class of medicines. I joined the company six years ago and the time and the story was nascent, the future was full of unknowns. I'm leaving now, as the company has multiple BLAs on the horizon with 23 important new potential medicines in the pipeline and I believe many more to come.

We've invested heavily in the platform to establish the front of the foundations of this new class of medicines and the team is growing with unbelievable new talent. I'm personally most proud of the financial foundation we've built to enable the company to invest appropriately in the business. It's been energizing and motivating to partner with Stephan, the Board, the executive team and the passionate Moderna employee base.

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For me, I'm hear to take next step in my career, which will be to stay close to innovation in biotech, but not as a company executive. I look forward to sharing more about these plans in the appropriate time down the road with many of you on this call. And with that, I'll turn it over to Stephane for closing remarks.

Stephane Bancel {BIO 15174250 <GO>}

Lorence, thanks again for commentary and your remarks that having you as my partner for those six years that has been quite incredible ride. On Slide 34, let me close by giving you a quick update where the company stands today starting with our pipeline. It's exciting to see that today, we have two candidates for which we are preparing for Phase 3, our CMV vaccine and SARS-CoV-2 vaccines.

We have now six candidates that are either in Phase 2 or preparing for Phase 2. 12 Phase 1 programs and 11 positive Phase 1 results, what an acceleration since our IPO in December 2018. Our programs are very exciting. We have seven first-in-class vaccines, where there are no approved vaccines on the markets against those viruses. Most of these vaccine candidates have multi-billion-dollar annual peak sales opportunity. As we share that our Vaccine Day presentation, we believe our innovative vaccines are going to be a very good business for Moderna. We have long-term annuity like opportunities as a high EBIT margin. We're also have quite exciting immuno-oncology program that are already in the clinic that are all combined with the commercial checkpoint. Four are disease program and two autoimmune disease programs. The company has never been stronger and look at confirmation. We have now dosed more than 1,900 healthy volunteers and patients in our studies.

The team is strong and getting stronger every month. We now have more than 900 employees who care deeply about our mission and are proud and energized by our progress and the meaning of our work. Last week, with the Lonza agreements our manufacturing capabilities has changed league. We not only have a fully integrated GMP site in Massachusetts, who many of you know, and have visited, but we've added a strategic partnership with Lonza that can enable us to up to 1 billion doses annually for vaccine against SARS-CoV-2, but also other product in our pipeline as we need to.

We have great partners, we have AstraZeneca, Merck and Vertex. I am very proud of a sensitive progress that the team of Stephen Hoge and Melissa Moore have done in the work with Vertex over the last few years. And we are very pleased that the Vertex decided expand the relationship with Moderna. That's why I'm also very thankful for partnership we've had of over years with BARDA, DARPA, CP and the Gates Foundations and of course, we are very thankful for the latest partnership with BARDA $483 million, to enable us to do the right clinical study as fast as we go, of course, focusing on safety first for the SARS-CoV-2 vaccine. And of course, we are well capitalized we have up to $2.4 billion to invest in the business and continue to be the leading mRNA company in the world.

We are very thankful for our investors for their trust and partnership as we build this unique company. We're energized by the opportunity ahead of us to build a new class of medicines. We are currently accelerating our development pipeline and within the company to potentially file its first BLA for mRNA-1273, which will be as you can

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appreciate, a historic moment for the company. We're investing in the processes to get us there, to get the right foundations for potentially many additional BLAs in the future, something with Zika vaccine and CMV vaccines behind the SARS-CoV-2, mRNA-1272. We are already scaling up the organization to address the need to supply up to a 1 billion doses for potentially first vaccine mRNA-1273. All those efforts, investment and processes will be very enabling for additional vaccines and therapeutics to come.

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I have never been as excited and optimistic about the future of Moderna in the last nine years. We are humbled and excited by the opportunity to bring forward a new class of medicines for patients that has been our North Star since we started the company. I would like to thank the great team of Moderna employees working very hard every day and literally many of them, seven days a week, now since January to fight the SARS-CoV-2 virus.

I would like to thank the many people who participate in our clinical studies, including patients, healthy volunteers, physician and nurses. I'd like to recognize all our partners that work with us to share our vision and helping us to achieve this vision to help patients.

With that, we are now happy to take any questions. Operator?

Questions And Answers

Operator

(Operator Instructions) Your first question comes from Matthew Harrison with Morgan Stanley. Please ask your question.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good morning. Thanks for taking the questions. I guess, first, you've highlighted the 50 microgram dose on the SARS-CoV-2 vaccine and I think Dr. Fauci in his interview also talked about good responses in low doses in animals. Can you just talk about your confidence in being able to move forward and with the right kind of immune response with the low dose as opposed to the other doses that you're testing? And then secondly, can you just update us on where the field is in figuring out what neutralizing antibody titers are and if you think they'll be available by the time you report initial data from the Phase 1 study? Thanks.

A - Tal Zaks {BIO 19987702 <GO>}

So this is Tal. Hi, Matthew. Let me take that question. To spot on things that we're looking at. So first of all 50 microgram is our current best guess. We -- this is short of data and it's based as you've seen Tony Fauci's remark on what we expect the platform could deliver. That being said, the final dose selection will really be a factor of, I think, three elements. The first is the overall sense of a dose response of how much more do you get as you go up in dose, because in a case of a pandemic, we obviously need to balance this with having enough doses available and so an unnecessarily overshoot.

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The second element is an understanding of what that those could mean as you compare to kind of a lesson share and so there's a lot of work being done on assay validation and I'll get back to that in a minute to understand what any given level of antibodies mean.

And the last element that I think will enable us to connect the dots is understanding the performance of the vaccine in additional animal models of SARS-CoV-2 and then seeing commensurate with the expected ability to protect those animals what levels of titers do we get and obviously the hardest piece is the more reliable that data is, but ultimately what we care about is being able to connect the dots for human disease. So it's a long story short. It's a best guess estimate for now. And based on the emerging data and we will continue to refine it as more data comes in.

Your question about the right kind of immune response. Look, I think the data we've seen to date, both across the clinical trials, across the experience that we have in the preclinical models, across the board, as I mentioned in all the other clinical trials, we've routinely reported neutralizing antibodies as there might have been logical success. And if you think about the kind of scientific first principles of how an mRNA technology presents an antigen from within the cell and mimics the instruction set the virus would otherwise give to cell to make an antigen, I -- we get the right kind of immune response, however, we want to characterize that neutralizing antibody Ph 1 versus Ph 2 etc., the emerging data that we're seeing preclinically with mRNA-1273 is all consistent with that.

Your final question on neutralizing the antibodies. Yes, those assays are being stood up as we speak. They're being been validated, they're being transferred to commercial vendors and the NIAID is actively looking that in parallel with the simpler types of binding antibodies. We expect to be able to report both kinds of data when we see the data from that Phase 1.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Thanks for the thorough answer.

Operator

Your next question comes from Cory Kasimov of JP Morgan. Please ask your question.

Q - Cory W. Kasimov {BIO 3009346 <GO>}

Thanks for taking my questions. I've got two of them for you as well. So I guess, first, can you talk more about what the Phase 3 COVID vaccine design might look like? I mean just obviously nothing traditional about this program. So how should we be thinking about -- and I think the endpoints interim analyzes and amount of follow up you think you need for either emergency use authorization or full approval?

And then my second question for you is regarding COVID -- also regarding COVID-19. There have been some conflicting reports out there on emerging mutations with the virus, be very interested to hear your views on this and what it could potentially mean for the effectiveness of your vaccine? Thanks a lot.

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A - Tal Zaks {BIO 19987702 <GO>}

Thanks, Corey. This is Tal. I'll take those questions. So look the Phase 3 design, let me make a couple of points, any pivotal trial in order to demonstrate efficacy as well as safety has to be placebo-controlled and large enough so that the people -- among the people that you will vaccinate there will by chance occur cases, right. And so it's a case-driven design and you set your statistics based on what you expect to see and how many cases you expect to see in the placebo and then how many fewer cases do you expect the vaccine to demonstrate.

Now any such trial to be effective depends on thee things; how big it is when you start. How good are you at predicting the attack rate in the population that you're vaccinate because it's a case-driven design, then we can vaccinate a whole lot of people, but if they end up for the months to come, not being exposed to the risk of an infection, then we won't know whether the vaccine work. And the third element is, how good our vaccine are is because the higher the point estimate for the vaccine efficacy, the clear the results are in the sooner you can find them.

Somewhere between those parameters, we are going to have to have a conversation it's ongoing between us, our collaborators at NIAID, at the NIH and ultimately FDA. The length of follow up here and how soon can we see the data, I think, is a function of all those design elements as well as where you sort of set the bar for cases and what expected benefit is.

Now you asked an interesting question on where does EUA come into this, where does approval and what kind of interim data one could expect. So I think as you get closer to it, my sense is that we're not looking at a binary event in the sense that, one day we know nothing and the next day is somebody available for everybody. I think as we learn more about the potential benefits. First, based on Phase 1 and 2 and potentially surrogate data in animal models and understanding what those levels could mean from kind of interim. We will gain more confidence as to the potential benefit of this vaccine. We will still not be talking about an approval. We will not have a full safety database. But you start to generate an anticipation of potential benefit in the context of a raging pandemic I think that's important.

The next step of data is then to get a sense that the vaccine is safe when given to a larger group of individuals, both healthy people, people with who are older with comorbidities and we need to go and build that safety database and do appropriate placebo-controlled i mentioned. And the final piece is then to actually demonstrate clinical utility benefit and that requires to have an endpoint that's meaningful. And I think the two endpoints that are relevant for thinking about a pivotal trial are going to be COVID-19 disease. So however, you define disease the appropriate symptomatology, severity and having a microbiological confirmation. And of course, infection per se is also a relevant endpoint because we know that asymptomatic people even if they themselves are asymptomatic if you can prevent infection you will on a population basis actually prevent others from getting infected and then being sick. So there is a benefit to society here of preventing infection, even if lesser to the individual vaccine. So between the disease endpoint in infection endpoint I think that's where you're going to see the pivotal trials in this space emerge.

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I hope that answers your question on the design as we get closer to it we lock it down with the NIH and the FDA, we will of course be describing it in public.

Your question regarding the emerging mutations, we're all following that closely. I would make two points here. Number one, so far from what we've seen none of the mutations that have been described are expected to significantly interfere with binding or neutralizing activities of antibodies generated to the full-length Spike protein and here I would make the remind you that our mRNA-1273 actually encodes for the full-length spike protein.

I think the mutation that everybody kind of saw last week had to do with potentially increase it's miscibility, but that mutation doesn't necessarily alter the critical neutralizing binding domains as we understand them. So we're clearly watching this area closely like everybody else to assess the potential impact.

The second point I'd say sort of with a more longer-term vision, should such a mutation arise and be relevant for the immunity of the population that's been exposed or the effectiveness of any vaccine, I would contend that actually our platform is going to be uniquely suited to address that for two reasons. Number one is as we've demonstrated, you can move very fast based on just understanding the sequence of the new mutation and you immediately generate a vaccine against that.

But importantly, as you look to the future, one could envision a world where if we've demonstrated efficacy and benefit against this virus in the appropriate randomized controlled trials. If there is a slight mutation and you alter the vaccine to kind of chase the virus, the path to approval and expected benefit for the next one should be much quicker and you can think of the way the world has evolved to deal with flu mutations, whereby since there is a new sequence that sequence is actually put into production and millions of doses of vaccines are generated, you don't need to replicate the entire Phase 1, through three development path, every time there is a minor mutation once you've established the platform.

So as I look to the future, I think we're in a very good place from the fundamentals of our platform to envision that sort of a response to any rising mutations.

Q - Cory W. Kasimov {BIO 3009346 <GO>}

Okay, thanks for the thorough responses and great to see the impressive progress you guys are making.

A - Tal Zaks {BIO 19987702 <GO>}

Thanks, Cory.

Operator

(Operator Instructions) Your next question comes from Ted Tenthoff of Piper. Please ask your question. Ted, you might be on mute.

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A - Lavina Talukdar {BIO 19691239 <GO>}

Operator, we'll come back to Ted. Can you go to the next question please.

Operator

Yes. Your next question comes from Salveen Ritzer of Goldman Sachs. Your line is open.

Q - Salveen Ritzer

Hello. Were you're looking at challenging animal models and then examining the antibody levels in humans? And then a second question around with regard to supply and demand constraints. Is the Lonza partnership really just kind of where you -- I guess is that, are you going to expand beyond that to kind of handle demand and supply?

A - Tal Zaks {BIO 19987702 <GO>}

This is, Tal. Let me try and take your first question. I think you got cut off, but if I understood you correctly, you asked whether we're running animal channel -- challenge models and whether we will be able to connect the dots between those, and what we see in human vaccines. And I think the answer is, yes. That work is ongoing.

It's been done in close collaboration with Barney Graham's team at the VRC of the NIH, and the assay development work that is ongoing is being deployed, so that we are able to connect the dots between the challenge models, convallis and serum the serum that we eventually expect to see from people who have been vaccinated.

So I hope that answers that question. Salveen, let me turn it over to Juan to talk about or Stephane to talk about the Lonza question.

A - Juan Andres {BIO 20291514 <GO>}

Hello, this Juan Andres, Chief Technical Operations and Quality Officer in Moderna. So let me take you -- let me take the second question that you have. Lonza brings an incredible track record in supporting and manufacturing products worldwide, Lonza's capacity together with the capacity that we have in our site in Massachusetts and the capability will be a great help for for Moderna scaling up in also producing the quantities?

We are going to manufacture together with Lonza, the formulated bulk and I expect that we will have more partnership with existing -- with existing CMOs for few finished and distribution and if needed if new ones. Thank you.

Q - Salveen Ritzer

Thank you.

Operator

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Thank you. Your next question comes from Ted Tenthoff with Piper. Please ask your question.

Q - Ted Tenthoff {BIO 1880164 <GO>}

Great, thank you. Can you hear me okay?

A - Stephane Bancel {BIO 15174250 <GO>}

Yes.

Q - Ted Tenthoff {BIO 1880164 <GO>}

Great. Sorry about that before. Good morning, everyone and thank you for all of the hard work, it's been just an incredible run during the last couple of weeks here and the company is really risen to the challenges. Lorence has been so nice working with you and I'm wishing all the best too.

So my question as it has to do with CMV. And I know you guys have talked about sort of the challenges just with getting the kind of data sets from the kind of process and other things. I wanted to see if there is an update on that and whether or not there's any changes to the expectation for data in the third quarter? And also how this general progress and investment in the vaccine platform will really help what you're doing in CMV? Thanks so much.

A - Tal Zaks {BIO 19987702 <GO>}

Thanks, Ted for the kind words. This is, Tal. Let me try take maybe both of those questions on clinic and add-on. On CMV, I believe we remain on track and it's, you can do the simple math here. If we've already vaccinated over 70% of people with the second dose and it's that critical post second dose interim analysis that should confirm our dose for Phase 3.

If you recall the data from the Phase 1 with much smaller numbers of subjects, we had pretty tight care of ours and a pretty good understanding of the dose response curve. Now, with a much larger study, even if it ran into some sort of difficulty because of COVID-19, we're going to be more than powered to understand the immunogenicity and the size was really driven not just by the need to understand immunogenicity, but also to validate the safety profile that we see here.

So I'm confident that with the numbers of people that we've managed to get into the second dose, the amendment of the protocols mentioned, for the remaining less than 30%, well, we will stay on track as we've discussed before to have the data and be able to move on and our plans for Phase 3 continue and remain fully on track for CMV.

Your question on how it's preparing the platform. I'll give you a sort of a brief answer from a perch of maybe medical and development and then I'll let Stephane talk, as it relates to the company becoming sort of moving to its commercial life phase. The COVID experience is doing really three things for us, it is accelerating our understanding of the

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safety and immunogenicity at a much wider level for the platform sort of the leading edge of data if you will and I expect that the ability to run a large placebo-controlled trial and expand the safety database at a much more rapid manner than we had so far in Phase 1s will be informative for all of us as to the performance of this platform, and here I sort of speak as a Chief Medical Officer with a keen eye on the safety profile of our platform. So far we've seen nothing unexpected and it's all been sort of consistent across the application, but of course, a database of 1,500 subjects will benefit greatly when we go into thousands with COVID.

The second element has to do with expanding our capabilities, building up the development team that can integrate and build a BLA file, building up our competencies on the regulatory front, the pharmacovigilance front, etc. all of that ahead of a large Phase 3 effort on CMV, I think is a tremendous benefit for us. And I will sort of -- I'll let Stephane speak to all the other elements where this is accelerating the progress of our company.

A - Stephane Bancel {BIO 15174250 <GO>}

Thanks, Tal. Hey, good morning, Ted. I would just add a few things. And I think Tal started to allude to it, which is the power of our platform, which will create some very powerful network effects, where if you take an example of something new we shared today, which is we had a positive Type C meeting last quarter around CMV for CMC for manufacturing. As you can appreciate, these dialogues with the agency around CMV Phase 3 is going to be very instrumental and had been dose on the Phase 3 for SARS-CoV-2 mRNA-1273. Because of the urgency that the agency has, we've had an amazing dialog with the FDA. The responsiveness seven days a week, we're very engaged, we're very willing to find a way to shape a the day for the process without making any shortcut on safety, obviously.

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So for this BLA process that we should be able to go through in the next months, both on the clinical side and also on the manufacturing side. The success with the agency disability to ask question to get clarification quickly will really help us to really build that capability within the team with sort of processes of the digital infrastructure, and data directing which is critical both on clinical and on CMC, then you're going to be able to use that very quickly on Zika, on CMV. And that's -- I think that's going to be very powerful, when it took effect, I think at some time and I appreciate it, because most companies, as you know, do not have platforms, whereas here because mRNA being an information molecule is really an ability to make Moderna very robust and to take you to the next level. So that's what we do on SARS-CoV-2 BLA-wise can be replicated much faster and much stronger on Zika, CMV and all the other programs. I didn't give the same things on the commercial with the arrival of Patrick, we are going to build very rapidly in our commercial infrastructure. We'll give you updates on that in the coming months.

But as you can appreciate, all that work that's going to happen very quickly on COVID will help us on the other products, but only on the company branding standpoint because as you appreciate the Moderna brand has been transformed in the last few months because of the results that the team has been able to accomplished. Those two are the products at the scientific level and the clinical level. So I think the momentum of Moderna is going to be extremely strong and extremely enabled by the SARS-CoV-2 refining process.

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Q - Ted Tenthoff {BIO 1880164 <GO>}

That's super helpful. Thank you very much.

A - Stephane Bancel {BIO 15174250 <GO>}

Thanks, Ted.

Operator

Thank you. (Operator Instructions) Your next question comes from Yasmeen Rahimi of ROTH Capital Partners. Please ask your question.

Q - Yasmeen Rahimi {BIO 20388907 <GO>}

Hi, team. Thank you for the continued amazing progress that you're making day-over-day. Two quick questions for you. The first question is related to, how are you -- are you defining age cut-offs at -- in the Phase 2, you mentioned, there will be a cohort of patients who are 55 and above. Is there may be a range above which you're not going to be going after? And then, if you're going to be a cohort among the Phase 2 and as you're thinking about 3, that are healthy, but are at highest risk given that maybe they have obesity or cardiovascular disease.

How are we thinking about this patient population that are at the highest risk to incorporate that into the Phase 2 and Phase 3 enrollment? And then the second question is in regards to manufacturing. If you could help us understand what is the single largest unknown when it comes to scaling up mRNA therapeutic? And thank you for taking our questions.

A - Tal Zaks {BIO 19987702 <GO>}

Hi. This is Tal. Let me start by answering the clinical ones and then I'll let Juan take the manufacturing question. The -- in our Phase 2, there is no upper limits. I think above 55, you've seen the NIH Phase 1 sort of parse it out a little bit more. Finally, I think for us, we're going to take all comers about 55 with no upper age limit. In terms of your question on the cohorts at higher risk for disease, should they get infected this relates to both the elderly and people with distinct comorbidities.

As we build the safety database, obviously we need to get there, but get there responsibly. I think in the Phase 2, the initial sort of expansion into larger numbers is people that do not have a high risk of disease should they get infected. In the Phase 3, we will clearly then open it up and we will do that in a manner that's responsible and takes the appropriate interim looks to make sure that we expand into that population, who needs it the most in a way that's careful and that's an ongoing discussion obviously between us, NIAID and FDA how to best achieve that goal. Let me let Juan take your manufacturing question.

A - Juan Andres {BIO 20291514 <GO>}

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Okay, thanks. Thanks for the question. Obviously, one of the unknowns we discussed before which the assumptions associated with those. And then in terms of the industrialization of the product, obviously, we're working very hard is in bringing the equipment, bringing the raw materials, bringing the people capabilities together as we scale up. I don't think it is a very single unknown in dose. We have done this before, probably not at the scale at which we are going, having the partnership with Lonza gives me a tremendous confidence that we are going to be doing these very rapidly. And obviously, speed is at the essence, bringing these three things together is what -- what is all about and that's what we do.

A - Stephane Bancel {BIO 15174250 <GO>}

Yes. And maybe, Yasmeen, just to add something, we are extremely fortunate to have Juan and his leadership team. As you know, he and the team have all come from large organization. They have managed very large manufacturing complex organization. The have a lot of experience. They know that every extra million dose we can get out of our system will be helping a lot of people. So I'm very thankful for the team. They are literally working seven days a week, pulling all night hours to share there whether we can -- so that we can really maximize the multi-output of the system and I'm tremendously thankful for them.

Q - Yasmeen Rahimi {BIO 20388907 <GO>}

Thank you, Stephane. And so we were very grateful for all the work that everyone at Moderna is doing on behalf of humanity.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you.

Operator

Your next question comes from Geoff Meacham of Bank of America. Please ask your question.

Q - Alec Stranahan {BIO 20630524 <GO>}

Hey, guys. This is Alex on for Geoff. Thanks for taking our question. And Lorence, we're sorry to see you go, but I assume you're moving on the bigger and better things. So my question is on capital allocation in the near-term. You reiterated your 2020 expense guidance, but I was hoping you could give a bit more color on the gives and takes within that vis-a-vis opex versus capex? And how much manufacturing build out and commercial readiness activities for COVID-19 are reflected within that?

And my second question is on the commercialization front. Do you intend to take the vaccine forward yourselves or do you think it will take partnering to deliver that scale or with the U.S. government potentially step in as well, any color you can give here? And if there is some historical context, you could point to that would be great. Thanks.

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A - Lorence Kim {BIO 18670491 <GO>}

Hey, Alec, it's Lorence. Let me handle the financial question. With respect to the guidance in the components. So as I mentioned around sort of the pre-COVID business if you will, I mentioned that we're seeing a bit of a slowdown in expenses opex related to lab work. And some of the clinical trials as we've noted, and so those expenses will be coming down relative to what we thought when we originally set out guidance.

The asset is I mean -- investments that we are making to be ready for all that's coming down the road, what we've mentioned is that the rapid acceleration of the COVID vaccine timelines and there is a lot that we need to do the company to be ready for potentially being commercial in 2021.

And so those offset. We will continue to update you as you -- as we regard -- as we scope those investments and as we move forward. With respect to capex, it is not a huge component here right now of the anticipated budget, mainly because of the leverage we've got in the platform as well as the benefit of having a great partner like Lonza on board. And again, we'll continue to update that guidance should I think change.

And then the last thing I would just reiterate is that there is substantial opex expected with respect to the COVID vaccine work being funded by BARDA in the clinical development to scale up, but that will be paid for by BARDA reimbursed on a very rapid cycle time. And so that's why I mentioned that there would be this matching of expense in reimbursement through the course of the year that would substantially offset.

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A - Stephane Bancel {BIO 15174250 <GO>}

Yes. Thanks, Lorence. And Alex, on commercialization. As you can appreciate as we've said before with the case of CMV, we do not anticipate at least the capability and investing to sell the products in our 40 countries. For SARS-CoV-2 I think it's important to think about the product into different time horizon. There is a pandemic phase in which obviously we all are and then we believe, as a company there is similar opportunity for this product in the endemic phase, because we do not believe these virus is going away.

So from a pandemic phase it will be mostly a partnership with governments. So in that case, you don't have to necessarily manage their complex sense of potential buyers, because we're going to be as we discussed at the global level across the industry, we're going to be supply constrained for some time, which is why as we've said publicly many times, we are working for everybody who is working on the vaccine and we're hoping that many vaccines are going to a finish line, because if you think about it, there are actually very few companies that have both the manufacturing scale that is required for the task ahead and are already in the clinic, meaning they can have the short to mid-term impact with our vaccine even there are just a couple of companies that have those two things.

And so if you think about it in a very supply constrained world in 2021, it's going to be mostly partnering with government, so that they will do allocation in the different geographies, we do not intend, for example, in the U.S. to decide who gets the vaccine that we can all be appropriate.

So we intend to continue our partnership with the U.S. Government like we've already done with NIAID and Anthony S. Fauci's team for few years, as you know in the clinic more recently. With BARDA and eventually, I assume the CDC to be able to supply to the U.S. government the doses for them to decide the allocation that makes sense for country.

Q - Alec Stranahan {BIO 20630524 <GO>}

Great. Thank you and congrats on the rapid progress.

A - Tal Zaks {BIO 19987702 <GO>}

Thank you.

Operator

Your next question comes from Alan Carr of Needham & Company. Please ask your question.

Q - Alan Carr {BIO 15355437 <GO>}

Hi, thanks for taking my questions and congratulations on the progress. I had a couple of them, I mean your increased focus and success with vaccines. Are you able to accelerate or what sort of extra emphasis you are putting in this early-stage vaccine programs. You've given this update on 1545 and well then meeting on RSV and EBV programs that are internal. How are those moving along and we don't give high resin for timelines but if you can?

And then the other question is around your COVID-19 program. To what extent is it feasible to have even an interim analysis of your planned Phase 3 trial in 2020? Thanks.

A - Stephane Bancel {BIO 15174250 <GO>}

So let me start maybe with your first question on EBV and RSV pediatric. As you know, we do not guide on programs timelines. So the team is working on advancing those important vaccines as fast as possible, which we have given the timelines. And we will not give timelines on the -- we tend as you appreciated over the quarters to give timelines we'll get closer to, kind of, late-stage development. And especially, we've the SARS-CoV-2 given the pandemic and given the suffering around the world, we think it's important to communicate our best plans. And I hope, everybody will appreciate that when we say, we aim to start the Phase 3 early summer this year is the best possible physical plan. 50 things can give us that but for early programs a lot of communicating. Tal, you want to take the COVID interim data question?

A - Tal Zaks {BIO 19987702 <GO>}

Yes, yes. Yes, it's a good question. I believe we should be able to have a sense of the cases and a potential early look by the end of the year. But again, that is a function of how soon can we start, how big the trial is, and how good are we at immunizing people who are then at risk for cases occurring. Because as I mentioned, it will end up being a case-driven design to be able to analyze it. And we'll share the data -- we'll share the details

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and the expectations once we lock down the design with our partners and read it with the agency.

Q - Alan Carr {BIO 15355437 <GO>}

Do you expect it could be just a U.S. trial or would you go global and I guess another follow-up to this is to what extent -- I mean if we talk about the possibility of a larger trial with multiple vaccines? Are you contemplating that too? Or is this just the trial is this kind of say to just a Moderna versus Moderna candidate which is as you know?

A - Tal Zaks {BIO 19987702 <GO>}

Yes, so let me take both questions on churn. This -- first pivotal trial there is going to be a partnership with NIAID with the NIH, so it will be at this stage either solo or predominantly U.S. trial, we're in parallel, looking at opportunities to launch parallel pivotal trials in Europe and globally, because I think ultimately, the more data we have here, the wiser we will be. I think, can you please remind me your second question?

Q - Alan Carr {BIO 15355437 <GO>}

Well. I think you answered. And I was wondering if -- as you were contemplating a trial, or a government is contemplating a trial...

A - Tal Zaks {BIO 19987702 <GO>}

All right. Right. The multi-arm trial. Yes. So there's been a lot of talk about that both on the WHO side as well as the NIH as you can clearly intuit, it's not front and center in migraine for two reasons. First, is we expect to be the first one out there for a pivotal trial and so we just have to get on and demonstrate our trial our vaccines' potential.

But the second one is more fundamental. I think, it is important for the field to use more or less (technical difficulty) line is case where it actually make sense to run many vaccines in the single trial. It's not like we're lacking for volunteers who would line up to be immunized and understand the benefit of a vaccine. And frankly the epidemic is so unpredictable and where it shows up and to what degree and how it comes down that there is no expectation of a consistency of attack rate over time that would make that add any scientific value.

So from my end, this is a personal opinion here I question the merits of that design from a scientific and the public health need perspective. I think what's critical here is that for every vaccine candidate is fund alluded to, we're going to need more than one of them, but it matters less whether there is a few percent difference on the apparent estimate of the point efficacy what matters is you know it works and you're able to scale it up and make it available to those who need the most.

Q - Alan Carr {BIO 15355437 <GO>}

Okay. Thanks very much.

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Operator

Your next question comes from Gobind Singh of BMO. Please ask your question.

Q - Gobind Singh {BIO 3104587 <GO>}

Hi everyone, this is Gobind on for George. Thanks for taking our questions. Two on 1273. The first one would be, can you help us understand if there is any profit share agreements in place without any other parties, including NIH around the vaccine? And just how do you guys see the commercial landscape evolving with so many other vaccine candidates in development?

And then just a follow-up maybe with NIAID's comments about their preclinical results that they saw? I understand they are probably doing their studies separate from you guys, but maybe you can help us understand what kind of preclinical results you've seen? And when might this data be presented that'll be really helpful? Thanks a lot.

A - Stephane Bancel {BIO 15174250 <GO>}

Yes. So Stephen I'm going to start and then the team might end up. So it is pretty as predicated there is preclinical work being done both in our labs and at NIAID Dr. Anthony Fauci and this team as soon as various body of data that makes scientific expense and is completed and holistic we intend to publish that work. So as soon as it's public you will be aware. In terms of the profit share, we have not disclosed previously any arrangement so I would not comment on this one. And what was your other question?

Q - Gobind Singh {BIO 3104587 <GO>}

The commercial landscape and how other coronavirus vaccines are at development?

A - Stephane Bancel {BIO 15174250 <GO>}

Yes. Thank you. So on the commercial landscape, as I briefly mentioned a few minutes ago, as you know, I mean we have hundred plus some that we see they are vaccine candidates being worked on around the world. The thing I think that's very important is manufacturing scale and where are those projects in the -- we serve for other clinics. As I said a few minutes ago, I believe that the project at this stage in research, we have a group that are of the ability to do tens of millions of those is come off ramping up to hundreds of millions per month. It is not going to be able to have a big dent on this pandemic.

And so if you use those two as a screen, which is what we do, I think you end up with very few number of players that number again gets changed in the 2021 timeframe to have an impact on this. Obviously, that's like always in drug development, not every candidate is going to get to the finish line. And I could as well anticipate that once a few vaccines are in late stage or are commercially approved a lot of the early projects might just stop investing because we got to be putting capital and talent for something that might have no commercial end. So I think while there is a lot of people on the staff lane, my sense is very few are going to get to the finish line.

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We've manufacturing scale that matters. 1 or 2 million doses, a year is only going to be very, very helpful at the global scale.

Q - Gobind Singh {BIO 3104587 <GO>}

Thank you for help. Good to know the progress journey.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you.

Operator

Your next question comes from Justin Kim of Oppenheimer. Please ask your question.

Q - Hartaj Singh {BIO 18796450 <GO>}

Hi, it's actually Hartaj on for Justin. So one thing first, Lorence. Thank you so very much. It was a real pleasure working with you, look forward to seeing you again sometime in the future. And then secondly, just to Moderna for all the work that you're doing, I think people, a lot of people really don't understand just the compression of the timelines that you and the government are engaging. It's really, really thing of beauty.

So two questions. One is manufacturing and second on regulatory strategy worldwide. So on manufacturing, if you could just talk a little bit about going from clinical to commercial batches. I know you've talked it's kind about going from millions, tens of millions in now dealing with Lonza, can you just talk broadly about the timing, when can you go from that clinical? I know you mentioned that Lonza will start manufacturing for batch in July and how that maps against to BLA that you'll be starting to file?

And then secondly on regulatory strategy. Japan has approved Remdesivir I guess the EU is going through an approval process fast approval process for Remdesivir. So how are you thinking the worldwide approval strategy aside from the United States where I assume you'll file the BLA towards the end of the year? And thank you for the question.

A - Stephen Hoge {BIO 17925815 <GO>}

So, Akash let me. Good morning. Let me maybe start quickly on manufacturing. We have not done and not shared precise output from all. What we've said is that given we're ramping up both Norwood, which we think could do up to $100 million doses per year at the 15-microgram dose and then the longer side as you can appreciate, is the every month this year, every month next year the output from all is going to increase.

And so the team which is working as hard as they can, because they do understand trust me that every extra 100,000, we get out of obviously spend, we will protect more people, we will slowdown the spread of this virus. And so it's not the linear process where you stop now at $100 million if the dose come out of course not. So it is just going to be an acceleration process, which is why this dialog with the government in terms of allocation, and we're going to be hand to mouth for quite some time where, as soon as product is

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made in QCD will go to the government and then they'll decide how they allocate it and just kind of be on a regular basis. Tal, do you want to take the regulatory question maybe?

A - Tal Zaks {BIO 19987702 <GO>}

Yes. Thanks, Stephen and thanks Hartaj for the asking that question. Look, we're in active dialog now with regulators beyond the U.S., I think having the partnership with Lonza is a huge enabler to envision the ability to scale up and eventually supply the vaccine on a global footprint to those who need them the most. That will take shape over the coming weeks and months. The expectation I have is that we will do more than one trial to demonstrate the benefit. That being said at a certain point we're going to, you have data both potential benefit and ultimately for benefit by and large that data should be applicable for filing in other territories.

And so we're actively mapping it out in our intent is absolutely to eventually be able to make this vaccine available to those who need it most.

Q - Hartaj {BIO 18796450 <GO>}

Okay. Thank you for all the questions.

A - Tal Zaks {BIO 19987702 <GO>}

Thank you.

Operator

There are no further questions at this time. Presenters, you may continue.

A - Stephen Hoge {BIO 17925815 <GO>}

So, thank you so much everybody for participating. And we look forward to talking to you or seeing you at the latest on June 2nd for the Moderna Science Day we have Stephane and his team with us. Thank you very much. Have a good day and stay safe. Bye-bye.

Operator

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

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