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EDITED TRANSCRIPT

MRNA.OQ - Q1 2020 Moderna Inc Earnings Call

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OVERVIEW:

Co. reported 1Q20 total revenue of \$8m and net loss of \$124m.



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PRESENTATION

Operator

Good morning, and welcome to Moderna's First Quarter 2020 Conference Call. (Operator Instructions) 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 - Moderna, Inc. - Head of IR

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 Stéphane Bancel, our 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 Stéphane.



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Stéphane Bancel - Moderna, Inc. - CEO & Director

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 versus traditional medicines and with better manufacturing capital efficiency and lower cost of goods than injectable recombinants.

Given the amounts of working with 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 into other modalities, prophylactic vaccines and systemic secreted and cell surface therapeutics, data that we believe fundamentally changed the risk profile for each of these 2 modalities that we now call comodalities. As a result, our strategy is to double down in these 2 comodalities with many important new development candidates space.

We have already announced 5 new development candidates in these comodalities since January 13 at the JPMorgan Conference: 3 new development candidates in infectious disease: prophylactic vaccines and 2 in the systemic secreted and cell surface therapeutics modality. While we focus on doubling down in comodalities, 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 2 distinct area of focus. This is a significant point in our strategy. We have comodalities we want to scale and invest and exploratory comodalities that continue to be a big driver to the company's future as we await clinical data to decide the path forward.

So stepping back, I would have 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. The company pivoted out of that growth phase when we entered the clinic with our 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 6 different modalities. We tested 16 different molecules in the clinic in a short 4-year period. In 2019, we generated important data in 2 of these 6 modalities and identified our first 2 comodalities, infectious disease prophylactic vaccines and systemic secreted and cell surface therapeutics.

Early in the year, we entered a new phase of company's development. Our goal for this next phase in our history is to file multiple BLAs while continuing our clinical programs in the 4 exploratory modalities and continue to invest aggressively in early 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 3 to 4 years. Our vaccine against SARS-CoV-2 virus, mRNA-1273, is a major acceleration of our company's development. Today, we are very happy to announce that we received yesterday clearance from the FDA to proceed with the Phase II. It's just 9 days from filing our IND on Monday, April 27, the FDA gave us a green light. We intend to start the clinical trial as soon as safely possible.

We've also announced this morning that we are finalizing the Phase III protocol. And our aim is to start dosing the Phase III in early summer 2020. This means that we have a potential for a BLA approval for mRNA-1273 in 2021. That is an acceleration of several years versus the plan we had just months ago. Moderna should be a commercial company -- sorry, Moderna should be a commercial-stage company in 2021. That is 2 to 3 years ahead of our previous plans, plans we outlined just months ago. This is a unique opportunity. So we are working actively to get the company ready.

To deliver on this acceleration of the company's plan, we're expanding our leadership team in areas where their expertise will be instrumental to allow us to successfully file several BLAs and be ready commercially. Today, we are announcing 3 new addition to the leadership roles of Moderna.



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First, Patrick Bergstedt. Patrick joins Moderna as Senior Vice President, Commercial Vaccines. Patrick will report to me. Patrick joins from Merck & Co. where he most recently was Head of Global Marketing & Commercial Operations for the entire vaccine business at Merck. Patrick will start on June 1. Patrick led global initiatives with a focus on revenue growth and access expansion. The 20-plus year veteran in the biopharma industry, Patrick has held various leadership positions 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. Jacqueline will be joining Moderna on May 11 from GSK as Senior Vice President, Infectious Disease Development. Jacqueline joins the company from GSK where she held a variety of leadership roles since 2005. Most recently, Jacqueline was the Vice President and Head, Clinical R&D and Epidemiology, where she built and led the clinical and epidemiology research team at the first GSK vaccine research and development center in the U.S.

And third, Dr. Charbel Haber. Charbel joined Moderna on April 21 as Senior Vice President for Regulatory Affairs. Charbel joined us from Biogen, where he served as Vice President, Global Safety and Regulatory Sciences since 2017. In this role, he built and led the Global Regulatory Strategy Department, the clinical trial application group and the Medical Writing group. Prior to Biogen, Dr. Haber, was Head, Global Regulatory Affairs-Immunology and Neurology at EMD Serono.

I am very excited to welcome Patrick, Jacqueline 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 0 development candidates. Lorence super-chanced on Stephen Hoge and I and decided to leave a great job by Goldman Sachs to join us. The company is now public with 23 development candidates and preparing its first Phase III. Lorence will manage with us for a smooth transition. He will do Moderna second quarter conference call in August with us before leaving the company. I am very thankful for Lorence's contribution over the years and for the 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 with 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 Russell Reynolds for the search for Moderna's next CFO. We will focus on a CFO who has 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 wanted to take a few minutes to frame the opportunity in our vaccine modality. We believe mRNA has the potential to be a new class of vaccines, where each of the 4 drivers of value apply. 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 products on the market today to protect as many people as we can. Second, a relatively high probability of technical success. As we discussed at our Vaccine Day, Dr. Andrew Lo from MIT has shown that from the start of a Phase II, i.e., post the Phase I, to approval, vaccines have 42% probability of approval. This is the highest probability amongst all categories of medicines in clinical trial. We think this is a very important value driver for this franchise.

Further, we think an important driver is speed, speed in the labs. Even we have a platform. We can study many candidates in parallel in preclinical setting. Most difficult development candidates to take into the clinic, we can do it very quickly, as we have shown recently with SARS-CoV-2 vaccine, going from design of a vaccine on January 13 to injecting the first human on March 16 in as little as 63 days.

Finally, we believe the capital efficiency of our platform offers significant advantages over traditional vaccines. Because the manufacturing process to make mRNA molecule is a cell-free manufacturing process, it can drive much lower CapEx versus recombinant protein manufacturing. The second dimension is the CapEx leverage across value chain. For example, when we decided to go after 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 - Moderna, Inc. - Chief Medical Officer

Thank you, Stéphane, and good morning, everyone. I'll start with a quick reminder on the data generated to date with our vaccines.



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In over 1,500 healthy volunteers and 7 positive Phase I data sets to date, we have observed a 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 will give more detail shortly. As you heard from Stéphane earlier, we have the FDA clearance to move into our Phase II study, and we plan to start it shortly. This study will run in parallel with the NIH-run Phase I study, which has completed enrollment of the first 3 dose cohorts. Our CMV Phase II 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 14, we announced positive interim analysis of our Phase I study for our Zika vaccine. At the 2 lower doses of 10 microgram and 30 microgram, we achieved seroconversion rates of 94% and 100%, respectively. The 2 higher dose cohorts of 100 microgram and 250 microgram are now fully enrolled. As a reminder, we paused our hMPV/PIV3 Phase Ib 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 pace everybody on the same place, our SARS-CoV-2 vaccine, mRNA-1273, which was a subject of much work and 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 24, and by March 4, was associated with an open IND that NIAID 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 17, we were awarded a contract from the U.S. government agency, BARDA, to accelerate the development. And on April 27, we announced an IND was submitted to the U.S. FDA for the Phase II 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. And of course, today, we announced the FDA clearance to start the Phase II part.

In parallel, we have been working on the Phase III protocol, and we are finalizing that with an aim to start the study in the summer of 2020. The design of the Phase I study is on Slide 17. The study started as a 45-subject trial with 3 dose cohorts, 25, 100 and 250 microgram, with each participant receiving 2 vaccinations a month apart. Phase III 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 2 additional age cohorts, a 56- to 70-year-old cohort and a 71-and-above age cohort. Each of these age cohorts will include 3 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 II study is expected to start shortly. This study will evaluate the safety, reactogenicity and immunogenicity of 2 vaccinations of mRNA-1273 given 1-month apart. Volunteers will receive either placebo, 50 or 250 micrograms at both vaccinations. This study will enroll 600 healthy participants and 2 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 I. We are finalizing, as I said, the Phase III protocol, and the study is expected to begin this summer.

Last week, Moderna and Lonza announced a 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's U.S. sites in July of this year. I would be remiss not to mention BARDA's role in this. The BARDA award is allowing for us to move as quickly as we are with 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 II 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 a dose for the Phase III after the first interim analysis, which is the data post the second vaccination. We continue to prepare for the Phase III, 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 the 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 I trial. This study has demonstrated a fairly benign safety profile, consistent with what we've



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seen before for other vaccines. And at the 2 lower doses of 10 and 30 micrograms after a 2 dose vaccination regimen, prime and boost, the seroconversion rates were 94% and 100%, respectively. These data are encouraging, and we are preparing to move forward with this program into a Phase II 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 and catalysts 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 H. Kim - Moderna, Inc. - CFO & Treasurer

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 in that discovery and development of potential mRNA medicines for the treatment of cystic fibrosis or CF by enabling cells in the lungs that people see us to potentially produce functional CFTR proteins. In July of 2019, the initial research term was extended by 6 months. And based upon promising preclinical data generated, in March of 2020, we were pleased that Vertex elected to extend this collaboration for a further 18 months.

Now let me turn to financial results. In today's press release, we 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 \$106 million for the first quarter of 2020 compared to \$144 million in 2019. And just as a reminder, that latter number includes an in-licensing payment of \$22 million, 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 of 2020 were \$24 million compared to \$27 million in Q1 2019. This decrease of \$3 million was primarily attributable to decreases in legal and other consulting and outside services spend. And net loss for Q1 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 items, 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 2 items, which is in line with our expectations. If you go back to Q1 2019, we used \$152 million of cash on these 2 items. And remember again, that number included that licensing payment.

Overall, you can see the decline in our quarter-over-quarter cash used for these items through Q4 2019 with 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 slow down 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.

We 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 a matching of expenses and reimbursements.



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Let's go 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, 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 and Melinda Gates Foundation, DARPA and another BARDA award comprising additional available funding of \$180 million. Together, this creates multiple years of cash runway, considering the cash guidance that we 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 Stéphane, 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 6 years ago, at a time when this story was nascent and 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 scientific 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 Stéphane, the Board, its executive team and the passionate Moderna employee base. For me, I'm going to take the 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 at an appropriate time down the road with many of you on this call.

And with that, I'll turn it over to Stéphane for closing remarks.

Stéphane Bancel - Moderna, Inc. - CEO & Director

Lorence, thanks again for your remarks. But having you as my partner for those 6 years has been quite a 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 2 candidates for which we are preparing for Phase III, our CMV vaccine and our SARS-CoV-2 vaccine. We have now 6 candidates that are either in Phase II or preparing for Phase II. 12 Phase I programs and 11 positive Phase I result. What an acceleration since our IPO in December 2018.

Our programs are very exciting. We have 7 first-in-class vaccines, where there are no approved vaccines on the market against those viruses. Most of these vaccine candidates have multibillion dollar annual peak sales opportunity. As we shared at our Vaccine Day presentation, we believe our innovative vaccines are going to be a very large business for Moderna with long-term annuity life opportunities at a high EBIT margin. We also have 5 exciting immuno-oncology programs that are already in the clinic, that are all combined with a commercial checkpoint, 4 rare disease program and 2 autoimmune disease programs.

The company has never been stronger and look at an formations. 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 agreement, 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 products in our pipeline as we need to. We have great partners with AstraZeneca, Merck and Vertex. I am very proud of the scientific progress that the team of Stephen Hoge and Melisa Moore have done in the work with Vertex over the last few years. And we are very pleased that Vertex decided to expand the relationship with Moderna.



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But we're also very thankful for a partnership we've had over the years with BARDA, DARPA, [CP] and the Gates Foundation. 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 with up to \$2.4 billion to invest in the business and continue to build 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 are energized by the opportunity ahead of us to build a new class of medicines. We are currently accelerating our development pipeline and readying the company to potentially file its first BLA for mRNA-1273, which will be, as you can 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, starting with the Zika vaccine and CMV vaccines behind the SARS-CoV-2 mRNA-1273. We are already scaling up the organization to address the need to supply up to 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.

I have never been as excited and optimistic about the future of Moderna in the last 9 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 7 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, physicians and nurses. I'd like to recognize all our partners that have worked 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 of Morgan Stanley.

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

Great. 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 elicit 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 and 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 I study?

Tal Zaks - Moderna, Inc. - Chief Medical Officer

So this is Tal. Let me take that question. 2 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, 3 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 the case of a pandemic, we obviously need to balance this with having enough doses available. And so you don't want to unnecessarily overshoot. The second element is an understanding of what that dose could mean as you compare to convalescent serum. 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 higher the species the more reliable that data is. But ultimately, what we care about is being able to connect the dots for human disease. So



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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 the measure of immunological 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 that a virus would otherwise give the cell to make an antigen, we get the right kind of immune response, however we want to characterize it, neutralizing antibody in Th1 versus Th2, et cetera. The emerging data that we're seeing preclinically with mRNA-1273 is all consistent with that.

Your final question, on neutralizing antibodies, yes, those assays are being stood up as we speak. They're being validated. They're being transferred to commercial vendors. And the NIAID is actively looking at 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 I.

Operator

Your next question comes from Cory Kasimov of JPMorgan.

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

I've got 2 of them for you as well. So I guess, first, can you talk more about what the Phase III COVID vaccine design might look like? And there's, obviously, nothing traditional about this program. So how should we be thinking about kind of like the endpoints interim analysis 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. I'd be very interested to hear your views on this and what it could potentially mean for the effectiveness of your vaccine.

Tal Zaks - Moderna, Inc. - Chief Medical Officer

Thanks, Cory. This is Tal. I'll take those questions. So look, the Phase III 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 3 things: how big it is when you start, how good are you at predicting the attack rate in the population that you vaccinated, because if it's 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 is, because the higher the point estimate for the vaccine efficacy, the clearer the results are and 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 if -- 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, it's suddenly available for everybody. I think as we learn more about the potential benefit first based on Phase I and II and potentially surrogate data in animal models, and an understanding what those levels could mean from convalesce 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 ranging pandemic, I think that's important.



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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 in the 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 2 endpoints that are relevant for thinking about a pivotal trial are going to be COVID-19 disease. So however you define a 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 fixed. So there's a benefit to society here of preventing infection even if less so to the individual vaccinee.

So between the disease endpoint and infection endpoint, I think that's where you're going to see the pivotal trials in the space emerge. 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 will make 2 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 -- I'd 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 increased submissibility 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 2 reasons.

Number one is, as we've demonstrated, you can move very fast based on just understanding the sequence of a new mutation and you immediately generate a vaccine against it. 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's 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 as soon as there's 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 I, II, III development path every time there's 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 response to any rising mutations.

Operator

(Operator Instructions) Your next question comes from Ted Tenthoff, Piper.

Lavina Talukdar - Moderna, Inc. - Head of IR

Ted, you might be on mute.



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Operator

Your next question comes from Salveen Richter of Goldman Sachs.

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

Where 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?

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

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 vaccinees.

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, convalescent serum and 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 Stéphane to talk about the Lonza question.

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

This is Juan Andres, Chief Clinical Operations and Quality Officer in Moderna. So 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 Moderna scaling up and 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 CMOs once we're finished in distribution, and if needed, with new ones. Thank you.

Operator

Your next question comes from Ted Tenthoff with Piper.

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

Great. Can you hear me okay?

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

Yes.

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

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



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So my question actually has to do with CMV. And I know you guys have talked about sort of the challenges just with getting the final data sets and the final process and all those things. So I wanted to see if there's 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.

Tal Zaks - Moderna, Inc. - Chief Medical Officer

Thanks, Ted, for the kind words. This is Tal. Let me try and take maybe both of those questions, and Stéphane can 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 III. If you recall the data from the Phase I, with much smaller numbers of subjects, we had pretty tight error bars and a pretty good understanding of the dose response curve.

Now with the 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 managed to get into the second dose, the amendment of the protocol, as mentioned for the remaining less than 30%, that 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 III continue and remain fully on track for CMV.

Your question on how it's preparing the platform. I'll give you sort of a brief answer from approach of maybe medical and development, and then I'll let Stéphane talk as it relates to the company becoming sort of moving to its commercial life phase.

The COVID experience is doing really 3 things for us. It is accelerating our understanding of the 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 I 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 a development team that can integrate and build a BLA file, building up our competencies on the regulatory front, the pharmacovigilance front, et cetera. All of that ahead of a large Phase III effort on CMV, I think, is a tremendous benefit for us.

And I'll sort of -- I'll let Stéphane speak to all the other elements where this is accelerating the progress of our company.

Stéphane Bancel - Moderna, Inc. - CEO & Director

Thanks, Tal. I would just add a few things. And I think Tal started to allude to it, which is the power of our platform, which really 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 CMNC support manufacturing.

As you can appreciate, this dialogue with the agency around CMV Phase III is going to be very instrumental in helping us on the Phase III for SARS CoV-2 mRNA-1273. Because of the urgency that the agency has, we've had an amazing dialogue with the FDA. The responsiveness, 7 days a week, very engaged, very willing to find every way to shape a deal process without making any shortcut on safety, obviously.

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. This access to the agency, with this ability to ask question, to get clarification quickly will really help us really build that capability within the team, but also all the digital infrastructure in terms of data gathering, 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 I think that's going to be very powerful.



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The network effect, I think are sometime underappreciated because most companies, as you know, do not have platforms, whereas here, because mRNA being information molecule, there's really an ability to make Moderna very robust and to take it 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 think it'll be the same things around 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 totally as a competitive 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 accomplish. First of all, the product at center of advancement at the clinical level. So I think the momentum of Moderna is going to be extremely strong and extremely enabled by the SARS CoV-2 verifying process.

Operator

(Operator Instructions) Your next question comes from Yasmeen Rahimi at Roth Capital Partners.

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

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 defining age cut-off? In the Phase II, you mentioned there will be a cohort of patients who are 55 and above. Is there maybe a range above which you're not going to be going after? And then is there going to be a cohort among the Phase II and as you're thinking about Phase III 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 II and Phase III 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 therapeutics?

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

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 II, there is no upper limits. I think above 55. You've seen the NIH Phase I sort of parse it out a little bit more finely. I think, for us, we're going to take all comers above 55 with no upper age limit.

In terms of your question on 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 the Phase II, 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 III, 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.

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

Okay. Thanks. Thanks for the question. Obviously, one of the unknowns we discussed before which is the assumptions associated with dose. And then in terms of the industrialization of the product, obviously, where we're working very hard is in bringing the equipment, bringing the raw materials, bringing the people capabilities together as we scale up.



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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 this very rapidly. And obviously, speed is of the essence. Bringing these 3 things together is what it's all about, and that's what we are doing.

Stéphane Bancel - Moderna, Inc. - CEO & Director

Yes. And maybe Yasmeen, just to add something. We are extremely fortunate to have Juan and this leadership team. As you know, he and the team have all come from large organization. They have managed a very large manufacturing complex organization. They 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 7 days a week, pulling all-nighters to shave every day we can so that we can really maximize the [mostly] output of the system, and I'm tremendously thankful for them.

Operator

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

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

This is Alec on for Jeff. And Lorence, we're sorry to see you go, but I assume you're moving on to 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 at scale? Or would the U.S. government potentially step in as well? Any color you can give here. And if there's some historical context you could point to, that would be great.

Lorence H. Kim - Moderna, Inc. - CFO & Treasurer

Alec, it's Lorence. Let me handle the financial question. With respect to the guidance and the components, so as I mentioned around sort of the pre-COVID business, if you will, I'd 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 offset is investments that we are making to be ready for all that's coming down the road. We've mentioned this -- the rapid acceleration of the COVID vaccine timelines, and there's a lot that we need to do at the company to be ready for potentially being commercial in 2021. And so those offset, we will continue to update you all as we -- as we scope those investments 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 anything 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, the clinical development at 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 and reimbursement through the course of the year that would substantially offset.



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Stéphane Bancel - Moderna, Inc. - CEO & Director

Yes. Thanks, Lorence. And Alec, on commercialization, as you can appreciate, as we've said before, with the case of CMV, we do not anticipate having the capability and investing to sell the products in [our complete] countries.

For SARS CoV-2, I think it's important to think about the product in 2 different time horizon. There is a pandemic phase, in which obviously, we all are. And then we believe, as a company, there's some opportunity for this product in the pandemic phase because we do not believe this virus is going away.

So for the pandemic phase, it's going to be mostly a partnership with governments. So in that case, you don't have to necessarily manage complex sets 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 with -- working on the vaccine. We are hoping that many vaccines are going to be finished. And 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 a short to midterm impact with our vaccine. In my opinion, there are just a couple of companies that have those 2 things.

And so if you think about it in a very supply-constrained world in 2021, it's going to be mostly partnering with governments. So that they will do the allocation in the different geographies. We do not intend, for example, in the U.S. to decide who gets the vaccine. That will not be appropriate. So we intend to continue our partnership with the U.S. government, that we've already done with NIAID. And Dr. Tony Fauci's team for a few years, as you know. And 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 the country.

Operator

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

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

Congratulations. I got a couple of them, in your increased focus and success with vaccines, are you able to accelerate? What sort of extra emphasis are you putting on these early stage vaccine programs? Can you give us an update on 1345 and 1189, your RSV and EBV programs that are internal? How are those moving along? I know you don't give high res info and timelines, but to the extent you can.

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

Stéphane Bancel - Moderna, Inc. - CEO & Director

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. But we have given no timelines, and we will not give timelines. On the retail, as you appreciated over the quarters, to give timelines, when we get closer to kind of late stage development and especially with 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 can appreciate that when we say we aim to start a Phase III early summer, this is the best possible physical plan. Fifty things can derail that. But for the early programs, we are not communicating.

Tal, do you want to take the COVID interim data question?



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Tal Zaks - Moderna, Inc. - Chief Medical Officer

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 details on the expectations once we lock down the design with our partners and vet it with the agency.

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

So do you expect it to be just a U.S. trial, or would you go global? And I guess another, I guess, follow-up to this is, to what extent (technical difficulty)

[I mean a] vaccine. Are you contemplating that, too? Or is this -- the trial that you're planning for Phase II just a Moderna versus -- a Moderna candidate versus placebo?

Tal Zaks - Moderna, Inc. - Chief Medical Officer

Yes. So let me take both questions in turn. This first pivotal trial is going to be a partnership with NIAID with the NIH. So it will be, at this stage, either solo or a 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?

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

Yes, I think you answered it. I was wondering if you were contemplating a trial -- or the government contemplating a trial.

Tal Zaks - Moderna, Inc. - Chief Medical Officer

All right. Right, the multi-arm trial, yes. Yes, yes, 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 my brain for 2 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 vaccine's potential.

But the second one is more fundamental. I think it is important for the field to use more or less the case where it actually makes sense to run many vaccines in a 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 in 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 for my -- this is a personal opinion here. I question the merits of that design from a scientific and a public health need perspective. I think what's critical here is that for every vaccine candidate, as Stéphane alluded to, we're going to need more than one of them. But it matters less whether there's 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 it the most.



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Operator

Your next question comes from Gobind Singh of BMO.

Gobind Singh - *BMO Capital Markets Equity Research - Senior Associate*

This is Gobind on for George. Two on 1273.

The first one would be, can you help us understand if there's any profit share agreements in place? Were there any other parties, including the 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 to follow-up maybe with the NIAID's comments about their preclinical results that they saw. I understand they're 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 would be really helpful.

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

Yes. So it's Stéphane. I'm going to start and then the team might think of issues I drop. So it is pretty -- as Tal said, there's preclinical work being done, both in the labs and at NIAID, both with Dr. Tony Fauci's team, as soon as they just -- body of data that makes sense, and is complete and holistic, we intend to publish that work. So as soon as it's public, you'll be aware.

In term of the profit share, we have not disclosed previously any arrangement. So I will not comment on this one. And what was your other question?

Gobind Singh - *BMO Capital Markets Equity Research - Senior Associate*

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

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

Yes. Thank you. So on the commercial landscape, as I briefly mentioned a few minutes ago, as you know, I mean there are 100-plus last time I checked on Wikipedia, vaccine candidates being worked on around the world. The thing I think that are important is manufacturing scale and where are those projects in research of the clinic.

As I said a few minutes ago, I believe that the project at this stage in research with a group that doesn't have the ability to do tens of millions of doses come off ramping up to hundreds of millions per month. He's not going to be able to have a big dent on this pandemic. And so if you use those 2 as a screen, which is what we do, I think we end up with a very few number of players, that have again a chance in the 2021 timeframe to have an impact on this. Obviously, like always, in drug development, not every candidate is going to get to a finish line. And I could also anticipate that once a few vaccines are in late stage or commercially approved, a lot of the early project might just stop investing because we are deploying capital and talent for something that might have no commercial end.

So I think while there is a lot of people on the stop lane, my sense is very few of them get to the finish line, with manufacturing scale that matters. One or 2 million doses a year is not going to be very, very helpful at the global scale.

Operator

Your next question comes from Justin Kim with Oppenheimer.



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

This is -- 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. I 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 a thing of beauty, knock on wood.

So 2 questions. One is manufacturing and a second on regulatory strategy worldwide. So on manufacturing, if you can just talk a little bit about going from clinical to commercial batches. I know you've talked, it's gone about going from millions, tens of millions to now billion with Lonza. Can you just talk broadly about the timing? When can you go from that clinical? I know you've mentioned that Lonza will start manufacturing first batches in July. And how that maps against the BLA that you'll be starting to file?

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

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

So Hartaj, let me maybe start quickly on manufacturing. We have not done and have shared precise output per month. What we've said is that given we're ramping up both Norwood, which we said could do up to 100 million doses per year at the 50-microgram dose, and then the Lonza site. As you can appreciate basically every month this year, every month next year, the output per month is going to increase. And so the team is working as hard as they can because they do understand, trust me, that every extra 100,000 vial we get out of the system, we will protect more people. We will slow down the spread of this virus.

So it's not a linear process where you start now at 100 million dose per month, of course not. So it's just going to be an acceleration process, which is why this dialogue with the government in term of allocation, and we're going to be hand to mouth for quite some time where as soon as product is made and QC'ed we will go to the government, and then they'll decide how they allocate it. And we'll just kind of be on a regular basis.

Tal, you want to take the regulatory question maybe?

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

Yes. Thanks, Stéphane, and thanks, Hartaj, for the question. Look, we're in active dialogue now with the 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 it the most. That will take shape over the coming weeks and months. The expectation I have is that we will do more than 1 trial to demonstrate the benefit.

That being said, at a certain point, we'll obviously 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, and our intent is absolutely to eventually be able to make this vaccine available to those who need it the most.

Operator

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



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Stéphane Bancel - Moderna, Inc. - CEO & Director

So thank you so much, everybody, for participating, and we look forward to talking to you, hosting you at the latest on June 2 for the Moderna Science Day. Stephen and his team will host. 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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